PROBLEM FORMULATION/SCOPING SUMMARY DOCUMENT

FIPRONIL

Draft August 16, 2016

Background

In 2013, the Department of Pesticide Regulation (DPR) contracted with the National Academy of Sciences (NAS) to conduct an independent peer review of DPR's risk assessment practices. The National Research Council (NRC), an external committee of NAS, completed its review and issued its report including recommendations to improve DPR's risk assessment process and reports in April 2015. NRC recommended that DPR conduct a Problem Formulation/Scoping phase prior to drafting the risk assessment. During this phase risk managers and risk assessors meet and discuss the scope of the risk assessment for a specific pesticide. Information and data relevant to the pesticide is reviewed and evaluated to determine the scope of the risk assessment. The information and data evaluated includes toxicology, pesticide use reports, pesticide sales, illness reports, primary uses of the pesticide, exposure scenarios identified on the labels, potential exposure pathways, adverse effects reports, relevant United States Environmental Protection Agency (U.S.EPA) risk assessments, important sources of uncertainty and variability in the data, and mitigation options that should be evaluated in the risk assessment.

The problem formulation/scoping discussions result in a Problem Formulation/Scoping Summary Document, and a diagram of exposure pathways. These documents will be presented to the Pesticide Registration and Evaluation Committee for comment; then they will be posted to DPR's website for public comment. Any written comments submitted to DPR will be considered in the preparation of the Risk Characterization Document for fipronil.

Summary

1. **Reasons for fipronil to enter the risk assessment process:**
   a. DPR has concerns regarding toxicity in animal studies:
      - **Chronic toxicity**:
        - **Convulsions** and other neurological disturbances in rats and dogs
        - **Oncogenicity** in rats (thyroid tumors) and mice (liver tumors)
      - **Acute neurotoxicity** in rats (convulsions)

   b. No-Observed-Effects-Levels (NOELs) are low (0.02 – 0.05 mg/kg/day) for acute, subchronic and chronic exposures. The lower the NOEL, the greater the concern for adverse effects in humans if there is a potential for human exposure.

   c. As required by adverse effects disclosure requirements (FAC section 12825.5), fipronil registrants notified DPR of a relatively large number of alleged adverse effects incidents to human health occurring nationwide from 2002-2015 arising

predominantly from the use of fipronil in dog and cat spot-on products for flea and tick control. Although these incidents are typically self-reported by the public and are not confirmed to be attributed to actual fipronil use or exposure, they indicate a potential for human exposure and suggest that further investigation of fipronil is warranted.

2. **Fipronil's primary uses in California**
   a. treatment in and around structures for termites, roaches, and ants; and
   b. treatment of pets for fleas and ticks.

3. **The critical NOELs for fipronil are summarized in Table 1 below.**

Table 1. No-Observed-Effect-Levels (NOELs) for fipronil: Best available estimates as of February 2016.

Duration (Route)	DPR NOELs mg/kg/day	Critical Endpoint	USEPA NOELs mg/kg/day
Acute (all routes)	0.03	Developmental Toxicity Study (pregnant rabbit; oral); decreased body weight gain within 2 days of Treatment. LOEL = 0.1 mg/kg/day (King, 1990)	0.03 (oral) 0.05 (dermal) 0.05 (inhalation)
Subchronic (all routes)	0.05	Developmental Neurotoxicity Study (rat; oral, 25-day treatment); Decreased body weights of pups and delay in preputial separation in male pups (Mandella, 1995)	0.03 (oral) 0.05 (dermal) 0.05 (inhalation)
Chronic (all routes)	0.02	Chronic Study (rat; oral); increase In incidence and severity of Progressive nephropathy LOEL= 0.06 mg/kg/day (Aughton, 1993)	0.02 (all routes)

4. **Exposure scenarios to be considered in the exposure assessment.**

During application, dermal contact and inhalation are the primary routes of fipronil exposure. The exposure may occur during mixing and loading of suspension concentrate and granular products as well as application of all products (all formulations). Because fipronil has a low vapor pressure, inhalation exposure from gas phase fipronil is anticipated to be low. However, inhalation of aerosols during loading of granular products and during mixing and application of liquid formulation products may constitute a non-negligible exposure route to fipronil.

