

Responses to Public Comments and Peer Reviews

Phase III: Bifenthrin Criteria Derivation Report

using the

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



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

Department of Environmental Toxicology
University of California, Davis

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Responses to Comments

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

Term	Definition
ACR	Acute to Chronic Ratio- used to estimate concentration that will protect against chronic toxicity
CDFG	California Department of Fish and Game
CVRWQCB	Central Valley Regional Water Quality Control Board
DPR	California Department of Pesticide Regulation
EC _x	The chemical concentration that has an effect on 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
UC Davis	University of California, Davis
US EPA	U.S. Environmental Protection Agency
Water Quality Objective (WQO)	The limits of water quality constituents or characteristics that are established for the reasonable protection of beneficial uses of water or the prevention of nuisance within a specific area.

1.0 Introduction

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

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

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

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

2.0 Response to Comment to Public Comments

2.1. Comment Letter 1 – Jeffery M. Giddings, Compliance Services International (CSI), sponsored by FMC Corporation

The complete comment document, containing all tables, appendices, and references referred to in the comment text, is available on the Central Valley Regional Water Quality Control Board website:

http://www.waterboards.ca.gov/centralvalley/water_issues/tmdl/central_valley_projects/central_valley_pesticides/criteria_method/index.shtml.

COMMENT 1-1: Derivation of Acute Criterion

UCD's draft Acute Criterion is based on data for 8 freshwater species, presented in Table 2 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. A full list of data, including some results not used or proposed for use in criteria derivation, is presented in Appendix A.

Response To Comment (RTC) 1-1: Any changes to toxicity values are discussed below in the species-specific comments (Comments 1-2 through 1-10). The CSI Table 1 and Appendix A are provided below.

Table 1. Summary of bifenthrin aquatic toxicity data endpoints used to derive criteria.

Species	Endpoint	UCD Conc (µg/L)	Reference	CSI Proposed	Reference
ACUTE TOXICITY					
<i>Ceriodaphnia dubia</i>	96h LC50	0.078	Guy 2000a	0.105	Geomean: Guy 2000a, Wheelock et al. 2004
<i>Chironomus dilutus</i>	96h LC50	2.615	Anderson et al. 2006	2.615	Anderson et al. 2006
<i>Daphnia magna</i>	48h EC50	1.6	Surprenant 1983	0.42	Geomean: Surprenant 1983, Surprenant 1985a
<i>Hyalella azteca</i>	96h LC50	0.0065	Geomean: Weston & Jackson 2009, Anderson et al. 2006 (N=5)	0.0075	Geomean: Weston & Jackson 2009, Anderson et al. 2006 (N=2)
<i>Lepomis macrochirus</i>	96h LC50	0.35	Hoberg 1983a	0.30	Geomean: Hoberg 1983a, Surprenant 1985b
<i>Oncorhynchus mykiss</i>	96h LC50	0.15	Hoberg 1983b	0.12	Geomean: Hoberg 1983b, Surprenant 1985c
<i>Pimephales promelas</i>	96h LC50	0.405	Geomean: McAllister 1988 and Guy 2000b	0.405	Geomean: McAllister 1988, Guy 2000b
<i>Proclaoon sp.</i>	48h LC50	0.0843	Anderson et al. 2006	0.0843	Anderson et al. 2006
<i>Gammarus pulex</i>	48h LC50	—	—	0.11	Hooftman et al. 2002
<i>Hexagenia sp.</i>	48h LC50	—	—	0.39	Hooftman et al. 2002
<i>Thamnocephalus platyurus</i>	24h LC50	—	—	5.7	Hooftman et al. 2002
Trichoptera	48h LC50	—	—	0.18	Hooftman et al. 2002
<i>Enallagma/Ishnura</i>	24h LC50	(1.1)	Siegfried 1993 ^a	(1.1)	Siegfried 1993 ^a
Heptageniidae	24h LC50	(2.3)	Siegfried 1993 ^a	(2.3)	Siegfried 1993 ^a
<i>Hydrophilus spp.</i>	24h LC50	(5.4)	Siegfried 1993 ^a	(5.4)	Siegfried 1993 ^a
<i>Hydropsyche/Cheumatopsyche</i>	24h LC50	(7.2)	Siegfried 1993 ^a	(7.2)	Siegfried 1993 ^a
<i>Simulium vittatum</i>	24h LC50	(1.3)	Siegfried 1993 ^a	(1.3)	Siegfried 1993 ^a
CHRONIC TOXICITY					
<i>Daphnia magna</i>	21d MATC	0.0019	Burgess 1989	0.0034	Geomean: Burgess 1989, Hoberg et al. 1985, Wang et al. 2009
<i>Oncorhynchus mykiss</i>	76d MATC	—	—	0.019	Surprenant and Yarko 1985
<i>Pimephales promelas</i>	92d MATC	0.06	McAllister 1988	0.06	McAllister 1988

^aRated "less reliable" by UCD and CSI, not confirmed for use in derivation of criteria.

Appendix A. Summary of aquatic toxicity data for bifenthrin.

Species	Endpoint	Conc (µg/L)	Reference	Rating	Rated by
<i>Americamysis bahia</i>	28d MATC	0.0012	Boeri and Ward 1991	LR (3)	UCD
<i>Americamysis bahia</i>	28d MATC	0.0025	Ward and Boeri 1991	LR (2,3)	UCD
<i>Americamysis bahia</i>	96h LC50	0.00397	Barrows 1986b	LR (3)	UCD
<i>Ceriodaphnia dubia</i>	96h LC50	0.05	Yang <i>et al.</i> 2006	RL (5)	UCD
<i>Ceriodaphnia dubia</i>	48h EC50	0.07	Mokry and Hoagland 1990	LR (1)	UCD
<i>Ceriodaphnia dubia</i>	96h LC50	0.078	Guy 2000a	RR	UCD
<i>Ceriodaphnia dubia</i>	96h LC50	0.079	Liu <i>et al.</i> 2005	RL (2,5)	UCD
<i>Ceriodaphnia dubia</i>	48h EC50	0.142	Wheelock <i>et al.</i> 2004	RR	UCD
<i>Ceriodaphnia dubia</i>	96h LC50	0.144	Liu <i>et al.</i> 2004	RL (5)	CSI
<i>Ceriodaphnia dubia</i>	24h LC50	0.31	Hooftman <i>et al.</i> 2002	RR	CSI
<i>Chironomus dilutus</i>	96h LC50	2.615	Anderson <i>et al.</i> 2006	RR	UCD
<i>Crassostrea virginica</i>	96h EC50	>2.15	Ward 1986a	LR (3,4)	UCD
<i>Crassostrea virginica</i>	96h EC50	>99.7	Ward 1986b	LR (3,4)	UCD
<i>Crassostrea virginica</i>	48h EC50	285	Ward 1987	LR (3)	CSI
<i>Cyprinodon variegatus</i>	96h LC50	17.8	Barrows 1986a	LR (3)	UCD
<i>Daphnia magna</i>	21d MATC	0.0015	Hoberg <i>et al.</i> 1985	LR (1) RR	UCD CSI
<i>Daphnia magna</i>	21d MATC	0.0019	Burgess 1989	RR	UCD
<i>Daphnia magna</i>	21d MATC	0.014	Wang <i>et al.</i> 2009	RR	CSI
<i>Daphnia magna</i>	48h EC50	0.11	Hoberg <i>et al.</i> 1985	LR (1)	UCD
<i>Daphnia magna</i>	48h LC50	0.11	Surprenant 1985a	RR	CSI
<i>Daphnia magna</i>	48h EC50	0.165	Williams 1985	LR (1)	CSI
<i>Daphnia magna</i>	96h LC50	0.175	Liu <i>et al.</i> 2004	RL (5)	CSI
<i>Daphnia magna</i>	48h EC50	0.32	Mokry and Hoagland 1990	LR (1)	CSI
<i>Daphnia magna</i>	48h EC50	0.37	Hooftman <i>et al.</i> 2002	RR	CSI
<i>Daphnia magna</i>	48h EC50	0.456	Handley <i>et al.</i> 1992a	LR (1)	CSI
<i>Daphnia magna</i>	48h LC50	0.99	Browne 1980	RL	CSI
<i>Daphnia magna</i>	48h EC50	1.6	Surprenant 1983	RR	UCD,CSI
<i>Enallagma/Ishnura</i>	24h LC50	1.1	Siegfried 1993	RL (5)	UCD,CSI
<i>Gammarus pulex</i>	48h LC50	0.11	Hooftman <i>et al.</i> 2002	RR	CSI
Heptageniidae	24h LC50	2.3	Siegfried 1993	RL (2,5)	UCD,CSI
<i>Hexagenia sp.</i>	48h LC50	0.39	Hooftman <i>et al.</i> 2002	RR	CSI
<i>Hyalella azteca</i>	96h LC50	0.0060	Weston & Jackson 2009	RR	UCD
<i>Hyalella azteca</i>	96h LC50	0.0093	Anderson <i>et al.</i> 2006	RR	UCD
<i>Hydrophilus spp.</i>	24h LC50	5.4	Siegfried 1993	RL (5)	UCD,CSI
<i>Hydropsyche/Cheumatopsyche</i>	24h LC50	7.2	Siegfried 1993	RL (5)	UCD,CSI
<i>Lepomis macrochirus</i>	96h LC50	0.26	Surprenant 1985b	RR	CSI
<i>Lepomis macrochirus</i>	96h LC50	0.35	Hoberg 1983a	RR	UCD
<i>Oncorhynchus mykiss</i>	76d MATC	0.019	Surprenant & Yarko 1985	RR	CSI
<i>Oncorhynchus mykiss</i>	96h LC50	0.1	Surprenant 1985c	RR	CSI
<i>Oncorhynchus mykiss</i>	96h LC50	0.15	Hoberg 1983b	RR	UCD
<i>Oncorhynchus mykiss</i>	96h LC50	0.91	Thompson 1985	LR (1)	CSI
<i>Oncorhynchus mykiss</i>	96h LC50	2.4	Handley <i>et al.</i> 1992b	LR (1)	CSI
<i>Pimephales promelas</i>	92d MATC	0.06	McAllister 1988	RR	UCD
<i>Pimephales promelas</i>	96h LC50	0.21	McAllister 1988	RR	UCD
<i>Pimephales promelas</i>	96h LC50	0.78	Guy 2000b	RR	UCD
<i>Procloeon sp.</i>	48h LC50	0.0843	Anderson <i>et al.</i> 2006	RR	UCD
<i>Simulium vittatum</i>	24h LC50	1.3	Siegfried 1993	RL (5)	UCD,CSI
<i>Thamnocephalus platyurus</i>	24h LC50	5.7	Hooftman <i>et al.</i> 2002	RR	CSI
Trichoptera	48h LC50	0.18	Hooftman <i>et al.</i> 2002	RR	CSI

COMMENT 1-2: *Ceriodaphnia dubia*

UCD calculates the Acute Criterion using the *C. dubia* 96-h LC50 of 0.078 µg/L from a test by the California Department of Fish and Game (Guy 2000a). A 48-h LC50 from another study (Wheelock et al. 2004) was also rated “relevant and reliable” but the result was excluded in the data reduction process in favor of the 96-h value. We believe this exclusion was unwarranted, as discussed below. Two other studies (Yang et al. 2006 and Liu et al. 2005) were rated “relevant but less reliable” by UCD, presumably due to inadequate detail in the publications (UCD provided Data Evaluation Forms only for studies rated Relevant and Reliable). A 48-h EC50 from a fifth study (Mokry and Hoagland 1990) was for a formulated product and was rated “less relevant but reliable” by UCD.

