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July 5, 2017

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SUBJECT: U.S. ENVIRONMENTAL PROTECTION AGENCY ECOLOGICAL RISK ASSESSMENT AND REGISTRATION REVIEW OF PYRETHROIDS AND PYRETHRINS (BIFENTHRIN, CYFLUTHRINS (& BETA), CYPERMETHRIN (ALPHA & ZETA), CYPHENOTHRIN, D-PHENOTHRIN, DELTAMETHRIN, ESFENVALERATE, ETOFENPROX, FENOPROPATHRIN, FLUMETHRIN, GAMMA-CYHALOTHRIN, IMIPROTHRIN, LAMBDA-CYHALOTHRIN, MOMFLUOROTHRIN, PERMETHRIN, PRALLETHRIN, PYRETHRINS, TAU-FLUVALINATE, TEFLUTHRIN, TETRAMETHRIN) (DOCKET IDENTIFICATION NUMBERS: EPA-HQ-OPP-2010-0384, EPA-HQ-OPP-2010-0684, EPA-HQ-OPP-2012-0167, EPA-HQ-OPP-2009-0842, EPA-HQ-OPP-2011-0539, EPA-HO-OPP-2009-0637, EPA-HO-OPP-2009-0301, EPA-HO-OPP-2007-0804, EPA-HO-OPP-2010-0422, EPA-HQ-OPP-2016-0031, EPA-HQ-OPP-2010-0479, EPA-HQ-OPP-2011-0692, EPA-HQ-OPP-2010-0480, EPA-HQ-OPP-2015-0752, EPA-HQ-OPP-2011-0039, EPA-HQ-OPP-2011-1009, EPA-HQ-2011-0885, EPA-HQ-OPP-2010-0915, EPA-HQ-OPP-2012-0501, EPA-HQ-OPP-2011-0907)

The purpose of this letter is to provide U.S. Environmental Protection Agency (U.S. EPA) feedback on its ecological risk assessment (ERA) for pyrethroids and pyrethrins and the methodologies used in its exposure assessment for urban, agricultural, and wastewater scenarios. When possible, we have provided links to referenced documents and web pages. The California Department of Pesticide Regulation (CDPR) generally agrees with the scientific approaches that were used by the ERA for assessing risks. We agree with the conclusion of the rationale document (EPA-HQ-OPP-2010-0384-0048) that the toxicity of pyrethroids to aquatic organisms drives the risk conclusion.

EPA-HQ-OPP-2010-0384-0045 provides a robust analysis of the environmental fate and ecological risk of the eight Pyrethroid Working Group (PWG) pyrethroids and pyrethrins. An estimated environmental concentration (EEC) is calculated for each use category that results in release of pyrethroids to the environment and subsequently compared to available environmental monitoring data. Many of the detailed comments provided herein address discrepancies between EECs and monitoring data (i.e., model inputs, individual chemical properties). Generally, we support the approach of evaluating synthetic pyrethroids and pyrethrins as a chemical class.

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However, there was not sufficient data provided in the ERA to compare the 10 non-PWG pyrethroids to the pyrethroids investigated in more depth. In the absence of a robust modeling effort, a summary of key model input parameters for the 10 non-PWG pyrethroids (cyphenothrin, d-phenothrin, etofenprox, flumethrin, imiprothrin, momfluorothrin, prallethrin, tau-fluvalinate, tefluthrin, and tetramethrin) should be included in the final ERA to inform risk management decisions.

The following comments are offered in response to the ERA for wastewater, urban, and agriculture. Specific comments may be helpful as U.S. EPA considers risk mitigation options to assure that the modeling adequately characterizes sources and model input values are accurate. In each section of the draft ERA, EECs are compared to available monitoring data. U.S. EPA considers model results within one order of magnitude of monitoring results adequate. However, we suggest an over-estimation is preferred to under-estimation. Figure 1 provides a visual comparison of over- and under-estimation between the modeled EECs and monitoring data presented throughout the draft ERA. Urban sediment concentrations are consistently under-estimated (with the exception of fenpropathrin) suggesting overarching model limitations.

