Notice of Proposed and Final Decisions and Public Reports

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Department of Pesticide Regulation
Pesticide Registration Branch

COMMENT PERIOD ENDS JUNE 28, 2020

NOTICE OF FINAL DECISIONS TO REGISTER PESTICIDE PRODUCTS AND WRITTEN EVALUATION

Pursuant to Title 3, California Code of Regulations section 6255, the Director of the Department of Pesticide Regulation (DPR), files this Notice of Final Decisions to Register Pesticide Products with the Secretary of the Resources Agency for posting. This notice must remain posted for a period of 30 days for public inspection. Between the time DPR posts a proposed registration decision for public comment and DPR makes a final decision regarding the product, non-significant changes may be made to the product label (e.g., revising the product name, changing a master label to an end-use marketing label, correcting typographical errors). If the changes are not significant, DPR will not re-notice the product for public review and comment. However, if significant changes are made to the product label that substantially affect DPR's analysis on direct or indirect significant adverse environmental or human health impacts that can reasonably be expected to occur from the proposed decision, DPR will re-notice the product label for public review and comment.

In addition, for any product that is posted proposed to register as a conditional registration, the registrant may address the conditions of registration by providing the appropriate data or modifying the product label (e.g., remove use site, add "not for use in California" to a use site) during the posting period. If the registrant adequately addresses the conditions of registration during the posting period and the resulting change to the product label is not significant such that DPR must re-post the product label for review and public comment, DPR will post the product below, but will no longer have a "conditional" designation by the registration type.

For information about submitting a request for any documents related to this notice, please visit https://www.cdpr.ca.gov/public_r.htm.

To view the public report that was issued when the product was proposed for registration, click on the hyperlinked Tracking Number for the product.

Tracking Number with hyperlink to public report – (EPA Registration Number)
Applicant / Brand Name

291401 - (91610 - 1)
GOLDWIN HOLDINGS LIMITED
MASTER LABEL - ATRAKTA
USE: INSECTICIDE - FOR THE CONTROL OF MOSQUITOES IN OUTDOOR TRAPS
TYPE: SECTION 3 REGISTRATION -
ACTIVE INGREDIENT(S):
1-OCTEN-3-OL
AMMONIUM BICARBONATE
LACTIC ACID
CAS NUMBER(S): 3391-86-4 , 1066-33-7 , 50-21-5 , 598-82-3 , 79-33-4

293131 - (192 – 223 – 92564)
SBM LIFE SCIENCE CORP.
BIOADVANCED SCIENCE-BASED SOLUTIONS ALL-IN-ONE ROSE & FLOWER CARE READY-TO-USE GRANULES 1
USE: FERTILIZER, FUNGICIDE, INSECTICIDE - FOR THE CONTROL OF INSECTS SUCH AS APHIDS, LEAFHOPPERS, AND LACE BUGS AND DISEASES SUCH AS POWDERY MILDEW, RUST, AND BLACK SPOT ON ROSES, AZALEAS, CAMELLIAS, IRIS, HIBISCUS, AND OTHER FLOWERS AND SHRUBS
TYPE: SECTION 3 SUBREGISTRATION - CONDITIONAL
ACTIVE INGREDIENT(S):
ACEPHATE
TEBUCONAZOLE
CAS NUMBER(S): 30560-19-1 , 107534-96-3 , 80443-41-0

274052 - (100 - 1601)
SYNGENTA CROP PROTECTION, LLC
MIRAVIS
USE: FUNGICIDE - FOR THE CONTROL OF DISEASES SUCH AS EARLY LEAF SPOT, PEPPER SPOT, AND WEB BLOTCH ON PEANUTS
TYPE: SECTION 3 REGISTRATION -
ACTIVE INGREDIENT(S):
PYDIFLUMETOFEN
CAS NUMBER(S): 1228284-64-7

274055 - (100 - 1603)
SYNGENTA CROP PROTECTION, LLC
MIRAVIS PRIME
USE: FUNGICIDE - FOR THE CONTROL OF DISEASES SUCH AS POWDERY MILDEW, SEPTORIA LEAF SPOT, AND GRAY MOLD ON CROPS SUCH AS KIWIFRUIT, GRAPES, AND AMARANTH
TYPE: SECTION 3 REGISTRATION -
ACTIVE INGREDIENT(S):
FLUDIOXONIL
PYDIFLUMETOFEN
CAS NUMBER(S): 131341-86-1 , 1228284-64-7

274051 - (100 - 1600)
SYNGENTA CROP PROTECTION, LLC
POSTERITY
USE: FUNGICIDE - FOR THE CONTROL OF DISEASES SUCH AS DOLLAR SPOT, FAIRY RING, AND MICRODOCHIUM PATCH ON GOLF COURSE TURFGRASSES ONLY
TYPE: SECTION 3 REGISTRATION -
ACTIVE INGREDIENT(S):
PYDIFLUMETOFEN
CAS NUMBER(S): 1228284-64-7

287620 - (67702 - 54)
W. NEUDORFF GMBH KG
HOMEPLATE
USE: ALGAECIDE, HERBICIDE - FOR THE CONTROL OF BROADLEAF WEEDS, GRASS, ALGAE, AND MOSS ON CROPS SUCH AS STRAWBERRY, HOPS, MINT, PEANUTS, LEMON, AND BROCCOLI; ALSO FOR USE ON NON-FOOD CROPS, NON-CROP SITES, AND IN GREENHOUSES
TYPE: SECTION 3 REGISTRATION -
ACTIVE INGREDIENT(S):
CAPRIC ACID
CAPRYLIC ACID
CAS NUMBER(S): 334-48-5 , 124-07-2

286210 - (62719 - 727)
DOW AGROSCIENCES LLC
TRANSFORM CA
Use: INSECTICIDE - FOR THE CONTROL OF INSECTS SUCH AS APHIDS, LEAFHOPPERS, AND SILVERLEAF WHITEFLY IN CROPS SUCH AS POTATOES, CHINESE ARTICHOKES, GINSENG, FAVA BEANS, TURMERIC, AND WHEAT
Type: SECTION 3 REGISTRATION -
Active Ingredient(s):
SULFOXAFLOR
CAS Number(s): 946578-00-3

286212* - (62719 - 623)
DOW AGROSCIENCES LLC
SEQUOIA CA
Use: INSECTICIDE - FOR THE CONTROL OF INSECTS SUCH AS APHIDS, LEAFHOPPERS, AND SILVERLEAF WHITEFLY IN CROPS SUCH AS CHINESE SPINACH, CELERY, DANDELION, OKRA, PISTACHIO, AND APPLE
Type: SECTION 3 REGISTRATION -
Active Ingredient(s):
SULFOXAFLOR
CAS Number(s): 946578-00-3
*This public report was updated to add text that was unintentionally omitted from the original report.

Written Evaluation

On December 6, 2019, the Department of Pesticide Regulation (DPR) proposed to register the following two pesticide products containing the new active ingredient sulfoxaflor: Sequoia CA (EPA Reg. No. 62719-623) and Transform CA (EPA Reg. No. 62419-727) (Notice of Proposed and Final Decisions, Vol. 2019-49). Each proposed decision to register was accompanied with a public report outlining the proposed action, a statement of any significant adverse environmental effect that can reasonably be expected to occur from the registration, and the conclusions of DPR's scientific evaluation. DPR received nine (9) unique comments in support of the proposed decisions, nine (9) unique comments opposing the proposed decisions, and approximately 4,390 identical comments received by e-mail opposing the proposed decisions.

Pursuant to Title 3, California Code of Regulations section 6254, this notice includes a written evaluation of significant adverse environmental points raised in comments submitted during the review and comment period required by Title 3, California Code of Regulations section 6253. DPR also provides responses to each unique commenter raising a significant adverse environmental point. Below, DPR provides written responses to all substantive comments, including the concern for honey bees and other pollinators addressed in the form letters.

Summary of Comments Raising a Significant Adverse Environmental Point

	Commenter	Comment	DPR Response
1.	Gregory C. Loarie, Staff Attorney Earthjustice on behalf of Pollinator Stewardship Council American Beekeeping Federation	*Sulfoxaflor mode of action is similar to neonicotinoids and therefore should be evaluated the same.	Responses #1-4, 8, 11-13
		*Sulfoxaflor presents a significant risk to honey bees and other insect pollinators	Response #2
		*Sulfoxaflor presents a significant risk to beneficial insects and other important agricultural organisms	Response #3
		*Sulfoxaflor presents a significant risk to water quality and aquatic ecosystems	Response #4
		*DPR's proposed decision failed to adequately discuss alternatives	Response #5
		DPR's analysis of the environmental baseline does not satisfy CEQA	Response #6
		DPR's analysis of direct and indirect impacts does not satisfy CEQA. DPR's public reports fail to disclose the actual scientific basis for its conclusion of no significant impacts.	Responses #2-4, 7, 9-13
		DPR's discussion of cumulative impacts does not satisfy CEQA	Responses #1-4, 8, 11-13

2.	Dr. Susan Kegley, Principal & CEO Pesticide Research Institute	*Sulfoxaflor mode of action sufficiently similar to neonicotinoids to require cumulative impact assessment.	Responses #1-4, 8, 11-13
		*USEPA's risk assessment and peer review information are not sufficient to support registration. Both suggest that adverse effects on pollinators and aquatic insects are highly probably and likely cumulative with similar effects caused by neonicotinoids.	Responses #2, 4, 8
		*The proposed registration of sulfoxaflor threatens commercial beekeeping operations, native pollinators, and growers depending on pollinators.	Response #2
		*Data gaps exist for sublethal effects of sulfoxaflor on beneficial insects	Response #3
		*DPR's proposed decision failed to adequately explore alternatives	Response #5
		*DPR's proposed decision does not provide sufficient information on the data DPR evaluated to reach the decision to approve the registration.	Responses #2-4, 7
		DPR failed to assess beneficial insect exposure through surface water and guttation water.	Responses #1, 4, 9
3.	Susan Bartow Pasadena, CA	*Concern about negative impact on pollinators	Response #2
		*Concern about negative impact on parasitic wasps and ladybugs	Response #3
		Concern for small mammals	Response #12
		Concern that sulfoxaflor has "suggested evidence for carcinogenic potential"	Response #11
		*Concern that sulfoxaflor will end up and build up in California waterways	Response #4
4.	Sally Bartow Los Angeles, CA	*Concern for negative impact on insect pollinators necessary to food supply	Response #2
		*Concern for impacts on safe drinking water	Responses #4, 11
5.	Kathryn Wild San Diego, CA	*Concern for negative impacts on bees	Response #2
6.	Eric Dynamic Berkeley, CA	*Relates sulfoxaflor to neonicotinoids	Response #1
		*Concern for negative impact on bees	Response #2
7.	Mary Schmidt San Francisco, CA	*Concern for negative impacts on bees and other pollinators	Response #2
		*Relates impacts of sulfoxaflor to neonicotinoids.	Response #1

8.	Chuck Leavell Anaheim, CA	*Concern for negative impact on pollinators	Response #2
		*Concern for negative impacts on human health, including children and in utero	Response #11
		*Concern for negative impacts on water supply and groundwater	Response #4
		Concern for negative impacts on air one is breathing	Response #13
9.	Leslie Colyer San Rafael, CA	*Relates impacts of sulfoxaflor to neonicotinoids.	Response #1
		*Concern for negative impacts on pollinators	Response #2

*Delineates that comment received from more than one commenter.

