Department of Pesticide Regulation

Julie Henderson
Director

Gavin Newsom
Governor

Yana Garcia
Secretary for Environmental Protection

California Notice 2023-06

POST UNTIL: June 19, 2023

NOTICE OF PROPOSED DECISION TO BEGIN REEVALUATION OF DIPHACINONE AND PUBLIC REPORT

Pursuant to Title 3 of the California Code of Regulations (3 CCR) sections 6220, 6253, and 6254, the Director of the Department of Pesticide Regulation (DPR) notices the proposed decision to begin reevaluation of pesticide products containing active ingredients diphacinone and diphacinone sodium salt (henceforth diphacinone).

This reevaluation would involve 12 registrants and 56 pesticide products currently registered in California. A list of products proposed to be included in the reevaluation is available upon written request to the address listed below or on DPR's Diphacinone Web site. <cdpr.ca.gov/docs/registration/reevaluation/chemicals/diphacinone.htm>.

COMMENT PERIOD

Interested persons may submit comments on the proposed decision to begin reevaluation of diphacinone. DPR will accept comments by mail and email up to and including June 19, 2023. Comments submitted by U.S. mail must be postmarked no later than June 19, 2023, and mailed to the Department of Pesticide Regulation, Pesticide Registration Branch, 1001 I Street, P.O. Box 4015, Sacramento, California 95812- 4015. Additionally, comments can be submitted by email to <Rodenticide.Comments@cdpr.ca.gov>.

BASIS OF REEVALUATION

Pesticide products containing the active ingredients diphacinone and diphacinone sodium salt are classified as first-generation anticoagulant rodenticides (FGARs). While both diphacinone and its sodium salt start as different chemical compounds, diphacinone sodium salt quickly converts to diphacinone in the environment. The data discussed in detail below will be reported as simply diphacinone in this investigation, unless otherwise noted. 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).

Following the 2018 Investigation of Anticoagulant Rodenticide Data Submitted to the Department of Pesticide Regulation (2018 Investigation), DPR commenced reevaluation of pesticide products containing the second-generation anticoagulant rodenticide (SGAR) active ingredients brodifacoum, bromadiolone, difenacoum, and difethialone in March 2019. At that time, DPR did not commence reevaluation of pesticide products containing the FGAR active ingredients diphacinone, warfarin, or chlorophacinone.

On September 29, 2020, Governor Newsom signed Assembly Bill (AB) 1788 (Chapter 250, Statues of 2020) which prohibited most uses of SGARs due to their threat to mountain lions and non-target wildlife. As of January 1, 2021, Food and Agricultural Code (FAC) section 12978.7 prohibits most uses of SGARs, with some exemptions, until DPR completes its ongoing SGAR reevaluation and adopts any necessary restrictions on use. The statute does not limit the use of any FGARs, including diphacinone.

On September 27, 2022, the California First District Court of Appeal ordered DPR to reconsider its decision to not commence reevaluation of pesticide products containing the active ingredient diphacinone after analyzing diphacinone-specific data in the 2018 Investigation relevant to assessing its potential impact on the environment, including performing a cumulative impacts analysis (*Raptors are the Solution v. California Department of Pesticide Regulation et al.* (Sept. 27, 2022; Alameda Co. Sup. Ct. Case No. RG 18908605 [nonpub. opn.])). In accordance with the Court's order, this document updates and supersedes the 2018 Investigation only with respect to the analysis of reported diphacinone exposure, sales, and use data and diphacinone-specific information from the 2018 Investigation indicating that diphacinone may have caused, or is likely to cause, a significant adverse impact pursuant to 3 CCR section 6220.

