

Responses to Public Comments and Peer Reviews

Phase III: Esfenvalerate Water Quality Criteria Derivation Report

using the

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



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Responses to Comments

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

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

1.0 Introduction

This document presents the responses to public comments and peer reviews received on a technical report prepared by the University of California at Davis, Environmental Toxicology Department, under contract to the Regional Water Quality Control Board, Central Valley Region (Regional Board). This report represents one of 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 Draft Phase II report details this new methodology and its application to bifenthrin. The third phase of the project was to apply the criteria derivation method to eight additional pesticides, of which esfenvalerate is one.

The esfenvalerate criteria report was submitted to peer review, conducted by an expert from academia and our sister agency the Department of Pesticide Regulation.

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

2.0 Response to Comment to Public Comments

2.1. Comment Letter 1 – Matthew D. McCoole, Ph.D., DuPont Crop Protection

COMMENT 1-1: The University of California, Davis has developed two new methodologies for deriving freshwater water and sediment quality criteria. These methodologies were put into practice to derive aquatic life criteria for a number of pesticides of concern in the Sacramento River and San Joaquin River watersheds, California. This report describes the procedures used to derive the water and sediment quality criteria for esfenvalerate. Although the methods used to derive these quality criteria are based on well grounded, previously accepted methodologies and approaches, there is a lack of critically important data for esfenvalerate which prevents a proper analysis from being conducted.

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

COMMENT 1-2: Considering the high degree of uncertainty, lack of available data for calculating criteria, and the reliance on an assessment factor approach rather than development of SSDs, it is recommended that the BSQC's for esfenvalerate not be calculated unless and until sufficient data is available.

RTC 1-2: The development of bioavailable sediment quality criteria (BSQC) for esfenvalerate has been separated from the development of water quality criteria for esfenvalerate because the sediment methodology has not been finalized. The BSQC were termed interim values to indicate that insufficient data is available to calculate unqualified BSQC, however, synthesizing available data in a report provides a useful document that compiles what is known about sediment toxicity and highlights the data gaps that should be prioritized and is thus a useful exercise.

COMMENT 1-3: Title, and throughout the report – I don't believe the word 'criteria' should be used as criteria are policy determined values. A better word might be benchmarks or objectives.

RTC 1-3: In California, objectives is a regulatory term. Criteria is used to indicate values determined solely considering scientific information for the protection of a beneficial use, which is consistent with how U.S. EPA uses the term criteria.

COMMENT 1-4: Section 7 – this report makes a lot of mention of other reports throughout the manuscript, and it causes the reader to have to do a lot of searching. In some cases the reader is referred to previous reports for descriptions of methods or background on an issue. This document

should be self-sufficient. Perhaps details for examples and calculations can be made more accessible in an appendix.

RTC 1-4: All of the documents referred to are available on the project website and the references in the criteria report include section numbers so that the references are easy to find. The development of the criteria follow the methodologies referred to, and are not meant to be independent of them. An understanding of the methodologies is necessary for understanding the criteria.

COMMENT 1-5: Page 8, Figure 3 – ‘percentile’ spelled incorrectly

RTC 1-5: This typo has been corrected.

COMMENT 1-6: Page 8, section 7.2 – before any calculations are conducted, a clear understanding needs to be conveyed to the audience what the term ‘interim’ means here. How is uncertainty accounted for? Also, it should be noted that these ‘interim’ values are not appropriate for regulatory use.

RTC 1-6: All of the information and calculations for the interim BSQC have been separated from the water quality criteria report and comments regarding the interim BSQC will be responded to when the sediment methodology and criteria reports are finalized.

COMMENT 1-7: Page 8, section 7.2 – change bifenthrin to esfenvalerate

RTC 1-7: See RTC 1-6.

COMMENT 1-8: Page 8, section 7.2 – there are a number of concerns with using the assessment factor approach when data is limited. Please see review from Hall, Lenwood of the University California, Davis Phase II methodology report.

RTC 1-8: See RTC 1-6.

COMMENT 1-9: Section 7.2 and 8.2 – I disagree with the calculation of BSQC with such a small data and sample size. The apparent strength in the Phase II UCDSM is that it is based on statistical approaches from other programs, adapted to sediments. The SMAV and AFs are very uncertain for such small sample sizes and will likely results in criteria that are highly over protective. The approach should be to establish stronger and more robust data sets for the criteria calculation.

RTC 1-9: See RTC 1-6.

COMMENT 1-10: Section 9.2 – Is this section needed? The authors state that *no studies on aquatic organisms were identified in the literature that could provide quantitative means to consider mixtures of esfenvalerate with other classes of pesticides*. The paragraph that this statement is included in should be sufficient.

RTC 1-10: Section 9.2 provides a qualitative overview of what is known about the toxicity of mixtures of esfenvalerate and other chemicals. Although there are no quantitative means to consider mixtures for criteria compliance, this qualitative information is summarized so that environmental managers have a more complete picture for risk assessment of esfenvalerate.

COMMENT 1-11: Page 14, middle paragraph – Although PBO is a widely used additive, I don't know of any examples where PBO is monitored in environmental monitoring studies. Do you have any information about its environmental fate? More information about the fate of PBO is needed here to make this section relevant.

RTC 1-11: Information on the half-life of PBO in water and sediment has been added to section 9.2, as well as further description of a study that showed vector control spraying of a product containing PBO synergized existing sediment pyrethroid residues.

COMMENT 1-12: Page 14, second paragraph, line 5 – replace 'a' with 'and'

RTC 1-12: This typo has been corrected.

COMMENT 1-13: Page 16-17, last paragraph – The authors state, *It should be noted that there are no data available for Hyalella azteca, which is known as a species that is particularly sensitive to pyrethroids. It is not clear if the WQC would be protective of these amphipods*. This data would be particularly important to have, as lab-reared *Hyalella* are shown to be quite sensitive to pyrethroids. Also, *Hyalella* is known to exist as a species complex with different characteristics depending on source. There are several papers about this issue and perhaps it should be discussed here. Lacking this data makes the data set used for quality criteria determination rather weak.

