

M E M O R A N D U M

Yana Garcia Secretary for Environmental Protection

TO:	Jennifer Teerlink, PhD
	Assistant Director

- FROM: Weiying Jiang, PhD, Staff Toxicologist, Exposure Assessment Section Eric Kwok, PhD DABT, Senior Toxicologist, Exposure Assessment Section Shelley DuTeaux, PhD MPH, Branch Chief Human Health Assessment Branch
- DATE: December 15, 2022
- SUBJECT: Response to Comments by the Office of Environmental Health Hazard Assessment on DPR's Draft Human Exposure Assessment for Fipronil

Background

At the request of the Human Health Assessment (HHA) Branch of the Department of Pesticide Regulation (DPR), the Office of Environmental Health Hazard Assessment (OEHHA) reviewed the January 2021 Draft Human Exposure Assessment for Fipronil. OEHHA was asked to respond to a series of charge questions covering the hazard identification, exposure assessment, risk characterization, and worker and bystander margins of exposure, and provided comments to DPR on May 13, 2021.

This memorandum summarizes DPR's responses to OEHHA's comments on the draft AITC EAD in an itemized fashion and is divided into the following sections: Summary of Review; Detailed Comments; Response to Charge Statements; and Minor Comments. Corresponding revisions were also made the final EAD and its appendices as appropriate. Responses specific to the hazard identification and risk characterization are detailed in a separate memorandum.

Note that references cited in this memorandum are specific to OEHHA comments or DPR's response, and not necessarily duplications of those in the draft or final EAD. Likewise, every effort has been made to ensure that any references to tables found in the draft or final EAD are clear. Tables specific to this memorandum are numbered independently of the EAD. All OEHHA comments in this memorandum are direct quotes from the documents, which can be found at

https://oehha.ca.gov/media/downloads/pesticides/document/fipronilcomments051321.pdf

OEHHA Summary of Review

OEHHA Summary Comment C.1: OEHHA suggests that the draft EAD aggregate exposures from all relevant pathways and sources, regardless of whether exposure levels exceed level of concern.

DPR Response: A detailed response to this comment can be found below. Due to the differences in exposure routes and durations, the potential health concerns associated with human exposure to fipronil via different sources and pathways (i.e., scenarios) should be addressed using the concept of aggregate risk instead of aggregate exposure. Both the draft and final Risk Characterization Documents (RCDs) included aggregate risks from different exposure routes (e.g., dermal, inhalation and oral), which are summarized in Tables 2-4 of the draft RCD. For residential post-application scenario (both adult and child), this assessment already considered possible fipronil exposures from different product uses by relying on the study by Mahler et al., 2009.

OEHHA Summary Comment C.2: OEHHA suggests that the draft EAD explain why exposure to fipronil degradants were included in some exposure pathways but not in others.

DPR Response: A detailed response to this comment can be found below, and revisions were also made to the EAD to clarify. In general, handlers were only assessed for fipronil exposures at the time application. For post-application scenarios, the exposures were assessed on the same day of application, as fipronil products do not have requirements on restricted entry interval (REI). Therefore, this assessment did not assess human exposures to fipronil degradates because the exposures to the parent fipronil are expected to be much higher than those of its degradates.

OEHHA Summary Comment C.3: OEHHA suggests that the draft EAD consider using highend exposure duration rather than using arithmetic means for estimating acute post-application exposure for pet owners.

DPR Response: A detailed response to this comment can be found below. In general, this assessment determined that using the higher-end exposure duration values would result in an overestimation of post-application exposures, considering other values used to estimate the exposures.