As a part of its continuous evaluation of pesticides in California, DPR tracks wildlife incident and mortality data received from the California Department of Fish and Wildlife (CDFW). DPR also tracks statewide sales and use reporting data for all pesticides, including anticoagulant rodenticides (ARs). The data and studies reviewed in the 2018 Investigation did not provide sufficient information to link reported adverse environmental impacts to diphacinone specifically and, at the time, sales of diphacinone and exposure rates were decreasing. Since publishing the 2018 Investigation, wildlife exposure data indicates a larger percentage of pesticide toxicosis cases are associated with exposure to diphacinone. Additionally, DPR's reported statewide sales and use reporting data for diphacinone have also shown increases. Based on the substantial increase in exposure of non-target wildlife to diphacinone, DPR finds that a significant adverse impact to non-target wildlife has occurred or is likely to occur from the use of diphacinone. DPR is proposing to begin a reevaluation of pesticide products containing the active ingredient diphacinone and its salt on this basis. This will allow for further evaluation of non-target wildlife exposure to determine if additional mitigation measures on the use of diphacinone are needed.

Diphacinone Data from the 2018 Investigation

When evaluating a pesticide's hazard to non-target organisms, toxicity, persistence, and bioaccumulation are important factors to be considered. As outlined in the 2018 Investigation, diphacinone is classified as moderately toxic to avian species (LD_{50} of 96.8 mg ai/kg body weight [bw]) and very highly toxic to mammals (LD_{50} of 0.2 mg ai/kg bw) via acute oral exposure. Diphacinone is not expected to persist in the livers of animals that have been exposed, with a hepatic (liver) half-life of 3 days (2018 Investigation). This short hepatic half-life suggests that an animal that ingests diphacinone may only carry the compound for a period of days.

Diphacinone has an octanol-water partition coefficient of 4.3, indicating that it has the potential to bioaccumulate (2018 Investigation).

During the 2018 Investigation, CDFW provided DPR with mountain lion AR exposure data. The data came from a two-year grant during which CDFW tested every mountain lion available for the presence of anticoagulant rodenticides. According to CDFW, many of these mountain lions were killed through depredation permits, but some were also killed in vehicular collisions, as well as other causes of death. This mountain lion AR exposure data indicated that from 2015-2016, 59% percent of the 64 tested mountain lions were exposed to diphacinone. WildCare, a non-profit organization that operates a wildlife rehabilitation hospital in the San Francisco Bay Area, provided DPR exposure data indicating up to 30% of 276 tested wild animals (birds and mammals) from 2013-2016 were exposed to diphacinone. Additional information about these datasets is described in the 2018 Investigation.

The 2018 Investigation also reviewed wildlife exposure data from peer-reviewed publications submitted to DPR. In Serieys et al. (2015), bobcat liver and blood samples from populations residing near Los Angeles, California were analyzed for AR exposure. Liver samples were collected from bobcats that died in wildlife rehabilitation centers or from opportunistically found bobcat carcasses. Blood samples were collected from trapped bobcats. Diphacinone was detected in about 40% and 30% of tested liver and blood samples, respectively. In Serieys et al. (2018), blood sample analysis was conducted for 98 bobcats from in and around the Santa Monica Mountains National Recreation Area; for 32 of these bobcats diphacinone was the only AR detected. In Poessel et al. (2015), the livers of 5 coyotes (*Canis latrans*) in Denver, Colorado were tested for ARs and none tested positive for diphacinone. In Gabriel et al. (2018), liver samples from 94 owls from Del Norte, Humboldt, Western Trinity, and Northern Mendocino Counties in Northern California were tested for exposure to ARs, and diphacinone was not detected in any of the owls. In Franklin et al. (2018), a single owl recovered from Humboldt County, California was tested for AR exposure and diphacinone was not detected. Additional information and limitations of these peer-reviewed publications are discussed in the 2018 Investigation.

Diphacinone exposure does not necessarily indicate the animal died due to diphacinone poisoning (toxicosis). However, exposures in the environment may still be associated with adverse impacts to non-target animals. In Serieys et al. (2015), the study authors found statistically significant associations between certain SGARs and mange, between the total number of compounds detected and mange, and between total AR residues and mange. However, the study authors did not find an association between diphacinone and mange. Despite the high exposure rates, only one bobcat was determined to have died directly because of AR exposure, and it is unclear if this specific animal was exposed to diphacinone.