RTC 1-13: Since the release of the draft criteria report for esfenvalerate, aqueous toxicity data for *Hyalella azteca* has become available and is now included in the criteria calculation.

COMMENT 1-14: Page 17, last paragraph, line 15 – add 'for' to the end of this line before 'benthic' and add 'at' before 10.

RTC 1-14: This sentence does not appear in the final water quality criteria report, but the typos will be corrected in the final sediment quality criteria report.

COMMENT 1-15: Section 10.3 – given the lack of chronic data for crustaceans and insects (and the uncertainty contained in the BSQC), an endangered species assessment should not be carried out.

RTC 1-15: The endangered species assessment summarizes any information that is known about effects on endangered species and the limitations are acknowledged.

COMMENT 1-16: Section 12.1 – how will these assumptions, limitation and uncertainties be used in developing potential policy?

RTC 1-16: This criteria report does not prescribe how the information will be or should be used in developing potential policy; policy development is a separate public process.

COMMENT 1-17: Section 12.1 – there is a call for a discussion for uncertainty, but there has not been any guidance provided on how that should be done. Was an uncertainty analysis performed?

RTC 1-17: The uncertainty analysis is primarily qualitative and is meant to identify the main sources of uncertainty in the derived criteria and point out key data gaps that if filled would most significantly reduce uncertainty. This section has been revised to include an explanation regarding whether filling each data gap would likely increase or decrease the criteria. The variability of the acute water quality criterion can be quantified by examining the 95% confidence interval of the 5th percentile value used to calculate the acute criterion. Uncertainty was not quantified for the chronic water quality criterion because a statistical method was not used to derive this value.

COMMENT 1-18: Section 12.1 – the authors point out here a number of flaws in the determination of the quality criteria, namely the lack of data, which forces the authors to use alternative methods to develop the criteria. Larger, more diverse data sets must be developed and evaluated before these criteria are used as regulatory values. With such sparse data, why was esfenvalerate chosen for the application of the methodologies developed in Phase II?

RTC 1-18: Esfenvalerate was chosen because it has been demonstrated that the pesticide has caused or contributed to water quality impairments in the Central Valley of California. The robustness of the data set cannot be known until the

data collection and evaluation steps are completed in the criteria development process. Criteria are desired for pesticides known to cause water quality impairments, regardless of how much data is available.

COMMENT 1-19: Section 12.3 – remove *The final water quality criteria statement is:* This comes off as too final and may be interpreted as to be included in regulatory decision processes.

RTC 1-19: This statement may be used in regulatory processes if environmental managers determine that it is appropriate for their purpose.

COMMENT 1-20: Section 12.3, paragraph 3 – *Although the criteria were derived to be protective of aquatic life in the Sacramento and San Joaquin Rivers, these criteria would be appropriate for any freshwater ecosystem in North America, unless species more sensitive than are represented by the species examined in the development of the present criteria are likely to occur in the ecosystem of interest.* Because of the lack of sensitive species data, this statement is too broad. Until sensitive species like *Hyaella* are examined, this blanket type statement should not be made.

RTC 1-20: The intention of this statement is to say that the species used to calculate these criteria are representative of freshwater ecosystems in North America, and are not specifically representative of the Sacramento River and San Joaquin River watershed.

COMMENT 1-21: Appendix A – Toxicity data summaries. The data quality scoring system that is presented seems to be subjective based on the individual reviewer. These reviews can be subjective on a number of different levels, and caution needs to be taken with discarding potentially useful data.

RTC 1-21: The goal of the data quality scoring system was to make the process of data evaluation clear and transparent. Best professional judgment is used in the process, and the data summaries are included in the report so that they are available for review.

COMMENT 1-22: Appendix A – for a number of studies (at least 2), there was a deduction of 7.5 points for “control description not reported.” It needs to be made clear exactly what this means, as it seems unlikely that these otherwise sound studies (denoted as RR in this scoring system) would not report control data. Would this not be an automatic basis for a downgraded reliability rating? How is the 7.5 determined? See above comment for subjectivity potential.

RTC 1-22: “Control description not reported” indicates that the study did not report whether they used a solvent control or dilution water control. Some studies report an acceptable control response, but fail to report the type of control used (solvent and/or dilution water).

COMMENT 1-23: Insufficient data is available to determine if the esfenvalerate criteria are over protective or under protective. Due to the lack of available data for calculating criteria, it is recommended that this report not be accepted at this time. Any criteria calculation methodology needs to be based on species sensitivity distributions rather than on an assessment factor approach. Because of these uncertainties, the values reported here should be reported as sediment quality benchmarks, rather than sediment quality criteria. These criteria should not be calculated unless and until sufficient data is available to do so.

RTC 1-23: This is an informational report intended to provide criteria that should be protective of aquatic life based on available high quality data, as well as point out data gaps and uncertainties in the criteria so that environmental managers can make informed decisions about whether and how to use the criteria.

2.2 Comment Letter 2 – Kelye McKinney, City of Roseville; Brant Jorgenson, Robertson-Bryan, Inc.

COMMENT 2-1: The criteria derivation document for esfenvalerate utilizes criteria derivation methodologies developed by UCD for limited datasets. The City has commented previously on the use of these methodologies for chlorpyrifos, diazinon, malathion, diuron, bifenthrin, cypermethrin, cyfluthrin, cyhalothrin and permethrin. The City has reiterated its general concerns in each comment letter, namely the use of these criteria to interpret the Basin Plan’s narrative toxicity objective and use of these criteria as enforceable regulatory thresholds. In order to derive criteria for pesticides with limited toxicity threshold datasets, the methodologies employ a series of conservative and compounding assumptions that likely result in substantially overprotective criteria. This is particularly the case with the derived chronic criteria, where chronic toxicity data are often completely absent, necessitating the use of default acute-to-chronic ratios (ACR). The City maintains these same concerns with this most recent criteria derivation document for esfenvalerate.

Specific comments are detailed below. The City formally requests that the Central Valley Water Board consider these comments, in light of its own

review of the UCD document, before accepting a final version of the document from UCD.

RTC 2-1: The Regional Board will consider all comments when considering the use of any UCD criteria as regulatory values.