OEHHA Detailed Comments - Exposure Assessment

1. Aggregate Exposure

OEHHA has concerns about the potential for underestimation of aggregate exposure from multiple sources that are not addressed by the draft EAD. Residents could receive cumulative exposure from multiple sources. Therefore, OEHHA suggests the draft EAD aggregate exposures from all relevant pathways and sources regardless of whether exposure levels exceed

the level of concern. For example, residents who treat their own pets (applicators) or bathe their pets (table 35, using surrogate scenario as recommended by US EPA) would likely also be exposed to additional post-application sources such as indoor dust and contaminated surfaces or residues that remain on the treated pet. This scenario is supported by a study cited in the draft EAD (Bigelow-Dyk et al., 2012), which found fipronil residues on the indoor areas frequently visited by treated pets and that these residues are transferable to humans. In another study, Mahler (2009) showed fipronil residues on indoor surfaces came from multiple sources that included transport from pet treatment. Among the five residences with the highest fipronil indoor dust concentrations, which ranged between 1100 to 9800 µg/kg, three residences reported regular use of fipronil on dogs. OEHHA suggests the draft EAD consider using this study to estimate residents' post-application exposure through contact with indoor surfaces or ingestion of house dust and include the result in the aggregate exposure assessment. Lastly, since no postapplication study data were available, the environmental monitoring data in the Mahler study (2009) was used as surrogate data to estimate post-application exposure. Because fipronil levels on outdoor surfaces were lower than on indoor surfaces the draft EAD conducted the exposure assessment for indoor surfaces but did not estimate any additional exposure from outdoor surfaces. The exposure assessment followed the US EPA SOP guidance (2012) and considered 4-hr exposure time for children exposed to indoor surfaces. However, besides the 4-hr indoor exposure, children may also be active outdoors and be further exposed to fipronil and its degradants through contact with outdoor surfaces.

DPR Response: It is DPR's practice to assess exposure by grouping human exposures into different exposure scenarios based on the pesticide formulation, application method, and occasion when the exposure occurs, in combination with California-specific data when available. For each scenario, the exposure was assessed for all possible exposure routes (e.g., inhalation). However, a direct combination of exposure values from different scenarios is not appropriate due to different exposure conditions (and therefore uncertainties) involved in each of the scenarios. Instead, DPR employs the practice of aggerating risk which focuses on evaluating the health risks of a single, specific, stressor from multiple exposure pathways or routes The aggregation of human health risks from different routes of exposure to fipronil was performed and summarized in Tables 2 through 4 of the draft RCD (i.e., margin of exposure aggregation). Updates to the margins of exposure are included in the final RCD based on refined exposure assessment values.

For most assessed scenarios, DPR did not estimate aggregate exposures from multiple products, because 1) for professional handlers (licensed pesticide applicators and professional groomers), this assessment already assumed 8-hr workday, so exposures to multiple fipronil products on the same day was not expected; 2) for post-application exposures, this assessment estimated human exposures immediately after the application was completed. This is considered the worst-case post-application scenarios and is based on the absence of restricted entry interval requirement for fipronil products. While multiple applications at a time are not likely, this assessment does conservatively assume that the most recently used product contributes the most, if not all, exposure to fipronil.

Mahler et al. (2009) was used to estimate residential post-application exposures. As mentioned in the section "V. EXPOSURE APPRAISAL," this study did not specify the source(s) of fipronil at each sampled home, so the measured fipronil compounds represent a cumulation of contamination from multiple products (including both structural and pet products) and multiple applications. Accordingly, an aggregation of exposures was inherent in the data used to establish residential post-application scenarios for adults and children.

DPR is aware of the study from Bigelow-Dyk, et al. (2012), but determined that this study lacked critical information needed for exposure assessment. A detailed discussion of this study is provided in the section "V. EXPOSURE APPRAISAL".

