Department of Pesticide Regulation

Julie Henderson
Director

Gavin Newsom
Governor

Yana Garcia
Secretary for Environmental Protection

California Notice 2023-10

To: Pesticide Registrants and Other Stakeholders

Subject: SEMIANNUAL REPORT SUMMARIZING THE REEVALUATION STATUS OF PESTICIDE PRODUCTS DURING THE PERIOD OF January 1, 2023, THROUGH June 30, 2023

California regulations require the Department of Pesticide Regulation (DPR) to investigate reports of possible adverse effects to people or the environment resulting from the use of pesticides. Reevaluation of a registered pesticide is required if a significant adverse impact occurred, or is likely to occur, from its use.

Title 3 of the California Code of Regulations (3 CCR) section 6221, specifies several factors under which DPR may initiate a reevaluation: (a) public or worker health hazard, (b) environmental contamination, (c) residue over tolerance, (d) fish or wildlife hazard, (e) lack of efficacy, (f) undesirable phytotoxicity, (g) hazardous packaging, (h) inadequate labeling, (i) disruption of the implementation or conduct of pest management, (j) other information suggesting a significant adverse effect, (k) availability of an effective and feasible alternative material or procedure that is demonstrably less destructive to the environment, and (l) discovery that data upon which a registration was issued is false, misleading, or incomplete. An ongoing DPR pesticide review may trigger a reevaluation. Reevaluation triggers also include data or information received from state and county pesticide use surveillance and illness investigations, pesticide residue sample analyses, environmental monitoring activities, and issues that may concern other state or federal agencies.

When a pesticide enters the reevaluation process, DPR reviews existing data and may require that registrants provide additional data to characterize the nature and extent of the potential hazard and identify appropriate mitigation measures if needed.

DPR concludes reevaluations in several different ways. If the data demonstrate use of the pesticide presents no significant adverse effects, DPR concludes the reevaluation without additional mitigation measures. If additional mitigation measures are necessary, DPR will place appropriate restrictions on the use of the pesticide to mitigate the potential adverse effect. If the adverse impact cannot be mitigated, DPR cancels or suspends the pesticide product registration.

This report complies with the requirement of 3 CCR section 6225, which requires DPR to prepare a semiannual report describing pesticides reevaluated, under reevaluation, or for which factual or scientific information was received, but no reevaluation was initiated. The report contains two sections:

I. *Formal Reevaluations*–initiated when an investigation indicates a significant adverse impact has occurred or is likely to occur; and,
II. *Preliminary Investigations (Evaluations)*–initiated when DPR receives possible adverse impact data or information resulting from the use of a product and/or active ingredient, but no formal reevaluation has been initiated.

CALIFORNIA NOTICE 2018-01

California Notice 2018-01 (Notice), titled *Expanding Use of Pesticide Products under Reevaluation* <cdpr.ca.gov/docs/registration/canot/2018/ca2018-01> was issued in January 2018. In accordance with this notice, DPR will not act upon an Application for Pesticide Registration or an Application to Amend Pesticide Product if it's relevant to the concern that prompted the reevaluation. The notice affects new products, supplemental distributor registrations, amendments, Special Local Needs, and Experimental Use Permits. DPR will evaluate Emergency Exemption requests on a case-by-case basis if a pest management or public health need arises. When DPR completes the reevaluation, DPR will be able to, in light of the reevaluation determination, consider the Application for Pesticide Registration or Application to Amend Pesticide Product.

FORMAL REEVALUATION

DPR initiates formal reevaluation when an investigation indicates a significant adverse impact has occurred or is likely to occur. Each reevaluation is summarized with regard to the following four areas: (1) *Basis and Scope*, (2) *Data Requirements* (if any), (3) *Summary of Scientific Evaluation* (e.g., protocol development, study/data submission and evaluation, DPR analysis papers, risk assessments), and (4) *Mitigation Efforts and Status*.

CHLOROPICRIN – 30 Products

Basis and Scope

In October 2001, DPR placed pesticide products containing the active ingredient chloropicrin into reevaluation. The reevaluation is based on air monitoring data, which found that air concentrations at some distances from treated greenhouses exceeded the National Institute for Occupational Safety and Health reference exposure limit and the Occupational Safety and Health Administration permissible exposure limit of 100 parts per billion (ppb), averaged over an eight-hour period. In addition, DPR found that data submitted under the Birth Defects Prevention Act indicated a potential for chloropicrin to cause adverse health effects at low doses.

