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Registration Decision RD2017-19

# Bifenthrin and Capture 240 EC

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## Registration Decision Statement[1] for Bifenthrin

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is cancelling the registration of Bifenthrin Technical Insecticide and Capture 240 EC, containing the technical grade active ingredient bifenthrin, as it meets the criteria for Track 1 substances under the Toxic Substances Management Policy (TSMP). In order to allow for the phase-out of Bifenthrin Technical Insecticide and Capture 240 EC for use on raspberries in British Columbia to control several insect pests, particularly those that are present at the time of harvest, and on potatoes to control wireworm, the PMRA requires that the following implementation timelines are followed.

Date of Last Sale by Registrant: December 31, 2018

Last Date of Sale by Retailers: December 31, 2019

Last Date of Permitted Use by Users: December 31, 2020

The Proposed Registration Decision PRD2017-11, *Bifenthrin and Capture 240 EC* contains a detailed evaluation of the information submitted and a proposal for cancelling the uses of bifenthrin on potato and raspberry, along with providing a three year phase-out for the critical need use on raspberry. Based on the information received during the public consultation, the PMRA agrees that the use of bifenthrin on potato to control wireworm also represents a critical need at this time. Therefore, the phase-out of bifenthrin on both raspberries in British Columbia and potato is subject to the three year phase-out period timeline, as provided above. The interim risk mitigation measures listed in PRD2017-11 will be integrated with additional protective instructions for use on potato to mitigate risks posed by use that may continue until 2020. See Appendix I for a summary of comments received during the consultation process as well as the PMRA's response to these comments.

## Other Information

The relevant test data on which the decision is based (as referenced in PRD2017-11) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[2] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Canada.ca website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

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1 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act.*

[2] As per subsection 35(1) of the *Pest Control Products Act*.

# Appendix I Comments and Responses

**Comment 1:**

Twenty-seven comments were received from individuals or organisations that outlined their support for the registration of Capture 240 EC, containing bifenthrin, to manage wireworm populations in potato. Several comments included rationales summarising why bifenthrin should be considered a critical need and outlined the following points:

- In locations with high populations, bifenthrin offers full season protection of long-season varieties (e.g., russet burbank), preventing damage of tubers up to harvest which is not achieved with registered alternatives.
- The importance of resistance management of wireworm using a rotation of bifenthrin, a group 3 insecticide, with phorate, a group 1B insecticide.
- Increasing wireworm pressure, especially in Prince Edward Island where the predominant species (*Agriotes sputator)* is difficult to manage.
- Significant economic loss in Prince Edward Island potatoes attributed to wireworms that include insecticide costs, crop insurance losses, processing losses, and the cost of cover crops used to suppress wireworm.

**PMRA Response:**

The PMRA acknowledges the submitted comments and agrees that use of bifenthrin on potato to control wireworms is a critical need.

**Comment 2:**

One comment was received that agreed with PMRA's decision to cancel the registration of bifenthrin on potatoes. It also expressed concern with the health and environmental risk indices of alternative products containing phorate and chlorpyrifos, and that cancellation of bifenthrin would result in greater use of these alternatives.

**PMRA Response:**

The PMRA assesses each pest control product individually for risks to human health and the environment. Before a product is approved for use in Canada, and during regular re-evaluation, it must undergo a thorough science-based risk assessment and have acceptable value.

**Comments on the Environmental Review Presented in PRD2017-11**

FMC submitted several documents during the public consultation on PRD2017-11. The FMC comments included the following documents:

- A review of PRD2017-11 from an environmental perspective completed by Intrinsic,
- Twenty journal publications relating to environmental issues that were cited in the Intrinsic review,
- Reference to reports previously submitted to the PMRA that address specific comments.

The following comments relate to environmental issues noted in the Intrinsic review document. The PMRA reviews of the 20 journal publications are included in the Appendix II of this document.

**Comment 3:**

The PMRA does not present any method for evaluating studies. The PMRA should use the Klimisch et al. (1997) criteria for evaluating study validity.

**PMRA Response:**

All studies reviewed by the PMRA are evaluated for data quality against generally recognized methods of the Organisation for Economic Co-operation and Development (OECD) or of other similar organisations. If no such methods exist, studies are reviewed in accordance with generally recognized methods within the scientific community and taking into account the intrinsic properties of the substance, the ecosystem under consideration and the conditions in the environment.

Although the PMRA does not strictly adhere to the Klimisch scoring method for reviewing studies, the elements of the Klimisch criteria are considered when assessing the acceptability of studies. All of the studies were fully reviewed in terms of their quality and acceptance for consideration in the risk assessment. While some studies were not conducted to guideline requirements, valuable information was still obtained. Any deficiencies, limitations, uncertainties identified were considered and taken into account when deriving the conclusion.

Additionally, the following guidance specific to assessing persistence and bioaccumulation under the Government of Canada’s Toxic Substances Management Policy - Persistence and Bioaccumulation Criteria (Environment Canada, 1995) was used:

***Protocols and test methods***

*At this stage, specific protocols and test methods are not prescribed by the ad hoc Science Group. As much as possible, internationally accepted methods (e.g., OECD protocols) should be used to generate the appropriate data. In the absence of such protocols, methods generally recognized and acceptable within the scientific community should be used.*

***Data Quality***

*Because of the inherent complexity of measurements and the numerous factors influencing persistence and bioaccumulation processes, there will often be a wide range of values for any one criterion for a given substance. For this reason, the ad hoc Science Group recommends the use of expert judgment to assess the quality of the data. In assessing quality, consideration should be given, among other things, to 1) the age of the data, objectives of the study, and discussion or acknowledgement of conflicting and supporting evidence; 2) the documentation of specific environmental and/or experimental conditions; 3) the method(s) used, its limitations, precision and accuracy.*

**Comment 4:**

The level of detail provided in the PRD2017-11 was insufficient to allow for the reproducibility of the Estimated Environmental Concentrations (EECs), effects endpoints and/or risk quotients (RQs).

**PMRA Response:**

The Overview of the PRD2017-11 'describes the key points of the evaluation'. Clarification on how specific EECs were calculated are provided in the relevant responses to comments that follow.

**Comment 5:**

The risk assessment should be reflective of the expected lawful application of the end-use product, including the inclusion of the vegetative strips, buffer zones, no contamination of adjacent water bodies, etc. The commenter suggested that the aquatic EECs and risk assessment should include the required buffer zones in the calculation. The commenter considered the PMRA refined assessment for drift is exceedingly conservative.

**PMRA Response:**

The risk assessment conducted by the PMRA is reflective of the use pattern that was proposed by the registrant at the time of the submission. For consistency, a standard regulatory approach is used for risk assessment and determining mitigation measures (for example, a whole system half-life is used in calculations as this represents degradation of a substance and not movement between environmental compartments). The requirement for specific mitigation measures, such as vegetative filter strips and buffer zones, is dependent on the hazards and risks identified during the risk assessment.

The risk assessment incorporates available mitigation measures to determine if the risk can be made acceptable under the proposed use pattern.

**Comment 6:**

Further refinements to exposure and effects assessments were not considered, including probabilistic methods. This prevents understanding the potential ranges of bifenthrin exposure and risk to aquatic and terrestrial biota.

**PMRA Response:**

The PMRA conducted a refined risk assessment for bifenthrin. The available data demonstrated that bifenthrin is persistent, bioaccumulative and toxic and, thus, met the Government of Canada's TSMP criteria for a Track 1 substance. A probabilistic risk assessment for bifenthrin would not have altered the classification of bifenthrin as a Track 1 substance. Therefore, a probabilistic risk assessment was not conducted nor required given that the registration decision is based on bifenthrin meeting the criteria for a Track 1 substance. Consequently, virtual elimination is the appropriate risk mitigation measure according to the Government of Canada policy.

**Specific comments related to fate and behaviour in the environment**

**Comment 7:**

Why did the PMRA report the solubility of bifenthrin as being < 1 µg/L instead of 14 ng a.i./L?

**PMRA Response:**

The PMRA evaluated all physiochemical studies submitted and re-confirmed that the appropriate solubility of bifenthrin is < 1 µg/L as reported in Section 1.2 (pg. 10) of PRD2017-11. The study submitted is a GLP laboratory study conducted following an internationally accepted guideline. The laboratory study in which the solubility of 14 ng/L is reported did not follow any international guideline to determine solubility, and, therefore, was not accepted by the PMRA to determine solubility. Moreover, surface water monitoring data show that under natural environmental conditions, bifenthrin concentrations in water can exceed the limit of solubility values established under laboratory conditions. For this reason, the PMRA chose to report the solubility value as < 1 µg/L.

**Comment 8:**

The reported $K_d$ values on pg. 24, 3rd paragraph should be corrected to “453-2685”.

**PMRA Response:**

The PMRA agrees that the $K_d$ values should be “453-2685”. The $K_{oc}$ values were incorrectly reported as the $K_d$ values in PRD2017-11.

**Comment 9:**

Clarification is required as to whether the foreign terrestrial field studies in PRD2017-11, Appendix I, Table 12 are representative of Canadian conditions, and were used to support the laboratory findings for $DT_{50}$s.

**PMRA Response:**

Terrestrial field dissipation studies are accepted if they are scientifically valid and are conducted in an ecoregion relevant to Canada. The submitted terrestrial field studies were assessed by the PMRA using the Europe-North America Soil Geographic Information for Pesticide Studies (ENASGIPS) to determine if these were conducted in Canadian relevant regions. According to the results of ENASGIPS, the PMRA concluded that these studies were conducted in ecoregions similar to those found in Canada and were used to assess persistence under field conditions and to support the laboratory findings.

**Comment 10:**

The Alabama pond study should not be used for risk assessment purposes. Additional environmental fate and ecotoxicity studies available in the public literature should be considered. In particular, the mean aerobic aquatic metabolism half-life of 189 days calculated based on half-lives ranging from 87.3 to 455 days in Meyer (2012) and reported in Melendez (2013).

**PMRA Response:**

The Alabama pond study (Primary Report, PMRA 1755966) was used to estimate bioaccumulation under field conditions and as supporting information to characterize the persistence and ecotoxicity of bifenthrin under field conditions. There are currently no standard international guidelines for conducting and assessing aquatic field studies. Consequently, the PMRA assessed the aquatic field studies based on existing guidelines for similar types of bioaccumulation (for example, OECD Guideline 305), field and mesocosm studies. Studies were evaluated in accordance with generally recognized methods within the scientific community with endpoints and conclusions reflecting the identified limitations of the study. All comments, documents and reports provided to the PMRA regarding the deficiencies and uncertainties of this study were considered in the review. For details, see Appendix II of this document. Despite the deficiencies and uncertainties that were identified, the PMRA considers the study design and results to be of sufficient quality to establish bioaccumulation under field conditions. The results from the Alabama pond study were not considered in isolation, but along with other lines of evidence (laboratory data) following a weight-of-evidence approach. Collectively, the information indicates that bifenthrin exceeds the TSMP criterion for biaoccumulation.

The ecotoxicity and persistence information obtained from the Alabama pond study was used in a qualitative manner and integrated with information from the laboratory and other field studies. The toxic effects observed in aquatic invertebrates in the pond study occurred at similar water concentrations to those observed under laboratory conditions as well as in other outdoor mesocosm studies. The toxicity results were not used directly in the risk assessment to quantify acute or chronic risk to aquatic organisms; however, the results were considered in a qualitative manner as a weight of evidence. The environmental concentration obtained from the pond study demonstrated that bifenthrin was much more persistent in a terrestrial-aquatic field study conducted in Alabama than was predicted by the laboratory biotransformation studies.

In the quantitative risk assessment, the PMRA used the whole system half-life value of 276 days determined from a registrant-generated GLP laboratory aerobic water-sediment study (reported in PRD2017-11, Appendix I, Table 12) to calculate estimated environmental concentrations (EECs) used in the risk assessment. The half-lives reported in Meyer (2012) of 87.3 to 455 days bracket the half-life of 276 days considered by the PMRA in the risk assessment. In addition, the mean aerobic aquatic metabolism half-life of 189 days from the Meyer (2012) study meets the TSMP persistence criterion of ≥182 days.

**Comment 11:**

The commenter requested clarification on how the half-life from the Alabama pond study was determined.

**PMRA Response:**

The results of the Alabama aquatic field and pond study were used in a qualitative manner as presented in Table 24 on page 99 of the PRD2017-11 to capture the long-term behaviour of bifenthrin in aquatic systems under realistic agricultural conditions. In the terrestrial environment, the $DT_{50}$ estimate in the top 0-15 cm of soil was 195 days. In the aquatic environment, bifenthrin remained very persistent at low concentrations with estimated $DT_{50}$

values of 609 days in the pond water. Although half-lives could not be estimated in the sediment, the mean concentration in sediment samples collected 737 days after the final application were approximately 21% of the highest mean observed. Bifenthrin residues in the runoff water and sediment were significantly higher than bifenthrin residues in pond water and sediment by at least one order of magnitude and very likely contributed to bifenthrin residues in Hagan's pond for months during the bifenthrin application periods and weeks after the last application.

Given the various potential routes of transformation/losses, a dissipation rate ($DT_{50}$) was estimated using the PestDF Tool developed by PMRA using R (R Core Team 2013) and the reported concentrations for the first sample after the final application of bifenthrin to the last sample date (471 days after the final application). Of the models considered, the single-first order SFO $DT_{50}$ of 609 days was the best fit. The $DT_{50}$s give a realistic picture of the potential aquatic exposure under field conditions resulting from all routes of exposure (for example, direct overspray, drift, run-off) and how a substance that is persistent in soil can contribute to the long term exposure in aquatic systems through run-off

**Comments related to bioaccumulation**

**Comment 12:**

The commenter disagrees with the PMRA's evaluation of study validity and reliability of the bioaccumulation studies.

**PMRA Response:**

The PMRA has considered all previous comments on this issue provided by the registrant and disagrees with the classification of these studies by the registrant. While respecting the limitations of the individual studies, the PMRA integrates information from all the acceptable studies in making a final determination of bioaccumulation. The results and the study limitations that were considered, along with other data (laboratory and field) that were used in assessing potential bioaccumulation are provided in Appendix II of this document.

**Comments related to the bioaccumulation assessment under field conditions**

**Comment 13:**

The commenter suggested that the Alabama field and pond study should not be considered in evaluating BAFs due to deficiencies in its study design and methodology. According to the commenter, the validity criteria of the OECD 305 (2012) guidance for determining bioaccumulation in fish were not met.

**PMRA Response:**

Under the TSMP, bioaccumulation is assessed through a sequential, tiered process by examining log $K_{ow}$, BCF and BAF. Field bioaccumulation factors (BAFs) usually provide a larger weight of evidence than laboratory studies as they take into account exposure from all sources (water, food), bioavailability and interactions under environmentally relevant conditions. The PMRA considered the Alabama pond to be an acceptable study for characterising the bioaccumulation potential of bifenthrin under field conditions. All comments, documents and reports provided to the PMRA regarding the deficiencies and uncertainties of this study were considered in the review. For details, see Appendix II of this document.

**Comment 14:**

The study by Alonso et al. (2012) should not be considered for TSMP evaluation of bifenthrin. According to the commenter, the study limitations preclude the data from determining the exposure pathway (diet vs. water) and the exposure is not reflective of the Canadian use pattern.

**PMRA Response:**

While the results reported by Alonso et al. (2012) were not used as part of a quantitative assessment against the TSMP criteria, the results did provide evidence of the potential for maternal transfer of bifenthrin as well as bioavailability of bifenthrin in the upper trophic levels of the food chain in a marine habitat at a significant distance from the source of release.