The major route of post-application exposure is expected to be dermal contact. Post-application exposure of young children through hand-to-mouth and object-to-mouth activities (i.e., non-dietary oral ingestion) should also be considered. In addition, available data on fipronil occurrence in surface water suggests possible exposure to swimmers (CDPR, 2015). The exposure routes for swimmers include inhalation, dermal and non-dietary oral ingestion.

Products with active registration in California are categorized based on 6 criteria: target site, formulation, application method, homeowner accessibility, personal protective equipment (PPE) requirement, and availability for indoor use (Table 2).

Table 2. Fipronil Products Categorized Based on Formulation and Label Requirements

Target site	Formulation	Application	Licensed user only?	PPE[a]?	Outdoor only?
Turf	RTU[b] granule	Broadcast	Yes	Yes	Yes
Dog/cat	RTU solution	Spot-on	No	No	No
Dog/cat	RTU solution	Spray	No	Yes[c]	No
Structure	RTU dust/powder	Injection	Yes	No	Yes
Structure	Liquid concentrate	Spray	Yes	Yes	Yes
Structure	RTU bait station	Placement	No	No	No
Structure	RTU gel	Spots along cracks/crevices	No	No	No

[a]PPE: personal protective equipment required by product labeling . Besides label requirements, California Code of Regulation requires most applicators to wear chemical resistant gloves and protective eyewear;
[b]RTU: ready-to-use; [c]: only gloves were mentioned in the labels.

Turf products

This represents ready-to-use (RTU) granule products used by licensed applicators to control imported fire ants (*Solenopsis spp.*). In California, the use is limited to the Coachella Valley in the months from April to September. PPE, including long sleeved shirts, long pants, waterproof gloves, shoes and socks, is required for loaders, applicators and persons who clean the application equipment. The potential primary exposure route for handlers is dermal contact and inhalation. The post-application scenarios involve both adults and children with routine outdoor activities. For adults, the exposure route is

dermal contact. For children, the exposure routes are dermal contact and non-dietary oral ingestion.

Structural products

-*Liquid concentrate.* This represents products used by licensed applicators to control structural pests such as termites. The products need to be diluted with water prior to application. Liquid concentrate products accounted for most (>95%) of the fipronil use in California. They can be applied for termite control during pre-construction (e.g., broadcast spray on surface to be covered beneath the concrete slab) and post-construction (e.g., trenching and rodding along exterior perimeter and in accessible crawl space). They can also be applied along the exterior foundation perimeter of homes to control invasive insects such as ants and spiders. They are not permitted for broadcast indoor applications. Labels require handlers to wear PPE, including long-sleeved shirts, long pants, socks, shoes, chemical resistant gloves and respirators. The potential exposure routes for handlers are dermal contact and inhalation. Bystander exposure is expected to be minimal since the labels do not allow any person to enter the treated area until sprays have dried. Post-application exposure of adults and children can occur via contact with the treated outdoor surfaces from routine outdoor activities. The exposure is expected to be minimal for adults since adults are expected to have minimal dermal contact with outdoor surfaces. Adult and children post-application exposures from routine indoor activities are possible due to fipronil transfer from outdoor to indoor areas.

-*Dust/powder.* This group represents RTU solid formulation in a non-refillable package for use with specially designed application equipment. The use of these products is limited to licensed applicators, and labels do not require PPE during application. The potential exposure routes for applicators are dermal contact and inhalation. Post-application exposure is expected to be low due to the non-accessible nature of the treated areas (e.g., voids) or low likelihood of building occupants in contact with treated areas (e.g., termite shelter tubes in crawl spaces) from routine activities.

-*Bait gel.* This represents RTU gel formulation and is applied via syringe by both licensed applicators and homeowners for spot treatment. These products can be used in both indoor and outdoor areas, and PPE is not required during application. The potential exposure route for handlers is dermal contact. Post-application exposure is expected to be minimal because of the low vapor pressure of fipronil, small treated areas and low application rates.

-*Bait station.* This represents RTU fipronil formulation in a secure reservoir. An applicator places these stations in areas with known or suspected pest activities, such as

along foraging trails and nesting sites. These products can be used in both indoor and outdoor areas, and PPE is not required during application. The potential handler and post-application exposure scenarios are expected to be the same as using bait gel, but the exposure amount is expected to be less.

Dog/Cat products

This contains the largest number of products registered in California. These pet products are used by both professional groomers and pet owners (adult only) to treat ticks, fleas and lice on cats and dogs. Based on the application methods, these products can be grouped into two categories: spot-on and spray.