The result from Wheelock et al. 2004 (48-h LC50 = 0.142 µg/L) was rated “RR” by UCD but was excluded in the data reduction process (see UCD’s Table 3) with a footnote indicating the following reason: “A more sensitive or more appropriate test duration was available from the same test.” However, there is no other result “from the same test.” A 48-h exposure duration is standard for *C. dubia*. The species geometric mean of the two values (0.105 µg/L) is appropriate for use in deriving water quality criteria.

RTC 1-2: The *Ceriodaphnia dubia* toxicity value from Wheelock *et al.* (2004) has been added back to the acceptable data set for criteria calculation (Table 2) and the SMAV for *C. dubia* was calculated to be 0.105 µg/L. The data summary sheets for studies rated less than RR have been added to Appendix B of the final bifenthrin report.

COMMENT 1-3: The results presented by Liu et al. (2005) are identical (to 2 significant figures) to those in Liu et al. (2004), and presumably come from the same test. Both publications report 96-h LC50 values for a bifenthrin enantiomer mix (racemate), corresponding to the commercial active ingredient, as well as for the 1R-cis isomer alone. The LC50 value cited by UCD, 0.079 µg/L, is for the 1R-cis isomer; the LC50 for the enantiomer mix is 0.144 µg/L. The water quality criteria for bifenthrin apply to the commercial enantiomer mix, not the single isomer, which is not the active ingredient in any registered pesticide product. The studies by Liu et al. (2005) and Yang et al. (2006) were rated “less reliable” by UCD. CSI notes that the methodology in these studies was strong but the documentation was incomplete, probably abbreviated in order to conform to the styles of the journals.

RTC 1-3: A citation for the Liu *et al.* study mentioned above (reported as 2004 in the comment, but the correct citation is 2005) has been added to the criteria report, as it was not previously included in the report. It does appear that the *C. dubia* data from the two Liu *et al.* (2005a, b) studies are identical, and are reported as such in the data summaries and Table 6. The toxicity value in Table

6 has been corrected to be the LC₅₀ for the racemic mixture of bifenthrin, not the 1R-cis isomer. It is acknowledged that the water quality criteria for bifenthrin only apply to the racemic mixture, not a single specific isomer. The Liu *et al.* (2005a, 2005b) studies rated as less reliable because they failed to document many important study parameters, including the control response. The Yang *et al.* (2006) study also rated as less reliable because they failed to document many important study parameters, which are listed in the corresponding data summary sheet in Appendix B of the final report.

COMMENT 1-4: The UCD database did not include the GLP study by Hooftman *et al.* (2002) with *C. dubia* as well as 5 other invertebrate species. CSI evaluated this study using the TenBrook *et al.* (2009) criteria and rated it relevant and reliable. However, the 24-h exposure duration used in this study was less than the standard 48-h exposure for *C. dubia*, so the result (24-h LC₅₀ = 0.31) is less relevant than the 48-h and 96-h LC₅₀ values from the other studies.

RTC 1-4: The Hooftman *et al.* (2002) study was twice requested from the US EPA in FOIA data requests in October 2008 and January 2009, but the study was never received. Our contact at the USEPA indicated that they did not have this study on file. The study cannot currently be used for criteria derivation because the original document is not available for our review.

COMMENT 1-5: *Daphnia magna*
UCD derived the Acute Criterion using the *D. magna* 48-h EC₅₀ of 1.6 µg/L from a GLP registration study (Surprenant 1983). Results are also available from 4 other GLP studies and 1 non-GLP study, as well as two studies with formulations. The additional 48-h and 96-h LC₅₀ values range from 0.11 µg/L (Surprenant 1985a) to 0.99 µg/L (Brown 1980). Only Surprenant (1983) and Surprenant (1985a) used flow-through exposure. The geometric mean of these two EC₅₀s, 0.42 µg/L, is the appropriate value to use for this species in deriving an Acute Criterion for bifenthrin.

RTC 1-5: The Surprenant (1985a) study was twice requested from the US EPA in FOIA data requests in October 2008 and January 2009, but the study was never received. Our contact at the USEPA indicated that they did not have this study on file. The study cannot be used for criteria derivation because the original document is not available for our review.

COMMENT 1-6: *Hyalella azteca*
UCD presents LC₅₀ data from two studies with *H. azteca*, including four tests by Weston and Jackson (2009) and one by Anderson *et al.* (2006). UCD's analysis used the geometric mean of the LC₅₀ values from the five tests (0.0065 µg/L). If the two studies (rather than the five tests) were weighted equally in the analysis, the species geometric mean would be 0.0075 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 1-6: The *H. azteca* SMAV will not be recalculated because repeated tests given in one study are recorded as separate tests according to the method. If results from different time points, different endpoints, or repeated tests are reported in a single study, they are recorded as separate tests, according to the methodology (section 3-2.2.2, TenBrook *et al.* 2009a). The species mean toxicity value is calculated from the most appropriate values determined by the data reduction process (section 3-2.4).

COMMENT 1-7: *Chironomus dilutus*

The 96-h LC50 for *C. dilutus* is shown as 26,150 ng/L (=26.15 µg/L) in the publication by Anderson *et al.* (2006). However, UCD notes that correspondence with the authors confirmed that the published value is in error, and the correct LC50 is 2.615 µg/L.

RTC 1-7: Comment acknowledged.

COMMENT 1-8: *Lepomis macrochirus*

UCD uses the 96-h LC50 of 0.35 µg/L reported by Hoberg (1983a) for *L. macrochirus*. Another relevant and reliable study (Surprenant 1985b) reported a 96-h LC50 of 0.26 µg/L. The species geometric mean, 0.30 µg/L, should be used in the calculation of the Acute Criterion.

RTC 1-8: The Surprenant (1985b) study was twice requested from the US EPA in FOIA data requests in October 2008 and January 2009, but the study was never received. Our contact at the USEPA indicated that they did not have this study on file. The study cannot be used for criteria derivation because the original document is not available for our review.

COMMENT 1-9: *Oncorhynchus mykiss*

UCD uses the 96-h LC50 of 0.15 reported by Hoberg (1983b) for *O. mykiss*. Another relevant and reliable study (Surprenant 1985c) reported a 96-h LC50 of 0.1 µg/L. The species geometric mean, 0.12 µg/L, should be used in the calculation of the Acute Criterion.

RTC 1-9: The Surprenant (1985c) study was twice requested from the US EPA in FOIA data requests in October 2008 and January 2009, but the study was never received. Our contact at the USEPA indicated that they did not have this study on file. The study cannot be used for criteria derivation because the original document is not available for our review.

COMMENT 1-10: Additional species

A study conducted under GLP by TNO Laboratories (Hooftman et al. 2002) was evaluated by CSI and rated relevant and reliable. The Study Evaluation Forms are presented in Appendix B. Results are available for four additional species, as follows:

Gammarus pulex: 48-h LC50 = 0.11 µg/L

Hexagenia sp.: 48-h LC50 = 0.39 µg/L

Thamnocephalus platyurus: 24-h LC50 = 5.7 µg/L

Note: the 24-h exposure is recommended for this species, according to study report.

Trichoptera (species unidentified): 48-h LC50 = 0.18 µg/L

Hooftman et al. also tested *C. dubia* (24-h EC50 = 0.142 µg/L) and *D. magna* (48-h EC50 = 0.37 µg/L). The 24-h exposure for *C. dubia* is less than the standard 48-h exposure for that species. The *D. magna* study was a static test. Both values were excluded by CSI during data reduction.

RTC 1-10: See RTC 1-4.

COMMENT 1-11: Calculation of Acute Criterion

The UCD report states that the ETX 2.0 software program (Van Vlaardingen et al. 2004) was used to fit the data set to a log-logistic distribution. UCD reported a median HC5 of 0.007460 µg/L. Using the same software and the data shown in UCD's Appendix B, CSI obtained a median HC5 value of 0.007694 µg/L, quite close to UCD's result. However, two of the data points in Appendix B differ from those shown in UCD's Table 2. First, Appendix B shows a value of 0.21 µg/L from McAllister (1988) for *Pimephales promelas*, rather than the species geometric mean of 0.405 µg/L for McAllister (1988) and Guy (2000b) as shown in Table 2. Second, Appendix B shows the value for *C. dubia* as 0.079 µg/L, not 0.078 µg/L as in Table 2 and in the original study report. Using UCD's final acute toxicity data as shown in their Table 2, CSI obtained a median HC5 value of 0.008068 µg/L (95% limits 0.0005-0.034 µg/L), corresponding to an Acute Criterion (acute value divided by 2, reported with one significant digit) of 4 ng/L, unchanged from UCD's recommended Acute Criterion.

Table 2. Summary of acute HC5 values and corresponding Acute Criterion values based on alternative data selections.

Data Selection	Acute Value, HC5 (Confidence Interval)	Acute Criterion
UCD (Appendix B data, and text)	0.007460 µg/L	4 ng/L
UCD (Table 2 data)	0.008068 µg/L (0.0005-0.034 µg/L)	4 ng/L
UCD with CSI revisions (<i>C. dubia</i> , <i>D. magna</i> , <i>H. azteca</i> , <i>L. macrochirus</i> , <i>O. mykiss</i>)	0.009860 µg/L (0.0008-0.036 µg/L)	5 ng/L
UCD with CSI revisions plus 4 additional species reported by Hooftman (2002)	0.013968 µg/L (0.0024-0.041 µg/L)	7 ng/L

RTC 1-11: Table 2 and the Acute Criterion Calculation section have been revised in the report to accurately reflect the change to the *Ceriodaphnia dubia* toxicity value in the data set from the draft report.

COMMENT 1-12: As discussed above, CSI proposes corrections to UCD’s toxicity values for *C. dubia*, *D. magna*, *H. azteca*, *L. macrochirus*, and *O. mykiss*. These proposed changes are summarized in Table 1. With these corrections, the median HC5 is calculated as 0.009860 µg/L (0.0008-0.036 µg/L) (Table 2). The Acute Criterion is 5 ng/L.

