



**PESTICIDE REGISTRATION  
AND EVALUATION COMMITTEE (PREC)  
Meeting Minutes – March 19, 2021**

**Committee Members/Alternates in Attendance:**

Amalia Neidhardt – Department of Industrial Relations (DIR)  
Dave Tamayo – Structural Pest Control Board (SPCB)  
David Ting – Office of Environmental Health Hazard Assessment (OEHHA)  
Heather Williams – Department of Resources Recycling and Recovery (CalRecycle)  
Jaime Rudd – Department of Fish and Wildlife (DFW)  
James Seiber – University of California (UC), Davis, Department of Environmental Toxicology  
Karen Morrison – Department of Pesticide Regulation (DPR)  
Kevi Mace – California Department of Food and Agriculture (CDFA)  
Lynn Baker – Air Resources Board (ARB)  
Rich Breuer – State Water Resources Control Board (SWRCB)  
Ruben Arroyo – CA Agricultural Commissioners and Sealers Association (CACASA)  
Valerie Hanley – Department of Toxic Substances Control (DTSC)

**Visitors in Attendance:**

*Note: Only attendees who identified themselves using their full name are listed below*

Anne Katten – California Rural Legal Assistance Foundation  
Brian Moore – California Air Resources Board (CARB)  
Emily Marquez  
Emily Saad – Exponent  
James Nakashima – Office of Environmental Health Hazard Assessment (OEHHA)  
Jeff Holmsen  
Jessica Jones  
Jing Tao – Office of Environmental Health Hazard Assessment (OEHHA)  
Katherine Sutherland-Ashley – Office of Environmental Health Hazard Assessment (OEHHA)  
Katy Hernandez  
Kelly Moran – TDC Environmental  
Matt McCoole  
Megan McKay – California Air Resources Board (CARB)  
Michael Zeiss  
Renee Pinel  
Ryan Weidling – Exponent  
Sarah Aird – Californians for Pesticide Reform  
Stephanie Hughes – Bay Area Clean Water Agencies (BACWA)  
Tammy Qualls  
Thomas Ineichen

**DPR Staff in Attendance:**

Aimee Norman – Integrated Pest Management Branch  
Aisha Iqbal – Pesticide Registration Branch  
Aniela Burant – Environmental Monitoring Branch  
Anna Kalashnikova – Human Health Assessment Branch  
Brandon Brown – Human Health Assessment Branch  
Brenna McNabb – Pesticide Registration Branch  
Brian Portoni – Pesticide Evaluation Branch  
Brittanie Clendenin – Pesticide Registration Branch  
Christopher DeMars – Human Health Assessment Branch  
Emily Bryson – Worker Health and Safety Branch  
Eric Kwok – Human Health Assessment Branch  
Francie Bishop – Pesticide Registration Branch  
Jennifer Teerlink – Environmental Monitoring Branch  
Kara James – Pesticide Registration Branch  
Kim Truong – Human Health Assessment Branch  
Laura Benn – Pesticide Registration Branch  
Leona Scanlan – Human Health Assessment Branch  
Minh Pham – Environmental Monitoring Branch  
Mitra Geier – Human Health Assessment Branch  
Peter Lohstroh – Human Health Assessment Branch  
Puttappa Dodmane – Human Health Assessment Branch  
Qiaoxiang Dong – Human Health Assessment Branch  
Shelley DuTeaux – Human Health Assessment Branch  
Svetlana Koshlukova – Human Health Assessment Branch  
Val Dolcini – Director’s Office  
Weiyang Jiang – Human Health Assessment Branch

**1. Introductions and Committee Business – Karen Morrison, Chair, DPR**

- a. Approximately fifty-seven (57) people attended the meeting.
- b. DPR has submitted three budget change proposals (BCPs) related to the tracking and reporting of chlorpyrifos applications, the relaunch of the California Pesticide Electronic Submission Tracking system (CalPEST), and the proposed change to the mill assessment.
- c. DPR recently released the [2021 rulemaking calendar](https://cdpr.ca.gov/docs/legbills/rule_calendar_2021.pdf).  
<cdpr.ca.gov/docs/legbills/rule\_calendar\_2021.pdf>
- d. DPR held IPM achievement awards in February and is in the process of launching the [Sustainable Pest Management Workgroup](https://cdpr.ca.gov/docs/pressrls/2021/031021.htm) <cdpr.ca.gov/docs/pressrls/2021/031021.htm>

**2. Disinfectants and Emerging Viral Pathogens: Registration and Evaluation Update – Aisha Iqbal and Brian Portoni, DPR**

***General Overview of Antimicrobial Products and Viral Workloads in 2020:***

Coronavirus Disease 2019 (COVID-19) is a contagious disease caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV2). Antimicrobial pesticides are essential public health tools to fight against pathogenic microorganisms. These pesticides are substances or mixtures of substances used to destroy or suppress the growth of harmful microorganisms, such as bacteria, viruses, or fungi on inanimate objects and surfaces. Antimicrobial products contain roughly 275 different active ingredients and are marketed in several formulations such as sprays, liquids, concentrated powders, and gasses. Approximately one billion dollars are spent each year on antimicrobial products. More than 5,000 such products are currently registered with the U.S. EPA and sold in the marketplace. These pesticides have two major uses: they disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or they protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime.