Spot-on products are applied by squeezing a full tube of liquid onto the back skin of a dog or cat between its shoulder blades. For cat treatment, the products have only one size. For dog treatment, the products have four sizes based on body weight ranges (i.e., ≤22 lbs, 23-44 lbs, 45-88 lbs and 89-132 lbs). PPE is not required when applying spot-on products.

Spray products are RTU liquid formulations in pressurized or hand-trigger containers. The applicator ruffles the hair of a dog or cat with one hand while holding and applying a spray product in the other hand. For head and eye areas, the handler sprays the product on one hand and then gently rubs the product onto the hairs of the dog or cat. Rubber or latex gloves are required when applying the spray products.

The handler exposure scenarios involve adults, either pet owners or professional groomers, who use either a spray or spot-on product to treat dogs or cats. The potential exposure routes include inhalation and dermal contact, but the inhalation exposure to spot-on products is expected to be low. The post-application exposure scenarios involve an adult pet owner or a child in contact with the treated dog(s) or cat(s). For adults, dermal contact is the potential primary route of post-application exposure, while for children, the potential exposure routes are dermal contact and non-dietary oral ingestion.

Tables 3a and 3b. Criteria for selecting fipronil exposure scenarios for detailed analysis in DPR's forthcoming risk analysis.

5. **Diagram of Potential Exposure Pathways** - See attachment.

6. **Potential mitigation measures to be considered for evaluation in the risk assessment.** The following list includes recommendations received from stakeholders. The list is not intended to be complete. These potential mitigation measures only address the exposure scenarios that are ranked "high" within Table 3, and primarily focus on dermal exposure as current information indicates that to be the major route of fipronil exposure. DPR's Executive Office might consider mitigation measures for additional scenarios and/or additional exposure routes if the risk assessment indicates excessive risks.

   To make it convenient to compare to Table 3, the list of potential mitigation measures is divided into measures for applicators/handlers during the application, and measures for reentry by members of the public after the application.

6.1 Potential mitigation measures for applicators/handlers (during the application)

a. **Dog/cat products (both spot-on and spray):**
   i. Restrict use to only certified applicators (for example, by designating these fipronil products as California Restricted Materials).
   ii. Require additional PPE (spray product labels already require "rubber gloves", but spot-on products do not).
   iii. Reduce amount of AI applied per animal (by reducing product concentration, or reducing the size of area treated per animal, or both).
   iv. Reduce frequency of application (probably effective only for reducing chronic exposure).
   v. Cancel California registrations for all fipronil dog/cat products that are labeled for home use.

b. **Structural pest control products (liquid concentrate products for use only by licensed professionals).**
   i. Require additional PPE (labels already require "waterproof gloves," long sleeved shirts, long pants, and shoes plus socks).
   ii. Require stewardship training from registrants about the importance of using PPE.
   iii. Require engineering controls for mixing / loading. Could include requiring "tip 'n pour" spouts that currently are present on some but not all containers of liquid products. Could include packaging as water-soluble bags.
   iv. Prohibit overhead applications.
   v. Reduce amount of AI applied per structure (by reducing product concentration, or size of area treated per structure, or both).
   vi. Reduce frequency of application (probably effective only for reducing chronic exposure).

6.2 Potential mitigation measures for post-application reentry (high priority scenarios, dermal exposure)

a. Turf products, (granular for use only by licensees):

i. Increase restricted entry interval.
ii. Require posting of warning signs around treated areas.

b. Dog/cat products (both spot-on and spray):

Note that labels currently require separating treated animals from all other dogs and cats for 24 hours, but no requirement for separating from humans. Further, labels prohibit children from applying the product, but do not prohibit children from being nearby during the application.

i. Restrict use to only certified applicators (for example, by designating these fipronil products as California Restricted Materials).
ii. Establish requirement for a minimum time that must elapse between application and owners' contact with treated pet. Could include a longer time for children's contact.
iii. Require a minimum time during which children must be excluded from room in which application took place (to reduce potential transfer from contaminated surfaces).
iv. Reduce amount of AI applied per animal (by reducing product concentration, or reducing the size of area treated per animal, or both).
v. Reduce frequency of application per animal (probably effective only for reducing chronic exposure).
vi. Cancel California registrations for all fipronil dog/cat products that are labeled for home use.

c. Structural liquid concentrate products:

i. Increase label requirement for time that must elapse between application and allowing residents to enter treated areas.
ii. Require posting of warning signs on treated areas.
iii. Reduce amount of AI applied per structure (by reducing product concentration, or reducing size of area treated per structure, or both).
iv. Reduce frequency of application per structure (probably effective only for reducing chronic exposure). Most product labels already limit to two applications per property per year.