Data Requirements

Under this reevaluation, DPR required chloropicrin registrants to conduct and submit data on various worker exposure and air quality monitoring studies from field and greenhouse

applications. In August 2005, DPR completed review of required monitoring data and began a risk assessment of chloropicrin uses as part of the reevaluation process to mitigate potential adverse effects at low concentrations. In January 2015, DPR notified chloropicrin registrants of a data requirement to determine if chronic exposure to chloropicrin presents a carcinogenic hazard requiring mitigation. In July 2015, DPR established a mechanistic study data requirement to assess the carcinogenic hazard of chloropicrin.

Summary of Scientific Evaluation

The required mechanistic study was divided into three phases. Following each phase, DPR scientists planned to evaluate the results of the study to determine the need for the next phase. In June 2016, DPR accepted the protocol for the Phase 1 mechanistic study titled, *Identification of mouse lung target cell type and target respiratory region for effects following nose-only inhalation exposure to chloropicrin vapor*. Due to several unforeseen circumstances and COVID-19 related delays, the final deadline for the Phase 1 final study report was delayed. CMTF submitted the results of the Phase 1 study in September 2022, and final nasal tissue analysis in January 2023.

After review of the Phase 1 data, DPR determined that the two remaining study phases would not generate the needed data and would unnecessarily extend the reevaluation process. In April 2023, and based on the state of the science, DPR notified CMTF of its preliminary plan to require a new approach to the mechanistic studies that would provide more precise data and could be completed in a shorter timeframe. DPR discussed these alternative studies with CMTF in a May meeting. In June 2023, CMTF responded to DPR regarding the studies. A July meeting with CMTF is scheduled to further discuss CMTF's comments and DPR's response. After that meeting, DPR will determine which studies to require.

Mitigation Efforts and Status

In February 2010, DPR completed a risk characterization document (RCD) for chloropicrin as a toxic air contaminant (TAC). The RCD analyzed the risks associated with potential exposures to residents and bystanders from ambient and offsite air concentrations of agricultural use chloropicrin products. Effective January 2011, DPR established by regulation chloropicrin as a TAC and initiated development of use restrictions following TAC procedures specified in state law. In November 2012, DPR completed its comprehensive RCD for chloropicrin, which included dietary and occupational exposure scenarios.

In May 2013, DPR proposed mitigation measures designed to protect bystanders and residents from acute exposures to chloropicrin for public comment. DPR proposed additional restrictions to protect residents and bystanders by including additional buffer zones, restrictions on buffer zone credits, acreage limits, time periods between applications with overlapping buffer zones, emergency preparedness and response, and notice of intent requirements. In January 2015, DPR issued "Control Measures for Chloropicrin: Control of Resident and Bystander Acute Exposure

from Soil Fumigation Applications." The controls are intended to reduce risk from acute exposures to residents and bystanders that might occur near fields fumigated with products containing chloropicrin. In April 2015, DPR issued interim recommended restricted material permit conditions for field fumigants containing chloropicrin. In February 2017, DPR issued revised interim permit conditions developed to mitigate hazards of offsite movement of field fumigation applications of chloropicrin.

In March 2020, U.S. EPA issued its interim registration review decision for chloropicrin products. The interim decision includes labeling changes such as general updates to the glove statement, clarification on shade houses, soil sealing, and application rates on the product label. DPR accepted the first amended product labels with this new federal language in late 2021. These federal revisions address separate issues from the scope of California reevaluation. DPR continues to monitor amended pesticide product registrations to ensure labeling compliance.

For information on human health risk assessment and mitigation for chloropicrin, visit Chloropicrin - Human Health Risk Assessment and Mitigation Documents and Activities <cdpr.ca.gov/docs/whs/active_ingredient/chloropicrin.htm>

CYFLUTHRIN - 17 Products

Basis and Scope

In May 1998, DPR placed pesticide products containing the active ingredient cyfluthrin into reevaluation. The reevaluation is based on DPR's investigations of a May 1997 respiratory irritation outbreak reported among orange harvesters exposed to cyfluthrin residues and other related pesticide illness reports. As part of the investigation, DPR's Worker Health and Safety Branch conducted two separate inhalation-monitoring studies in orange groves during orange harvest. As dust and pollen are a part of the normal working environment, DPR determined that additional variables in the work environment led to the workers' respiratory irritation symptoms. DPR compiled the results in its monitoring study titled, *Health and Safety Report HS – 1765*, which found a probability that cyfluthrin, applied close to harvest, led to the symptoms experienced.

