



Environmental Utilities
2005 Hilltop Circle
Roseville, California 95747

November 13, 2012

Tessa Fojut, PhD
Regional Water Quality Control Board, Central Valley Region
11020 Sun Center Drive, #200
Rancho Cordova, CA 95670-6114

Submitted by E-mail.

RE: Comments on Central Valley Pyrethroid Pesticides Total Maximum Daily Load and Basin Plan Amendment

Dear Dr. Fojut:

On October 30, 2012, staff of the Central Valley Regional Water Quality Control Board (Regional Water Board) held a California Environmental Quality Act (CEQA) Scoping meeting regarding the development of a Basin Plan Amendment (BPA) and Total Maximum Daily Load (TMDL) for pyrethroid pesticides. At the meeting, public comments were solicited with regard to a range of project actions, alternatives, reasonably foreseeable methods of compliance, environmental impacts and potential mitigation measures that should be considered and addressed by the Regional Water Board. Staff of the City of Roseville (City) could not attend the scheduled scoping meeting date, but were represented by the City's consultant, Dr. Brant Jorgenson of Robertson-Bryan, Inc. (RBI).

The City appreciates this opportunity to provide written scoping comments regarding this proposed project, due on November 13, 2012 to the Regional Water Board. The City is particularly interested in this project due to existing Clean Water Act 303(d) listings for pyrethroid related sediment toxicity in various reaches of the Pleasant Grove Creek watershed and the associated ramifications of future waste load allocations related to the pending TMDL, as well as the adoption of specific pyrethroid and other pesticide Basin Plan objectives as part of the BPA. The City holds National Pollutant Discharge Elimination System (NPDES) permits for both municipal stormwater and municipal wastewater (i.e., POTW) discharges to Pleasant Grove Creek. The City has been an active participant and stakeholder in the Regional Water Boards Central Valley Pesticide BPA and TMDL project, having provided previous comments on Regional Water Board related actions such as the derivation of pesticide aquatic life criteria and Aquatic Life Uses report.

Many of our concerns regarding this pyrethroid BPA and TMDL project, and the various related historic reports and studies leading up to this project, have been expressed verbally at previous stakeholder meetings and as formal written comments related to the Regional Water Boards Central Valley Pesticide BPA and TMDL project (now apparently focused exclusively on chlorpyrifos and diazinon). The bulleted comments provided below reflect much of this history and attempt to focus more generally on the City's broad concerns versus specific detailed concerns since exact BPA language has currently not been proposed.

1. Range of Project Alternatives: The City requests that Regional Water Board staff include in its list of water quality objective alternatives the alternative of adopting water quality objectives based solely on aquatic life criteria derived utilizing national recommended EPA methodology¹. The City has provided formal written comment on three separate occasions regarding the use of alternative methodology developed by the University of California at Davis for the derivation of pesticide criteria from limited datasets (i.e., UC Davis methodology). As previously expressed in written comments, the City does not believe use of the UC Davis methodology and criteria are appropriate for the adoption of formal Basin Plan objectives (i.e., water quality standards), nor does the City believe that staff of the Regional Water Board have fully considered the ramifications of setting such a precedent. In lieu of summarizing the City's specific concerns with the various UC Davis methodology derived pesticide criteria, the City's previously submitted comments are attached to this letter.

The City understands that to utilize the EPA methodology additional toxicity tests would need to be conducted. The City does not believe this to be too large a financial hurdle. Depending on the pesticide, only a handful of targeted toxicity tests would be required to fill existing data gaps. It is possible that funding for such additional toxicity tests could be obtained from the Regional Water Board's regulatory partners, such as federal EPA and the California Department of Pesticide Regulation.

2. Economic Costs of Compliance and Cumulative Impacts: The City requests that a comprehensive economic analysis and cumulative environmental impact analysis be conducted. In particular, if the adopted TMDL includes language that broadly and indiscriminately targets potential sources that are *tributary* to an impaired water body, without language or discretionary authority aimed at limiting the list of sources in some scientifically defensible way, cases will exist where dischargers that are technically tributary will be burdened with waste load allocations, effluent limits, and monitoring reporting requirements when in reality they represent virtually no risk whatsoever. Under such a scenario, a greater share of discharger resources will be directed at managing a regulatory created environmental risk which could result in the diversion of resources from management activities that actually provide measurable environmental benefits. The City suggests that in such tributary language an exemption for dischargers that can demonstrate de minimis risk. Presently the City is confronted with new significant regulatory burdens related to diazinon and chlorpyrifos TMDLs on the Sacramento River because Pleasant Grove Creek is tributary to the Sacramento River, despite the fact that flows on Pleasant Grove Creek are diverted for agriculture, diluted by multiple other agricultural return waters and tributary streams before reaching the Sacramento, if ever reaching the Sacramento River at all. In fact, virtually every named waterbody in the Sacramento Valley is tributary to the Sacramento River, and thus nearly every NPDES permit holder in the Sacramento Valley should technically receive a waste load allocation and monitoring and reporting requirements for chlorpyrifos and diazinon despite any evidence to the contrary.

¹ U.S. Environmental Protection Agency. 1985. Guidelines for deriving numerical national water quality criteria for the protection of aquatic organisms and their uses. PB-85-227049. United States Environmental Protection Agency, National Technical Information Service, Springfield, VA.

City of Roseville Comment Letter

Central Valley Pyrethroid Pesticides Total Maximum Daily Load and Basin Plan Amendment

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Please enter these comments into the projects administrative record and address them accordingly as the project further develops. We look forward to our continued participation in this Regional Water Board project.

Thank you for your time and consideration.

Sincerely

A handwritten signature in black ink, appearing to read "Kelye A. McKinney". The signature is fluid and cursive, with a large initial "K" and "M".

Kelye A. McKinney
Engineering Manager

Cc: Danny McClure, Central Valley Regional Water Quality Control Board

Attachments (3 letters)



Environmental Utilities Department
Engineering Division
2005 Hilltop Circle
Roseville, California 95747

May 9, 2011

Danny McClure
Regional Water Quality Control Board, Central Valley Region
11020 Sun Center Drive, #200
Rancho Cordova, CA 95670-6114

**RE: Comments on Draft Aquatic Life Criteria for Permethrin and Cypermethrin
Developed by the University of California at Davis**

Dear Mr. McClure:

The City of Roseville (City), with assistance from Robertson-Bryan, Inc., has reviewed draft water quality criteria derivation reports for permethrin and cypermethrin prepared by the University of California at Davis (UCD) while under contract to the Central Valley Regional Water Quality Control Board (Regional Water Board). These draft criteria derivation reports were made available for public review through email notice received on March 24, 2011. Comments are due to the Regional Water Board by May 9, 2011.

The City bases the following comments on the detailed review provided in the enclosed attachment. The City formally requests that the Regional Water Board consider these comments, and the items listed in the enclosed attachment, in light of its own review of the UCD documents and before these draft criteria are utilized for any regulatory planning or enforcement purposes.

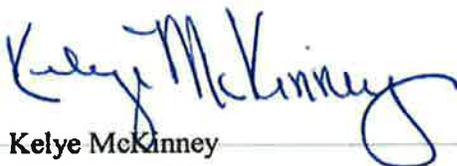
- The City does not accept the validity of the permethrin chronic criterion. The draft chronic criterion for permethrin may be overprotective. The ACR used to calculate the criterion was heavily influenced by a default ACR derived solely on classes of pesticides whose structures are different, environmental fate is different, and modes of toxic action are mostly different than permethrin.
- The City does not accept the validity of the cypermethrin chronic criterion, particularly the use of the *Daphnia magna* ACR of 949. The draft criteria for cypermethrin appears to misinterpret guidance provided in the methodology. Furthermore, guidance provided in the methodology does not appear to address the specific issues related to cypermethrin and the use and reduction of available empirical data. Related, it is the City's position that the Kim *et. al.* 2008 study on which the ACR of 949 is derived should be excluded from use in derivation of the chronic criteria. The subject study was excluded from derivation of the acute criterion, and no justification is provided as to why the study would be acceptable for derivation of the chronic criterion. Furthermore, authors of the study state that they followed OECD guidance, however OECD test acceptability criteria were not achieved and OECD test methodology were not followed. Given the lack of clear guidance in the criteria derivation

methodology, the apparent misinterpretation of guidance, and the use of a study that should have been excluded from the data set, the City requests that the chronic criterion be re-calculated. Because issues related to the derivation of the chronic criteria are several-fold, the City requests that the cypermethrin criteria document be suitably revised to address our concerns related to interpretation of the methodology and the use of Kim *et. al.* 2008 *Daphnia magna* study, and resubmitted in draft form for public comment. The City requests this additional opportunity for comment because the City believes the methodology, as presently written, does not provide clear guidance and will ultimately require subtle interpretation, on which the City desires the opportunity to review and provide new comment.