2. Fipronil Degradants

OEHHA suggests that the draft EAD explain why exposure to fipronil degradants were included in some exposure pathways but not in others. DPR provided the following information on degradants in the draft RCD:

- For indoor surfaces, two degradants from the Mahler study were included in the exposure assessment. For residential outdoor surfaces, degradant levels were reported in Jiang et al. 2016a (EAD, page 11 of 66, Table 3) but these degradants were not considered in the assessment.
- For the drinking water exposure, fipronil degradants were reported in the DPR surface water database (SURF), (EAD Table 4 Page 12 of 66), but were not included in the drinking water exposure assessment (EAD Page 48).
- The draft RCD considered degradants in food. However, degradant residues in the USDA Pesticide Data Program (PDP) data were all non-detects and therefore the degradants were not quantitatively evaluated in the dietary exposure assessment.
- For spray pet products (post-application), two degradants were measured on gloves in the de Fontenay et al. study (1997a), but it is not clear if they were included in the exposure assessment (draft EAD page 34-35 of 66). The appraisal (page 55 of 66) mentioned other data available on degradants in spray pet products in the Bigelow-Dyk et al. study (2012) that were not considered in the draft EAD.

DPR Response: A new section "A. Exposure to fipronil degradants" has been added to "V. EXPOSURE APPRAISAL" in the final EAD to clarify. Briefly, this assessment evaluated exposures occurring at the time of application, so the primary human exposure is to the parent compound (fipronil). For post-application scenarios, this assessment estimated human exposures on the same day of the application. This is considered the worst-case post-application scenario and is based on the absence of restricted entry interval requirements for fipronil products. Based on the fipronil half-life, degradation within one day is expected to be minimal. Therefore, human exposure to fipronil degradates are expected to be much lower compared to exposure to the parent fipronil (US EPA, 2020).

With regards to Mahler et al. (2009), the investigators did not collect information on the number of days that elapsed between fipronil treatments and the sampling. Therefore, to derive the worst-case post-application scenario (which assumes all the exposures occur on the same day as the application), this assessment assumed 1) that all fipronil degradants were formed from the same application event, and 2) used the total concentration of all three fipronil compounds (parent fipronil and two measured degradants) to represent the maximum amount of fipronil deposited on indoor surfaces. Details are provided in the section "IV. EXPOSURE ASSESSMENT" in the final EAD.

With regards to de Fontenary et al. (1997a), the highest transferable residue of fipronil was measured at 4 hours after application. The fipronil degradants were not included in this assessment, as their amounts were either below the limit of quantification or much lower than the measured fipronil amounts (< 5%) as shown in the study results. As mentioned earlier, DPR was aware of the study from Bigelow-Dyk, et al. (2012), but determined that it lacked critical information needed for exposure assessment. Detailed discussions of this study are provided in the section "V. EXPOSURE APPRAISAL" in the final EAD.

With regards to drinking water, degradates were not included in the potable surface water analysis because all degradate data came from a subset of the same samples that were analyzed for fipronil. The results indicated concentrations of degradates low enough to have no impact on the acute exposure estimate (based on the highest detected value) and would only reduce the chronic exposure estimate by 0.003 ppb). Including degradate samples did not add any new spatial or temporal information that influenced the estimated exposure values.

Note: Responses to comments on the dietary exposure assessment are included in a separate memorandum on the toxicity and risk characterization.

3. Exposure duration assumption for pet owners

OEHHA is concerned that the assumption to use arithmetic means to set time spent with animals may lead to an underestimation of post-application exposure from pet products. The draft EAD sets the time spent with animals at 1 hr for children and 0.77 hr for adults using the arithmetic means found on Tables 8-2, 8-5 and 8-6 of US EPA SOP (2012). The 95th percentile are respectively 2.3 and 2.5. Since this is for estimating acute exposure, OEHHA suggests it is more appropriate to use high-end exposure duration rather than using arithmetic means.

DPR Response: As described in the US EPA standard operating procedures for residential pesticide exposure assessment (page 8-10) (US EPA SOP), the exposure time values listed in Table 8-5 do not "*necessarily represent the time volunteers were actively engaged in constant contact with the animal as is implicit in the post-application dermal and incidental oral algorithms*," and include time spent for activities that might not have physical contact with pet(s), such as walking a dog (US EPA, 2012). Therefore, using the

> upper-bound values (95th percentile) of the exposure time will overestimate postapplication exposures. To estimate short-term exposures, this assessment already uses upper-bound values for dislodgeable residues and assumed pet owners contact the treated pet(s) on the same day as the application. Therefore, it is appropriate and not overly conservative to use the arithmetic mean value of the exposure time to calculate postapplication exposures.