**Comment 15:**

The PMRA did not consider European field biomonitoring studies when evaluating the bioaccumulation criterion.

**PMRA Response:**

As stated in PRD2017-11, page 26 the PMRA evaluated the European field biomonitoring studies. The results of these European studies are considered to be of limited value in terms of assessing bioaccumulation in aquatic biota because in most cases, residues in water and sediment were undetectable, very close to or below the limit of quantitation (LOQ) and could not confirm exposure which precluded calculating a bioaccumulation ratio under field conditions.

The applied European application rate was only 9% of the Canadian label rate. The lack of detections in aquatic environment under the European conditions may be attributable to the low application rate that was used in comparison to the application rates for Canada and, therefore, cannot be interpreted as a lack of exposure under Canadian use conditions.

**Specific comments related to risks to terrestrial organisms**

**Comment 16:**

The commenter noted an error in risk quotients for the screening level assessment for bees. They also noted that PRD2017-11 does not mention a repellent effect on bees that was documented in the EFSA (2011) and the draft assessment report prepared by France (2006). The commenter suggested the bee risk assessment should be refined based on application timing for potatoes, label instructions for raspberry and off-field exposure.

**PMRA Response:**

The PMRA confirms that an error was made in the reporting of risk quotients for the screening level assessment for bees in PRD2017-11. The corrected EEC values for acute oral and contact exposure for bee are 3.25 µg a.i./bee and 0.269 µg a.i./bee, respectively. The corrected RQ values for acute oral and contact exposure for bee are 3.8 and 25, respectively. The level of concern for bees of 0.4, as per the risk assessment guidance for bees (EPA, PMRA and CDPR, 2014), is exceeded.

The EFSA (2011) and the draft assessment report prepared by France (2006) accepted and reported the results of several field and tunnel studies. Two studies reported no repelling effect of bifenthrin on bees; however, one study reported repellent effects of bifenthrin on bees within the first 30 minutes of application, while another study reported repellent effects observed within the first 5 hours post-treatment with bifenthrin (in one of two trials). The PMRA does not consider that these results provide strong enough evidence of a repelling effect of bifenthrin to bees due to lack of consistency among the studies.

Capture 240 EC is applied to potatoes in-furrow. Given that bifenthrin is not systemic, exposure to bees is not expected to occur. As risks to bees from application of bifenthrin on raspberries were identified, the PMRA implemented label statements which prohibit application during the crop blooming period which will reduce exposure to bees.

Further refinement of the bee risk assessment will not be revisited, given that the registration decision is based on bifenthrin meeting the criteria for a Track 1 substance. For the remaining period of use during the phase-out period, the implemented label statements are expected to limit the exposure of bees to bifenthrin.

**Comment 17:**

The commenter asked for clarification on the uses considered in the EEC calculation, how the EEC was calculated and how uncertainty factors were used for non-target arthropod risk assessment.

**PMRA Response:**

Given that bifenthrin use on potatoes is limited to in-furrow application, negligible exposure to non-target arthropod is anticipated. Hence, the non-target arthropod risk assessment was conducted on exposure from uses on raspberries.

The maximum cumulative application rate for bifenthrin was calculated using the application rate and the re-application intervals for use on raspberries. In the absence of foliar dissipation data, a default foliar dissipation half-life of 10 days was used to account for dissipation between applications. The resulting maximum cumulative application rate for bifenthrin for the use on raspberries is 126 g a.i./ha. The maximum spray drift deposition at one meter downwind from the point of application is assumed to be 59% of the application rate for late season airblast. The maximum percent deposition on non-target plants located one metre downwind from the point of application would therefore be 74.3 g a.i./ha for late season airblast application on raspberries. As such, non-target arthropods located on the field could be exposed to a level of 126 g a.i./ha and those located off field could be exposed to a level of 74.3 g a.i./ha.

The PMRA does not apply an uncertainty factor for endpoints of laboratory studies which are conducted on natural substrates for non-target arthropods.

**Comment 18:**

The commenter requested clarification and explanation on the applications of foliar interception factors and a vegetation distribution factor for non-target arthropod risk assessment.

**PMRA Response:**

For the in-field exposure assessment, crop-specific interception factors (F) proposed by Linders et al. (2000) are applied to estimate the ratio of pesticide residues reaching the foliage ($F_{int}$) and the soil ($F_{soil}$). The $F_{int}$ value of 0.8 for plants implies that 80% of the applied active ingredient is present on plant surfaces and 20% is present on the soil. The foliar deposition fractions are applicable to the standard test species (*T. pyri* and *A. rhopalosiphi*) and to foliar-dwelling arthropod species from the extended laboratory tests. Soil deposition fractions are applicable to ground-dwelling arthropods. These are based on the assumption that the foliar deposition fraction plus the soil deposition fraction is unity ($F_{int} + F_{soil} = 1$), and that these processes are instantaneous.

Refined in-field EEC for foliar-dwellers = cumulative application rate × $F_{int}$
Refined in-field EEC for ground-dwellers = cumulative application rate × $F_{soil}$

For the off-field exposure estimate, a vegetation distribution factor of 0.10 is applied since the drift values overestimate drift to the lower or interior portions of a three-dimensional habitat structure. Most of the drift would be intercepted by the top or side portions of the habitat structure. This default value was estimated to be appropriate based on data presented at the ESCORT workshop (Candolfi et al. 2001).

Refined off-field EEC = off-field EEC × vegetation distribution factor of 0.10

**Comment 19:**

The commenter noted that with the information provided within the PRD2017-11, it was not possible to reproduce the values presented for estimated daily exposures (EDEs) and RQs. The commenter noted that EDEs calculated by EPA T-REX are different from those reported in the PMRA public document for small mammals risk assessments.

**PMRA Response:**

The PMRA does not calculate EDEs using the USEPA tool T-REX. The PMRA estimated the concentration of pesticide residues on potential food items (vegetation, seeds, insects) using a nomogram developed by the USEPA from the data of Hoerger and Kenaga (1972) and Kenaga (1973), and modified according to Fletcher et al. (1994).

**Specific comments related to risks to aquatic organisms**

**Comment 20:**

Why does the PMRA consider direct overspray in their screening assessment if bifenthrin is not allowed to be applied directly to water? This is overly conservative, unrealistic and not representative of what is on the label.

**PMRA Response:**

The overspray scenario used by the PMRA is a screening assessment which considers the most conservative exposure situation. While this is highly conservative and may not represent realistic conditions, it is intended to be a quick screening tool designed to quickly identify those pesticide and uses where there are no risks of concern. Further refinements to the risk assessment (as were completed with bifenthrin) are considered only if the level of concern is exceeded at the screening level.

**Comment 21:**

The commenter requested that the PMRA include citations of ecotoxicity data considered in the effect assessment. In addition, there is no information on the data collection criteria, nor on the criteria for determining data quality of this data.

**PMRA Response:**

All registrant-provided studies were compared against the appropriate internationally-accepted guideline or protocol. The endpoints of accepted ecotoxicity studies are reported with reference in Appendix I, Table 15 and Table 20 of PRD2017-11.

The published ecotoxicity literature studies that were considered in the risk assessment [i.e., species sensitivity distribution (SSD) studies] were omitted from PRD2017-11 in error. A list of these studies is provided in the References section of this document.

**Comment 22:**

The commenter requested more detailed information related to aquatic SSD methodology and calculations. Specifically, although the software and $HC_5$ are reported, there is no discussion of the minimum data requirements (for example, number of unique species required), the datasets used for SSD generation including any averaging of within-species values, and goodness-of-fit statistics indicating whether the model fit was acceptable.

**PMRA Response:**

Details related to the calculation of the SSDs were omitted from PRD2017-11 and are provided in Appendix III of this document.

**Comment 23:**

The commenter noted a typographical error of acute $HC_5$ for freshwater fish on page 32 (0.008 µg a.i./L).

**PMRA Response:**

The PMRA agrees the correct value should be 0.078 µg a.i./L, and not the reported value of 0.008 µg a.i./L, which was a typographical error. The correct value of 0.078 µg a.i./L was used in the risk assessment.

**Comment 24:**

Why did the PMRA only calculate risk quotients based on water exposures of bifenthrin and did not derive EECs for bifenthrin in sediment or pore water given that bifenthrin is strongly bound by sediment? The commenter mentioned that previous PMRA assessments have compared both sediment and overlying water EECs to endpoints of *Chironomus riparius* sediment toxicity studies. In addition, the USEPA has recently released guidance for the ecological risk assessment of benthic invertebrates which recommends calculating RQs based on exposure and toxicity data for pore water, sediment and water column concentrations.

**PMRA Response:**

The PMRA agrees that additional analysis with respect to organisms that may be exposed to pore water would add further context to the risk posed to aquatic organisms; however, given that the registration decision is based on bifenthrin meeting the criteria for a Track 1 substance, the risk assessment for freshwater aquatic invertebrates will not be further refined at this time.

**Comment 25:**

The commenter noted the reference table was missing PMRA document numbers 1755962, 1755966, 1759123 and 1755945.

**PMRA Response:**

The references that were missing in PRD2017-11 are as follows:

| PMRA | Reference |
|---|---|
| 1755962 | 2005, Bifenthrin 80 g as/L SC: Assessment of the Ecological Effects on Aquatic Communities Using Outdoor Aquatic Mesocosms after Duplicate Treatment at 14 Days Interval, DACO: 9.9 |
| 1755966 | 1989, Bifenthrin Pond Study: Ecological Effects during Treatment and Post-Treatment Follow-Up Studies of Hagans Pond, Orrville, Alabama, DACO: 9.9 |
| 1759123 | 1992, The Acute Toxicity of Talstar 80 g/l Flowable Formulation to Rainbow Trout, DACO: 9.5.4 |
| 1755945 | 2002, Testing of Toxic Effects of Talstar 8 SC on the Single Cell Green Alga *Desmodesmus Subspicatus* (formerly *Scenedesmus Subspicatus*), DACO: 9.3.5,9.8.6 |

**Comment 26:**

The commenter considers the results of the Alabama study by Sherman (1989) not relevant to the assessment of bifenthrin risks to aquatic invertebrate communities for current labeled uses in Canada.

**PMRA Response:**

As identified in responses to Comment 10, the Alabama pond study (PMRA 1755966) was determined to be scientifically sound and used in the risk assesment; however, the PMRA recognizes the limitations of this study. As noted in PRD2017-11 page 33, the results of this study were not used in the quantitative risk assessment. The PMRA noted the results of this study support the findings of other studies because the concentrations in the pond resulted in effects to the aquatic invertebrate population consistent with the ecotoxicity information derived from laboratory and mesocosm studies.

As reported in PRD2017-11, neither the EECs nor the ecotoxicity endpoints used in the aquatic risk assessment were derived from the results of the Alabama pond study.

**Comment 27:**

The commenter provided a list of published literature for higher tier studies with bifenthrin on aquatic taxa. The commenter suggested the PMRA incorporate the results of these studies into the PMRA's assessment.

**PMRA Response:**

The PMRA has reviewed the list of published literature provided by the commenter; however, given that the registration decision is based on bifenthrin meeting the criteria for a Track 1 substance, the risk assessment for aquatic organisms will not be further refined at this time.

**Comment 28:**

The commenter questioned the use of PRZM/EXAMS to calculate EECs used in the runoff risk assessment scenario. The commenter suggested that the PMRA use Surface Water Concentration Calculator (SWCC) and Soil and Water Assessment Tool (SWAT) developed by the USEPA to calculate sediment, pore water and surface water EECs.

**PMRA Response:**

When the EECs for surface and pore water were originally calculated for bifenthrin, PMRA was conducting water modelling using PRZM/EXAMS as a standard model for all pesticide risk assessments. Since then, PMRA has adopted the Pesticides in Water Calculator (PWC) model to estimated EECs in water. The PWC model is harmonized with that used by the USEPA. Currently, the PMRA does not use the SWAT model. Given that the registration decision is based on bifenthrin meeting the criteria for a Track 1 substance, the EECs will not be refined at this time.

**Comment 29:**

The method employed by the PMRA to derive the new restrictions and buffer zones for field spray is not explained, and should be made explicit in the registration decision.

**PMRA Response:**

The proposed restrictions on field spray applications are warranted as the initial spray buffer zone determination exceeded the limit of the field sprayer model (>120 m) for protection of marine habitats. Without these restrictions on ground application, there is the potential that the risk posed by spray drift to marine habitats would not be mitigated with a maximum buffer zone of 120 m. Also, the buffer zones for freshwater habitats are large and therefore, potentially less practical from a user perspective. Overall, spray application restrictions are required to facilitate more practical spray buffer zones.

Additional drift mitigation measures required for field sprayer application of bifenthrin include: a minimum ASAE medium spray quality, an 8 km/h wind speed restriction and the requirement to use drift-reducing air induction nozzles. Calculated buffer zone distances were adjusted according to windspeed (0.2×) and low drift nozzle (0.75×) modifiers.

The adjusted windspeed factor of 0.2× (for 8 km/h) is based on field data obtained from Wolf and Caldwell (the same researchers that generated the data for the field sprayer model). The low-drift nozzle factor of 0.75× is the minimum spray drift reduction of 25% as obtained through information from nozzle manufactures.

Buffer zones that exceed the 120 m limit are adjusted manually based on restricted spray parameters (such as wind speed and nozzle type) that would effectively reduce spray drift. In this case, wind speed is restricted to no greater than 8 km/h and the nozzle type to low drift. Thus, the buffer zone of 368 m was modified manually as follows:

368 m × 0.20 (windspeed) × 0.75 (low drift) = 55.2 m rounded off to 55 m.

Buffer zones for all water depths for field sprayer applications were modified according to this calculation.

Note: the initial buffer zone determination did not utilize the correct aerobic whole system half-life of 276 days. Hence, the corrected spray buffer zones are as follows:

| Method of application | Crop | | Buffer Zones (metres) Required for the Protection of: | | | |
|---|---|---|---|---|---|---|
| | | | Freshwater Habitat of Depths: | | Estuarine/Marine Habitats of Depths: | |
| | | | Less than 1 m | Greater than 1 m | Less than 1 m | Greater than 1 m |
| Field sprayer | Raspberries | | 15 | 5 | 55 | 25 |
| Airblast | Raspberries | Late growth stage | 60 | 55 | 75 | 65 |

**Comment 30:**

Why did the PMRA not take the limit of solubility of bifenthrin into consideration when conducting the risk assessment for green algae, eastern oyster embryos and acute sheepshead minnow for which the endpoints are above the limit of solubility for bifenthrin?

**PMRA Response:**

The PMRA did consider the solubility limit of bifenthrin for the aquatic risk assessment; however, since water monitoring data included measured concentrations of bifenthrin that exceeding the reported solubility values under environmentally-relevant conditions, the EECs were not capped at the solubility limit.

**Comment 31:**

The PMRA's assessments and EEC calculations gave no consideration to the solubility, degradation or expected rapid partitioning of bifenthrin to sediment and particulate over time and are unrealistic.

**PMRA Response:**

The EECs were modelled using PRZM/EXAM which requires a variety of fate input parameters including half-lives, $K_{oc}$ and solubility that consider degradation/transformation and partitioning to sediment. However, since water monitoring data included measured concentrations of bifenthrin that exceeded the reported solubility values under environmentally-relevant conditions, the EECs were not capped at the solubility limit.

**Comment 32:**

The commenter thought that using a pond scenario to derive marine EECs was not realistic and overly conservative.

