

Department of Pesticide Regulation



California Notice 2018-18

SEMIANNUAL REPORTS SUMMARIZING THE REEVALUATION STATUS OF PESTICIDE PRODUCTS DURING THE PERIOD OF July 1, 2017 through December 31, 2017 AND January 1, 2018 through June 30, 2018

California regulations require the Department of Pesticide Regulation (DPR) 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 a number of 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. Often, an ongoing DPR pesticide review triggers 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 a number of different ways. If the data demonstrates 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 (see page 2); and,

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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 (see page 14).

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 Application to Amend Pesticide Products if 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 Section 18, Emergency Exemption requests, submissions 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 Products.

FORMAL REEVALUATION

Formal reevaluation is initiated 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*.

ANTIFOULING PAINT PESTICIDES (COPPER) – 217 Products

<u>Basis and Scope:</u> On June 1, 2010, DPR placed antifouling paint (AFP) pesticide products containing the active ingredients copper oxide, copper hydroxide, and cuprous thiocyanate into reevaluation. The reevaluation is based on findings from a June 2009 DPR report titled, *Monitoring for Indicators of Antifouling Paint Pollution in California Marinas*. The report found that dissolved copper concentrations in more than half the water samples taken from salt and brackish water marinas exceeded the California Toxics Rule chronic water quality standard. Also, a third of the samples exceeded the acute (short-term) standard.

The California Regional Water Quality Control Board (CRWQCB) water quality criteria requires that all waters be maintained free of toxic substances in concentrations that are toxic to, or that produce detrimental physiological responses in human, plant, animal, or aquatic life. Dissolved copper concentrations violate CRWQCB's water quality objectives for toxicity. DPR's report found that copper-based AFP pesticides applied to boat hulls are likely a major source of dissolved copper in salt and brackish water marinas, particularly during dry weather periods. The report concluded that the main pathways of copper contamination appear to be passive leaching and in-water boat hull cleaning of copper-based antifouling painted boats.

<u>Data Requirements:</u> Under this reevaluation, DPR required registrants of copper-based AFPs to submit the following: (1) information identifying the paint type (e.g., ablative, epoxy ester); (2) data characterizing the product's copper leach rate; (3) specific mitigation strategies that reduce dissolved copper concentrations in California salt and brackish water marinas; and, (4) marina monitoring data after mitigation strategies have been implemented. In March 2011, DPR notified copper-based AFP registrants of an additional data requirement to examine the impact of in-water hull cleaning activities on copper concentrations in California marinas.

<u>Summary:</u> DPR completed its evaluation of leach rate and paint type information for all copperbased AFP pesticide products and continues to require this data for newly registered products. The International Organization for Standardization (ISO) method 10890:2010 is used to determine each AFP's copper release (leach) rate. Using this data and an established adjustment factor for comparison to actual environmental leach rates, DPR calculates a final daily mean copper release rate. A list of currently registered copper-based AFP products by leach rate category is available on DPR's copper reevaluation page listed below. Based on submitted paint type information, most copper AFPs are either copolymer ablative or epoxy ester. Copper leach rate and paint type provides DPR with important data and information to better assess factors that contribute to high copper concentrations dissolved in marinas from AFP pesticides. In June 2012, DPR approved the American Coating Association Antifouling Working Group's in-water hull cleaning study protocol. DPR requested academia be involved in all aspects of this study and the findings be submitted to a peer-reviewed journal.

On November 7, 2013, the final report titled, "Life Cycle Contributions of Copper from Vessel Painting and Maintenance Activities" was published in *Biofouling: The Journal of Bioadhesion and Biofilm.* DPR completed its evaluation of the study. Based on the required hull cleaning study, utilization of the Marine Antifoulant Model to Predict Environmental Concentrations (MAMPEC) modeling tool (to simulate the fate of copper in typical California marinas), and all available information, DPR made certain mitigation recommendations.