7. **<u>How DPR will address data gaps:</u>**
During the problem formulation phase, DPR has identified a few gaps in the exposure data for fipronil. DPR believes that filling these data gaps will avoid the use of generic data and/or surrogate exposure scenarios. Historically, generic data and surrogate exposure scenarios usually result in conservative exposure estimates and, therefore, unacceptable margins-of-exposure (MOE). However, in the absence of chemical-specific information, these data gaps are addressed as described below.

1. Turf granule products: The product labels suggest irrigating treated turf after application. There is no information on how irrigation of the treated turf affects child post-application exposure through episodic granule ingestion. Accordingly, DPR proposes to follow the procedure of episodic granule ingestion (i.e., without irrigation) in the U.S. EPA Standard Operation Procedures (SOP) for Residential Pesticide Exposure Assessment (USEPA, 2012).

2. Structural liquid concentrate products: Information on handler exposure via dermal and inhalation is not available. Hence, DPR proposes to employ a generic Pesticide Handlers Exposure Database (PHED) of low pressure hand wand mixer/loader/applicator (i.e., Scenario 22 as described in HS-1826 [Beauvais et al., 2007]) for use in assessing the handler exposure. Akin to the handler exposure, information on the post-application exposure of residential occupants (i.e., adults and children) is not available. Methods for characterizing the post application scenario are being developed.

3. Structural bait gel products: Information on the post-application exposure to residential occupants (i.e. adults and children) is not available. To characterize the post-application exposure, DPR proposes to employ a surrogate exposure scenario of indoor cracks and crevices as described in the U.S. EPA SOP for Residential Pesticide Exposure Assessment (USEPA, 2012).

4. Structural dust products: Information on the exposure of handler and post-application exposure of residential occupants (i.e., adults and children) is not available. To evaluate the handler exposure, DPR proposes to employ a surrogate exposure scenario of indoor plunger dusters as described in the U.S. EPA residential SOP (USEPA, 2012). Methods for characterizing the post application scenario are being developed.

5. Pet spray and spot-on products: The transfer rate of fipronil residue from treated dogs/cats to humans is not available. The derivation of the transfer rate is being

conducted by DPR based on studies submitted by the registrants and peer-reviewed open literatures.

In addition to the exposure assessment, data gaps exist for developing mitigation measures.

6. Structural liquid concentrate and dust products: For the handlers, no information is available on the work activities associated with the highest exposure. Also, for the residential bystander, there is no information on the highest exposure that results from different post-application behaviors.

8. <u>Analysis Plan.</u>

Based on the Problem Formulation, DPR (HHAB, WHS and EM Branches) plans to evaluate:

1. Potential exposure to applicators who apply fipronil products to turf, structural sites and companion animals (cats and dogs), and to residents (adults and children) who enter the treated areas or contact the treated surfaces after application. The exposure may occur through inhalation, dermal contact and/or non-dietary oral ingestion (for children only).
2. Potential exposure to humans (adults and children) who swim in a fipronil-contaminated surface water body. The major exposure routes are expected to be dermal contact and non-dietary oral ingestion. The concept model of these exposure scenarios is provided in an attachment.
3. Fipronil is not registered for use on crops in California. DPR plans to utilize the U.S. EPA dietary exposure assessment for food, but conduct a California specific drinking water exposure assessment.