A copy of the full comment letters can be viewed below. A copy of DPR's individual responses can be obtained through submission of a public records act request by emailing Amy.Duran@cdpr.ca.gov or calling 916-445-2047.

COMMENT #1:
The commenters express concern that sulfoxaflor's mode of action is sufficiently similar to neonicotinoids and therefore should be evaluated the same.

RESPONSE #1:
DPR uses chemical specific data to evaluate pesticides considered for registration. Thus, DPR's scientific evaluations focused on data specific to the active ingredient sulfoxaflor.

Sulfoxaflor is not a neonicotinoid; rather, it is part of a distinct class of insecticides called sulfoximines. The Insecticide Resistance Action Committee (IRAC) is an international authority that has classified sulfoxaflor as a "sulfoximine" and has placed it as a subgroup to the IRAC Group 4: "nicotinic acetylcholine receptor agonists." Group 4 is divided into five subgroups: Group 4A: neonicotinoids; Group 4B: nicotine; Group 4C: sulfoximines; Group 4D: Butenolides; and Group 4E: Mesoinoics. The chemicals in these subgroups target the nicotinic acetylcholine receptor in insects, but the subgroups have different modes of action. One of the most important differences between sulfoxaflor and neonicotinoids, when considering environmental impact, is their relative persistence in the terrestrial environment. When applied to a terrestrial environment, sulfoxaflor is expected to degrade rapidly (aerobic soil metabolism half-life = 0.13-0.86 days; CA field dissipation half-life = 1.6-6 days), whereas neonicotinoids are expected to persist for much longer (aerobic soil metabolism and terrestrial field dissipation half-lives for neonicotinoids can range anywhere from approximately 100-1300 days). U.S. EPA's decision document also notes that sulfoxaflor is an effective tool for growers and has a lower environmental impact because it disappears from the environment faster than widely-used alternatives like neonicotinoids. (USEPA, Decision Memorandum Supporting the Registration Decision for New Uses of the Active Ingredient Sulfoxaflor, July 12, 2019, p.11.)

COMMENT #2:
The commenters expressed concern that approving the sulfoxaflor product labels will have significant adverse effects on honey bees and other insect pollinators.

RESPONSE #2:
DPR evaluated the proposed product labels and associated data for sulfoxaflor for potential impacts to pollinators. During its evaluation, DPR scientists found that the original proposed labels for Sequoia CA and Transform CA did not adequately mitigate exposure because they included Directions for Use that allowed applications during bloom to the bee attractive crop group, Root and Tuber Vegetables. DPR informed the registrant of its concerns and as a result, Dow AgroSciences voluntarily agreed to remove the entire Root and Tuber Vegetables crop group from the Sequoia CA label, and specifically prohibit applications during bloom for that crop group on the Transform CA label, and submit the revised label to U.S. EPA and DPR for consideration. The proposed labels now prohibit all applications during bloom (when pollinators would be in contact with plant pollen and nectar that could potentially contain pesticide residue), thereby eliminating exposure to pollinators.

The proposed label for Transform CA is specifically for control or suppression of aphids, plant bugs, leafhoppers, whiteflies, stink bugs, potato psyllid, and thrips on crops such as barley; triticale; wheat; canola (rapeseed) (subgroup 20A); potatoes (crop group 1C, 1D, and root and tuber vegetables); and succulent, edible podded, and dry beans. DPR found that the Transform CA label mitigates pollinator exposure by including only use sites that either: (1) do not require bee pollination and are not attractive to pollinators according to the United States Department of Agriculture's 2017 Attractiveness of Agricultural Crops to Pollinating Bees for the Collection of Nectar and/or Pollen report (i.e., barley, triticale, and wheat), or; (2) are limited to applications made after petal fall (i.e., not during bloom). Specifically, no applications can be made to the canola subgroup; potatoes crop groups (including root and tuber vegetables); and succulent, edible podded, and dry beans until after petal fall. Crops harvested before the bloom period or after petal fall should not have flowers to attract pollinators. There is substantial evidence to conclude that when used according to its label, pollinators would not be exposed to Transform CA. As a result, the proposed decision to register Tranform CA is not reasonably expected to result in significant adverse impacts to pollinators.

The proposed label for Sequoia CA is specifically for control or suppression of insects such as aphids, plant bugs, leafhoppers, whiteflies, pear psylla, San Jose scale, thrips, and mealybugs on Brassica (cole) leafy vegetables (crop group 5), fruiting vegetables (crop group 8) and okra, leafy vegetables (except Brassica) (crop group 4) and watercress, pome fruits (crop group 11), small fruit vine climbing (except fuzzy kiwifruit) (subgroup 13-07F), low growing berry (except strawberry) (subgroup 13-07G), stone fruits (crop group 12), tree nuts (crop group 14), and pistachio. DPR found that the Sequoia CA label mitigates potential pollinator exposure by including only use sites that are either: (1) harvested prior to bloom, or; (2) limited to applications made after petal fall (i.e., not during bloom). Specifically, no applications can be made to fruiting vegetables, okra, pome fruits, small fruit vine climbing, low growing berry, stone fruits, pistachio, and tree nuts until after petal fall. In addition, for applications to Brassica leafy vegetables, leafy vegetables, and watercress, which are harvested prior to bloom, the label prohibits application to crops grown for seed. Although crops grown for seed do not necessarily

pose a risk to pollinators, they do create a potential exposure pathway because they are allowed to go through a blooming period, which could attract and expose pollinators. In contrast, crops harvested before the bloom period or after petal fall should not have flowers to attract pollinators. There is substantial evidence to conclude that when used according to its label, pollinators would not be exposed to Sequoia CA. As a result, the proposed decision to register Sequoia CA is not reasonably expected to result in significant adverse impacts to pollinators.

The commenter cites studies to support the assertion that acute and chronic exposure to sulfoxaflor present a significant risk to bees. As a threshold issue and as explained in the proposed decisions to register, substantial evidence supports DPR's conclusion that the products are not reasonably expected to result in exposures to pollinators. Therefore, the submitted studies discussing exposure from treated fields are of limited scientific relevance for these proposed decisions and do not support the commenter's assertion that the proposed decisions to register will present significant risk to bees. However, DPR would evaluate pollinator exposure studies in connection with any future application to register a sulfoxaflor product that contains use sites or use patterns that may result in pollinator exposure.

As described above and below, the labels for Transform CA and Sequoia CA contain multiple provisions to mitigate potential acute exposure and any resulting adverse impacts to pollinators. Although both product labels state that they are highly toxic to bees exposed through contact during spraying and while spray droplets are still wet, and may be toxic to bees exposed to treated foliage for up to 3 hours following application, the labels mitigate potential pollinator exposure by only including use sites that either do not require bee pollination and are not attractive to pollinators according to the USDA's 2017 Attractiveness of Agricultural Crops to Pollinating Bees for the Collection of Nectar and/or Pollen report, harvested before bloom, or are limited to applications made after petal fall (i.e., not during bloom).

In addition, the labels also include provisions to mitigate potential pollinator exposure from off-site movement. Specifically, the Spray Drift Management section of the label prohibits application when wind speed exceed 10 mph and requires the use of medium or coast spray nozzles. The labels also state, "Do not apply this product or allow drift to blooming crops or weeds while bees or other pollinators are actively foraging this treatment area." In addition, to minimize incidental contact with managed bees and native pollinators, the labels advise applications to occur before 7 a.m. or after 7 p.m., or anytime when the temperature is below 50° F, since pollinators are not prone to foraging at night or at colder temperatures. To protect native pollinators, each crop group also contains the following use restriction "If blooming vegetation is present 12 feet out from the downwind edge of the field, a downwind 12-foot on-field buffer must be observed." The 12-foot spray drift buffer for blooming vegetation on the label was determined using drift modeling in U.S. EPA's ecological risk assessment. As a result of the limited use sites and label restrictions and mitigation incorporated into the labels, DPR does not expect use of these products in accordance with their label directions and any applicable use restrictions in regulation will have a significant adverse effect on pollinators or other nontarget fauna.

In addition, the proposed decisions to register noted actual sulfoxaflor use on multiple agricultural use sites in California under previously approved under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) section 24(c) special local need registrations and FIFRA

section 18 emergency exemptions. To date, there have been no adverse effects reported associated with the use of either the section 18 emergency exemption or section 24(c) special local need registration in California.

Based on its scientific evaluation, limited use sites on the label, prohibitions of applying during bloom, and additional label mitigation, there is substantial evidence to support DPR's conclusion that the proposed decisions to register are not reasonably expected to result in significant adverse impacts on bees or other pollinators. DPR will consider pollinator exposure studies in connection with any potential future registration decision involving sulfoxaflor products that contain use sites or use patterns that may result in pollinator exposure.

COMMENT #3:
The commenter expressed concern regarding potential adverse impacts to beneficial organisms, such as earthworms, parasitic wasps, and ladybird beetles.

RESPONSE #3:
In order to obtain registration of a new pesticide with U.S. EPA, a registrant must submit a number of required ecotoxicology studies for indicator species for evaluation. DPR follows U.S. EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) guidelines for evaluating pesticide studies for the purpose of making regulatory decisions. The OCSPP's guidelines are issued for use in testing pesticides to develop data for submission to U.S EPA under FIFRA. Studies conducted according to these test guidelines may be used to satisfy FIFRA data requirements. (*See* https://www.epa.gov/sites/production/files/2019-10/documents/ocspp-testguidelines_masterlist-2019-09-24.pdf.) DPR regulations require the registrant to also submit those studies to DPR during the initial registration process. (Cal. Code of Regs., tit. 3, § 6170.) The test indicator species selected for the ecotoxicology evaluation are intended to broadly represent a range of nontarget birds, mammals, pollinators, fish, aquatic invertebrates, and plants. These indicator species provide an information base for assessing potential risks to nontarget fauna, as it is impossible to test every possible species with each new pesticide (such as the specific beneficial organisms identified by the commenters). Neither U.S. EPA nor DPR require an evaluation of the specific beneficial organisms identified by the commenters—earthworms, parasitic wasps, or ladybird beetles.