- The City does not accept the assumption of dose additivity. Compliance with criteria should not be based on simplifying assumptions of concentration addition as the principals of concentration addition do not necessarily hold true under all possible environmental mixture scenarios. Assumptions of dose additivity are unsuitable for regulatory purposes in this case and as such, the report should specifically recommend against inclusion of dose-additivity assumptions for compliance determination purposes.
- The City disagrees that whole water analysis is valid for criteria compliance. Scientific evidence points to freely dissolved pyrethroid as the bioavailable fraction. Compliance should be measured against that portion of a pyrethroid that is known to be toxic. The draft criteria reports should be revised in a manner that retains the scientifically-based recommendation for compliance determinations based on either direct measurement of the bioavailable fraction or allowing for some compensating factor accounting for particulate matter and dissolved organic matter, but should remove statements regarding the validity of whole water measurements for compliance, which are not supported.
- The limited capability of commercial laboratories in achieving low enough reporting limits is very troubling to the City. Similar to the standardization of minimum mandatory reporting limits in the State Implementation Plan (SIP), the City requests similar effort of standardization for these pesticides. Without such standardization, monitoring and compliance efforts can produce data of limited to no value, and likely at considerable economic expense to the regulated community.

Thank you for the opportunity to comment and we look forward to your response.

Sincerely,



Kelye McKinney
Engineering Manager

Att: 1



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TECHNICAL MEMORANDUM

Date: May 9, 2011

To: Delyn Ellison-Lloyd, Kelye McKinney, Ken Glotzbach (City of Roseville)

From: Brant Jorgenson, Ben Giudice, M.S., Michael Bryan, Ph.D.

Re: Review of Draft Permethrin and Cypermethrin Aquatic Life Criteria Reports
Developed by the University of California at Davis

1 Introduction

Robertson-Bryan, Inc (RBI) has reviewed draft water quality criteria derivation reports prepared by the University of California at Davis (UCD) while under contract to the Central Valley Regional Water Quality Control Board (Regional Water Board). Under this contract, UCD has prepared methodology and draft aquatic life criteria for a list of pesticides that the Regional Water Board has identified as posing high risk to water quality. The proposed methodology allows for the derivation of acute and chronic aquatic life criteria for pesticides with limited toxicity datasets. Although these criteria do not represent water quality objectives or standards at present, they may be implemented as quantitative interpretations of Basin Plan narrative toxicity objectives, and thus are of particular relevance to local agencies who manage discharges to water bodies that may be impacted by pesticides. The Regional Water Board recently adopted and submitted to the State Water Board for its approval Clean Water Act Section 303(d) listings for pyrethroid insecticide-related toxicity on Pleasant Grove Creek, South Branch Pleasant Grove Creek, and Kaseberg Creek, making the development of these draft criteria particularly relevant to the City of Roseville's (City) wastewater and storm water management operations.

This technical memorandum (TM) specifically reviews criteria derivation documents that were recently released for public review by the Regional Water Board for the pyrethroid insecticides permethrin and cypermethrin. Comments for permethrin and cypermethrin are due by May 9, 2011. Incorporated throughout these criteria derivation documents is reference to a recently developed criteria derivation methodology. Review of the criteria derivations requires review and comment on the methodology used to derive the criteria and, therefore, review of the methodology also was conducted. Due to the similarities across pyrethroid insecticides, a number of findings included in this TM are similar to those previously provided for bifenthrin, lambda-cyhalothrin, and cyfluthrin. This TM summarizes RBI's findings from this review and assessment and incorporates, where appropriate, comments previously provided for bifenthrin, lambda-cyhalothrin, and cyfluthrin (See RBI TMs dated January 14, 2010 and February 18, 2010).

2 Draft Criteria and Background

Draft aquatic life criteria statements from UCD for permethrin and cypermethrin are provided below. Specific comment on the criteria values and means of measuring compliance are provided in Section 3 and 4 of this memo.

“Aquatic life in the Sacramento River and San Joaquin River basins should not be affected unacceptably if the four-day average concentration of permethrin does not exceed **0.002 µg/L (2 ng/L)** more than once every three years on the average and if the one-hour average concentration does not exceed **0.01 µg/L (10 ng/L)** more than once every three years on the average.” (Fojut *et. al.* 2011a)

and,

“Aquatic life in the Sacramento River and San Joaquin River basins should not be affected unacceptably if the four-day average concentration of cypermethrin does not exceed **0.000003 µg/L (0.003 ng/L)** more than once every three years on the average and if the one-hour average concentration does not exceed **0.001 µg/L (1 ng/L)** more than once every three years on the average.” (Fojut *et. al.* 2011b)

These criteria were developed following a methodology published in September 2009. In *Methodology for Derivation of Pesticide Water Quality Criteria for the Protection of Aquatic Life, Phase II: Methodology Development and Derivation of Chlorpyrifos Criteria* (TenBrook *et al.*, 2009), a new method of criteria derivation is formalized and a step-by step procedure for deriving criteria from small toxicity datasets is provided. A new criteria derivation methodology was necessary because these limited datasets are deficient in one manner or another for use with the existing EPA methodology (EPA, 1985). The draft criteria derivation reports, which are the principal subject of this review, follow this step-by-step procedure.

The UCD methodology has been revised based on comments received from both peer review and public comment. In general, the UCD methodology developed for the task of deriving aquatic life criteria for pesticides of concern is scientifically sound. The UCD methodology is rather unique in that it lays a foundation for a regional regulatory body to develop criteria from toxicity datasets found to be incomplete by the conventional EPA method (EPA, 1985), which is most commonly used for criteria derivation purposes.

The specific manner in which this new methodology is applied in the derivation of specific aquatic life criteria is of key importance. The UCD methodology provides more than a means to derive numeric criteria; it also considers factors of bioavailability, mixture effects, and the effect of other tangential water quality parameters on pesticide toxicity (e.g., temperature and pH). Considering these other factors is complex, and caution is warranted in how assumptions are employed in developing final criteria statements and execution of those statements.

The remainder of this review summarizes specific findings in the development and execution of these draft aquatic life criteria. Only brief effort was made to review the toxicity value screening procedure because conducting a thorough review of this aspect of the methodology was beyond the scope of this

review effort. However, it should be noted that the screening of available toxicity values largely determines the criteria derivation outcome and, therefore, a thorough review of the toxicity value screening procedure by an outside party is recommended.

3 Assessment of Methodology and Draft Derivation of Permethrin and Cypermethrin Criteria

3.1 Implementation of Acute to Chronic Ratios

In cases when data from fewer than five taxa are present, the methodology requires that acute-to-chronic ratios (ACRs) be used. Acute-to-chronic ratios for a given pesticide can vary considerably among species. In general, ACRs have been found to vary from 1 to 20,000 (Chapman *et al.*, 1998). In the methodology, the authors acknowledge that "...there is no evidence that default ACR values are appropriate for pesticides in general." They go on to conclude that, nevertheless, some means of calculation of an ACR is necessary, and so accept a default value of 12.4 based on the 80th percentile of ACRs for 8 pesticides, including 5 organochlorine pesticides and 3 organophosphate pesticides (TenBrook *et al.*, 2009). ACRs for pyrethroids have been found to vary between 2 and 415 for a variety of species (Solomon *et al.*, 2001).

3.1.1 Permethrin

In the case of permethrin, the final ACR is calculated as the geometric mean of one ACR for *Americanmysis bahia*, and two default values of 12.4, which are based on no data from pyrethroids, but instead are derived solely on classes of pesticides whose structures are different, environmental fate is different, and modes of toxic action are mostly different. The chronic criterion calculated using this ACR is 2 ng/L. The most sensitive maximum acceptable toxicant concentration (MATC) in the data set was 16 ng/L (Fojut *et al.*, 2011a). In this case, the derived criterion may be over-protective, owing to the use of default ACRs which are not based on pesticides with similar mechanisms of action.