The following data will be used to estimate human exposures during application and post-application of fipronil products:

- Data from the Pesticide Handlers Exposure Database (PHED) and the U.S. EPA Standard Operating Procedures for Residential Pesticide Exposure Assessment
- Data from published peer-review literature, pesticide registrants and/or consumer groups
- Data on fipronil use and sales in California
- Information provided on the labels of products that contain fipronil
- Data on fipronil environmental occurrences provided by the Environmental Monitoring Branch of DPR
- Physico-chemical properties of fipronil

For the Toxicology Profile and Hazard Identification, DPR/HHAB plans to identify the main toxicological effects and the points of departure (PoD) according to the relevant routes of exposure from the following databases:

- Toxicological studies submitted to DPR by the registrant or published in peer-reviewed literature
- Human Incident Data (DPR's Pesticide Illness Surveillance Program, PISP); Sentinel Event Notification System for Occupational Risks (SENSOR)-Pesticides program; case reports with fipronil self-poisoning, and Adverse Human Health Effects Reports
- U.S. EPA Toxicity Forecaster (ToxCast) high-throughput screening assays (HTS, including zebrafish) for indications of pathway disruptions that could lead to toxic outcomes.
- Existing human health risk assessments by other regulatory agencies (i.e., U.S. EPA, the Australian APVMA and the European Food Health Safety Agency, AFSSA/Environmental Health Safety Agency, AFSSE)

For risk characterization, DPR/HHAB will use the relevant PoDs and measured or estimated exposures to estimate non-cancer Margins of Exposure (MOEs) and/or cancer risk. These risk estimates will be compared to selected targets.

For Risk Appraisal, DPR/HHAB will inform the risk manager of the confidence it has in the risk estimates by discussing overall uncertainty and variability in the risk assessment.

Following review by the Office of Environmental Health Hazard Assessment (OEHHA) and U.S.EPA, DPR will respond to reviewers and generate a finalized risk assessment document.

9. Timeline for completion of the Risk Characterization Document (RCD).

The Human Health Assessment Branch plans to complete the draft RCD by December 2016.

10. References.

Aughton, P. 1993. M&B 46030*: Combined Oncogenicity and Toxicity Study by Dietary Administration to CD Rates for 104 Weeks Including a 13 Week Reversibility Period on Completion of 52 Weeks of Treatment*. Pharmaco-Life Science Research LTD., Eye Suffolk, UK. LRS Report 93/RHA432/0166. Vol. 52062-034.

California Department of Pesticide Regulation (CDPR), 2015. Surface Water Database (SURF). available at http://www.cdpr.ca.gov/docs/emon/surfwtr/surfcont.htm

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Mandella, R.C. 1995. *A Developmental Neurotoxicity Study of Fipronil in the Rat Via Dietary Administration*. Pharmaco–Life Science Research, Toxicology Services Worldwide, East Millstone, NJ. Study No. 93-4508. Vol. 52062-0367.

NRC (National Research Council). 2015. *Review of California's risk-assessment process for pesticides.* National Academy of Sciences, Washington D.D. 56 pp. Available at: http://www.nap.edu/catalog/21664/reviw-of-californias-risk-assessment-process-for-pesticides

11. Comments.

This Summary will be posted on DPR's website on our Risk Characterization Document page (http://www.cdpr.ca.gov/docs/risk/rcd.htm) for public viewing after being presented to the Pesticide Registration Evaluation Committee. Written comments may be sent to:

Risk Assessment – (Fipronil)
Attn: Ann Hanger
Pesticide Registration Branch
Department of Pesticide Regulation
1001 I Street, P.O. Box 4015
Sacramento, CA 95812-4015

Responses to written comments will be incorporated into the final Fipronil Risk Characterization Document.

Table 3a. Priority Decision for Handler Exposure Scenarios during Application

Exposure Scenario	Human receptor	Exposure based evidence					Use and illness based adjustment								Final priority decision
		Exposure estimate			Amount handled[d]	Preliminary priority decision[e]	Use restricted to licensed applicator[f]?	PUR data (Licensed use)		Sales data (if exempt from PUR)		Illnesses within CA (CalPISP[j])		Increase from preliminary priority decision?	
		Source of exposure estimate[a]	Label-required PPE deviated from default PPE[b]?	Exposure estimate[c]				Priority[g]	Source	Priority[h]	Source	% of Cases in 5 yrs[i]	Highest association		
Turf, Granule	Handler	DPR Scenario 27	No	High	Low	Medium	Yes	Low (< 10% of use)	2010-2014 PUR					No	Medium
Pet, Spray	Handler, Pet owner	EPA C-113	Yes (gloves)	High	Low	Medium	No			Low	Internal database, 2015	7% (1 / 15)	Probable	Yes	High
	Handler, Groomer	EPA C-113	Yes (gloves)	High	Low	Medium								Yes[k]	High
Pet, Spot-on	Handler, Pet owner	EPA C-130	No	High	Low	Medium	No			Low	Internal database, 2015	27% (4 / 15)	Definite	Yes	High
	Handler, Groomer	EPA C-130	No	High	Low	Medium								Yes	High
Structural, Dust	Handler	EPA C-32	No	High	Low	Medium	Yes	Low (< 10% of use)	2010-2014 PUR			7% (1 / 15)	Possible	No	Medium
Structural, Liquid concentrate	Handler	DPR Scenario 23	No	High	Medium	High	Yes	High (> 90% of use)	2010-2014 PUR			7% (1 / 15)	Possible	No	High
Structural, Bait gel	Handler	EPA 7-4	No	Low	Low	Low	No			Low	Internal database, 2015			No	Low
Structural, Bait station	Handler	EPA 7-4	No	Low	Low	Low	No			Low	Internal database, 2015			No	Low