Gabriel et al. (2015) determined that AR toxicosis was the cause of death for 11 fishers collected from two sub-populations in California, and that there was a significant association between the

number of ARs to which a fisher has been exposed and the increasing probability of death due to poisoning (compared to other causes of death). However, the manuscript did not provide enough details to determine if individuals that died of AR toxicosis were exposed to diphacinone specifically. In Fraser et al. (2018), the study authors examined various sublethal effects of rodenticide exposure using 52 blood samples collected from bobcats captured in the Simi Hills, the Hollywood Hills, and the Santa Monica Mountains. This study determined an association between the upregulation and downregulation of certain genes with AR exposure status. However, this study did not link any of these associations specifically to diphacinone.

Based on the studies reviewed in the 2018 Investigation, it is not possible to link the reported effects on non-target wildlife with exposure to diphacinone specifically.

Updated California Department of Fish and Wildlife Diphacinone Exposure Cases

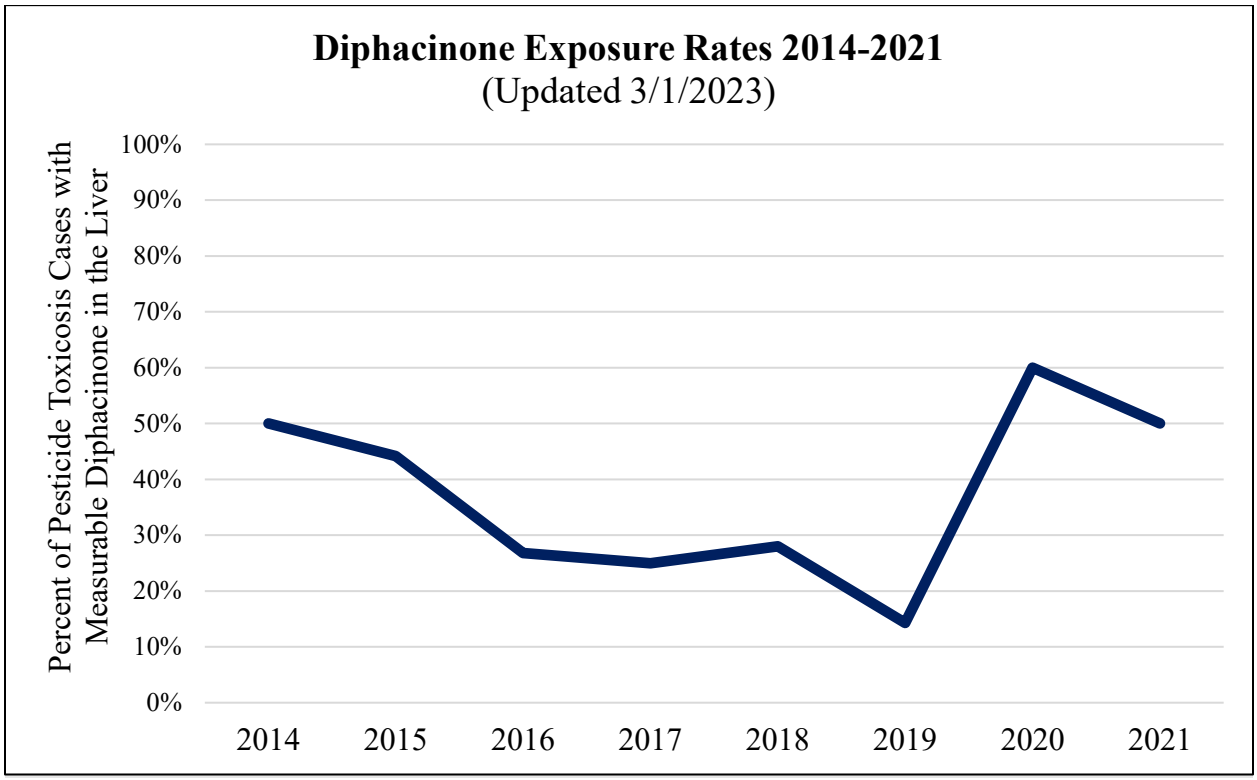
After the 2018 Investigation, DPR continued tracking wildlife incident and mortality data received from the CDFW. CDFW receives animal carcasses from various sources including wildlife rehabilitation centers and County Agricultural Commissioners. These animals are generally necropsied by CDFW. Liver samples are sent to the California Animal Health and Food Safety Laboratory at University of California, Davis for pesticide testing. CDFW then submits loss reports to DPR for non-target wildlife where exposure to pesticides couldn't be ruled out as a cause of death (pesticide toxicosis). The animals tested may test positive for more than one AR and the diagnosis generally does not implicate a specific AR in the toxicosis. DPR reviews the submitted loss reports and compiles the information for analysis. At the time of the 2018 Investigation, the percent of non-target wildlife with exposure to diphacinone was decreasing. Roughly 15% of animals that died from exposure to pesticides had measurable amounts of diphacinone in their livers in 2019.