Responses to Exposure Assessment Charge Questions

Exposure Charge Question 1. Due to a lack of fipronil monitoring data, handler exposures for structural liquid concentrate (LC), structural dust and turf granule products were assessed using surrogate data.

OEHHA Comment: OEHHA agrees with DPR's use of approaches from the Pesticide Exposure Handlers Database and surrogate chemical for estimating handler exposure to structural LC, structural dust, and turf granular products.

DPR Response: Comment on this question is noted.

Exposure Charge Question 2. Due to lack of post-application monitoring data, environmental sampling data at residential homes were used to assess post-application dermal and oral exposures for structural LC products.

OEHHA Comment: Since the USGS residential indoor surface monitoring dataset does not have information about the source or the timing of fipronil LC product applications, the acute dermal and oral exposure estimates based on this dataset would have large uncertainties. However, this issue is mitigated to some extent by using the highest estimates.

DPR Response: The US Geological Survey study from Mahler et al. (2009) was the only study identified by DPR that quantified fipronil levels on residential indoor surfaces. To address the uncertainties and to establish the worst-case post-application exposure scenario (i.e., exposures on the same day after the application), this assessment used the total concentration of all three fipronil compounds (parent fipronil and two measured degradates) to represent the maximum amount of fipronil deposited on indoor surfaces, assuming all degradates were formed from the same application event. Detailed discussions are provided in the sections "IV. EXPOSURE ASSESSMENT" and "IV. EXPOSURE ASSESSMENT" of the final EAD.

Exposure Charge Question 3. The drinking water assessment only relied on a subset of measured water samples.

OEHHA Comment: OEHHA agrees that using data from the SURF to estimate fipronil concentration in drinking water is a conservative approach. However, OEHHA is concerned that the analysis method as described in Appendix I (Assessment of human exposure to fipronil) did not include several key details, as described in the Minor comments in this report (section IV.B).

DPR Response: Please see the response to "Minor comments", Comment 5 for details.

Responses to Risk Characterization Charge Questions

Risk Characterization Charge Question 2. Risks to workers were estimated for short-term, seasonal and annual exposures.

OEHHA Comment: For the worker exposure estimates, OEHHA concurs with the approach used in the draft RCD and EAD, but has noted several issues that affect the structural bait gel, structural LC and structural dust estimates that may lead to an underestimation of worker exposure (see section IV.B).

DPR Response: DPR does not anticipate an underestimation of worker (handler) exposures for these products. Detailed responses are provided below to IV. MINOR COMMENTS, Questions 2-4. In addition, this assessment did not estimate the worker (handler) exposures for structural bait gel products as they are expected to be low because 1) the products contain low concentrations of fipronil, 2) the applied amount is small, and 3) the worker has no direct contact with the fipronil product. This has been discussed in the section "III. EXPOSURE SCENARIOS AND CONCEPTUAL MODELS" of the final EAD.

Risk Characterization Charge Question 3. Risks to home users were estimated for short-term exposures.

OEHHA Comment: OEHHA is concerned the draft EAD assessed only short-term exposure for home users. Home users of pet products likely receive additional exposure due to post-application contact with residues on treated pets and indoor surfaces. OEHHA suggests risk be assessed for aggregate exposures for home user from all relevant pathways and sources, regardless of whether exposure levels exceed level of concern. OEHHA also recommends reconsidering the assumptions for assessing only acute exposure.

DPR Response: See the earlier response to "OEHHA detailed comments", Comment 1 for details.

Risk Characterization Charge Question 4. Post-exposure risks to child and adult residents were estimated for short-term and seasonal exposures.

