Department of Pesticide Regulation

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California Notice 2022-17

To: Pesticide Registrants and Other Stakeholders

Subject: SEMIANNUAL REPORT SUMMARIZING THE REEVALUATION STATUS OF PESTICIDE PRODUCTS DURING THE PERIOD OF January 1, 2022, THROUGH June 30, 2022

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 registration of the pesticide product.

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, titled Expanding Use of Pesticide Products under Reevaluation, was issued on January 3, 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 is 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.

To view the notice, please visit DPR's California Notices to Stakeholders Web page at <cdpr.ca.gov/docs/registration/canot/camenu.htm>.

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* (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 registrants of pesticide products containing the active ingredient chloropicrin to conduct and submit data on various worker exposure and air quality monitoring studies from field and greenhouse applications. In August 2005, DPR completed its review of the required monitoring data and began work on 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 new 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 for the scientific assessment of the carcinogenic hazard of chloropicrin based on evaluation of submitted and other available data and information.

Summary

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. The California Air Resources Board's Scientific Review Panel on Toxic Air Contaminants completed its peer review of the document in April 2010. In December 2010, DPR filed a regulation listing chloropicrin as a TAC. Also in December 2010, based on the TAC risk assessment, DPR issued a risk management directive (RMD) to address resident and bystander exposures identified by the TAC evaluation. This RMD determined that the appropriate regulatory target level to restrict acute exposure to chloropicrin is 73 ppb averaged over an eight-hour period. Chloropicrin was designated as a TAC effective January 8, 2011, and DPR 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 July 2015, DPR established a new mechanistic data requirement to attain more information on the potential carcinogenicity of chloropicrin. The mechanistic study is proposed to be completed in 3 phases, depending on the outcome of each phase. Following each phase, DPR scientists will review the results to determine the need for the next phase, approve protocols, and set due dates. On several occasions, the Chloropicrin Manufacturers' Task Force (CMTF), which represents chloropicrin registrants, met with DPR to discuss technical elements, methodology, and study protocol. In June 2016, DPR accepted the CMTF protocol for Phase 1 of the mechanistic study titled, *Identification of mouse lung target cell type and target respiratory region for effects following nose-only inhalation exposure to chloropicrin vapor*. In December 2016, DPR met with CMTF to discuss study timeline, logistics, technical challenges, an extension request from CMTF, and an additional information request from DPR.

In March 2017, CMTF provided additional information and an update on the initiation of the study. In April 2017, CMTF provided a progress report. In May 2017, DPR granted CMTF's extension request establishing a new final study submission due date for Phase 1 of December 2020, and added the requirement to submit quarterly interim reports. In 2018 and 2019, CMTF

submitted the required quarterly interim reports.

In March 2019, DPR met with CMTF to discuss the on-going study. During the meeting, CMTF recommended DPR review and consider public literature, which DPR received in May 2019. DPR scientists will incorporate relevant public literature into their review of Phase 1 results. In October 2019, in response to a question from DPR scientists, CMTF submitted clarification on the protocol.

CMTF submitted two draft amendments to the Chloropicrin Mechanistic Study Protocol for Phase 1, one in December 2019, and the other in January 2020. CMTF and the Study Director met with DPR to provide clarification on the draft protocol amendments in January 2020. Based on the clarification provided, DPR found the draft protocol amendments acceptable and concur that the revisions will result in an improved study protocol. Additionally, a minor protocol amendment to the laboratory location was submitted and approved in March 2020.

In January and May 2020, CMTF submitted the required quarterly interim reports. In the May 2020 interim report, CMTF notified DPR of laboratory closure due to COVID-19. Subsequently, CMTF formally requested a study extension based on uncertainties in laboratory reopening. In June 2020, DPR granted CMTF's extension request and established a new final study submission due date for Phase 1 of June 2021. In September and December 2020, CMTF submitted the required quarterly interim reports. At the end of 2020, CMTF requested further study extension based on continued laboratory closure due to COVID-19.

In January 2021, CMTF and the Study Director met with DPR to discuss the new request for an additional study extension. After the meeting, DPR required additional information and approximate timelines from CMTF to support the extension request. Upon CMTF submission, DPR reviewed the extension request and additional information. DPR established a preliminary study summary report submission due date for Phase 1 of January 31, 2022, and established a new final study submission due date of June 30, 2022.