3.1.2 Cypermethrin

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

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

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

"1) If the SMACR seems to increase or decrease as the SMAVs increase, calculate the ACR as the geometric mean of the ACRs for species whose SMAVs are close to the

acute criterion (this includes species whose SMACRs are within a factor of 10 of the SMACR of the species whose SMAV is nearest the 5th percentile value);

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

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

1. None of the conditions specified in parts 1, 2, or 3 of section 3-4.2.1 of the methodology are applicable to the cypermethrin scenario. Part 1 only applies when the SMACR seems to increase or decrease as the SMAVs increase, which the authors state is not the case. Part 2 only applies when there is *both* no major trend, *and* when all SMACRs are within a factor of 10, which is not applicable to the cypermethrin case. Part 3 only applies if the most appropriate SMACRs are less than 2, which is not the case for cypermethrin. Finally, the methodology states that if the requirements in bullets 1, 2, and 3 are not met, the ACR should be calculated using the default ACR of 12.4, per section 3-4.2.2. This last method appears to be the path most consistent with the methodology, although the use of a default ACR is dubious to begin with (see discussion on permethrin above), especially when cypermethrin ACRs for *Arcatia tonsa* and *Oncorhynchus mykiss* exist.
2. The authors of the cypermethrin document appear to have attempted to follow Part 1, even though there was no trend apparent. However there are two issues that arise from doing so.
 - Part 1 of the methodology appears to have an internal inconsistency. First, it states that the geometric mean of the ACRs for species whose SMAVs are close to the *acute criterion* is to be used. The parenthetical phrase that follows appears to define what “close” means, that is, species whose SMACRs are within a factor of 10 of the SMACR of the species whose SMAV is nearest the 5th percentile value. The acute criterion and the 5th percentile value differ by an imposed factor of 2, and in this case, the species whose SMAV is nearest the acute criterion (*Daphnia magna*) is not the same as the species whose SMAV is nearest the 5th percentile value (*Arcatia tonsa*). If the parenthetical phrase is not meant to define what “close” means, then close remains undefined, and the issue remains that ACRs of species whose SMAV is close to the acute criterion are different than the ACRs within a factor of 10 of the species whose SMAV is nearest the 5th percentile value (see also number 3, below).
 - The authors misinterpret the language in Part 1. The authors’ state that the methodology indicates that the ACR should be calculated based on the ACRs of species whose SMAVs are within a factor of 10 of the acute 5th percentile value. The methodology does not indicate this. Rather, the methodology appears to indicate that the ACR should be calculated based on those SMACRs which are within a factor of 10 of the SMACR for the species whose SMAV is nearest the acute 5th percentile value (as noted above). However, even if the authors are correctly interpreting the

methodology, which does not appear to be the case, they then have incorrectly applied the methodology to the cypermethrin scenario, as described below.

- The authors appear to have misapplied their interpretation of the methodology that “only the SMACRs for species with SMAVs within a factor of 10 of the acute 5th percentile value should be used for the final multi-species ACR” (Fojut *et al.*, 2011b). Although it is never specified in either the methodology or in the draft criteria derivation document whether the acute 5th percentile value refers to the median (50% confidence limit) or the 95% confidence limit 5th percentile value, we assume it refers to the median 5th percentile value (0.0126904 µg/L), since this is the value used previously in the acute criterion derivation and used with the ACR in the initial calculation of the draft chronic criterion. If this is so, the authors appear to have erroneously determined that the SMAV for *Daphnia magna* was within a factor of 10 of the acute 5th percentile value, and simultaneously determined that the SMAV for *Acartia tonsa* was not. Table 1 shows the MATC, SMAV, ACR, and the factor between the calculated ACR and the acute median 5th percentile value, for reference. The SMAV for *Daphnia magna* is a factor of 21.2 lower than the acute 5th percentile value, while the SMAV for *Acartia tonsa* is a factor of 8.52 greater than the acute 5th percentile value. According to the authors interpretation of the methodology and recommendation cited above, the ACR thus should have been calculated as simply the ACR for *Acartia tonsa*, or 2.11. If the parenthetical expression of part 1 of section 3-4.2.1 is then added to this interpretation, the final ACR should actually be the geometric mean of the ACR for *Acartia tonsa* and for *Oncorhynchus mykiss* (since this ACR is within a factor of 10 of the ACR for *Acartia tonsa*), which would have resulted in an ACR of 2.18. Either way, the impact on the initial calculation of the chronic criterion is substantial. Instead of 0.01 ng/L, the chronic criterion would be calculated as 6 ng/L, equivalent to the draft acute criterion.

Table 1. Acute-to-Chronic Ratios used for derivation of the cypermethrin chronic criterion, and factor between species mean acute value (SMAV) and acute 5th percentile value.

Species	Common identifier	MATC (µg/L)	SMAV (µg/L)	ACR (LC ₅₀ /MATC)	Factor ^a
<i>Acartia tonsa</i>	Marine copepod (invertebrate)	0.0512	0.1081	2.11	8.52
<i>Daphnia magna</i>	Daphnid (invertebrate)	6.3E-07	0.0006	949	21.2
<i>Oncorhynchus mykiss</i>	Rainbow trout (fish)	0.65	1.47	2.26	116

^a – Factor calculated as SMAV/median acute 5th percentile value in the case of *Acartia tonsa* and *Oncorhynchus mykiss* (i.e., SMAV > median acute 5th percentile value), and as median acute 5th percentile value/SMAV in the case of *Daphnia magna* (i.e., SMAV < median acute 5th percentile value). Median 5th percentile value was 0.0126904 µg/L.

The authors later adjust the acute criterion, using instead the 1st percentile, 50% confidence limit value to re-calculate the acute criterion, in order to protect sensitive species since the initially determined acute criterion was higher than the SMAV for some species in the data set. The resulting acute criterion is 1 ng/L (Fojut *et al.*, 2011b). Using the calculated ACR of 2.11 or 2.18 with the 1st percentile, 50% confidence limit value results in an adjusted chronic criterion of 1 ng/L, equivalent to the adjusted acute criterion. However, the methodology does

not address selection of appropriate ACRs based on use of the 1st percentile, 50% confidence limit value. When compared to this value (0.0025723 µg/L), the only species with a SMAV within a factor of 10 is *Daphnia magna*, which if used in place of the 5th percentile acute value, would result in an ACR of 949, and an adjusted chronic criterion of 0.003 ng/L. This approach, however, is technically inconsistent with the methodology. Furthermore, *Daphnia magna* is not very acutely sensitive (LC₅₀ of 147 ng/L), but apparently very chronically sensitive to cypermethrin, resulting in a very large ACR. Applying this ACR to an acute value driven largely by data for *Hyalalela azteca*, which is very acutely sensitive, results in a criterion that is very likely overprotective.

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

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

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

3.2 Assumed Dose-Effect Additivity

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

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

Indeed, in investigations conducted by Trimble et al. (2009) on additivity in binary mixtures of Type I and Type II pyrethroids, although concentration addition models predicted experimental results well, as would be hypothesized, in some cases so did independent action models. Furthermore, actual toxicity often deviated substantially from predicted toxicity at low toxicant concentration, well below expected LC₅₀ values (i.e., in the range of the derived acute criterion). There is enough inherent uncertainty in the use and applicability of concentration addition models, be they toxic unit or relative potency factor approaches, that compliance determinations should not be based on assumed additivity. The reports should be revised to clearly state that dose-additivity is not recommended for the purposes of compliance determinations.

3.3 Bioavailability

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

“[Studies] suggest that the freely dissolved fraction of permethrin/cypermethrin is the primary bioavailable phase, and that this concentration is the best indicator of toxicity, thus, it is recommended that the freely dissolved fraction of permethrin/cypermethrin be directly measured or calculated based on site specific information for compliance assessment. Whole water concentrations are also valid for criteria compliance

assessment, and may be used at the discretion of environmental managers, although the bioavailable fraction may be overestimated with this method” (Fojut *et al.*, 2011a; Fojut *et al.*, 2011b).

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

3.4 Analytical Concerns

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

4 Summary of Review Findings

Review findings are summarized as follow:

1. The draft acute criteria for permethrin and cypermethrin are based on a species distribution approach and result in supportable criteria.
2. Available data indicate that the draft chronic criterion for permethrin may be overprotective. The ACR used to calculate the criterion was heavily influenced by a default ACR derived solely on classes of pesticides whose structures are different, environmental fate is different, and modes of toxic action are mostly different than permethrin.