While the CDFW loss reports can provide some information regarding trends in non-target wildlife exposure, there are several limitations associated with the data. First, CDFW only provides reports for non-target wildlife where pesticide toxicosis cannot be ruled out; DPR does not receive reports for all of the animals submitted to the lab, or even all of the animals that test positive for ARs. Second, the animals are not collected randomly and not representative of the general population. Animals that are brought to wildlife rehabilitation centers are distressed or dead, and not representative of healthy animals. Third, when wildlife rehabilitators suspect that an animal may have been exposed to rodenticides, they send the body to CDFW for necropsy, further biasing the data collected toward positive tests for rodenticide exposure. Finally, CDFW prioritizes which animals to necropsy and test for rodenticide exposure, and the criteria that CDFW uses to prioritize animals for necropsy is unknown.

Since the 2018 Investigation and the enactment of FAC section 12978.7, loss reports indicate that the percentage of animals with diphacinone exposure has increased in recent years (2020-2021) (Figure 1). Recently received data indicates that up to 50% of animals that DPR received

loss reports for had measurable amounts of diphacinone in their livers. While there is no data directly linking the reported effects on wildlife with a specific AR, the increase in diphacinone exposure rates is concerning given that diphacinone is moderately toxic to avian species and very highly toxic to mammals in the lab setting and has the potential to bioaccumulate.

Figure 1 – DPR's analysis of non-target wildlife exposure to diphacinone based on loss reports submitted by CDFW. Diphacinone exposure rates represent the percent of pesticide toxicosis cases that had diphacinone present in their livers.