Taking into account the 4 additional species reported by Hooftman *et al.* (2002) as well as the corrections for the five other species, the HC5 for bifenthrin is 0.013968 µg/L (0.0024-0.041). This is the most appropriate estimate of the HC5, because it incorporates all available data from studies rated Relevant and Reliable. The corresponding Acute Criterion is 7 ng/L.

RTC 1-12: The only change to the acute data set is the change in the *Ceriodaphnia dubia* value, as discussed in RTC 1-2. With this change in the UCD data set, the median 5th percentile value is calculated as 0.00803 µg/L, which yields an acute criterion of 4 ng/L.

COMMENT 1-13: The study of Siegfried (1993) included acute toxicity data for 5 other species, but was incompletely documented and was therefore rated “less reliable” by both UCD and CSI. If these species were included in the analysis, the HC5 for bifenthrin would be 0.022469 µg/L (0.0051-0.060), and the Acute Criterion would be 11 ng/L. However, given the age of the study, it is unlikely that the missing elements of the documentation could be obtained to raise the study rating to Reliable, so the data cannot properly be used in derivation of the Acute Criterion.

RTC 1-13: The Siegfried (1993) study was evaluated and rated as RL, as reported in Table 6. The data summary sheet for this study is now included in Appendix B.

COMMENT 1-14: UCD's draft Acute Criterion for bifenthrin was 4 ng/L. This result was based on toxicity values for two species that differed from those in UCD's Final Acute Toxicity Data Set (their Table 2), but the Acute Criterion was unaffected by these discrepancies.

RTC 1-14: The discrepancies in the toxicity values have been corrected, and the revised results are shown in the final report, although the acute criterion did not change as a result.

COMMENT 1-15: CSI proposes corrections to the values used for *Ceriodaphnia dubia*, *Daphnia magna*, *Hyalella azteca*, *Lepomis macrochirus*, and *Oncorhynchus mykiss*. Based on these corrected values, the Acute Criterion for bifenthrin is 5 ng/L.

RTC 1-15: See RTC 1-2, 1-4, 1-6, 1-8, and 1-9. The values for *D. magna*, *H. azteca*, *L. macrochirus*, and *O. mykiss* will not be changed, and the acute criterion for bifenthrin is 4 ng/L as calculated with the data set in the final bifenthrin criteria report.

COMMENT 1-16: Data for 4 additional species are available from a relevant, reliable study that was not considered by UCD. When these data are included in the analysis, the Acute Criterion for bifenthrin is 7 ng/L. This is the value recommended by CSI.

RTC 1-16: See RTC 1-10. The results from the aforementioned study could not be added to the acute data set, and the acute criterion calculated in the final bifenthrin report is 4 ng/L.

COMMENT 1-17: Data for 5 additional species are available from another relevant but less reliable study. If these data were included in the analysis, the Acute Criterion for bifenthrin would be 12 ng/L. However, unless the study can be upgraded to a rating of Reliable (through communication with the author, for example), these additional data cannot be used.

RTC 1-17: See RTC 1-13.

COMMENT 1-18: Derivation of Chronic Criterion

UCD's draft bifenthrin criteria document discussed chronic toxicity data for *Daphnia magna* and *Pimephales promelas* (Table 1). For *D. magna* UCD used the 21-d MATC of 0.0019 µg/L from a study by Burgess (1989). Two other available studies were not included in UCD's dataset: Hoberg *et al.* (1995) and Wang *et al.* (2009). CSI evaluated these studies using the UCD methodology (TenBrook *et al.* 2009) and rated them Relevant and Reliable (Rating Forms are presented in Appendix B). The geometric mean of the three MATC values is 0.0034 µg/L.

RTC 1-18: The Wang *et al.* (2009) study has been evaluated and added to the report. It was rated as RL and the toxicity values from this study are listed in Table 6 of the final bifenthrin report. The Hoberg *et al.* (1985) study the author refers to is evaluated in the bifenthrin report and is rated less relevant because they tested a formulation containing only 10.4% bifenthrin. This study is not appropriate for criteria derivation, and when properly rated using Table 3.6 of the UCD method, scores an 85 for relevance, which is a rating of less relevant (L). The data summary sheet for this study has been added to Appendix B of the final bifenthrin report.

COMMENT 1-19: A chronic test with *Oncorhynchus mykiss* was also available (Surprenant and Yarko 1985). Chronic toxicity data are also available for *Americamysis bahia* (formerly *Mysidopsis bahia*), a marine invertebrate (Boeri and Ward 1991; Ward and Boeri 1991); UCD rated these studies Less Relevant (because of the marine test species) but Reliable.

RTC 1-19: The Surprenant and Yarko (1985) study was twice requested from the US EPA in FOIA data requests in October 2008 and January 2009, but the study was never received. Our contact at the USEPA indicated that they did not have this study on file. The study cannot be used for criteria derivation because the original document is not available for our review. Marine species are not appropriate for direct use in freshwater criteria derivation.

COMMENT 1-20: Derivation of a chronic criterion using the SSD approach would have required, in addition to the species listed above, data on toxicity to a benthic invertebrate and an aquatic insect. EPA's Acute-to-Chronic Estimator (ACE) program is intended to generate chronic toxicity values for this purpose (TenBrook *et al.* 2009), but UCD did not use ACE, "to avoid excessive layers of estimation." Instead, UCD applied an Acute-to-Chronic Ratio (ACR) approach. Since none of the available chronic toxicity values is matched by an acute toxicity value meeting the criteria outlined in Section 3-4.2.1 of TenBrook *et al.* (2009), the default ACR value of 12.4 was used.

As discussed in Section 2.8, the acute toxicity value (HC5) derived based on CSI's amended dataset is 0.013968 µg/L. Applying the default ACR, the Chronic Criterion is 0.0011 µg/L, or 1 ng/L. This value is approximately a factor of 3 below the lowest acceptable chronic value of 3.4 ng/L for *Daphnia magna*.

RTC 1-20: The chronic criterion calculation has been revised due to the slight change in the recommended acute value. In the final report, the recommended acute value is the median 5th percentile estimate of 0.00803 µg/L. The chronic criterion is calculated by dividing the acute value by the default ACR of 12.4 to yield a chronic criterion 0.6 ng/L.

COMMENT 1-21: Data collection

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

TenBrook *et al.* (2009, Section 3-2.1) note that “data from agencies [i.e., GLP studies submitted to agencies by registrants] can make up most of the high quality toxicity studies available, especially for compounds with limited data. “ We agree with this generalization. The deficiencies of academic studies published in the open literature are generally of two kinds: use of non-standard test protocols, and failure to report data critical to evaluation of study acceptability This issue is further discussed in Section 4.2 below.

RTC 1-21: Comment acknowledged.

COMMENT 1-22: TenBrook *et al.* (2009, Section 3-2.1.1.2) state, “For derivation of chronic criteria or acute-to-chronic ratios, obtain maximum acceptable toxicant concentrations (MATCs). Chronic data expressed as ECx values (from regression analysis), may be used for criteria derivation only if studies are available to show what level of x is appropriate to represent a no-effect level.” However, use of the MATC does not address the question of determining an appropriate value of x; the MATC is based on determinations of statistical significance, regardless of biological significance or magnitude of effect. An MATC can be associated with a wide range of ECx values depending on the nature of the measurement endpoint and the variability of the measurements. We believe it is better to establish (as a matter of policy grounded in science) a tolerable level of effect for a particular species and endpoint, and use concentration-effect models (e.g., regression analysis) to estimate the concentration corresponding to that level of effect, i.e., the ECx.

RTC 1-22: The UCD methodology recognizes the limitations of hypothesis test data, and chronic data expressed as results of hypothesis tests are evaluated to ensure that the reported toxicity values are reasonable estimates of no-effect levels (section 2.1.2, TenBrook *et al.* 2009). Because the goal of the method is to prevent detrimental effects to organisms, an EC₅₀ is not a valid toxicity value for use in derivation of a chronic criterion because a 50% reduction compared to the

control cannot be considered “no effect.” If a study were available that demonstrated what level of x represented a no-effect level, then an EC_x toxicity value could be used in chronic criterion calculation (section 2-2.1.2, TenBrook *et al.* 2009).

COMMENT 1-23: Data evaluation

The UCD methodology calls for an evaluation of the data for relevance first, and for reliability only if the relevance score is 70 or greater. This tiered approach makes data selection more efficient, because a relevance evaluation can usually be done very quickly and no further time needs to be invested in evaluating the reliability of an irrelevant study.

For relevant studies, the recommended process is to extract information to data sheets, and use the results to evaluate reliability according to the rating systems shown in Tables 3.7 and 3.8 of TenBrook *et al.* (2009). While the data extraction process (using the forms provided) can be cumbersome, it is objective and reasonably complete, and does provide a good basis for evaluating data reliability and documenting the evaluation.

RTC 1-23: Comment acknowledged.

COMMENT 1-24: Two categories of reliability criteria are used: Documentation and Acceptability. Many criteria in the two groups are related. For example, failure to report dissolved oxygen concentrations results in loss of 4 points for Documentation, and inability to confirm that dissolved oxygen concentrations were acceptable results in loss of 6 points for Acceptability. Thus, a peer-reviewed open-literature publication that fails to report dissolved oxygen concentrations has already lost 10 points (out of 200) in its Reliability score. Failure to report pH, hardness, alkalinity, and conductivity results in loss of 16 more points. These water quality variables are needed only to confirm that the test was run under acceptable conditions – they generally do not affect the outcome of the test – yet their omission from a publication results in a substantially reduced reliability rating.

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

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

non-standard species. In CSI's evaluation of the acute toxicity data for bifenthrin (Section 2), addition of data on non-standard (and generally less sensitive) species was seen to result in a substantial increase in the derived Acute Criterion (Table 2). The use of sensitive species in standard toxicity tests therefore results in additional conservatism of the derived criteria.

RTC 1-24: Three of the seven peer-reviewed open-literature studies were rated RR. Eight of the thirteen registrant-submitted studies rated as RR. There does not appear to be a strong bias for GLP studies being rated RR and peer-reviewed studies being rated less than RR. Additionally, the authors of the UCD pesticide criteria reports have often attempted to contact authors of peer-reviewed open-literature studies to obtain additional information so that their data may be included in the criteria derivation process, with some success. What is clear is that there are very few studies in general on the toxicity of bifenthrin to aquatic organisms, especially chronic exposures.

COMMENT 1-25: Acute Criterion derivation using SSD

The UCD methodology (TenBrook *et al.* 2009) requires data for at least 5 species representing at least the following 5 groups: the family Salmonidae, a warm water fish (e.g. bluegill sunfish, fathead minnow), a planktonic crustacean – at least one from the family Daphniidae (e.g. *Daphnia magna*, *Ceriodaphnia dubia*), a benthic crustacean (e.g., *Hyalella azteca*, *Gammarus pulex*), and an aquatic insect (e.g., *Chironomus dilutus*). UCD's acute dataset for bifenthrin, with 8 species, fulfilled all five categories.