Mitigation Efforts and Status: In February 2013, the California Legislature introduced Assembly Bill (AB) 425, which required DPR to propose a copper leach rate for recreational vessels and make mitigation recommendations by February 1, 2014. On October 5, 2013, AB 425 was signed into law. On January 30, 2014, DPR proposed establishment of two maximum allowable leach rates depending on cleaning practice. These leach rates are 9.5 μg/cm²/day, if cleaning is limited to no more than once per month and follow best management practices using soft-pile carpet, and 13.4 μg/cm²/day for products that prohibit in-water hull cleaning. In addition, DPR recommended several mitigation measures. DPR presented the leach rates and mitigation recommendations to registrants, stakeholders, and sister agencies at several meetings. After discussions with stakeholders and accounting for enforcement challenges, DPR determined establishing a single maximum allowable leach rate of 9.5 μg/cm²/day for recreational vessel copper-based AFP products would be the most effective way to reduce copper contamination in California surface waters. Meanwhile, in December 2015, DPR collaborated with the Port of San

Diego and other state and local water agencies on published boater education and outreach material for Southern California.

In early 2016, DPR initiated the rulemaking process to establish the maximum allowable release rate for copper-based AFPs into regulation and submitted its leach rate methodology for external scientific peer review. Reviewers provided their comments, which were largely supportive of DPR's methodology. DPR responded to the reviewers comments. On November 18, 2016, DPR provided public notice of the proposed regulatory action on copper-based AFPs. The notice stated, effective July 1, 2018, the proposed action would establish a maximum allowable leach rate for current and newly registered copper-based AFP products for use on recreational vessels. The proposed action would also require registrants to submit ISO leach rate data. The 45-day comment period for the comment period closed on January 4, 2017. DPR responded to the comments received. On January 20, 2017, DPR gave a presentation to the Pesticide Registration and Evaluation Committee on the copper-based AFP reevaluation and the status of DPR's copper mitigation activities. DPR filed, on July 21, 2017, the new copper-based antifouling paints and coatings regulation with the secretary of state, establishing data requirements and use restrictions.

Effective January 1, 2018, the regulation requires registrants of new copper-based AFP products to submit ISO leach rate data and supporting documentation. Effective July 1, 2018, the regulation establishes a maximum allowable leach rate for current and newly registered copper-based AFP products for use on recreational vessels.

On January 16, 2018, DPR concluded the copper-based AFP reevaluation and determined that no additional mitigation measures were necessary. However, DPR will continue to look for collaborative opportunities with its partners, including with the U.S. Environmental Protection Agency (U.S. EPA) as they conduct their copper registration review, on copper mitigation and outreach activities to further mitigation efforts and actions to reduce copper concentrations in California marinas.

For more information on this reevaluation please, visit DPR's Reevaluation Web page at http://www.cdpr.ca.gov/docs/registration/reevaluation/chemicals/antifoulant_paints.htm.

CHLOROPICRIN - 32 Products

<u>Basis and Scope:</u> On October 16, 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's reference exposure limit and the Occupational Safety and Health Administration's permissible exposure limit of 100 parts per billion (ppb) averaged over an eight-hour period. Also, DPR found that data submitted under the Birth Defect Prevention Act indicated chloropicrin has the potential to cause adverse health effects at low doses.

<u>Data Requirements:</u> 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, based on evaluation of submitted and other available data and information, DPR established a mechanistic study data requirement for the scientific assessment of the carcinogenic hazard of chloropicrin.

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 Scientific Review Panel completed its peer review of the document in April 2010 and a regulation listing chloropicrin as a TAC was filed on December 9, 2010. 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. After chloropicrin was designated as a TAC effective January 8, 2011, DPR initiated development of use restrictions following TAC procedures specified in state law. On November 14, 2012, DPR completed its comprehensive chloropicrin RCD, which includes dietary and occupational exposure scenarios.

On July 24, 2015, DPR established a new mechanistic data requirement to attain more information on the potential carcinogenicity of chloropicrin. On several occasions, the Chloropicrin Manufacturers' Task Force (CMTF), on behalf of chloropicrin registrants, met with DPR to discuss technical elements, methodology, and the study protocol. In June 2016, DPR accepted the CMTF protocol for 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 an extension request, study timeline, logistics, technical challenges, and requested additional information. In March 2017, CMTF provided additional information and an update on the initiation of the study. In April 2017, CMTF provided a progress report. On May 1, 2017, DPR granted CMTF's extension request and established a new required final study submission date along with required submissions of regular interim reports.

On January 2, 2018 and May 3, 2018, CMTF submitted the required quarterly interim reports. DPR scientists evaluated the reports and reiterated the required final study submission date.