**PMRA Response:**

It is acknowledged that the marine scenario used by the PMRA is conservative and the PMRA is in the process of revising its approach to conducting marine/estuarine risk assessments; however, given that the registration decision is based on bifenthrin meeting the criteria for a Track 1 substance, no revisions to the marine assessment are warranted at this time.

**Comment 33:**

The commenter also reported calculation errors for the acute RQ for mysid and chronic mesocosm RQ for freshwater invertebrates.

**PMRA Response:**

The PMRA agrees that the acute RQ for mysid and chronic mesocosm RQ for freshwater invertebrates should be 13 568 and 3200, respectively.

**Comment 34:**

Considering the water solubility limit, the commenter questioned why the PMRA used a surface water EEC of 5.2 µg/L to assess risk to freshwater invertebrates when PRZM/EXAMS EECs for runoff were used to calculate RQs for all other aquatic taxa. The commenter speculates this value was a maximum concentration for bifenthrin in whole water samples from urban flowing water sites based on the information presented in the USEPA's recent preliminary risk assessment for pyrethroids and pyrethrins. The commenter considers this value inappropriate given that urban uses of bifenthrin are not registered in Canada. Moreover, the PMRA should take into account bifenthrin bioavailability in surface water in calculating EECs.

**PMRA Response:**

The EEC of 5.2 µg/L is reported in the California Department of Pesticide Regulation water monitoring data (2013). As the use pattern in the US is different than the use pattern in Canada, the EEC should be 4.1 µg a.i./L. Given that the registration decision is based on bifenthrin meeting the criteria for a Track 1 substance, the EECs will not be refined at this time.

**Vegetative Filter Strips for Reducing Runoff to Aquatic Habitats**

**Comment 35:**

The PMRA did not present any data, analyses or scientific justifications to demonstrate that a 10-m vegetative filter strip (VFS) is necessary to be protective of aquatic habitats with label uses of Capture 240 EC in Canada.

**PMRA Response:**

As reported in Section 4.2.4 (pg. 37) of PRD2017-11, the PMRA is proposing a mandatory 10-metre vegetative filter strip for all pyrethroid insecticides based on their common chemical and toxicological properties. This is consistent with the use of vegetative filter strips for pyrethroid pesticides by other jurisdictions (in particular, USEPA and Province of Prince Edward Island).

As of October 2017, the PMRA is proposing vegetative buffer strips for chemicals that demonstrate characteristics of being practically insoluble in water, having a high soil adsorption coefficient, being expected to partition to sediment, and showing a potential risk to aquatic organisms from exposure to runoff from treated fields.

**Toxic Substances Management Policy Considerations**

**Comment 36:**

The commenter disagrees with the PMRA's conclusion that bifenthrin is bioaccumulative. The commenter considers the key studies on which the PMRA relied to be not reliable and should therefore be excluded from the TSMP assessment while other studies were reliable and showed BCF values of bifenthrin below the criterion of 5000 for a variety of taxa. In addition, an aquatic food web model predicts BAFs less than 5000 and BMFs below 1.

**PMRA Response:**

The PMRA disagrees with the commenter's conclusion that three bioaccumulation studies should be classified as not reliable and excluded from the TSMP assessment. As per the PMRA Response to Comment 12, the PMRA reviewed the studies and found them acceptable for inclusion in the bioaccumulation assessment. Any deficiencies and limitations were identified and considered when interpreting study results and conclusions. A summary of the PMRA's assessment of the submitted bioconcentration and bioaccumulation studies is provided in Appendix II in this document.

The PMRA identified a number of deficiencies in all of the submitted laboratory BCF studies (Appendix II of this document); however, deficiencies identified in one study were often addressed through information provided in another study. As an example, OECD Guideline 305 (2012) requires testing of a substance at two or more concentrations; however, the Suprenant (1986) study only tested one concentration of bifenthrin. The OECD Guideline 305 indicates that one test concentration is sufficient if it can be shown that BCF is independent of concentration. This was confirmed in the Gries and Schanné (2006) study which showed that the BCF of bifenthrin is independent of exposure concentrations. Therefore, having only one exposure concentration in the Suprenant (1986) study does not affect the validity and acceptability of this study.

In addition, if limitations to a study were identified, these were considered when reporting the PMRA conclusion of a study. As an example, in McAllister (1988), the authors reported BCF values for embryo, larval and $F_0$ adult generation. After a review of the information, the PMRA concluded that the estimated BCF values for embryo and larval were unreliable due to low sample numbers and high variability in tissue concentrations; however, the PMRA also concluded that the BCF values for the $F_0$ adult generation were considered reliable and relevant to exposure in the environment. Therefore, the PMRA only reported one of the three endpoints.

One study showed that bifenthrin does not biomagnify in fish when only considering the dietary route of exposure under laboratory conditions (BMFs <1.0).

The BAF results of the aquatic food web model depend on the laboratory BCF studies chosen as input parameters. As discussed previously, the PMRA disagrees with the exclusion of key studies from the bioaccumulation assessment.

Under the TSMP, field BAFs are prefered over laboratory BCFs as they take into account exposure from all sources (water, food), bioavailability and interactions under environmentally-relevant conditions. Sufficient information was provided to show that bifenthrin BAFs > 5000 were sustained in the Alabama pond study.

Although the European field studies demonstrated that mitigation measures may reduce exposure in aquatic systems, the bioaccumulation potential of bifenthrin could not be assessed as exposure concentrations were too low in the water to calculate a BAF.

# Appendix II Summaries of the PMRA's Assessment Bioconcentration and Bioaccumulation Studies

| Species and Reference | Summary of PMRA assessment |
|---|---|
| Bluegill sunfish (*Lepomis macrochirus*)<br><br>Gries and Schanné 2006<br>(PMRA 1755215) | Based on Mean Measured Concentrations:<br>$BCF_{SS}$: 1584-1649 (not reliable)<br>$BCF_{SS}$: 5% lipid normalized: 2507 - 2820 (not reliable)<br>$BCF_{K}$: 2117-2147<br>$BCF_{K,G}$: 2251-2325<br>$BCF_{K,G,L}$: 3400-3511<br>$t_{1/2}$: 22.6 – 29.7 days<br><br><u>Comments:</u><br>· **Study Acceptability:** A number of deficiencies were identified in the study. Although there is some uncertainty with the estimated BCF values, the PMRA considers the study results to be acceptable as a BCF study. The results and the study limitations will be considered along with other data (laboratory and field) in assessing potential bioaccumulation.<br>· **Guideline Followed:** OECD Guideline 305: Bioconcentration: Flow-through fish test (1996). The PMRA also considered the new 2012 OECD Guideline 305 in assessing the validity of this study.<br>· EAD calculated $BCF_{k}$, $BCF_{k,G}$ and $BCF_{k,G,L}$ using equations from OECD Guideline 305 (2012), calculating $k_2$ from the depuration data and sequentially determining $k_1$ using non-linear regression using R (R Core Team (2012) according to OECD Guideline 305 (2012).<br>· Exposure was via static renewal. A flow-through system is the preferred design according to the OECD 305 guidelines (1996 and 2012).<br>· The radioactivity was not identified, however, the results of the Suprenant (1986) study indicate that the majority of the residues in fish tissue are likely bifenthrin.<br>· According to OECD Guideline 305, a steady-state is reached when three successive analyses of concentrations in fish made on samples taken at intervals of at least two days are within 20% of each other. The PMRA reviewer disagrees with the study author's claim that steady state was reached because bifenthrin concentration in whole fish was more than 20% higher on day 60 than on day 48 for both treatment groups. Steady state was not achieved for either of the two treatment levels. Under these conditions, the BCFss represents an underestimate of bioconcentration potential in fish. Further evidence of the fish not reaching steady state comes from OECD guidance. OECD Guideline 305 (2012) states that $BCF_{SS}$ is doubtful if the $BCF_{K}$ is significantly larger than the $BCF_{SS}$ as this can be an indication that steady-state has not been reached (which appears to be the case for this study). The $BCF_{SS}$ represents a potential underestimate of bioconcentration. The kinetic $BCF_{K}$ is considered more reliable.<br>· One of the five validity criteria of OECD Guideline 305 (2012) was not met in this study. The concentration of bifenthrin in the chambers was not maintained within ±20% of the mean of the measured values during the uptake phase. There was significant variability in the measured exposure concentrations during the uptake phase (57 to 159% across all exposure treatments); the cause of this variability was likely the result of the semi-static renewal conditions employed. Based on the high variability observed, reliance on geometric mean measured water concentrations for the calculation of BCF values may represent either a potential overestimate or underestimate of the true BCF values. Therefore, this is considered a restriction.<br>· OECD Guideline 305 (2012) recommends selecting the highest concentration of the test substance to be about 1% of its acute asymptotic $LC_{50}$ and to be at least 10-fold higher than its detection limit in water. The 96-h $LC_{50}$ of bluegill sunfish is 0.26 µg a.i./L, 1% of this $LC_{50}$ is 0.0026 µg a.i./L. The nominal test concentrations for this study (0.007 and 0.085 µg a.i./L) were considerably higher than the OECD |

| Species and Reference | Summary of PMRA assessment |
|---|---|
| | recommendation. Considering that fish remained healthy and there were no overt signs of toxicity in the fish in this study, the concentrations chosen for this study should not affect the acceptance of this study.<br>· The authors state that preliminary testing showed that bifenthrin adsorbed to test vessel walls of a flow-through system, consequently resulting in low exposure concentration and non-homogeneous distribution of bifenthrin in the test solution. This appears to be the rationale for using a static renewal system for the uptake phase of the bioconcentration study. To reduce loss of bifenthrin from exposure solutions, test vessels were pre-rinsed with bifenthrin solution that was at a concentration 10 times the target exposure concentration; this was done in an attempt to saturate the active sites of test vessel walls. This method is very labour intensive and assumes that binding is instantaneous and irreversible which may not be the case (i.e., irreversible adsorption of bifenthrin to active sites within a test vessel may take time). The reviewer agrees that initial low exposure concentration of bifenthrin may occur within a flow-through system until saturation of active binding sites is achieved; after a sufficient period of equilibrium, a more consistent homogenous concentration in water would be expected. During the renewal of test medium, fish were transferred to new test vessels every second day and the test vessels were thoroughly cleaned with water, liquid soap, tap water and ethanol. No effects were observed on control fish subjected to this renewal process. The effect of this unusual renewal and fish transfer procedure on fish stress and potential impact on bioconcentration results is unclear but is assumed to be negligible.<br>· The study author reported that sampled fish were washed with water and dried with paper towel. Washing is not required by the OECD Guideline 305 (2012), rinsing is recommended. |
| Bluegill sunfish (*Lepomis macrochirus*)<br><br>Suprenant 1986 (PMRA 1755218) | Based on measured time-weighted average bifenthrin concentrations in water:<br>$BCF_{SS}$: 6090 (not reliable)<br>$BCF_{K}$: 12850<br><br>Based on nominal bifenthrin in water:<br>$BCF_{SS}$: 2107 (not reliable)<br>$BCF_{K}$: 5250<br><br>$t_{1/2}$: 57 days<br><br><u>Comments:</u><br>· **Study Acceptability:** A number of deficiencies were identified in the study. Although there is some uncertainty with the estimated BCF values, the PMRA considers the study results to be acceptable in terms of assessing the TSMP criteria for bioaccumulation (i.e., BCF > 5000).<br>· This study was conducted prior to the development of OECD guidance for bioaccumulation. Therefore, the EAD evaluated this study considering the OECD Guideline 305 (1996 and 2012) to facilitate the evaluation. The study design was found to follow the majority of the guideline recommendations.<br>· EAD calculated $BCF_{k}$, $BCF_{k,G}$ and $BCF_{k,G,L}$ using OECD Guideline 305 (2012) equations, calculating $k_2$ from the depuration data and sequentially determining $k_1$ using non-linear regression using R (R Core Team (2012) according to OECD Guideline 305 (2012).<br>· The exposure was via a flow-through system which is preferred design according to both guidelines as the exposure concentration can be better maintained.<br>· Residue analysis was performed. The results showed that the majority of the residues in fish tissue were bifenthrin.<br>· Steady state was not reached because bifenthrin concentrations in whole fish continued to increase. No measurement of lipid content or fish growth for correcting $BCF_{k}$ was |

| Species and Reference | Summary of PMRA assessment |
|---|---|
| | available. The $BCF_{ss}$ represents a potential underestimate of bioconcentration. The kinetic $BCF_K$ is considered more reliable. This is further supported by the guidance in OECD Guideline 305 which states that "The resulting $BCF_{SS}$ is doubtful if the $BCF_K$ is significantly larger than the $BCF_{SS}$, as this can be an indication that steady-state has not been reached or growth dilution and loss processes have not been taken into account." A comparison of the assumed BCFss (6090) to the PMRA calculated $BCF_K$ (12,850), clearly demonstrates that steady state was not reached.<br>· Only a single concentration was used in the exposure phase of the experiment. The current OECD Guideline 305 (2012) indicates that one test concentration is sufficient if it can be shown that BCF is independent of concentration. The Gries and Schanné (2006) study showed that the BCF is independent of exposure concentrations. Therefore, having only one exposure concentration does not affect the validity and acceptability of this study.<br>· No lipid analysis or growth measurement was conducted in this study. Although this prevents correction for these factors, it should be assumed that the lack of growth correction would underestimate the BCFk unless there was no growth during the course of the study. Considering the concern raised in Putt and Suprenant (2009) about the food used that may result in increased lipid and growth and the fact that the study was 84 days in length, growth would likely have been substantial and the uncorrected BCFk is likely underestimated.<br>· The exposure concentrations in test vessels were not kept consistent according to the measured concentrations of bifenthrin in water. The lowest measured concentration (0.0006 µg/L) was only 43% of the highest measured concentration (0.0014 µg a.i./L). The PMRA used nominal bifenthrin concentrations in water to determine the BCFk for whole fish as well as BCFk based on time-weighted average of the measured concentrations in water to bracket the potential BCFk. The BCF based on nominal water concentrations is 5250; this is considered an underestimate of the true BCF.<br>· Fish were not washed prior to analysis, however, washing is not required by the OECD Guideline 305 (2012), rinsing is recommended.<br>· Only one aquarium was used and only two fish for each whole body analysis. The study author did not provide the raw data of the measurement; therefore, the variability among tissues samples was unknown. OECD Guideline 305 (2012) recognizes that pooled analysis may be required if single fish analysis is not feasible. This is considered a minor deficiency.<br>· Based on initial mean wet weight of 2.9 and 110 fish in a 75L volume, the loading rate is much higher than 1.06 g/L that is reported (4.25 g/L –reviewer calculated). Fish exhibited normal behavior, fed readily and were in excellent physical condition during both the exposure and depuration periods (no mortality was reported). The higher loading rate is considered a minor deficiency.<br>· The temperature range used during the study ranged from 16 to 18°C, which is lower than the temperature range in Gries and Schanné 2006 (20 – 24°C). Accumulation of pyrethroids in aquatic organisms could be higher at lower temperatures.<br>· OECD Guideline 305 recommends the use of silanized glass for test substances with high adsorption coefficient such as the synthetic pyrethroids. The guideline also states "It is preferable to expose test systems to concentrations of the test substance to be used in the study for as long as is required to demonstrate the maintenance of stable exposure concentrations prior to the introduction of test organisms." The approach used in Suprenant 1986 is more or less consistent with that of OECD Guideline 305. Suprenant used a pre-equilibrium period to establish full saturation of potential binding sites in a flow through design (18-day pre-equilibrium period); this method is likely a much better method to reduce the effect of bifenthrin loss from exposure solution as well as to maintain potentially stable concentrations during the exposure phase. The reviewer notes that the water concentrations measured during the uptake phase of the Suprenant 1986 study (flow through design, 18-day pre-equilibration) were low relative to the targeted test concentration (23 – 46% of nominal); however, the variability |