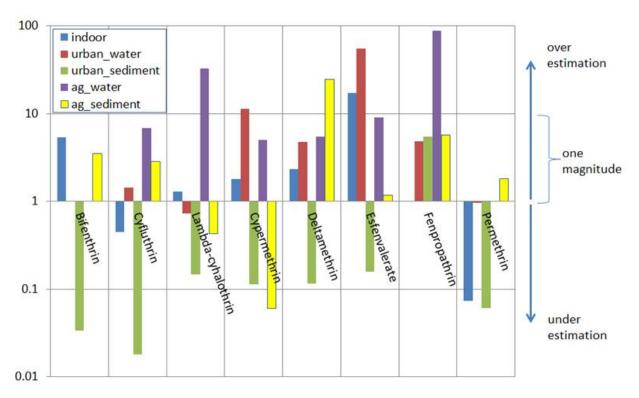


Figure 1 - Comparison between EEC and available monitoring data presented in the ERA for the eight PWG pyrethroids. EECs exceeding water solubility limits are not presented. Data from EPA-HQ-OPP-2010-0384-0045: Part I (POTWs), Table 13, Part II (non-agricultural), Tables 56 and 58, and Part III (agricultural), Tables 63 and 65.

EPA-HQ-OPP-2010-0384-0045 Part I. Assessing Pyrethroid Releases to POTW

In general, we agree with U.S. EPA's risk determinations for down-the-drain uses of pyrethroids and pyrethrins for freshwater and estuarine/marine fish and invertebrates. However, we have several recommendations for model input parameters and interpretations. In order to effectively construct a mitigation strategy, we recommend addressing the issues outlined below.

- 1. EPA has classified spot-on pet products as "lower potential for release" and they are not currently considered as a source in model calculations. Section 5.1, suggests that owners would not be likely to wash animals shortly after application as rationale for exclusion as a source. However, pesticides from spot-on treatments can be washed off long after application. A CDPR study measured the washoff of fipronil spot-on products during routine bathing and found fipronil in all samples (3.6–230.6 mg per dog) with an average of 21, 16, and 4% washed off at 2, 7, and 28 days post-application, respectively (Teerlink et al., 2017b). The study confirms the suspected pathway. A subsequent study found pyrethroids in addition to imidacloprid and fipronil in the waste stream from a pet grooming operation (Teerlink et al., 2017a). We strongly recommend U.S. EPA include spot-on products in down-the-drain modeling to determine the relative contribution based on Biological and Economic Analysis Division (BEAD) usage data. Further, we recommend mitigation efforts targeted at spot-on products.
- 2. Down-the-drain transport of residues from activities such as cleaning and laundry have been well established for other classes of indoor use chemicals (Schreder and La Guardia, 2014). We agree with the exclusion of crack and crevice products and containerized baits and gels. However, we recommend the inclusion of foggers and aerosols. Indirect transport of spot-on products is also highly likely (Dyk et al., 2012), adding further justification for inclusion of spot-on products.
- 3. The household wastewater volume used in the E-FAST model is 388 liters per person per day based on the 50th percentile of a 1996 U.S. EPA Clean Water Needs Survey. In arid regions of the United States, municipalities promote permanent water saving programs to decrease per capita usage. The California State Water Resources Control Board reports water usage of 230 liters per person per day, including outdoor uses. Updated national data are available through the 2012 U.S. EPA Clean Water Needs Survey. We recommend using an updated value that is more representative of current domestic water usage. Further we recommend providing a range to better represent arid regions.