<u>Mitigation Efforts and Status:</u> During this reevaluation, the U.S. EPA developed label mitigation measures under its Reregistration Eligibility Decision (RED) 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 on December 31, 2010 and December 1, 2012. The measures added more restrictions, prohibitions, and human health protection language and information on the product label. DPR completed its fumigant label reviews and continues to monitor new and amended pesticide product registrations to ensure labeling compliance.

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 Air Resources Board, the air pollution control districts, and the county agricultural commissioners, as required by California Food and Agricultural Code section 14024(a). In addition to consulting with state and local agencies required by law, DPR also discussed early mitigation concepts with worker advocate groups and registrants. DPR also submitted its initial technical analysis for scientific peer review. DPR received comments from several thousand people and three external scientific peer reviewers. DPR responded to the comments received.

In early January 2015, DPR posted "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. On January 16, 2015, DPR presented the chloropicrin mitigation measures to the Pesticide Registration and Evaluation Committee members and public attendees. On April 6, 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 chloropicrin human health risk assessment and mitigation documents are available on DPR's Web site at http://www.cdpr.ca.gov/docs/whs/active_ingredient/chloropicrin.htm.

For more information on this reevaluation, please visit DPR's Reevaluation Web page at http://www.cdpr.ca.gov/docs/registration/reevaluation/chemicals/chloropicrin.htm.

CYFLUTHRIN - 43 Products

<u>Basis and Scope:</u> On May 5, 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. DPR determined that, as dust and pollen are a part of the normal working environment, additional variables in the work environment led to the workers' respiratory irritation symptoms experienced. DPR compiled the results in its monitoring study titled, *Health and Safety Report HS – 1765*, which found probability that cyfluthrin, applied close to harvest, led to the symptoms experienced. The monitoring study can be viewed on DPR's Web site at http://www.cdpr.ca.gov/docs/whs/pdf/hs1765.pdf>.

<u>Data Requirements:</u> Under this reevaluation, DPR required registrants of pesticide products containing the active ingredient cyfluthrin to provide the following: (1) respiratory irritation study, (2) worker exposure study, and (3) monitoring data for structural application. 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 RD50 Determination in Rats*. Based on this data, DPR determined structural monitoring data was no longer required. However, during the course of 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 during sweet corn harvesting be conducted. The results of the study were submitted to DPR in October 2004.

<u>Summary:</u> In 2006, DPR determined a comprehensive exposure assessment is necessary for cyfluthrin. In September 2008, DPR completed an exposure-scoping document for cyfluthrin intended to lay the groundwork for the risk assessment process. DPR completed review of cyfluthrin sweet corn hand harvester studies and reevaluation is pending further assessment of the potential risks associated with the use of cyfluthrin. In August 2015, an update to DPR's Summary of Toxicology Data document for chronic health effects on cyfluthrin was completed.

Mitigation Efforts and Status: The problem formulation document was posted to DPR's Web site on January 30, 2018. In February 2018, DPR presented the problem formulation document and initiation of the risk assessment for cyfluthrin at the Pesticide Registration and Evaluation Committee meeting. Additionally, U.S. EPA's registration review of cyfluthrin is currently in progress. DPR will collaborate with U.S. EPA on the risk assessment, where possible. Human Health Assessment Branch plans to release the draft RCD in 2019. If DPR's risk characterization concludes that use of cyfluthrin poses a risk to workers, DPR will proceed with mitigation. More information on cyfluthrin human health risk assessment and additional resources are available on DPR's Web site at http://www.cdpr.ca.gov/docs/whs/active ingredient/cyfluthrin.htm>.

For more information on this reevaluation, please visit DPR's Reevaluation Web page at http://www.cdpr.ca.gov/docs/registration/reevaluation/chemicals/cyfluthrin.htm.

DIAZINON - 4 Products

<u>Basis and Scope:</u> On February 19, 2003, DPR placed all agricultural use diazinon products labeled as dormant sprays into reevaluation. The reevaluation is based on monitoring studies

conducted between 1991 and 2001 by the U.S. Geological Survey, Dow AgroSciences, Central Valley Regional Water Quality Control Board (CVRWQCB), State Water Resources Control Board (SWRCB), and DPR. These studies reported the presence of diazinon in surface waters of the Sacramento-San Joaquin (SJ) Valley at levels that exceed water quality criteria (WQC), especially during the dormant spray season.