COMMENT 2-2: The City does not accept the validity of the esfenvalerate chronic water quality criterion. The draft chronic water quality criterion may be overprotective. The ACR used to calculate the criterion utilizes a default ACR, which itself is largely derived from classes of pesticides whose physical, chemical, and toxic modes of action are different from that of esfenvalerate.

RTC 2-2: The default ACR used for esfenvalerate was re-calculated from the default ACR in the UC Davis Method to include data for the pyrethroids cyfluthrin and lambda-cyhalothrin so that it is more representative of pyrethroids, such as esfenvalerate. The default ACR used to calculate the chronic criterion was 11.4, which is lower than the *Daphnia magna* ACR of 14 based on esfenvalerate test data. The final ACR for esfenvalerate is the geometric mean of the *Daphnia magna* ACR of 14, and two default ACRs of 11.4, which results in a final ACR of 12.2. This ACR results in a larger chronic criterion than if only the esfenvalerate *Daphnia magna* ACR was used, making it less likely that the chronic criterion is overprotective.

COMMENT 2-3: The City questions the utility of the esfenvalerate acute water quality criterion, which was derived from datasets absent toxicity values for *Hyalella azteca*. *Hyalella azteca* is the most sensitive species in datasets for other pyrethroids. While the City objects to the possible regulatory use of any criterion derived utilizing the UCD methodologies, the derivation of the acute criteria for esfenvalerate despite the absence of toxicity data for *Hyalella azteca* highlights the significant potential for misapplication of the methodology. While the criteria derivation report provides an accounting of its limitations, this accounting is a weak safeguard for its potential misapplication. For esfenvalerate, efforts would have been better spent developing the necessary acute toxicity value for *Hyalella azteca* rather than attempting to derive a criterion under such flawed circumstances.

RTC 2-3: Since the release of the draft criteria report for esfenvalerate, aqueous toxicity data for *Hyalella azteca* has become available and is now included in the criteria calculation

COMMENT 2-4: The criteria derivation report is incorrect when it states “whole water concentrations are also valid for criteria compliance assessment” (page 12). No scientific justification is provided to support this statement. Rather, it appears this is a policy statement. As detailed in

the criteria derivation report, scientific evidence strongly points to freely dissolved pyrethroid as the bioavailable fraction. As such, compliance should be measured against that portion of a pyrethroid that is known to be toxic. The draft criteria reports should be revised in a manner that retains the scientifically-based recommendation for compliance determinations based on either direct measurement of the bioavailable fraction or allowing for some compensating factor accounting for particulate matter and dissolved organic matter, but should remove statements regarding the validity of whole water measurements for compliance, which are not supported.

RTC 2-4: While studies have demonstrated that the freely dissolved fraction correlates to toxicity better than whole water concentrations, there is still a strong correlation between whole water concentrations and toxicity. Whole water concentrations are what are typically available for laboratory toxicity tests as well as ambient sampling and provide valuable information.

COMMENT 2-5: The City does not accept the validity of sediment criteria derived when utilizing assessment factors (AF) and default acute-to-chronic ratios (ACR). It is unlikely that any sediment criteria derived by the new methodology would be derived by any other means than through the use of AFs and a default ACR. This leads to a high degree of uncertainty relative to the accuracy of any derived criteria. As such, criteria should not be used as strict regulatory thresholds or used to set remediation goals.

RTC 2-5: At this time the interim bioavailable sediment criteria are not being proposed for use as regulatory values. The sediment criteria derivation method and associated sediment criteria reports have not been finalized and have been separated from the esfenvalerate water quality criteria report.

COMMENT 2-6: Derived esfenvalerate sediment criteria are most likely substantially overprotective, thus illustrating the degree of uncertainty, and degree of unreliability inherent to these sediment criteria values. As calculated in the criteria derivation report, the acute and chronic interstitial concentrations of the derived esfenvalerate sediment criteria are substantially smaller than any previously derived acute and chronic pyrethroid criteria. Moreover, following the EPA's proposed EqP methodology for calculating organic carbon normalized equilibrium partitioning sediment guidelines (ESG_{oc}), the esfenvalerate ESG_{oc} would equal 640 ng/g-organic carbon ($ESG_{oc} = K_{oc} * FCV$), which is substantially higher than the sediment criteria derived for esfenvalerate (i.e., acute of 12 ng/g-OC and chronic of 2.1 ng/g-OC). Lastly, as calculated in the criteria derivation report, the lowest empirically derived maximum acceptable toxicant concentration is 230 ng/g-OC, which was for the very sensitive species *Hyalella azteca*. Sediment criteria for esfenvalerate are

almost certainly substantially overprotective. The derived sediment criterion should be more explicitly qualified as such.

RTC 2-6: All of the information and calculations for the interim BSQC have been separated from the water quality criteria report and comments regarding the interim BSQC will be responded to when the sediment methodology and criteria reports are finalized.

COMMENT 2-7: The final chronic water quality criterion for esfenvalerate is incorrectly rounded. The final chronic criterion should be 4 ng/L, not 3 ng/L as presented in the criteria derivation report in Section 8.1. All subsequent reference to 3 ng/L should similarly be corrected, including calculations of corresponding interstitial concentrations.

RTC 2-7: There was a rounding error in the draft report; the chronic criterion was recalculated in the final report due to the availability of additional data and the chronic criterion is now 0.03 ng/L.

COMMENT 2-8: Equation 1 in Section 9.1 appears to be incorrect. Koc should be multiplied by foc (fraction organic carbon), not divided by foc.

RTC 2-8: This error has been corrected in equation 1.

2.3. Comment Letter 3 – Theresa A. Dunham, Somach Simmons & Dunn on behalf of the Pyrethroid Working Group

COMMENT 3-1: Our firm, Somach Simmons & Dunn, represents the Pyrethroid Working Group (PWG). On their behalf, we previously submitted comments on the University of California Davis Methodology for Derivation of Pesticide Sediment Quality Criteria for the Protection of Aquatic Life (UCDSM) dated March 7, 2014. With respect to the Draft Water and Sediment Quality Criteria Report for Esfenvalerate (Draft Esfenvalerate Report), we wish to reiterate some of the same concerns previously conveyed.