OEHHA Comment: For the pet products, estimates for post-application exposure to pest products were solely based on the amount of fipronil transferred to receptors due to direct dermal

contact with treated pets and incidental oral contact (for children). As noted in the detailed comments (section II.B.1), indoor dust from homes with treated pets contains high levels of fipronil and its degradants (Mahler, 2009) and this may provide an additional exposure source, especially for children. For structural LC products, the draft EAD did not consider child residents. OEHHA suggests estimating risk for aggregate exposures from all relevant pathways and sources, regardless of whether exposure levels exceed level of concern.

DPR Response: See the earlier response to "OEHHA detailed comments", Comment 1 for details. As mentioned, the methods used by Mahler et al., 2009 resulted in the representation of overall contamination from all possible fipronil use of different products (including both structural and pet products). Correspondingly, the estimated exposures already represent what could be considered aggregated values from multiple products and applications. For structural LC products, this assessment already evaluates post-application exposure estimates for child residents. The results are presented in Tables 13 and 15 of the final EAD.

Other OEHHA Comments on the Draft Exposure Assessment Document (Note: Numbering added for ease of response)

OEHHA Comment B.1. OEHHA is concerned that some of the assumptions made in the exposure assessment may lead to an underestimation of exposure.

OEHHA Comment B.1a. For pet product applicators (home users), the draft EAD assumed 2 dogs per house referring to an average found in American Veterinary Medical Association sourcebook (AVMA, 2012). The most recent AVMA publication reports an average of 2.2 pets per household (AVMA, 2018). In addition, over 35% of pet-owning households have more than 2 pets. OEHHA suggests DPR consider the possibility of more than 2 pets/household. The draft EAD did not calculate seasonal and lifetime exposure because it assumed one application per month. A pet owner can have many pets sequentially and treat them with fipronil products. This could lead to chronic or even lifetime exposure. Moreover, if fipronil persists on pets, even once a month application may lead to seasonal exposure for pet owners. OEHHA suggests DPR reconsider this assumption.

DPR Response: Text in the section "IV. EXPOSURE ASSESSMENT" was revised to clarify and the new survey from American Veterinary Medical Association (2019) was added into the EAD as reference. Data from both 2012 and 2019 AVMA surveys were used in this assessment because 1) the 2019 survey did not contain information on the pet size distribution in U.S. homes, and 2) most of other findings in the 2019 survey (e.g., number of dogs per household) are very similar to those in the 2012 survey (AVMA, 2012; AVMA, 2019). The 2019 AVMA report indicates that 2.2 is the average combined number of pets per household, including dogs, cats, and other pets such as birds. The average number of dogs owned per household is 1.6, which is the same as reported in the 2012 survey

(AVMA, 2012; AVMA, 2019). For US homes that own dog(s), 60.4% own one dog while 27.8% own 2 dogs. These values are very similar to the 2012 survey findings (61.8% and 26.0% for one- or two-dog homes, respectively), indicating most US homes have two or fewer dogs. Similar results were reported for cats. Therefore, this assessment considered each home user treating 2 dogs/cats per day as a reasonable assumption for the exposure assessment. With regards to the use of fipronil pet products, this assessment did not assess intermediate- and long-term exposures for home users as per department practice (DPR, 1996). As mentioned in the EAD, the pet owners are expected to use these products once per month as suggested on the labels.

OEHHA Comment B.1b. For the structural bait gel scenario, the draft EAD states that fipronil content ranges from 0.001--0.01% (page 43). However, the DPR Product database shows that two products - Maxforce FC Magnum Roach Killer Bait Gel (432-1460-AA) and Nouvel Sales Fipronil Roach Bait Gel (92028-4-AA) contain 0.05% fipronil. OEHHA recommends that DPR update the dose estimates for the bait gel scenario.

DPR Response: The text in the final EAD was revised and the exposure assessment for structural bait gel product was updated. As stated in the section "II. FACTORS CONSIDERED TO DEVELOP EXPOSURE SCENARIOS" of the EAD, this assessment analyzed DPR's Product Database as of 2016 when the Problem Formulation of fipronil risk assessment was initiated. DPR will analyze the database again and update the exposure assessment if needed during the risk mitigation phase.