In June 2021, CMTF submitted a minor protocol amendment to revise the study sponsor representative due to retirement of the previous representative. In July 2021, DPR accepted the minor protocol amendment to Phase 1.

In July 2021, CMTF submitted the required draft of the Chloropicrin Mechanistic Study Protocol for Phase 2. DPR reviewed and requested clarification of the study. In August 2021, DPR received a second letter with revised draft Phase 2 protocol. DPR reviewed and found the revision appropriate and required submission of the final Phase 2 protocol by July 29, 2022, if Phase 2 is deemed necessary after receiving the results from Phase 1.

In August and September 2021, CMTF submitted the final 2021 quarterly interim reports for Phase 1. Later in December 2021, CMTF submitted a proposed amendment to the Phase 1 protocol.

DPR met with the Study Director and CMTF in January 2022 to discuss provided clarification on the proposed protocol amendment. On January 31, 2022, CMTF submitted the preliminary study summary report for Phase 1, outlining preliminary results. DPR reviewed and identified deviations from the approved protocols. In March 2022, DPR requested CMTF address the deviations from Phase 1 of the chloropicrin mechanistic study by April. Between April and May 2022, CMTF responded to certain deviations, by amending the preliminary study summary report and committing to nasal tissue analysis for the final study report.

CMTF continued to submit quarterly interim reports for Phase 1 until January 31, 2022. DPR removed the interim progress report requirement between January and June 2022, to allow focus on Phase 1 data analysis and final report generation due June 30, 2022.

On June 29, 2022, DPR received a letter from CMTF requesting an additional 30 days to submit the Phase 1 final study report due to an unforeseen personnel issue. DPR granted an additional 30 days for submission of the final Phase 1 study report to August 1, 2022.

Mitigation Efforts and Status

During this reevaluation, U.S. EPA developed label mitigation measures under its Reregistration Eligibility Decision for products containing chloropicrin. These soil fumigant label measures require users to prepare site-specific Fumigant Management Plans and are intended to mitigate unacceptable exposures to workers, residents, and bystanders. The measures were implemented in two phases and went into effect in December 2010 and December 2012. The measures added more restrictions, prohibitions, human health protection language, and information on the product label.

In May 2013, DPR proposed mitigation measures designed to protect bystanders and residents from acute exposures to chloropicrin for public comment. DPR developed these mitigation measures using U.S. EPA's label changes as the foundation for mitigating offsite exposures. DPR proposed additional restrictions beyond labeling and regulation to protect residents and bystanders including additional buffer zones, restriction on buffer zone credits, acreage limits, time periods between applications with overlapping buffer zones, emergency preparedness and response, and notice of intent requirements. DPR developed the proposed mitigation measures in consultation with the California Air Resources Board, the air pollution control districts, and the county agricultural commissioners, as required by California Food and Agricultural Code (FAC) section 14024(a). In addition to consulting with state and local agencies required by law, DPR discussed early mitigation concepts with worker advocate groups and registrants. DPR also submitted its analysis entitled, "Evaluation of Chloropicrin as a Toxic Air Contaminant, Part B Human Health Assessment" for scientific peer review. DPR received and responded to comments from several thousand people and three external scientific peer reviewers.

In early 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. Also in January 2015, DPR presented the chloropicrin mitigation measures to the Pesticide Registration and Evaluation Committee (PREC) and members of the public. 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. More information on human health risk assessment and mitigation for chloropicrin is available on DPR's Human Health Risk Assessment and Mitigation Web page at <cdpr.ca.gov/docs/whs/active_ingredient/chloropicrin.htm>.

In March 2020, U.S. EPA issued its interim registration review decision for products containing chloropicrin. 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.

CYFLUTHRIN - 19 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.
However, during this reevaluation, DPR determined it had insufficient data regarding worker exposure during the hand harvesting of sweet corn. As a result, in February 2002, DPR required

a worker exposure study be conducted during the harvesting of sweet corn. The results of the study were submitted to DPR in October 2004.