The California Department of Food and Agriculture (CDFA) began to review antimicrobial products soon after the adoption of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) in 1972. In the 1990s, DPR was formed as a department separate from CDFA, and in 1999, DPR began allowing companies to submit concurrent applications for products classified by U.S. EPA as “Public Health Pesticides” or “Antimicrobial Pesticides”. Today, the Pesticide Registration Branch (PRB) within DPR processes applications for public health and non-public health antimicrobial pesticides. Scientists with expertise in microbiology in the Pesticide Evaluation Branch of DPR review scientific data to determine if antimicrobial products are efficacious.

Antimicrobial pesticides can be categorized as either public health pesticide products or non-public health pesticide products. The most common public health pesticide products are sterilizers, which destroy or eliminate all forms of microbial life in the inanimate environment, including all forms of bacteria, fungi, fungal spores, and viruses. These products are commonly used in hospitals, laboratories, and similar environments where sterilization is crucial. A disinfectant is a mixed substance or mixture of substances that destroys or irreversibly inactivates the bacteria, fungi, and viruses, but not the fungal spores, and is stronger in efficacy than a sanitizer. A sanitizer reduces the microorganisms in the inanimate environment by significant numbers, but does not destroy or eliminate all microorganisms. Other public health pesticide products include germicides, fungicides, virucides, and tuberculocides. Non-public health pesticide products are used to control the growth of microorganisms of economic and aesthetic significance and are not considered to be human-health related. This general category includes products used in cooling towers, jet fuel, paints, and treatments for textile and paper products.

The best disinfectants for viruses are alcohol, bleach, hydrogen peroxide, and quaternary ammonium compounds. These active ingredients are the most common on the U.S. EPA's list of registered disinfectants against the coronavirus. Alcohols such as isopropanol or ethanol are effective disinfectants when used at a high enough concentration. The active ingredient in bleach is sodium hypochlorite, which can kill viruses, bacteria, and fungi. Hydrogen peroxide is not as strong as bleach, but does have disinfectant properties that effectively kill viruses and bacteria. Quaternary ammonium compounds are widely used as surface disinfectants and can be found in many household cleaners, including disinfectant wipes and sprays. Other active ingredients on the U.S. EPA list are phenolic, lactic acid, and citric acid.

In early March 2020, U.S. EPA released List N: Disinfectants for Coronavirus (COVID-19). A disinfectant on List N means U.S. EPA expects the product to be effective against SARS-CoV-2 (COVID-19) on surfaces, when used according to the label directions. The initial list contained approximately 90 products and is updated weekly, now surpassing over 500 products.

Emerging viral pathogens are viruses that cause an infectious disease that have appeared in a human or animal population for the first time, or that may have existed previously but are rapidly increasing in incidence or geographic range. SARS-CoV-2, the coronavirus that causes COVID-19, is a pathogenic virus. The qualifying product label should have a disinfectant efficacy claim against at least one of the following viral pathogen groupings: enveloped virus, large non-enveloped virus, or small non-enveloped virus.

DPR is currently prioritizing applications for disinfectant products that appear on U.S. EPA's List N. Applicants wishing to register disinfectant products should note on the cover letter that the product is included on List N. Additionally, according to DPR, applications for additional brand names and supplemental distributor products of disinfectants on List N are also eligible for prioritization. PRB has processed over 600 expedited packages in 2020.

DPR has processed over 250 new product applications in 2020, including master labels, alternate/additional brand names, and supplemental distributors. A master label contains most or all U.S. EPA accepted uses, but is not intended for marketing, sale, or use in California. Antimicrobial companies submitted applications to register new master labels to PRB for concurrent submissions with U.S. EPA. The new master labels included emerging viral pathogen claims. In 2020, PRB processed a number of alternate brand names of spray, wipes, and laundry disinfectant products to add SARS-CoV-2 (COVID-19) claims or surrogate viruses. Supplemental distributors, referred to as sub-registrants, may distribute or sell another registrant's product instead of or in addition to their own. In 2020, a number of new companies applied for product registrations to sell or distribute a primary registrant's disinfectant product.

In order to address COVID-19 claims on already registered products, DPR received around 350 applications for label amendments in 2020. The requested changes were typically to add or revise emerging viral pathogens; add SARS-CoV-2 claims, use directions, and contact times in end use labels; add marketing claims and/or graphics related to COVID-19; add additional

container sizes to already registered products; change the storage and disposal sections of disinfectant labels; or submit new product sizes, such as travel size disinfectants.

Section 18 of FIFRA authorizes U.S. EPA to allow Emergency Exemptions (also called “Section 18s”) for unregistered uses of pesticides to address emergency conditions. If granted, such exemptions would allow the use of non-registered pesticides or the “off-label” uses of a registered pesticide for a specified time period. Both U.S. EPA and DPR must conduct assessments of potential risks to human health and the environment to ensure the pesticide use meets the required safety standards. In order to address coronavirus disinfection, DPR is currently reviewing two Section 18 requests. The first is for the use of Grignard Pure, which contains Triethylene Glycol (TEG). This product is unique in its ability to control the spread of COVID-19 viral particulates in the air through a fogging treatment. The second is for the use of SurfaceWise 2, which contains dimethyl octadecyl 3-(trimethoxysilyl) and propyl ammonium chloride. This product has long-term residual activity to kill COVID-19 particulates on various hard, non-porous surfaces.