TenBrook *et al.* (2009) provide detailed statistical guidance for SSD analysis, but recommend using a program such as the ETX program (Van Vlaardingen *et al.* 2004) to derive the Acute Criterion. ETX is one of many tools and methods available for estimating the 5th percentile of the SSD; it has the advantages of being well-tested, standardized, and widely accepted throughout the world. Use of ETX avoids controversy about the suitability of the statistical methods used to derive the criteria.

RTC 1-25: Comment acknowledged.

COMMENT 1-26: Chronic Criterion derivation

Deriving a Chronic Criterion using the SSD approach requires MATC values for at least five species from the same categories as the acute criterion. Reasons for using ECx values rather than MATCs were presented above (Section 4.1), though we acknowledge the lack of agreement about what x should be for a particular taxon and endpoint.

If chronic data are insufficient for an SSD approach, an ACR approach is used (TenBrook *et al.* 2009, Section 3-4.2). At first, TenBrook *et al.* (2009,

Section 3-4.2.1) seem to require that the acute and chronic data used to calculate an ACR must come from the same study in the same dilution water, but then this requirement is relaxed to allow a different study in the same laboratory under identical conditions, or even in a different laboratory – in other words, only the dilution water must be the same. The rationale for this requirement is unclear, since toxicity values are not presumed to be strongly affected by the source of dilution water.

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

RTC 1-26: The requirement to use the same dilution water in acute and chronic studies to calculate an ACR for a given species is based on guidance from the US EPA methods (1985, 2003).

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

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

COMMENT 1-27: Bioavailability of Bifenthrin

The draft criteria report summarizes evidence that pyrethroids bound to particulate matter are not biologically available to aquatic organisms and do not contribute to toxicity; only freely dissolved pyrethroids are bioavailable and toxic. Bound pyrethroids become bioavailable only when they desorb from particles or dissociate from dissolved organic matter.

The UCD report notes the possibility that pyrethroids can be taken up from ingested particles, citing the findings of Mayer *et al.* (2001) as evidence that hydrophobic compounds can be desorbed by digestive juices. The cited study involved uptake of benzo(a)pyrene and zinc by 18 species of benthic marine invertebrates, including 10 species of worms, 5 species of echinoderms, 2 species of mollusks, and a sea anemone. The relevance of these findings to uptake of pyrethroids by sensitive freshwater taxa (such as insects and crustaceans) is unclear. There is no evidence for uptake of pyrethroids by this route, and the UCD report in fact summarizes the evidence to the contrary.

RTC 1-27: One study that demonstrates pyrethroid toxicity to aquatic insects via ingestion has been added to the bioavailability section of the bifenthrin report. Palmquist *et al.* (2008) examined the effects due to dietary exposure of the pyrethroid esfenvalerate on three aquatic insects with different feeding functions: a grazing scraper (*Cinygmula reticulata* McDunnough), an omnivore filter feeder (*Brachycentrus americanus* Banks), and a predator (*Hesperoperla pacifica* Banks). The researchers observed adverse effects in *C. reticulata* and *B. americanus* after feeding on esfenvalerate-laced food sources and that none of the three insects avoided the contaminated food. The effects included reduced growth and egg production of *C. reticulata* and abandonment and mortality in *B. americanus*. This study indicates that ingestion may be an important exposure route, but it is not currently possible to incorporate this exposure route into criteria compliance assessment.

COMMENT 1-28: 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 bifenthrin and other pyrethroids, of which only the freely dissolved phase is bioavailable. Pyrethroid concentrations in the freely dissolved phase can be measured using techniques such as solid-phase microextraction (SPME), or calculated based on partitioning coefficients (Equation 3.6, TenBrook *et al.* 2009). The equilibrium partitioning model requires input values for dissolved and particulate organic carbon (OC); UCD considers these values to be site-specific properties that are “laborious” to measure. CSI disagrees: measurement of dissolved and particulate organic carbon and total suspended solids is not particularly difficult (compared to analysis of bifenthrin, for example) and is useful for calculation of freely

dissolved lipophilic chemicals. The US EPA uses equilibrium partitioning models to estimate freely dissolved concentrations of pyrethroids in sediment pore water, based on measured or default values for dissolved and particulate organic carbon concentrations (e.g., USEPA 2005).

In laboratory toxicity tests using low-particulate, low-OC water as the exposure medium, pyrethroids are much more bioavailable than in water with natural levels of particulates and OC. Because aquatic toxicity test guidelines require the use of water containing minimal amounts of particulate matter and dissolved organic carbon, bioavailability is not a significant factor under standard test conditions. In ambient water, however, analysis of total pyrethroid is liable to overestimate the bioavailable concentration by at least an order of magnitude. For these reasons, we believe that evaluation of water quality compliance for pyrethroids should be based on measured or calculated concentrations of freely dissolved pyrethroid, consistent with the recommendations of TenBrook *et al.* (2009, Section 3-5.1).

UCD concludes that that laboratory toxicity data based on nominal whole-water concentrations are likely to overestimate freely dissolved pyrethroid, citing one test with only 30% recovery of added bifenthrin. This is an extreme example. Most measured concentrations in the bifenthrin studies used in this analysis (those rated Relevant and Reliable) are much closer to nominal values (Table 3), and do not support UCD's contention that toxicity values based on nominal concentrations greatly underestimate the toxicity of the freely dissolved fraction. As discussed above, nearly all of the bifenthrin present in toxicity test solutions is likely to be freely dissolved and bioavailable.

UCD also cites an example from a spiked sediment study with *Chironomus dilutus* (Xu *et al.* 2007), in which total concentrations in pore water were more than an order of magnitude higher than freely dissolved concentrations measured using SPME. This is not unexpected in sediment toxicity tests, due to the presence of dissolved organic carbon (and possibly residual particles, depending on the efficiency of centrifugation) in the pore water. The situation is much different in water-only toxicity tests, in which dissolved and particulate matter are kept to a minimum and most of the pesticide is bioavailable.

We therefore do not concur with UCD's recommendation that criteria compliance be based on whole-water bifenthrin concentrations, without consideration of bioavailability. UCD concedes that use of whole-water concentrations is likely to be overprotective, but accepts such overprotection as "compensating for the use of nominal concentrations and unknown effects of dietary exposure." Since the bioavailable fraction may be on the order of a few percent or less of the whole-water bifenthrin

concentration, the overprotection that would be incurred by basing compliance on whole-water concentrations greatly outweighs the potential underprotection (a factor of 2 or 3 at most) caused by use of nominal concentrations. UCD suggests that this recommendation should be revised when more toxicity data based on measured concentrations are available. We note that measured concentrations are already available for 20 of the 25 Relevant and Reliable studies listed in Table 3.

Table 3. Measured bifenthrin concentrations in toxicity tests rated Relevant and Reliable, as a percentage of nominal concentrations.

Species	Endpoint	Reference	Measured, % of nominal
<i>Ceriodaphnia dubia</i>	96h LC50	Guy 2000a	85%
<i>Ceriodaphnia dubia</i>	48h EC50	Wheelock <i>et al.</i> 2004	Not measured
<i>Ceriodaphnia dubia</i>	24h LC50	Hooftman <i>et al.</i> 2002	77 (62-89) %
<i>Chironomus dilutus</i>	96h LC50	Anderson <i>et al.</i> 2006	36-65%
<i>Daphnia magna</i>	21d MATC	Hoberg <i>et al.</i> 1985	54 (38-78) %
<i>Daphnia magna</i>	21d MATC	Burgess 1989	50-76%
<i>Daphnia magna</i>	21d MATC	Wang <i>et al.</i> 2009	Not measured
<i>Daphnia magna</i>	48h LC50	Surprenant 1985a	79 (69-89) %
<i>Daphnia magna</i>	48h EC50	Hooftman <i>et al.</i> 2002	105 (98-112) %
<i>Daphnia magna</i>	48h EC50	Surprenant 1983	Not measured
<i>Gammarus pulex</i>	48h LC50	Hooftman <i>et al.</i> 2002	80%
<i>Hexagenia sp.</i>	48h LC50	Hooftman <i>et al.</i> 2002	71 (59-86) %
<i>Hyalella azteca</i>	96h LC50	Weston & Jackson 2009	114 (64-189) %
<i>Hyalella azteca</i>	96h LC50	Anderson <i>et al.</i> 2006	19-56%
<i>Lepomis macrochirus</i>	96h LC50	Surprenant 1985b	101 (76-142) %
<i>Lepomis macrochirus</i>	96h LC50	Hoberg 1983a	Not measured
<i>Oncorhynchus mykiss</i>	76d MATC	Surprenant & Yarko 1985	87 (67-107) %
<i>Oncorhynchus mykiss</i>	96h LC50	Surprenant 1985c	100 (56-145%)
<i>Oncorhynchus mykiss</i>	96h LC50	Hoberg 1983b	Not measured
<i>Pimephales promelas</i>	92d MATC	McAllister 1988	53-146%
<i>Pimephales promelas</i>	96h LC50	McAllister 1988	73-88%
<i>Pimephales promelas</i>	96h LC50	Guy 2000b	184-204%
<i>Procladius sp.</i>	48h LC50	Anderson <i>et al.</i> 2006	55-77%
<i>Thamnocephalus platyurus</i>	24h LC50	Hooftman <i>et al.</i> 2002	105 (83-120) %
Trichoptera	48h LC50	Hooftman <i>et al.</i> 2002	81 (77-86) %

RTC 1-28: The bioavailability section of the final bifenthrin criteria report has been revised to recommend the use of the dissolved fraction of bifenthrin for compliance. While use of the dissolved fraction is preferred for criteria compliance, whole water measurements may also be used for compliance at the discretion of the environmental manager.

COMMENT 1-29: The data selected by UCD for derivation of the Acute Criterion for bifenthrin overlooked several Relevant and Reliable studies. Inclusion of these studies resulted in a recalculated Acute Criterion of 7 ng/L. (UCD's recommended Acute Criterion was 4 ng/L.)

Due to limited data available on chronic toxicity, an Acute-to-Chronic Ratio (ACR) approach was used to derive the Chronic Criterion for bifenthrin. Based on the default ACR of 12.4 and the recalculated acute value, the recalculated Chronic Criterion is 1 ng/L. (UCD's recommended Chronic Criterion was 0.3 ng/L.)

RTC 1-29: The acute criterion recommended by UCD is still 4 ng/L, not the recalculated 7 ng/L recommended by CBI/FMC (see RTC 1-14), and the chronic criterion has been re-calculated to be 0.6 ng/L in the final bifenthrin report.