Summary

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 to initiate risk assessment. In February 2018, DPR presented the problem formulation document and initiation of the risk assessment for cyfluthrin to the 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. If upon completion of the risk characterization, DPR concludes that use of cyfluthrin poses a risk to workers, DPR will proceed with mitigation. More information on the human health risk assessment for cyfluthrin and additional resources are available on DPR's Human Health Risk Assessment and Mitigation by Active Ingredient Web page at <cdpr.ca.gov/docs/whs/active_ingredient/cyfluthrin.htm>.

NEONICOTINOIDS (NITROGUANIDINE INSECTICIDES) - 188 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 to provide the following data for each active ingredient: (1) LC_{50} (acute) toxicity study, categorized as a Tier I 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 imidacloprid, thiamethoxam, clothianidin, and dinotefuran registrants to conduct these two-year prescriptive residue studies for certain commodities.

Additionally, U.S. EPA required higher tier honey bee toxicity studies and additional field-based residue studies for their reevaluation of neonicotinoids, which were shared with DPR and the Pest Regulatory Management Agency (PRMA) Health Canada. A Tier II study, or a feeding study, exposes bee colonies to known concentrations of a pesticide and examines the chronic effect. A Tier III study, or full field study, is a field-level study that looks at long-term effects under environmentally realistic exposure conditions.

Summary (by Active Ingredient)

Imidacloprid: In September 2009, DPR notified registrants of products containing the active ingredient imidacloprid of the LC_{50} and field residue study data requirements. DPR required residue data on the following eight commodities: almonds, citrus, cotton, cucurbits, fruiting vegetables, pome fruit, strawberries, and later, also required data on stone fruits. Rather than conduct a residue study for almonds, beginning in January 2011, imidacloprid registrants removed use on almonds from their labels.

In May 2011, DPR received final reports for residue studies conducted on citrus, cotton, and tomato. Upon review of the submitted reports, DPR found both the cotton and tomato studies to be unacceptable because they did not represent worst-case scenarios. As a result, in March 2012, DPR expanded the crops required to be tested to include stone fruit, and required two-year prescriptive residue studies representing worst-case scenarios for cotton, tomatoes, pome fruit, and stone fruit.

In March 2012, DPR received a final report on chronic toxicity effects to larval honey bees. In April 2012, the primary manufacturer submitted additional studies on citrus. In December 2012, DPR received final reports on strawberry and melon. In December 2014, DPR received a final report on chronic toxicity effects to adult honey bees and received U.S. EPA-required residue data on blueberry, citrus, corn, cotton, stone fruit, and rotational white clover used as forage. In January and April 2016, DPR received final reports on cotton, tomatoes, apples, and cherries. In March and July 2017, DPR received U.S. EPA-required full field data on cotton and pumpkins.

Thiamethoxam: In September 2009, DPR notified registrants of products containing the active

ingredient thiamethoxam of the LC_{50} and field residue study data requirements. DPR required residue data on the following eight commodities: cucurbits, fruiting vegetables, pome fruit, strawberries, and later, on almonds, citrus, cotton, and stone fruit.

In March 2011, the primary manufacturer requested a waiver for the residue study requirement on pome fruit and strawberries due to limited California field applications of thiamethoxam in 2009 and 2010. DPR granted a waiver for the residue study on pome fruit. In January 2012, the primary manufacturer submitted final reports for residues in tomatoes and acute toxicity effects to larval honey bees.

In October 2012, DPR expanded the testing requirements to include almond, citrus, cotton, and stone fruit. In addition, DPR required two-year prescriptive residue studies for strawberry, almond, citrus, cotton, and stone fruit. In January 2013, DPR received a final report on cucurbits (cucumbers). In February 2013, rather than conduct a residue study for almonds, thiamethoxam registrants removed use on almonds from their labels. In December 2015, DPR received final reports on cotton and stone fruit (cherry, peach, and plum), as well as U.S. EPA-required residue data on cranberry, cucumber, pepper, tomato, and soybean treated seed. In March 2016, DPR received a final report on a voluntary orange study and U.S. EPA-required residue data on citrus. In March and July 2017, DPR received final reports on citrus and strawberry, as well as U.S. EPA-required residue data on tomato, pumpkin, melon, corn, and apple. In November 2017, DPR received a final report on chronic toxicity effects to adult honey bees, an amended final report on cotton, and U.S. EPA-required residue data on sweet orange and blueberry. In April 2018, DPR received amended U.S. EPA-required residue data on citrus.