RTC 3-1: Comment acknowledged.

COMMENT 3-2: Most importantly, the PWG maintains its significant concerns with the sediment methodology, and criteria resulting from said methodology. As expressed previously, our concerns pertain to the level of uncertainty associated with criteria developed from the methodology, and the assessment factor approach contained in the report.

RTC 3-2: All of the information and calculations for the interim BSQC have been separated from the water quality criteria report and comments regarding the

interim BSQC will be responded to when the sediment methodology and criteria reports are finalized.

COMMENT 3-3: Considering the inherent uncertainty in the methodology, we do not believe it appropriate to continue developing “interim” numeric criteria in accordance with the methodology. Accordingly, the PWG recommends that the Draft Esfenvalerate Report not be accepted by the Regional Water Quality Control Board at this time.

RTC 3-3: At this time the interim bioavailable sediment criteria are not being proposed for use as regulatory values. The sediment criteria derivation method and associated sediment criteria reports have not been finalized and have been separated from the esfenvalerate water quality criteria report.

2.4. Comment Letter 4 – Linda Dorn, Sacramento Regional County Sanitation District

COMMENT 4-1: The Sacramento Regional County Sanitation District (Regional San) appreciates the opportunity to comment on the *Draft Water and Sediment Quality Criteria Report for Esfenvalerate. Phase III: Application of the Pesticide Water and Sediment Quality Criteria Methodologies* (draft criteria) developed by the University of California, Davis (UCD) (Trunnelle et al., 2014). Regional San owns and operates the Sacramento Regional Wastewater Treatment Plant, and provides wastewater collection, conveyance and treatment services to over 1.3 million residents and thousands of commercial and industrial customers in the Sacramento region. Our mission is to protect human health and the environment by keeping the Sacramento River clean and safe. We take our mission very seriously and work on a daily basis to meet our obligations to protect water quality and beneficial uses in the Sacramento River and Delta.

Regional San understands the Central Valley Regional Water Quality Control Board’s (Regional Board) interest and efforts to protect the environment from adverse effects due to pesticides. However, we have concerns about the potential implementation of the draft water quality criteria (WQC) and sediment quality criteria (SQC) despite their development methods generally following risk assessment and risk management practices for developing toxicity screening values. A primary concern with the draft criteria directly relates to the Regional Board staff potentially using draft criteria, developed with multiple layers of uncertainty, to interpret narrative objectives in the Sacramento-San Joaquin Basin Plan.

Regional San also has the following concerns with the development of the esfenvalerate WQC and SQC:

- Limited toxicity data,
- Laboratory-reared *Hyalella azteca* for representing the benthic community,
- Environmental variables that could affect toxicity are lacking or uncertain,
- Practical implications of applying the draft criteria, and
- Cumulative impacts of uncertainties.

Due to all of our concerns, detailed below, we recommend only using these values as one line of evidence in the evaluation of potential impacts, and not as formal criteria that are the basis for regulation.

RTC 4-1: Policy issues regarding how the criteria are applied are outside of the scope of the derivation of criteria by UCD contractors. The criteria document does not address policy issues such as how the criteria could be used by the Regional Board or others.

COMMENT 4-2: With the exception of the draft acute WQC which fulfilled the data requirement of five taxa, the primary limiting factor for the esfenvalerate chronic WQC and SQC development is the lack of high quality toxicity data. The paucity of toxicity data contributing to high uncertainty with the derived draft SQC for bifenthrin was also a major concern of the following experts:

- Dr. Chris Ingersoll, director, USGS Columbia Environmental Research Center,
- Dr. G. Allen Burton, Director, Professor and Director, School of Natural Resources & Environment and Cooperative Institute for Limnology & Ecosystem Research, University of Michigan,
- Dr. Steve Bay, head of the Toxicology Department, Southern California Coastal Water Research Project, Dr. Peter Landrum, Ph.D., Scientist Emeritus, National Oceanic and Atmospheric Administration, Great Lakes Environmental Research Laboratory, and
- Dr. Lisa Nowell, Research Chemist, USGS.

The concerns of these experts regarding using limited data sets for bifenthrin SQO development are also applicable to the draft, interim, esfenvalerate criteria.

Although adequate data are available to develop a species sensitivity distribution for acute WQC, acceptable toxicity data (as defined by the methodology) were available for only three of the five taxa needed to construct a chronic species sensitivity distribution. Representative toxicity data were not available for salmonids or benthic crustaceans, leaving

substantial uncertainty in the representativeness of the chronic toxicity data used to derive the esfenvalerate chronic WQC. This is in contrast to the development of statistically-based chronic toxicity values that would be supported with a more robust data set being more fully representative of the aquatic community.

RTC 4-2: We agree that a larger more diverse chronic data set would be more representative of sublethal chronic effects on the aquatic community. However, the goal of this report is to determine a chronic level of protection for aquatic life based on available data and to recognize any limitations or uncertainties in the derivation of the criteria so that environmental managers may choose whether and how to appropriately use the values.

The sediment criteria derivation method and associated sediment criteria reports have not been finalized and have been separated from the esfenvalerate water quality criteria report. All of the information and calculations for the interim BSQC have been separated from the water quality criteria report and comments regarding the interim BSQC will be responded to when the sediment criteria report is finalized.

COMMENT 4-3: Likewise, there were few paired acute and chronic data to develop an acute-to-chronic ratio (ACR) and thus a median ACR had to be calculated with default values to determine the chronic WQC. UCD methodology allows for the lack of acceptable chronic data by applying a conservative default ACR, which is not based upon directly-applicable toxicological data. The limitations in the available toxicity data is likely to result in criteria with a high degree of uncertainty and with questionable representativeness of environmentally relevant species, while the use of conservative assessment factors may result in values that are overly protective, ***especially when compounded as done according to the UCD Methodology.***

RTC 4-3: The default ACR is not inherently conservative; it is based on paired acute and chronic data for ten pesticides. The default ACR used for esfenvalerate was re-calculated to include data for two pyrethroid pesticides, making it more representative of esfenvalerate, which is also a pyrethroid. There was paired acute and chronic esfenvalerate data for *Daphnia magna*, which resulted in an ACR of 14. The default ACR is 11.4 and does not appear to be conservative based on this species.