| Species and Reference | Summary of PMRA assessment |
|---|---|
| | measured in the Gries and Schanné 2006 study (static renewal) was far greater (47 – 159% across treatments).<br><br>The PMRA response to comments from Suprenant and Putt (2009):<br>1. *The adsorption of bifenthrin to sampling equipment used to siphon water from the exposure tanks was likely a result of measured concentrations in water being artificially lowered.*<br><br>To alleviate the concerns on this matter, the PMRA calculated the BCFk by using time weighted average (TWA) from measured concentrations in the vessels as well as the nominal concentration specified in the study report. In this way, the potential BCFk were bracketed from a potential underestimation (nominal concentrations) to a potential overestimation (TWA).<br><br>2. *Uneaten food was not removed immediately following feeding which could have resulted in increased exposure of bifenthrin to the fish if eaten.*<br><br>Fish are generally voracious feeders in these studies. If uneaten food was not removed immediately it would provide a substrate for bifenthrin to sorb to, decreasing dissolved concentrations of bifenthrin in water, which is theoretically the most bioavailable form to fish via water. The consumption of the excess food could result in increased exposure, but the amounts absorbed by the food would be miniscule in comparison to the concentrations in the water. The PMRA does not consider this to be a concern for acceptance of this study.<br><br>3. *Concentrations of bifenthrin were not measured in gut contents contributing to the overall burden in fish and artificially increasing the BCF. If measured, the BCF could have been corrected by discounting the residues in the gut.*<br><br>The study report clearly states that fish were sampled just prior to the next feeding occasion. This methodology is recommended in OECD Guideline 305 (2012) to reduce potential concentrations of test item in gut contents. There is no requirement in the guideline for analyzing gut contents separately. In addition, gut contents are more of a concern in feeding studies where spiked food could remain in the gut and be analyzed with the fish. The PMRA does not see this as a concern for acceptance of this study.<br><br>4. *Different food was fed to fish in this study compared to other studies with lower BCFs and this may have resulted in increased lipid production and accumulation of larger amounts of bifenthrin. No lipid analysis was done during this study which prevents lipid correction for this problem.*<br><br>The PMRA confirms that different food sources could be cause for concern; however, the registrant supplied no evidence that the contracting company changed food to reduce lipid and growth. Suprenant and Putt (2009) provided a statement that they changed food sources, but did not provide any additionaldocumentation. The PMRA sees the increased growth from the food used in this study as a much larger concern. Growth has the effect of diluting concentrations of accumulated test item, resulting in lower BCFs. This is why OECD Guideline 305 (2012) recommends correcting for growth when calculating BCFk. The potentially larger lipid pool resulting from the food used in this study will likely result in a much smaller effect on increasing the concentrations of bifenthrin accumulated than the effect of growth would have on reducing the BCFk. In the absence of lipid analysis, it is common practice to assume the lipid |

| Species and Reference | Summary of PMRA assessment |
|---|---|
| | content is 5%. Taking these factors into consideration the PMRA considers the lack of lipid analysis to be a minor deficiency.<br><br>5. *Adsorption of bifenthrin to sampling equipment used to siphon water from the exposure tanks likely resulted in measured concentrations in water being artificially lowered. Using these artificially lower bifenthrin concentrations in water would result in overestimation of the BCF.*<br><br>The PMRA noted that OECD Guideline 305 cautions that “Experience has shown that for test substances with high adsorption coefficient, such as the synthetic pyrethroids, silanized glass may be required.” The guideline also states “It is preferable to expose test systems to concentrations of the test substance to be used in the study for as long as is required to demonstrate the maintenance of stable exposure concentrations prior to the introduction of test organisms.” The approach used in Suprenant 1986 is more or less consistent with that of OECD Guideline 305. The 18-day equilibration period (prior to fish introduction) included delivery of bifenthrin into test system; this would have potentially offset any loss from the water prior to and during the experimental uptake phase as the number of adsorption sites in the tank would have been decreased. The reviewer notes that the water concentrations measured during the uptake phase of the Suprenant 1986 study were low relative to the targeted test concentration (23 – 46% of nominal).; however variability was low in comparison to other studies (e.g., Gries and Schanné, 2006-static renewal) as the variability measured was far greater (47 – 159% across treatments). |
| Carp<br>(*Cyprinus carpio*)<br>Saito 1993<br>(PMRA 1755224) | Based on measured time-weighted average bifenthrin concentrations in water:<br>$BCF_{SS}$: 709 – 1170<br>$BCF_{SS,L}$: 1108-1828<br>$BCF_{K}$: 815-1200<br>$BCF_{K,G}$: 809-1191<br>$BCF_{K,G,L}$: 1265 – 1861<br><br>$t_{1/2}$: 9.74 – 12.5 days<br><br><u>Comments:</u><br>· **Study Acceptability:** Acceptable<br>· Conducted in Compliance with OECD Guideline 305C Bioaccumulation, test for the degree of bioconcentration in fish. (This is an older version of the current OECD Guideline 305).<br>· PMRA calculated $BCF_k$, $BCF_{k,G}$ and $BCF_{k,G,L}$ using OECD Guideline 305 (2012) equations, calculating $k_2$ from the depuration data and sequentially determining $k_1$ using non-linear regression using R (R Core Team (2012) according to OECD Guideline 305 (2012).<br>· Steady state was achieved. In both the low and high exposure groups, BCFk and BCFss were very similar. Because growth was very limited in both treatment groups, the $BCF_{k,G}$ estimates were very similar to the $BCF_k$.<br>· The depuration period was only 2 weeks long, and the study author only sampled test fish and water once per week. Although not ideal, the results were still used by PMRA to determine depuration rate constants and $BCF_k$, and the $r^2$ values of the regression of the depuration over time were 0.73 and 0.85 for the low and high exposure studies, respectively. |

| Species and Reference | Summary of PMRA assessment |
|---|---|
| | · The study author did not report how fat content was determined. Therefore, the PMRA could not determine whether the fat content reported by the study author was related to lipid content.<br>· Even though the study author did not analyze the fish or water samples to differentiate bifenthrin from its metabolites, the $^{14}C$-residues were predominantly bifenthrin based on characteristics of bifenthrin and results of Suprenant (1986). |
| Fathead minnow (*Pimephales promelas*)<br><br>McAllister 1988 (PMRA 1755225) | $BCF_{SS}$: 21000 - 30000<br><br><u>Comments:</u><br><br>**Study Acceptability:** A number of deficiencies were identified in the study. Although there is uncertainty with the estimated embryo and larval BCF values due to low sample numbers and variability in tissue concentrations, the PMRA considers the BCF values for the F0 adult to be reliable and relevant to exposure in the environment. The results and the study limitations will be considered along with other data (laboratory and field) in assessing potential bioaccumulation.<br><br>The study was designed to assess the effects of bifenthrin over the full life-cycle of the fathead minnow and to assess bioconcentration at various life-cycle stages.<br>· This study was conducted based on U.S. EPA "User's Guide for Conducting Life-Cycle Chronic Toxicity Tests with Fathead Minnows (Pimephales promelas)", ASTM Standard Practice for Conducting Toxicity Tests with Early Life Stages of Fishes, and U.S. EPA "Recommended Bioassay Procedure for Fathead Minnow Chronic Tests."<br>· This study was conducted prior to the development of OECD guidance for bioaccumulation. Therefore, the EAD evaluated this study considering the OECD Guideline 305 (1996 and 2012) to facilitate the evaluation. The study design was found to follow the majority of the guideline recommendations.<br>· PMRA calculated $BCF_k$, $BCF_{k,G}$ and $BCF_{k,G,L}$ using equations from OECD Guideline 305 (2012), calculating $k_2$ from the depuration data and sequentially determining $k_1$ using non-linear regression using R (R Core Team (2012) according to OECD Guideline 305 (2012).<br>· The exposure was via a flow-through system which is preferred design according to both guidelines as the exposure concentration can be better maintained.<br>· Steady state was not validated but is assumed based on the prolonged exposure duration prior to sampling relative to other fish bioconcentration studies. The study did not include a depuration phase; therefore, kinetic BCF values could not be determined.<br>· The measured concentrations of bifenthrin in water fluctuated more than 20% throughout the study and could potentially affect the uptake of bifenthrin; however, this has been shown to be very typical of majority of studies conducted with bifenthrin. To alleviate concerns that the exposure regime was inconsistent and resulted in unreliable BCFs, the PMRA chose to recalculate BCFs for adult $F_0$ using the nominal concentrations of bifenthrin in water.<br>· The PMRA noted that despite the variability in measured concentrations, the variability in $F_0$ fish tissue concentration is relatively low (RSD = 2.4 – 18%). The range of BCF values corresponding to day 127, 206 and 254 of continuous exposure are also fairly consistent; 14400 – 19800 and 25263 – 26842 based on the low and high nominal water exposure concentration (0.005 and 0.019 ug/L, respectively). In contrast, tissue concentrations measured in the filial generation (embryos <48-h and 96-h of age) were highly variable resulting in a broad range of BCF values (600 – 10 000); the extent of tissue variability in larvae could not be determined as only a single larva was collected for analysis.<br>· The reason for the high variability observed in embryo concentrations is uncertain. The BCF values for embryo are not considered by the PMRA to represent a reasonable estimate of bioconcentration. |

| Species and Reference | Summary of PMRA assessment |
|---|---|
| | The fact that there is no depuration phase after the uptake phase is only relevant if a kinetic BCF is being calculated. There is no depuration phase in monitoring studies, yet these studies provide relevant information for determination of accumulation under "real world" conditions.<br><br>The PMRA response to comments from Suprenant and Putt (2009):<br><br>1. *The study design was intended to determine long-term toxicity in fathead minnows and did not follow OECD 305 guidelines and the BCF endpoint was an add-on to the toxicity test*.<br><br>As mentioned, the McAllister (1988) study predates the establishment of the OECD protocol for bioaccumulation. The study was designed to determine effects of bifenthrin toxicity to fathead minnows; however, the introduction of the study clearly indicates that one of four primary objectives of the study was the determination of "bioconcentration of FMC 54800 in several life stages of fathead minnows". The PMRA considered the guidance in the current OECD Guideline 305 when assessing these studies. The PMRA found the embryo and larval bioaccumulation endpoints were not reliable. The PMRA found that the fathead minnow BCF values were reliable.<br><br>*2. The fish were under a variable exposure regime without a depuration phase prior to collection of tissue for processing:*<br><br>The fact that there is no depuration phase after the uptake phase is only relevant if a kinetic BCF is being calculated. There is no depuration phase in monitoring studies, yet these studies provide relevant information for determination of accumulation under "real world" conditions. The PMRA considers the concern regarding the lack of a depuration phase prior to collection of tissue for processing does not affect the conclusions reached by the PMRA.<br><br>3. *The bifenthrin that was sorbed to the accumulated debris and detritus in the test chambers as well as the fish themselves prevented an accurate assessment of the true exposure concentration as the measured test solution concentration is lower than the actual $^{14}C$ bifenthrin loading rate. The actual $^{14}C$ bifenthrin loading rate was in excess of measured concentrations in the test solutions with the total amount of bifenthrin injected into the exposure system ranging between 70.9 µg/day over days 0-121 into four 11-L test chambers and 80.3 µg/day over days 121-386 into 4 11-L test chambers and 2 35-L test chambers. In addition, there is no practical way to remove debris and detritus from samples prior to analysis which would have further contaminated the samples*.<br><br>Bifenthrin sorbed to accumulated debris and detritus in the test chambers would be unavailable to fish for accumulation. Sorption to debris and fish scales/skin would account for apparent loss of $^{14}C$ compared to the loading rate when only using the measured concentrations in water to determine a mass balance. The study report also indicates that the growth and spawning chambers were "routinely cleaned at least once a week by brushing and siphoning" and "all the aquaria were siphoned at least 5 times each week to remove fecal material and excess food." Therefore, accumulated debris and detritus would have been kept to a minimum. The flow-through design of the study also acts to limit algal growth. Under natural conditions the sorption of bifenthrin to algae on egg masses would form part of a chemical exposure. |

| Species and Reference | Summary of PMRA assessment |
|---|---|
| | 4. *Tissue processing for the pre- and post-spawn adults consisted of whole carcass homogenization with dry ice prior to combustion. The adult fish were not rinsed clean and the intestinal tract was not removed, so measured tissue concentrations used to calculate the BCF may have included test substance that was not actually incorporated into tissue. The intestinal tract in the larvae was not purged prior to collection.*<br><br>OECD Guideline 305 (2012) recommends whole fish analysis and explicitly states that "The BCF is based on the total concentration in the fish (i.e. per total wet weight of the fish)." They continue "However, for special purposes, specified tissues or organs (e.g. muscle, liver), may be used if the fish are sufficiently large or the fish may be divided into edible (fillet) and non-edible (viscera) fractions." Concern about concentrations of bifenthrin in gut tissue would not be an example of "special circumstances". Residues present in the gut contents are more of a concern in BMF studies where the fish is consuming treated food. In that case, OECD Guideline 305 recommends sampling fish just prior to the next feeding schedule so that gut content is limited. OECD Guideline 305 (2012) does not recommend a purging step in a BMF study. Purging of gut content is not required in OECD Guideline 305 guidance and is only recommended in soil and sediment accumulation studies with caution because of the potential for depuration of accumulated residues of quickly depurating substances. Given that the study states that fish were not fed 24 hours prior to termination, gut content was likely a minimal contributor to total bifenthrin residues. In addition, the study protocol included in the study report (PMRA 1755227, page 1862) explicitly states that "Since fathead minnows are a forage species that are usually consumed as whole organisms by predators, only the residues in the whole embryo, larvae, juveniles and adult fish stages will be analyzed for the test compound." and "Adult fathead minnows will be sampled for whole body tissue analysis following the schedule…" In this respect, whole fish analyses provide a more accurate representation of the true body burden to which piscivorous fish, birds or mammals might be exposed to through consumption under natural conditions.<br><br>Rinsing of fish is recommended prior to analysis; however, the contribution of residues from this source is likely very small for adult fish. This was previously raised as a cause for concern in other BCF studies; however, residues on the mucous layer of fish was minor in EU field studies (e.g., no residues were measured in fish mucous;PMRA 2630696). The contribution of residues on the surface area of eggs due to algae could be a concern; however, it is unlikely to be a major contributor to free-swimming adults in test vessels that are siphoned 5 days a week and brushed and siphoned at least once a week. The study report states that when eggs were removed from the tiles they "were individually selected and transferred to watch glasses for placement into available growth chambers. Each replicate growth chamber was disinfected with a solution of providone iodine before eggs were placed into the incubation cups. This was done in an effort to reduce biological growth and provide for better hatchability and fry survival." Considering that the growth of algae and other biotic material on the incubation cups and that the eggs would have been kept to a minimum due to treatment with |