- 4. Section 7.2.5 provides a comparison between modeled and monitored concentrations using the Markle et al., 2014 database. As noted in the discussion, Markle et al. utilized grab samples rather than flow or time weighted composites. Concentrations of organic pollutants entering wastewater treatment facilities are highly variable, and can vary several orders of magnitude in a 24-hour period (Teerlink et al., 2012). We acknowledge that there are limited data available. However, agreement between results should be treated with caution.
- 5. EECs for permethrin values were considerably lower than monitoring values. In section 7.2.5, the use of FDA regulated lice control products are cited as a probable cause. However, permethrin is common in spot-on products and should be considered.
- 6. Conceptually, the E-FAST down-the-drain module considers the entire annual production volume evenly distributed through the population and parceled out on a mass release per capita per day. Given the seasonality of pest pressures, this approach is likely to underestimate modeled environmental concentrations.
- 7. The assessment identifies wastewater treatment removal as an area of uncertainty. EFED suggests bench scale studies may be required during new chemical registration process or during future Registration Review. We strongly encourage thoughtful development of requirements that include: 1) environmentally relevant pesticide concentrations (ng/L-µg/L), 2) treatment processes conducted in sequence, and 3) the use of a representative wastewater matrix. The studies referenced in 5.4.2 were treated as separate modules and are not the best representation of wastewater treatment processes that are designed to operate in sequence. Experiments with relatively high pesticide concentrations are not expected to be representative of removal efficiency of pyrethroids in the ng/L range in a rich wastewater matrix.
- 8. Fenpropathrin is registered for nursery and ornamental uses. Occurrences in monitoring results suggest inclusion of nursery uses may be appropriate. Although no reference is provided, the assessment states nurseries are not typically plumbed to the sewer line. However, commercial/hardware stores with plant selection during the summer months may release irrigation runoff water to the sewer.

EPA-HQ-OPP-2010-0384-0045 Part II. Assessing Non-Agricultural Outdoor Urban Uses of Pyrethroids

CDPR agrees with the risk hypothesis for non-agricultural uses of pyrethroids stated in Section 3.5.1: "Pyrethroids and pyrethrins, when used outdoors in accordance with registered labels in urban environments, will likely lead to off-site movement of the compound via urban runoff, spray drift, and eroded soil, leading to exposure of non-target aquatic animals and plants. Based on information on the environmental fate, mode of action, direct toxicity and potential indirect effects, EFED assumes that registered uses of pyrethroids and pyrethrins have the potential to cause reduced survival, growth, and reproduction to non-target aquatic animals, but not to non-target aquatic plants."

The approach to support this hypothesis seems reasonable; model parameters used with various models: Pesticide Water Calculator (PWC), Pesticide Root Zone Model (PRZM), and Variable Volume Water Model (VVWM) appear to be appropriate. In addition, models were reran for deltamethrin and esfenvalerate using lower K_{oc} values as suggested by PWG (MRIDs 49410301 and 49544001; Part II, Section 7.2.4), giving about 10 fold lower pore water EECs but similar sediment EECs. Correspondingly, RQs were lower for water but approximately the same for sediment. RQs with the higher K_{oc} values were still of concern (>1.0), especially chronic RQs. Furthermore, CDPR staff conducted modeling simulations for deltamethrin and esfenvalerate using CDPR's runoff model developed by Dr. Yuzhou Luo that is adapted to California conditions (smaller lots, higher percentage of impervious surfaces, dry weather runoff; Part II, Section 7.2.6). Results showed higher EECs, which would result in higher RQs for these conditions as discussed in the draft document.

Generally, CDPR's model gave EEC results that seem reasonable for PWG pyrethroids, especially for 21 and 60-day averages (based on CDPR urban monitoring results from 2008–2016). But we do have a few disagreements or concerns with the modeling parameters and results:

1. The aquatic anaerobic metabolism half-life for cyhalothrins (6,084 days) was a magnitude or two higher than other pyrethroids. Given that other half-lives for cyhalothrins (i.e., aerobic soil metabolism and aerobic aquatic metabolism) are some of the lowest of all the pyrethroids, this particular data point seems high. In the descriptions of Table 33 that the 6,084-days value is derived from three data points (142, 6,320, 57.7 days), the noticeably large half-life value considerably increases the variance associated with the mean value used to calculate anaerobic aquatic metabolism half-life. The use of the median value or some other means estimator may be more appropriate. Comparing EECs to CDPR monitoring data, sediment EECs seem reasonable; water EECs are high but not unreasonable (Figure 2 of this document).