COMMENT 4-4: Acceptable acute sediment toxicity data (as defined by the SQC methodology) were available for only two of the five taxa needed to construct a species sensitivity distribution. Data were unavailable for an infaunal invertebrate, a mollusk, amphibian, other, and a benthic invertebrate from an unrepresented family. Due to these few data an assessment factor of 12 was used, meaning, available toxicity data were divided by 12, and this was in addition to a default assessment factor of 2

to derive a conservative acute SQC. Likewise, due to the lack of chronic sediment toxicity data for esfenvalerate, a default ACR of 11.4 was applied to the acute value (the lowest species mean acute toxicity value divided by its assessment factor of 12). Therefore there was a lack of toxicity data for the development of acute and chronic SQC with an acceptable level of uncertainty.

RTC 4-4: All of the information and calculations for the interim BSQC have been separated from the water quality criteria report and comments regarding the interim BSQC will be responded to when the sediment criteria report is finalized.

COMMENT 4-5: Based on data limitations, and given a conclusion by the author that the draft esfenvalerate criteria should not be considered more than interim values due to these uncertainties in the underlying data (Trunelle et al., 2014), these esfenvalerate criteria should not be used as a basis for regulatory compliance at this time. The proposed values are appropriate as screening levels to indicate if further assessment is needed to determine if adverse effects are occurring when concentrations are elevated beyond the WQC and SQC.

RTC 4-5: At this time the interim bioavailable sediment criteria are not being proposed for use as regulatory values. The esfenvalerate water quality criteria are being considered for use as regulatory values, and the Regional Board will consider your comments in that public process.

COMMENT 4-6: Available toxicity data may not accurately represent the sensitivity of the benthic community *Hyalella azteca*, one of the two test species for which acceptable sediment toxicity data for determining the bioavailable sediment quality criteria were available has been reported to have a much greater sensitivity to pyrethroids in sediment than a suite of other aquatic taxa (Palmquist et al. 2011). Moreover, laboratory-reared *H. azteca* have been reported to be up to 700 times more sensitive than resident populations in the Central Valley (Weston et al., 2013). Use of lab-based *H. azteca* toxicity data in criteria development may overestimate the potential for adverse effects to the benthic community, downwardly biasing the draft SQC. Trunelle et al., (2014) expressed concern over a lack of *H. azteca* data and inclusion of these data should be considered with caution.

RTC 4-6: According to Weston et al. (2013), the reason that some field populations of *H. azteca* are less sensitive to pyrethroids such as esfenvalerate than laboratory-reared populations is that the field populations have developed resistance due to high levels of exposure to pyrethroids. The development of genetic resistance is not considered a positive effect because it can cause genetic bottle-necking, meaning that there is likely less genetic diversity in these populations. This is similar to what is seen in agricultural pests that develop

resistance to a pesticide that is repeatedly applied. There are also sensitive field populations of *H. azteca* in areas with few pesticide inputs (as reported in Weston et al. 2013), and the goal of the UCD criteria is to be protective of those sensitive populations, not to bias the criteria toward protection of resistant populations.

COMMENT 4-7: Environmental variables that could affect toxicity are lacking or uncertain

Available information indicates that ambient temperature can have a significant effect on the toxicity of pyrethroids in sediment. Wheelock et al. (2008) demonstrated an inverse relationship between temperature and the toxicity of pyrethroids to aquatic invertebrates. Temperature has in fact been used as a method in Toxicity Identification Evaluation procedures to help determine if the cause of toxicity to invertebrates is due to pyrethroids. This relationship, although noted as an uncertainty in the methodology document, is not accounted for by the current model. Between 2006 and 2008, for example, surface water temperature in the Sacramento River around the Sacramento Regional Wastewater Treatment Plant discharge ranged from 43 to 73°F. Although identified as a potential uncertainty in Trunnelle et al. (2014), there were no recommendations to account for the effect of this broad range in temperature on the toxicity of esfenvalerate. WQC and SQC that do not consider temperature may not accurately estimate the potential for adverse effects to organisms and result in criteria that are not representative of ambient conditions.

RTC 4-7: The process for developing a quantitative relationship between temperature and toxicity in the UCD methodologies requires having toxicity data at multiple temperatures for at least two species (one fish, one invertebrate). This data was not available for aqueous or sediment exposures, and thus a temperature relationship could not be quantitatively established for either type of criteria.

COMMENT 4-8: When developing sediment criteria, the bioavailability of esfenvalerate in sediment is adjusted based on consideration of the organic carbon content in sediment. Although it is recognized that site-specific partition coefficients should be used when available, it is proposed that the geometric mean of acceptable partition coefficients (Koc of 161,000) be used in the absence of a site-specific value. The values reported in Trunnelle et al. (2014) as acceptable varied by more than two orders of magnitude (5,248 to 630,957), and use of the geometric mean with such a broadly-ranging set of values may mask the high degree of variability, and possible uncertainty, associated with this indicator of bioavailability.

The form of carbon also has been shown to have a significant effect on the partitioning (and bioavailability) of organic compounds in sediment. Black carbon, for example, has been demonstrated to have an increased partitioning coefficient relative to other forms of carbon in sediment (Burgess and Lohmann 2004; Burgess et al. 2013). Based on the possible range of Koc values and its critical impact on the resulting sediment criteria, use of the geometric mean Koc is likely to be overly simplistic when developing the sediment criteria.

Trunnelle et al., (2014) recommended that the freely dissolved esfenvalerate concentration be measured for determining WQC compliance because this appears to be the best predictor of the bioavailable fraction. This freely dissolved fraction is a data gap in developing appropriate toxicity data for WQC and SQC. Environmental factors that significantly affect esfenvalerate toxicity need to be considered and fully evaluated in the development of these draft criteria.

RTC 4-8: Responses to the comments regarding bioavailability and the sediment quality criteria will be given when the sediment criteria report is finalized.

For the water quality criteria, it is recognized that the freely dissolved fraction has been shown to be the best predictor of toxicity in several studies and the lack of esfenvalerate toxicity data based on freely dissolved concentrations has been recognized as a data gap.