Notwithstanding the above, DPR's Ecotoxicology Evaluation Station reviewed the two earthworm studies on file with DPR[1] (DPR Study IDs 269822 and 269823), as well as the earthworm literature study (Fang et al, 2018) cited by a public comment, to determine if the proposed uses of sulfoxaflor pose unmitigated risk to earthworms. All three studies were conducted according to standard methodologies for testing toxicity to earthworms and were determined to be scientifically valid. Two of the three studies were conducted with the active ingredient, sulfoxaflor. The toxicity endpoints determined from these two studies are acute Lethal Concentration 50 values (LC_{50}) of 0.54 and 0.885 mg ai/kg sediment, and a No Observed Effect Concentration (NOEC) of 0.313 mg ai/kg sediment. One of the three studies was conducted with a metabolite of sulfoxaflor and established an LC_{50} of greater than 1000 mg ai/kg sediment. DPR calculated the expected environmental concentration in soil immediately

[1] These studies were not required as part of registration with U.S. EPA or DPR. Sometimes registrants include non-required studies in the general registration package, which were required by another international agency.

following a single sulfoxaflor application at maximum rate assuming that all of the applied active ingredient is evenly distributed in the top 5 cm of soil in typical dry soil bulk density (1.5 g/cm^3).The use of maximum application rate and presuming that all of the application bypasses the plant and goes directly to the soil are both conservative assumptions and generate a worst-case estimate of soil concentration. DPR's calculated concentration in soil was lower than all of the toxicity endpoints determined in the earthworm toxicity studies mentioned above. This comparison indicates that DPR lacks substantial evidence to show that the proposed uses of sulfoxaflor pose significant risks to earthworms.

Sulfoxaflor is an insecticide and therefore toxic to insects, including parasitic wasps and possibly ladybird beetles. There are currently no specific federal guidelines describing methods for testing conventional pesticides on ladybird beetles or parasitic wasps, so it is unclear how the exposure methods in the studies submitted by the commenter (He et al. 2019; Nawaz et al. 2018; Jiang et al. 2019) compare to field realistic conditions and applications. DPR reviewed the studies submitted by the commenter to further evaluate potential environmental risks to parasitic wasps and ladybird beetles. The commenter submitted He et al. 2019 for the assertion that sulfoxaflor may significantly impair ladybird beetle population parameters and reduce its potential biological control activity. A review of this study revealed that it tested both the acute and life cycle toxicity of technical grade sulfoxaflor sprayed directly on larval ladybird beetles. The study may not realistically capture contact exposure of larval ladybird beetles in the field, as applications under the proposed label use a diluted concentration of sulfoxaflor. The study also does not provide the raw data for each replicate, which prevents an independent analysis of the results.[2] DPR typically conducts an independent analysis of the raw data to ensure that the calculated results are consistent across studies. As this study was performed on the larval stage of ladybird beetles, it is further unclear if similar effects would be observed in adult lady bird beetles that are exposed to a direct spray, or if these effects would translate to population-level effects. The commenter also submitted Nawaz et al. 2018 for the assertion that sublethal exposure to sulfoxaflor damages the ladybug genome. A review of the Nawaz et al. 2018 study revealed that it tested gene expression in larval ladybird beetles exposed to a 1 µL drop of technical grade sulfoxaflor at a concentration of 0.02129 µg ai/larvae, rather than direct damage to the genome. The authors do not mention damage anywhere in the study. Although it is possible for genome damage to affect the expression of genes, the authors do not investigate the causes. Changes in gene expression may result from a variety of factors, and DPR's review of the studies required for genotoxicity by U.S. EPA were negative for genotoxicity. The endpoint defined in the study (changes in gene expression) cannot be used to determine risk because it is unclear how the change affects biological parameters. Although the study describes the up- and down- regulation of various genes in the larval ladybird beetle genome and gene expression, it is unclear if or how these changes ultimately affect biological parameters, such as reproduction and survival. Additionally, it is difficult to extrapolate the effects on the genomic level of an individual to an overall population effect in the field. Finally, the commenter submitted Jiang et al. 2019 which documented effects of technical grade sulfoxaflor on three species of parasitic

[2] Raw data is important for running an independent analysis of the data (e,g., running statistics or identifying performance of independent replicates). In the cited articles, results were reported as means for the entire treatment group. This prevents DPR from determining if the means for the treatment group accurately reflect what occurred in all replicates, or if the mean was skewed from one replicate performing very differently than the rest of the replicates in that treatment group.

wasps. DPR reviewed the study and found that it lacked the level of reporting typically seen in studies DPR evaluates for pesticide registration (*see* federal guidelines OCSPP 850.3000 and OCSPP 850.2000 (general terrestrial guidelines)). Further, the article did not provide raw data or data for individual replicates in order to conduct an independent analysis of the results. It is unclear how the methods of exposure evaluated in this lab-based study (i.e. adult wasps confined to glass tubes and host eggs submerged in solution) relate to exposure in the field. In the field, adult wasps would be able to move freely in and out of the treatment area and host eggs are unlikely to be fully immersed in spray solution.

Overall, the three cited articles lack detail in reporting that do not allow independent analysis of the results. Further, it is difficult or impossible to compare the level of exposure tested to the level of exposure that may result in the field from applications of the proposed sulfoxaflor products. As an insecticide, sulfoxaflor is likely toxic to parasitic wasps and may be toxic to ladybird beetles; however, the mitigation incorporated into the product labels are intended to minimize off-target movement of the pesticide and thus provide additional protection to pollinators and other nontarget insects, including parasitic wasps and ladybird beetles. Examples of label mitigation that minimizes off-target movement of the pesticide include: "Do not apply this product or allow it to drift to blooming crops or weeds while bees or other pollinating insects are actively foraging the treatment area." and "If blooming vegetation is present 12 feet out from the downwind edge of the field, a downwind 12-foot-on-field buffer must be observed." See also, Response #2, above. Further, both the Transform CA and Sequoia CA labels recommend the product for use in Integrated Pest Management Programs (IPM) in labeled crops, and encourage use only "when field scouting indicates target pest densities have reached the economic threshold." Based on DPR's scientific evaluation and mitigation incorporated into the product labels, substantial evidence continues to support the conclusion that the proposed decisions to register will not have significant adverse impacts on nontarget, beneficial organisms.

COMMENT #4:
The commenters expressed concern that approving the sulfoxaflor product labels will have a negative effects on a range of non-target invertebrates in terrestrial and aquatic habitats and significant adverse environmental impact on aquatic ecosystems and water quality.

RESPONSE #4:
The commenter cited the Worldwide Assessment on Systemic Insecticides, Pisa et al 2015 for the assertion that neonicotinoids have negative effects on a range of non-target invertebrates in terrestrial and aquatic habitats. First, as stated in Response Number 1, above, DPR's evaluation focused on chemical specific data for sulfoxaflor, not neonicotinoids. Further, DPR's scientific evaluation determined that when applied to a terrestrial environment, sulfoxaflor is expected to degrade more rapidly and is less persistent than neonicotinoids. *See also*, Response Number 3 (non-target beneficial invertebrates). Moreover, DPR's evaluation determined that on an acute basis, sulfoxaflor is practically non-toxic to slightly toxic to aquatic invertebrates (water flea) and oysters.

The commenter also referenced three studies for the assertion that aquatic systems are threatened by the high toxicity and persistence of neonicotinoid insecticides (Yamauro et al. 2019), and that the presence of neonicotinoids in surface water and ground water throughout the United States is well-documented (Hladik et al. 2015; Klarich et al. 2017). Again, the cited studies focus on

neonicotinoids, which are distinct from sulfoxaflor and have greater persistence. (*See* Response Number 1, above.). All the same, DPR's scientific evaluations focus on chemical specific data and seek to prevent adverse environmental impacts on aquatic ecosystems and water quality from use of sulfoxaflor by reviewing sulfoxaflor specific data.

DPR's scientific review evaluated the products for potential environmental impacts, including aquatic ecosystems, in surface water and groundwater. DPR does not expect use of the proposed products in accordance with their label directions and any applicable use restrictions in regulation will have a significant adverse effect on surface water or groundwater. DPR scientists reviewed phytotoxicity, terrestrial field dissipation (TFD), and ecotoxicology data submitted to support the registration of these products. The phytotoxicity data indicated that use of the products was unlikely to result in damage to the listed crops or to aquatic and terrestrial non-target plants. DPR also evaluated the groundwater contamination potential of sulfoxaflor and its metabolites through a review of submitted TFD studies and numerical modeling. Sulfoxaflor was found to have low persistence in the TFD studies and subsequent modeling also predicted no significant potential for sulfoxaflor or its metabolites to contaminate groundwater when applied in accordance with the label directions. There is substantial evidence to support DPR's conclusion that the proposed decisions to register are not reasonably expected to result in significant adverse impacts on groundwater.

DPR also evaluated ecotoxicology data to determine the potential for surface water contamination by sulfoxaflor and its metabolites. DPR scientists acknowledged that the physical-chemical properties of sulfoxaflor indicate the potential for off-site movement of the products into surface water. Although DPR scientists determined that the products are toxic to aquatic invertebrates, DPR determined that the mitigation on the product labels, including use instructions, environmental hazards statements, and spray drift management section, mitigate risk to aquatic organisms. Specifically, the product labels prohibit applications made directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. In addition, to avoid off-site movement, only applications with medium or coarser spray nozzles—which output spray droplets less prone to drift--are allowed. The labels also prohibit applications when wind speed exceeds 10 mph. DPR scientists also found that due to sulfoxaflor's rapid soil degradation, moderately low toxicity to organisms such as fish and various aquatic invertebrates, and low potential to bioaccumulate, it is unlikely that sulfoxaflor will reach concentrations in surface waters that will result in adverse effects to various aquatic organisms. As a result, there is substantial evidence to support DPR's conclusion that the proposed decisions to register are not reasonably expected to result in significant adverse impacts to aquatic organisms or surface water. However, DPR will add sulfoxaflor to its surface water monitoring program as part of continuous evaluation and take further action if additional mitigation is determined to be necessary.

COMMENT #5:
The commenters expressed concern that DPR failed to adequately evaluate alternatives to the proposed registration actions identified above.