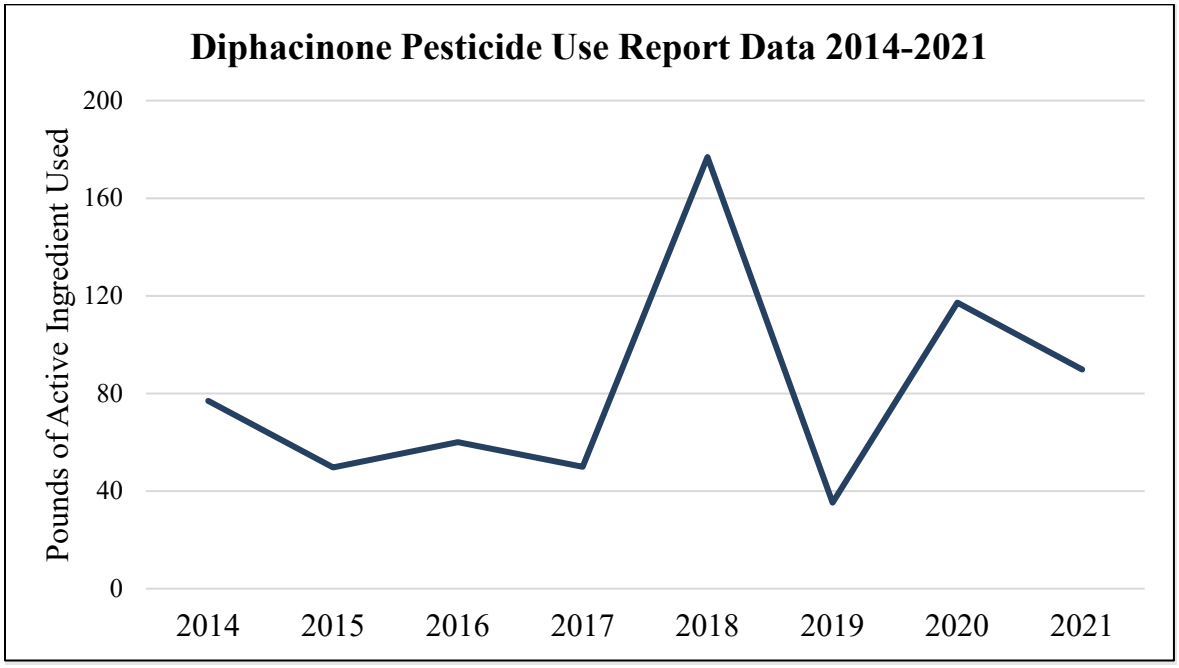


Updated DPR Pesticide Sales and Use Reporting Data

DPR tracks the sales and use of pesticides in California, including ARs. Pesticide use reporting data only includes pesticides used by professional applicators that have been licensed and certified by DPR. All certified applicators in California are required to submit pesticide use reports to County Agricultural Commissioners, who in turn, report to DPR. The 2018 Investigation includes pesticide use reporting data for diphacinone through 2017. This data indicated that diphacinone use was on a slight downward trend at the time of the 2018 Investigation's completion. However, according to DPR's updated pesticide use reporting data (Figure 2), diphacinone use has increased in certain recent years indicating an increased diphacinone prevalence in California's environment. From 2014 to 2017, there was an average

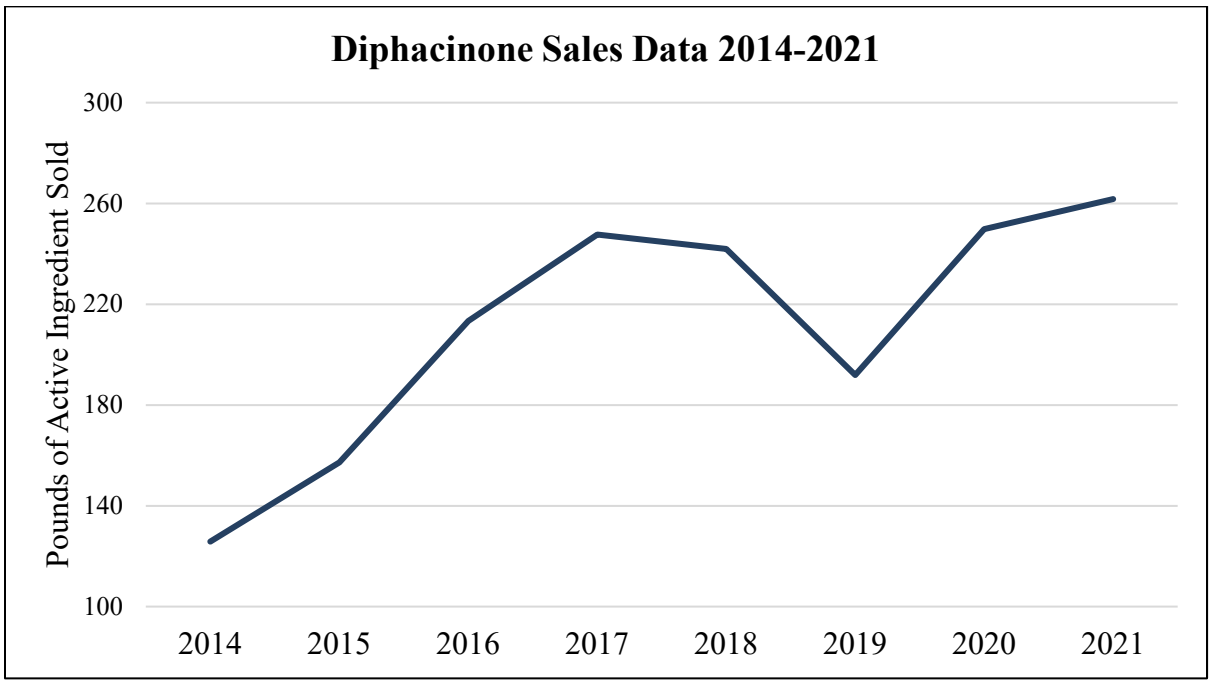
reported use of 59 pounds of diphacinone active ingredient (AI) per year. Whereas from 2018 to 2021, there was an average reported use of 105 pounds of AI per year. When comparing the two sets of 4-year averages, there is a 178% increase in reported use data from 2014-2017 versus 2018-2021.