<u>Data Requirements:</u> Under this reevaluation, DPR required registrants of pesticide products containing the active ingredient diazinon to: (1) identify the processes by which diazinon dormant spray products are contributing to detections of diazinon in surface water at levels that exceed WQC; and, (2) identify mitigation strategies that will reduce or eliminate diazinon residues in surface water. In June 2010, based on analysis of monitoring data, DPR expanded the reevaluation to include in-season uses as well as dormant season applications. Additionally, DPR required diazinon registrants to: (1) collect and evaluate all relevant (2005-2009) surface water monitoring data; and, (2) establish crop-specific mitigation measures based upon results of submitted monitoring data. Furthermore, at initiation of this reevaluation, diazinon registrants responded to DPR's concerns by developing and implementing supplemental labeling for dormant spray products.

Summary: In July 2005, DPR approved monitoring protocols submitted by the primary manufacturer intended to evaluate the effectiveness of the proposed mitigation strategies. In September 2006, the final studies were submitted, but did not state whether diazinon registrants intended to use the information to develop and implement additional mitigation measures. Meanwhile, DPR began working on possible mitigation measures. In July 2006, DPR approved dormant spray regulations to restrict pesticide application during the dormant season (i.e., rainy season in winter). These regulations require the operator of the property to follow certain practices, prohibits certain applications, and requires written recommendation from a pest control adviser before an application. By December 2006, all dormant spray diazinon product labels were amended. The supplemental labels added more ecologically protective language such as prohibiting application when soil moisture is at field capacity and/or when a storm event is likely, and restricting dormant applications on orchards to ground application equipment only.

In February 2007, DPR received a report prepared by University of California, Davis (UCD) titled, Residues of the 2006 TMDL Monitoring of Pesticides in California's Central Valley Waterways, January—March 2006. This study found diazinon concentrations measured during the 2006 dormant spray season were still exceeding WQC. DPR forwarded the UCD study to diazinon registrants and requested the development and implementation of further mitigation measures to reduce or eliminate diazinon residues in surface water. In February 2008, the primary manufacturer submitted two reports titled, Analysis of Diazinon Environmental Monitoring Data from the Sacramento/Feather River Watersheds: 2001–2007, and Project Report: Landguard OP-A as a Best Management Practice in Dormant Season Use, December 2007. In October 2008, the primary manufacturer submitted another report titled, Analysis of Diazinon Environmental Monitoring Data from the San Joaquin River Watershed: 2001–2007.

In October 2009, DPR analysis of monitoring data from 2003-2008 found that diazinon was detected in 637 out of 2,635 samples collected from water bodies located in the Central Valley, Central Coast, and southeastern California. As a result, on June 22, 2010, the Director expanded the reevaluation to include in-season uses as well as dormant season applications and required additional data of diazinon registrants to better assess surface water runoff and exceedances. In March 2011, the primary manufacturer submitted a combined monitoring report for both dormant and in-season monitoring titled, *Summary of Diazinon Water Column Monitoring Data for Nine California Regions:* 2005-2010, which DPR found to be acceptable. In September 2011, DPR completed an analysis memo titled, *Analysis of Diazinon Agricultural Use in Regions of Frequent Surface Water Detections*. In June 2017, DPR completed an analysis of diazinon monitoring and use data titled, "A review of diazinon use contamination in surface waters, and regulatory actions in California across water years 1992-2014" which was published in the journal of *Environmental Monitoring and Assessment*.

Mitigation Efforts and Status: During the course of this reevaluation, various mitigation measures have been implemented. In 2004, U.S. EPA eliminated all sales of outdoor residential use diazinon products. In July 2006, U.S. EPA finalized its RED on diazinon requiring certain mitigation measures to reduce human health and ecological risk such as provisions to cancel certain agricultural crop uses and aerial applications, reduce the amount and frequency of use, and employ engineering controls and other protective measures. On July 18, 2006, DPR adopted dormant spray regulations that placed further restrictions on the use of diazinon products. Additionally, through the Dormant Spray Water Quality Initiative, DPR continues to work to prevent aquatic toxicity from residues of diazinon in the Sacramento and SJ rivers. DPR's recent analysis paper on diazinon monitoring and use data provides a comprehensive surface water assessment and will inform the next steps of this reevaluation. Additionally, DPR will continue to monitor the efforts of U.S. EPA, SWRCB, and CVRWQCB for possible opportunities to collaborate on mitigation.