Data Requirements

Under this reevaluation, DPR required registrants of pesticide products containing the active ingredient cyfluthrin to provide (1) a respiratory irritation study, (2) a worker exposure study, and (3) monitoring data for structural applications. In October 2001, the primary manufacturer submitted two worker exposure studies regarding hand harvesting of oranges and sweet corn, four indoor exposures studies, and a study titled, *Study on the RD_{50} Determination in Rats*. Based on this data, DPR determined structural monitoring data was no longer required. In February 2002, DPR required a worker exposure study during the harvesting of sweet corn. The results of the study were submitted to DPR in October 2004.

Summary of Scientific Evaluation

In 2006, DPR determined a comprehensive exposure assessment was necessary for cyfluthrin. In September 2008, DPR completed a cyfluthrin Exposure Scoping Document intended to lay the groundwork for the risk assessment process. DPR completed its review of the cyfluthrin sweet corn hand harvester studies. In August 2015, DPR completed a Summary of Toxicology Data document for chronic health effects on cyfluthrin.

Mitigation Efforts and Status

In January 2018, DPR issued a problem formulation document (PFD) to initiate risk assessment. In February 2018, DPR presented the PFD and initiation of the risk assessment for cyfluthrin to the Pesticide Registration Evaluation Committee (PREC). U.S. EPA completed its registration review and released the draft human health risk assessment in May 2020 and the interim registration review decision in September 2020. In March 2021, U.S. EPA revised the Agency's interim registration review decision. DPR continues to review and monitor federal decisions on cyfluthrin pesticide product registrations. If upon completion of the RCD, DPR concludes that use of cyfluthrin poses a risk to workers, DPR will proceed with mitigation.

For information on human health risk assessment for cyfluthrin, visit Cyfluthrin and Beta-Cyfluthrin - Human Health Risk Assessment and Mitigation Documents and Activities <cdpr.ca.gov/docs/whs/active_ingredient/cyfluthrin.htm>.

NEONICOTINOIDS (NITROGUANIDINE INSECTICIDES) - 181 Products

Basis and Scope

In February 2009, DPR placed certain pesticide products containing the active ingredients imidacloprid, thiamethoxam, clothianidin, and dinotefuran into reevaluation. The reevaluation is based on an adverse effects disclosure involving the active ingredient imidacloprid. DPR's evaluation of the adverse effects data noted two critical findings: (1) high levels of imidacloprid in leaves and blossoms of treated plants and (2) increases in residue levels over time. Thiamethoxam, dinotefuran, and clothianidin are in the same chemical family as imidacloprid, known as the nitroguanidine insecticide class of neonicotinoids, and have similar properties and characteristics (e.g., soil mobility, half-lives, and toxicity to honey bees).

Data Requirements

Under this reevaluation, DPR required registrants of pesticide products containing the active ingredients imidacloprid, thiamethoxam, clothianidin, and dinotefuran (collectively referred to as

neonicotinoids) to provide the following data for each active ingredient: (1) LC_{50} (acute) toxicity study, on honey bees, starting at the larval stage through emergence; and (2) field-based residue studies in pollen, nectar, and leaves from specific agricultural orchard and row crops. For field-based residue data requirements, DPR used its Pesticide Use Reporting database to determine the crops of focus for each active ingredient. DPR determined that initial field residue studies were inconclusive and did not involve "worst-case" scenarios (i.e., a residue study conducted at the permitted California maximum application rate and the minimum reapplication interval). DPR modified its residue study strategy to require controlled applications at the highest maximum application rate per year for two consecutive years. DPR required neonicotinoid registrants to conduct these two-year prescriptive residue studies for certain commodities.

Additionally, U.S. EPA required honey bee toxicity studies and additional field-based residue studies for their reevaluation of neonicotinoids, which were shared with DPR and the Health Canada Pest Regulatory Management Agency (PRMA).

Summary of Scientific Evaluation

In September 2009, DPR notified neonicotinoid registrants of the LC_{50} and field residue study data requirements. DPR received all required data by 2018. The data was evaluated and DPR issued a risk determination in July 2018. See more information below on this report.

Mitigation Efforts and Status

Between 2010 and 2012, imidacloprid and thiamethoxam registrants, respectively, agreed to remove almond use from all California product labels. DPR considered this an important step in pollinator protection since almond orchards require a large number of pollinators.

In August 2013, U.S. EPA notified registrants of neonicotinoids of new labeling requirements for all products having outdoor foliar use directions (except granular formulations). All California registered products contain the necessary pollinator protective label language.

In June 2014, DPR, U.S. EPA, and PRMA completed a collaborative document titled, *Guidance for Assessing Pesticide Risks to Bees*. In June 2014, a Presidential Memorandum creating a federal strategy to promote the health of honey bees and other pollinators was signed. In 2016 and 2017, U.S. EPA released a preliminary pollinator risk assessment for each of the active ingredients, which was a collaborative effort between DPR, U.S. EPA, and PRMA.