The Microbiology Program of the Pesticide Evaluation Branch handles the scientific evaluation of data related to various label changes such as adding or revising the emerging viral pathogen claims, adding SARS-CoV-2 (COVID-19) claims, and adding surrogate viruses to the label. It is important to note that Human Coronavirus and SARS-CoV-2 claims are not the same. In addition to standard data requirements that apply to all pesticides, pesticides designed to control microbial pests, such as viruses and bacteria, must have data proving the efficacy, or ability to kill these pests. The Microbiology Program is currently reviewing data for SARS-CoV-2 Strain: USA-WA1/2020 of SARS-CoV-2 (COVID-19) for use on product end-use labels as well as master labels. At this time, DPR is not allowing the use of surrogates for the addition of SARS-CoV-2 efficacy claims.

#### ***Emerging Viral Pathogens 2009-H1N1 to COVID-19:***

The Microbiology Program of DPR’s Pesticide Evaluation Branch reviews antimicrobial efficacy data for both health based and non-health/industrial based antimicrobial products. The program is also responsible for reviewing microbial chemistry data for bacteria-, fungi-, and virus-based pesticide products. In a given year, the program typically reviews nearly 200 pesticide products. However, in 2020 that number increased to 248 products, with roughly half of those consisting of expedited product reviews.

Some of the commonly reviewed antimicrobial products can be categorized as sterilants, disinfectants, sanitizers, or virucides. U.S. EPA defines sterilants as pesticide products that result in  $\geq 6$  LOG<sub>10</sub> reduction of microorganisms and spores, resulting in no viable microorganisms/spores on a hard, non-porous surface after use according to the label directions. Disinfectants are products that result in  $\geq 5$  LOG<sub>10</sub> reduction of bacteria, sanitizers result in  $\geq 3$  LOG<sub>10</sub> reduction of bacteria, and virucides result in  $\geq 3$  LOG<sub>10</sub> reduction of viral particles.

As mentioned briefly in the previous section, viruses can be grouped into three categories: small, non-enveloped viruses; large, non-enveloped viruses; and enveloped viruses. Small, non-enveloped viruses are highly resistant to virucides and are basically protein capsids with DNA or RNA. A common example of this category is norovirus. Large, non-enveloped viruses are modestly resistant to virucides and also consist of protein capsids with DNA or RNA. Common examples of this type of virus are adenovirus, rotavirus, and papillomavirus. Enveloped viruses are the least resistant to virucides, and consist of a phospholipid bilayer originating from the host cell with protein capsid that encloses DNA or RNA within. Common examples of this group include human immunodeficiency virus (HIV), influenza, hepatitis, and coronavirus.

There have been several recent emerging viral pathogens of note, starting in 2001 with Influenza Virus Type-A Strain: A/Mexico/4108/2009 (Novel H1N1), which became a pandemic. Another example is the Ebola Virus Strain: Zaire-Kikwit (EBOV), which transitioned from typically being transmitted in rural areas to being spread in urban areas, constituting a change in geographic range. There have also been several recent coronavirus outbreaks in recent past. These are bat-derived viruses that infect a secondary host before being transmitted into humans. Severe Acute Respiratory Syndrome Associate Coronavirus (SARS-CoV-1) is believed to have been transmitted from bat to civet cat to humans. Middle East Respiratory Syndrome Coronavirus (MERS-CoV) was transmitted from a bat to an unknown secondary host, which led to transmission to camels and then to humans. Recently, Severe Acute Respiratory Syndrome Related Coronavirus (SARS-CoV-2) originated in a bat host, transmitted into an unknown secondary host, and eventually was transmitted to humans.

In 2009, there was an outbreak of Influenza A virus, which has a serotype of H1N1. At the time the virus was detected in April 2009, there were no pesticide products registered for control of the virus. U.S. EPA allowed any Influenza A virus efficacy data to be used to support 2009-H1N1 Influenza A Virus efficacy claims. U.S. EPA also issued guidance for testing and labeling claims against pandemic 2009 H1N1 Influenza A Virus (formerly called swine flu). California issued comparable guidance in CA Notice 2009-09. U.S. EPA followed a similar process when confronted with an outbreak of the Ebola virus in 2014, establishing List L: Disinfectants for Use Against the Ebola Virus. The coronavirus outbreaks originated in China in 2002 (SARS-CoV-1), Saudi Arabia in 2012 (MERS-CoV), and China in 2019 (SARS-CoV-2).

The Centers for Disease Control and Prevention (CDC) declared SARS-CoV-2 an “Emerging Viral Pathogen” on January 29, 2020. At this time, U.S. EPA initiated the Emerging Viral Pathogen Program, originally established in August 2016, to handle the problem of having no disinfectant or sanitizing products registered for use against a novel pathogen during an active outbreak. U.S. EPA released List N: Disinfectants for Coronavirus (COVID-19) in March 2020. Products on this list are expected to be effective against SARS-CoV-2, but have not been specifically tested against this virus. Efficacy tests of antimicrobial products against SARS-CoV-2 are underway and those with data showing appropriate levels of efficacy may add these claims to product labeling.