3. Regarding cypermethrin, there are several inconsistencies and/or errors in the methodology, in the authors' interpretation of the methodology, and in the application of that interpretation that result in an unsupported ACR and, therefore, an unsupported chronic criterion. Instead of the draft chronic criterion of 0.003 ng/L, if the methodology were applied as written, the cypermethrin adjusted chronic criterion should be 0.2 ng/L. However, if the authors' interpretation of the methodology takes precedence over a literal reading of the methodology, the adjusted chronic criterion should be 1 ng/L. Furthermore, the authors use a study in the derivation of the chronic criterion which was previously excluded from the derivation of acute criterion, thus introducing a methodological inconsistency. It is recommended that the authors revisit the methodology and/or the cypermethrin chronic criterion derivation, and subsequently re-release a draft report for public comment. The issue appears too complex and substantial (in terms of its effect on the proposed criterion) to allow a final revision not subject to peer scrutiny and public comment.
4. For all draft criteria, it is not clear whether the assumption of dose additivity between pyrethroids of similar mode of toxicity is assumed for compliance determination. Caution is advised in applying concentration addition principals to compliance measurements. Dose additivity is not settled science, and its accuracy as a model predictor is sensitive to many variable factors and thus not always good. Where science is not settled, compliance should not be based on simplifying assumptions.
5. The current scientific understanding regarding pesticide bioavailability should be applied to criteria compliance determinations. The freely dissolved fraction of pyrethroid insecticides, including permethrin and cypermethrin, is a far better predictor of the bioavailable fraction than is total recoverable measurements. Therefore, compliance determinations should be based on measurements that most accurately predict toxicity. Either compliance should be determined using analytical procedures measuring the dissolved fraction, or compliance should be determined using total recoverable methods but adjusted for pyrethroid sorption to particulate matter and dissolved organic matter. There is no scientific support for using whole-water concentrations for compliance determinations.
6. Achieving commercially available analytical reporting limits below the draft criteria utilizing EPA approved methods is currently lacking or limited. Maximum matrix-specific reporting limits should be considered so as to avoid the potential of reporting false positives and errant detections.

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Environmental Utilities
Administration
2005 Hilltop Circle
Roseville, California 95747

February 18, 2010

Danny McClure
Regional Water Quality Control Board, Central Valley Region
11020 Sun Center Drive, #200
Rancho Cordova, CA 95670-6114

RE: Comments on Draft Aquatic Life Criteria for Lambda-Cyhalothrin and Cyfluthrin Developed by the University of California at Davis

Dear Mr. McClure:

The City of Roseville (City), with assistance from Robertson-Bryan, Inc., has reviewed draft water quality criteria derivation reports for lambda-cyhalothrin and cyfluthrin prepared by the University of California at Davis (UCD) while under contract to the Central Valley Regional Water Quality Control Board (Regional Water Board). These draft criteria derivation reports were made available for public review through email notice received on January 21, 2010 and February 4, 2010. Comments for lambda-cyhalothrin and cyfluthrin are due to the Regional Water Board by February 21, 2010 and March 6, 2010, respectively. The following comments are provided for both criteria derivation reports in advance of the February 21, 2010 deadline.

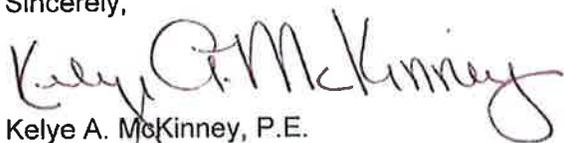
The City bases the following comments on the detailed review provided in the enclosed attachment. The City formally requests that the Regional Water Board consider these comments, and the items listed in the enclosed attachment, in light of its own review of the UCD documents and before these draft criteria are utilized for any regulatory planning or enforcement purposes.

- The City does not accept the validity of the cyfluthrin acute criterion, derived utilizing an assessment factor applied to the most sensitive freshwater species *Hyallela azteca*. Use of the assessment factor provides for unnecessary extrapolation and results in an overprotective numeric criterion. In this case, use of an assessment factor for cyfluthrin is not scientifically defensible and results in aquatic life criteria unsuitable for regulatory purposes.
- The City does not accept the validity of the cyfluthrin chronic criterion. The acute-to-chronic ratio derived is of dubious scientific applicability to the acute criterion. The use of this acute-to-chronic ratio, combined with the assessment factor used to derive the acute criterion, results in an overprotective chronic criterion for cyfluthrin that is unsuitable for regulatory purposes.
- The City does not accept the assumption of dose additivity. Compliance with criteria should not be based on simplifying assumptions of concentration addition as the principals of concentration addition do not necessarily hold true under all possible environmental mixture scenarios. Assumptions of dose additivity are unsuitable for regulatory purposes in this case and as such allowance for dose additivity should be omitted.
- The City disagrees that pyrethroid compliance should be measured against whole water analysis. Scientific evidence points to freely dissolved pyrethroid as the bioavailable

- fraction. Compliance should be measured against that portion of a pyrethroid that is known to be toxic. The draft lambda-cyhalothrin criteria report should be revised in a manner that allows for either direct measurement of the bioavailable fraction or allow for some compensating factor accounting for particulate matter and dissolved organic matter effects.
- The recommendation in the cyfluthrin report that whole water analysis should be used in cases where total recoverable analysis achieves lower detection limits confuses the issue of analytical capability with that of toxicological relevancy. This recommendation should be removed from the cyfluthrin report and the report suitably revised to recommend that treatments or measurements of the dissolved fraction be the basis of compliance determinations.
- The capabilities of commercial laboratories in achieving low enough reporting limits is very troubling to the City. Similar to the standardization of minimum mandatory reporting limits in the State Implementation Plan (SIP), the City requests similar effort of standardization for these pesticides. Without such standardization, monitoring and compliance efforts can produce data of limited to no value, and likely at considerable economic expense to the regulated community.
- When considering the plausible future use of these draft criteria, as quantitative interpretations of existing Basin Plan narrative toxicity objectives, the City is troubled by the seeming lack of critical quality assurance review. The rounding error in the lambda-cyhalothrin report represents the second draft criteria report to include an arithmetic-related error (the first being a derivation methodology error in the bifenthrin report), and the cyfluthrin report includes an error in the description of the final criteria statement. Acute criteria should be expressed as one-hour averages and chronic criteria should be expressed as four-day averages, not the inverse. These errors unfortunately call into question the accuracy of all work pertaining to the derivation – namely the compilation, review and screening of studies for which the toxicity values are selected. The City requests a thorough outside review of all the derivation reports.

Thank you for the opportunity to comment and we look forward to your response.

Sincerely,



Kelye A. McKinney, P.E.
Engineering Manager

enclosure



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TECHNICAL MEMORANDUM

Date: February 18, 2010
To: Delyn Ellison-Lloyd, Kelye McKinney, Art O'Brien (City of Roseville)
From: Michael Bryan, Ph.D., Brant Jorgenson, Ben Giudice, M.S.
Cc:
Re: Review of Draft Lambda-Cyhalothrin and Cyfluthrin Aquatic Life Criteria Reports
Developed by the University of California at Davis

1 Introduction

Robertson-Bryan, Inc (RBI) has reviewed draft water quality criteria derivation reports prepared by the University of California at Davis (UCD) while under contract to the Central Valley Regional Water Quality Control Board (Regional Water Board). Under this contract, UCD has prepared methodology and draft aquatic life criteria for a list of pesticides that the Regional Water Board has identified as posing high risks for adversely impacting water quality. The proposed methodology allows for the derivation of acute and chronic aquatic life criteria for pesticides with limited toxicity datasets. Although these criteria do not represent water quality objectives or standards at present, they may be implemented as quantitative interpretations of Basin Plan narrative toxicity objectives, and thus are of particular relevance to local agencies who manage discharges to water bodies that may be impacted by pesticides. The Regional Water Board recently adopted and submitted to the State Water Board for its approval Clean Water Act Section 303(d) listings for pyrethroid insecticide-related toxicity on Pleasant Grove Creek, South Branch Pleasant Grove Creek, and Kaseberg Creek, making the development of these draft criteria particularly relevant to the City of Roseville's (City) wastewater and storm water operations.