On January 22, 2018, DPR concluded the diazinon reevaluation with California Notice 2018-05. DPR determined the reevaluation provided all the required data and concluded that the use of diazinon in recent years has decreased to a level that does not pose a risk to aquatic organisms. DPR has determined that no additional mitigation measures are necessary and continues to monitor dormant and in-season diazinon surface water data.

For more information on this reevaluation, please visit DPR's Reevaluation Web page at http://www.cdpr.ca.gov/docs/registration/reevaluation/chemicals/diazinon.htm.

NEONICOTINOIDS (NITROGUANIDINE INSECTICIDES) – 276 Products

<u>Basis and Scope:</u> On February 27, 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: high levels of imidacloprid in leaves and blossoms of treated plants and 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).

<u>Data Requirements:</u> Under this reevaluation, DPR requires registrants of neonicotinoid pesticide products containing imidacloprid, thiamethoxam, clothianidin, and dinotefuran to provide, for each active ingredient, the following data: LC₅₀ (acute), categorized as a Tier I study, on honey bees starting at the larval stage through emergence; and, field-based residue studies in pollen, nectar, and leaves from specific agricultural orchard and row crops. For field-based residue data requirement purposes, DPR's Pesticide Use Reporting database was used to determine the crops of focus for each active ingredient. During the course of this reevaluation, initial field residue data provided were found to be inconclusive and did not involve "worst-case" scenarios. DPR modified its residue study strategy to require controlled applications at the highest maximum application rate per year for two consecutive years. DPR required these two-year prescriptive residue studies of imidacloprid, thiamethoxam, clothianidin, and dinotefuran registrants for certain commodities.

Additionally, U.S. EPA requires higher tier honey bee toxicity studies and additional field-based residue studies for their reevaluation of neonicotinoids, which are shared with DPR and the Pest Regulatory Management Agency (PMRA) 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. DPR continues to receive Tier I, Tier II and Tier III studies for the active ingredients imidacloprid, thiamethoxam, clothianidin, and dinotefuran.

Summary (by Active Ingredient):

<u>Imidacloprid</u>: DPR notified registrants of products containing the active ingredient imidacloprid of the LC₅₀ 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 required stone fruits. Rather than conduct a residue study in almonds, imidacloprid registrants removed use on almonds from their labels.

In April 2010, the primary manufacturer submitted draft residue study protocols for cotton, melons, tomatoes, apples, and strawberries. The draft protocols were reviewed by DPR, U.S. EPA, and PMRA Health Canada. In May 2011, DPR received final reports from residue studies conducted on citrus, cotton, and tomato. In March 2012, DPR provided a review of the submitted reports and found both the cotton and tomato studies to be unacceptable because they did not represent worst-case scenarios. As a result, DPR required two-year prescriptive residue studies representing worst-case scenarios for cotton, tomatoes, pome fruit, and expanded the crops required to include stone fruit.

On March 21, 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 May 2012, DPR reviewed and accepted four two-year prescriptive residue study protocols for cotton, tomato, apple, and cherry. On December 28, 2012, DPR received final reports on strawberry and melon. On June 3, 2014, DPR received revised interim reports on cotton and tomato. On November 20, 2014, DPR received interim reports on apple and cherry. In December 2014, DPR received a final report on chronic toxicity effects to adult honey bees and received submissions of U.S. EPA required residue data on blueberry, citrus, corn, cotton, stone fruit, and on rotational white clover used as forage. On June 30, 2015, DPR received a final report on cotton and a progress report on tomatoes. 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.

<u>Thiamethoxam</u>: DPR notified registrants of products containing the active ingredient thiamethoxam of the LC₅₀ 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 stone fruit. In February 2013, rather than conduct a residue study on almonds, thiamethoxam registrants removed almond use from their labels.