2. Part II, Section 5.6.5.2 states sediment monitoring data for all pyrethroids, except for fenpropathrin, were above modeled concentrations (Figure 1 of this document). More investigations were conducted with CDPR urban monitoring data from 2008–2016 with bifenthrin as an example. The results (Figure 3 of this document) showed that the maximum predicted commercial and residential impervious EEC (333 μg/kgoc dry wt; Part II, tables 37and 58) and the predicted EEC for California residential impervious (25 μg/kgoc dry wt) were below the 10th percentile from CDPR's monitoring results. The underestimation could be due to 1) the suburban residential settings not being representative of California conditions, 2) a single application used as an input in the model, and 3) a low K_d value (3,104 L/kg) used as an input in the model.

Bifenthrin is of particular concern in California because of its high detection frequency in water and sediment samples. Bifenthrin contributes the highest percentage of calculated potential toxicity in the majority of sediment samples (Ensminger et al., 2013). CDPR monitoring shows that bifenthrin stands out from other pyrethroids. This point can be highlighted by comparing bifenthrin to permethrin (Figure 4), the two highest-use pyrethroids in urban (structural) pest control in California (CDPR, 2017a). Permethrin generally has more use than bifenthrin; since CDPR monitoring began in 2008, permethrin has averaged 1.5 times the yearly reported use of bifenthrin. Yet bifenthrin is detected more frequently in water samples (76% compared to 31%), detected at higher concentrations (bifenthrin median concentration, 8.7 ng/L; permethrin, < method detection limit [1.05 ng/L]).

CDPR monitoring program finds bifenthrin concentrations correlate with laboratory *Hyalella azteca* toxicity (Figure 5). Figure 5A shows correlation ($r^2 = 0.66$) of bifenthrin concentration and toxicity. By including total pyrethroid concentration (Figure 5B), the correlation is about the same ($r^2 = 0.65$).

In sediments, although bifenthrin and permethrin are detected at similar frequencies (100 and 98%, respectively), bifenthrin accounts for more potential toxicity (5.6 and 0.1 TU, respectively) (Ensminger et al., 2013), based on commonly accepted LC₅₀ values (Amweg and Weston, 2007). There are numerous CWA 303(d) listings for sediment toxicity in California. Based on CDPR's monitoring results, it is possible that many of these listings could be associated with bifenthrin.

Recent modeling by CDPR (Luo, 2017) suggests that current mitigation measures (label changes resulting from: 1] the bifenthrin MOA between CDPR and registrants, 2] U.S. EPA's 2009 and 2013 labeling initiatives, and 3] California surface water regulations) may not reduce bifenthrin runoff from urban areas to concentrations below aquatic

toxicity thresholds. This was noted in recent monitoring data evaluations where detections of bifenthrin still remain numerous with concentrations above aquatic thresholds (Budd et al., 2017). Additional mitigation measures may be necessary to further reduce runoff of bifenthrin to surface water.

- 3. Fenpropathrin (water and sediment) and permethrin (water) EECs were highly overestimated for California. Fenpropathrin is rarely detected in California surface waters in water or sediment (detection frequency 0.7% and 2.7%, respectively (SWRCB, 2017)), and only has minor non-agricultural use in California (including nursery applications). Bifenthrin or permethrin is a more representative pyrethroid for modeling of multiple applications. However, modeled EECs for permethrin in water were highly overestimated compared to CDPR monitoring data. The maximum sediment EEC was also high but not unreasonable compared to CDPR data. In water, CDPR data (estimated freely bioavailable permethrin concentrations) were comparable to only the modeled EECs for turf and not for other scenarios (Figure 6, this document).
- 4. Tables 55, 56, and 57 (Part II, Section 5.6.4) show estimated freely dissolved concentrations of the high values of detected pyrethroids from Table 49 based on DOC/POC levels in Table 54. CDPR recommends that U.S. EPA not include, in its dataset, the single CDPR sample that exhibits the highest concentration of certain pyrethroids in urban runoff. Estimated values for bifenthrin, cyfluthrin, deltamethrin, lambda-cyhalothrin, and permethrin are based on a CDPR sample collected on 4/14/2009. This sample contained unusually high levels of suspended sediment (12,176 mg/L) and TOC (259 mg/L) that are an order of magnitude higher than those typically observed. With bifenthrin as an example, using the correct concentration of TOC and estimating reasonable concentrations of POC and DOC in Equation 2 (either using CDPR's estimate of 95% of TOC = DOC, or U.S. EPA estimates of 86%, 91%, or 79% TOC = DOC [Table 54]), estimates of freely dissolved concentrations of bifenthrin are between 5–7 ng/L instead of the listed concentrations of 1165, 315, and 84 ng/L, respectively in Tables 55, 56, and 57.
- 5. CDPR reviewers identified to notable typos in Part II of the ERA:
 - Section 7.2.6, in the first paragraph, CDPR's model is referred to as the Surface Water Protention (SWPP); this should be Surface Water Protection Program.
 - Section 8, in the second paragraph, after reiterating the hypothesis, the text states: "Based on an analysis, this assessment concludes that the **agricultural** use patterns of synthetic pyrethroids and pyrethrins result in multiple exceedances..." We believe that this should state **non-agricultural** use.