This technical memorandum (TM) specifically reviews criteria derivation documents that were recently released for public review by the Regional Water Board for the pyrethroid insecticides lambda-cyhalothrin and cyfluthrin. Comments for lambda-cyhalothrin and cyfluthrin are due by February 21, 2010 and March 6, 2010, respectively. Incorporated throughout these criteria derivation documents is reference to a recently developed criteria derivation methodology. Review of the criteria derivations requires review and comment on the methodology used to derive the criteria and, therefore, review of the methodology also was conducted. Due to the similarities across pyrethroid insecticides, a number of findings included in this memo are similar to those previously provided for bifenthrin. This TM summarizes RBI's findings from this review and assessment and incorporates, where appropriate, comments previously provided for bifenthrin (See RBI TM dated January 14, 2010 and submitted to the Regional Water Board on January 15, 2010).

2 Draft Criteria and Background

Draft aquatic life criteria statements from UCD for lambda-cyhalothrin and cyfluthrin are provided below. Specific comment on the criteria values and means of measuring compliance are provided in Section 3 and 4 of this memo.

“Aquatic life in the Sacramento River and San Joaquin River basins should not be affected unacceptably if the four-day average concentration of lambda-cyhalothrin does not exceed **0.001 µg/L (1 ng/L)** more than once every three years on the average and if the one-hour average concentration does not exceed **0.001 µg/L (1 ng/L)**¹ more than once every three years on the average.” (Fojut *et. al.* 2010a)

and,

“Aquatic life in the Sacramento River and San Joaquin River basins should not be affected unacceptably if the four-day average concentration of cyfluthrin does not exceed **0.0002 µg/L (0.2 ng/L)**² more than once every three years on the average and if the one-hour average concentration does not exceed **0.00004 µg/L (0.04 ng/L)** more than once every three years on the average.” (Fojut *et. al.* 2010b)

These criteria were developed following a methodology published in September 2009. In *Methodology for Derivation of Pesticide Water Quality Criteria for the Protection of Aquatic Life, Phase II: Methodology Development and Derivation of Chlorpyrifos Criteria* (TenBrook *et al.*, 2009), a new method of criteria derivation is formalized and a step-by-step procedure for deriving criteria from small toxicity datasets is provided. A new criteria derivation methodology was necessary because these limited datasets are deficient in one manner or another for use with the existing EPA methodology (EPA, 1985). The draft criteria derivation reports, which are the principal subject of this review, follow this step-by-step procedure.

The UCD methodology has been revised based on comments received from both peer review and public comment. In general, the UCD methodology developed for the task of deriving aquatic life criteria for pesticides of concern is scientifically sound. The UCD methodology is rather unique in that it lays a foundation for a regional regulatory body to develop criteria from toxicity datasets found to be incomplete by the conventional EPA method (EPA, 1985), which is most commonly used for criteria derivation purposes.

The specific manner in which this new methodology is applied in the derivation of specific aquatic life criteria is of key importance. The UCD methodology provides more than a means to derive numeric criteria; it also considers factors of bioavailability, mixture effects, and the effect of other tangential water quality parameters on pesticide toxicity (e.g., temperature and pH). Considering these other factors is complex, and caution is warranted in how assumptions are employed in developing final criteria statements and execution of those statements.

¹ This value is believed to be in error. See Section 3.6.

² The values for the four-day average concentration and the one-hour average concentration criteria are reversed. See Section 3.6.

The remainder of this review summarizes specific findings in the development and execution of these draft aquatic life criteria. Only brief effort was made to review the toxicity value screening procedure because conducting a thorough review of this aspect of the methodology was beyond the scope of this review effort. However, it should be noted that the screening of available toxicity values largely determines the criteria derivation outcome and, therefore, a thorough review of the toxicity value screening procedure by an outside party is recommended.

3 Assessment of Methodology and Draft Derivation of Lambda-Cyhalothrin and Cyfluthrin Criteria

3.1 Use of Assessment Factor Approach for Cyfluthrin

In the development of draft criteria utilizing the UCD methodology, several safety factor iterations are employed in order to compensate for informational deficiencies in limited datasets. In the case of the draft cyfluthrin criteria derivation report (Fojut *et al.*, 2010b), an acute criterion was derived by taking the single most sensitive acute result of 0.0023 µg/L and dividing it by an assessment factor of 5.1 (due to only 4 taxa being available—as per Table 3.13 in the methods), and dividing by a further factor of 2 to convert from an LC₅₀/EC₅₀ to an assumed NOEC. As required by the UCD methodology, the assessment factor approach was utilized in place of the more robust species sensitivity distribution approach because data for only four of the necessary five taxa were available. The missing taxa was an insect.

The lowest species mean acute value of 0.0023 µg/L was for *Hyalalella azteca*. *H. azteca* is known to be an exceedingly sensitive freshwater species to pyrethroid exposure. In the draft criteria reports for bifenthrin, lambda-cyhalothrin, and cyfluthrin, *H. azteca* is presented as the most sensitive species when comparing species mean acute toxicity values. In Solomon *et al.* (2001), the authors assert that variation in pyrethroid species sensitivity is similar. However, using the assessment factor approach for cyfluthrin results in an acute criterion nearly one order of magnitude less than that derived for bifenthrin and lambda-cyhalothrin. The most sensitive freshwater species, as presented in these three pyrethroid datasets are the same – *H. azteca*. Actual sensitivities in *H. azteca*, as summarized in the pyrethroid criteria reports, varies by a factor of 3.

Derivation of the draft cyfluthrin criteria illustrates some of the short-comings inherent to the assessment factor approach in the UCD methodology. When a dataset is limited by the absence of an acute toxicity value representative of a specifically required taxa, use of an assessment factor presumes the potential existence of a more sensitive species not reflected in the available data. In the case of cyfluthrin, *H. azteca* is very likely the most sensitive freshwater species, and applying an uncertainty factor of 5.1 likely overestimates species sensitivity, resulting in an overly conservative acute criterion.

Assessment factors themselves are cumbersome tools when used to derive quantitative aquatic life criteria for regulatory purposes. They act as semi-quantitative uncertainty factors in order to overcome gaps and deficiencies in a dataset. The assessment factors employed in the UCD methodology are semi-quantitative inasmuch that they are based on toxicity datasets for chlorpyrifos, DDT, toxaphene, endrin, lindane, aldrin, dieldrin, heptachlor, chlordane, and endosulfan, none of which are pyrethroid insecticides. While use of assessment factors can serve to reduce the probability

of underestimating risk in cases where data are limited, the very conservative nature of assessment factors greatly increases the probability that risk is overestimated. While criteria developed by including such uncertainty factors may serve a suitable purpose in risk assessment evaluations, they should not be used for regulatory compliance purposes. And while uncertainty factor driven criteria maintain utility in a risk assessment arena, before their use they should be evaluated against other lines of evidence that suggest they might err unnecessarily in favor of overprotection, as in this case with cyfluthrin. Context and scientific knowledge are important considerations in the use of assessment factors, and the context here suggests that the draft criteria for cyfluthrin is overprotective.

3.2 Implementation of Acute to Chronic Ratios

In cases when data from fewer than five taxa are present, the methodology requires that acute-to-chronic ratios (ACRs) be used. For lambda-cyhalothrin and cyfluthrin, ACR's were derived from pyrethroid specific datasets. However, *H. azteca* is the most sensitive species and the one that drives the acute value. There is no ACR in the datasets for this species or its taxon. Furthermore, for cyfluthrin, the concentrations at which ACRs are derived in Table 8 are ~2 orders of magnitude higher than the acute value. For these reasons, it is not clear that the ACR methodology provides a scientifically reasonable means of deriving chronic criteria, particularly in the case of cyfluthrin, for which the derived chronic criterion is 332 times lower than the most sensitive chronic value in the acceptable dataset. The use of the derived ACR, combined with the assessment factor used to derive the acute criterion, results in an overprotective chronic criterion for cyfluthrin.

3.3 Assumed Dose-Effect Additivity

Environmental toxicologists recognize the importance of considering toxicant mixtures when evaluating and predicting toxicity to an organism. It is a held theory that toxicants of similar mode of action can act additively on an organism. Through such simplifying models of concentration addition, the effect of dose additivity can be predicted. In the lambda-cyhalothrin and cyfluthrin criteria reports, where toxic modes of action are considered the same, the reports state in similar fashion:

“Since compounds in this class have a similar mode of action, either the toxic unit or the relative potency factor approach can be used to determine compliance in cases where pyrethroid mixtures are present in environmental samples...” (Fojut *et al.*, 2010a)

Admittedly, this principal of toxicology holds well, but one must question how *similar* a toxic mode of action must be, how many mixture components there are, and at what concentration ratios for the assumption of additivity to hold true under all likely environmental scenarios. Caution is advised in applying concentration addition models in cases of compliance determination. For example, Trimble *et al.* (2009) investigated additivity in binary mixtures of Type I and Type II pyrethroids. Although concentration addition models predicted experimental results well, as would be hypothesized, in some cases so did independent action models. Furthermore, actual toxicity often deviated substantially from predicted toxicity at low toxicant concentration, well below expected LC₅₀ values (i.e., in the range of the derived acute criterion). There is enough inherent uncertainty in the use and applicability of concentration addition models, be they toxic unit or relative potency factor approaches, that pause should be taken before assessing compliance based on assumed additivity.