RESPONSE #5:
Under section 6254 of Title 3 of the California Code of Regulations, DPR's certified regulatory program requires each notice of proposed decision to register a pesticide product contain a statement of reasonable alternatives to the proposed action to reduce any significant adverse environmental impact that could reasonably be expected to occur. First, DPR's scientific review determined that the projects of registering the pesticide product labels would not have any reasonably expected significant adverse impact on human health or the environment. Next, both of DPR's proposed decisions to register considered four project alternatives: (1) accept the proposed pesticide product containing a new active ingredient; (2) require revision of the proposed pesticide product label; (3) adopt a regulation; and (4) no action (deny the proposed pesticide product containing the new active ingredient sulfoxaflor). During its evaluation of the projects, DPR identified potential environmental concerns associated with certain use sites that were not adequately mitigated by the original pesticide product labels submitted for review. Specifically, DPR scientists found that the original proposed labels for Sequoia CA and Transform CA did not adequately mitigate exposure to honey bees because they included Directions for Use that allowed applications during bloom to the bee attractive crop group, Root and Tuber Vegetables. As a result, Dow AgroSciences voluntarily agreed to revise the label to remove the entire crop group from the Sequoia CA label and prohibit applications during bloom for the crop group on the Transform CA label. Although federal preemption prohibits DPR from requiring the registrant to revise the proposed labels, the registrant chose to voluntarily amend the labels to address the identified concerns and submit the updated labels to U.S. EPA and DPR for consideration. Based on its scientific review, DPR determined that accepting the newly submitted proposed pesticide product labels would not have any reasonably expected significant adverse impacts on human health or the environment. As a result, DPR selected Alternative #1 [accept the proposed pesticide product containing a new active ingredient] as the preferred alternative.

COMMENT #6:
The commenter expressed concern that DPR failed to adequately analyze the environmental baseline in the proposed registration actions identified above.

RESPONSE #6:
See Response Number 1, above. In addition, DPR's proposed registration decisions established the environmental baseline by outlining the approximate total number of pesticide products and active ingredients registered in California. The proposed decisions provided relevant information for the past three years of actual sulfoxaflor use in California reported as being applied on certain agricultural use sites under FIFRA section 24(c) special local need registrations and FIFRA section 18 emergency exemptions, as the appropriate baseline.

COMMENT #7:
The commenters expressed concern that DPR failed to adequately discuss potential direct and indirect environmental impacts, including impacts to pollinators, and provide scientific data it evaluated for the proposed registration actions identified above.

RESPONSE #7:
See Response Numbers #2-4, 9-13. Before a pesticide product containing a new active ingredient is registered in California, DPR performs a comprehensive review of data submitted on the active ingredient and pesticide product and reviews the proposed product label to determine how the product may affect human health or the environment. DPR scientists reviewed the proposed projects of registering Sequoia CA and Transform CA, relevant data submitted, and the product labels to evaluate whether the projects had the potential to cause a significant adverse impact on human health, flora, fauna, water, and air, and described its conclusions regarding potential direct or indirect environmental impacts in its proposed decisions to register.
The commenter expressed concern that DPR failed to disclose the specific scientific basis behind the proposed decisions to register products containing sulfoxaflor. Although DPR's proposed decisions summarized the scientific basis for its conclusions, it did not include hard copies of all 152 pages of DPR's scientific evaluation reports and 912 studies listed on file with DPR regarding sulfoxaflor. However, each proposed decision contains a statement that any person can request documents related to the notice, including the full scientific evaluation report. On December 17, 2019, Earthjustice did just this, requesting "all documents underlying and relating to DPR's December 6, 2019 proposed decision to register sulfoxaflor. Such records should include, but not be limited to, all data and evaluations possessed by DPR regarding sulfoxaflor, as well as any internal or external correspondence relating to DPR's proposed registration decision." Within 5 business days, DPR provided Earthjustice with 152 pages of DPR's scientific evaluation reports and 62 pages listing the 912 studies on file with DPR, on sulfoxaflor. DPR's evaluation reports and proposed decisions discussed and summarized relevant studies and data, identified potential impacts and mitigation, and concluded that DPR does not expect use of Sequoia CA or Transform CA in accordance with its label directions or any mitigation contained in existing regulations will have a significant adverse effect on human health or the environment.

COMMENT #8:
The commenter expressed concern that DPR failed to discuss cumulative impacts from the proposed registration actions identified above.

RESPONSE #8:
The commenter expressed concern that sulfoxaflor, like neonicotinoids, presents a significant cumulative risk to honey bees and other insect pollinators. Again, sulfoxaflor is distinct from neonicotinoids. (*See* Response to Comment #1, above.) DPR's proposed decisions to register note that DPR's registration of a particular pesticide product is only a general license to sell the product in California and does not identify anticipated future use of the products once registered. In addition, DPR is not aware of a valid methodology to scientifically evaluate potential cumulative interactions between sulfoxaflor and other active ingredients as part of a regulatory decision. Therefore, it is not reasonably foreseeable to predict or analyze cumulative impacts from this proposed registration decision. Finally, although the commenter cites to the Worldwide

Assessment on Systemic Insecticides (Pisa et al. 2015) for support that DPR failed to consider cumulative impacts of its proposed decision to register sulfoxaflor products, that report itself concedes significant knowledge gaps on the interactions between systemic insecticides and other stressors such as disease and food stress; that "quantifying the suite of co-occurring pesticides is largely an intractable problem"; and that "[g]iven these knowledge gaps, it is impossible to properly evaluate the full extent of risks…"

Notwithstanding the above, these proposed decisions to register have limited use sites, additional label mitigation, and prohibit applications during bloom (when pollinators would be in contact with plant pollen and nectar that could potentially contain pesticide residue) and are therefore not reasonably expected to result in exposures to pollinators. As a result, the proposed decisions to register are not reasonably expected to result in significant adverse effects to pollinators at either an individual project level or cumulative level in combination with other pesticides. (See Comment Number 2, above.) Here, DPR's scientific evaluation of the proposed decisions to register Transform CA and Sequoia has not identified direct or indirect significant adverse impacts on human health or the environment, including significant adverse impacts on pollinators, from use of these pesticide products in a manner consistent with their labels. (*See also,* Response to Comments #2-4, 11-13)

DPR's certified regulatory program incorporates the consideration of cumulative impacts by requiring DPR to continuously evaluate pesticides registered for use in California and take necessary action if a potential concern is identified. (FAC § 12824.) DPR accomplishes its mandate to continuously evaluate pesticides by conducting a number of activities including, but not limited to: ongoing DPR registration reviews that involve conducting human health risk assessments on individual active ingredients to comply with its statutory obligations to protect human health (FAC §§ 14021-14025; FAC § 13129); investigating reports of adverse environmental or human health effects from pesticide use submitted by the applicant/registrant as required (3 CCR § 6210) or received from the public; investigating reports of pesticide illness; sampling for pesticide residue on produce; monitoring the environment (air/water); and evaluating information submitted by other entities, including state and federal agencies, or contained in studies conducted by public or private research entities according to established scientific standards. In addition, pesticide use reporting aids DPR in evaluating cumulative impacts from specific pesticide use. DPR must also investigate all reported episodes and information received that indicate a pesticide may have caused or is likely to cause a significant adverse impact. If the Director finds from the investigation that a significant adverse effect has occurred or is likely to occur, DPR must reevaluate the pesticide involved. (3 CCR §§ 6220-6226). As a result of DPR's continuous evaluation and investigation into ongoing pesticide use and identified potential impacts, DPR has placed numerous products and classes of pesticides into reevaluation where it may evaluate cumulative effects and determine appropriate mitigation measures. (*See* https://www.cdpr.ca.gov/docs/registration/reevaluation/reevals.htm.) In the event DPR determines additional mitigation is necessary, DPR will develop those additional required mitigation measures and may initiate further evaluation of the pesticide product or active ingredient to address the identified or potential concern.

COMMENT #9:
The commenter expressed concern for pollinator exposure through surface water and guttation water from treated areas.

RESPONSE #9:
The commenter asserts that exposure to pollinators through drinking water and guttation water was not assessed by U.S. EPA or DPR, but has the potential to be a major exposure pathway for pollinators and other beneficial insects The commenter noted that neonicotinoids were reported to be found in 63% of 48 streams sampled waters across the United States, but acknowledged that there have been no comparable studies for sulfoxaflor. The studies cited by the commenter involve reports of neonicotinoids, not sulfoxaflor, in U.S. streams. As stated above, sulfoxaflor is not a neonicotinoid and DPR evaluates chemical specific data. (*See* Response Number 1.) As explained in its proposed decisions to register, DPR scientifically evaluated the surface water contamination potential of sulfoxaflor and its metabolites. (*See* Response #4, above.) Substantial evidence supports a conclusion that the use of the proposed products—in accordance with their label directions and any restrictions in regulations—will not have an adverse impact on surface. Nonetheless, DPR will add sulfoxaflor to its surface water monitoring program as part of continuous evaluation as an additional mitigation measure. In the event DPR determines additional mitigation is necessary, DPR will develop additional required mitigation measures and may initiate further evaluation of the pesticide product or active ingredient to address the identified or potential concern.

COMMENT #10:
The commenter expressed concern that approving the sulfoxaflor product labels will have significant adverse effect on drinking water.

RESPONSE #10:
See Response #4, above.

COMMENT #11:
The commenter expressed concern that approving the sulfoxaflor product labels will have significant adverse effect on human health.

RESPONSE #11:
DPR reviewed human health toxicology data and determined that the data was adequate for a complete acute toxicological evaluation. The labels prohibit applications that will contact workers or other person either directly or through drift. The labels also prohibit residential use. DPR's proposed decisions to register also referenced US EPA's July 2019 Decision Memorandum Supporting the Registration Decision for New Uses of the Active Ingredient Sulfoxaflor, which did not identify any risks of concern to human health for all population subgroups, including children, and occupational handlers. Based on the available data to support the registration of the proposed products, substantial evidence supports DPR's conclusion that the proposed decisions to register are not reasonably expected to have a significant adverse effect to human health when this product is used according to the label and any applicable use restrictions in regulation.

COMMENT #12:
The commenter expressed concern that approving the sulfoxaflor product labels will have a significant adverse impact on small mammals.

RESPONSE #12:
Based on data reviewed, DPR determined that the expected environmental concentrations for the proposed product are all less than one-half of the toxicity value for small mammals when modeled by DPR using US EPA's Terrestrial Residue Exposure model, Version 1.5.2. DPR's modeling indicates that the intended use of the proposed products are not reasonably expected to pose significant adverse impacts to small mammals. DPR also determined that the data on the metabolites of sulfoxaflor indicate the metabolites are generally less toxic than the parent compound. Substantial evidence supports DPR's conclusion that the use of these products in accordance with their label directions are not reasonably expected to have a significant adverse effect on small mammals.

COMMENT #13:
The commenter expressed concern that approving the sulfoxaflor product labels will have a significant adverse effect on air quality.

RESPONSE #13:
DPR evaluated sulfoxaflor's vapor pressure, water solubility, and Henry's Law Constant and determined that based on its physicochemical properties, sulfoxaflor is highly water soluable and has low volatility. In addition, sulfoxaflor is not federally listed as a hazardous air pollutant and DPR has not designated sulfoxaflor as a toxic air contaminant or regulated it as a potential source of volatile organic compound that may adversely impact the attainment of health-based air quality standards. Despite its low volatility, the proposed product labels provide additional mitigation to minimize potential drift by prohibiting applications when wind speeds exceed 10 mph. Additional prohibitions and instructions to avoid spray drift are also contained in the spray drift management section on the proposed labels. Further, as discussed in Response to Comment #11, above, there were no identified risks of concern to human health for all population subgroups, including children. Based on the available data and scientific evaluations of the projects to support the registration of the proposed products, DPR does not expect a significant adverse effect to human health or air quality when this product is used according to the label and any applicable use restrictions in regulation.