| Species and Reference | Summary of PMRA assessment |
|---|---|
| | providone iodine, algal growth would not have been substantial during the 48 or 96 hours in test solution prior to residue analysis.<br><br>5. *The 10-14 day old larvae sample consisted of only a single sample from the middle test substance treatment.*<br><br>The PMRA Response: The PMRA agrees that the larval sample indicating a BCF of 6000 is only based on a single sample and should not be used as an indication of the bioconcentration potential of bifenthrin in larval fish.<br><br>6. *The adult fish were not sexed so it cannot be determined if they were male or female. The females would have had a disproportionate amount of lipid content compared to the males. At test termination in this type of study, there are distinct morphological differences related to sex and, depending where in the spawning cycle the test is terminated, females often carry large numbers of unreleased eggs in the ovary, thus contributing to a high lipid content. Given the small sample size and the whole fish homogenization that took place these results are inherently variable.*<br><br>To determine the relevance of this concern, the PMRA explored the scientific literature to determine if differences in lipid were apparent between the sexes of fathead minnows during the various stages of reproduction.<br><br>Ankley et al. (2001) described a short-term reproduction test with the fathead minnow exposed to methoxychlor and methyltestosterone. In that study, they found that mean (SE) lipid content in all males and females (across treatments) were 1.45 (0.2) and 2.73 (0.05)%, respectively. They did find that on a wet-weight basis, females accumulated a factor of two to three times higher concentrations of methoxychlor than the males; however, the difference between the sexes was essentially eliminated through lipid normalization of concentrations of the organochlorine (Ankley et al. 2001).<br><br>Suedel et al. (1997) describes a subchronic study (13 weeks) on the effects of five di-ortho-PCBs to fathead minnow. Lipid content of fish at test initiation was 7.6% for males and 6.7% in females. Lipid content was not significantly different between sexes during the pre-spawn period. During the post-spawn period females generally had higher lipid content that males (Table 8); however, the female lipid content was not statistically significantly greater on every sample occasion. significant reductions in lipid content were observed across all treatments between the pre and post-spawning periods. Post-spawning reductions were more pronounced in males (47–72% reduction) compared to females (41–46% reduction). The study authors surmised that this consistent loss of lipid content among treatments following spawning was likely due to increased breeding activities such as cleaning of spawning tiles and defending of nests by males and egg-laying by females.<br><br>Taking these studies into consideration, it is apparent that there may have been differences in lipid content in the males and females during the post-spawning samples of the McAllister (1988) study. This would include the day 206 and day 254 sample periods when residue analyses were conducted. However, during the pre-spawn period, which would coincide with the day 127 residue analysis of F0 adult fathead minnows, there would likely not have been statistically significant differences in lipid. Table 5 indicates that the standard error between fish sampled |

| Species and Reference | Summary of PMRA assessment |
|---|---|
| | on each sample day is relatively small (CV ranges from 3-17%). This indicates to PMRA that although there could have been differences in lipid content between the fish sampled, it was not enough to result in significant differences in residues in the fathead minnow samples analysed by the study authors.<br><br>7. *The composite embryo and larvae masses were combusted whole without rinsing or homogenization.*<br><br>Please see the above response regarding the issue of rinsing and analysis under Bluegill sunfish (Lepomis macrochirus) for Gries and Schanné 2006 (PMRA 1755215). In terms of the analytical process, if sample size is small enough, there is no need to homogenize a sample that is being combusted via an oxidizer. Complete combustion would occur resulting in complete $^{14}C$ release and trapping by scintillation fluid. If there is an incomplete burn due to sample size then this would require a reconsideration of the analytical processing; however, there was no indication in the study report that this was a concern.<br><br>8. *The majority of the embryo samples were a composite of individual samples collected over an extended period of time in the same collection container. In these cases there is a significant amount of actual test solution that is transferred into the collection vessel and is frozen along with the tissues, introducing $^{14}C$ contamination of the samples.*<br><br>According to the study report, newly fertilized embryos (< 48 hours old) used for residue analysis were samples from single days or were combined samples from a number of samples days. This is also reported in Table 6. There is no information in the report to determine how samples were combined. Given the length of time over which < 48-hour embryo composite samples were collected, the PMRA assumes that samples were frozen immediately and that each additional sampling was added to a frozen composite; under this sampling regime, freezing would prevent continuous adsorption of $^{14}C$ bifenthrin into the embryo composite. A comparison of BCF values for embryos (< 48 hours old) shows that composite-based BCF values are generally higher than single day-based values. Although this suggests that composited embryos may have potentially continued to adsorb $^{14}C$ bifenthrin introduced at each sampling event by the addition of test solution, the PMRA feels that such an assertion is speculative based on the high degree of variability shown between composite and single sampling data (water and tissue concentrations). The PMRA notes that the 96-h old embryo samples used for residue analysis were all sampled on the same sample day; storage and reintroduction of further sample mass did not occur. |
| Bluegill sunfish (*Lepomis macrochirus*)<br><br>EFSA 2010 (PMRA 2533236) | $BMF_{K,}$= 0.08<br>$BMF_{K,G,}$= 0.13<br>$BMF_{K,G,L}$ = 0.28<br><br><u>Comments:</u><br>· **Study Acceptability:** Acceptable<br>· Steady state was not reached. The $BMF_{SS}$ represents a potential underestimate of biomagnification. The kinetic $BMF_K$ is considered more reliable.<br>· Assimilation efficiency was very low and could indicate that steric effects and/or irreversibly bound bifenthrin to food decreased uptake from food. |

| **Species and Reference** | **Summary of PMRA assessment** |
|---|---|
| **Field data** | |
| Various fish species in Alabama field Study:<br><br>PMRA 1755966 | <u>BAF</u><br>Catfish: 134 – 5385<br>Channel catfish: 77 – 12 682<br>Gizzard shad: 499 – 12 458<br>Threadfin shad: 182 – 1855<br>Redear sunfish: 51 – 3844<br>Spotted sucker: 535 – 11 564<br><br>Bluegill sunfish: 11 – 7430<br>White crappie: 11 – 3430<br>Largemouth bass: 116 – 8715<br><br>**Study Acceptability:** Bioaccumulation of bifenthrin in fish was monitored in a pond for up to 471 days after bifenthrin was applied aerially to adjacent cotton fields. The highest average bifenthrin concentration in water was used to calculate BAF values for all fish samples regardless of the timing of sampling. Although, there are uncertainties and variability (spatial and temporal) with field studies, the field BAF values are considered to offer a reasonable characterization of the exposure history of the pond fish and were found to be consistent with BCF values obtained under controlled, steady state laboratory conditions.<br><br>OECD Guideline 305 (2012) is designed for determining laboratory BCF and BMF values and was not developed to evaluate the validity of BAFs derived from a field study. There are currently no standard guidelines for conducting and assessing bioaccumulation data from field studies. Consequently, the PMRA assessed the field study taking into account guidance in existing guidelines for bioaccumulation, field dissipation, and mesocosm studies.<br><br>Specific comments received regarding the Alabama pond study and responses follow:<br><br>1. *Bioaccumulation should be tested at 1% of the acute asymptotic* $LC_{50}$.<br><br>OECD Guideline 305 (2012) specifies that the concentration of the test substance should be selected to be below its chronic effect level or 1% of the acute asymptotic $LC_{50}$ (paragraph 51).<br><br>In the Alabama pond study, the average bifenthrin residues in pond water varied between 1.95 ppt and 17.9 ppt during the treatment period. During the one-year post treatment period, the average bifenthrin residues in pond water collected on the first 14 sampling dates fluctuated from 2.66 ppt to 8.67 ppt with two exceptions (i.e., below detection and 0.88ppt on day 275 and 329 after the last application, respectively). Bifenthrin residues in pond water persisted up to the last day of sampling, 471 days after the last application (i.e., approximately 8% of the highest average residues measured). Given that all detectable concentrations measured during the pond study are well below the lowest chronic fish endpoint (NOEC = 0.04 µg a.i./L for fathead minnows, Table 20 in PRD2017-11), the PMRA considers the bifenthrin concentration exposure conditions present in the pond to be consistent with OECD Guideline 305.<br><br>*2. The use of field BAF to assess bioaccumulation (exposure pathways are not apparent). Uptake and depuration phases are not well defined.*<br><br>A limitation of both the field BAF and BSAF metrics is that determination of steady state or non-steady state conditions can be difficult to evaluate for field measurements. BAFs and BSAFs obtained from field measurements are typically calculated assuming steady |

| Species and Reference | Summary of PMRA assessment |
|---|---|
| | state. If steady state has not been reached BAF and BSAF values may be underestimated.<br><br>In the Alabama pond study, the exposure regime was difficult to confirm with accuracy as is the case with any field derived BAF. However, the report did provide long term monitoring data from which average, upper- and lower-bound exposure estimates could be derived. The exposure duration of aquatic organisms in the field study was much longer than the exposure periods of the laboratory BCF and BMF studies. As steady-state was achieved in the laboratory studies of shorter exposure periods, it was reasonable to calculate a BAF assuming steady-state under these particular field conditions. Even though the exposure regime was variable, the fish accumulated significant amounts of the substance. The BAF estimates calculated from the average and upper-bound water concentrations provide a reasonable estimate of bioaccumulation observed under field conditions while considering the exposure variability. A factor to take into consideration is that more than 1600 gizzard shad (almost the entire population died the winter following applications and all tested had high concentrations of bifenthrin residues in their tissue (400pptr). The U.S. EPA (PMRA 1755587) estimated BCFs of >50,000 for these fish.<br><br>Given the information detailed above, the PMRA determined that it was reasonable to calculate a BAF assuming steady-state under these particular field conditions. As the field study was determined to be a fairly good estimate of steady state, defining uptake and depuration phases was not necessary for calculating the estimates.<br><br>*3. Uncertainty to estimate accurate BAFs due to study design*<br>In order to determine a field BAF, the media sampled should be spatially representative of the areas where the aquatic organism lives (Burkhard et al. 2012). The timing of the media sampling event can correspond to the timing of the aquatic organism sampling (i.e., synoptic sample collection), or can take place at different times provided that the frequency and duration of sampling is sufficient to characterize the exposure history of the organism (e.g., an average concentration over a period prior to collection). Based on these fundamental criteria the monitoring regime (spatial and temporal) used in the Alabama pond study to measure bifenthrin residues in fish, water and sediment is considered representative of a suitable test design in which field BAFs can be estimated. As expressed previously, the PMRA considers the field BAF values to offer a reasonable characterization of the exposure history of the pond fish; these values are shown to be consistent with BCF values obtained under the comparatively conservative, controlled steady state laboratory conditions.<br><br>*4. The application rate used in the Alabama pond study is exaggerated compared to the Canadian application rate*.<br><br>The Alabama pond study was used to characterise bioaccumulation. As bioaccumulation estimates are ratios between biota and water, they are not concentration dependent. The application rate should have no impact on the bioaccumulation conclusions.<br><br>*5. Variability in concentrations in water and fish may result in uncertainty in BAF estimates.*<br><br>One disadvantage of field studies relative to laboratory studies is greater inter-individual variability in the results. Additional variability, and therefore possible uncertainty, associated with field measurements compared to laboratory measurements is that environmental and biological conditions vary both spatially and temporally (Selck et al. 2012). As such, the bioaccumulation results may be spatially and temporally dependent as field measurements may only represent conditions at a specific time point. This snapshot in time may represent the best-case, worst-case, or average conditions (Burkhard et al. 2012). To address this uncertainty, the PMRA used the highest mean bifenthrin concentration in |

| Species and Reference | Summary of PMRA assessment |
|---|---|
| | water to calculate the field BAFs in fish which will underestimate BAFs and represent a lower bound estimate. The calculated field BAFs in fish from this study may represent a lower bound estimate.<br><br>*6. Concentrations of bifenthrin were not measured in gut contents.*<br><br>This comment has been addressed previously.<br><br>*7. Fish were not washed prior to analysis resulting in contributions of bifenthrin from the skin and mucous layer that would result in increased body burden of bifenthrin in fish and subsequently increase BCF values*<br><br>This comment has been addressed previously. |

# Appendix III Species Sensitivity Distributions for Bifenthrin

## Background Information

The median $HC_5$ and confidence values were reported for the species sensitivity distributions (SSDs). The hazardous concentration to 5% of species ($HC_5$) is theoretically protective of 95% of all species at the effect level used in the analysis. The variability in the data sets is indicated by the upper and lower bound $HC_5$ estimates and also the confidence limit of the fraction of species affected (FA), which is the theoretical minimum and maximum percent of species that could be affected when the population is exposed to the $HC_5$ concentration. An SSD was conducted for aquatic taxonomic groups including freshwater invertebrates and fish. The software program ETX 2.1 was used to generate SSDs. It was developed by RIVM and is available from the RIVM website (Rijksinstituut voor Volksgezondheid en Milieu, The Netherlands).

## SSD Toxicity Data Analysis for Bifenthrin

Both registrant submitted data and published studies were consulted in the risk assessment process. The following databases were searched for published studies for articles in English or French; Scopus, Medline, Embase, Agricola, CAB Abstracts, Global Health and Toxline. For use in the SSD analysis, searches were performed for studies examining the toxicity of bifenthrin to aquatic organism. Results were then screened for environmental relevance, and were divided into sub categories. A total of forty-one records from the published literature were found to be relevant to the bifenthrin aquatic toxicology risk assessment.

Only those studies with acceptable quantitative effects endpoints were considered for the SSDs. Additional sorting was done for inclusion into taxonomic sub groups. Studies from the published literature were deemed acceptable if they reported the appropriate biologically relevant endpoints and generally followed recognized methods such as the Organisation for Economic Co-operation and Development (OECD).

The data were sorted for use in the SSDs as follows:

- The measurement endpoints within data subsets are similar (exposure units, toxicity units) and appropriate to the duration category.
- The endpoints included in all data sets are those assumed to ultimately affect survival of the test organisms or populations.
- All short term exposure data were grouped together as “acute” (i.e., 24 hours, 48 hours, 96 hours, etc.) for individual taxonomic groups.
- All data which were considered to be “chronic” were group together for individual taxonomic groups (i.e., studies examining the survival or sublethal effects from long exposure periods).
- Geometric means of toxicity values were calculated for multiple endpoints for the same species.
- Where more than one measurement endpoint was available for a given study, the more sensitive endpoint was used and not a geometric mean.
- If multiple endpoints were reported over the exposure period for the same study (e.g., endpoints for 12 hours, 24 hours, 48 hours and/or 96 hours), the most sensitive endpoint was chosen.

- Study results which were insufficient or not compatible for inclusion in the taxonomic sub groups established for the current assessment were not used. This includes for example incompatible effects levels such as $EC_{25}$, different or unique exposure matrix studies and units, different exposure time/method, etc.
- For the acute freshwater invertebrate SSD, only $LC_{50}$ results were used due to the available data set.
- For chronic effects on freshwater invertebrates, NOEC values were used.
- All aquatic toxicity data derived from studies conducted with the EUP were converted to TGAI concentrations such as "mg a.i./L" as needed.

Studies selected for use in the SSD assessments are summarised in Tables 1-9.