3.4 Bioavailability

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

The draft criteria reports make two different recommendations on the matter of bioavailability. Similar to the recommendation contained in the previously published bifenthrin report, the lambda-cyhalothrin report recommends that compliance with the lambda-cyhalothrin criteria be determined based on the total recoverable, whole-water fraction. This recommendation is made rather arbitrarily in an effort to balance error associated in toxicity measurements reporting nominal spiked concentration with that of the error in predicting toxicity with the use of whole-water measurements. By assuming these relative errors to be equal, and thus cancelling, the authors attempt to strike a balance between the over prediction of toxicity when utilizing a total recoverable analytical measurement with the under prediction of toxicity when utilizing a nominal spike concentration in determining LC_{50} 's. There is no justification for this balance, the result of which knowingly biases a compliance measurement in favor of overprotection once again.

Conversely, the cyfluthrin report makes the recommendation that compliance determinations be based on the freely dissolved fraction which more accurately reflects scientific understanding of pyrethroid bioavailability in the environment. However, this recommendation is made with a caveat, that dissolved pyrethroid analytical measurements should only be used if analytical method detection limits meet or exceed the total recoverable analytical counterpart. The reasoning for this caveat centers around dissolved fraction analytical sensitivity concerns. Analytical sensitivity is an issue of concern regardless of analytical methodology employed, particularly with acute and chronic criteria in the part-per-trillion and sub-part-per-trillion range. Analytical detection issues aside (see Section 3.5 for more detail), if a total recoverable analytical method could give a lower reporting limit in comparison to an appropriate dissolved analytical method, the lower analytical reporting limit itself does not, by any scientific standard, make the result a more accurate measure of the truly bioavailable fraction. In light of the current scientific understanding of pyrethroid bioavailability, any total recoverable measurement unadjusted to account for the fraction that is not bioavailable represents a knowingly biased measurement and should not be used for compliance determination.

3.5 Analytical Concerns

For compliance testing purposes through National Pollutant Discharge Elimination System (NPDES) permits, EPA approved methodologies must be used. Existing analytical methods for the measurement of semi-volatile organic pollutants such as pyrethroid insecticides are limited in the capability of achieving the draft criteria values derived for lambda-cyhalothrin and cyfluthrin. Only the most diligent commercial laboratories can achieve reporting limits near the acute lambda-cyhalothrin criterion using these analytical methods and employing good laboratory practices and standard quality assurance. There is limited commercial analytical capacity in California, and at

present most laboratories could only assure reporting limits several times greater than the draft acute criteria. This limits the utility of criteria altogether, and potentially returns the regulated community to a position of providing the Regional Water Board with analytical results containing varied reporting limits. When using such criteria, maximum matrix-specific reporting limits should be considered so as to avoid the potential of reporting false positives and errant detections.

3.6 Calculation Error and Error In Criteria Statements

The final chronic criterion derived for lambda-cyhalothrin appears to include a rounding error. The chronic criterion for lambda-cyhalothrin should be 0.5 ng/L.

In the cyfluthrin draft derivation report, the concluding criteria statement confuses averaging periods for acute and chronic criteria. Acute criteria should be one-hour average values and chronic criteria should be four-day average values.

4 Summary of Review Findings

Review findings are summarized as follow:

1. Overly conservative extrapolation through the use of an assessment factor (i.e., uncertainty factor) for cyfluthrin yields an acute criterion of questionable scientific validity. Context and scientific knowledge should be employed in evaluating the appropriateness of the utilized assessment factor. The assessment factor used not only was derived from a list of insecticides that does not include any pyrethroids, the assessment factor was applied to a *H. azteca* LC₅₀ value. *Hyallela azteca* is known to be exceptionally sensitive to pyrethroid exposure; indeed, *H. azteca* pyrethroid sensitivity is rarely exceeded.
2. The acute criterion for lambda-cyhalothrin is based on a species distribution approach and results in a supportable criterion compared to that derived from an assessment factor approach.
3. The ACR derived for lambda-cyhalothrin is based on a dataset that does not contain the most sensitive species *H. azteca* or its taxon. Therefore, there is no way to determine whether the derived value of the ACR is appropriate for application to the acute value. The ACR derived for cyfluthrin has the same deficiency, but also relies on a dataset in which LC₅₀s are ~2 orders of magnitude higher than the LC₅₀ to which the ACR is applied. The resulting ACR is of questionable scientific validity, and this shortcoming is compounded by the assessment factor used to derive the acute criterion, as discussed above. The use of the derived ACR, combined with the assessment factor used to derive the acute criterion, results in an overprotective chronic criterion for cyfluthrin.
4. For all derived criteria, the assumption of dose additivity between pesticides of similar mode of toxicity is assumed. Caution is advised in applying concentration addition principals to compliance measurements. Dose additivity is not settled science, and its accuracy as a model predictor is sensitive to many variable factors. Where science is not settled, compliance should not be based on simplifying assumptions.

5. The current scientific understanding regarding pesticide bioavailability should be applied to criteria compliance determinations. The freely dissolved fraction of pyrethroid insecticides, including lambda-cyhalothrin and cyfluthrin, is the fraction that is bioavailable. Compliance should be based on measurements that most accurately predict toxicity. Either compliance should be determined using analytical procedures measuring the dissolved fraction, or compliance should be determined using total recoverable methods but adjusted for pyrethroid sorption to particulate matter and dissolved organic matter.
6. Achieving commercially available analytical reporting limits below the pyrethroid criterion utilizing EPA approved methods is currently lacking or limited. Maximum matrix-specific reporting limits should be considered so as to avoid the potential of reporting false positives and errant detections.
7. The rounding error contained in chronic criterion for lambda-cyhalothrin should be corrected. The final criteria statement for cyfluthrin should accurately state acute and chronic averaging periods.

5 References

- Fojut, T.L., R.S. Tjeerdema. 2010a. *Lambda-Cyhalothrin Criteria Derivation*. Draft. Environmental Toxicology Department, University of California, Davis. Davis, CA.
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- Solomon, K., R., J. M. Giddings, S. J. Maund. 2001 Probabilistic risk assessment of cotton pyrethroids: I. Distributional analysis of laboratory aquatic toxicity data. *Environmental Toxicology and Chemistry*. 20:652-659.
- Tenbrook, P.L., A.J. Palumbo, R.S. Tjeerdema. 2009. *Methodology for Derivation of Pesticide Water Quality Criteria for the Protection of Aquatic Life; Phase II: Methodology Development and Derivation of Chlorpyrifos Criteria*. Environmental Toxicology Department, University of California, Davis. Davis, CA.
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Environmental Utilities
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January 14, 2010

Danny McClure
Regional Water Quality Control Board, Central Valley Region
11020 Sun Center Drive, #200
Rancho Cordova, CA 95670-6114

RE: Comments on Draft Aquatic Life Criteria for Bifenthrin and Malathion Developed by University of California at Davis

Dear Mr. McClure:

The City of Roseville (City), with assistance from Robertson-Bryan, Inc., has reviewed draft water quality criteria derivation reports for bifenthrin and malathion prepared by the University of California at Davis (UCD) while under contract to the Central Valley Regional Water Quality Control Board (Regional Water Board). These draft criteria derivation reports were made available by the Regional Water Board for public review in December 2009 by e-mail notification and the comment period was subsequently extended to January 15, 2010.

The City makes the following comments based on the detailed technical comments prepared by Robertson-Bryan, Inc. (RBI) on the City's behalf, which are provided in the enclosed attachment. This letter, together with the attached Technical Memorandum, contains the City's complete comments at this time.

The City formally requests that the Regional Water Board consider these comments, and the items listed in the enclosed attachment, in light of its own review of the UCD documents and before these draft criteria are utilized for any regulatory planning or enforcement purposes.