Footnotes Table 3a:
a: Two references were used to determine exposure estimate: DPR, which represents DPR Memo HS-1826 (http://www.cdpr.ca.gov/docs/whs/pdf/hs1826.pdf), and EPA, which represents U.S.EPA Standard Operation Procedure (SOP) for Residential Pesticide Exposure Assessment (https://www.epa.gov/sites/production/files/2015-08/documents/usepa-opp-hed_residential_sops_oct2012.pdf).

b: Exposure estimates provided in DPR (HS-1826) and U.S. EPA SOP include description of PPE used (i.e., default PPE) when the exposure estimates were obtained. If the actual PPE of this specific scenario and specific pesticide is different from the default PPE, the exposure estimate will be lower (for actual PPE is more protective than default PPE) or higher (for actual PPE is less protective than default PPE).

c: Exposure estimates of >5000, 500-5000 and <500 µg/lb active ingredient were categorized as "High", "Medium" or "Low" respectively.

d: "High" represents handling of >100 ac area or >100 gallons of finished solution; "Medium" represents handling of 1-100 ac area or 1-100 gallons of finished solution; "Low" represents handling of <1 ac area or <1 gallon of finished solution.

e: Preliminary decision was based on "Exposure estimate" and "Amount handled". See the table below for details.

Exposure estimate	Amount handled	Preliminary priority decision
High	Low	Medium
High	Medium	High
High	High	High
Medium	Low	Medium
Medium	Medium	Medium
Medium	High	High
Low	Low	Low
Low	Medium	Medium
Low	High	Medium

f: If yes (i.e., products with use restricted to licensed applicators), use “PUR data"; If no (i.e., use of products not restricted to licensed applicators), use “Sales data”.

g: High, Medium or Low is assigned to a category that accounts for >50%, 10-50% or <10% use of the active ingredient. A "High" in "PUR data" will increase "Final priority decision" from "Preliminary priority decision” by one level.

h: High, Medium or Low was assigned to a category that account for >50%, 10-50%, or <10% sale of the active ingredient. Even though the percent active ingredient may be low in some products, substantial

sales of the low-percentage products cause the associated potential exposure to increase. Accordingly, a "High" in "Sales data" will increase "Final priority decision" from "Preliminary decision on exposure priority" by one level.

i: Intentional pesticide ingestion (e.g., suicide commitment) and any other illegal exposure was removed. The percentage sum of "% of cases" may not equal to 100% because some illness cases were not possible to determine the exposure scenario.

j: Observation of CalPISP case(s) with "Definite" or "Probable" association will increase "Final decision on exposure priority" by one level.

k: Pet groomers handler more pets per day than pet owner. Therefore, even though use and illness evidence did not suggest adjustments, we gave groomer exposure scenario the same priority decision as pet owner scenario.