Tulio Macedo

Tulio Macedo, Chief
Pesticide Registration Branch

05/29/2020

Dated

EARTHJUSTICE

January 2, 2020

Via Electronic & U.S. Overnight Mail

Ann M. Prichard, Chief
Pesticide Registration Branch
Department of Pesticide Regulation
P.O. Box 4015
Sacramento, CA 95812-4015
registration.comments@cdpr.ca.gov

Re. Comments Regarding Notice of Proposed Decision to Register Pesticide Products Containing the New Active Ingredient Sulfoxaflor

Dear Ms. Prichard:

Please accept these comments on behalf of the Pollinator Stewardship Council and American Beekeeping Federation regarding the proposed decision of the California Department of Pesticide Regulation (DPR) to register pesticide products containing the new active ingredient sulfoxaflor. (See Notice of Proposed and Final Decisions and Public Reports, Vol. 2019-49, available at https://www.cdpr.ca.gov/docs/registration/nod/2019-49.pdf.)

Sulfoxaflor is an extremely toxic and highly controversial insecticide that has been the subject of past and ongoing federal litigation.[1] DPR nevertheless posted notice of its proposed registration decision on Friday afternoon, December 6, 2019, affording the public only 18 business days spanning the winter holidays to review and comment upon a proposal to register sulfoxaflor for the first time in California.

While the short comment deadline has curtailed the public's ability to digest and respond fully to DPR's proposed registration decision, there is ample scientific evidence that DPR's proposal will have a significant adverse environmental impact, not only on honey bees and other insect pollinators, but also on aquatic ecosystems and beneficial organisms such as ladybugs and earthworms that are critical to sustainable agriculture in California. In violation of the California Environmental Quality Act (CEQA) and DPR's own laws and regulations, the "public reports" posted by DPR do not sufficiently assess and disclose the environmental impacts of and alternatives to registering sulfoxaflor as proposed. For these reasons, we urge DPR to withdraw its proposed decision and decline to register sulfoxaflor for use in California.

[1] See *Pollinator Stewardship Council v. U.S. Envt'l Prot. Agency* (9th Cir. 2015) 806 F.3d 520 [vacating U.S. EPA's initial registration of sulfoxaflor]; *Pollinator Stewardship Council v. Wheeler* (9th Cir., filed Sept. 6, 2019) No. 19-72280 [challenging U.S. EPA's approval of new uses for sulfoxaflor].

Sulfoxaflor

Sulfoxaflor is the first of a new subclass of insecticides called sulfoximines. Because sulfoxaflor works by disrupting the nicotinic acetylcholine receptor in the insect nervous system, it has the same "mode of action" as other insecticides in "IRAC Group 4," including neonicotinoid insecticides like imidacloprid, clothianadin, and thiamethoxam. (IRAC 2015; Culter et al. 2012; Ulens et al. 2019.)[2] As summarized by the Ninth Circuit Court of Appeals:

> Neonicotinoids, including sulfoxaflor, are "systemic" insecticides, which means that they are sprayed onto plants, which then absorb the chemicals and distribute them throughout the plant, into the tissues, pollen, and nectar. Sulfoxaflor and other systemic insecticides therefore kill insects in two different ways: insects die when they come into contact with the pesticide, as when they are sprayed with it, and also when they ingest the plant which has absorbed the pesticide.

(*Pollinator Stewardship Council v. U.S. Envt'l Prot. Agency* (9th Cir. 2015) 806 F.3d 520, 523.)

DPR proposes to register two consumer-use pesticide formulations (or "products") manufactured by Dow AgroSciences, both of which contain sulfoxaflor as their active ingredient. The first, marketed under the brand name "Transform CA," contains 50% sulfoxaflor by weight. According to DPR's public report:

> [Transform CA] is a water dispersible granule intended for use in agricultural settings. Transform CA is mixed with water and can be applied as a ground or aerial spray. Based on the proposed label, this product is for:
>
> • Control or suppression of aphids, plant bugs, leafhoppers, whiteflies, stink bugs, potato psyllid, and thrips.
> • Use on crops such as barley, wheat, canola, flax seed, milkweed, mustard seed, poppy seed, rapeseed, Chinese artichoke, Jerusalem artichoke, potato, sweet potato, yam, ginger, chickpea, cowbean, lima bean, kidney bean, pinto bean, and snap bean

(Transform Pub. Rpt. at 8.)

The second product marketed under the brand name "Sequoia CA" and contains 21.8% sulfoxalfor by weight. According to DPR's public report:

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[2] References cited herein are listed in Attachment A, and electronic copies in .pdf are provided on the compact disc (CD) that accompanies these comments.

> [Sequoia CA] is a liquid suspension concentrate intended for use in agricultural settings. Sequoia CA is mixed with water and can be applied as a ground (including airblast) or aerial spray. Based on the proposed label, this product is for:
>
> • Control or suppression of aphids, plant bugs, leafhoppers, whiteflies, pear psylla, San Jose scale, thrips, and mealybugs.
> • Use on crops such as broccoli, Brussels sprouts, cauliflower, bell pepper, hot pepper, sweet pepper, tomato, lettuce, spinach, apple, pear, grape, nectarine, peach, plum, prune, cherry, almond, pistachio, and walnut.

(Sequoia Pub. Rpt. at 8.)

Pollinator Stewardship Council
& American Beekeeping Federation

Pollinator Stewardship Council (PSC) is a non-profit organization of beekeepers working to help beekeepers founded in 2012 to defend managed and native pollinators vital to a sustainable and affordable food supply from the adverse impacts of pesticides. Fully one-third of the Nation's food supply requires pollination, and PSC works to protect the pollinators and commercial beekeepers that provide pollinators to the farmers. PSC accomplishes its mission by: (1) ensuring that federal and state agencies enforce and comply with laws to protect pollinators from pesticides; (2) providing advocacy, guidance and tools for beekeepers to defend their bees from the detrimental effects of pesticides; and (3) raising awareness about the adverse impacts of pesticides on pollinators. PSC's board includes many of the Nation's leading commercial honey beekeepers. Some of these are California-based businesses, and virtually all of PSC's board and commercial beekeeper members provide commercial honey bee pollination services in California to California farmers on almonds and other crops.

The American Beekeeping Federation (ABF) is a non-profit organization founded in 1943 dedicated to advancing the interests of all beekeepers, large or small, and other interests associated with the industry to ensure the future of the honey bee. ABF currently has approximately 1,300 members, making it the largest beekeeping organization in the United States. Approximately 25% of the commercial beekeepers in the United States are members of ABF, and ABF members harvest roughly 30% of the honey produced in the United States each year, much of that from smaller producers. ABF works

Regulatory Background

Under California law, it is the responsibility of DPR "to protect the environment from environmentally harmful pesticides by prohibiting, regulating, or ensuring proper stewardship of those pesticides." (Food & Agr. Code § 11501, subd. (b).) To this end, every pesticide sold in California must be approved, or "registered," by DPR. (*Id.* § 12811.)

Upon receipt of an application to register a new pesticide, DPR must conduct a "thorough and timely evaluation." (Id. § 12824.) During its review, DPR must first ensure the applicant has submitted all of the data required by law and that such data is reliable and sufficient. (See, e.g., Cal. Code Regs. tit. 3, § 6170; Food & Agric. Code §§ 13126 [Birth Defects Prevention Act], 13126 [Pesticide Contamination Prevention Act].) For example, "[e]ach applicant to register a pesticide product which, under field conditions, may be likely to contact commercial apiaries or pollinating bees shall submit to the director test data indicating the product's acute chronic toxicity to bees." (Cal. Code Regs. tit. 3, § 6187.) DPR must then "give special attention" to a number of factors, including the "potential for environmental damage," "toxicity to aquatic biota or wildlife," and "the availability of feasible alternatives." (Cal. Code Regs., tit. 3, § 6158.) "If any of these factors are anticipated to result in significant adverse impacts which cannot be avoided or adequately mitigated, registration will not be granted unless [DPR] makes a written finding that the anticipated benefits of registration clearly outweigh the risks." (Ibid.)

The Secretary of Resources has designated DPR's pesticide registration process as a "certified regulatory program" under the California Environmental Quality Act (CEQA). (See Cal. Code Regs., tit. 14, § 15251, subd. (i)(1).) The Secretary's designation means DPR need not prepare a separate, stand-alone environmental impact report (EIR) or negative declaration when registering pesticides. (Pub. Res. Code § 21080.5, subd. (c).) Instead, the environmental documents prepared by DPR during the registration process "are considered the 'functional equivalent' of documents CEQA would otherwise require." (*Pesticide Action Network N. America v. Cal. Dept. of Pesticide Regulation* (2017) 16 Cal.App.5th 224, 239 [quoting *City of Arcadia v. State Water Res. Ctrl. Bd.* (2006) 135 Cal.App.4th 1392, 1422].) DPR's certified regulatory program"—and the environmental review documents [DPR] prepares—remain subject to the broad policy goals and substantive standards of CEQA." (*Id.* at 242.) As a result, DPR's decision to register a pesticide must involve "essentially the same consideration of environmental issues as is provided by use of EIRs and Negative Declarations." (Cal. Code Regs., tit. 14, § 15002, subd. (l).)

To implement CEQA, regulations governing DPR's registration program require DPR to prepare a "public report" prior to registering a pesticide. (Cal. Code Regs., tit. 3, § 6253.) The public report 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 impact." (*Id.*, § 6254.) The report must "also contain a statement and discussion of reasonable alternatives which would reduce any significant environmental impact." (*Id.*, § 6254, subd. (a).)

Specific Comments

I. DPR's Proposed Decision to Register Sulfoxaflor Will Have a Significant Adverse Impact on the Environment.

The public reports posted by DPR for Transform CA and Sequoia CA, which are nearly identical, assert that registration of the products "is not expected to have any significant adverse effect that can reasonably be expected to occur, directly or indirectly, to human health or the environment." (Transform Pub. Rpt. at 10; Sequoia Pub. Rpt. at 10.) As set forth below and further detailed in the review of Dr. Susan Kegley that follows these comments as Attachment B, DPR's assertion is unsupported by substantial evidence and directly contradicted by a wealth of readily available scientific research and literature.