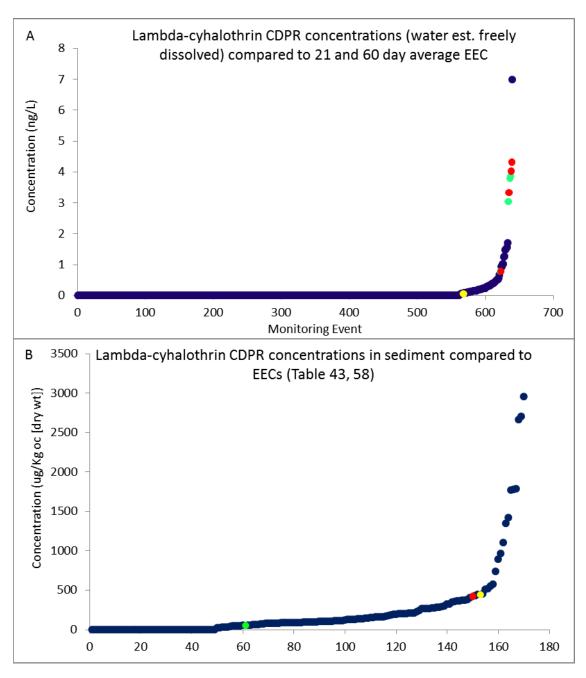


Figure 2 - Lambda-cyhalothrin EECs compared to CDPR monitoring data (CDPR, 2017b). A, estimated freely dissolved water EECs from Table 43 (red circles = 21 day averages; green circles = 60 day averages for California scenarios); yellow circle, CDPR 90th percentile. B, red circle, maximum residential sediment EEC (Table 43); green circle, U.S. EPA modeled California residential EEC (Part II, Table 43); yellow circle, CDPR 90th percentile. Lambda-cyhalothrin water concentrations are estimated freely bioavailable concentrations (CVRWQCB, 2017). U.S. EPA EECs are estimated by OC = 4% (Table 58).

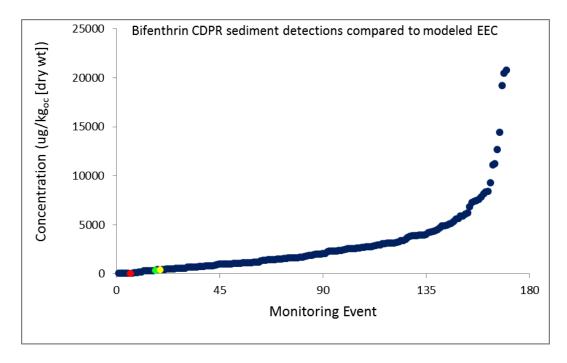


Figure 3 - Bifenthrin CDPR sediment detections (CDPR, 2017b) compared to U.S. EPA modeled maximum sediment commercial and residential EEC (μ g/kg_{oc}). Blue circles, CDPR detections 2008-2016; yellow circle, CDPR 10th percentile; green circle = U.S. EPA modeled maximum residential EEC (Part II, Tables 37 and 58); red circle = U.S. EPA modeled California residential EEC (Part II, Table 37; OC estimates based on TOC=4% [Table 58]).