**Table 1 Freshwater invertebrate species data considered for the acute SSD assessment**

| Species name | Study duration | Toxicity Endpoint | Value (ng a.i./L) | Measurement endpoint | Reference | Remark |
|---|---|---|---|---|---|---|
| **TEST MATERIAL: TGAI ( technical materials)** | | | | | | |
| *Hyalella azteca* | 96 hours | $LC_{50}$ | 9.3 | mortality | Anderson et al. 2006 | Nominal; single endpoint; used |
| | N/A | N/A | N/A | N/A | Harwood et al. 2013 | The study design was exploratory examining effects of bioavailability on toxicity; Not used |
| | N/A | N/A | N/A | N/A | Maul et al. 2008a | Endpoint/exposure matrix were incompatible with other studies considered; Not used |
| *Hyalella azteca* | N/A | N/A | N/A | N/A | Weston et al. 2009 | Endpoint matrix was not compatible with aqueous exposure; Not used |
| *Chironomus dilutus* | 96 hours | $LC_{50}$ | 26,150 | mortality | Anderson et al. 2006 | Nominal; geomean; Used |
| | 96 hours | $LC_{50}$ (1 R-cis bifenthrin) | 79 | mortality | Liu et al. 2005a | Nominal; geomean; Used |
| | Not provided | $LC_{50}$ (racemic mix cis bifenthrin) | 144 | mortality | Liu et al. 2005a | Nominal; geomean; Used |
| | 96 hours | $LC_{50}$ (1 S-cis bifenthrin) | 1342 | mortality | Liu et al. 2005b | Nominal; geomean; Used |
| | 96 hours | $LC_{50}$ | 50 | mortality | Yang et al. 2006 | Nominal; geomean; Used |
| | N/A | N/A | N/A | N/A | Harwood et al. 2013 | The study design was exploratory examining effects of bioavailability on |

| Species name | Study duration | Toxicity Endpoint | Value (ng a.i./L) | Measurement endpoint | Reference | Remark |
|---|---|---|---|---|---|---|
| | | | | | | toxicity; Not used |
| *Daphnia magna* | 96 hours | $LC_{50}$ (1 R-cis bifenthrin) | 81 | mortality | Liu et al. 2005b | Nominal; geomean; Used |
| | 96 hours | $LC_{50}$ (racemic mix cis bifenthirn) | 175 | mortality | Liu et al. 2005b | Nominal; geomean; Used |
| | 96 hours | $LC_{50}$ (1 S-cis bifenthrin) | 1803 | mortality | Liu et al. 2005b | Nominal; geomean; Used |
| | 12 hours | $LC_{50}$ (1 R-cis bifenthrin) | 2100 | mortality | Liu et al. 2005b | Not used; multiple values were obtained from the same study and only the 96 hours endpoint was used. |
| | 12 hours | $LC_{50}$ (1 S-cis bifenthrin) | 28900 | mortality | Liu et al. 2005b | Not used; multiple values were obtained from the same study and only the 96 hours endpoint was used. |
| | 24 hours | $EC_{50}$ | 3240 | behavior | Ye 2004 | Not used; multiple values were obtained from the same study and only the 9 hours endpoint was used. |
| | 48 hours | $LC_{50}$ | 12400 | mortality | Ye 2004 | Not used; multiple values were obtained from the same study and only the 96hours endpoint was used. |
| | 96 hours | $LC_{50}$ | 1400 | mortality | Ye 2004 | Geomean; Used |
| | 48 hours | $LC_{50}$ | 118 | mortality | 1755275 | Used; Geomean |
| | N/A | N/A | N/A | N/A | Zhao et al. 2009 | Acceptable for qualitative assessment only (not acceptable for quantitative assessment); Not used |
| *Chironomus tentans* | 10 days | $LC_{50}$ | 6.2 ug/g organic carbon | Mortality | Maul et al 2008b | Endpoint/exposure matrix were incompatible with other studies; Not used |
| | N/A | N/A | N/A | N/A | Xu et al. 2007. | Endpoint matrix was not compatible with aqueous exposure; Not used |

| Species name | Study duration | Toxicity Endpoint | Value (ng a.i./L) | Measurement endpoint | Reference | Remark |
|---|---|---|---|---|---|---|
| adult grass shrimp *Palaemonetes pugio* | 96 hours | $LC_{50}$ | 20 | mortality | Harper et al. 2008 | Nominal; Single endpoint; marine species; Used |
| | 24 hours | $LC_{50}$ | 38 | mortality | Harper et al. 2008 | Not used; multiple values were obtained from the same study and only the 96 hours endpoint was used. |
| | 24 hours | $LC_{50}$ (sediment) | 339 | mortality | Harper et al. 2008 | Not used; multiple values were obtained from the same study and only the 96 hours endpoint was used. |
| larval grass shrimp *Palaemonetes pugio* | 24 hours | $LC_{50}$ | 48 | mortality | Harper et al. 2008 | marine species; Not used; multiple values were obtained from the same study and only the 96 hours endpoint was used. |
| | 24 hours | $LC_{50}$ (sediment) | 210 | mortality | Harper et al. 2008 | marine species; Not used; multiple values were obtained from the same study and only the 96 hours endpoint was used. |
| | 96 hours | $LC_{50}$ | 13 | mortality | Harper et al. 2008 | Nominal; Used; multiple values were obtained from the same study and only the 96 hours endpoint was used. |
| Black fly *Simulium vitattum* | 24 hours | $LD_{50}$ | 1300 | mortality | Siegfried 1993 | Nominal; single endpoint; Used |
| Caddisfly *Hydropsyche and Cheumatopsyche spp.* | 24 hours | $LD_{50}$ | 7200 | mortality | Siegfried 1993 | Nominal; single endpoint; Used |
| May fly *Heptageniidae* | 24 hours | $LD_{50}$ | 2300 | mortality | Siegfried 1993 | Nominal; single endpoint; Used |
| Damselfly *Enellagma* and *Ishnura* spp | 24 hours | $LD_{50}$ | 1100 | mortality | Siegfried 1993 | Nominal; single endpoint; Used |
| Water scavenger beetle *Hydrophilus* spp | 24 hours | $LD_{50}$ | 5400 | mortality | Siegfried 1993 | Nominal; single endpoint; Used |

| Species name | Study duration | Toxicity Endpoint | Value (ng a.i./L) | Measurement endpoint | Reference | Remark |
|---|---|---|---|---|---|---|
| *Lumbriculus variegatus* | N/A | N/A | N/A | N/A | You et al. 2009 | Bioaccumulation/ bioavailability test; endpoint not relevant; Not used |
| Outdoor pond mesocosms | 10 months | N/A | N/A | N/A | Auber et al. 2011 | Insufficient information available on endpoints available; incompatible study design; Not used |
| Freshwater community | N/A | N/A | N/A | N/A | Hoagland et al. 1993 | Insufficient information available on endpoints available; results were not specific to bifenthrin as it examined mixture effects; Not used |
| Freshwater invertebrate acute SSD | N/A | 5th centile | <3.8 | Mortality | Solomon et al. 2001. | SSD analysis; SSD endpoints cannot be used in other SSD analyses; Not used. |

N/A-Not available or not applicable

## Table 2 Freshwater invertebrate species used in acute SSD

| Species name | Acute Toxicity value $LC_{50}$ (µg a.i./L) |
|---|---|
| *Hyalella Azteca* | 0.0093 |
| *Palaemonetes pugio* | 0.016* |
| *Procleon sp.* | 0.084 |
| *Chironomus dilutus* | 0.46* |
| *Daphnia magna* | 0.352* |
| *Enellagma, Ishnura* | 1.1 |
| *Simulium vitattum* | 1.3 |
| Heptageniidae | 2.3 |
| *Hydrophilus sp.* | 5.4 |
| Hydropsyche, Cheumanopsyche | 7.2 |

*: Geometric mean of toxicity data for this sp.

## Table 3 Freshwater invertebrate species considered for the chronic SSD

| Species name | Study duration | Endpoint | Toxicity Value (ng a.i./L) | Measurement endpoint | Reference | Remark |
|---|---|---|---|---|---|---|
| **TEST MATERIAL: TGAI ( technical materials)** | | | | | | |
| *Hyalella azteca* | 10 days | $LC_{50}$ | 0.18 ug a.i./g organic carbon (OC) | mortality | Amweg et al. 2005 | Not used; result units are not compatible with EEC and other organisms; $LC_{50}$ is not considered a chronic endpoint |
| | 10 days | NOEC | 0.6 | growth | Deanovic et al. 2013 | Used; geomean |
| | 10 days | NOEC | <1 | growth | Deanovic et al. 2013 | Used; geomean; this less than value was used as it fell within the spread of the data and it was deemed unlikely to affect the results. |
| | 10 days | NOEC | 2 | mortality | Deanovic et al. 2013 | Used; geomean |
| | 10 days | NOEC | 1 | mortality | Deanovic et al. 2013 | Used; geomean |
| | 10 days | $LC_{50}$ | 2.7 | mortality | Deanovic et al. 2013 | Not used; $LC_{50}$ is not considered a chronic endpoint |
| | 10 days | $LC_{50}$ | 2.3 | mortality | Deanovic et al. 2013 | Not used; $LC_{50}$ is not considered a chronic endpoint |
| | 10 days | $EC_{25}$ | 1.3 | fecundity | Deanovic et al. 2013 | Not used; $LC_{50}$ is not considered a chronic endpoint |
| | 10 days | $EC_{25}$ | 0.5 | fecundity | Deanovic et al. 2013 | Not used; $LC_{50}$ is not considered a chronic endpoint |
| | 10 days | $LC_{50}$ | 0.105 ug a.i./g OC in sediment | mortality | Maul et al. 2008a | Not used; result units are not compatible; $LC_{50}$ is not considered chronic data |
| | 10 days | $LC_{50}$ | 0.065 ug a.i./g OC in leaf | mortality | Maul et al. 2008a | Not used; result units are not compatible; $LC_{50}$ is not considered chronic data |
| | 10 days | $LC_{50}$ | 0.152 ug a.i./g OC in mixed | mortality | Maul et al. 2008a | Not used; result units are not compatible; $LC_{50}$ is not considered chronic data |
| | 10 days | $LC_{50}$ | 0.45 ug a.i./g OC | mortality | Weston et al. 2009 | 18$^{o}$C; Not used; result units are not compatible; $LC_{50}$ is |

| Species name | Study duration | Endpoint | Toxicity Value (ng a.i./L) | Measurement endpoint | Reference | Remark |
|---|---|---|---|---|---|---|
| | | | | | | not considered chronic data |
| | 10 days | $LC_{50}$ | 0.99 ug a.i./g OC | mortality | Weston et al. 2009 | 23°C; Not used; $LC_{50}$ is not considered chronic data |
| *Chironomus tentans* | 10 days | $LC_{50}$ | 6.2 ug/g OC | mortality | Maul et al. 2008b | Not used; $LC_{50}$ is not considered chronic data |
| | 10 days | $EC_{50}$ | 2.2 ug/g OC | immobilization | Maul et al. 2008b | Not used; endpoint is not considered chronic |
| | 10 days | $IC_{50}$ | 2.4 ug/g OC | growth based on AFDM (ash-free dry mass) | Maul et al. 2008b | Not used; $IC_{50}$ is not considered chronic data |
| | 10 days | $IC_{50}$ | 1.5 ug/g OC | instantaneous growth rate (IGR) | Maul et al. 2008b | Not used; result units are not compatible; $IC_{50}$ is not considered chronic data |
| | 10 days | $LC_{50}$ | 314 ng/L pore water | mortality | Xu et al. 2007 | Not used; result units are not compatible; $LC_{50}$ is not considered chronic data |
| | 10 days | $LC_{50}$ | 258 ng a.i./L pore water | mortality | Xu et al. 2007 | Not used; result units are not compatible; $LC_{50}$ is not considered chronic data |
| | 10 days | $LC_{50}$ | 608 ng a.i./L pore water | mortality | Xu et al. 2007 | Not used; result units are not compatible; $LC_{50}$ is not considered chronic data |
| | 10 days | $LC_{50}$ | 402 ng a.i./L pore water | mortality | Xu et al. 2007 | Not used; result units are not compatible; $LC_{50}$ is not considered chronic data |
| | 10 days | $LC_{50}$ | 48 ng a.i./L freely dissolved pore water | mortality | Xu et al. 2007 | Not used; result units are not compatible; $LC_{50}$ is not considered chronic data |
| | 10 days | $LC_{50}$ | 53 ng a.i./L freely dissolved pore water | mortality | Xu et al. 2007 | Not used; result units are not compatible; $LC_{50}$ is not considered chronic data |
| | 10 days | $LC_{50}$ | 48 ng a.i./L freely dissolved | mortality | Xu et al. 2007 | Not used; result units are not compatible; $LC_{50}$ is |

| Species name | Study duration | Endpoint | Toxicity Value (ng a.i./L) | Measurement endpoint | Reference | Remark |
|---|---|---|---|---|---|---|
| | | | pore water | | | not considered chronic data |
| | 10 days | $LC_{50}$ | 51 ng a.i./L freely dissolved pore water | mortality | Xu et al. 2007 | Not used; result units are not compatible; $LC_{50}$ is not considered chronic data |
| | 28 days | NOEC | 320 | emergence | 1755267 | Used; NOEC |
| *Ceriodaphnia dubia* | 7 days | $LC_{50}$ | 345 | mortality | Deanovic et al. 2013 | Not used; $LC_{50}$ and $EC_{25}$ are not considered chronic data |
| | 7 days | $LC_{50}$ | 266 | mortality | Deanovic et al. 2013 | Not used; $LC_{50}$ and $EC_{25}$ are not considered chronic data |
| | 7 days | $EC_{25}$ | 245 | fecundity | Deanovic et al. 2013 | Not used; $LC_{50}$ and $EC_{25}$ are not considered chronic data |
| | 7 days | $EC_{25}$ | 232 | fecundity | Deanovic et al. 2013 | Not used; $LC_{50}$ and $EC_{25}$ are not considered chronic data |
| | 7 days | NOEC | 288 | fecundity | Deanovic et al. 2013 | Used |
| | 7 days | NOEC | 179 | fecundity | Deanovic et al. 2013 | Used |
| | 7 days | NOEC | 288 | mortality | Deanovic et al. 2013 | Used |
| | 7 days | NOEC | 179 | mortality | Deanovic et al. 2013 | Used |
| *Daphnia magna* | 21 days | NOEC | 10 | reproduction | Wang et al. 2009 | Used |
| | 21 days | $EC_{50}$ | 3.1 | longevity | Wang et al. 2009 | Not used; $EC_{25}$ are not considered chronic data |
| | 21 days | $EC_{50}$ | 19 | reproduction | Wang et al. 2009 | Not used; $EC_{25}$ are not considered chronic data |
| | 21 days | NOEC | 1.3 | reproduction | 1755269 | Used |

N/A-Not available or not applicable

## Table 4 Freshwater invertebrate species used in chronic SSD

| **Species name** | **Chronic Toxicity value NOEC (µg a.i./L)** |
|---|---|
| *Hyalella Azteca* | 0.001* |
| *Daphnia magna* | 0.0036* |
| *Ceriodaphnia dubia* | 0.227* |
| *Chironomus tentans* | 0.320 |

*: Geometric mean of toxicity data for this sp.