A. Sulfoxaflor Presents a Significant Risk to Honey Bees and Other Insect Pollinators.

Sulfoxaflor is a relatively new active ingredient that has essentially never been used in California and has not been widely used elsewhere in the United States, but there is already ample scientific evidence that its use may result in significant adverse impacts to honey bees and other insect pollinators. The labels for both Transform CA and Sequoia CA confirm, "This product is highly toxic to bees exposed through contact during spraying and while spray droplets are still wet." (Transform Label at 1; Sequoia Label at 1.) According to the U.S. Environmental Protection Agency's July 2019 ecological risk assessment, sulfoxaflor's "acute contact LD_{50}" for foraging honey bees is a mere 0.13 micrograms, meaning that 50% of foraging honey bees exposed to just 0.13 micrograms of sulfoxaflor will die soon after contact. (See https://www.regulations.gov/document?D=EPA-HQ-OPP-2010-0889-0566.)

While sulfoxaflor's acute toxicity alone presents a significant risk to bees, far more insidious is the impact that chronic, "sublethal" exposure to sulfoxaflor has on the entire bee colony. For example, Siviter et al. 2018 demonstrated that "chronic exposure to the sulfoximine-based insecticide sulfoxaflor, at dosages consistent with potential post-spray field exposure, has severe sub-lethal effects on bumblebee (*Bombus terrestris*) colonies." Similarly, Taning et al. 2019 found "treatment with field-realistic concentrations of sulfoxaflor (1, 5 and 15 µg/ ml) significantly reduced the survival of *B. terrestris* workers." Siviter et al. 2019 "confirm that sulfoxaflor exposure at the levels we tested could be hazardous to bumblebees and suggest that reduced egg laying is a possible mechanism driving previously described effects of sulfoxaflor exposure on bumblebee colony reproductive output." The impact associated with chronic

exposure to sublethal quantities of sulfoxalfor is particularly concerning, given that Kammon et al. 2019 detected sulfoxaflor in honey samples in areas where it has been registered for use.

Sulfoxaflor will also have a significant and adverse cumulative impact on honey bees and other pollinators. At this point, there is overwhelming scientific evidence that widespread agricultural use of neonicotinoids is devastating insect pollinators. For example, Whitehorn et al. 2012 concluded field-realistic levels of the neonicotinoid imidacloprid "may be having a considerable negative impact on wild bumble bee populations across the developed world." Mitchell et al. 2013 "confirm the exposure of bees to neonicotinoids in their food throughout the world." And the results of Sandrock et al. 2014 "clearly indicate that neonicotinoids negatively impact on honeybee colony performance after chronic sublethal exposure throughout two brood cycles."

In 2015, the landmark Worldwide Assessment on Systemic Insecticides analyzed the state of the science regarding the impact of neonicotinoids on pollinators and concluded:

> Overall, the existing literature clearly shows that present-day levels of pollution with neonicotinoids and fipronil caused by authorized uses (i.e. following label rates and applying compounds as intended) frequently exceed the lowest observed adverse effect concentrations for a wide range of non-target species and are thus likely to have a wide range of negative biological and ecological impacts.

(van der Sluijs et al. 2015.) Moreover, the authors of the Worldwide Assessment found:

> At present, no studies have addressed the additive or synergistic effects of simultaneous exposure to multiple compounds of the neonicotinoid family, *i.e*. imidacloprid, clothianidin, thiamethoxam, dinotefuran, thiacloprid, acetamiprid, sulfoxaflor, nitenpyram, imidaclothiz, paichongding and cycloxaprid, into an aggregated dose of *e.g*. "imidacloprid equivalents." Currently, risk assessments are done for each chemical separately, while many non-target species, such as pollinators, are simultaneously being exposed to multiple neonicotinoids as well as other pesticides and stressors. *As a consequence, the risks have been systematically underestimated.*

(*Ibid*. [emphasis added].)

In response to the clear evidence that existing agricultural use of neonicotinoids is having a significant, cumulative impact on pollinators and has become a driving force behind global pollinator declines, 233 prominent scientists called for aggressive regulatory action in 2018. They explained:

> It is the view of the undersigned scientists that the balance of evidence strongly suggests that these chemicals are harming beneficial insects and contributing to the current massive loss of global biodiversity. As such, there is an immediate need for national and international agreements to greatly restrict their use, *and to prevent registration of similarly harmful agrochemicals in the future.*

(Goulson et al. 2018 [emphasis added].)

In short, DPR's assertion the proposed agricultural use of sulfoxalfor will have no significant adverse impact on honey bees and other pollinators is contrary to the available scientific evidence and unsupported. DPR's assertion that the proposed label instructions are sufficient to prevent significant adverse direct, indirect, and cumulative impacts to pollinators is likewise unsupported.

B. Sulfoxaflor Presents a Significant Risk to Beneficial Insects and other Important Agricultural Organisms.

There is substantial scientific evidence that sulfoxaflor will also have a significant adverse impacts on other non-pollinating organisms that are nevertheless critical to agriculture in California. For example, Fang et al. 2018 found "sulfoxaflor is a supertoxic pollutant to earthworms that easily bioaccumulates in earthworms," and "[s]ince earthworms significantly contribute to soil function and ecosystems, the high safety risks of sulfoxaflor to the earthworm could extend to the environment." He et al. 2019 found that "Sulfoxaflor, at ≥45 g a. i. ha^{-1} [i.e., ≥0.04 lbs a.i. per acre] may significantly impair *H. axyridis* [i.e., ladybug] population parameters and reduce its potential biological control activity." Nawaz et al. 2018 further demonstrated how sublethal exposure to sulfoxaflor damages the ladybug genome. In addition, Jiang et al. 2019 documents significant effects of sulfoxaflor on three species of parasitic wasps that "play a critical role in insect pest management in agricultural environments."

In sum, the available scientific information regarding sulfoxaflor's effect on a host of beneficial organisms furthers contradicts DPR's conclusion that registering the active ingredient for use in California will have no significant adverse environmental impact.

C. Sulfoxaflor Presents a Significant Risk to Water Quality and Aquatic Ecosystems.

Finally, there is substantial scientific evidence that DPR's proposed decision to register sulfoxaflor will have a significant adverse direct, indirect, and cumulative impact on water quality and aquatic ecosystems in California. The public reports for both Transform CA and Sequoia CA concede "[t]his product is toxic to aquatic invertebrates." (Sequoia Pub. Rpt. at 9.)

They likewise acknowledge "[t]he physical-chemical properties of sulfoxaflor indicate the potential for off-site movement of the product into surface water and groundwater." (*Ibid.*)

As part of the Worldwide Asessment on Systemic Insecticides, Pisa et al 2015 found "[a]t field-realistic levels of pollution, neonicotinoids and fipronil generally have negative effects on physiology and survival for a wide range of non-target invertebrates in terrestrial, aquatic, marine and benthic habitats." More recently, Yamauro et al. 2019 demonstrated "aquatic systems are threatened by the high toxicity and persistence of neonicotinoid insecticides." The presence of neonicotinoids in surface and ground water throughout the United States resulting from agriculture use of these pesticides is also well documented. (See, e.g., Hladik et al. 2015; Klarich et al. 2017.)

In sum, DPR's assertion that the proposed uses of sulfoxalfor will have no significant adverse impact on water quality and aquatic ecosystems is unsupported. DPR's conclusion that the proposed label instructions are sufficient to ensure use of sulfoxaflor will not have a significant impact on these resources is similarly unsupported by substantial evidence.

II. The Public Reports Prepared by DPR Fail to Comply with CEQA.

The public reports posted by DPR in connection with its decision to register Transform CA and Sequoia CA do not comply with CEQA. As set forth below, DPR's discussion of alternatives is wholly inadequate, as is DPR's discussion of the environmental baseline and the direct, indirect, and cumulative environmental impacts of its proposed decision.

A. DPR's Discussion of Alternatives Is Inadequate.

A public report "must include some consideration of feasible alternatives even if the project's significant environmental impacts will be avoided through mitigation measures." (*Pesticide Action Network N. America, supra,* 16 Cal.App.5th at 245 [quoting *Friends of the Old Trees v. Department of Forestry & Fire Protection* (1997) 52 Cal.App.4th 1383, 1395].)

DPR's public reports identifies "four alternatives to the project of registering a pesticide product containing a new active ingredient in California." (Sequoia Pub. Rpt. at 4-5; Transform Pub. Rpt. at 4-5.)

- Alternative # 1: Accept the proposed pesticide product containing a new active ingredient.
- Alternative # 2: Require revision of the proposed pesticide product label.
- Alternative # 3: Adopt a regulation.
- Alternative # 4: No Action (Decision to Deny the Proposed Pesticide Product Containing a New Active Ingredient.)

DPR identifies Alternative 1 as the agency's "preferred" alternative, "[d]ue to the lack of feasibility and speculative nature of Alternatives #2, #3, and #4." ((Sequoia Pub. Rpt. at 5; Transform Pub. Rpt. at 5.) This cursory treatment of alternatives does not satisfy CEQA.

First, DPR"s evaluation of the "no action" alternative (Alternative # 4) is inadequate. It reads:

> The no action alternative means that DPR would not accept the proposed end-use pesticide product containing a new active ingredient. As DPR's scientific evaluation of this project has not identified a significant adverse environmental or human health impact that is reasonably expected to occur from this proposed registration action, and this project would provide and additional pest control option, this is not a preferred alternative.

(Transform at 5.) In violation of CEQA, DPR's description and discussion of the "no action" alternative provides no information about that alternative's potential *impact* on the environment. DPR's failure to undertake any analysis of the environmental impacts associated with the no action alternative precludes the public and DPR decisionmakers from comparing the potential pros and cons of the no action alternative to that of DPR's preferred alternative, in violation of CEQA. Moreover, California law specifically directs DPR to refuse to register any pesticide "[f]or which there is a reasonable effective and practicable alternate material or procedure that is demonstrably less destructive to the environment. (Food & Agric. Code § 12825, subd. (c).) Here, DPR's public reports provide no information whatsoever that would allow the public to evaluate whether any such alternate material or procedure exists. As Hon. Judge Rosch, Alameda County Superior Court in prior litigation involving DPR's decision register methyl iodide:

> I can tell you that my concept of a no project alternative is: what if the Department of Pesticide Regulation declines to register a certain chemical as pesticide? And the things that I think that you should be looking at in that alternatives evaluation are things like, well, all right, if we don't approve X pesticide will the glassy wing sharp-shooters destroy the asparagus crop, or is there some alternative for the farming industry that needs to protect the asparagus crop? . . . [S]omebody in the Department has to recognize that those are the sorts of things that the decision-makers need to know before they can approve a discretionary determination about any kind of a pesticide and that's their job. They really do know how to do this.

(Gorecki 2012 at 12-13.) The public reports DPR prepared for sulfoxaflor nevertheless do not evaluate the potential environmental impacts associated with adopting the no action alternative.