Clothianidin: In September 2009, DPR notified registrants of products containing the active ingredient clothianidin of the LC_{50} and field residue study data requirements. DPR required residue data on the following five commodities: almonds, cucurbits, fruiting vegetables, pome fruit, and stone fruits. In November 2009, the clothianidin primary manufacturer requested, and was granted, a waiver for the residue study on pome fruit due to limited use in California. In February 2012, the primary manufacturer submitted a final report on chronic toxicity effects to larval honey bees.

In May 2013, DPR required two-year prescriptive residue studies on almond, cucurbit, fruiting vegetable, and stone fruit. In October 2015, DPR received a final residue report on cotton. In April and May 2015, DPR received a final report on pumpkins and U.S. EPA-required residue data on citrus and cucurbits. In lieu of conducting the residue studies on fruiting vegetables, clothianidin registrants removed fruiting vegetables from their labels. From March to July 2016, DPR received U.S. EPA-required residue data on cotton, pumpkin, potato, as well as additional residue data on cucurbit and citrus. In February 2017, DPR received a final residue study report on almonds, a final report on chronic toxicity effects to adult honey bees and received U.S. EPA-required residue data on corn, grapevines, apples, and melon. From March 2017 to March 2018, DPR received additional final reports on chronic toxicity effects to adult honey bees and submissions of U.S. EPA-required residue data on soybean treated seed, peach, and additional

residue studies on corn and citrus.

Dinotefuran: In September 2009, DPR notified registrants of products containing dinotefuran of the LC_{50} toxicity and field residue study data requirements. DPR required residue data on the following three commodities: cotton, cucurbits, and fruiting vegetables. In response, the primary manufacturer submitted data and information, including limited use data, for DPR review and consideration.

In March 2012, the primary manufacturer provided DPR with reports evaluating foraging honey bees and hives after exposure to dinotefuran, and acute toxicity effects to honey bee data. In October 2015, DPR received a final report on acute larval toxicity effects to honey bees. During the report period, DPR received final residue reports on cucurbits (cucumber) and fruiting vegetables (tomatoes). In February and March 2016, DPR received U.S. EPA-required residue data on potato, pumpkin, cherry, and cranberry. In February 2017, DPR received a final residue report on cotton, chronic toxicity effects to adult honey bees, and U.S. EPA-required residue data on stone fruit, bell pepper, cucurbit, cantaloupe, and blueberry.

Mitigation Efforts and Status

In April 2010 and December 2012, imidacloprid and thiamethoxam registrants, respectively, agreed to remove use on almonds from all product labels in California. DPR considered this an important mitigation 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). This required registrants to include prescribed bee protective language on their product labels by the 2014 agricultural-use season for both existing and new product registrations. In November 2013, DPR required registrants to submit amended labels to California within 30 days of U.S. EPA acceptance. DPR completed its review of the U.S. EPA required label changes. Any of these products sold in the California marketplace must contain the improved pollinator protective label language.

In June 2014, DPR, U.S. EPA, and PRMA Health Canada 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 January 2016, U.S. EPA released a preliminary pollinator risk assessment for imidacloprid, which was a collaborative effort between DPR, U.S. EPA, and PRMA Health Canada. In January 2017, U.S. EPA released the preliminary pollinator risk assessments for thiamethoxam, clothianidin, and dinotefuran.

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. The risk

determination report is a refined Tier II assessment built off U.S. EPA's preliminary pollinator risk assessments and includes additional data that DPR received after U.S. EPA's preliminary pollinator risk assessments were issued. The determination report compares colony feeding study values to worst-case scenario residue values to determine risks to honey bees. After issuing the determination report, DPR received information identifying inconsistencies. Based on the newly available information, DPR issued an addendum to the California Neonicotinoid Risk Determination in January 2019. Additionally, in September 2018, DPR presented the risk determination report and the next steps required by FAC section 12838 to the PREC.

In January 2020, U.S. EPA issued their proposed interim registration review decisions (PIDs) for the four neonicotinoid active ingredients. DPR staff have assessed the PIDs to determine if any other considerations should be incorporated into the mitigation efforts.