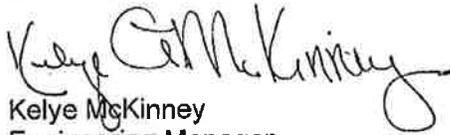
- The City does not accept the validity of chronic criteria derived when utilizing default acute-to-chronic ratios (ACR). The use of default ACRs is not scientifically defensible and, therefore, results in aquatic life criteria unsuitable for regulatory purposes.
- The City disagrees with the assumption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

Finally, the City requests 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.

Thank you for the opportunity to comment and we look forward to your responses to our comments.

Sincerely,



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Encl.



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TECHNICAL MEMORANDUM

Date: January 14, 2010

To: Delyn Ellison-Lloyd, Kelye McKinney, Art O'Brien (City of Roseville)

From: Michael Bryan, Ph.D., Brant Jorgenson, Ben Giudice, M.S.

Re: Review of Draft Derivation of Bifenthrin and Malathion Water Quality Criteria

1 Introduction

Robertson-Bryan, Inc (RBI) has reviewed and provided comments on draft water quality criteria derivation reports prepared by the University of California at Davis (UCD) while under contract to the Central Valley Regional Water Quality Control Board (Regional Water Board). Specifically, this Technical Memorandum (TM) provides comments based on our technical review of criteria derivation documents for the pyrethroid insecticide bifenthrin and the organophosphate insecticide malathion that were recently released for public review by the Regional Water Board through email notice, and the criteria development methodology employed to derive criteria for these compounds.

Under its contract, UCD has prepared methodology and draft aquatic life criteria for a list of pesticides that the Regional Water Board has identified as posing high risks for adversely impacting water quality. The proposed methodology allows for the derivation of acute and chronic aquatic life criteria for pesticides with limited toxicity datasets. Although these criteria do not represent water quality objectives or standards at present, they may be implemented as quantitative interpretations of Basin Plan narrative toxicity objectives, and thus are of particular relevance to local agencies who manage discharges to water bodies known to be, or potentially, impacted by pesticides. The Regional Water Board recently adopted and submitted to the State Water Board for its approval, Clean Water Act Section 303(d) listings for pyrethroid insecticide-related toxicity on Pleasant Grove Creek, South Branch Pleasant Grove Creek and Kaseberg Creek making the development of these draft insecticide criteria particularly relevant to the City's wastewater and storm water operations.

Incorporated throughout the UCD criteria derivation documents is reference to a recently developed criteria development methodology. Review of the criteria derivations requires review and comment on the methodology used to derive the criteria and, therefore, review of the methodology also was conducted and comments on the methodology relative to its application for deriving draft criteria are provided herein.

2 Draft Criteria and Background

Draft aquatic life criteria statements for bifenthrin and malathion are provided below. Specific comment on the criteria values and means of measuring compliance are provided in Section 3 and 4 of this TM.

“Aquatic life in the Sacramento River and San Joaquin River basins should not be affected unacceptably if the four-day average concentration of bifenthrin does not exceed **0.3 ng/L**¹ more than once every three years, on the average, and if the one-hour average concentration of bifenthrin does not exceed **4 ng/L** more than once every three years on the average.” (Palumbo *et. al.* 2009a)

and,

“Aquatic life in the Sacramento River and San Joaquin River basins should not be affected unacceptably if the four-day average concentration of malathion does not exceed **0.03 µg/L** more than once every three years, on the average, and if the one-hour average concentration of malathion does not exceed **0.15 µg/L** more than once every three years on the average.” (Faria *et. al.* 2009)

These criteria, and draft criteria for the insecticides chlorpyrifos and diazinon and the herbicide diuron, were developed following a methodology published in September 2009. In *Methodology for Derivation of Pesticide Water Quality Criteria for the Protection of Aquatic Life, Phase II: Methodology Development and Derivation of Chlorpyrifos Criteria* (TenBrook *et al.*, 2009), a new method of criteria derivation is formalized and a step-by step procedure for deriving criteria from small toxicity datasets is provided. A new criteria derivation methodology was necessary because these limited datasets are deficient in one manner or another for use with the existing EPA methodology (EPA, 1985). The draft criteria derivation reports, which are the principal subject of this review, follow this step-by-step procedure.

The UCD methodology has been revised based on comments received from both peer review and public comment. In general, the UCD methodology developed for the task of deriving aquatic life criteria for pesticides of concern is scientifically sound. The UCD methodology is rather unique in that it lays a foundation for a regional regulatory body to develop criteria from toxicity data sets found to be incomplete by the conventional EPA method (EPA, 1985), which is most commonly used for criteria derivation purposes. Although principally intended for use on limited toxicity datasets, draft criteria were developed for some pesticides meeting the acceptability criteria of the conventional EPA derivation methodology (e.g., chlorpyrifos and diazinon).

The specific manner in which this new methodology is applied in the derivation of specific aquatic life criteria is of key importance. The UCD methodology provides more than a means to derive numeric criteria; it also considers factors of bioavailability, mixture effects, and the effect of other tangential water quality parameters on pesticide toxicity (e.g., temperature and pH). Considering these other factors is complex, and caution is warranted in how assumptions are employed in developing final criteria statements and execution of those statements.

The remainder of this review summarizes specific findings in the development and execution of these draft aquatic life criteria. Only brief effort was made to review the toxicity value screening procedure because conducting a thorough review of this aspect of the methodology was beyond the scope of this

¹ This value is believed to be in error; see Section 3.7.

review effort. However, it should be noted that the screening of available toxicity values largely determines the criteria derivation outcome and, therefore, a thorough review of the toxicity value screening procedure by an outside party is recommended.

3 Assessment of Methodology and Draft Derivation of Bifenthrin and Malathion Criteria

3.1 Uncertain Need for New Criteria

The UCD method was developed specifically to address data shortages that precluded the use of the established U.S. EPA methodology (EPA, 1985). Since ample data is available and multiple criteria have already be developed for diazinon and chlorpyrifos using several different methods, it is unclear why it is necessary to derive additional criteria for these compounds by this new methodology, which uses smaller data sets. Any new published data since the last derivation using the conventional EPA methodology could have been used with that EPA methodology to update previously derived criteria. and, by itself, does not necessitate wholly new criteria using a new derivation methodology.

3.2 Use of Safety Factors and Small or Limited Toxicity Datasets

Use of safety factors in derivation of aquatic life criteria is standard practice. However, in the development of draft criteria utilizing the UCD methodology, several safety factor iterations are employed in order to compensate for inherent informational deficiencies in limited datasets. In the case of the draft diuron criteria derivation report (Fojut *et al.*, 2009), an acute criterion was derived by taking the single most sensitive acute result of 12 mg/L and dividing it by an assessment factor of 36 (due to only 2 taxa being available—as per Table 3.13 in the methods), dividing by a further factor of 2 to convert from an LC50/EC50 to an assumed NOEC, then dividing by 2 again to both account for uncertainty in the assessment factor approach, which was not developed for herbicides, and to protect the most sensitive species. Ultimately, the compounded safety and assessment factor of 144 was used to correct for a data set that had been limited to a great degree by the screening procedures outlined in the UCD methodology. This is compounded on the fact that an assessment factor approach for diuron is inconsistent with the published methodology, which in section 3-3.3 states, “For herbicides (or if plants are most sensitive), however, another procedure should be used as described in section 3-4.3” (TenBrook *et al.*, 2009). Section 3-4.3 refers to derivation of chronic criteria and does not address acute derivation.

While it is true that derivation of criteria using sparse datasets does more to meet the water quality protection goal than no criteria at all, when criteria are based on the single most sensitive data-point in a data set and then divided by a safety factor of 144, the resulting criteria has very little scientific defensibility. Such criteria represent more of a conservative “guess” at the NOEC than a data-derived calculation or estimate of the NOEC. The draft diuron criteria, as it is presented in its attending report, should not be considered for application until data are sufficient to derive criteria with fewer compounded safety factors.

The case of diuron illustrates the inherent short-comings of the UCD methodology when applied to datasets that inherently prove themselves too limited, too small, or too encumbered. Certainly under the data screening procedures of the methodology itself, this is the case.

In the case of malathion, data were found insufficient to develop an acute criterion based on a species sensitivity distribution. As a result, the lowest acute toxicity value was divided by an assessment factor of 5.1 per Table 3.13 of the UCD methodology, and then further divided by a safety factor of 2 for a total compounded factor of 10.2. The case of malathion represents a much more scientifically defensible derivation, with reasonable safety factors that are scientifically derived from data on similar compounds.