Figure 2 – Reported Use of Diphacinone by Professional Applicators (pounds active ingredient) from 2014-2021.



Sales data reflects pounds of pesticides sold as self-reported by registrants and is not necessarily reflective of its use. Sale of a product in California does not indicate that it was used in California, nor is it indicative of when the product might be used. The 2018 Investigation includes sales data for 2014 through 2017 for diphacinone. Data at the time indicated that the sale of diphacinone was increasing and, with the exception of a slight dip in 2019 (consistent with corresponding use data), the updated sales data continues that trend (Figure 3). From 2014 to 2017, there was an average reported sale of 186 pounds of diphacinone per year. Whereas from 2018 to 2021, there was an average reported sale of 236 pounds of diphacinone per year. When comparing the two sets of 4-year averages, there is a 127% increase in reported sales data from 2014-2017 versus 2018- 2021.

Figure 3 – A Summary of Diphacinone Sales Data from 2014-2021.



Cumulative Impacts from Diphacinone

There are various significant sublethal and lethal effects associated with general AR exposure and these effects may be more likely when animals are exposed to multiple ARs or higher overall AR residues. However, the studies reviewed for the 2018 Investigation did not provide information on the specific combinations of ARs present in cases where effects/toxicosis was observed, or whether diphacinone specifically was present in these cases. Gabriel et al. (2015) determined that AR exposure was the cause of death for 11 fishers and that exposure to multiple rodenticides increased the likelihood of mortality from rodenticide poisoning. However, that study did not provide information about the specific combinations of ARs the fishers were exposed to, or whether diphacinone was included in those poisoning cases. Similarly, Serieys et al. (2015) indicated that severe mange was positively associated with anticoagulant exposure (total residues) and number of ARs detected (strong association between exposure to >2 compounds and notoedric mange) but did not find an association between effects (e.g., mange) and diphacinone.

Loss reports submitted by CDFW since the 2018 Investigation indicate that an increasing percentage of wildlife with pesticide toxicosis had diphacinone exposure and that most of these animals had multiple anticoagulant rodenticides detected in their livers. However, considering

the current state of knowledge, it is impossible to tease out the contributing effects of diphacinone specifically when multiple compounds are detected.

The data reviewed in the 2018 Investigation and the updated exposure, sales, and use data do not provide evidence of cumulative impact to non-target wildlife resulting from diphacinone exposure combined with other AR exposure. While there is evidence that non-target wildlife exposure to diphacinone and other ARs, and that mange is associated with exposure to multiple compounds, the degree to which there are interactive effects between the different AR active ingredients, including diphacinone, is unknown at this time. Any further cumulative analysis based on the information evaluated in the 2018 Investigation would be speculative.