## Table 5 Freshwater fish species data considered for acute SSD

| **Species name** | **Study duration** | **Endpoint** | **Toxicity value (µg a.i./L)** | **Measurement endpoint** | **Reference** | **Remark** |
|---|---|---|---|---|---|---|
| *Oncorhynchus mykiss* | 96 hours | $LC_{50}$ | 0.10 | Survival | 1755251 | Used; Geomean |
| | 96 hours | $LC_{50}$ | 0.256 | Survival | 2533229 | Used; Geomean |
| | N/A | N/A | N/A | N/A | Babìn and Tarazona, 2005 | As the in-vitro effect was not related to an adverse effect, the endpoints were not included in the risk assessment; Not used |
| | N/A | N/A | N/A | N/A | Forsgren et al. 2013 | Purpose of the study (examining the impact of salinity on fish exposed to bifenthrin) was not relevant to the SSD; Not used. |
| | N/A | N/A | N/A | N/A | Riar et al. 2013. | Endpoints can only be used qualitatively; Not used |
| | N/A | N/A | N/A | N/A | Schlenk et al. 2012 | Results are presented as mixtures and $EC/LC_{50}$ values are not available; Not used |
| | N/A | N/A | N/A | N/A | Velisek et al. 2009b | Study not available to PMRA; the molecular level effect was not related to an adverse effect, the endpoint is not likely relevant to the risk assessment; Not used |

| Species name | Study duration | Endpoint | Toxicity value (µg a.i./L) | Measurement endpoint | Reference | Remark |
|---|---|---|---|---|---|---|
| *Lepomis macrochirus* | 96 hours | $LC_{50}$ | 0.260 | Survival | 1755246 | Used; Geomean |
| *Lepomis macrochirus* | 96 hours | $LC_{50}$ | 0.269 | Survival | 2533231 | Used; Geomean |
| *Pimephales promelas* | 96 hours | $LC_{50}$ | 0.21 | Survival | 1755227 | Used; Geomean |
| | 96 hours | $LC_{50}$ | 0.234 | Survival | 2533232 | Used; Geomean |
| | | | | | Beggel et al. 2011 | As the molecular level effect was not related to an adverse effect, the endpoints were not included in the risk assessment; Not used |
| | 24 hours | $LC_{50}$ | 1.90 | survival | Beggel et al. 2010 | The endpoints were comparable to endpoints derived from registrant provided studies*; Not used |
| *Menidia beryllina* | N/A | N/A | N/A | N/A | Brander et al 2012 | As the molecular level effect was not related to an adverse effect, the endpoints were not included in the risk assessment; Not used |
| *Oryzias latipes* | 96 hours | $LC_{50}$ | 1.77 | Survival | 2533234 | Used. |
| *Cyprinus carpio* | 96 hours | $LC_{50}$ | 0.64 | Survival | 2533235 | Used. |
| *Danio rerio* | 96 hours | $LC_{50}$ | 1.97 | Survival | 2767951 | Used. |
| *Danio rerio* embryo | 6 days | $LC_{50}$ | 190 | Survival | DeMicco et al. 2010 | The endpoints were comparable to endpoints derived from registrant provided studies*; Not used |
| | N/A | N/A | N/A | N/A | Padilla et al. 2012 | While toxicity to bifenthrin was part of the study, the focus of this study is on toxicity model using zebrafish embryo, not determining risk assessment endpoint for bifenthrin; Not used |
| | 96 hours | $EC_{50}$ | 256 and 109 | Pericardial edema and curved body | Jin et al. 2009 | The endpoints were comparable to endpoints derived |

| Species name | Study duration | Endpoint | Toxicity value (µg a.i./L) | Measurement endpoint | Reference | Remark |
|---|---|---|---|---|---|---|
| | | | | axis | | from registrant provided studies*; Not used |
| *Dorosoma cepedianum* And mesocosms | 8 days | $LC_{50}$ | 0.52 and 0.207 | survival | Drenner et al. 1993 | Study was not acceptable; Not used |
| *Various fish species* | N/A | N/A | N/A | N/A | Ponepal et al. 2010 | Not the original study; Not used |
| *Cyprinus carpio L.* | N/A | N/A | N/A | N/A | Velisek et al. 2009a | The endpoints were comparable to endpoints derived from registrant provided studies*; Not used |
| *Ictalurus punctatus* | N/A | N/A | N/A | N/A | You and Lydy. 2004. | The study is relevant to method development; study not available to the PMRA; Not used |
| *Brachydanio rerio* | N/A | N/A | N/A | N/A | Zhang et al. 2010. | The endpoints were comparable to endpoints derived from registrant provided studies*; Not used |

N/A-Not available or not applicable
* A sufficient number of high quality registrant studies were provided that followed internationally acceptance guidance and including raw data for analyses. As fish were not the most sensitive aquatic endpoint used in the risk assessment, it was determined that no further SSD analyses were required.

## Table 6 Freshwater fish species used in acute SSD

| Species name | Acute Toxicity value $LC_{50}$ (µg a.i./L) |
|---|---|
| Rainbow trout | 0.16* |
| Bluegill sunfish | 0.26* |
| Fathead minnow | 0.22* |
| Medaka | 1.77 |
| Common Carp | 0.64 |
| Zebra fish | 1.97 |

*: Geometric mean of toxicity data for this sp.

## Table 7 Freshwater fish species data considered for chronic SSD

| Species name | Study duration | Endpoint Toxicity | Value (µg a.i./L) | Measurement endpoint | Reference | Remark |
|---|---|---|---|---|---|---|
| **TEST MATERIAL: TGAI ( technical materials)** | | | | | | |
| *Pimephales promelas* | Full life cycle 120 days | NOEC | 0.04 | Parental fry survival | 1755227 | |
| *Insufficient number of species to conduct a SSD* | | | | | | |

## Table 8 Marine fish species data considered for acute SSD

| Species name | Study duration | Endpoint Toxicity | Value (µg a.i./L) | Measurement endpoint | Reference | Remark |
|---|---|---|---|---|---|---|
| **TEST MATERIAL: TGAI ( technical materials)** | | | | | | |
| *No information. Insufficient number of species to conduct a SSD* | | | | | | |

## Table 9 Marine fish species data considered for acute SSD

| Species name | Toxicity Endpoint | Value (µg a.i./L) | Measurement endpoint | Reference | Remark |
|---|---|---|---|---|---|
| *Cyprinodon variegatus* sheepshead minnow | 96 hours; $LC_{50}$ | 19.8 | mortality | Harper et al. 2008 | |
| adult grass shrimp *Palaemonetes pugio* | 96 hours; $LC_{50}$ | 20 | mortality | Harper et al. 2008 | |
| | 24 hours; $LC_{50}$ | 38 | mortality | Harper et al. 2008 | Not used; multiple values were obtained from the same study and the 96 hour endpoint was used. |
| | 24 hours; $LC_{50}$ (sediment) | 339 | mortality | Harper et al. 2008 | Not used; multiple values were obtained from the same study and the 96 hour endpoint was used. |
| larval grass shrimp *Palaemonetes pugio* | 24 hours; $LC_{50}$ | 48 | mortality | Harper et al. 2008 | Not used; multiple values were obtained from the same study and the 96 hour endpoint was used. |
| | 24 hours; $LC_{50}$ (sediment) | 210 | mortality | Harper et al. 2008 | Not used; multiple values were obtained from the same study and the 96 hour endpoint was used. |
| | 96 hours; $LC_{50}$ | 13 | mortality | Harper et al. 2008 | |
| *Insufficient number of species to conduct a SSD* | | | | | |

**Results of SSD Analysis for Bifenthrin Insecticide:**

Distributions were determined for the following taxonomic groups (results are reported in summary Table 10):

- Freshwater invertebrates, acute and chronic.
- Freshwater fish, acute.

Bifenthrin is an order of magniture more toxic acutely to freshwater aquatic invertebrates than to fish. It is also an order of magnitude more toxic to invertebrates on a chronic basis. The acute $HC_5$ for freshwater invertebrates is 0.009 µg a.i./L, while the $HC_5$ for chronic effects is 0.0001 µg a.i./L. For freshwater fish the difference in acute vs. chronic sensitivity is smaller, being twofold, rather than tenfold for invertebrates. The acute $HC_5$ for freshwater fish is 0.078 µg a.i./L. A chronic $HC_5$ value is not available for fish, however, the life cycle NOEC is 0.04 µg a.i./L.

The confidence intervals (CI) on the $HC_5$ and the FA indicate relatively high variability in the data sets. This variability may indicate that a 95% protection level may or may not be achieved and potentially a higher fraction of species could be affected above the 5% level. For example, as a worst case scenario, up to 27.7% of all freshwater fish could be affected at the $EC_{50}$ level if exposed to 0.078 µg a.i./L of bifenthrin.

**Table 10 Summary of Species Sensitivity Distribution (SSDs) toxicity data analysis for bifenthrin insecticide by taxonomic group.**

| Exposure | Freshwater invertebrates (µg a.i./L) | Freshwater fish (µg a.i./L) |
|---|---|---|
| Acute | $HC_5$: 0.0088($LC_{50}$)<br>Species count: 10 | $HC_5$: 0.078 ($LC_{50}$)<br>Species count: 6 |
| | CI: 0.0006-0.044<br>FA: 0.61-20.1% | CI: 0.009-0. 203<br>FA: 0.25-27.7% |
| Chronic | $HC_5$: 0.0001(NOEC)<br>Species count: 4 | NA |
| | CI: 8.0E-09-0.003<br>FA: 0.07-37.1% | |

(CI): lower and upper confidence level of $HC_5$; (FA): fraction of species affected; NA: data are insufficient/not available; (NOEC/ $LC_{50}$/): $HC_5$ is derived from these endpoints.

# Appendix IV Water Modelling and Monitoring Information

**Bifenthrin Aquatic Ecoscenario and Drinking Water Assessment**

## 1.0 Introduction

The following sections review the estimated environmental concentrations (EECs) of bifenthrin resulting from water modelling and the available water monitoring data with respect to environmental exposure and drinking water.

Monitoring data and modelling estimates provide different types of information, and therefore are not directly comparable. Pesticide concentrations in water are highly variable in time and location, and Canadian monitoring data usually are sparse, so comparing monitoring results to modelling is not straightforward. Despite this, these two types of data are complementary and should be considered in conjunction with each other when considering the potential exposure of aquatic organisms or humans through drinking water.

## 2.0 Modelling Estimates

### 2.1 Application Information and Model Inputs

Bifenthrin is an insecticide proposed for use on raspberries and potatoes. The maximum annual application rate is for use on potatoes, with a single application of 0.337 kg a.i./ha, by either in-furrow or t-band application. Use pattern on raspberries is two applications of 0.112 kg a.i./ha, at a 30-day interval, by foliar airblast application. Application information and the main environmental fate characteristics used in the models are summarized in Table 1.

**Table 1 Major groundwater and surface water model inputs for Level 1 assessment of bifenthrin**

| Type of Input | Parameter | Value |
|---|---|---|
| Application Information | Crop(s) to be treated | Raspberries, potatoes |
| | Maximum allowable application rate per year (g a.i./ha) | 224, 337 |
| | Maximum rate each application (g a.i./ha) | 112, 337 |
| | Maximum number of applications per year | 2, 1 |
| | Minimum interval between applications (days) | 30, NA |
| | Method of application | airblast, in-furrow or T-band |
| Environmental Fate Characteristics | Hydrolysis half-life at pH 7 (days) | stable |
| | Photolysis half-life in water (days) | 41.7 |
| | Adsorption $K_{OC}$ (mL/g) | 72490 (20th percentile of four $K_{OC}$ values for "bifenthrin") |
| | Aerobic soil biotransformation half-life (days) | 167 (90th percentile confidence bound on mean of four half-life values adjusted to 25ºC) |
| | Aerobic aquatic biotransformation half-life (days) | 276 (longest of two half-lives) |
| | Anaerobic aquatic biotransformation half-life (days) | 0 (only value available) |

## 2.2 Aquatic Ecoscenario Assessment: Level 1 Modelling

For Level 1 aquatic ecoscenario assessment, estimated environmental concentrations (EECs) of bifenthrin from runoff into a receiving water body were simulated using the PRZM/EXAMS models. The PRZM/EXAMS models simulate pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. For the Level 1 assessment, the water body consists of a 1 ha wetland with an average depth of 0.8 m and a drainage area of 10 ha. A seasonal water body was also used to assess the risk to amphibians, as a risk was identified at the screening level. This water body is essentially a scaled down version of the permanent water body noted above, but having a water depth of 0.15 m. Pore water EECs in an 80 cm water depth was also used, as risk was identified at the screening level for chironomid.

Fine standard regional scenarios were modelled to represent different regions of Canada. Twenty initial application dates between April and September were modelled. Table 2 lists the application information and the main environmental fate characteristics used in the simulations. Preliminary investigation showed that raspberry use pattern resulted in higher EECs, and thus only raspberry use pattern was simulated in the current modelling. The EECs are for the portion of the pesticide that enters the water body via runoff only; deposition from spray drift is not included. The models were run for 50 years for all scenarios.

The EECs are calculated from the model output from each run as follows. For each year of the simulation, PRZM/EXAMS calculates peak (or daily maximum) and time-averaged concentrations. The time-averaged concentrations are calculated by averaging the daily concentrations over five time periods (96-hour, 21-day, 60-day, 90-day, and 1 year). The 90$^{th}$ percentiles over each averaging period are reported as the EECs for that period.

The largest EECs of all selected runs for raspberry use pattern are reported in Tables 2 through 4 for the 15 cm and 80 cm water bodies, and in benthic pore water layer (sediment) in 80 cm wetlands, respectively.

**Table 2 Level 1 aquatic ecoscenario modelling EECs (µg a.i./L) for bifenthrin in a water body 0.15 m deep, excluding spray drift.**

| Region | EEC (µg a.i./L) | | | | | |
|---|---|---|---|---|---|---|
| | **Peak** | **96-hour** | **21-day** | **60-day** | **90-day** | **Yearly** |
| **Use on raspberries, 2 × 0.112 kg a.i./ha, at 30-day intervals** | | | | | | |
| British Columbia | 1.5* | 0.20 | 0.058 | 0.032 | 0.026 | 0.018 |
| Prairie | 7.1* | 1.1* | 0.34 | 0.21 | 0.18 | 0.13 |
| Ontario | 2.2* | 0.39 | 0.13 | 0.094 | 0.085 | 0.070 |
| Quebec | 4.2* | 0.61 | 0.24 | 0.19 | 0.18 | 0.15 |
| Atlantic | 7.2* | 1.4* | 0.62 | 0.37 | 0.32 | 0.21 |

*note: Reported EECs are above the limit of solubility in distilled water (< 1µg a.i./L)

**Table 3 Level 1 aquatic ecoscenario modelling EECs (μg a.i./L) for bifenthrin in a water body 0.8 m deep, overlying water layer, excluding spray drift.**

| Region | EEC (μg a.i./L) | | | | | |
|---|---|---|---|---|---|---|
| | Peak | 96-hour | 21-day | 60-day | 90-day | Yearly |
| **Use on raspberries, 2×0.112 kg a.i./ha, at 30-day intervals** | | | | | | |
| British Columbia | 0.29 | 0.051 | 0.024 | 0.019 | 0.019 | 0.017 |
| Prairie | 1.4* | 0.27 | 0.16 | 0.14 | 0.13 | 0.12 |
| Ontario | 0.46 | 0.12 | 0.071 | 0.067 | 0.065 | 0.061 |
| Quebec | 0.85 | 0.22 | 0.15 | 0.15 | 0.14 | 0.13 |
| Atlantic | 1.4* | 0.41 | 0.25 | 0.22 | 0.21 | 0.19 |

*note: Reported EECs are above the limit of solubility in distilled water (< 1μg a.i./L)

**Table 4 Level 1 aquatic ecoscenario modelling EECs (μg a.i./L) for bifenthrin in a water body 0.8 m deep, pore water concentration, excluding spray drift.**

| Region | EEC (μg a.i./L) | | | | | |
|---|---|---|---|---|---|---|
| | Peak | 96-hour | 21-day | 60-day | 90-day | Yearly |
| **Use on raspberries, 2 × 0.112 kg a.i./ha, at 30-day intervals** | | | | | | |
| British Columbia | 0.012 | 0.012 | 0.012 | 0.012 | 0.011 | 0.011 |
| Prairie | 0.081 | 0.081 | 0.081 | 0.079 | 0.079 | 0.075 |
| Ontario | 0.041 | 0.041 | 0.041 | 0.040 | 0.040 | 0.038 |
| Quebec | 0.090 | 0.090 | 0.089 | 0.089 | 0.088 | 0.083 |
| Atlantic | 0.13 | 0.13 | 0.13 | 0.13 | 0.13 | 0.12 |

## 2.3 Estimated Concentrations in Drinking Water Sources: Level 1 Modelling

EECs of bifenthrin in potential drinking water sources (groundwater and surface water) were generated using computer simulation models. EECs of bifenthrin in groundwater were calculated using the LEACHM model to simulate leaching through a layered soil profile over a 50-year period. The concentrations calculated using LEACHM are based on the flux, or movement, of pesticide into shallow groundwater with time. EECs of bifenthrin in surface water were calculated using the PRZM/EXAMS models, which simulate pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. Pesticide concentrations in surface water were estimated in a small reservoir.