OEHHA Comment B.1c. For the structural LC handler scenario, the draft EAD assumed handling amount 40 gallon/day as recommended by US EPA. Assuming 2 or 4 gallons per 10 linear feet as suggested by the draft EAD, 40 gallons/day means 200 linear feet/day or less, which is much less than the linear feet treated for most of houses listed in Table 11. Therefore, the draft EAD may have assumed multiple applicators are needed to treat a house within a day. OEHHA recommends the draft EAD include additional information about the application practice to support the assumption of 40 gallons/day per handler.

DPR Response: In the Honeycutt and Kennedy study (2001), it was unclear how many handlers were present at each treated home. The 40 gal/day used in this assessment is the default assumption used by DPR for handheld sprayers and is based on the Policy 9.1 from US EPA (US EPA, 2001).

OEHHA Comment B.1d. For the structural dust scenario, the draft EAD cited 2012-2014 Pesticide Use Report (PUR) data and used a median value to estimate the amount of product handled. The draft EAD noted this amount, 0.04g/day AI (~8g/day of product), was roughly consistent with US EPA's default value of 2 "cans" of product used per application (US EPA, 2012). PUR data from 2014 and 2018 shows that many applications were substantially larger than this median amount and 20-25% of all applications exceeded 0.227g AI (equal to 0.1 lb product). Given the wide range shown by the PUR data, OEHHA is concerned that using median

values to estimate the usage amount (product g/day) may underestimate exposure. OEHHA recommends that DPR use the average for acute and chronic exposure assessments.

DPR Response: As noted by the reviewers, the 2 "cans" of products per day was suggested by US EPA (US EPA, 2012). This approximates the median amount of dust-formulated fipronil used in one application in California. A higher amount was not used because the exposure values used in this assessment were obtained from a surrogate study, which might already have overestimated the handler exposures to fipronil structural dust products (Merrick, 1997). The reasoning behind this approach are 1) the package of fipronil dust product is directly connected to a specially designed duster, so the exposure during loading and unloading the product from the duster is expected to be lower than that measured in the surrogate study; 2) fipronil is applied by inserting duster outlet tip into a pre-drilled hole, therefore drift during the application is unlikely and inhalation exposure is expected to be lower than measured in the surrogate study; and 3) the fipronil dust product was applied into structural voids, and air flow generated in each pump is unlikely to cause additional handler exposure through re-suspension of already-applied product. As a reminder, this assessment already used upper-bound exposure values (95th percentile estimates) to estimate short-term exposures, which is a conservative assumption. Detailed reasons have been provided the section "V. EXPOSURE APPRAISAL" of the EAD.

OEHHA Comment B.2. OEHHA suggests the draft EAD include more details to support the approach and datasets used in the exposure assessment. For example:

OEHHA Comment B.2a. Fipronil residue in drinking water: the fipronil concentration in drinking water was estimated using the SURF database, which contains monitoring results from a wide variety of surface water sources. OEHHA suggests the draft EAD include more details on data analysis such as the period or years of extracted data, the approach used to determine the monitoring site source categories (canal, ditch, storm drain, slough, and other), and the rationale for including waterways such as canals and ditches as representative drinking water sources.

DPR Response: Time range of extracted data was added to the final EAD. Monitoring site source categories were determined using the SURF site_name field and extracting the keywords (canal, ditch, storm drain, slough). This methodology may categorize some canal/ditch/drain/slough sites as "other" because the name lacks a keyword. DPR's Environmental Monitoring Branch is completing an intensive site categorization update, information from which will be incorporated into future exposure assessments. It is important to note, however, that once storm drains and sloughs were removed from this analysis, the remaining possibly problematic site types (canal & ditch) had negligible measured concentrations or number of samples and thus had minimal influence in the calculated acute and chronic estimates. A brief description of this reasoning was added to the final EAD.