In February 2020, DPR solicited formal scientific peer review on the documents used to scientifically support mitigation decisions, including the California Neonicotinoid Risk Determination and addendum. The peer review was completed in June 2020, and their feedback was incorporated into 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 contracted with the California Department of Food and Agriculture (CDFA) Office of Pesticide Consultation and Analysis to provide an economic analysis of various proposed mitigation alternatives.

In July 2020, DPR presented an overview of the next steps in the reevaluation and proposed mitigation plan for neonicotinoid uses on specific agricultural crops and crop groups to the PREC. In August 2020, DPR held stakeholder outreach webinars with Spanish interpretation to discuss the draft regulation proposal and solicit feedback. DPR posted copies of the mitigation proposal, the slides presented at the webinars, and recordings of the webinars on DPR's Neonicotinoid Reevaluation Web page linked below. Following the webinars, DPR accepted comments from the public and stakeholder on the draft meeting proposal through October 2020. During the comment period, DPR also posted additional background information, including CDFA's draft economic analyses.

After sharing the draft regulations with the public in August 2020, DPR received over 9,000 comments on the draft mitigation proposal. Staff reviewed the comments received and performed additional scientific analysis which resulted in a document titled "DPR's Response to Public Comments Received in Response to August 2020 Neonicotinoid Webinars" dated February 2022. DPR used this feedback along with the U.S. EPA PIDs and peer review feedback to refine and update the regulation proposal as appropriate.

DPR continues to collaborate with CDFA to determine the economic impact to growers from its proposed neonicotinoid control measures. Economic analysis reports were provided to DPR in

August 2019, July 2020, and July 2021 as DPR explored mitigation options and revised the proposed regulations. DPR presented an update on the neonicotinoid reevaluation and upcoming mitigation to the PREC in January 2022.

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 to receive oral or written comments regarding the proposed changes for DPR's consideration. The comment period ended on April 26, 2022. DPR received 18 comments. Additional information regarding DPR's proposed neonicotinoid pesticide exposure rulemaking can be found on DPR's Web page at <cdpr.ca.gov/docs/legbills/rulepkgs/22-001/22-001.htm>.

DPR staff are reviewing and developing responses to public comments received on the proposed regulations. Depending on the public comments, DPR will either amend the proposed regulations and solicit additional public comment or finalize the regulations and submit for review by the Office of Administrative Law.

For more information on the reevaluation for neonicotinoids, please visit DPR's Reevaluation Web page at <cdpr.ca.gov/docs/registration/reevaluation/chemicals/neonicotinoids.htm>.

SECOND-GENERATION ANTICOAGULANT RODENTICIDES (SGARs) - 64 Products

Basis and Scope

Second-generation anticoagulant rodenticide (SGAR) products are those that contain the active ingredients brodifacoum, bromadiolone, difenacoum, and difethialone. 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.

DPR's preliminary investigation determined that despite the 2014 regulations that changed SGAR use patterns by restricting their purchase, sale, and use, reported rates of non-target wildlife exposure to SGARs had not decreased. Additionally, the investigation found evidence of possible population-level impacts among non-target wildlife in California due to statistically significant associations with SGAR exposure and sublethal impacts. The investigation indicates that non-target wildlife exposure may be significant due to the chemical characteristics of SGARs, which are known to have properties of high toxicity, persistence, and bioaccumulation. The investigation also notes that brodifacoum has relatively higher rates of exposure among non-target wildlife compared to other SGARs.

Based on the preliminary investigation, the DPR Director found that a significant adverse impact has occurred or is likely to occur from the use of SGARs and proposed to begin reevaluation. In November 2018, DPR issued its proposed decision to begin reevaluation for SGAR products containing the active ingredients brodifacoum, bromadiolone, difenacoum, and difethialone and

allowed a 60-day comment period. DPR presented the proposed decision to begin reevaluation of SGARs to the PREC in January 2019 and to the Agricultural Pest Control Advisory Committee in March 2019.

On March 12, 2019, DPR issued its final decision to begin reevaluation for SGAR products containing the active ingredients brodifacoum, bromadiolone, difenacoum, and difethialone. The notice of final decision included a summary of the 17,234 comments received and provided response to relevant comments.