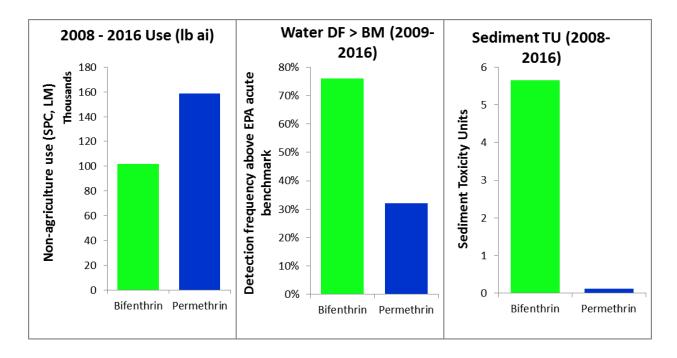


Figure 4 - Bifenthrin use and detections in California compared to permethrin. Monitoring data from CDPR monitoring studies 89, 260, 261, 463, and 465 (CDPR, 2017b).

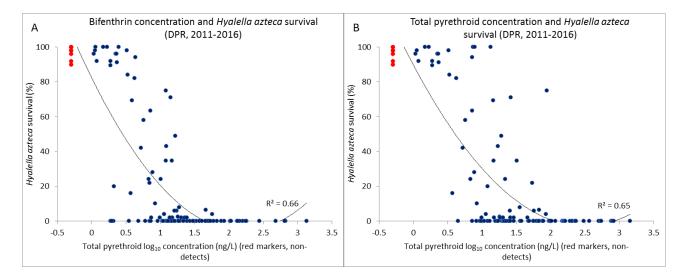


Figure 5 - Bifenthrin (A) and total pyrethroid concentration (B) versus survival of Hyalella~azteca (red markers are non-detects and were given a value of 0.5 ng/L; lowest reporting limit was 1 ng/L). Water samples collected by CDPR (n=116), chemical analysis by California Department of Food and Agriculture, laboratory toxicity tests conducted by University of California, Davis, Aquatic Toxicity Laboratory

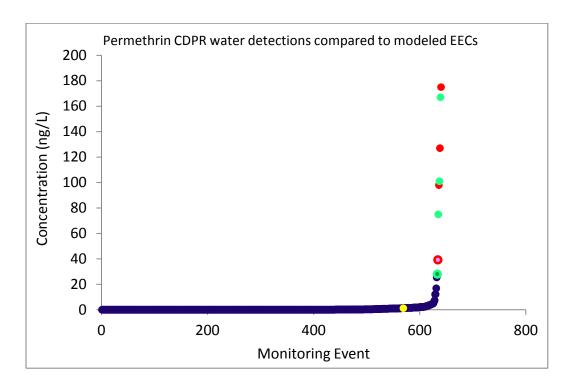


Figure 6 - Permethrin water detections compared to U.S. EPA modeled maximum water column EECs. Red circles = U.S. EPA modeled EEC (Part II, Table 39, California scenarios; 21 day EEC average; haloed circle is turf EEC); green circles = U.S. EPA modeled EEC (60 day average; haloed circle is turf EEC); yellow circle = CDPR 90th percentile (1.23 ng/L) from monitoring data 2009-2016 (CDPR, 2017b). Permethrin concentrations are estimated freely bioavailable concentrations (CVRWQCB, 2017).