COMMENT 4-9: The practical implications of applying the proposed criteria should be further considered

Given the uncertainties associated with these values, further discussion is necessary about the appropriate application of such criteria to achieving regulatory objectives, with detailed consideration given to the practical implications of applying these criteria to the Sacramento and San Joaquin River basins. Additionally, specific guidance for the implementation of these values needs to be developed to ensure that any implementation of WQC or SQC that are highly uncertain are used only as triggers for further investigation, and not as the basis for regulatory limits.

RTC 4-9: The adoption of UCD criteria as regulatory values is up to the discretion of the Regional Board. Comments regarding the implementation of the criteria as regulatory values may be submitted as part of that separate public process.

COMMENT 4-10: The cumulative impacts of uncertainties have not been fully characterized

Trunnelle et al. (2014) provides a useful and important summary of assumptions, limitations, and uncertainties associated with the derivation of the draft criteria (Section 12.1). This section would benefit from

additional evaluation considering the relative importance and the potential direction and magnitude of the bias/error associated with each assumption, limitation, and uncertainty discussed in this section, and the effect it is expected to have on the draft criteria. In particular, it is recommended this section consider the cumulative impact of these factors on the proposed criteria, and the range of criteria values that could result from the cumulative effect of the assumptions, limitations, and uncertainties on the criteria values. Please note that in section 7.2 “*only 2 of 5 taxa ...available for bifenthrin...*” should probably be referring to esfenvalerate.

RTC 4-20: Section 12.1 has been revised to more fully characterize the uncertainties and their potential effects on the criteria. The typographical error will be corrected in the final sediment criteria report.

COMMENT 4-11: Conclusion

Although the methodology used for the development of the proposed criteria is generally acceptable, there are substantial uncertainties associated with the development and application of these interim WQC and SQC for esfenvalerate. Based on the many uncertainties associated with the proposed interim draft criteria, and the potential over-protectiveness of the methodology with the implementation of conservative default assumptions, Regional San cannot currently support the implementation of the draft WQC and SQC by the Regional Board. Better characterization of esfenvalerate toxicity, factors affecting its toxicity, and defined and practical methodologies for the determination of criteria exceedance in surface water and sediment would help gain support for these criteria. Until these uncertainties are addressed, care must be taken in the application of these values and they should serve as only one line of evidence in the evaluation of potential impacts, and not as formal criteria that are the basis for regulation.

RTC 4-10: We agree that additional high quality data to fill the identified data gaps would increase the certainty of the esfenvalerate criteria. The adoption of UCD criteria as regulatory values is up to the discretion of the Regional Board and these comments will be shared with the Board in that process.

3.0 Response to Comment to Peer Reviews

3.1. Peer Review 1 – Evan Gallagher, Ph.D., University of Washington

REVIEW 1-1: *Summary*

Esfenvalerate is a class-II pyrethroid insecticide that is used in a number of commercial insecticide products, including Asana, Asana XL, Supercidin, Halmark and Sumidan. Esfenvalerate is a highly potent insecticide and has been shown to be toxic to non-target organisms such as fish and other aquatic life. The criteria report for esfenvalerate was conducted based on two new methodologies developed for water quality (TenBrook et al. 2009) and sediment quality (Fojut et al. 2014) assessments directed towards the protection of aquatic life. The authors conducted a thorough evaluation of the currently available toxicity data for esfenvalerate and for the derivation of the proposed criteria. There are reports in the literature demonstrating cellular effects of esfenvalerate on salmonids at environmental concentrations, and potentially including immunotoxic and neurotoxic effects. However, the outcomes of such effects are unknown. The authors had to bridge several key data gaps using assumptions and extrapolations associated with the ecological risk assessment. Despite these limitations, the report thoughtfully addresses the unknowns and the limitations of the current state of knowledge of esfenvalerate aquatic toxicity and establishes reasonable water quality criteria. The recommendation to recalculate the criteria when new and highly rated data is available is appropriate.

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

Review 1-2: *Physicochemical data*

The physicochemical data included in the report appears to be thorough and addresses the critical chemical properties needed to ascertain environmental fate and partitioning characteristics of esfenvalerate.

RTR 1-2: Comment acknowledged.

Review 1-3: *Data availability and prioritization*

There were available bioconcentration data for only two species (bluegill sunfish and common carp), both of which are warm water fish. This is somewhat problematic for applications for the state of California. Unfortunately there did not appear to be bioconcentration data available for cold-water fish species such as salmonids, and none for insects or crustaceans, which is problematic as these are common organisms in the Sacramento and San Joaquin surface waters. Dietary data for

esfenvalerate was also limited, and based upon the authors literature review there was only wildlife dietary exposure data for Mallard ducks. The FDA currently has no action levels for esfenvalerate, but does appear to have a food tolerance level set at 15mg/kg.

For criteria derivation, numerous studies were analyzed and rated based on a numeric grading system summarized in TenBrook et al. (2009) and Fojut et al. (2014). The resulting numerical scores were then assigned relevance and reliability scores. Data from studies scoring relevant and reliable (RR) scores were used for criteria calculations. Data from studies rated as *less relevant* and *less reliable* (RL, LL, or LR) were used only to compare the derived criteria against data for a sensitive or endangered species, where data was often lacking. For the acute water quality criteria (WQC), data from 8 acute toxicity studies were deemed RR. For the chronic WQC, data from only 3 chronic toxicity studies was deemed RR and used for criteria calculation. For ecosystem studies, 12 mesocosm and microcosm studies were identified. Out of those 12, 4 were scored as RR and used for criteria evaluation. Few studies have investigated the effects of esfenvalerate as a mixture and there was little data on the modulating effects of pH and water temperature on esfenvalerate toxicity, despite increasing evidence that temperature plays a large role in the toxicity of pyrethroids. This reviewer, although not an expert in derivation of work quality criteria, found no obvious shortcomings with the author's methods for data prioritization and literature data searching.

RTR 1-3: Comment acknowledged.