OEHHA Comment B.2b. All the 95th percentiles estimates summarized in the draft EAD cited the method introduced in Frank (2009) and were not the commonly known 95th percentiles in

statistical analysis. OEHHA suggests the draft EAD clearly state the difference between these two estimations as recommended by OEHHA in the review for AITC (OEHHA, 2020).

DPR Response: For handler and post-application scenarios, this assessment used the same method as the AITC EAD to estimate the 95th percentile (Jiang, 2022). This method is based on the assumption that exposure values are log-normally distributed (Frank, 2009). Additional statistical analyses (Shapiro-wilk test) were performed to confirm this distribution assumption. Footnotes of all relevant tables are revised accordingly.

OEHHA Comment B.2c. In some instances, DPR refers to an external document (US EPA 2012) which makes it hard for the reader to verify assumptions and calculations. That is the case for Tables 15, 21, 28, 30, and 32 in Appendix 1. OEHHA suggests the draft EAD provide all the equations used to calculate exposure including the ones for estimating oral exposures.

DPR Response: DPR reviewed the entire EAD to make sure all the equations to estimate exposures were listed in the footnotes of relevant tables unless the equations were too long to be inserted. If that was the case, the page numbers of these equations in the reference (US EPA SOP) were provided in the footnotes of all the relevant tables.

OEHHA Comment B.2d. Similarly, some estimates could not be reproduced because productspecific data were not provided or cited. For example, the specific gravity values for individual fipronil pet products were necessary to replicate dose estimates, but they were not provided. OEHHA recommends that these values be provided in the draft EAD.

DPR Response: The entire document was checked to make sure all necessary parameters needed to re-produce exposure estimates have been provided.

OEHHA Comment B.2e. The draft RCD did not include an assessment of the swimmer scenario. The draft EAD stated that a preliminary swimmer assessment was conducted, however the model inputs and results were not reported. OEHHA recommends the model inputs and results be included.

DPR Response: A new table (Table 7) for the preliminary exposure assessment for swimmers is added in the section "III. EXPOSURE SCENARIOS AND CONCEPTUAL MODELS" of the final EAD.

OEHHA Comment B.2e. For the structural dust scenario, OEHHA is concerned about the assumed size of the product container as it relates to the calculation of the amount of fipronil handled. The US EPA SOP (2012) used to evaluate this scenario assumes each handler applies 2 "cans" per application. However, it is unclear if this product is only available in 5g "cans" as the product label does not indicate container size or amount. Also, in response to a recent OEHHA query, the registrant, BASF, indicated that production of the Termidor Dry California product

ceased in 2018. OEHHA suggests that DPR include additional information about the product container size.

DPR Response: The 5 grams per can was based on the product Termidor[®] Dry (Registration number: 499-546-ZA), which is still actively registered in California as of July 23, 2022.

V. EDITORIAL COMMENTS:

1. EAD, Page 15, paragraph 2 - Misspelling: "Therefore, swimmer exposure was not assessment in this document." It should be "assessed"

DPR Response: This comment was followed, and "assessment" was replaced with "assessed".

2. EAD, Pages 26-27 - Tables 11 and 12 do not cite the source of the study data

DPR Response: This comment was followed, and the reference (data source of each table) was added into the table footnotes.

3. Number of significant figures used varied. For example, Table 13, All STADD values have 2 significant figures, but Adult SADD has one significant figure and child SADD has two. Table 15, STADD values have 2 significant figures but all SADD has 1 significant figure. The document should either use all the same significant figures or the same decimal places

DPR Response: Tables in the entire document is checked to make sure for exposure estimates with decimal numbers, 2 significant figures are used.

4. EAD Page 34 - Table 19, footnote "a" - Typo - fipronil handled for applicator home user is 0.99 g/d and not 0.74 g/d

DPR Response: This typo in the footnote of Table 19 was corrected.

5. EAD Pages 35 and 38 -, both tables 20 and 24 contain the same error. Both tables refer to a footnote "a" which does not appear in the table.