Conclusion

As discussed at length above, since the 2018 Investigation was published the percentage of non-target wildlife, as represented in the CDFW loss reports, with diphacinone exposure have increased substantially. In other words, non-target wildlife that have died due to pesticide exposure are found to have diphacinone in their livers at a greater rate in recent years. Considering that diphacinone is classified as moderately toxic to avian species (LD_{50} of 96.8 mg ai/kg bw) and very highly toxic to mammals (LD_{50} of 0.2 mg ai/kg bw) via acute oral exposure (2018 Investigation), and that it has the potential to bioaccumulate, this recent increase in exposure rates is concerning. Additionally, sale and use of diphacinone have continued to increase meaning that there is increasing amounts of diphacinone in California's environment. DPR concludes that a significant adverse impact to non-target wildlife has occurred or is likely to occur from the use of diphacinone and, that further evaluation of ecological risks and a reevaluation of diphacinone containing products is necessary to determine if further mitigation actions are warranted. DPR is therefore proposing to begin a reevaluation of diphacinone.

IDENTIFICATION OF ANY SIGNIFICANT ADVERSE ENVIRONMENTAL EFFECT THAT CAN REASONABLY BE EXPECTED TO OCCUR FROM IMPLEMENTING THE PROPOSAL

The Secretary of Natural Resources determined that DPR's pesticide regulatory program, including the registration, evaluation, and classification of pesticides, qualifies as a certified regulatory program under Public Resources Code section 21080.5 and Title 14, California Code of Regulations (14 CCR) section 15251(i). This determination means DPR's pesticide regulatory program is functionally equivalent to the California Environmental Quality Act's (CEQA) requirements for preparing environmental impact reports (EIRs), negative declarations, and initial studies, and is therefore exempt from such requirements. This public report satisfies the requirements of DPR's CEQA certified regulatory program for the reevaluation of pesticides at 3 CCR sections 6252-6255.

DPR's public report, as the substitute document satisfying CEQA functional equivalency requirements, must include a description of the proposed action, a statement of any significant adverse environmental effect that can reasonably be expected to occur, directly or indirectly, from implementing the proposal, and a statement of any reasonable mitigation measures that are available to minimize significant adverse environmental impacts. Each public report shall also contain a statement and discussion of reasonable alternatives which would reduce any significant environmental impact. DPR shall not approve any activity which would cause a significant adverse environmental impact if there is a feasible alternative or feasible mitigation measure available which would substantially lessen any significant adverse impact that the proposal may reasonable be expected to have on the environment (3 CCR section 6254).

DPR is proposing to begin a reevaluation of pesticide products containing diphacinone in order to obtain relevant data. Such data would be evaluated by DPR scientists to determine if additional restrictions on use are necessary or if the registration of the pesticide should be cancelled or suspended pursuant to Section 12824, 12825 or 12826 of the Food and Agricultural Code. DPR is not proposing any restrictions at this time that would change the rate, timing, use, type, or amounts of pesticides applied, and so, the proposed decision would have no effect on these environmental factors.

Instead, the proposal is for DPR scientists to review existing data and potentially to require additional data to determine whether current uses of diphacinone poses unacceptable risks to non-target wildlife. Against this environmental and regulatory baseline, no possible significant adverse effect to human health or the environment can reasonably be expected to occur from the proposed decision. Therefore, the proposed decision is categorically exempt from environmental review under 14 CCR section 15061(b)(3). Because no significant adverse effect to human health or the environment can reasonably be expected to occur, no alternatives or mitigation measures are proposed to lessen any significant adverse effects on the environment.

For information regarding the reevaluation process, please contact Ms. Brenna McNabb, at <Brenna.McNabb@cdpr.ca.gov> or at 916-445-0179.

Original signed by | *May 19, 2023*

Tulio Macedo, Chief
Pesticide Registration Branch
916-324-3572

Date

cc: Ms. Brenna McNabb, DPR, Senior Environmental Scientist (Specialist)

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