PESTICIDE REGISTRATION
AND EVALUATION COMMITTEE (PREC)
Meeting Minutes –August 19, 2016

Committee Members/Alternates in Attendance:

Charles Salocks, Office of Environmental Health Hazard Assessment (OEHHA)
Eric Lauritzen, California Agricultural Commissioners and Sealers Association (CACASA)
James Seiber, University of California, Department of Toxicology
Liz Pelham, Department of Pesticide Regulation (DPR)
Lynn Baker, Air Resources Board (ARB)
Patti TenBrook, U.S. Environmental Protection Agency (EPA), Region 9 –via webcast
Perry Poe, California Department of Food and Agriculture (CDFA)
Rebecca Sisco, University of California, IR-4 Program
Rich Breuer, State Water Resources Control Board (SWRCB)

Visitors in Attendance:

Anne Katten, California Rural Legal Assistance Foundation
Arthur Lawyer, Technology Sciences Group, Inc.
Bryan Eya, OEHHA
Darren Van Steenwyk, Clark Pest Control
James Nakashima, OEHHA
Katherine Sutherland-Ashley, OEHHA
Laura Whatley, BASF Corporation –via webcast
Lori Lim, OEHHA
Rachel Kubiak, Western Plant Health Association (WPHA)
Rima Woods, OEHHA
Terry Davis, UNIVAR Environmental Sciences

DPR Staff in Attendance:

Amy Budahn, Environmental Monitoring Branch
Andi Cameron, Pesticide Registration Branch
Andy Rubin, Human Health Assessment Branch
Ann Hanger, Pesticide Registration Branch
Emma Wilson, Worker Health and Safety Branch
Eric Kwok, Human Health Assessment Branch
Gregory Wroblicky, Worker Health and Safety Branch
Jeanne Martin, Enforcement Branch
Jesse Cuevas, Office of Legislation and Policy
Jill Townzen, Office of Legislation and Policy
John Sanders, Pesticide Programs Division

Cont. DPR Staff in Attendance:

Jolynn Mahmoudi-Haeri, Pesticide Registration Branch
Kelsey Craig, Environmental Monitoring Branch
Kevin Solari, Worker Health and Safety Branch
Leona Scanlan, Human Health Assessment Branch
Lisa Ross, Worker Health and Safety Branch
Marylou Verder-Carlos, Pesticide Programs Division
Mike Zeiss, Worker Health and Safety Branch
Shelley DuTeaux, Human Health Assessment Branch
Susan McCarthy, Product Compliance Branch
Svetlana Koshlukova, Human Health Assessment Branch
Terry Barry, Human Health Assessment Branch
Weiying Jiang, Human Health Assessment Branch

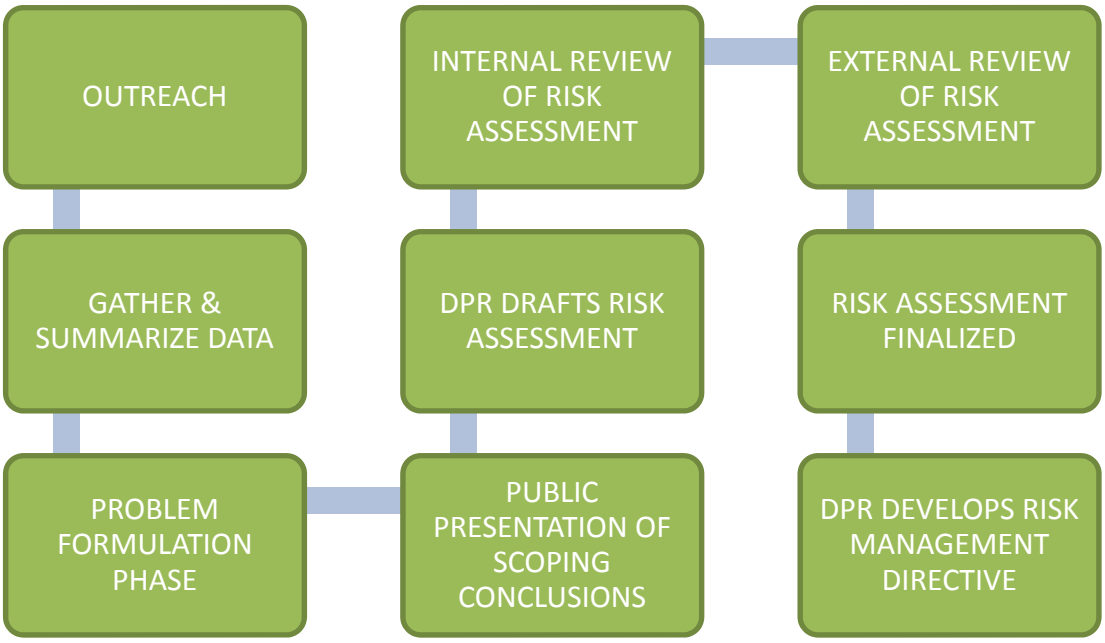
1. **Introductions and Committee Business –Liz Pelham, Acting Chair, DPR**

About forty-one (41) people attended the meeting.