DPR Response: The footnotes for both tables were revised.

6. A reference to pages in the US EPA SOP (2012) was incorrect: Hand to mouth for pet groomer is found in section 8 and not 7 as mentioned in the draft EAD (Page 36, Table 21, footnote "b", Page 41, Table 28, footnote "d")

DPR Response: This comment is followed and the footnotes in both tables are updated.

7. EAD Page 44, paragraph 2 - Suggest revising the last sentence to read "The surrogate pesticide..."

DPR Response: This comment is followed, and the last sentence is changed to "The surrogate pesticide ...".

8. EAD Page 45, Table 31 – typo. Consistent with the stated use of 0.03 ng/cm2 as the abamectin surface deposition (page 44), abamectin deposition in the third column should be expressed in units of ng/cm2.

DPR Response: This comment is followed and the unit in the title of the third column in Table 31 is changed to "ng/cm²".

9. EAD Page 59, paragraph 2 – typo - "flower dust" should be "flowable dust"

DPR Response: This comment is followed, and "flower" is replaced with "flowable".

10. EAD Pages 61-66 - All hyperlinks to referenced DPR documents are broken

DPR Response: These documents were removed from the external website to comply with state regulations.

11. One reference link is missing (DPR 2020. California product/label database application homepage, Sacramento, CA)

DPR Response: The reference was linked to appropriate place in the EAD.

References:

AVMA 2012. U.S. Pet Ownership & Demographics Sourcebook (2012).

- AVMA 2019. AVMA Pet Ownership & Demographics Sourcebook 2017-2018 Edition.
- Bigelow-Dyk, M. M., Liu, Y., Chen, Z., Vega, H., and Krieger, R. I. 2012. Fate and distribution of fipronil on companion animals and in their indoor residences following spot-on flea treatments. *Journal of Environmental Science and Health, Part B* 47:913-924.
- de Fontenay, G., Campagna, J. F., Suberville, S., Birckel, P., and Weil, A. 1997a. Dislodgeable residues of fipronil following a topical application of Frontline® spot-on treatment to cats. Iselin, NJ: Merial Limited. (DPR Vol. No. 52062-224, Record No. 162592).
- DPR, 1996. Parameters defining insignificant exposure. HSM-96006. Worker Health and Safety Branch, Department of Pesticide Regulation.
- Honeycutt, R., and Kennedy, S. 2001. Determination of inhalation exposure to house occupants and pest control operators from fipronil during and after the application of Termidor® 80 WG as as termiticide treatment to homes. Research Triangle Park, NC: Aventis CropScience. (DPR Vol. No. 52062-0342, Record No. 200907).
- Jiang, W. 2022. Human exposure assessment for allyl isothiocyanate as soil fumigant. https://www.cdpr.ca.gov/docs/risk/rcd/aitc-final-exposure-assessment.pdf
- Mahler, B. J., Van Metre, P. C., Wilson, J. T., Musgrove, M., Zaugg, S. D., and Burkhardt, M. R. 2009. Fipronil and its degradates in indoor and outdoor dust. *Environmental science & technology* 43:5665-5670.
- Merricks, D. 1997. 2,4-D: carbaryl mixer/loader/applicator exposure study during application of RP-2 liquid (21%), Seven ready to use insect spray or Seven 10 dust to home garden vegetables. Research Triangle Park, NC: Rhone-Poulenc Ag Company. MRID 44459801. (DPR Vol. No. 142-0215, Record No. 175244).
- US EPA. 2001. Policy 9.1. Standard values for daily acres treated in agriculture.
- US EPA. 2012. Standard operating procedures for residential pesticide exposure assessment. (October, 2012). <u>https://www.epa.gov/sites/production/files/2015-08/documents/USEPA-opp-hed_residential_sops_oct2012.pdf</u>.

US EPA. 2020. Fipronil: Draft ecological risk assessment for registration review. (May, 2020). <u>https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0448-0071</u>.