The primary manufacturer submitted draft protocols for residue studies in melons, tomatoes, and apples, which were reviewed by DPR, U.S. EPA, and PMRA Health Canada. 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 tomatoes and acute toxicity effects to larval honey bees.

In October 2012, DPR required two-year prescriptive residue studies for strawberry, and expanded the required crops to include almond (registrants removed use from label), citrus, cotton, and stone fruit. On January 23, 2013, DPR received a final report on cucumbers, and final protocols on citrus, cotton, and stone fruits (cherry, peach, and plum). In September 2014, DPR received interim reports on citrus and cotton. On July 22, 2015, DPR received a final report on cotton. On October 26, 2015, DPR received an interim report on strawberry. On December 29, 2015, DPR received a final report on cotton, stone fruit (cherry, peach, and plum), and received U.S. EPA required reside data on cranberry, cucumber, pepper, tomato, and soybean treated seed. In March 2016, DPR received a final report on a voluntary orange study and a submission of U.S. EPA required residue data on citrus. In March and July 2017, DPR received a final report on citrus, strawberry, and 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 file report on cotton, and U.S. EPA required residue data on sweet orange and blueberry. On April 2018, DPR received amended U.S. EPA required residue data on citrus.

<u>Clothianidin:</u> DPR notified registrants of products containing the active ingredient clothianidin of the LC₅₀ 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 a waiver due to limited use in California. DPR granted a waiver for the residue study on pome fruit. In January and April 2011, the primary manufacturer submitted an acute larval toxicity study protocol and a proposed residue study draft protocol on cucurbits (pumpkins). In February 2012, the primary manufacturer submitted a final report on chronic toxicity effects to larval honey bees.

On May 9, 2013, DPR required two-year prescriptive residue studies for almond, cucurbit, fruiting vegetable, and a stone fruit. In May 2013, DPR received an interim report on pumpkins. In August 2013, the primary manufacturer submitted a combined orchard protocol (almond, pome, and stone fruit) to address U.S. EPA, PMRA Health Canada, and DPR's reevaluations. On March 4, 2014, DPR received an interim report on pumpkins. In October 2015, DPR received an interim residue report on almond, a final residue report on cotton, and a submission of U.S. EPA required interim residue data on apple. On April and May 2015, DPR received a final report on pumpkins and submissions of 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 submissions of U.S. EPA required residue data on cotton, pumpkin, potato, and additional 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 submissions of 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 studies on soybean treated seed, peach, and additional corn, and citrus.

<u>Dinotefuran:</u> DPR notified registrants of products containing dinotefuran of the LC₅₀ 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 January 2014, the registrant submitted a protocol to conduct an acute larval toxicity study. In January 2015, DPR jointly reviewed residue protocols required by U.S. EPA for potato, tomato, pumpkin, cucumber, cherry, cotton, and cranberry. On October 28, 2015, DPR received a final report on acute larval toxicity effects to honey bees. During this report period, DPR received residue study final reports on cucurbits (cucumber) and fruiting vegetables (tomatoes). In February and March 2016, DPR received submissions of U.S. EPA required residue data on potato, pumpkin, cherry, and cranberry. In February 2017, DPR received a final residue study 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.

<u>Multi-Agency Collaboration:</u> On June 20, 2014, a Presidential Memorandum creating a federal strategy to promote the health of honey bees and other pollinators was signed. In June 2014, a DPR, U.S. EPA, and PMRA Health Canada collaborative document titled, *Guidance for Assessing Pesticide Risks to Bees* was completed and posted on U.S. EPA's Pollinator Protection Web site located at http://www2.epa.gov/pollinator-protection>.

On January 6, 2016, U.S. EPA released a preliminary pollinator risk assessment for imidacloprid, which was a collaborative effort between PMRA Health Canada, DPR and U.S. EPA. On January 12, 2017, U.S. EPA posted the preliminary pollinator risk assessments for thiamethoxam, clothianidin, and dinotefuran. DPR will continue to work closely with its partners to investigate all available sources of bee attractive residue and honey bee effects data that may be scientifically meaningful to the reevaluation.

<u>Mitigation Efforts and Status:</u> In April 2010 and December 2012, imidacloprid and thiamethoxam registrants, respectively, agreed to remove use on almonds from all product labels in California. DPR considers this an important mitigation step in pollinator protection since almond orchards require a large number of pollinators.