Data Requirements

Under this reevaluation, DPR required registrants of pesticide products containing the active ingredients brodifacoum, bromadiolone, difenacoum, and difethialone to (1) submit compliance proposals by May 2019, and (2) submit existing data related to non-target wildlife exposure by June 2019. Registrants of SGAR products containing brodifacoum, bromadiolone, and difethialone submitted the required compliance proposals and existing non-target wildlife exposure data.

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 SGAR 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.

Related Legislation

In September 2020, Governor Newsom signed Assembly Bill (AB) 1788 (Chapter 250, Statutes of 2020) to prohibit uses of SGARs due to their threat to mountain lions and other wildlife. As of January 1, 2021, AB 1788 prohibits the use of SGARs statewide subject to limited exceptions until the DPR Director certifies the department's completion of its reevaluation of SGARs, and the department's development, in consultation with the California Department of Fish and Wildlife (CDFW), and adoption of any additional use restrictions necessary to protect wildlife.

AB 1298 (Chapter 479, Statutes of 2021), signed in October 2021, revised a specific section in the FAC created by AB 1788. With this revision, effective January 1, 2022, the law provides an additional exemption when CDFW determines its necessary to control or eradicate an invasive rodent population for the protection of threatened or endangered species or their habitats.

Mitigation Efforts and Status

In place of submitting compliance proposals and data, registrants submitted voluntary cancellations for all three previously registered difenacoum products. As of May 2019, DPR no

longer has any difenacoum products registered for use in California.

In July and December 2019, DPR met with rodenticide stakeholders to discuss non-regulatory mitigation strategies and on-going scientific studies on SGARs. In December 2019 and April 2020, a registrant voluntarily submitted for DPR's review and consideration information about studies they intended to conduct. In May 2020, DPR presented the status of the SGAR reevaluation and data review to the PREC. In August 2020, DPR met with rodenticide stakeholders to discuss the SGAR reevaluation and the data identification letter.

In December 2020, DPR met with CDFW to discuss the SGAR reevaluation and consultation process. In March 2021, DPR met with rodenticide stakeholders to discuss the status of the reevaluation, the potential development of a task force and on-going scientific studies on SGARs. In June 2021, DPR met with CDFW to discuss the SGAR reevaluation status. DPR also met with U.S. EPA to discuss the federal timeline on rodenticide registration review, secondary exposure consideration, task force data and outreach.

In 2020, DPR contracted with Dr. Niamh Quinn of the University of California to conduct a study on rodenticide Best Management Practices (#19-C0061). This study is not limited to SGARs and the ongoing reevaluation; however, the results may provide general information to DPR on rodenticide practices. In April 2021, DPR authorized Dr. Quinn's use of SGARs in compliance with FAC section 12978(e)(7). DPR determined that under the terms of the contract the proposed research relates to SGAR reevaluation and its objective to ensure that any continued use of SGARs would not be expected to result in a potential significant adverse effect to non-target wildlife. Preliminary study results are expected in 2022.

DPR and CDFW met in March 2022 to discuss SGAR reevaluation. DPR and CDFW will continue to meet to ensure effective consultation under current legislation. Later in March 2022, DPR received a request for SGAR research authorization from Dr. Quinn. This request is currently under DPR review to determine if it complies with FAC section 12978(e)(7) with a decision expected July.

In June 2022, DPR started an ecosystems monitoring contract (#21-C0091) with Dr. Quinn to monitor for SGARs in urban carnivores. This contract ends in 2024.

DPR continues to work with stakeholders, including SGAR researchers, to facilitate discussions of potential mitigation strategies. Additionally, U.S. EPA is currently conducting a registration review of several rodenticide pesticide chemicals, which include SGAR chemicals. DPR continues to monitor federal decisions on SGAR pesticide product registrations.

For more information on the reevaluation for SGARs, please visit DPR's Reevaluation Web page at <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. No preliminary investigations are underway at this time.

For more information on this semiannual report or any of DPR's reevaluations, please visit DPR's Reevaluation Program Web page at <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 Tulio Macedo — *September 6, 2022*

Tulio Macedo, Chief
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Date

cc: Mr. Andrew Turcotte, Environmental Scientist