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Date: 3/6/10

Review of the Draft Report: Bifenthrin Criteria Derivation
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Overview
The freshwater criteria for bifenthrin (2-methyl[1,1'-biphenyl]-3-yl)methyl (1R,3R)-rel-3-[(1Z)-2-chloro-3,3,3-trifluoro-1-propenyl]-2,2-dimethylcyclopropanecarboxylate) defined in this draft report was derived using methodology recently developed by Tenbrook *et al*. (2009)[1]. The methodology considers relevance of the endpoints and quality of the data in derivation of the criteria. This methodology was motivated by the California Regional Water Quality Control Board's desire to employ rigorous methods to develop criteria for protection of the Sacramento and San Joaquin River Watershed.

Basic information and physical-chemical data
The report provides a comprehensive summary of the physical-chemical data for bifentrhin. This data set indicates that this pesticide has low solubility, low volatility, high potential to bioaccumulate, high potential to sorb to sediments, and is persistent in aqueous environments (i.e., low rates of hydrolysis, photolysis, and biodegradation). Accordingly, this pesticide's physical-chemical characteristics make its exposure to aquatic organisms a relevant concern, due to its persistence and high potential for bioaccumulation and food-web transfer.

Human and Wildlife Dietary Values
The FDA has not set action levels for bifenthrin in fish tissue but has set a level for meat (e.g., cattle, hogs) at 0.5 mg/kg. Toxicity to mallard ducks is relatively low, with an LC_{50} (which should be reported as an LD_{50}) value for food of 1,280 mg/kg and an NOEC of 2,150 mg/kg body weight being reported.

Ecotoxicity data and data reduction
The authors evaluated approximately 40 published studies of bifenthrin toxicity to develop the proposed criteria. Relevance was determined using the aforementioned methods[1] and only data for studies that were deemed acceptable were used in the criteria derivation. Adequate and reliable data was available for determining acute toxicity using animal studies and exclusion criteria appear to have been applied properly. Nine acute, four microcosm and ecosystem studies were used as supporting data and 3 studies of effects on wildlife were reviewed for relevance to bioaccumulation. Studies selected for derivation of the chronic criterion were not mentioned and need to be defined in this section.

Acute criterion calculation

[1] P. Tenbrook *et al*. (2009). *Methodology for derivation of pesticide water quality criteria for the protection of aquatic life in the Sacramento and San Joaquin River basins. Phase II: Methodology development and derivation of chloropyriphos criteria.* Report prepared for the Central Valley Regional Water Quality Control Board, Rancho Cordova, CA.

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

Chronic criterion calculation

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

Bioavailabilty

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

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

Mixtures

Because bifenthrin often occurs in the presence of other pyrethroid insecticides that have a similar mode of action, the toxic unit or relative potency factor approaches are appropriate to use. However, compounds that have dissimilar modes of action may exhibit additive, synergistic, or antagonistic effects in the presence of bifenthrin. The conclusion that non-additive effects cannot be used for criteria compliance is appropriate due to the lack of a robust predictive model.

Temperature, pH effects

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

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

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

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

Threatened and endangered species
Data on bifenthrin toxicity is only available for one threatened or endangered species (steelhead trout). Because this species has an LC_{50} of 0.15 µg/L, the authors conclude that the proposed criteria will protect this species. It is not clear if this concentration of bifenthrin reported for this study was corrected for chemical purity (i.e., 88.4%). Also, it would be more appropriate to compare the proposed criteria to an NOEC for this species rather than the LC_{50} value. Both of these questions should be addressed in the final report.

Data for other threatened or endangered species, including plants, were not in the data set and appropriate surrogates were not available. Accordingly, specific conclusions could not be offered for these species. Overall, the proposed criteria would appear to be protective of threatened and endangered species.

Bioaccumulation
Bifenthrin has a relatively high K_{ow} and therefore a high potential to bioaccumulate in aquatic organisms. Reported bioconcentration factors are consistent with this K_{ow} and a bioaccumulation factor (BAF) approach was used to estimate the water concentration of bifenthrin that would result in a lethal concentration in wildlife that would consume contaminated fish. Using this approach, a water concentration of 267 ng/l would be required to produce a body burden of bifenthrin in fish that would be toxic to mallard ducks. Using tolerance levels for bifenthrin in meat (i.e., 0.5 mg/kg) that would be protective of human health, an equivalent concentration in fish would require a water concentration of 23 ng/L. Although both of these levels are below the

proposed criteria, it should be mentioned that the water concentrations of bifenthrin that would be required to cause concern for food-web transfer would likely result in acute toxicity to fish and aquatic invertebrates.

Harmonization with Air and Sediment Criteria
Sediment and air quality standards for bifentrhin do not exist. Partitioning into the water column could serve as a proxy for sediment burdens.

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

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

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

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