COMMENT 1-30: The UCD methodology for deriving numeric water quality criteria (TenBrook *et al.* 2009) is generally sound, though some details of the data selection process could be improved.

The data evaluation criteria favor studies conducted by pesticide registrants following standard test guidelines and Good Laboratory Practices. Non-guideline studies reported in the open literature, which are the source of most data on non-standard species, are more likely to fail the reliability evaluation. Failures are mainly due to non-standard test protocols and deficiencies in reporting, not to unreliable results. The SSD approach requires data for as many species as possible, and too-stringent evaluation criteria may severely limit its applicability.

RTC 1-30: The data evaluation process of the methodology has been thoroughly reviewed by both peer review and public comment processes, but may be revised in the future.

COMMENT 1-31: Many standard tests involve sensitive test species such as daphnids, amphipods, and rainbow trout. As a result, Species Sensitivity Distributions (SSD) based mainly on data from standard tests tend to be biased toward sensitive species. In the case of bifenthrin, the 5th percentile (HC5) of the SSD increased when more non-standard species were included in the analysis. Even with these additional species, the bifenthrin SSD included no data for freshwater mollusks, a major aquatic group that is known to be insensitive to pyrethroids.

RTC 1-31: See RTC 1-24. No studies for freshwater mollusks were identified, and therefore could not be included in the criteria calculation.

COMMENT 1-32: The ETX program (Van Vlaardingen *et al.* 2004) is an appropriate tool for deriving an acute value (median value of the 5th percentile, or HC5) from an SSD. It has the advantages of being well-tested, standardized, and widely accepted throughout the world.

RTC 1-32: Comment acknowledged.

COMMENT 1-33: For derivation of Chronic Criteria, ECx values are preferable to MATCs. An MATC simply reflects a determination of statistical significance, regardless of biological significance or magnitude of effect. An ECx represents a specific magnitude of effect. Appropriate values of x have not yet been agreed upon, but they should be selected with biological significance in mind.

RTC 1-33: See RTC 1-22.

COMMENT 1-34: Pyrethroids bound to particulate matter or associated with dissolved organic matter are not biologically available to aquatic organisms and do not contribute to toxicity; only freely dissolved pyrethroids are bioavailable and toxic. In laboratory toxicity tests using water with minimal particulate or dissolved organic matter, nearly all the pyrethroid is bioavailable. In ambient water, only a small fraction – a few percent or less – of the total pyrethroid may be bioavailable. Compliance with bifenthrin water quality standards should therefore be based on concentrations of freely dissolved bifenthrin, not total bifenthrin. Freely dissolved bifenthrin can be measured directly using solid phase microextraction (SPME), or estimated using an equilibrium partitioning model such as the one presented by Tenbrook *et al.* (2009).

RTC 1-34: See RTC 1-28.

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

(Comments that were unrelated to bifenthrin are not reported in this document)

COMMENT 2-1: The City does not accept the validity of chronic criteria derived when utilizing default acute-to-chronic ratios (ACR). The use of default ACRs is not scientifically defensible and, therefore, results in aquatic life criteria unsuitable for regulatory purposes.

RTC 2-1: The default ACR was calculated using a procedure described and utilized by the US EPA (USEPA 2003, Host *et al.* 1995). The use of a default ACR is accepted by the US EPA for derivation of water quality criteria (USEPA 2003).

COMMENT 2-2: The City disagrees with the assumption of dose additivity. Compliance with criteria should not be based on simplifying, inaccurate assumptions of concentration addition as the principals of concentration addition do not necessarily hold true under possible environmental mixture

scenarios. Until clearly demonstrated among specified compounds, assumptions of dose additivity are unsuitable for regulatory purposes and as such allowance for dose additivity should be omitted.

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

COMMENT 2-3: The City disagrees that bifenthrin compliance should be measured against whole water analysis. Scientific evidence points to freely dissolved bifenthrin as the bioavailable fraction. Compliance should be measured against that portion of bifenthrin that is known to be toxic (i.e., the bioavailable fraction of the total measured amount). The draft bifenthrin criteria report should be revised in a manner that allows for either direct measurement of the bioavailable fraction or allows for some compensating factor accounting for particulate matter effects (i.e., the biologically unavailable fraction).

RTC 2-3: See RTC 1-28.

COMMENT 2-4: The capabilities of commercial laboratories in achieving sufficiently low 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 use, yet at considerable economic expense to the party collecting the data.

RTC 2-4: 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 water quality criteria are derived with only the objective of the protection of aquatic life.

COMMENT 2-5: Finally, the City request correction of an apparent derivation error, as described in the enclosed attachment, in which the chronic criterion for bifenthrin appears to have been calculated in a manner that is inconsistent with the UCD methodology. If a chronic criterion is to be derived, which we argue against based on the scientific shortcomings of the methodology, the chronic criterion should at least be derived consistent with the UCD derivation methodology.

RTC 2-5: The chronic criterion derivation error has been corrected in the final report.

COMMENT 2-6: Acute criteria developed for malathion and bifenthrin are within five times the values that would have been derived utilizing the U.S. EPA methodology and the same dataset set of species mean toxicity values. However, through use of default ACRs in deriving chronic criteria, and the attending uncertainties associated with deriving the default ACR from insecticides of dissimilar mode of toxicity, the chronic criteria as derived are of questionable scientific validity and, therefore, are not appropriate for regulatory use.

RTC 2-6: See RTC 2-1.

COMMENT 2-7: Use of default ACRs should be cautioned and is likely not scientifically defensible in all cases. Acute-to-chronic ratios for a given pesticide can vary considerably (i.e., by orders of magnitude) among species. The default ACR used in criteria derivation for malathion and bifenthrin was developed from a short-list of insecticides that do not all share the same mode of toxic action. In the case of bifenthrin, the default ACR of 12.4 incorporates no data on pyrethroids, but instead is derived solely on classes of pesticides whose structures are different, environmental fate is different, and modes of toxic action are mostly different.

RTC 2-7: See RTC 2-1.

COMMENT 2-8: For all derived criteria, the assumption of dose additivity among pesticides of similar mode of toxicity is assumed. Caution is advised in applying concentration addition principals to compliance measurements unless additivity among specified compounds has been clearly demonstrated. Dose additivity is not settled science because additivity is not always observed, and its accuracy as a model predictor is sensitive to many variable factors. Where science is not settled, compliance should not be based on simplifying assumptions.

RTC 2-8: See RTC 2-2.

COMMENT 2-9: The current scientific understanding regarding pesticide bioavailability should be applied to criteria compliance determinations. The freely dissolved fraction of pyrethroid insecticides, including bifenthrin, is the fraction that is bioavailable. Compliance should be based on measurements that most accurately predict toxicity. Either compliance should be determined using analytical procedures measuring the dissolved fraction, or compliance should be determined accounting for pyrethroid sorption to particulate matter.

RTC 2-9: See RTC 1-28.

COMMENT 2-10: Achieving commercially viable analytical reporting limits below the draft bifenthrin criterion utilizing EPA approved analytical methods is currently lacking or limited. Defensible maximum matrix-specific reporting limits should be defined so as to avoid the potential of reporting false positives and errant detections.

RTC 2-10: See RTC 2-4.

COMMENT 2-11: The chronic criterion for bifenthrin should be corrected. A clerical error appears to have been made in dividing the acute *criterion* by the default ACR when in fact the 5th percentile acute value should have been divided by the default ACR.

RTC 2-11: See RTC 2-5.

2.3. Comment Letter 3 –Sherill Huun and Dan Gwaltney, Sacramento Stormwater Quality Partnership

COMMENT 3-1: The chronic criterion is problematic for a number of reasons, including the lack of available data and the use of the default acute-to-chronic ratio (ACR) for its calculation. The suggested chronic criterion (0.3 ng/L) was derived using an ACR of 12.4 developed from literature information for other pesticides instead of using actual bifenthrin chronic toxicity data. This estimate of a final chronic criterion is highly speculative due to this lack of data, and is potentially more overprotective than the acute value.

RTC 3-1: See RTC 2-1.

COMMENT 3-2: In addition, the use of a default ACR itself is problematic for a number of reasons. The default ACR was derived using pesticides that are not related to pyrethroids. The default ACR was calculated from the 80th percentile value of ACRs from chlordane (ACR of 14), chlorpyrifos (2.2), diazinon (3.0), dieldrin (8.5), endosulfan (3.9), endrin (4.0), lindane (25), and parathion (10). The pesticides with the highest ACRs (chlordane, lindane) are banned organochlorine pesticides that have different mechanisms of action than pyrethroids. The ACR for chlordane also includes data for a saltwater species and is inflated by ACRs for acutely insensitive fish species (bluegill and sheepshead minnow, a saltwater species) that are not representative of the effects of pyrethroids on sensitive invertebrates. Similarly, the ACR for lindane is based on results

for three invertebrate species that are relatively acutely insensitive to lindane (e.g., with mean acute values that are 33 to 242 times the acute criterion for lindane). In essence, the ACR for these other pesticides already included questionable assumptions that should not be translated to pyrethroids.

RTC 3-2: The use of a default ACR was thoroughly reviewed by the peer review and public comment processes during the review of the UCD methodology.

COMMENT 3-3: While the authors state that use of the default ACR "seems a reasonable approach because it is based on ACRs that have been derived from carefully reviewed studies," it focused on pesticides with mechanisms dissimilar to pyrethroids, and ensures that the final ACR for bifenthrin will be inflated by data for insensitive species and intentionally biased by use of an upper percentile of the ACR distribution. Within the draft criteria, the authors recognize that "the default ACR would benefit from the generation and incorporation of more multispecies pesticide ACRs, making the default ACR a better representative of currently used pesticides." The authors essentially admit that the default ACR does not adequately represent pesticides that are in current use. Furthermore, the authors of the criteria development methodology acknowledge that there is "no evidence that default ACR values are appropriate for pesticides in general."

RTC 3-3: We recognize that additional data representing additional pesticide classes would improve the default ACR, but at this time there is no such data to incorporate. The default ACR was calculated with all multispecies pesticide ACRs available from US EPA criteria documents.

COMMENT 3-4: Because there are not adequate data or literature information to set a chronic criterion, the Partnership recommends that the draft criteria refrain from setting a chronic criterion until adequate scientific information is available or additional studies are completed. 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."

RTC 3-4: The criteria calculation procedures were thoroughly reviewed by the peer review and public comment processes during the review of the UCD methodology. One of the main goals of the UCD methodology was to create a methodology that allowed for the derivation of criteria with data sets with varying quantities of toxicity values and diversity. Thus, a chronic criterion is calculated

for bifenthrin according to the UCD methodology, even though there is limited chronic data.