The coronavirus particle contains various proteins, including the highly recognizable spike glycoprotein that studs the surface or envelope. The virus replicates the ribonucleic acid (RNA) within the envelope, however this process may result in errors that can either inactivate the virus or create a variant. Because an infection is typically comprised of billions to trillions of viral particles, the mutations that occur during replication create a community of viruses within the host. As these particles pass on to another host, variants emerge and may spread. It is important to note that variants may be named for regions where that specific mutation is spreading, however that same mutation may originate multiple times in multiple areas.

### ***Committee Comment***

Rich Breuer asked if the department tracks the quantity of products used each year. Karen Morrison replied that the department tracks products used agriculturally and in schools, but does not track home use of products. Karen added that the closest baseline for these products would be sales, which is not a perfect measure of use, but provides a rough estimate. Karen further added that sales of products on U.S. EPA's List N have increased substantially over the last year.

Amalia Neidhardt asked if the registration application indicates how the pesticide will be applied, and whether DPR has seen products being applied via sprayers/fumigators. Aisha Iqbal replied that the second page of the application includes information on the manner in which the pesticide is to be applied. Brian Portoni replied that there are currently coarse-sprayers and electrostatic sprayers. Brian added that products to be applied via electrostatic sprayer require additional efficacy data to be submitted. Karen Morrison commented that there has been recent action within DPR's Enforcement Branch, as well as U.S. EPA to address illegal pesticide applications using products or applicators that have not been approved. Karen added that this illegal use can be a concern for efficacy as well as worker and individual safety.

### ***Public Comment***

Michael Zeiss asked what percentage of antimicrobial registration applications were rejected by DPR in 2020 and asked how that percentage compares to previous years before the pandemic. Brian Portoni replied that rejections have been quite low recently and most of the time the department will work with the registrant to get the product registered. Aisha Iqbal clarified that the criteria for rejection did not change in 2020 – if the application is incomplete or the submitted documents are incorrect the package will be rejected, however if the submitted package meets the application criteria, the package will not be rejected.

Emily Saad asked how many of the expedited packages were submitted concurrently with U.S. EPA and how much communication occurred between the efficacy evaluators of U.S. EPA and DPR. Brian Portoni replied that DPR staff met with U.S. EPA staff when SARS-CoV-2 was declared an Emerging Viral Pathogen, however direct contact in the time since then has been limited. Brian added that approximately 80% of expedites are concurrent submissions with U.S. EPA.

### **3. 1,3-D Pilot Project Update - Minh Pham, DPR**

1,3-Dichloropropene (1,3-D) is a pre-plant soil fumigant used to control nematodes, insects, and disease organisms. It is widely used in California, especially on crops such as fruit and nut trees, strawberries, grapes, and carrots. 1,3-D is classified as a restricted material, requiring a permit from the local county agricultural commissioner prior to application. Various mitigation measures to control exposure to 1,3-D have been in place since 1995. Most of these mitigation measures are related to long-term or chronic exposures, though DPR is proposing additional requirements focused on reducing short-term acute risk to children and infants.

The 1,3-D Pilot Project began in Fall 2020 in selected high-use areas and is scheduled to continue for one year. DPR has identified several mitigation options that result in 1,3-D emission reductions of at least 60% compared to a standard fumigation. Emissions reduction options include fumigant injection at deeper soil depths, increased soil moisture, complete and partial totally impermeable film (TIF) tarping, application rate reductions, acreage limits, and setbacks from occupied sensitive sites.

One major project took place in Oakdale, CA in November 2020. This was a multi-stakeholder collaboration coordinated by TriCal. For this project, TriCal performed field preparation and application, Ajwa Laboratories conducted air sampling and sample analysis, and DPR assisted in air sampling setup as well as performing soil analysis and conducting on-site weather monitoring. This project occurred over three separate fields of two acres each in the Oakdale area. Each field targeted a different application process to investigate air concentration and emission behaviors. One field utilized an 18" deep injection with higher field moisture, one utilized an 18" deep injection with higher field moisture and trailing flat roller for compaction, and the third utilized a 24" deeper injection with higher field moisture. The application process for this project was completed in November, with air monitoring continuing into December. DPR is currently awaiting report(s) that Ajwa Laboratories will produce.

At the same time, DPR had another project underway in Shafter, CA in collaboration with UC Kearney Agricultural Research and Extension Center. This project consisted of a 1.4 acre field with a focus on an 18" deep injection with higher field moisture. TriCal performed the application for this project as well, however, DPR performed the air sampling, soil analysis, and on-site weather monitoring, and CDFA Laboratories conducted sample analysis. This study was completed in December 2020 and DPR and CDFA are currently analyzing the air and soil samples. DPR expects to be able to aggregate the data for this project within the next month or two.

In March 2021, DPR conducted a study in Denair, CA on a five acre field provided by a private grower. This study focused on a 24" deeper injection application process. Again, application was performed by TriCal, DPR performed air sampling, soil analysis, and on-site weather monitoring, and CDFA Laboratories conducted sample analysis. DPR completed the monitoring phase of this study and both DPR and CDFA are scheduled to begin analysis of air and soil samples.



DPR solicited potential upcoming studies from stakeholders in different areas of agriculture such as the County Agricultural Commissioner's Offices, pesticide applicators, UC researchers, grower groups and associations, and private farmers. DPR will continue conversations with stakeholders on prospective field studies and plans to evaluate four to five alternative application methods. Counties targeted for possible participation based on use include Stanislaus, Merced, Fresno, and Kern.