Review 1-4: *Acute and chronic criteria calculations*

For the acute WQC, all five taxa requirements of the species sensitivity distribution (SSD) were met and at least five toxicity values were acceptable for use. The authors used a log-logistic SSD procedure (TenBrook et al. 2009) to establish the acute criterion, as there were not more than eight acceptable acute toxicity values. Based on the values, the authors calculated an acute WQC of 20 ng/l. Chronic water toxicity values were only available for 3 of the 5 taxa requirements, including an insect, a warm water fish, and a planktonic crustacean. Of these taxa, three values were deemed acceptable for use. Due to the lack of data for the other two taxa requirements (cold-water fish and benthic crustaceans) the acute-to-chronic ratio (ACR) method was used to calculate the chronic WQC (TenBrook et al. 2009). Only one of the chronic values was comparable to an acute value to establish an ACR, 14. The other two chronic values had no comparable acute values and the authors utilized a default ACR of 11.4. Using these values, the authors calculated a chronic WQC of 3 ng/L.

The acute bioavailable sediment quality criterion (BSQC) was calculated using the assessment factor method as a result of limited toxicity data on only two taxa. These included an amphipod (*H. azteca*) and a benthic

insect (*C. dilutus*). The acute criterion was calculated by dividing the lowest species mean acute value (SMAV) from an RR rated study (0.29 ug/g for *H. azteca*) by an assessment factor of 12. The authors calculated an acute BSQC of 12 ng/g OC. For the chronic BSQC, there was no toxicity data for chronic sediment exposures. Based on this, the authors could not calculate the appropriate ACR and used the default ACR of 11.4. The authors calculated the chronic BSQC to be 2.1 ng/g OC.

RTR 1-4: Comment acknowledged.

Review 1-5: *Water quality effects*

Bioavailability of esfenvalerate is generally poor in surface waters due to low water solubility and binding to suspended particles. It is generally believed that only the dissolved fraction is responsible for the toxicity to aquatic organisms, and most studies indicate a decrease in pyrethroid toxicity associated with increasing dissolved organic carbon (DOC). However, as the authors noted, there are a few studies that have suggested that it is possible for pyrethroids to desorb from organic matter once ingested by an aquatic organism and this could further increase pyrethroid exposures. Due to the lack of studies on partitioning and dietary exposures, it is not possible to incorporate this information into the current exposure criterion. As a result, the authors recommend criteria compliance should be calculated using the dissolved fraction concentration as whole water concentration could overestimate the bioavailable amount.

It is often assumed that mixtures of pyrethroids have an additive toxicity in aquatic organisms, although there's little information on sublethal effects of these mixtures. By contrast, there are literature studies reporting that certain mixtures of pyrethroids may have antagonistic interactions. The authors partially attribute these aforementioned discrepancies to the type of pyrethroids used in the studies. For example, type-2 pyrethroids, such as cyfluthrin, can outcompete type-1 pyrethroids for binding sites resulting in competitive agonism. Piperonyl butoxide (PBO) is commonly added to pyrethroid mixtures and increases the toxicity of these agents as noted in a study on *Hyalella azteca* dosed with PBO and cyfluthrin. To date, there have been little, or no studies quantifying the combined toxicity of PBO and esfenvalerate on aquatic organisms. Furthermore, there is little information on the toxicity of mixtures of esfenvalerate with other pyrethroids on aquatic organisms. These are important data gaps in the ecological risk of these agents. Mixture studies of esfenvalerate and organophosphate pesticides are also sparse, and suggest a more than additive toxicity on a few aquatic organisms such as fathead minnows and midge larvae. Synergy between pyrethroids and azole fungicides has been reported in aquatic organisms. However, the authors indicate that while there is evidence of mixture effects between pyrethroids and other common pesticides, the current studies are not consistent, and thus it was not appropriate to generate a multispecies interaction coefficient for

incorporation into the criteria compliance calculations. The aforementioned is a reasonable decision by the authors based upon limitations of the state of the science.

RTR 1-5: Comment acknowledged.

Review 1-6: *Modifying effects*

An important consideration for esfenvalerate toxicity is the potential modulation by water temperature and pH. However, the authors report that due to the limited amount of studies addressing the effects of water temperature on pyrethroids toxicity, they could not reliably construct a temperature coefficient into the criteria calculation. There were several studies reported that showed a significant increase in pyrethroid toxicity in aquatic organisms as temperature decreased. Only one study investigated temperature related effects on esfenvalerate toxicity. Toxicity of sediment bound esfenvalerate exposures using *H. azteca* was lower when exposures occurred at 23°C vs. 18°C. Despite the evidence of temperature related effects on pyrethroid toxicity, the authors were justified for not attempting to incorporate this interaction into the criteria derivation.

RTR 1-6: Comment acknowledged.

Review 1-7: *Comparison of ecotoxicity data and derived criteria*

Based on the studies (rated RR, LR or LL) analyzed in this report, the authors compared their derived WQC and BSQC against the most sensitive species investigated for esfenvalerate toxicity. The lowest acute LC₅₀ for an aquatic exposure was 49 ng/L for *Ceriodaphnia dubia*; this value is more than 2-fold higher than the authors derived acute WQC of 20 ng/L. One study did note adverse effects on egg hatching following 48hr exposures to 20 ng/L. However, this study was considered chronic for the *Baetis* spp. The authors conclude that based on current data the acute WQC would be protective of the most sensitive species reported in the literature. The lowest chronic toxicity value reported was 17 ng/L for bluegill sunfish, which was based on incidence of tremors not a LC₅₀. The authors derived chronic WQC of 3 ng/L would be protective of this species. One species the authors mention that is highly sensitive to pyrethroids is *H. azteca*. There is no data on waterborne esfenvalerate toxicity for this species however, and it is uncertain if the author's acute and chronic WQC would be protective of this sensitive species.

The sediment exposure studies indicate the most sensitive species was *H. azteca*, which had a 10-day LC₅₀ of 0.29 ug/g OC. The proposed acute BSQC is 12 ng/g OC and is a factor of 24 below the *H. azteca* LC₅₀. The only available chronic sediment esfenvalerate exposure data was for a saltwater aquatic organism, which had a reported MATC of 1.5 ug/g. The proposed chronic BSQC of 2.1 ng/g would be more than protective of that

organism. The author's proposed acute and chronic BSQC would be protective of sensitive species based on the current literature. However, there was a significant lack of data available for esfenvalerate sediment exposures for relevant aquatic species and the author's proposed BSQCs could need revising in the future.