COMMENT 3-5: Furthermore, the low value of the chronic criterion would present implementation challenges. Both acute and chronic criteria are below reporting limits and detection limits for most, if not all, labs (in a clean matrix such as deionized water). Moreover, the ability to detect concentrations below one part per trillion (ppt), that is less than one ng/L, in a complex matrix typically found in the creeks or rivers to be protected by this criterion is even more challenging than detecting these low concentrations in a clean matrix. In fact, because of the challenges, detections below one ppt have yet to be demonstrated. Currently, one ppt detection limits are the goal of California organizations evaluating pyrethroids (i.e., DPR, TriTAC, and the Pyrethroid Working Group (PWG)).

RTC 3-5: See RTC 2-4.

COMMENT 3-6: Based on the acknowledged over-protectiveness, and the uncertainty of the chronic criterion, the Partnership suggest that the acute criterion alone would provide adequate protection while avoiding unnecessary implementation challenges presented by a chronic criterion that can't be assessed with current analytical methods.

RTC 3-6: Acute and chronic criteria are both derived by the UCD methodology, and environmental regulators may choose which values to implement in policy.

COMMENT 3-7: In addition, the Partnership is generally concerned with the Regional Board bypassing the USEPA process of deriving water quality criteria to create independent criteria which may be used to interpret narrative water quality objectives. Until the draft criteria are incorporated into the Basin Plan, they have not been thoroughly vetted by the USEPA, but still can be potentially used by the Regional Board in NPDES permits. Considering the uncertainties associated with the draft criteria, it is ill-advised to release them at least until they can undergo the process toward adoption as water quality objectives.

RTC 3-7: Policy issues on the how the criteria are applied are outside of the scope of the derivation of criteria by UCD contractors. The criteria document does not address policy issues such as how the criteria could be used by the Regional Board or others.

COMMENT 3-8: As we have seen in recent years with manufacturer replacement and State registration, controlling one specific pesticide does not necessarily result in the protection of beneficial uses. Although this research and aquatic toxicity data are useful in understanding pesticides, until a more holistic approach is used with regard to pesticide registration,

use, and control, (including establishment of requirements for pesticide registrants to provide a more comprehensive set of toxicity data that is adequate for assessment of potential water quality impacts), establishing estimated and highly conservative pesticide water quality criteria is counterproductive to improving water quality.

RTC 3-8: Policy issues on the how the criteria are applied are outside of the scope of the derivation of criteria by UCD contractors. The criteria document does not address policy issues such as how the criteria could be used by the Regional Board or others.

2.4. Comment Letter 4 – Nasser Dean, Western Plant Health Association

COMMENT 4-1: Pyrethroids bound to particulate matter or associated with dissolved organic matter are not biologically available to aquatic organisms and do not contribute to toxicity; only freely dissolved pyrethroids are bioavailable and toxic. In laboratory toxicity tests using water with minimal particulate or dissolved organic matter, nearly all the pyrethroid is bioavailable. In ambient water, only a small fraction – a few percent or less – of the total pyrethroid may be bioavailable. Compliance with bifenthrin water quality standards should therefore be based on concentrations of freely dissolved bifenthrin, not total bifenthrin. Freely dissolved bifenthrin can be measured directly using solid phase micro-extraction (SPME), or estimated using an equilibrium partitioning model such as the one presented by Tenbrook et al. (2009).

RTC 4-1: See RTC 1-28.

COMMENT 4-2: The data selected by the UCD authors (Palumbo et al.) for derivation of the acute criterion for bifenthrin overlooked several relevant and reliable studies. Inclusion of these studies resulted in a recalculated acute criterion of 7ng/L. The UCD author's recommended acute criterion was 4ng/L. We request that the CVRWQCB reconsider and include the studies before finalization of the Method.

RTC 4-2: Most of the mentioned studies were not overlooked, they were twice requested from the US EPA through a FOIA request, but they were never received, and therefore cannot be included in the criteria report. Please see RTC 1-2, 1-3, 1-4, 1-5, 1-8, 1-9, and 1-10 for further details about individual studies. Two of the studies (Liu *et al.* 2005b, Wang *et al.* 2009) have been added to the data set.

COMMENT 4-3: For derivation of chronic criteria, ECx values are preferable to maximum acceptable toxicant concentrations (MATCs). A

MATC simply reflects a determination of statistical significance, regardless of biological significance or magnitude of effect. An EC_x represents a specific magnitude of effect. Appropriate values of x have not yet been agreed upon, but they should be selected with biological significance in mind.

RTC 4-3: See RTC 1-22.

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

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

RTC 5-1: A factor of 2 was applied to the median 5th percentile acute value to derive the acute criterion, but not because of the number of toxicity values in the acute data set. The factor of 2 is applied to the acute value because the LC₅₀ toxicity values indicate a 50% effect level, and the goal is to set the criterion at a no-effect level (section 2-3.1.6, TenBrook *et al.* 2009). A concentration of ½ of the LC₅₀ is accepted as a good approximation of a no-effect concentration (section 2-3.1.2 TenBrook *et al.* 2009). The USEPA (1985) criteria derivation methodology also applies a factor of 2 to the final acute value (see section 20 of the final criteria report).

COMMENT 5-2: The suggested chronic criterion (0.3 ng/L) was derived using a literature derived acute-to-chronic ratio (ACR) of 12.4 instead of using of actual chronic toxicity data. This final chronic value is highly-speculative due to this lack of data, and is potentially more overprotective than the acute value. The resulting draft criteria (4.0 and 0.3 ng/L acute and chronic, respectively) create a number of problematic analytical issues for SRCSD. Both criteria are below reporting limits and detection limits for most, if not all, labs (in clean matrix such as deionized water). Although not recognized in the draft criteria document, analytical quantitation limits have an impact on the ability of SRCSD achieving compliance with effluent limitations and receiving water limits derived from the draft criteria. Moreover, the ability to detect concentrations below one ppt (less than one ng/L) in a complex matrix such as effluent is even more challenging than detecting these low concentrations in a clean matrix. In

fact, because of the challenges, detections below one ppt have yet to be demonstrated. Currently, one ppt detection limits are the goal of California organizations evaluating pyrethroids (i.e., DPR, TriTAC, and the Pyrethroid Working Group (PWG)).

Further, the lack of a standard EPA methodology for analyzing pyrethroids may also pose a problem for pyrethroid analyses. For example, the academic lab of Dr. Mike Lydy (University of Southern Illinois) claims one of the lowest reporting limits (3 ng/L) for pyrethroids, yet it is still 10 times higher than the suggested chronic criterion in the draft criteria. Questions have been raised about the possibility of interferences or false positive identifications without confirmation by other methods. To achieve such low reporting limits, Dr. Lydy must perform multiple clean-up steps that are not available or commonly performed by commercial labs, and samples are concentrated 20,000 times (1,000~is normal). These extreme steps have an unknown effect on analytical precision and accuracy.

RTC 5-2: The use of a default ACR of 12.4 has been thoroughly reviewed by both peer review and public comment processes. 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 5-3: The draft criteria authors' note that the dietary pathway for chronic exposure from bifenthrin is poorly understood and that evidence points to toxicity from the freely-dissolved fraction as being the crucial component. The presence of suspended solids and sediments in samples greatly modified and decreased toxicity. Based on this information, the authors' concluded that bioavailability has to be estimated based on dissolved phase measurements or from calculations. Thus, to estimate bifenthrin toxicity in natural waters, detailed site-specific data on suspended sediments and organic fractions is essential.

RTC 5-3: Comment acknowledged.

COMMENT 5-4: Likewise, temperature is an important factor in determining pyrethroid toxicity and should be included in any model for determining the bifenthrin criteria because pyrethroid toxicity increases at lower temperatures when enzymes break down these chemicals more slowly.

RTC 5-4: Unfortunately, there is limited data on the effects of temperature on toxicity using aquatic exposures with aquatic species, making it infeasible to quantify the relationship between the toxicity of bifenthrin and temperature for water quality criteria at this time (section 3-5.3, TenBrook *et al.* 2009a).

COMMENT 5-5: Moreover, the measurement of the draft criteria in whole water, as recommended by the UCD authors, is contrary to applicable literature, which suggests strong and highly variable interactions with suspended particulates and bifenthrin concentrations in the dissolved phase. As a result, the authors acknowledge that the suggested criteria are likely to be overprotective.

RTC 5-5: The bioavailability section of the criteria report has been revised to recommend that the dissolved fraction of bifenthrin is used for criteria compliance. If a dissolved fraction measurement is not feasible or available, whole water measurements are also valid for criteria compliance.

COMMENT 5-6: Further, supportive data were inconclusive or unavailable on the effects of pesticide mixtures, temperature effects for freshwater organisms, and the effects on the most sensitive species. For example, for effects to sensitive species the UCD authors cited the lowest reported sensitive freshwater invertebrate chronic toxicity value of 1.9 ng/L. However, contrary to this value, the UCD authors propose a chronic criterion value of 0.3 ng/L.

RTC 5-6: The toxicity values of sensitive species are compared to the derived criteria to make sure that the criteria are below those values (section 3-6.1, TenBrook *et al.* 2009), which is the case for the bifenthrin criteria.

COMMENT 5-7: With respect to sensitive species, epibenthic invertebrates (e.g., *H. azteca*) are the most sensitive model species for toxicity tests with pyrethroid. This sensitive species drives criteria development. However, tests with species similar to local, listed species of fish yielded toxicity values of 5 to 10-fold higher than the suggested chronic criterion. Therefore, these criteria are highly protective of fish.

RTC 5-7: The goal of aquatic life criteria is to protect all species in an ecosystem; therefore, the most sensitive species must be included in criteria derivation.

COMMENT 5-8: Because of the lack of confidence in the chronic criterion, and over-protectiveness of the proposed value SRCSD, cannot support their use by the Regional Board until there is a better understanding of fate and transport, chronic toxicity, and affects of dissolved solids and suspended particles that can be accounted for in an empirical model.

RTC 5-8: The chronic criterion calculation has been altered in the final criteria document, and the chronic criterion is now calculated as 0.6 ug/L. Because the chronic criterion is calculated with an ACR, the uncertainty cannot be calculated. 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.

COMMENT 5-9: Concerns with Use of Draft Criteria to Interpret Narrative Water Quality Objectives

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

RTC 5-9: Policy issues on the how the criteria are applied are outside of the scope of the derivation of criteria by UCD contractors. The criteria document does not address policy issues such as how the criteria could be used by the Regional Board or others.