### ***Committee Comment***

Kevi Mace asked where stakeholders can access the results of the studies once the analysis is complete. Minh Pham replied that the data will likely be compiled into a report that will be released on DPR's website. Minh added that it is not yet certain if the data will be aggregated into one large pilot project report or published as individual study reports. Karen Morrison commented that DPR presents updates on this project regularly at PREC and would anticipate an additional presentation with further studies as well as initial data analysis.

Lynn Baker asked if Ajwa Laboratories used charcoal tubes for sampling, and if DPR will be using modeling to compare the monitoring results with what the models expected for the various alternative application methods. Minh Pham confirmed that Ajwa Laboratories used charcoal tubes for sampling. Minh added that in addition to the analysis, Ajwa Laboratories will provide the raw data for the study, which DPR will then compare to internal sampling data. DPR will evaluate the provided data and look to validate the sampled results against back calculation and air dispersion computer models.

Rich Breuer asked if any of the 1,3-D is partitioning into the aqueous phase and whether the deeper injections may impact groundwater. Minh Pham replied that 1,3-D is injected as a gas and is unlikely to partition into an aqueous phase. Minh added that the Air Protection Program works closely with the Surface Water Protection Program and will discuss the issue if it becomes a concern. Lynn Baker clarified that 1,3-D is injected as a liquid, which volatilizes in the soil and becomes a gas. Karen Morrison added that 1,3-D is on DPR's list of compounds identified as having the characteristics with potential to move to groundwater. Lynn commented that U.S. EPA was reviewing 1,3-D as a groundwater contaminant in 1990 when the Air Program began studying the effects of the compound in the air.

Kevi Mace asked if the fields in the study were irrigated to reach the higher moisture content before application. Minh Pham replied that fields in some areas may have higher moisture content due to rain and weather patterns, whereas fields in drier areas would typically need to be irrigated at some level to reach the moisture content requirements on the product label. Karen Morrison added that the feasibility of additional irrigation is one of the elements under consideration when evaluating the alternative application methods.

***Public Comment***

James Nakashima asked how long samples are collected post-application. Minh Pham replied that DPR conducted a background sample the day before application and then sampled at six and twelve hour durations for eight days. Minh added that the larger field in the Oakdale study was sampled for 21 days.

Anne Katten asked about the size of the treated orchard. Minh Pham replied that the plot was five acres and clarified that the application was pre-plant, so there were no trees in the field at the time of application. Anne also asked about the difference in detection limit between the sorbent tubes and canisters that are used for sampling. Minh replied that he did not have numbers on hand, but added that DPR traditionally uses sorbent tubes in field studies due to the duration of sampling. Anne further asked when the air monitoring database would be updated. Minh replied that the data is being finalized and will be released concurrently with the Air Monitoring Network report. Anne also commented that high levels of 1,3-D have been detected in sites such as Parlier and Shafter and the California Rural Legal Assistance Foundation is anxious for mitigation measures to be adopted to reduce exposures in these communities. Karen Morrison added that the data gathered through the 1,3-D Pilot Project is intended to inform the decisions around 1,3-D mitigation measures.

Jing Tao asked where the samplers are located in or around the field, and whether multiple flux estimation methods will be used and compared with each other. Minh Pham replied that the monitoring is conducted around the edge of the field using 14 samplers. Minh added that there were no samplers located within the field, however the Air Program is considering the feasibility of this option. Minh also added that if the data from Ajwa Laboratories contains information beyond edge-of-field monitoring, the Air Program will compare that data as well.

Sarah Aird submitted the following comment via email:

This is Sarah Aird with the Californians for Pesticide Reform statewide coalition. We really appreciate the work that DPR's been doing on the Telone fumigant pilots but also want to flag it's been 3 years since levels of Telone were found in the air in Shafter, Kern County, and Parlier, Fresno County, higher than what was found in 1990 when Telone was banned for use in the state for 5 years. Yet three years later no mitigations have been adopted. Air monitoring is critical, but when unacceptable air levels of pesticides are found, it defeats the purpose of air monitoring to take no action to protect communities. For families we work with living near these air levels, the lack of mitigations is just not acceptable. It's also critical that DPR move more quickly on the Telone regulation - by court order the draft regulation should have been promulgated nearly two years ago. It would be great to hear from DPR what their current timeline is for announcing the draft regulation. Thanks

#### **4. Fipronil Draft Risk Characterization Document – Leona Scanlan and Weiving Jiang, DPR**

Fipronil is a pesticide that is registered in California to control insect and arachnid pests. The largest use of fipronil in pounds per year is for outdoor, structural control such as around a home's foundation or in the eaves overhead. This compound is also used in turf grass to control fire ants and in spot-on and spray formulations to control ticks and fleas on companion dogs and cats. Fipronil kills pests through a neurotoxic mechanism; it inhibits  $\gamma$ -aminobutyric acid (GABA)-gated chloride channels in the brain, also called GABA receptors. GABA is an inhibitory neurotransmitter, leading to excitation of the central nervous system. Fipronil is an effective pesticide because it has a much higher affinity for the insect GABA-receptor than the mammalian receptor (19-158x). However, fipronil can cause toxicity to humans at sufficiently high doses. Effects of exposure include irritation at the exposure site (eyes, skin, gastrointestinal tract, and lungs) as well as central nervous system effects such as headache, vertigo, disorientation, dizziness, and tremors. Higher exposure to fipronil can result in convulsions and seizures, liver and kidney effects, and death.