Table 3b. Priority Decision for Reentry Exposure Scenarios after Application

Category	Human receptor	Exposure based evidence					Use and illness based adjustment								Final priority decision
		Transfer coefficient			Child involved?[d]	Preliminary priority decision[e]	Use restricted to licensed applicator?[f]	PUR data (Licensed Use)		Sales data (if exempt from PUR)		Illnesses within CA (CalPISP)[j]		Increase from preliminary decision?	
		Source of transfer coefficient[a]	Transfer coefficient[b]	Exposure duration[c]				Priority[g]	Source	Priority[h]	Source	% of Cases in 5 yrs[i]	Highest Association[j]		
Turf, Granule	Reentry, Adult	EPA 3-9	High	Medium	No	High	Yes	Low (< 10% of use)	2010-2014 PUR					No	High
	Reentry, Child	EPA 3-9	High	Medium	Yes	High								No	High
Pet, Spray	Reentry, Adult	EPA 8-7	High	Low	No	Medium	No			Low	Internal database, 2015			No	Medium
	Reentry, Child	EPA 8-7	Medium	Medium	Yes	High						13% (2 / 15)	Probable	Yes	High
Pet, Spot-on	Reentry, Adult	EPA 8-7	High	Low	No	Medium	No			Low	Internal database, 2015			No	Medium
	Reentry, Child	EPA 8-7	Medium	Medium	Yes	High						20% (3 / 15)	Probable	Yes	High
Structural, Dust	Reentry, Adult	Professional judgement	Low	Low	No	Low	Yes	Low (< 10% of use)	2010-2014 PUR			13% (2 / 15)	Probable	Yes	Medium
	Reentry, Child	Professional judgement	Low	Low	Yes	Medium								No	Medium
Structural, Liquid concentrate	Reentry, Adult	EPA 7-24[k]	High	Low	No	Medium	Yes	High (> 90% of use)	2010-2014 PUR			40% (6 / 15)	Probable	Yes	High
	Reentry, Child	EPA 7-24	Medium	Low	Yes	High								No	High
Structural, Bait gel	Reentry, Adult	EPA 7-24	High	Medium	No	High	No			Low	Internal database, 2015			No	High
	Reentry, Child	EPA 7-24	Medium	Medium	Yes	High								No	High
Structural, Bait station	Reentry, Adult	Professional judgement	Low	Low	No	Low	No			Low	Internal database, 2015	7% (1 / 15)	Possible	No	Low
	Reentry, Child	Professional judgement	Low	Low	Yes	Low								No	Low
Public	Swimmer, Adult	N/A	N/A	N/A	No	Low[l]								No	Low
	Swimmer, Child	N/A	N/A	N/A	Yes	Low								No	Low

Footnotes Table 3b:
a: Transfer coefficient was obtained primarily from U.S.EPA Standard Operation Procedure for Residential Pesticide Exposure Assessment (https://www.epa.gov/sites/production/files/2015-08/documents/usepa-opp-hed_residential_sops_oct2012.pdf).

b: Transfer coefficients of >5000, 1000-5000, and <1000 cm^2/hr were categorized as "High", "Medium" and "Low," respectively.

c: Exposure times of >4, 1-4 and <1 h were categorized as "High", "Medium" and "Low," respectively.

d: If the human receptor is a child/toddler, the preliminary priority decision will be increased by one level from the decision based on transfer coefficient and exposure duration (e.g., increase from "Medium" to "High"). The only exception is when the pesticide is in a closed container, such as bait station.

e: Preliminary decision was based on both "Transfer coefficient" and "Amount handled". See the table below for details.

Transfer coefficient	Exposure duration	Preliminary priority decision
High	Low	Medium
High	Medium	High
High	High	High
Medium	Low	Medium
Medium	Medium	Medium
Medium	High	High
Low	Low	Low
Low	Medium	Medium
Low	High	Medium

f: If yes (i.e., products with use restricted to licensed applicators), use “PUR data"; If no (i.e., use of products not restricted to licensed applicators), use “Sales data”.

g: High, Medium or Low is assigned to a category that accounts for >50%, 10-50% or <10% use of the active ingredient. A "High" in "PUR data" will increase "Final priority decision" from "Preliminary priority decision" by one level.

h: High, Medium or Low was assigned to a category that accounts for >50%, 10-50%, or <10% sale of the active ingredient. Even though the percent active ingredient may be low in some products, substantial sales of the low-percentage products may cause the associated potential exposure to increase. Accordingly, a "High" in "Sales data" will increase "Final priority decision" from "Preliminary decision on exposure priority" by one level.