Second, DPR rejects the alternative of adopting a California-specific label (Alternative #2) as infeasible, but the public reports for both Transform CA and Sequoia CA elsewhere acknowledge: "The proposed label is specific for use in California." (Transform Pub. Rpt. at 8; Sequoia Pub. Rpt. at 8.) Given that DPR's proposed decision entails the approval of labels that are specific to California, there is no reason DPR could not have sought to negotiate with the U.S. Environmental Protection Agency (USEPA) a range of alternative labels options and mitigation measures, including for example larger buffers and reduced application rates. DPR's cursory dismissal of Alternative #2 and failure to explore the full range of possibilities associated with a California specific label violates CEQA.

Third, DPR rejects the alternative of adopting a regulation placing appropriate restrictions on the use of sulfoxaflor as "time-consuming." DPR fails, however, to evaluate the substantial environmental benefits that would result from a rulemaking. For example, the formal, rule-making process would allow all stakeholders to assist in the development and evaluation of mitigation measures to prevent risk to pollinators and other environmental resources. Mitigation measures adopted through a rulemaking will be more effective and easier to enforce than fine-print label restrictions. Indeed, some of the proposed label restrictions DPR proposes to rely upon to mitigate the risk to bees are voluntary and entirely unenforceable. (See, e.g., Transform Pub. Rpt. at 9 ["[T]he label *advises* applications to occur before 7 a.m. or after 7 p.m., or anytime when temperature is below 50º F."].) DPR also could and should have evaluated a rulemaking to designate sulfoxaflor as a restricted material. DPR's cursory dismissal of Alternative #3 and failure to evaluate the potential environmental benefits of a rulemaking violates CEQA.

For all these reasons, DPR's discussion of alternatives is insufficient under CEQA.

B. DPR's Discussion of Environmental Impacts Is Inadequate.

DPR's public reports must include "a statement of any significant adverse environmental effect that can reasonably be expected to occur, directly or indirectly, from implementing the proposal." (Cal. Code Regs., tit. 3, § 6254.) As the First District Court of Appeal recently explained:

> [DPR]'s regulations which require review when a significant adverse effect "can reasonably be expected to occur" is not meaningfully different from CEQA regulations imposing a fair argument review when an activity "may have a significant environmental effect." The Supreme Court has noted that under the CEQA Guidelines, "[I]t is appropriate for agencies to apply the fair argument standard in determining whether there is a reasonable possibility of a significant effect on the environment.

(*Pesticide Action Network N. America, supra,* 16 Cal.App.5th at 246-47 [citing *Berkeley Hillside Preservation v. City of Berkeley* (2015) 60 Cal.4th 1086, 1115].)

DPR's statement of the direct, indirect, and cumulative impacts that may result from its proposed decision to register sulfoxaflor is also inadequate under CEQA.

1. DPR's Analysis of the Environmental Baseline Does Not Satisfy CEQA.

"To decide whether a given project's environmental effects are likely to be significant, the agency must use some measure of the environment's state absent the project, a measure sometimes referred to as the 'baseline' for environmental analysis." (*Communities for a Better Env't v. S. Coast Air Quality Mgm't Dist.* (2010) 48 Cal. 4th 310, 315.) DPR's public reports do not adequately describe the baseline environmental setting.

First, the public reports fail to disclose that we are in the midst of an unprecedented and worsening pollinator die-off. (*Pollinator Stewardship Council, supra,* 806 F.3d at 522 ["Bees are essential to pollinate important crops and in recent years have been dying at alarming rates."].) According to the most recent survey of winter honey bee loses:

> During the 2018-2019 winter . . . an estimated 37.7% of managed honey bee colonies in the United States were lost. This represents an increase of 7 percentage points compared to last year (30.7%), and an increase of 8.9 percentage points compared to the 13-year average winter colony loss rate of 28.8%. *This year's estimate is the highest level of winter losses reported since the survey began in 2006-2007.*

(Bruckner et al. 2019 [emphasis added].) Native pollinators are faring no better. Indeed, following a scientific review by the California Department of Fish and Wildlife, the California Fish and Game Commission recently designated four separate species of bumble bees as candidates for listing as endangered under the California Endangered Species Act. (CFGC 2019; CDFW 2019.) In violation of CEQA, DPR's public reports make no mention of this crisis.

Second, the public reports do not disclose the critical importance of honey bees and other insect pollinators to California agriculture. As summarized by the First District Court of Appeal:

> Honeybees are vital to the pollination of many of California's agricultural crops, which are critical to our national food system and essential to the economy of the state. Improving the health of honey bee colonies is considered imperative to meet the demands of U.S. agriculture for pollination and to ensure food security.

(*Pesticide Action Network N. America, supra,* 16 Cal.App.5th at 234.) DPR has elsewhere summarized the significance of insect pollinators to California agriculture in the following terms:

> California leads the nation in cash farm receipts, and its agricultural production includes more than 400 commodities representing over a third of the country's vegetables and two-thirds of the country's fruits and nuts. Many of these agricultural commodities rely on pollination by bees for optimal production. Today, more than 2.5 million honey bee colonies in the United States pollinate an estimated $15 billion of crops each year, ranging from almonds to zucchini. Of these, approximately 1.8 million colonies are used in the pollination of California's almond crops alone. Colony losses of these critical natural and managed pollinators have triggered worldwide concern in recent years. Multiple factors may contribute to colony losses and other risks to pollinator and hive health, including possible effects of neonicotinoid pesticides.

(CDPR 2018a at 1.) In violation of CEQA, DPR's public reports for Transform CA and Sequoia CA include no equivalent disclose of insect pollinators' leading role in California agriculture.

Third, the public reports to do no describe the baseline with respect to registered use of other neonicotinoids. For example, DPR fails to disclose that it has registered myriad pesticide products containing an "IRAC Group 4" active ingredient with the same mode of action as sulfoxaflor and similar toxicity to pollinators. These include: 301 products containing imidacloprid; 42 products containing clothianidin, 46 products containing dinotefuran; 28 products containing thiamethoxam, and 4 products containing flupyradifurone. (See CDPR 2019 [listing pesticide products within IRAC Group 4 with active DPR registrations].) According to van der Sluijs 2013, these past registration decisions have "transformed the agrochemical landscape to one in which most flowering crops and an unknown proportion of wild flowers contain varying concentrations of neonicotinoids in their pollen and nectar."

Fourth, the public reports do not disclose that DPR is in the process of "reevaluating" its registration of neonicotinoid pesticides, based on DPR's 2009 finding that then-existing use of neonicotinoids may be having a significant adverse impact on honey bees. (See CDPR 2009; CDPR 2019.) Incredibly, DPR's public reports fail to mention that DPR has advised pesticide manufacturers it will be unable to approve any application to register new uses for neonicotinoids pending the conclusion of its neonicotinoid reevaluation. (CDPR 2018.) DPR's public reports also fail to address DPR's recent Neonicotinoid Risk Determination, which found a risk to bees from numerous approved uses of neonicotinoids. (CDPR 2018a, CDPR 2019c.)

In these and other respects, DPR's discussion of the existing environmental baseline is inadequate under CEQA.

2. DPR's Analysis of Direct and Indirect Impacts Does Not Satisfy CEQA.

As noted previously, DPR's public reports must include "a statement of any significant adverse environmental effect that can reasonably be expected to occur, directly or indirectly, from implementing the proposal." (Cal. Code Regs., tit. 3, § 6254.) The public reports DPR prepared for Transform CA and Sequoia CA fail in this regard as well.

First, DPR's public reports fail to disclose the actual scientific basis for DPR's assertion that registering sulfoxaflor will have no significant environmental impact. DPR claims to have "evaluated the project (new pesticide product containing a new active ingredient) and scientific data supporting this registration action." (Transform Pub. Rpt. at 10.) DPR fails, however, to disclose what specific "scientific data" it received and evaluated, nor does it disclose what they agency's "evaluation" actually entailed. DPR's failure to "show its work" frustrates the public's ability to review and comment meaningfully on DPR's proposed registration decision, in violation of CEQA.[3] As the First District Court of Appeal recently made clear, DPR's CEQA certified regulatory program "does not excuse the Department from CEQA's substantive requirements or explaining its analysis." (*Pesticide Action Network N. America, supra,* 16 Cal.App.5th at 247.) As a result, "even if [DPR's] finding of no significant impacts was meaningfully derived, it does not excuse [DPR] from showing how it reached its conclusion." (*Ibid*.) An earlier opinion described this requirement of disclosure under CEQA as follows:

> A certified program's statement of no significant impact must be supported by documentation showing the potential environmental impacts that the agency examined in reaching its conclusions, and this documentation would be similar to an initial study.

(*City of Arcadia, supra,* 135 Cal.App.4th at 1424, n.11.) Here, DPR's public reports are legally inadequate because they do not "allow meaningful public comment directed at the rationale for [DPR's] decision." (*Pesticide Action Network N. America, supra,* 16 Cal.App.5th at 247.)

Second, DPR's effort to dismiss the significant environmental impact of its proposed decision as somehow "unknowable" is both factually incorrect and contrary to CEQA. DPR claims that "acceptance of a proposed pesticide product containing a new active ingredient does

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[3] The notice of DPR's proposed decision to register sulfoxaflor directs the public to submit a formal Public Records Act (PRA) request "for any documents related to this notice." (Notice at 1.) On December 17, 2109, undersigned counsel sent DPR a PRA request for records supporting DPR's proposed registration. (See Attachment C hereto.) On December 24, 2019, DPR emailed undersigned counsel approximately 210 pages of documentation in partial response to the PRA request. A complete response is still pending.

not translate to guaranteed future use," and DPR deems it "speculative to determine whether accepting this proposed new pesticide product would cause the product to be used at all." (Transform Pub. Rpt. at 4, 7.) By DPR's flawed logic, almost any governmental permit or approval could be excused from CEQA, on the grounds that approval does not guarantee execution. Moreover, "[t]he fact that precision may not be possible . . . does not mean that no analysis is required." Banning Ranch Conservancy v. City of Newport Beach (2017) 2 Cal.5th 918, 938. To comply with CEQA, "an agency must necessarily engage in some forecasting. (Cal. Code Regs., tit. 14, § 15144.) "While foreseeing the unforeseeable is not possible, an agency must use its best efforts to find out and disclose all that it reasonably can." (Ibid.) Here, it is completely foreseeable and reasonable to conclude that DPR's registration of sulfoxaflor will result in its use in California. DPR's public reports acknowledge that sulfoxalfor was used in California from 2015-2018 pursuant to special registration exemptions. (Transform Pub. Rpt. At 6-7.) Past patterns of sulfoxaflor use in other states is also available to DPR. Such evidence of past sulfoxaflor use is ample evidence that sulfoxaflor will be used in California in the future if registered by DPR. DPR objects that "the registrant/applicant has not provided any information regarding its estimation on potential future use of this product in California." (Transform Pub. Rpt. at 7.) However, it is DPR's responsibility—not Dow's—to evaluate carefully a pesticide's "potential for environmental damage." (Cal. Code Regs., tit. 3, § 6158.) The need to evaluate a pesticide's potential environmental impact is especially great when the pesticide involves an entirely new active ingredient, as is the case with sulfoxalfor. Given that DPR registers only a handful of new active ingredients each year—many of which are inherently low risk—there is no evidence that compliance with CEQA would be overly burdensome. (See CDPR 2019a. [listing new active ingredients approved by DPR from 2015-2018].)