DPR has four data sources for effects of fipronil in humans: the Pesticide Illness Surveillance Program (PISP), adverse effects reports, case studies, and population-based studies. From 1999 to 2017, 68 cases of illness following fipronil exposure were reported via PISP. PISP cases are evaluated by health care professionals and, of the 68 cases, three were determined to be definitely caused by fipronil exposure, 18 were deemed probable, and 47 were deemed possible. Adverse effects reports are provided to DPR by the pesticide registrants. DPR identified approximately 6,000 cases of individuals who reported illness following exposure to fipronil. These reports included two deaths attributed to fipronil. The majority of the reports were from pet product use. It is important to note that the exposures and effects in these reports are not validated by medical professionals. Published scientific literature provides additional information via case studies and population-based studies. Case studies are based on people who were accidentally or purposefully exposed to fipronil and received medical treatment. Population-based monitoring studies include a group of occupational workers in a fipronil packaging facility, a group of newborns and their parents, and volunteers in different geographical regions.

Risk is dependent on both exposure and toxicity. DPR estimated fipronil exposure to occupational workers, home users, and residents post-application. This included fipronil handlers and pest-control operators, as well as pet groomers and adult and child residents. Exposure estimates were determined for relevant short-term, seasonal, and annual exposure durations. To determine the level of fipronil that would be safe for human exposure, DPR reviewed registrant-submitted toxicity studies conducted in laboratory animals, as well as published studies on animals and case studies on humans. This review included toxicity data for oral, dermal, and inhalation routes of exposure and covered acute, subchronic, and chronic exposure durations.

Fipronil toxicity is dependent on several chemical species – the parent compound, two metabolites, and the photodegrade product. DPR reviewed approximately 60

registrant-submitted toxicity studies and over 100 published studies, including studies with the parent, metabolites, and photodegrade products. DPR considers the critical points of departure for fipronil to be protective against toxicity from exposure to the related chemical species. In laboratory animals, fipronil caused a variety of effects, including neurotoxic effects and a suite of related effects in the liver, kidney, and thyroid. Altered thyroid hormone regulation and thyroid follicular cell tumors occurred in the rats through a mechanism that is not relevant to humans. Fipronil also caused oxidative stress and cellular damage in the liver, kidney, and thyroid. It is important to note that rats have biological differences from humans, however, they have similar organ systems. Effects observed in the laboratory animals were similar to those observed in humans with fipronil exposure. Toxicity at acute, subchronic, and chronic levels included neurobehavioral effects, mortality, and effects to the liver, thyroid, and kidney. Developmental delays were also observed after subchronic exposure duration.

After reviewing the available toxicity database, DPR identified the critical points of departure for acute, subchronic, and chronic exposure to fipronil. These values are used in risk calculations and represent exposure levels where toxicity was not observed. The acute point of departure for oral, dermal, and inhalation routes (0.87 mg/kg/day) was based on decreased hindlimb splay observed in rats in an acute neurotoxicity study. DPR used benchmark dose modeling to derive the point of departure. Hindlimb splay is a laboratory measurement of neurotoxicity. The subchronic point of departure (0.02 mg/kg/day) was based on convulsions, mortality following convulsions, and sustained decreases of the thyroid hormone T<sub>4</sub> observed in rats after subchronic exposure duration in a chronic toxicity study. The chronic point of departure (0.02 mg/kg/day) for all exposure routes was based on convulsions, mortality, sustained decreases in T<sub>4</sub>, and increased progressive senile nephropathy in the kidney. These effects were observed in rats in a chronic toxicity study. DPR also assessed thyroid cancer risk with a threshold approach, using T<sub>4</sub> levels as an upstream marker of oncogenesis.

Fipronil was the first compound to enter the new risk assessment process after reviews from the National Research Council (NRC) in 2015. Correspondingly, this assessment was conducted by factoring in NRC recommendations, emphasizing the use of California-specific data, and inviting input from stakeholders. Part of the outcome, including the development and prioritization of exposure scenarios, was completed during the problem formulation stage and was presented previously to PREC.

The current exposure assessment considered all fipronil products that were actively registered in California and all possible human exposures from legal fipronil use as described on the product labels. For different use purposes and formulations, fipronil products can be grouped into seven categories. Among these categories, pet spot-on products represent the largest number of products registered in California, while the structural liquid concentrate products accounted for the most fipronil use.

Overall, DPR conducted quantitative exposure assessments for 18 scenarios – eight handler/applicator scenarios (including home uses), five post-application adult resident scenarios, and five post-application child resident scenarios. DPR assessed short-, intermediate-,

and long-term exposure periods for dermal contact, inhalation, incidental oral ingestion, and dietary exposure routes. Exposure values for different scenarios were collected primarily through fipronil-specific studies and in some cases through surrogate data or the default database where data gaps occurred. These situations are covered in detail in the exposure appraisal section of the exposure assessment document.

The exposure assessment generated a total of 88 exposure estimates for different scenarios, routes, and exposure periods. Using selective short-term exposure as an example, the highest estimated exposure is dermal exposure for groomers using pet spray products and one of the lowest exposures is home-resident exposures from structural bait gel products. DPR then combined the exposure estimates with appropriate toxicity end points to calculate risks.