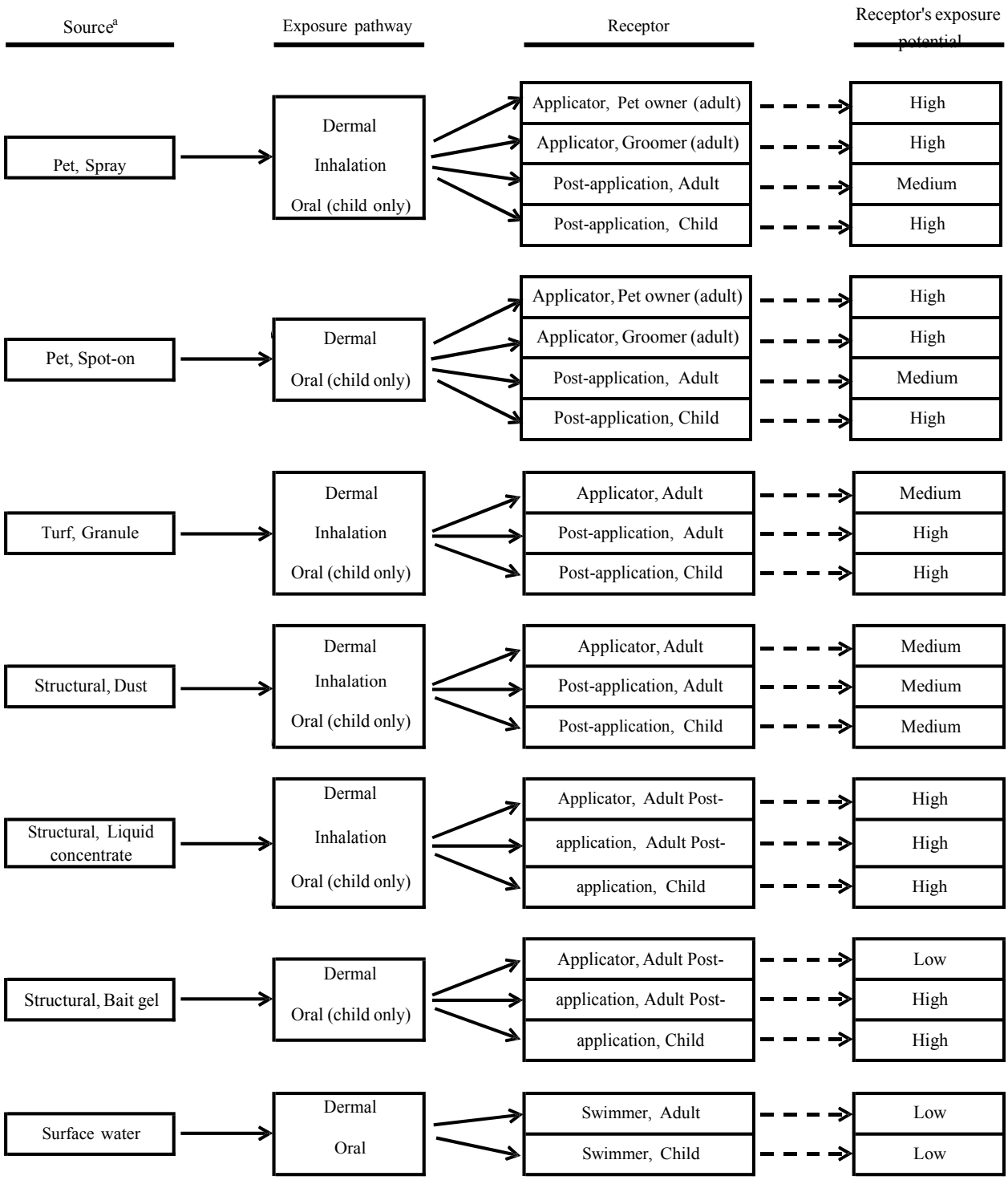
i: Intentional pesticide ingestion (e.g., suicide commitment) and any other illegal exposure were removed. The percentage sum of “% of cases” may not equal to 100% because some illness cases were not possible to determine the exposure scenario.

j: Observation of CalPISP case(s) with "Definite" or "Probable" association will increase "Final priority decision" from "Preliminary priority decision" by one level.

k: No reference is available. Indoor hard surface was used as surrogate. The exposure duration was determined as low because of less time spent in outdoor areas than indoor areas.

l: Swimmer exposure will be categorized as "High" or "Low" based on whether this pesticide is allowed to be applied directly to natural water bodies. Also child shares the same exposure routes (dermal and oral) as adult, so child exposure scenario will not be offered a higher priority.

Potential Exposure Pathways for Fipronil



a: This document includes all fipronil exposure sources, except the exposure from (1). bait station, for which the exposure is considered negligible, and (2). food and drinking water.