COMMENT 5-10: SRCSD is concerned with the use of the draft criteria to interpret narrative objectives as it creates de facto water quality objectives that have not been adopted in accordance with the law. Under Porter-Cologne Water Quality Control Act (Porter-Cologne), the Regional Board is required to regulate water quality in a manner that attains the highest level of water quality which is reasonable, considering all demands being made and to be made on those waters. (See Wat. Code, § 13000.) Further, water quality objectives are supposed to be established to ensure reasonable protection of beneficial uses, considering a number of different factors. The factors that must be considered include: past, present and probable future beneficial uses; environmental characteristics of the hydrographic unit under consideration, including the quality of water; water quality conditions that could reasonably be achieved through the coordinated control of all factors which affect water quality in the area; economic considerations; the need for developing housing; and the need to develop and use recycled water. (Wat. Code, § 13241.) Also, the Regional Board is required to adopt a program of implementation for achieving water quality objectives at the time of adoption. (See Wat. Code, § 13242.) In other words, when adopting water quality objectives, the Regional Board must determine if the objective is necessary to provide for reasonable protection of the beneficial uses, and the Regional Board must balance all of the competing demands on the water and consider the economic implications associated with adoption of water quality

objectives. SRCSD respectfully requests that the Regional Board refrain from using the draft criteria for bifenthrin until the criteria are properly adopted as water quality objectives pursuant to all requirements in Porter-Cologne.

RTC 5-10: 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.

2.6. Comment Letter 6 – Debbie Webster, Central Valley Clean Water Association

COMMENT 6-1: CVCWA is concerned with the proposed draft bifenthrin criteria. We believe a better understanding of fate and transport, chronic toxicity, and affects of dissolved solids and suspended particles are needed. CVCWA shares the concerns regarding the draft criteria as derived that are outlined and explained in more detail in the Sacramento Regional County Sanitation District's January 14, 2010 letter on this matter (see attached). Our concerns include:

- The lack of good toxicity data;

RTC 6-1: We rated nine acute studies and two chronic studies as highly relevant and highly reliable. We agree that the lack of data was the most important limitation for bifenthrin criteria calculation.

COMMENT 6-2: The choice to use a literature-based acute-to-chronic ratio (ACR) literature, instead of using of actual chronic toxicity data;

RTC 6-2: There was not enough chronic data in the data set to derive the chronic criterion with measured toxicity data.

COMMENT 6-3: The lack of established and available analytical methods, and issues surrounding this such as:

- o Not having analytical methods that can monitor complex matrixes to detection levels,
- o Unanswered questions about interferences,
- o The levels of concentration needed for even clean matrixes;

RTC 6-3: The derivation of water quality criteria do not take into account reporting limits of commercial laboratories or other economic feasibility issues. These considerations are taken into account when setting water quality objectives, while water quality criteria are derived with only the objective of the protection of aquatic life.

COMMENT 6-4: The lack of understanding of dietary pathways for chronic exposure and evidence that points to the freely-dissolved fraction as being the crucial component;

RTC 6-4: See RTC 1-27 and 1-28.

COMMENT 6-5: The lack of consideration of site/sample specific requirements for water quality factors affecting toxicity in determining appropriate criteria for the waterbody;

RTC 6-5: Several site-specific parameters are considered in the bifenthrin criteria report: reduced bioavailability caused by the presence of dissolved organic carbon or suspended solids, increased toxicity caused by lower temperatures, and the presence of pesticide or chemical mixtures in the environment. Unfortunately, there is not enough data to account for temperature-related or non-additive mixture effects. The effects of dissolved organic carbon and suspended solids are accounted for by use of a site-specific model for criteria compliance, or the measurement of the dissolved fraction of bifenthrin.

COMMENT 6-6: The likelihood that the proposed chronic criteria are overprotective.

RTC 6-6: The bifenthrin data set indicated that setting the criteria higher would not be protective of sensitive species that are present in aquatic ecosystems.

COMMENT 6-7: CVCWA is concerned with the Central Valley Water Board's proposed use of the *draft criteria* to interpret narrative water quality objectives and potential use of the criteria to set water quality based effluent limitations in NPDES permits, as it will create liability for wastewater dischargers in the Central Valley. Considering the liability associated with complying with such effluent limitations, the Central Valley Water Board should take care in using only criteria that are well-developed and well-founded.

Moreover, CVCWA is concerned with the use of the draft criteria to interpret narrative objectives because it creates de facto water quality objectives that have *not* been adopted in accordance with the law. Under Porter-Cologne Water Quality Control Act (Porter-Cologne), the Central Valley Water Board is required to regulate water quality in a manner that attains the highest level of water quality which is reasonable, considering all demands being made and to be made on those waters. (See Wat. Code, § 13000.) Porter-Cologne requires that water quality objectives be established to ensure *reasonable* protection of beneficial uses, considering a number of different factors and requires the Regional Water Board to adopt a program of implementation for achieving water quality objectives at the time of adoption. (See Wat. Code, § 13242.) In other

words, when adopting water quality objectives, the Central Valley Water Board must determine if the objective is necessary to provide for *reasonable* protection of the beneficial uses, and the Central Valley Water Board must balance all of the competing demands on the water and consider the economic implications associated with adoption of water quality objectives.

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

RTC 6-7: Policy issues on the how the criteria are applied are outside of the scope of the derivation of criteria by UCD contractors. The criteria document does not address policy issues such as how the criteria could be used by the Regional Board or others.

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 bifenthrin (2-methyl[1,1'-biphenyl]-3-yl)methyl (1R,3R)-rel-3-[(1Z)-2-chloro-3,3,3-trifluoro-1-propenyl]-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 bifenthrin. This data set indicates that this pesticide has low

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.

solubility, low volatility, high potential to bioaccumulate, high potential to sorb to sediments, and is persistent in aqueous environments (i.e., low rates of hydrolysis, photolysis, and biodegradation). Accordingly, this pesticide's physical-chemical characteristics make its exposure to aquatic organisms a relevant concern, due to its persistence and high potential for bioaccumulation and food-web transfer.

RTR 1-2: Comment acknowledged.

Review 1-3: *Human and Wildlife Dietary Values*

The FDA has not set action levels for bifenthrin in fish tissue but has set a level for meat (e.g., cattle, hogs) at 0.5 mg/kg. Toxicity to mallard ducks is relatively low, with an LC₅₀ (which should be reported as an LD₅₀) value for food of 1,280 mg/kg and an NOEC of 2,150 mg/kg body weight being reported.

RTR 1-3: The dietary exposure value is reported as a LC₅₀, as done by the USEPA, because they are concentrations in feed, whereas the oral toxicity values are reported as LD₅₀s because they are tests that administer a pure chemical dose via oral intubation or oral gavage.

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

The authors evaluated approximately 40 published studies of bifenthrin toxicity to develop the proposed criteria. Relevance was determined using the aforementioned methods¹ and only data for studies that were deemed acceptable were used in the criteria derivation. Adequate and reliable data was available for determining acute toxicity using animal studies and exclusion criteria appear to have been applied properly. Nine acute, four microcosm and ecosystem studies were used as supporting data and 3 studies of effects on wildlife were reviewed for relevance to bioaccumulation. Studies selected for derivation of the chronic criterion were not mentioned and need to be defined in this section.

RTR 1-4: This section of the report has been revised to summarize the chronic data.

Review 1-5: *Acute criterion calculation*

The acute criterion for bifenthrin was calculated using methods defined by Tenbrook *et al.* (2009). Data for all five required taxa was available and a criterion of 4 ng/L was derived using acceptable calculations.

RTR 1-5: Comment acknowledged.

Review 1-6: *Chronic criterion calculation*

The acute-to-chronic ratio (ACR) method was used to derive the chronic criterion using data for only two of the five required taxa. The lack of

corresponding acute toxicity data made this exercise unreliable; therefore, the default value of 12.4 was used. This was appropriate given the general paucity of toxicity data. The subsequent calculation of the chronic criterion divided the acute 5th percentile acute value by the ACR of 12.4 to arrive at the final value of 0.3 ng/L. Because this value is lower than the lowest MATC of 1.9 ng/L reported for *Daphnia magna*, it would appear to be a conservative value. However, the lack of a robust, data-based ACR means that the confidence in the derived value is relatively low.

RTR 1-6: Comment acknowledged.

Review 1-7: Bioavailability

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

The practical matter of assessing bioavailability is addressed and the conclusion that it cannot be accurately estimated without site-specific data is a valid conclusion. The following discussion of nominal vs. measured concentrations of bifenthrin is relevant as the properties of this compound make it difficult to accurately assess exposure concentrations in toxicity tests. Nominal (i.e., added concentrations) are likely to over-estimate exposure concentrations due to sorption of bifenthrin to organic phases as well as container surfaces (this effect has the result of under-predicting toxicity). Accordingly, the authors recommend that criteria compliance be based on whole-water concentrations of bifenthrin, as this will provide a conservative (i.e., over-protective) estimate of this compound's availability. This is a prudent recommendation given uncertainties in reported exposure concentrations.

RTR 1-7: The word portion has been changed to fraction in the final report. It should be noted that the bioavailability section has been revised to recommend that compliance should be based on the freely dissolved fraction of bifenthrin, if such methods are available.

Review 1-8: Mixtures

Because bifenthrin often occurs in the presence of other pyrethroid insecticides that have a similar mode of action, the toxic unit or relative potency factor approaches are appropriate to use. However, compounds that have dissimilar modes of action may exhibit additive, synergistic, or

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

RTR 1-8: Comment acknowledged.

Review 1-9: *Temperature, pH effects*

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

RTR 1-9: Additional safety factors are not recommended for the bifenthrin 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.

Review 1-10: *Sensitive Species*

The calculated acute and chronic criteria (4- and 0.3-ng/L, respectively) are both below the lowest acute and chronic values reported in the data set. The conclusion that these criteria derived in this report should be adequately protective is reasonable.

RTR 1-10: Comment acknowledged.

Review 1-11: *Ecosystem and Other Studies*

The authors reviewed four studies of microcosm and ecosystem tests that had acceptable ratings. These studies provide a realistic approximation of bifenthrin bioavailability as they included sediments as the principal source of contaminant. In each of these studies, toxicity was only reported for water concentrations that were higher than the proposed acute and chronic criteria.

Field studies of bifenthrin have been conducted but are difficult to interpret due to the lack of data on the compounds concentration water. It is clear from toxicity identification evaluation studies that bifenthrin that enters the environment through normal use and its subsequent presence in runoff can result in toxicity to aquatic invertebrates.

RTR 1-11: Comment acknowledged.

Review 1-12: *Threatened and endangered species*

Data on bifenthrin toxicity is only available for one threatened or endangered species (steelhead trout). Because this species has an LC₅₀ of 0.15 µg/L, the authors conclude that the proposed criteria will protect this species. It is not clear if this concentration of bifenthrin reported for this study was corrected for chemical purity (i.e., 88.4%). Also, it would be more appropriate to compare the proposed criteria to an NOEC for this species rather than the LC₅₀ value. Both of these questions should be addressed in the final report.

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. Overall, the proposed criteria would appear to be protective of threatened and endangered species.

RTR 1-12: The LC₅₀ for *O. mykiss* was not corrected for the chemical purity, but if it had been, it would still likely be much more than twice the acute criterion of 4 ng/L. Unfortunately, there are no chronic data available for this species, or any other threatened or endangered species, in the data set. We conclude that there are no toxicity values in the acute or chronic data sets that indicate underprotection of endangered species.