DPR also evaluated fipronil concentrations in drinking water using data collected in the Surface Water Database (SURF). DPR included samples from areas with high fipronil use, but excluded samples from storm drains and sloughs, as they are not likely drinking water sources. This assessment provided estimates for both short-term exposure concentration as well as intermediate and long-term exposure concentrations.

Dietary exposure is calculated by multiplying the pesticide residue found on a specific commodity by the consumption rate for that commodity. The dietary exposure assessment included all foods with fipronil tolerances as well as drinking water. DPR performed acute and chronic exposure estimates in the U.S. general population as well as three of the most sensitive populations of concern: infants under one year old, children one to two years old, and females of childbearing age. The residue data were derived from the USDA Pesticide Data Program and from fipronil tolerances. DPR used consumption data from the CDC's National Health and Nutrition Examination Survey (NHANES) and calculated exposure using the Dietary Exposure Evaluation Model-Food Consumption Intake Database (DEEM-FCID) computational model. Exposures ranged from 0.07 µg/kg/day for chronic exposures to 0.35 µg/kg/day for acute exposure scenarios.

Risk is expressed as a margin of exposure (MOE). MOEs are equal to the critical point of departure, divided by the estimate for human exposure. DPR used a target MOE of 100 in this calculation to protect human health. This target includes a 10x uncertainty factor for interspecies extrapolation from rats to humans and a 10x uncertainty factor for intraspecies variation within humans. DPR also calculated aggregate risk using a hazard index approach. The aggregate MOE is equal to the inverse of the sum from  $i$  to  $n$  of the inverse of all relevant MOEs, including dermal, oral, and inhalation where appropriate.

Overall, risk from exposure to fipronil was driven by the dermal route. For occupational exposure, in addition to risk from the dermal route, DPR identified one scenario (pet spray) with potential risk by the inhalation route. In the home user or the person who applies pet products at home, pet spray exposure to fipronil was identified as a potential risk via the dermal route. For adult residents post-application, potential risk was identified for pet products, and for child residents post-application, potential risk was identified for incidental oral (also called

hand-to-mouth) route of exposure to turf granules and for dermal exposure to pet products. It is important to note that fipronil exposure from diet and drinking water was minimal compared to the other exposures. To view the data tables with specific MOEs, request a copy of the Draft Risk Characterization Document via email to [publicrecords@cdpr.ca.gov](mailto:publicrecords@cdpr.ca.gov)

### ***Committee Comment***

Dave Tamayo asked if there is a test available for clinical diagnosis of exposure to fipronil that would differentiate it from other neurotoxins. Leona Scanlan replied that the physician could run a mass-spectrometry assay on a blood sample to determine if fipronil is present.

Rich Breuer commented that sometimes in attempting to mitigate risk to humans, the trend is to move to alternatives that may then cause risk to the environment. Rich added that DPR is now finding home use and industrial use insecticides in wastewater, which is important in understanding the risks in the pathways of exposure not just to humans, but also the environment. Rich further added that in order to develop comprehensive solutions to protect human health and the environment, staff and departments across disciplines will need to work together. Karen Morrison commented that fipronil has been a concern for DPR in terms of impacts to surface water as well as wastewater. Karen added that DPR's analysis of human health effects of exposure to fipronil offers an opportunity to consider the environmental factors as well.

Dave Tamayo commented that the Sacramento region discharges into the Sacramento River, and that there are significant drinking water intakes downstream. Dave added that this may be an area for further study.

David Ting commented that OEHHA is currently reviewing DPR's Draft Risk Characterization Document and Exposure Assessment Document and will provide comments.

### ***Public Comment***

Michael Zeiss asked about next steps in this analysis and when DPR will release a risk mitigation directive. Karen Morrison replied that the next step is to complete the risk characterization documents, as this is currently in a draft stage. Karen added that the document is out for peer review and DPR will likely consider feedback from this presentation as well as additional factors impacting risk in the process, both of which will affect the timeline for releasing the directive.

Michael Zeiss asked if the risk characterization process developed any conclusions on fipronil risk to pets, as has been in the news related to non-fipronil pet products. Leona Scanlan replied that this process did not consider risk to pets, however there is data showing that some pets have adverse reactions to fipronil. Karen Morrison added that DPR is aware of and tracking reports related to adverse effects from pet treatments.

An anonymous participant asked about the main pest that structural applications of fipronil are used to control. Weiyang Jiang replied that both ants and termites are target pests for structural application of fipronil, however the application methods differ. Weiyang added that applications to control termites are typically limited to inaccessible areas, where contact with the product is unlikely, however applications to control ants are typically around the house foundation or under the eaves. Weiyang further added that fipronil is also used to control fire ants in some areas of California.

Stephanie Hughes commented that due to the aquatic toxicity of fipronil and potential alternatives, such as imidacloprid and pyrethroids, Bay Area Clean Water Agencies (BACWA) has been assessing the transport of these pesticides from indoor pet use to the sewer collection systems, and evaluating alternatives the indoor spot-on and spray products. Stephanie added that BACWA has identified a number of non-pesticide alternatives, such as oral pharmaceuticals and indoor cleaning options, and has shared insights and sought input from veterinary professionals, most recently the Environmental Issues Committee of the American Veterinary Medical Association (AVMA). Stephanie further added that leaders of that committee have indicated interest in engaging in conversation toward developing ways of providing cost-effective companion animal pest control, while protecting water quality and human health. Stephanie concluded by commenting that BACWA is confident that alternatives to flea and tick control pesticide treatments are available, and the path forward for consumers, pets, and water quality can be found through cooperating and seeking support from AVMA and the wastewater agencies. Stephanie also offered to connect DPR with a member of the AVMA Environmental Issues Committee, who also works with the poison control call center of the American Society for the Prevention of Cruelty to Animals, regarding issues of pet toxicity.