In July 2018, DPR issued the California Neonicotinoid Risk Determination and submitted it to the State Legislature in accordance with the requirements of FAC section 12838. Shortly after, DPR incorporated newly available information and issued an addendum to the California Neonicotinoid Risk Determination in January 2019. The Risk Determination and Addendum compares colony feeding study values to worst-case scenario residue values to determine risks to

honey bees. In 2020, DPR received a formal scientific peer review on the Risk Determination and Addendum and incorporated feedback into the mitigation efforts.

In accordance with the requirement of FAC section 12838 for DPR to adopt necessary control measures to protect pollinator health, DPR continued to review data and consult with experts and other stakeholders to help inform potential mitigation decisions. DPR developed several mitigation options and contracted with the California Department of Food and Agriculture (CDFA) to provide an economic analysis of the various options. CDFA provided economic analysis reports to DPR in August 2019, July 2020, and July 2021, as DPR explored mitigation options and revised the proposed regulations.

On February 25, 2022, DPR initiated formal rulemaking with a Notice of Proposed Action for Neonicotinoid Pesticide Exposure Protection. In April 2022, DPR held a virtual public hearing regarding the proposed changes. The comment period ended on April 26, 2022. DPR received 18 comments.

After consideration of the comments received, DPR proposed modifications to the rulemaking where appropriate. On October 5, 2022, DPR published a Notice of Modifications to Text of Proposed Regulations and a Notice of Addition of Documents to Rulemaking File, at which point a 15-day comment period began. DPR received 64 comments.

On April 12, 2023, the adoption of sections 6990 through 6990.16 of 3 CCR was approved as control measures necessary to protect pollinator health as identified in the 2018 California Neonicotinoid Risk Determination and Addendum. The regulations will become effective on January 1, 2024. Pesticide applicators must review and comply with the regulations. Neonicotinoid product labels will not be updated with these requirements.

For current information on DPR's rulemaking, visit Neonicotinoid Pesticide Exposure Protection #22-001 <cdpr.ca.gov/docs/legbills/rulepkgs/22-001/22-001.htm>. For more information on the reevaluation for neonicotinoids, visit Reevaluation - Neonicotinoids <cdpr.ca.gov/docs/registration/reevaluation/chemicals/neonicotinoids.htm>.

SECOND-GENERATION ANTICOAGULANT RODENTICIDES (SGARs) - 65 Products

Basis and Scope

Second-generation anticoagulant rodenticide (SGAR) products are those that contain the active ingredients brodifacoum, bromadiolone, difenacoum, and difethialone (collectively referred to as SGARs). DPR conducted a preliminary investigation of unpublished wildlife incident data and mortality data and public literature submitted by California Department of Fish and Wildlife (CDFW) and other sources on anticoagulant rodenticides and prepared a report on its findings.

Based on the investigation, the Director found that a significant adverse impact has occurred or is

likely to occur to non-target wildlife from the use of SGARs and proposed to begin reevaluation. In November 2018, DPR issued its proposed decision to begin reevaluation for SGAR products for public comment. On March 12, 2019, DPR issued its final decision to begin reevaluation for SGAR products.

Data Requirements

Under this reevaluation, DPR required registrants of SGAR pesticide products to (1) submit compliance proposals by May 2019, and (2) submit existing data related to non-target wildlife exposure by June 2019. Registrants of brodifacoum, bromadiolone, and difethialone products complied with these timelines. However, in place of submitting compliance proposals and data, difenacoum registrants submitted voluntary cancellations for all registered difenacoum products. As of May 2019, DPR no longer has any difenacoum products registered for use in California.

In August 2020, DPR asked companies to identify efficacy data that could inform mitigation by demonstrating a lower concentration of active ingredient in the target pests, such as through reduced application rates, lowered concentration of the active ingredient, and alternative bait timings. By November 2020, companies either submitted new data to DPR or identified relevant studies for review from previous submissions. DPR scientists have completed their initial review of company identified data, data on file, and public literature.

In 2020, DPR contracted with Dr. Niamh Quinn of the University of California to conduct a study on rodenticide Best Management Practices (#19-C0061). DPR authorized the researcher under Food and Agricultural Code (FAC) Section 12978.7, and the final report is pending department review. In 2022, DPR received a second research authorization request for SGARs from Dr. Quinn. DPR's conditional authorization of additional research by Dr. Quinn's ends July 2023.