During the course of this reevaluation, on August 15, 2013, U.S. EPA notified registrants of neonicotinoids of new labeling requirements for all formulations having outdoor foliar use directions (except granular products). This required registrants to include prescribed bee protective language on their product labels by the 2014 agricultural use season for existing and new product registrations. In November 2013, DPR required registrants to submit amended labels to California shortly after U.S. EPA acceptance. DPR has completed its pollinator label review and continues to monitor new and amended product registrations to ensure labeling compliance. Improved pollinator protective labels are currently in the California marketplace.

DPR continues to work closely with beekeepers and County Agricultural Commissioners to prevent problems through apiary inspector trainings, workshops, and outreach and educational material. In June 2014, DPR held an apiary workshop to educate and inform beekeepers, biologists, and County Agricultural Commissioners on how to identify bee hive disease and pests. The workshop addressed how to investigate incidents of bee colony damage where pesticides are suspected of playing a role. In November 2015, DPR held a "Bee Aware!" symposium to increase communication, collaboration, and cooperation for greater bee awareness. In May 2016, DPR held apiary inspectors trainings for County Agricultural Commissioner biologists. On February 14, 2017, DPR held a second "Bee Aware!" symposium on bee awareness and best management practices for the protection of pollinators.

On or before July 1, 2018, DPR will submit the California Neonicotinoid Risk Determination to the State Legislature in accordance with California Food and Agricultural Code (FAC) §12838. FAC §12838 states that DPR must adopt necessary control measures to protect pollinator health within two years of the determination document being issued. Within the two-year period, DPR

will continue reviewing data and consulting with experts and other stakeholders to help inform mitigation decisions. Additionally, U.S. EPA is scheduled to issue their final pollinator risk assessments for the four compounds in the spring of 2019, which may also contain useful information for mitigation.

For more information on this reevaluation, please visit the following Web page: http://www.cdpr.ca.gov/docs/registration/reevaluation/chemicals/neonicotinoids.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.

FIPRONIL - 3 Products

DPR conducted a preliminary investigation of pesticide products containing the active ingredient fipronil due to California surface water concerns. DPR identified water quality concerns based on environmental monitoring, ecotoxicology, and environmental fate data indicating products containing fipronil may adversely affect California surface waters. Fipronil, an insecticide, has been detected in approximately half of all monitoring samples at concentrations above toxicity thresholds set by U.S. EPA. DPR investigated probable sources and transport of fipronil containing products and initiated discussions with registrants and stakeholders regarding fipronil and water quality concerns. Outdoor applications, especially those to impervious surfaces such as driveways, are considered significant sources for off-site movement of fipronil and its' degradates to urban receiving waters. DPR identified two liquid formulated outdoor perimeter structural use products as contributing to urban runoff concentrations.

DPR notified fipronil registrants of the water quality concerns and initiated information and data gathering with them and other stakeholders. Through investigation, research, and collaboration, DPR developed two fipronil analysis papers: Fipronil Monitoring and Model Scenarios; and, an Addendum document to the first paper. Using these documents DPR presented this data and information to registrants and stakeholders, and engaged in potential mitigation discussions to fipronil liquid outdoor perimeter structural use products. The registrants voluntarily agreed to add California specific label mitigation use restrictions under the appropriate section of the label that include the following: reduced active ingredient concentration applied; rainy season prohibition; reduced application bandwidth; reduced application volume; prohibiting application to driveway/garage door; prohibiting reapplication intervals less than sixty (60) days.

The label changes are approved in California. DPR will continue to conduct public outreach to applicators regarding the California specific use restrictions and monitor the registration of new fipronil products in California.

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For more information on this semiannual report or a reevaluation, please visit DPR's Web site at https://www.cdpr.ca.gov/docs/registration/reevaluation/reevals.htm or contact either Mr. Russell Darling, Senior Environmental Scientist (Specialist), at Russell.Darling@cdpr.ca.gov or by telephone at 916-324-3547 or Ms. Brenna McNabb, Environmental Scientist at Brenna.McNabb@cdpr.ca.gov or by telephone at 916-445-0179.

Original signed by Ann M. Prichard

October 23, 2018

Ann M. Prichard, Chief Pesticide Registration Branch 916-324-3931 Date

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