3.3 Implementation of Acute to Chronic Ratios

In cases when data from fewer than five taxa are present, the methodology requires that acute-to-chronic ratios (ACRs) be used. The specific method of implementation of this procedure varies between the 5 pesticides for which the authors have derived criteria. In the case of chlorpyrifos and diazinon, an increasing trend of ACR with species mean acute value (SMAV) was detected, so ACRs were calculated using only those ACRs for SMAVs within a factor of 10 of the acute criterion. Because diuron is a herbicide, the ACR approach was not employed—instead, the lowest NOEC available was used. For malathion, invertebrate data were unavailable, so a default ACR of 12.4 was included in the data set of ACRs for the final calculation of a geometric mean ACR. In the case of bifenthrin, initial chronic data requirements were not met, so a default ACR of 12.4 was selected.

Acute-to-chronic ratios for a given pesticide can vary considerably among species. In general, ACRs have been found to vary from 1 to 20,000 (Chapman *et al.*, 1998). In the methodology, the authors acknowledge that "...there is no evidence that default ACR values are appropriate for pesticides in general." They go on to conclude that, nevertheless, some means of calculation of an ACR is necessary, and so accept a default value of 12.4 based on the 80th percentile of ACRs for 8 pesticides, including 5 organochlorine pesticides and 3 organophosphate pesticides (TenBrook *et al.*, 2009).

The authors of the draft bifenthrin criteria note that ACRs for pyrethroids have been found to vary between 2 and 425 for a variety of species (Palumbo *et al.*, 2009a). 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.

In the case of malathion, the most sensitive SMAV for fish was 349 µg/L, which is over 1200 times higher than the 5th percentile value (0.29 µg/L). Due to a lack of data, the default ACR of 12.4 was applied for invertebrates and included in the calculation of the geometric mean. Other organophosphate insecticides have invertebrate-specific ACRs of 1.0 (chlorpyrifos, TenBrook *et al.*, 2009) and 2.3 (diazinon, Palumbo *et al.*, 2009b). Acute-to-chronic ratios derived for organophosphate pesticides, and included in the authors' derivation of the default value, are 2.2 (chlorpyrifos), 3.0 (diazinon), and 10 (parathion) (TenBrook *et al.*, 2009). By applying a default ACR derived partially from a different class of chemicals, and by including species whose acute endpoints far exceed the derived acute endpoint, the resulting chronic criterion has a weak scientific basis.

3.4 Assumed Dose-Effect Additivity

Environmental toxicologists recognize the importance of considering toxicant mixtures when evaluating and predicting toxicity to an organism. It is a held theory that toxicants of similar mode of action can act additively on an organism. Through such simplifying models of concentration addition, the effect of dose additivity can be predicted. In the bifenthrin and malathion criteria reports, in fact all the draft criteria derivation reports, where toxic modes of action are considered the same, the reports state in similar fashion:

“Since compounds in this class have a similar mode of action, either the toxic unit or the relative potency factor approach can be used to determine compliance in cases where pyrethroid mixtures are present in environmental samples” (Palumbo *et al.*, 2009a)

Admittedly, this principal of toxicology holds well, but one must question how *similar* a toxic mode of action must be, how many mixture components there are, and at what concentration ratios for the assumption of additivity to hold true under all likely environmental scenarios. Caution is advised in applying concentration addition models in cases of compliance determination. For example, Trimble *et al.* (2009) investigated additivity in binary mixtures of Type I and Type II pyrethroids. Although concentration addition models predicted experimental results well, as would be hypothesized, in some cases so did independent action models. Furthermore, actual toxicity often deviated substantially from predicted toxicity at low toxicant concentration, well below expected LC₅₀ values. There is enough inherent uncertainty in the use and applicability of concentration addition models, be they toxic unit or relative potency factor approaches, that pause should be taken before assessing compliance based on assumed additivity.

3.5 Bioavailability

The UCD criteria derivation methodology should be lauded for including considerations of bioavailability. In Section 11 of the draft bifenthrin criteria report the propensity of pyrethroid insecticides to sorb to particulate matter, sediments, and laboratory equipment is discussed. In this discussion several studies are mentioned providing evidence that pyrethroid toxicity in the water column is associated with the dissolved fraction, and that the freely dissolved fraction is the better predictor of toxicity. Despite this admission, the draft criteria report recommends that compliance with the bifenthrin criteria be determined based on the total recoverable, whole-water fraction. This recommendation is made rather arbitrarily in an effort to balance error associated in toxicity measurements reporting nominal spiked concentration with that of the error in predicting toxicity with the use of whole-water measurements. By assuming these relative errors to be equal, and thus cancelling, the authors attempt to strike a balance between the over prediction of toxicity when utilizing a total recoverable analytical measurement with the under prediction of toxicity when utilizing a nominal spike concentration in determining LC₅₀'s. There is no justification for this balance, the result of which knowingly biases a compliance measurement in favor of overprotection. Furthermore, the lowest acute toxicity value for *Hyaella azteca* is based on directly measured bifenthrin concentration, not nominal concentration. The *Hyaella azteca* toxicity value already greatly influences the species sensitivity distribution that is used in setting the acute, and by extension,

chronic criterion. Since conservative overprotection is inherently built into the criteria derivation methodology through the use of safety factors and default ACRs, this additional level of protection is unnecessary and only compounds bias upon bias. The direction of science and the direction in Section 3-5.1 of the method development criteria itself should be followed, and compliance measurements for bifenthrin should be based on the dissolved fraction, despite any associated analytical challenges.

3.6 Analytical Concerns

For compliance testing purposes through National Pollutant Discharge Elimination System (NPDES) permits, EPA approved methodologies must be used. Existing analytical methods for the measurement of semi-volatile organic pollutants such as pyrethroid insecticides are limited in the capability of achieving the draft criteria values derived for bifenthrin. Only the most diligent commercial laboratories can achieve reporting limits near the acute bifenthrin criterion using these analytical methods and employing good laboratory practices and standard quality assurance. There is limited commercial analytical capacity in California, and at present most laboratories could only assure reporting limits several times greater than the draft acute bifenthrin criteria. This limits the utility of criteria altogether, and potentially returns the regulated community to a position of providing the Regional Water Board with analytical results containing varied reporting limits. Using such a criterion should consider setting maximum matrix-specific reporting limits so as to avoid the potential of reporting false positives and errant detections.

3.7 Calculation Error

In the bifenthrin draft criteria derivation report (Fojut et al., 2009), the calculation of the final chronic criterion is inconsistent with other criteria derivations and the methodology. According to the methodology Section 3-4.2.4, the criterion is to be taken as a product of the selected percentile value (generally, the 5th percentile value) divided by the calculated ACR (TenBrook *et al.*, 2009). The final acute percentile value was calculated in Section 9 to be 0.007460 µg/L, but in Section 10, the acute criterion of 3.730 ng/L is divided by the ACR to arrive at a chronic criterion of 0.3 ng/L. This is in error as it inappropriately includes the safety factor of 2 that is used to derive the acute criterion. The chronic criterion should in fact be 0.6 ng/L. Derivation of the chronic criterion should be revised accordingly.

4 Summary of Review Findings and Comments

Review findings and comments are summarized as follow.

1. 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.
2. The UCD methodology has been used to derive criteria for pesticides (e.g., chlorpyrifos and diazinon) for which the U.S. EPA methodology is appropriate and has been applied. The UCD

method was developed specifically to address data shortages that precluded the use of the established U.S. EPA methodology. Derivation of new criteria using this new derivation approach is both unnecessary and is not defensible.

3. The UCD methodology has been applied to the derivation of diuron criteria in a manner that is of weak scientific validity. Due to uncertainties with regard to assessment factors for herbicides and inherent informational deficiencies in the diuron data set, a compounded safety and assessment factor of 144 is used to derive the acute criterion. The draft diuron criteria, as it is presented in its attending report, should not be considered for regulatory application until data are sufficient to derive criteria with fewer compounded safety factors and uncertainties.
4. 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. Similarly for malathion, by applying a default ACR derived partially from a different class of chemicals, and by including species whose acute endpoints far exceed the derived acute endpoint, the resulting chronic criterion has a weak scientific basis.
5. 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.
6. 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.
7. Achieving commercially available 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.
8. 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.

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