2. **Risk Assessment on Fipronil; DPR's New Process –John Sanders, DPR**

In 2013, the Department of Pesticide Regulation (DPR) contracted with the National Academy of Sciences (NAS) to peer review DPR's risk assessment practices. NAS completed the review in 2015 with several recommendations to DPR. One recommendation included DPR conducting a "Problem Formulation/Scoping Phase" prior to drafting a Risk Characterization Document (RCD). DPR is currently in the problem formulation phase of a risk assessment on fipronil.

Chart 1. Risk Assessment Process.



The problem formulation phase will determine the scope of the RCD. Additionally, risk assessors and risk managers meet to identify the components of the RCD. This phase will determine the endpoints to consider, the exposure scenarios to include or exclude, mitigation options to be included or excluded, and a description of uncertainties. At this point, information and data can be provided by stakeholders, including registrants, users, and county agricultural commissioners.

Chart 2. Problem Formulation Phase.

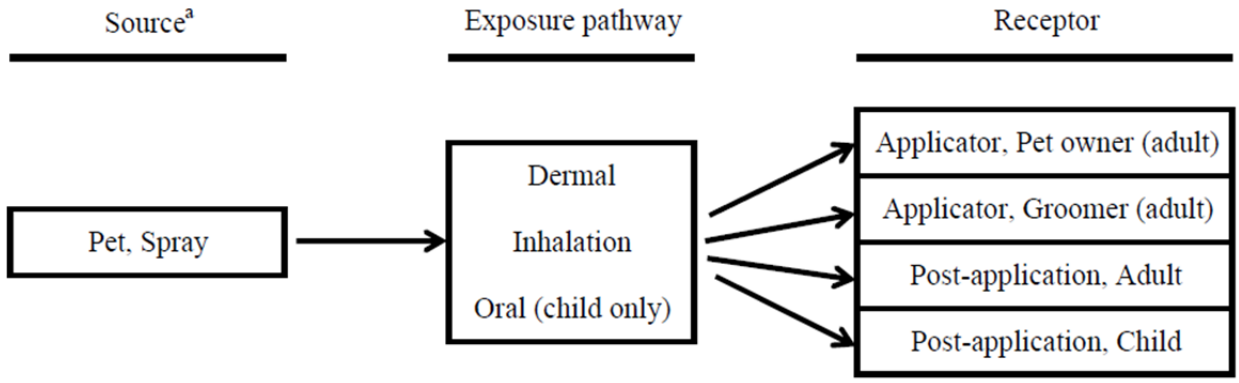
DPR initiated the risk assessment of fipronil due to the potential for human exposure and concerns regarding toxicity in animal studies. Furthermore, fipronil registrants notified DPR of large number of alleged adverse effects in humans (2002-2015) from use of spot-on flea and tick control products. Animal studies in rats indicate an acute neurotoxicity in rats (convulsions) and other neurological disturbances in rats and dogs, and oncogenicity in rats (thyroid) and mice (liver). There were low No-Observed-Effect Levels (NOELs). The lower the NOEL, the greater the concern is for adverse effects in humans. The primary uses of fipronil in California include: treatment in and around structures for termites, roaches, ants, treatment of pets for fleas and ticks. There is one registered product for agricultural use in California (turf). DPR is only considering fipronil products that are actively registered in California and exposures from legal fipronil use as described in the product labels registered in California.

Table 1. Fipronil Products in California.

Target site	Formulation	Application	Licensed user only?	Personal Protective Equipment?	Outdoor Only?
Turf	Ready-to-use granule	Broadcast	Yes	Yes	Yes
Dog/cat	Ready-to-use solution	Spot-on	No	No	No
Dog/cat	Ready-to-use solution	Spray	No	Yes	No
Structure	Ready-to-use dust/powder	Injection	Yes	No	Yes
Structure	Liquid concentrate	Spray	Yes	Yes	Yes
Structure	Ready-to-use bait station	Placement	No	No	No
Structure	Ready-to-use gel	Cracks/crevices	No	No	No

DPR is considering the potential human receptor for each scenario including the handler (persons mixing, loading, transferring and/or applying fipronil), persons entering fipronil-treated area or contacting treated objects, and the general population (persons exposed from contaminated air, soil, and/or water). A conceptual model illustrates the sources, receptors and exposure pathways, and clarifies steps needed for exposure calculation.

Chart 3. Conceptual Exposure Model.



DPR is screening all exposure scenarios and identifying the exposure scenarios with high potential exposure to humans at different life stages (i.e., children and adults). DPR is prioritizing resources by focusing on the exposure scenarios most significant to California. Scenarios will be classified based on their exposure potential. Exposure potential evaluation is based on U.S. EPA Standard Operating Procedure for Residential Pesticide Exposure Assessment, Surrogate Handler Exposure Estimates for Use in Assessments (HS-1826), exposure assessment document of other pesticide(s) with similar uses, and peer review literature and professional judgements. Scenarios with significant use/sales in California or with illness cases reported will be assigned higher prioritization.