Emily Saad commented that U.S. EPA published a draft fipronil human health risk assessment as a part of registration review for fipronil, adding that both the Environmental Monitoring Branch and Pesticide Registration Branch of DPR made comments on various documents throughout the process. Emily then asked if U.S. EPA and DPR toxicologists have been in communication as both agencies work toward finalizing human health risk assessments for fipronil. Leona Scanlan replied that DPR is in contact with U.S. EPA specifically regarding fipronil. Karen Morrison added that as a general practice, when DPR is actively working on a human health risk assessment that has not been completed, the department will not comment on draft materials from U.S. EPA. Emily asked for clarification that communication between DPR and U.S. EPA includes discussion related to both the hazard and exposure aspects of the Draft Risk Characterization Document. Leona confirmed that DPR is communicating regarding hazards. Weiyang Jiang commented that U.S. EPA has a comprehensive SOP on residential pesticide exposure, which covers many of the same scenarios expressed in DPR's Draft Risk Characterization Document. Weiyang added that unlike at the federal level, fipronil has no registered agricultural produce use in California, which results in differences in exposure scenarios between documents from the two agencies. Weiyang further added that DPR is attempting to use California-specific data as much as possible for this analysis, based on recommendations from the National Research Council.

James Parish submitted the following comment via email:

Hello and thank you for accepting my comments on Item 4. My name is James Parrish, and I'm an Environmental Scientist with the San Francisco Bay Water Board in its NPDES Wastewater Division. While I appreciate that Item 4 is about fipronil as it relates to human health, I would like DPR to remain cognizant of some issues of fipronil as it relates to aquatic life.

Fipronil is an active ingredient in pet "spot-on" treatments. It is highly toxic to aquatic life and can pass through municipal wastewater treatment plants and discharge into surface waters. In fact, monitoring conducted by the San Francisco Estuary Institute has identified fipronil as a contaminant of emerging concern in San Francisco Bay. Fipronil concentrations have been detected in the Bay above U.S. EPA aquatic life benchmarks. Additionally, fipronil has been found in over half of the influent and effluent samples from our local wastewater treatment plants. Fipronil can get into wastewater influent and effluent when these spot-on products are washed down the drain, either by washing pets, washing clothing that these treatments rubbed off on, or washing hands after application or pet petting.

This is a legitimate concern for the Water Board. As a regulatory agency, we must ensure compliance with the Clean Water Act and its national requirement that surface waters are not toxic to aquatic life. Our local wastewater agencies have no viable means of controlling the use of pesticides in consumer products like pet spot-ons. When pesticides like fipronil enter wastewater treatment plants, they can disrupt the biological treatment process. As pesticides pass through the treatment process, this can result in toxic discharges to waters of the State, as well as significant compliance penalties that can cost up to \$10/gallon discharged or \$10,000/day (i.e., millions of dollars). We note that we had a wastewater agency fail 21 out of 27 toxicity tests, up to 8 times the toxicity threshold, before discovering the cause of toxicity was pyrethroids in its effluent. If we deem our receiving waters impaired by pesticides, we can develop (and have developed) onerous Total Maximum Daily Loads to bring receiving waters back into compliance. Preventing these pesticides from discharging to POTWs in the first place can prevent these cumbersome and expensive efforts.

It is imperative that DPR considers these "down-the-drain" risks when considering future risk management responses to fipronil and other pesticides used in pet spot-on treatments (e.g., imidacloprid and pyrethroids), so that DPR decisions don't end up shifting the market from one toxic pesticide to another.

Thank you.

Kelly Moran commented that in addition to the potential toxicity and Clean Water Act compliance issues posed by the presence of fipronil and other pet flea control products in wastewater effluent, another area of concern involves California's long-term plans to recycle wastewater effluent through advanced treatment processes so that it becomes a future source of drinking water. Kelly clarified that the concern is not about the potential for pesticides to pass through the advanced treatment process, as it seems to robustly remove pesticides, but rather the



concern is for the disposal option for the concentrated waste generated by the process. Kelly added that the process continually produces millions of gallons of concentrated waste per day, and that the cost-effective disposal strategy is to send the concentrate back into surface water. Kelly further added that although further treatment could be done, it is unknown whether it is technologically feasible to remove all the pesticides, and fipronil and imidacloprid are particularly challenging in this area due to their solubility. Kelly concluded by stating the importance of a comprehensive analysis of the environmental and long-term effects of fipronil use and risk mitigation, including the impacts of alternative pesticide products.

#### **5. Agenda Items for Next Meeting**

Dave Tamayo requested a discussion on DPR's notification process and access to regulatory documents.

The next meeting is scheduled for May 21, 2021 at 10:00 a.m. This meeting will be held virtually on the Zoom platform and broadcast live on the [CalEPA webcast page](https://video.calepa.ca.gov/). <video.calepa.ca.gov/>

#### **6. Adjourn**