EPA-HQ-OPP-2010-0384-0045 Part III. Assessing Agricultural Uses of Pyrethroids

- 1. U.S. EPA's assessment compiled toxicity profiles for eight PWG pyrethroids and pyrethrins from the most recent studies, identified acute and chronic toxicity values from the most sensitive species and applied those values as measures of effect for risk determinations. This assessment addressed the data gaps that existed in U.S. EPA's Registration Eligibility Decisions from 2008. As a result, this ERA provides risk assessments more protective to non-targeted aquatic organism, especially invertebrates.
- 2. The ERA identified and modeled EECs for three high-use rice pesticides (i.e., pyrethrins, lambda-cyhalothrin, and cypermethrin). As a general approach, the assessment only presents the scenario yielding the highest EECs related to a high use area in the EEC tables and the RQ tables. In this case, U.S. EPA selected the California rice scenario as representative for measures of exposure for the three chemicals. California pesticide use reporting for rice from 2011–2015 shows only one use record for pyrethrins (0.34 lb. in 2015), relatively low uses of cypermethrin (1,029 lbs. a.i. in average annual use, and 586 lbs. a.i. used in 2015), and higher uses of lambda-cyhalothrin (5,200 lbs. a.i. in average annual use). The California rice scenario appears to be appropriate for the risk assessment of lambda-cyhalothrin but may not be the best choice for pyrethrins and cypermethrin.
- 3. In Section 5.4. Monitoring Data, the ERA reviewed and summarized the monitoring data provided by PWG in 2014 (Giddings, 2014). The data sets included monitoring data for eight PWG pyrethroids in surface water and sediment nationwide as of July 31, 2013. An updated dataset including monitoring data available as of January 31, 2016, was submitted to CDPR on December 22, 2016 (Giddings, 2016). The PWG report indicated that the size of their database has more than doubled since the 2014 report. We compared the detection frequencies and maximum concentrations for the eight pyrethroids in whole water and sediment samples between PWG's 2014 and 2016 reports (Table 1). Detection frequencies for both whole water and sediment in the 2016 report more than doubled those in the 2014 report for 6 of 8 pyrethroids. The maximum monitored concentrations were higher for three pyrethroids in whole water and for four pyrethroids in sediment. Although the new data sets will likely not change the general conclusions of U.S. EPA's pyrethroid risk determinations, they provide stronger lines of evidence for environmental exposure of those chemicals. In several cases, the higher maximum concentrations better

support the modeled EECs for agricultural settings. We suggest updating Section 5 with the new PWG data sets.

- 4. The updated 2016 database reports a maximum observed sediment concentration for L-cyhalothrin that is 6 times lower than that in the 2014 report and subsequently used in the U.S. EPA ERA (Table 1). U.S. EPA should verify the discrepancy of the two data points and include the appropriate value in the final ERA.
- 5. In Section 7.2.3. Comparison of Risk Quotients based on Monitored Concentrations (Page 72). This section needs to be revised accordingly as the updated monitoring data are incorporated into Section 5.4.
- 6. Page 138, typo last line, "whith" should be "with".

Pyrethroid	Whole water		Whole water		Sediment		Sediment Max.	
	DF (%)		Max. Conc.(ng/L)		DF (%)		Conc. (µg/g OC)	
	2014	2016	2014	2016	2014	2016	2014	2016
Bifenthrin	7	23	2300	2300	23	41	8.8	23.1
Cyfluthrin	2	7	158	3400	4	9	0.63	1.55
L-cyhalothrin	2	17	140	1235	10	21	35	4.46
Cypermethrin	1	6	519	519	4	8	75	75
Deltamethrin	1	1	37	37	2	3	0.13	0.13
Esfenvalerate	1	7	166	3480	10	21	7	8.07
Fenpropathrin	10	6	64	64	9	9	11	11
Permethrin	2	8	17458	17458	23	34	47	196.9

Table 1- Comparisons of detection frequency and maximum monitored concentration in whole water and sediment samples between PWG reports in 2014 and 2016. Bolded italic values are updated in the 2016 dataset. The grey shaded values for lambda-cyhalothrin show a decrease from the 2014 dataset. DF= detection frequency.

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CDPR anticipates that these comments will strengthen the ERA and inform the eventual risk management decisions for pyrethrins and pyrethroids. At this time, CDPR is moving forward to address the efficacy of our 2012 pyrethroid surface water regulations. Ultimately, we hope that an improved ERA modeling approach will be used to evaluate insecticides with similar uses and to support future U.S. EPA risk management decisions.

We appreciate the opportunity to comment on this Registration Review. If you have any questions, please contact Jennifer Teerlink of my staff by phone at 916-445-3195 or e-mail at <Jennifer.Teerlink@cdpr.ca.gov>.

Sincerely,

Original Signed by

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