Comments from Evan Gallagher, Ph.D., University of Washington

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Esfenvalerate water and sediment quality criteria draft: Peer review: 3-20-14

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

Specific Comments:

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

Data availability and prioritization. There were available bioconcentration data for only two species (bluegill sunfish and common carp), both of which are warm water fish. This is somewhat problematic for applications for state of California. Unfortunately there did not appear to be bioconcentration data available for cold-water fish species such as salmonids, and none for insects or crustaceans, problematic as these are common organisms in the Sacramento and San Joaquin surface waters. Dietary data for esfenvalerate was also limited, and based upon the authors literature review there was only wildlife dietary exposure data for Mallard ducks. The FDA currently has no action levels for esfenvalerate, but does appear to have a food tolerance level set at 15mg/kg.

For criteria derivation, numerous studies were analyzed and rated based on a numeric grading system summarized in TenBrook et al. (2009) and Fojut et al. (2014). The resulting numerical scores were then assigned relevance and reliability scores. Data from studies scoring relevant and reliable (RR) scores were used for criteria calculations. Data from studies rated as *less relevant* and *less reliable* (RL, LL, or LR) were used only to compare the derived criteria against data for a sensitive or endangered species, where data was often lacking. For the acute water quality criteria (WQC), data from 8 acute toxicity studies were deemed RR. For the chronic WQC, data from only 3 chronic toxicity studies was deemed RR and used for criteria calculation. For ecosystem studies, 12 mesocosm and microcosm studies were identified. Out of those 12, 4 were scored as RR and used for criteria evaluation. Few studies have investigated the effects of

esfenvalerate as a mixture and there was little data on the modulating effects of pH and water temperature on esfenvalerate toxicity, despite increasing evidence that temperature plays a large role in the toxicity of pyrethroids. This reviewer, although not an expert in derivation of work quality criteria, found no obvious shortcomings with the author's methods for data prioritization and literature data searching.

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

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

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

It is often assumed that mixtures of pyrethroids have an additive toxicity in aquatic organisms, although there's little information on sublethal effects of these mixtures. By contrast, there are literature studies reporting that certain mixtures of pyrethroids may have antagonistic interactions. The authors partially attribute these aforementioned discrepancies to the type of pyrethroids used in the studies. For example, type-2

pyrethroids, such as cyfluthrin, can outcompete type-1 pyrethroids for binding sites resulting in competitive agonism. Piperonyl butoxide (PBO) is commonly added to pyrethroid mixtures and increases the toxicity of these agents as noted in a study on *Hyalella azteca* dosed with PBO and cyfluthrin. To date, there have been little, or no studies quantifying the combined toxicity of PBO and esfenvalerate on aquatic organisms. Furthermore, there is little information on the toxicity of mixtures of esfenvalerate with other pyrethroids on aquatic organisms. These are important data gaps in the ecological risk of these agents. Mixture studies of esfenvalerate and organophosphate pesticides are also sparse, and suggest a more than additive toxicity on a few aquatic organisms such as fathead minnows and midge larvae. Synergy between pyrethroids and azole fungicides has been reported in aquatic organisms. However, the authors indicate that while there is evidence of mixture effects between pyrethroids and other common pesticides, the current studies are not consistent, and thus it was not appropriate to generate a multispecies interaction coefficient for incorporation into the criteria compliance calculations. The aforementioned is a reasonable decision by the authors based upon limitations of the state of the science.

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

Comparison of ecotoxicity data and derived criteria. Based on the studies (rated RR, LR or LL) analyzed in this report, the authors compared their derived WQC and BSQC against the most sensitive species investigated for esfenvalerate toxicity. The lowest acute LC_{50} for an aquatic exposure was 49 ng/L for *Ceriodaphnia dubia;* this value is more than 2-fold higher than the authors derived acute WQC of 20 ng/L. One study did note adverse effects on egg hatching following 48hr exposures to 20 ng/L. However, this study was considered chronic for the *Baetis* spp. The authors conclude that based on current data the acute WQC would be protective of the most sensitive species reported in the literature. The lowest chronic toxicity value reported was 17 ng/L for bluegill sunfish, which was based on incidence of tremors not a LC_{50}. The authors derived chronic WQC of 3 ng/L would be protective of this species. One species the authors mention that is highly sensitive to pyrethroids is *H. azteca*. There is no data on waterborne esfenvalerate toxicity for this species however, and it is uncertain if the author's acute and chronic WQC would be protective of this sensitive species.

The sediment exposure studies indicate the most sensitive species was *H. azteca*, which had a 10-day LC_{50} of 0.29 ug/g OC. The proposed acute BSQC is 12 ng/g OC and is a factor of 24 below the *H. azteca* LC_{50}. The only available chronic sediment esfenvalerate exposure data was for a saltwater aquatic organism, which had a

reported MATC of 1.5 ug/g. The proposed chronic BSQC of 2.1 ng/g would be more than protective of that organism. The author's proposed acute and chronic BSQC would be protective of sensitive species based on the current literature. However, there was a significant lack of data available for esfenvalerate sediment exposures for relevant aquatic species and the author's proposed BSQCs could need revising in the future.

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

The derived criteria were compared to the toxicity values for threatened and endangered species. Toxicity data from two threatened species were available for comparison using the USEPA interspecies correlation estimation website. Two studies yielded a SMAV for *O. mykiss* of 0.26 ug/L and a 96-hr LC_{50} for *O. tshawytscha* of 16.7 ug/L. Using those values the authors were able to calculate a estimated acute toxicity value for the most sensitive salmon, coho salmon, of 0.266 ug/L. Based on this data, the authors proposed acute and chronic WQC would be protective of these species. There was no listed data for threatened species in the BSQC data set. However, the authors calculated interstitial water concentration of esfenvalerate based on the acute and chronic BSQC values to be 0.075 ng/L and 0.013 ng/L. These values are far lower than the rainbow trout toxicity value of 260 ng/L, and should be protective for salmonids.

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

Conclusions. This report is thorough in its scope and the authors have identified the major concerns associated with derivation of the criteria as best as the current data allows. The authors conducted a thorough review of the literature. These limitations were predominantly associated with a lack of species diversity in the data sets, lack of data on water temperature and pH modulation of esfenvalerate toxicity in relevant aquatic species, lack of data on the toxicity of esfenvalerate in mixtures and the use of default values for the derivation of the criteria. The authors' appropriately suggest that a recalculation of the criteria would be in order as new and highly rated data become available. The authors also state that due to the lack of extensive data on esfenvalerate toxicity in aquatic organisms, it would not be appropriate to compare their methods to those of the EPA. Although this reviewer is not an expert in the derivation of water quality guidelines for acute toxicity of pesticides to aquatic life, it appears reasonable to conclude that the derived criteria in this report are likely to be protective of aquatic organisms in the Sacramento and San Joaquin Rivers, and most likely other freshwater systems.

Other minor comments:

List of abbreviations: please add SSTT (spiked-sediment toxicity testing) to the list of abbreviations
Section 7.2, first paragraph, first sentence: *Bifenthrin* is written instead of esfenvalerate
Section 7.2, third paragraph, first sentence: Table 3 should be table 8.
Section 9.3, last paragraph, first sentence: *Permethrin* is written where esfenvalerate should be written.