The authors reviewed twelve ecosystem studies describing the effects of esfenvalerate on mesocosm, microcosm and model ecosystems. Out of those twelve, four were rated as RR and used for comparison. Most of the studies reported NOEC of 0.005- 0.3 ug/L with suggests that the author's derived chronic WQC of 3 ng/L would be protective.

The derived criteria were compared to the toxicity values for threatened and endangered species. Toxicity data from two threatened species were available for comparison using the USEPA interspecies correlation estimation website. Two studies yielded a SMAV for *O. mykiss* of 0.26 ug/L and a 96-hr LC₅₀ for *O. tshawytscha* of 16.7 ug/L. Using those values the authors were able to calculate an estimated acute toxicity value for the most sensitive salmon, coho salmon, of 0.266 ug/L. Based on this data, the authors proposed acute and chronic WQC would be protective of these species. There was no listed data for threatened species in the BSQC data set. However, the authors calculated interstitial water concentration of esfenvalerate based on the acute and chronic BSQC values to be 0.075 ng/L and 0.013 ng/L. These values are far lower than the rainbow trout toxicity value of 260 ng/L, and should be protective for salmonids.

The author's assessment of bioaccumulation was based on some assumptions, mainly a default biomagnification factor (BMF) as none were available for esfenvalerate. Using this and a bioconcentration factor (BCF) for carp and a NOEC for a mallard duck, the authors were able to calculate a NOEC for bioaccumulation of 14.5 ug/L. The use of a default value for the BMF and a BCF for a non-native fish is less than desirable. However, the authors were justified in their methods as the data is limited for comparison.

RTR 1-7: Comment acknowledged.

Review 1-8: Conclusions

This report is thorough in its scope and the authors have identified the major concerns associated with derivation of the criteria as best as the current data allows. The authors conducted a thorough review of the literature. These limitations were predominantly associated with a lack of species diversity in the data sets, lack of data on water temperature and pH modulation of esfenvalerate toxicity in relevant aquatic species, lack of data on the toxicity of esfenvalerate in mixtures and the use of default values for the derivation of the criteria. The authors' appropriately suggest

that a recalculation of the criteria would be in order as new and highly rated data become available. The authors also state that due to the lack of extensive data on esfenvalerate toxicity in aquatic organisms, it would not be appropriate to compare their methods to those of the EPA. Although this reviewer is not an expert in the derivation of water quality guidelines for acute toxicity of pesticides to aquatic life, it appears reasonable to conclude that the derived criteria in this report are likely to be protective of aquatic organisms in the Sacramento and San Joaquin Rivers, and most likely other freshwater systems.

RTR 1-8: Comment acknowledged.

Review 1-9: *Other minor comments*

List of abbreviations: please add SSTT (spiked-sediment toxicity testing) to the list of abbreviations

Section 7.2, first paragraph, first sentence: *Bifenthrin* is written instead of esfenvalerate

Section 7.2, third paragraph, first sentence: Table 3 should be table 8.

Section 9.3, last paragraph, first sentence: *Permethrin* is written where esfenvalerate should be written.

RTR 1-9: These typographical errors have been corrected in the final report, or will appear in the final sediment criteria report.

3.2. Peer Review 2 – Xin Deng, California Department of Pesticide Regulation

REVIEW 2-1: The report described the procedures for derivation of esfenvalerate water and sediment quality criteria (WQC and SQC) by applying the water and sediment quality criteria derivation methodologies (UCDM and UCDSM) developed by the University of California, Davis. The report explicitly followed the data evaluation criteria of the methodologies and identified acceptable acute and chronic toxicity values for water and sediment. Based on the methodologies, the acute WQC was derived by using the log-logistic species sensitivity distribution procedure. The chronic WQC, and acute and chronic SQCs were derived by applying either an Assessment Factor or default acute-chronic ratios (ACRs).

RTR 2-1: Comment acknowledged.

REVIEW 2-2: The application of UCDM and UCDSM resulted in an acute WQC of 20 ng/L, chronic WQC of 3 ng/L, interim acute SQC of 12 ng/g OC and interim chronic SQC of 2.1 ng/g OC. Comparisons to the existing toxicity data from sensitive species, threatened and endangered species and ecosystem studies suggested that the derived acute and chronic

criteria be protective of aquatic organisms under the current knowledge of esfenvalerate water and sediment toxicity.

RTR 2-2: Comment acknowledged.

REVIEW 2-3: The report appropriately discussed the limitations and uncertainties involving in the criteria derivation. For the acute WQC, the limitations were primarily attributed to the limited number of acute toxicity data that were based on flow-through tests and measured concentrations, and absence of the toxicity data for the known sensitive species *Hyalella azteca*. For the chronic WQC, the limitations were due to the lack of toxicity data on *H. azteca* and fewer than required number of chronic values for species sensitivity analysis. The report particularly noted that it was uncertain whether the acute and chronic WQCs were protective of amphipods as no water toxicity data was available for the sensitive species *Hyalella azteca*. We noted that the acute WQC of 20 ng/L was more protective than the lowest acute US EPA aquatic life benchmark of 25 ng/L and could be potentially applied for data evaluations in DPR's surface water monitoring programs. The chronic WQC of 3 ng/L, however, is below the current reporting limit of 5 ng/L for esfenvalerate in the DPR's chemistry report, thus, it may not be feasible to be used as a criterion for evaluation of esfenvalerate contamination in surface water. For the acute and chronic SQC, lack of sediment toxicity data primarily contributed to the limitations and uncertainties. Other uncertainties were related to toxicity changes with lower temperatures and addition of PBO (piperonyl butoxide) in pyrethroid formulations that could not be quantified with limited data sources. We agree with the report to consider the SQC interim values until more data are available to better address the limitations and uncertainties in the future.

RTR 2-3: Comment acknowledged.

4.0 References

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