In June 2022, DPR contracted with Dr. Quinn through 2024 to monitor for SGARs in urban carnivores (#21-C0091). This study and its results may provide general information to DPR on SGARs and this work is ongoing. DPR and CDFW continue to meet at least yearly to ensure effective consultation under current legislation.

Mitigation Efforts and Status

In November 2022, U.S. EPA issued their proposed interim decision (PID) for anticoagulant rodenticides which included all SGARs. The federal comment period closed February 2023. DPR continues to review and monitor federal decisions on SGAR pesticide product registrations. By the end of 2022, DPR completed review of data on file. DPR is committed to a timely completion of the reevaluation and continues to work with SGAR registrants, the Rodenticide Task Force, interested stakeholders, researchers, and federal counterparts to discuss potential mitigation strategies and any proposed actions on anticoagulant rodenticides.

Throughout 2023, DPR met with and solicited feedback from Pest Control Operators, non-governmental organizations, California Department of Public Health, CDFA, and CDFW to discuss potential mitigation measures.

For more information on the reevaluation for SGARs visit Second-Generation Anticoagulant Rodenticides (SGARs) <cdpr.ca.gov/docs/registration/reevaluation/chemicals/sgars.htm>.

PRELIMINARY INVESTIGATIONS (EVALUATIONS)

DPR conducts preliminary investigations of products (and active ingredients) for which the Department, or other State or county agencies, have identified possible hazards. As a result of evaluation, the investigation may lead to formal reevaluation.

DIPHACINONE AND DIPHACINONE SODIUM SALT – 56 Products

Basis and Scope:

Pesticide products containing the active ingredients diphacinone and diphacinone, sodium salt (henceforth collectively referred to as diphacinone) are classified as a first-generation anticoagulant rodenticide (FGAR). While both diphacinone and its sodium salt start as different chemical compounds, diphacinone sodium salt quickly converts to diphacinone in the environment. These products are registered for rodent control use by both professional applicators and the general public. In target rodents, death is usually delayed by several days after direct consumption of a lethal dose. Non-target wildlife may be exposed by direct consumption of diphacinone or when they consume target rodents that have fed on diphacinone (indirect consumption).

DPR's 2023 Public Report on diphacinone concluded that there have been substantial increases in diphacinone exposure rates to non-target wildlife, as represented in the CDFW loss reports. These increases are concerning given the toxicity of diphacinone to mammals and birds, and potential to bioaccumulate. This, along with increases in sales and use data of diphacinone in recent years, suggests that there are increasing amounts of diphacinone in California's environment, which could result in potential adverse impacts to non-target wildlife.

On May 19, 2023, DPR published California Notice 2023-06, Notice of Proposed Decision to Begin Reevaluation of Diphacinone and Public Report, outlining the basis for this proposed reevaluation and seeking public comment. On June 5, 2023, the Rodenticide Task Force requested an extension of the public comment period. A 30-day extension was granted by DPR in California Notice 2023-08, with the new deadline for public comment set for July 19, 2023. DPR staff presented on this recent action at the June 16, 2023, PREC meeting.

PARAQUAT DICHLORIDE (Paraquat) – 8 Products

Basis and Scope:

Pesticide products containing the active ingredient paraquat dichloride (commonly shortened to paraquat) are registered in California for use as an herbicide and defoliant on a variety of agricultural plants. Paraquat dichloride is listed as a California restricted material, and therefore not available for homeowner use and no products are registered for application in residential areas. In response to California Notice 2022-18 (Notice), titled *Notice of Proposed Decision to Renew Pesticide Product Registrations for 2023* <cdpr.ca.gov/docs/registration/canot/2022/ca2022-18>, DPR received comments requesting that DPR reevaluate, suspend, or cancel products containing paraquat dichloride. DPR received 4,683 identical or substantially similar comments submitted pursuant to an email campaign, as well as six unique comments containing references to public literature and studies. The comments expressed concern regarding human health and environmental issues regarding the use of paraquat dichloride. DPR continues to evaluate the data associated with the public comments on paraquat dichloride renewal and plans to issue a response after considering the comments and available information.

For more information on this semiannual report or any of DPR's reevaluations, visit Pesticide Registration Branch - Reevaluation Program <cdpr.ca.gov/docs/registration/reevaluation/reevals.htm> or contact Mr. Andrew Turcotte, Environmental Scientist, at <Andrew.Turcotte@cdpr.ca.gov> or 916-445-4403.

Original Signed by — *September 14, 2023*

Tulio Macedo, Chief
Pesticide Registration Branch
916-324-3527

Date

cc: Mr. Andrew Turcotte, Environmental Scientist