Review 1-13: Bioaccumulation

Bifenthrin has a relatively 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 bifenthrin that would result in a lethal concentration in wildlife that would consume contaminated fish. Using this approach, a water concentration of 267 ng/l would be required to produce a body burden of bifenthrin in fish that would be toxic to mallard ducks. Using tolerance levels for bifenthrin in meat (i.e., 0.5 mg/kg) that would be protective of human health, an equivalent concentration in fish would require a water concentration of 23 ng/L. Although both of these levels are below the proposed criteria, it should be mentioned that the water concentrations of bifenthrin that would be required to cause concern for food-web transfer would likely result in acute toxicity to fish and aquatic invertebrates.

RTR 1-13: The NOEC_{water} levels calculated in the bioaccumulation section would be likely to result in acute toxicity to many organisms, but the chronic criterion is well below both of them, and therefore the criterion should be protective of both toxicity and bioaccumulation.

Review 1-14: Harmonization with Air and Sediment Criteria

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

RTR 1-14: Comment acknowledged.

Review 1-15: *Assumptions, Limitations, and Uncertainties*

The authors correctly point out that the major source of uncertainty in this evaluation stems from the lack of viable bifenthrin toxicity data for three of the five required taxa. The approaches used (i.e., ACR and Assessment Factor) were appropriate given this limitation. However, the lack of chronic data for *Hyalella azteca* is cause for concern as this is the most sensitive species for acute effects. Coupled with the potential heightened sensitivity of this species at low water temperatures, it is possible that the proposed chronic criterion would not be protective under all environmental conditions. Although the authors are correct to point out that an application of an additional safety factor has merit, there is little discussion of how such a factor could or should be derived. At minimum, a more thorough description of temperature effects derived from the Weston *et al.* (2008) study would be appropriate.

RTR 1-15: If toxicity data from aqueous exposures for multiple species at multiple temperatures was available, then an equation could be derived to incorporate this effect into criteria compliance, as described in section 3-5.3 of the methodology. The Weston *et al.* (2008) study used sediment exposures, and therefore cannot be incorporated in to criteria compliance for water quality criteria.

Review 1-16: *Comparison to National Standard Methods*

EPA (1985) methods were also used to derive acute and chronic criteria for bifenthrin. The EPA method faces limitations because data for some required organisms (i.e., chordates and arthropods) is not available. The authors used proper caveats and calculations in performing this analysis. The acute criterion proposed in this study is higher than the EPA-derived value for invertebrates (4 ng/L vs. 2 ng/L, respectively). This difference between these values appears to be due to the fact that the EPA method included data for 7 taxa rather than the 5 used in this study. The authors conclude that the EPA method cannot be used for acute criterion development because it falls short on meeting all of the required elements. Although this is an accurate conclusion, a more specific explanation of the root cause of the differences between the acute criteria would be useful. This is particularly important as the potential for higher toxicity of bifenthrin at low temperatures suggests that a more conservative acute criterion may be prudent.

A chronic criterion for bifenthrin could not be calculated using the EPA methodology due to the lack of an acceptable acute-to-chronic ratio.

RTR 1-16: The root cause of difference between the acute criteria calculated by the USEPA (1985) and UCD methodologies is that different distributions are used by the two methodologies. The UCD data set is used to derive criteria by the USEPA (1985) method in section 20 of the criteria report, so there are no differences in the data sets. The USEPA (1985) method uses a log-triangular distribution; it has been demonstrated in the diazinon and chlorpyrifos criteria reports that the log-logistic and Burr Type III distributions used in the UCD methodology give different criteria results than the log-triangular distribution. The log-triangular distribution heavily weights the sensitive end of the data set, but it does not always produce a lower value than the distributions used in the UCD methodology, as demonstrated in the diazinon and chlorpyrifos criteria reports.

Review 1-17: Final Bifenthrin Criteria Statement

EPA water quality criteria do not exist for bifenthrin and the California Department of Fish & Game has not set criteria due to the inability to meet all of the required elements of the EPA methods. Based on the best available data, the acute criterion of 4 ng/L and the chronic criterion of 0.3 ng/L proposed in this report should be protective of aquatic species in the Sacramento and San Joaquin River basins. However, these criteria need to be re-evaluated as soon as additional data for sensitive species (acute and chronic) and temperature effects becomes available.

RTR 1-17: Comment acknowledged.

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

REVIEW 2-1: Acute and chronic criteria proposed for bifenthrin are 4 ng/L and 0.3 ng/L, respectively. Given the limited chronic toxicity values available, the chronic value appears appropriate.

RTR 2-1: Comment acknowledged.

REVIEW 2-2: However, the acute value does not appear sufficiently low to protect sensitive aquatic invertebrates. Five acute toxicity tests for amphipod *Hyaella azteca* had a range of LC₅₀ values from 2.7 to 9.3 ng/L with no obvious outliers. This range of sensitivities has been demonstrated in recent field work. To prevent acute toxicity and adhere to the Basin Plan, the acute criterion should be lowered to ½ the LC₅₀ value to 1.4 µg/L.

RTR 2-2: The most robust toxicity value for *Hyaella azteca* is the species mean acute value (SMAV) of 0.0065 µg/L. While there is one *H. azteca* toxicity value in the RR data set that is below the derived acute criterion, the SMAV is the most robust toxicity value to represent a species. The *H. azteca* SMAV is based on five separate tests, and is therefore a more robust and reliable value than a

single test value. A SMAV is calculated for use in the SSD so that no single species or single test for a species receives undue weight in the derivation process (section 2-2.7, TenBrook *et al.* 2009a). The goal of a SSD is to utilize the whole data set to derive protective estimates, not to simply choose the lowest toxicity value and divide it by a factor of 2. In this case, it is not recommended that the acute criterion be adjusted downward based on one of five toxicity values for *H. azteca*, because the SMAV indicates that the acute criterion of 0.004 µg/L will be protective of this species. Downward adjustment of criteria can be recommended when a proposed criterion is higher than toxicity values for a sensitive species (section 3-6.1, TenBrook *et al.* 2009a), especially when there is very little data for a species, but it is not recommended in this case because there is ample data highly rated acute data for *H. azteca*.

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

REVIEW 3-1: The bifenthrin water quality criteria were derived by applying a new methodology recently developed by the University of California, Davis. Explicitly following the data evaluation criteria of the methodology, the author(s) sorted out 40 original studies for bifenthrin aquatic toxicity, and identified nine acute and two chronic toxicity studies that were reliable and relevant for criteria derivation. As acute toxicity data were acceptable from five taxa (i.e., a warm water fish, a cold water fish, a planktonic crustacean, a benthic crustacean, and an insect), a species sensitivity distribution (SSD) procedure was applied for the acute water quality criterion derivation that yielded a recommended acute value of 4 ng/L. The chronic criterion calculated by using the acute-to-chronic ratio (ACR) with a default ACR value yielded a value of 0.3 ng/L.

RTR 3-1: Comment acknowledged.

REVIEW 3-2: Although the chronic criterion had limitations due to the limited data sets and absence of acceptable ACR value, it is likely protective of aquatic organisms given the fact that the value is six times lower than that of the lowest maximum acceptable toxicant concentration (MATC) from most sensitive species tested.

RTR 3-2: Comment acknowledged.

REVIEW 3-3: The water solubility data need to be updated. Three values of bifenthrin water solubility provided in the report are extremely varied, i.e., over several thousand folds of difference from each other. This is unusual for a relatively constant parameter like water solubility when the data were measured in relatively standard conditions. The highest value,

i.e. 100 µg/L cited from “Agrochemicals Handbook by Kidd & James 1991” might have been outdated. A similar data was reported in “The Pesticide Manual by Tomlin 1994, Tenth Edition” but not cited for water solubility in the report). However, the recent edition (Twelfth) of “The Pesticide Manual” updated the value equal to 1 µg/L. Similarly, the value 2.5 µg/L cited from FOOTPRINT 2008 could not be found on its website. Instead, a value smaller than 1 µg/L was posted in 2009. The lowest value 0.014 µg/L was referred to a review paper by Laskowski (2002). The actual source was from Herbst (1983a), which is even older than the value from Kidd & James (1991). It may be beneficial to readers to cite original data sources and to keep citation sources relatively consistent as standard formats in compiling future reports for criteria derivation.

RTR 3-3: The water solubility has been updated and older, less reliable studies have been removed from the report.

REVIEW 3-4: The conclusion for the protectiveness of the derived acute toxicity criterion does not seem to be fully supported by the acceptable acute toxicity data sets for the following reasons: 1) As discussed in the report, the criterion likely underestimated the sensitivity of organisms to bifenthrin due to the nominal toxicity values used for the derivation. However, the recommended acute criterion could only be revised until measured data are available (Page 11, the report); 2) The derived criterion is higher than the lowest LC₅₀ value of 2.7 ng/L for *Hyalella azteca* and similar to the LC₅₀ of 3.97 ng/L for *Mysidopsis bahia*. Thus, the discussion for the acute criterion in the report on Section 14 Sensitive Species (Page 13) is irrelevant to support the conclusion “the acute criterion appears to be protective of freshwater organisms”; 3) As shown by empirical data of 219 toxicity tests (discussed in the UC Davis Phase Two report for water quality criteria derivation, Page 2-41), a concentration that is less than approximately half of the mean LC₅₀ values may not cause mortality greater than that in controls. However, the derived bifenthrin criterion (4 ng/L) is greater than the half of the geometric LC₅₀ mean (6.5 ng/L) of five tests for the most sensitive species *Hyalella azteca*. Based on the reasons discussed above, I would recommend considering those factors in the criteria derivation for bifenthrin.

RTR 3-4: The above points are addressed as follows:

- 1) Six of the thirteen toxicity values in the acute RR data set used estimated concentrations and one value used measured concentrations. The estimated concentrations were estimated from recovery data from measurements for a portion of the tested concentrations. Estimated or measured data is available for three species, including the most sensitive species, *H. azteca*. The toxicity values of these species are not likely underestimations.
- 2) See RTR 2-2 regarding the use of a SMAV instead of individual toxicity test results for criteria adjustment. The SMAV is the most robust and reliable toxicity

value for *H. azteca*. *Mysidopsis bahia* is a saltwater species, and saltwater and freshwater species are not presumed to have similar toxicity values. Saltwater data are not appropriate for use in criteria generation or adjustment, but they may be used to calculate ACRs.

3) The safety factor of 2, discussed in the methodology and used in the USEPA (1985) methodology, is applied to the acute value determined by the distribution. Criteria are not calculated by simply dividing the lowest LC₅₀ value by a factor of 2 because a more robust value is determined by using a distribution that takes all of the toxicity data into account.

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