A Level 1 drinking water assessment was conducted using conservative assumptions with respect to environmental fate, application rate and timing, and geographic scenario. The Level 1 EEC estimate is expected to allow for future use expansion into other crops at this application rate. Table 1 lists the application information and main environmental fate characteristics used in the simulations. Fifteen initial application dates between February and September were modelled.

The model was run for 50 years for all scenarios. The largest EECs of all selected runs are reported in Table 5 below. In this case, both the modelled EECs and the limit of solubility are reported.

**Table 5 Level 1 estimated environmental concentrations of bifenthrin in potential sources of drinking water**

| Crop | Groundwater (µg a.i./L) | | Surface Water (µg a.i./L) | | |
|---|---|---|---|---|---|
| | | | Reservoir | | |
| | Daily[1] | Yearly[2] | Daily[3] | Yearly[4] | Simulation average[5] |
| Raspberries | NM | NM | 1.5[5] | 0.29 | 0.25 |
| Potatoes | 0 | 0 | NM | NM | NM |

1 90th percentile of daily average concentrations
2 90th percentile of yearly average concentrations
3 90th percentile of yearly peak concentrations
4 90th percentile of yearly average concentrations
5 average of yearly average concentrations
Note: The limit of solubility in pH 7 buffered water is 1 µg a.i./L
NM Not modelled

## 3.0 Water Monitoring Data

### 3.1 Sources of Data

Emergency registrations for use of bifenthrin have been granted on approximately 800 ha in raspberry-growing areas of British-Columbia over the last few years. Extensive amounts of Canadian monitoring data for bifenthrin would not be expected based on the relatively small scale of use. Monitoring data were available for three sites along Mill Creek, in British-Columbia for the year 2008. No other Canadian monitoring data on bifenthrin in water were found.

Bifenthrin is already registered for use in the United States. US databases were searched for monitoring data on bifenthrin in water. Data on residues present in water samples taken in the US are important to consider in the Canadian water assessment given the extensive monitoring programs that exist in the US. Local weather patterns, runoff events, circumstantial hydrogeology as well as testing and reporting methods are probably more important influences on residue data than Northern versus Southern climate. As for climate, if temperatures are cooler, residues may break down more slowly, on the other hand if temperatures are warmer, growing seasons may be longer and pesticide inputs may be more numerous and frequent.

Bifenthrin was part of the analyte list in the US Geological Survey National Water Quality Assessment program (NAWQA) database and in the US Environmental Protection Agency's Storage and Retrieval (STORET) data warehouse. Bifenthrin was monitored as part of the US Department of Agriculture (USDA) Pesticide Data Program. The Environmental monitoring Branch of California Department of Pesticide Regulation (DPR) also monitored for bifenthrin. Bifenthrin was not part of the analyte list for the United States Geological Survey National Stream Quality Accounting Network (NASQAN).

A summary of the findings is below.

## 3.2 Summary of available water monitoring data

*Canadian monitoring data (PMRA 1971119)*

Bifenthrin monitoring data were available for a total of six samples collected at three sites along Mill Creek, British-Columbia in May and October 2008. The monitoring was part of Environment Canada's Pesticide Science Fund. Bifenthrin was not detected in any of the six water samples. The detection limit varied by sample and ranged from 0.00531 to 0.00893 µg/L.

Given the localized nature and the limited sampling for this active ingredient in Canada, this information is not considered sufficient to describe the potential for bifenthrin to reach Canadian water bodies under normal use. At present, the scale of use of bifenthrin in Canada is small; as such, a monitoring dataset that would fulfill this need was not expected.

*USGS NAWQA (PMRA 2360803)*

As part of the USGS NAWQA Program, bifenthrin was analyzed in 495 surface water samples collected between the years 1999 and 2013 and 308 groundwater samples collected between 2001 and 2005. The sampling sites for the NAWQA program include 31 integrator sites on large rivers and streams in addition to ground water sources from agricultural and urban wells. The well samples do not represent drinking water directly, and some of the wells are shallow "monitoring wells". All samples analyzed in this program are filtered prior to analysis. The limit of detection ranged from 0.0013 and 0.019 µg/L for surface water and from 0.0013 and 0.0053 µg/L for groundwater. Bifenthrin was not detected in any of the 803 samples.

*USEPA STORET (PMRA 2360800)*

Available data from the USEPA's STORET data warehouse indicate that bifenthrin was analyzed in a total of 198 water samples collected between 2003 and 2013 in four States - California, Washington, Kansas and Missouri. Bifenthrin was detected in 11 samples (5.6% detection), 10 of which had levels above the limit of detection but below the limit of quantification. The detection limit for these 10 samples ranged from 0.032 to 0.1 µg/L. The single validated concentration of bifenthrin was 0.0095 µg/L. The limit of detection for all 198 water samples ranged from 0.0047 to 0.0005 to µg/L. Ancillary information on the sampling locations such as the latitude and longitude specifications was provided; however information on the use of bifenthrin in the sampling areas was not available.

*California DPR (PMRA 2360805)*

Bifenthrin was monitored in numerous counties in California from 1999 to 2009. Water samples were taken from California rivers, creeks, agricultural drains and urban streams. The LOQ for bifenthrin ranged from 0.001 to 0.1 µg/L. Bifenthrin was detected in 105 of the 1581 water samples analysed (6.6% detection frequency). The highest concentration of bifenthrin (5.2 µg/L) was detected in a storm drain sample collected in 2009. Four water samples had levels of bifenthrin exceeding 1 µg/L; the $95^{th}$ percentile of the detected concentrations was 0.81 µg/L. Ancillary information on the sampling locations such as the latitude and longitude specifications was provided; however information on the use of bifenthrin in the sampling areas was not available.

*USDA Pesticide Data Program (PMRA 1774484, 1852614/1957282, 1852616, 1852618, 1852619, 1857388, 1857396, 1857399, 2312776, 2312778, 2312780)*

Bifenthrin was analyzed in untreated and treated surface water from municipal water treatment facilities and in potable groundwater as part of the USDA Pesticide Data Program. The data included samples from several States, with surface water samples for the years 2001 to 2010 and groundwater samples for the year 2011. The municipal water treatment sites selected used surface water as the primary source of water; and were located in regions of heavy agriculture where known amounts of pesticides were applied. Water treatment method was not part of the selection criteria. Groundwater samples were from private domestic wells as well as from school/daycare facilities. The groundwater survey was voluntary and sites were selected based on agricultural chemical usage in the watershed and geographic region.

Bifenthrin was detected in only one of the 1585 untreated water samples (0.06% detection), at a concentration of 0.008 µg/L. It was detected in two of the 2610 treated water samples (0.08% detection); levels detected were 0.036 and 0.053 µg/L. Bifenthrin was not detected in any of the 93 private residential wells or any of the 233 school/daycare wells sampled in 2011. The level of detections (LODs) ranged from 0.0032 to 0.011 µg/L. The LOD ranged from 0.0032 to 0.025 µg/L for surface water and was 0.0032 µg/L for groundwater. No specific information was available as to the areas of sampling in relation to areas of bifenthrin use

*Urban storm drains in California (PMRA 2387015)*

Bifenthrin was analyzed in runoff from two urban storm drains in residential neighbourhoods around Sacramento, California during the course of one year (July 2006 to April 2007). Four samples per site were collected during the dry season, while eight samples were collected during rainfall events. Overall, bifenthrin was detected in 23 of the 24 samples analyzed (96% detection). The maximum concentration was 0.0727 µg/L. The limit of detection was 0.0025 µg/L. Although this study shows that bifenthrin is routinely detected in urban creeks in California, where use of bifenthrin in urban settings is registered, the results are not particularly relevant to Canada because only agricultural uses of bifenthrin on raspberries and potatoes are being proposed. It should be noted that sediment concentrations were reported, but only water data are summarize here.

## 4.0 Discussion and Conclusions

Only a few sources of bifenthrin monitoring data were available, mainly from the United States. The available data are fairly recent (1999-2013) and in many cases samples were from high pesticide use regions of the United States, with sampling being done throughout the year. Some data did not have specific information on the use of bifenthrin in the areas being sampled. It is noted that application rates in the United States are higher than those being proposed in Canada. In addition, uses of bifenthrin in urban settings are registered in the United States, whereas only agricultural uses of bifenthin are being proposed in Canada.

Based on available monitoring data, bifenthrin is rarely detected in surface water and was not detected in any groundwater samples. This is expected, due to the low solubility of bifenthrin (1 µg/L in pH 7 buffered water) and its high sorption to soil (20$^{th}$ percentile Koc value of 72490 ml/g). It is strongly hydrophobic.

It should be noted that bifenthrin was detected in 23 out of 24 samples collected from two urban storm drains in California. These do not constitute drinking water sources. Uses of bifenthrin in urban settings are not being proposed in Canada.

Surface water detections of bifenthrin were generally below the limit of solubility (< 1 µg/L); however, it is noted that four surface water samples had detections of bifenthrin above 1 µg/L, with a maximum measured concentration of 5.2 µg/L. Factors potentially influencing the solubility of bifenthrin in ambient water could include, among others, pH, organic matter, particulate matter and temperature. These factors could affect the solubility of bifenthrin, resulting in levels in ambient water which were higher than the limit of solubility for pH 7 buffered water. The four detections above 1 µg/L were from samples collected in storm drains, channels and sloughs in the United States. These water bodies are unlikely to be used as a drinking water source.

Three of the detections had bifenthrin concentrations higher than the modelled daily concentration in surface water (for the drinking water assessment) and some of the peak concentrations in water bodies 15 cm and 80 cm deep (for the aquatic risk assessment). The higher rates of application for bifenthrin in the United States compared to what is proposed for Canada could be one reason why the modelling estimates were less than some of the detections based on monitoring data.

For high-end exposure estimates it is recommended that for acute exposure, the highest detection of bifenthrin out of all surface water samples collected (5.2 µg/L) be used in the human health dietary assessment because some detections observed in water monitoring were higher than those predicted by water models. The highest detection is considered conservative for the following reasons: it was collected from a storm drain, which would be expected to have higher concentrations of chemicals than a drinking water source would have; and it was collected in the United States, where the rates of application of bifenthin are higher than those proposed for Canada. The predicted daily exposure value from the models can also be considered as it was calculated with Canadian specific use information. For the chronic and cancer assessments for human health, the concentrations estimated via modelling represent reasonable high-end exposure estimates for drinking water and should be considered in the human health dietary risk assessment.

For the aquatic risk assessment, the highest detection in water (5.2 µg/L) is within the range of the peak concentration predicted by modeling as such, this value should be considered along with the modelling numbers in the acute assessment for aquatic organisms (both 15 cm and 80 cm depths). For longer term exposures, the concentrations estimated via modelling represent reasonable high-end exposure estimates for aquatic habitats.

# List of Abbreviations

| | |
|---|---|
| °C | degrees Celsius |
| < | less than |
| > | greater than |
| ≥ | greater than or equal to |
| ± | plus or minus |
| % | percent |
| µg | microgram(s) |
| a.i. | active ingredient |
| ASAE | American Society of Agricultural Engineers |
| BAF | bioaccumulation factor |
| BCF | bioconcentration factor |
| $BCF_K$ | kinetic BCF |
| $BCF_{kG}$ | kinetic BCF corrected for growth |
| $BCF_{kGL}$ | kinetic BCF corrected for growth and lipid content |
| BCFss | kinetic BCF at steady state |
| BMF | biomagnification factor |
| BSAF | biota-sediment accumulation factor |
| $^{14}C$ | symbol for carbon 14 |
| CDPR or DPR | California Department of Pesticide Regulation |
| CI | confidence interval |
| cm | centimetre(s) |
| CV | coefficient of variation |
| DACO | data code |
| $DT_{50}$ | dissipation time 50% (the dose required to observe a 50% decline in concentration) |
| EC | emulsion |
| $EC_{25}$ | effective concentration on 25% of the population |
| $EC_{50}$ | effective concentration on 50% of the population |
| EDE | estimated daily exposure |
| EEC | estimated environmental concentration |
| EFSA | European Food Safety Authority |
| e.g. | for example |
| ENASGIPS | Europe-North America Soil Geographic Information for Pesticide Studies |
| EPA | USA Environmental Protection Agency |
| ESCORT | European Standard Characteristics of Beneficials Regulatory Testing |
| EU | European Union |
| EUP | end-use product |
| F | interception factors |
| $F_0$ | parental generation |
| FA | fraction of affected species |
| $F_{int}$ | ratio of pesticide residues reaching plant foliage |
| $F_{soil}$ | ratio of pesticide residues reaching soil |
| FMC | FMC Corporation |
| g | gram(s) |
| GLP | Good Laboratory Practice |

| | |
|---|---|
| h | hour(s) |
| ha | hectare(s) |
| $HC_5$ | hazardous concentration to 5% of the species |
| $IC_{50}$ | inhibitory concentration on 50% of the population |
| i.e. | that is; in other words |
| $k_1$ | uptake rate constant |
| $k_2$ | depuration rate constant |
| $K_d$ | soil-water partition coefficient |
| km | kilometre(s) |
| $K_{oc}$ | organic-carbon partition coefficient |
| $K_{ow}$ | n–octanol-water partition coefficient |
| L | litre(s) |
| $LC_{50}$ | lethal concentration 50% |
| LEACHM | Leaching Estimation and Chemistry Model |
| LOD | limit of detection |
| LOQ | limit of quantitation |
| m | metre(s) |
| mL | millilitre(s) |
| NA | not available |
| NASQAN | US Geological Survey's National Stream Quality Accounting Network |
| NAWQA | US Geological Survey's National Water Quality Assessment program |
| ng | nanogram(s) |
| NM | not modelled |
| NOEC | no observed effect concentration |
| OC | organic carbon content |
| OECD | Organization for Economic Cooperation and Development |
| pg. | page(s) |
| PMRA | Pest Management Regulatory Agency |
| ppt | parts-per-trillion |
| PRD | Proposed Registration Decision document |
| PRZM/EXAMS | Pesticide Root Zone Model / Exposure Analysis Modelling System |
| PWC | Pesticides in Water Calculator |
| RQ | risk quotient |
| RSD | relative standard deviation |
| RIVM | Rijksinstituut voor Volksgezondheid en Milieu, The Netherlands |
| SE | standard error |
| SSD | species sensitivity distribution |
| STORET | United States EPA's Storage and Retrieval Data Warehouse |
| SWAT | Soil and Water Assessment Tool |
| SWCC | Surface Water Concentration Calculator |
| $t_{1/2}$ | half-life |
| TGAI | technical grade active ingredient |
| T-REX | United States EPA's Terrestrial Residue Exposure model |
| TSMP | Toxic Substances Management Policy |
| TWA | time weighted average |

| | |
|---|---|
| US or U.S. | United States of America |
| USDA | United States Department of Agriculture |
| USGS | United States Geological Survey |
| VFS | vegetative filter strips |

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