Mitigation measures must be efficacious and feasible. For post-application turf products, mitigation measures could include increasing restricted entry intervals and/or requiring warning signs be posted. For applicators and handlers of structural products, mitigation measures could include requiring additional personal protective equipment, engineering controls for mixing/loading, reducing the amount applied per structure, and/or reducing the frequency of application. For post-application structural products, mitigation measures could include increasing the reentry interval for residents, requiring warning signs be posted, and/or reducing the amount applied per structure. For applicators and handlers of pet products, mitigation measures could include requiring personal protective equipment, reducing the amount applied per animal, reducing the frequency of application (effective only for chronic exposure), and/or restricting use to certified applicators. For post-application pet products, mitigation measures could include requiring time between treatment and children contact with pet, requiring time when children are excluded from the treatment room, reducing the amount applied per animal, reducing the frequency of application, and/or restricting use to certified applicators. If risks from pet products cannot be mitigated, then cancellation will be considered.

DPR will evaluate potential exposure to applicators, handlers, and residents, evaluate data sources to estimate human exposure, evaluate data sources for toxicology profile and hazard identification, and estimate non-cancer margins of exposure and cancer risk. Additionally, DPR will inform the Risk Manager of the confidence the Risk Assessor has in the risk estimates and respond to comments from U.S. EPA and OEHHA reviewers. DPR anticipates a draft to be completed by December 2016. Questions can be sent to Senior Environmental Scientist (Specialist), Ann Hanger, at <Ann.Hanger@cdpr.ca.gov> or by telephone at 916-324-3535. Written comments can be sent to the following address:

Department of Pesticide Regulation
Pesticide Registration Branch
Attn: Ann Hanger
1001 I Street, P.O. Box 4015
Sacramento, California 95812-4015

3. Committee Comment

Rich Breuer inquired whether the sales data exempt from the PUR is able to link quantity of use with exposure. John Sanders stated DPR is relying on sales data. Rich Breuer further inquired if the sales data is regional enough to identify population exposure. John Sanders stated yes.

James Seiber asked if there are any precautions or steps to take when washing a treated pet to keep the product out of public waterways. John Sanders stated DPR has an initiative to address the environmental contamination of fipronil; however, the Risk Characterization Document focuses on human health issues.

Rebecca Sisco inquired how the public swimmer category relates to fipronil use. John Sanders stated fipronil has been detected in California surface water and is being considered by DPR due to the potential exposure.

Lynn Baker asked what chemical DPR is planning to conduct a risk assessment on after fipronil. John Sanders stated DPR just started a risk assessment on cyfluthrin.

Charles Salocks requested clarification of "exposure-based criteria." Weiying Jiang stated DPR is currently using U.S. EPA's policies published in 2012. Exposure is based on the specific activity and time of exposure. Charles Salocks further requested clarification on restricting use to certified applicators and DPR Enforcement stating this "might be a prerequisite for any measures for pet products." John Sanders stated DPR Enforcement is stating the first step may be to classify fipronil as a restricted material.

Rich Breuer stated the information and data used in conducted a Risk Characterization Document could be useful to SWRCB.

4. Public Comment

A person in attendance inquired if the information presented is more relevant to the exposure assessment document. John Sanders stated DPR combines the hazard identification and the exposure assessment document into the risk characterization document.

Arthur Lawyer asked if DPR has reviewed U.S. EPA's risk assessment on fipronil. John Sanders stated U.S. EPA has not completed a risk assessment on fipronil. DPR will consider U.S. EPA's risk assessment on fipronil once completed. Marylou Verder-Carlos stated DPR has been in contact with U.S. EPA.

Anne Katten expressed concern regarding the critical endpoints. John Sanders stated DPR is currently determining the scope of the Risk Characterization Document and nothing is final. Anne Katten inquired if the endpoints will be reviewed by OEHHA. John Sanders stated yes. Anne Katten expressed concerns regarding excluding certain scenarios too early. John Sanders stated DPR is considering information and data from all stakeholders.

Anne Katten asked why fipronil granules are excluded from the risk characterization. John Sanders stated the registered products are only used at certain times during the year and in certain counties for fire ants. Anne Katten commented fire ants are a growing problem and the use could increase in the future. John Sanders stated at this point, fipronil granules have low sales in California and U.S. EPA does not use fipronil in the control of fire ants. Anne Katten commented if the use were to increase, then it should be included in the evaluation.

5. Agenda Items for Next Meeting

The next meeting is scheduled for Friday, October 21, 2016 at 10:00 a.m. in the Sierra Hearing Room on the second floor of the CalEPA building, located at 1001 I Street, Sacramento, California.

6. Adjourn