Third, DPR's assessment of sulfoxaflor's direct and indirect impacts fails to contend with the overwhelming scientific evidence—including the literature discussed in this letter and by Dr. Kegley—indicating use of sulfoxaflor presents a significant risk to pollinators, other beneficial organisms, and aquatic ecosystems. DPR's failure to grapple with this science to undertake a comprehensive evaluation of environmental impacts prior to registering this new active ingredient for the first time is especially concerning. As Siviter et al. 2018 underscored: "There is an urgent need to pre-emptively evaluate the potential sub-lethal effects of sulfoximine-based pesticides on pollinators, because such effects are rarely detected by standard ecotoxicological assessments, but can have major impacts at larger ecological scales."

In short, DPR's discussion of the direct and indirect environmental impacts of its decision to register sulfoxaflor violates CEQA.

3. DPR's Discussion of Cumulative Impacts Does Not Satisfy CEQA.

When evaluating a pesticide proposed for registration, DPR must conduct "at least a preliminary search for potential cumulative environmental effects, and if any such effect were

perceived, at least a preliminary assessment of its significance." (*Pesticide Action Network N. America, supra,* 16 Cal.App.5th at 249 [quoting *Laupheimer v. State of Cal.* (1988) 200 Cal.App.3d 440, 462-63].) "While technical perfection in a cumulative impact analysis is not required, courts have looked for adequacy, completeness, and a good faith effort at full disclosure." (*Id.* at 250 [quoting *Joy Road Area Forest & Watershed Assn. v. Cal. Dept. of Forestry & Fire Protection* (2006) 142 Cal.App.4th 656, 676].)

As discussed previously in this letter, there is substantial scientific evidence that DPR's proposed decision to register sulfoxaflor will have a significant adverse impact on pollinators and other beneficial organisms, as well as aquatic ecosystems. DPR's public reports for Transform CA and Sequoia CA does not disclose or evaluate this evidence of environmental impacts. Instead, DPR incorrectly claims "it is not reasonably foreseeable to predict or analyze cumulative impacts from this proposed registration decision." (Transform Pub. Rpt. at 8; Sequoia Pub. Rpt. at 8.) According to DPR, "it is too speculative for DPR to predict whether the availability of this pesticide product containing a new active ingredient, as proposed in this registration decision, will increase the overall future use of other active ingredients with similar use patterns. (Transform Pub. Rpt. at 7; Sequoia Pub. Rpt. at 7.)

DPR's cumulative impact "analysis" for sulfoxaflor does not reflect the requisite "good faith effort at full disclosure." (*Pesticide Action Network N. America, supra,* 16 Cal.App.5th at 250.) To comply with CEQA, DPR must—at the very least—disclose and address the facts and evidence discussed previously showing: (1) that sulfoxaflor has similar toxicological properties and the same mode of action as other neonicotinoids in IRAC group 4; (2) that DPR has already registered over 400 pesticide products containing IRAC group 4 active ingredients for use on a specific crops; (3) that DPR has determined existing agricultural use of IRAC group 4 pesticides may be having a significant adverse impact on the environmental; and (4) that DPR's proposed decision to register sulfoxaflor may have a significant cumulative impact on the pollinators and other environmental resources when considered together with DPR's prior registration decisions involving IRAC Group 4 pesticides.

In an effort to excuse its failure to analyze cumulative impacts, DPR claims its certified regulatory program "incorporates the consideration of cumulative impacts by requiring DPR to continuously evaluate pesticides registered for use in California and take necessary action if a potential concern is identified." (Transform Pub. Rpt. at 7; Sequoia Pub. Rpt. at 7.) This "promise of more analysis to come following the conclusory explanation here simply does not measure up to CEQA's mandate that relevant information on the effects of a project be made available as soon as possible and presented in a way that is useful to decisionmakers and the public." (*Pesticide Action Network N. America, supra,* 16 Cal.App.5th at 250.)

DPR also claims it is "not aware of a scientifically valid methodology to evaluate potential cumulative interactions between the new active ingredient contained in this product

with other active ingredients to support a proposed regulatory decision. (Sequoia Pub. Rpt. at 7-8.) However, USEPA has published guidance and a framework for assessing cumulative impacts from pesticides. (USEPA 2002; USEPA 2016.) The National Academies of Sciences has also identified methodologies that "provide an objective, quantitative, and practical framework for incorporating baseline conditions and projected future cumulative effects into the ecological risk assessment." (NRC 2013 at 101.) In fact, USEPA has completed cumulative risk assessments for several classes of pesticides. (See https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.)

In sum, DPR's treatment of sulfoxaflor's cumulative impacts falls well short of what CEQA requires.

Conclusion

We urge DPR to withdraw its proposed decision to register pesticide products containing the new active ingredient sulfoxaflor and to deny Dow's application to register sulfoxalflor in California.

Sincerely,

Gregory C. Loarie
Earthjustice

Counsel for Pollinator Stewardship Council and American Beekeeping Federation

Attachment A: List of References
Attachment B: Review of Dr. Susan Kegley
Attachment C: PRA Request to DPR

Pesticide Research Institute

January 2, 2020

Via Electronic & US Mail

Ann M. Prichard, Chief
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P.O. Box 4015
Sacramento, CA 95812-4015
registration.comments@cdpr.ca.gov

Re: Comments Regarding Notice of Proposed Decision to Register Pesticide Products Containing the New Active Ingredient Sulfoxaflor

Dear Ms. Prichard:

I am writing regarding the proposed decision by the California Department of Pesticide Regulation (DPR) to register products containing sulfoxaflor as an active ingredient.[1] This letter provides additional scientific context for the comments submitted by Earthjustice, representing the Pollinator Stewardship Council and American Beekeeping Federation.

Background and Experience

My expertise is in the chemistry of pesticides and their impacts on humans and animals, risk assessment, fate and transport of pesticides in air and water, methods of pesticide sampling and analysis, pesticide use trends, and mechanisms of pesticide action on both target pests and non-target organisms. My PhD degree is in Organic Chemistry from UNC-Chapel Hill (1982), with postdoctoral work carried out at Colorado State University in 1983. From 1983-1998, I was in academia, teaching and conducting research on the fate and transport of chemicals in the environment, including the development of analytical methods and assessment of transport mechanisms and environmental degradation pathways.

From 1998–2007, I was a Staff Scientist and Senior Scientist at Pesticide Action North America. While at PAN, I wrote a number of reports evaluating and summarizing the scientific literature on the impacts of pesticides on the environment and human health. I developed an air monitoring device (the Drift Catcher) and a training program that allowed residents affected by pesticide drift to monitor pesticides in air near their homes. I conducted a number of air monitoring studies on chlorpyrifos and fumigant pesticides and submitted these data to both US EPA and DPR in support of regulatory reform regarding risk assessments of volatilization drift. I also created the PesticideInfo website[2] that integrates available data on pesticide toxicity, use, physical properties, symptoms of poisoning, and registration.

In 2007, I founded Pesticide Research Institute (PRI), an environmental consulting firm focused on understanding the scope of pesticide impacts on the environment and human health. I currently serve as Principal Scientist and CEO of PRI. At PRI, I work to provide data and toxicological information to help governments and consumers understand the potential impacts of pesticides and make informed decisions. I worked with the City of San Francisco to develop the San Francisco Hazard Tier rating system[3] for pesticide products as a tool for the City's IPM program. I also developed the PRI Pesticide Product Evaluator[4] and PestSmart[5] websites that utilize the San Francisco Hazard Tier rating system to assess LEED-certification related to the use of pesticide products. I continue to provide data for Pesticide Action Network's PesticideInfo website.[2]

As part of my work for PRI, I have conducted environmental monitoring of air, water, plants, and beehive matrices, using the data to better understand the fate and transport of pesticides and their potential for effects on human health and the environment. Working with Friends of the Earth, PRI developed and implemented a multi-year sampling and analysis plan for assessing the distribution of neonicotinoid residues in bee-attractive ornamental plants sold at big box stores around the U.S.[6]

I have also worked with governments, the US Forest Service, and non-profit organizations to develop quantitative risk assessments on the potential impacts of pesticides on human and environmental receptors, in particular herbicide risk assessments for the Marin Municipal Water District, the University of California, San Francisco, and the California Invasive Plant Council.

I have used pesticide data to predict and describe fate and transport of these chemicals in the environment and to model their expected impacts. A recent example of this type of work is described in my 2019 publication entitled *An assessment of acute insecticide toxicity loading (AITL) of chemical pesticides used on agricultural land in the United States*, in which pesticide use, physical properties and toxicity data are used to assess potential for pesticide exposure and risk for insects in agricultural landscapes.[7]

Since 2010, I have been working on the assessment of potential effects of pesticides on pollinators, especially honey bees that may contact pesticide residues through their use in commercial pollination. In 2014, I worked with commercial beekeepers to conduct a longitudinal hive tracking project to measure the potential impacts on colony health of pesticide residues in hive matrices, as well as honey bee pathogens and pests. One paper has been published on this work[8] and another is in preparation for submission. I served on US EPA's Pesticide Program Dialog Committee for seven years, and was a member of the US EPA Pollinator Protection Workgroup from 2012–2014. I have been a beekeeper since 2010 and currently maintain approximately 10 colonies of honey bees. Beekeeping experience and collaboration with commercial beekeepers allow me to accurately assess the utility and credibility of various studies on pesticide impacts on pollinators published in both the regulatory and scientific literature.

Please see my CV for a complete listing of publications and prior work.[9]

Sulfoxaflor Registration

I have reviewed DPR's proposed decision to register sulfoxaflor-containing products, as well as US EPA risk assessments regarding sulfoxaflor.[10] I have also studied the peer-reviewed literature on sulfoxaflor, researching mode of action, toxicity to insects in general and honey bees in particular, pesticide use patterns that allow prediction of exposure potential for pollinators based on environmental fate and proposed uses, and the potential for synergistic combinations with other chemicals.

The 2013 challenge to the federal registration of sulfoxaflor and the court decision to vacate this registration highlighted some of the potential problems with registering yet another pesticide with a mode of action (MoA) as a nicotinic acetylcholine receptor (nAChR) agonist, in IRAC Group 4, the same as the neonicotinoids. In particular, the data were non-existent or inadequate to support registration by US EPA. In 2015, the court agreed, and the registration was vacated. US EPA required Corteva Agriscience to submit additional studies to support the registration.

In the interim period, US EPA approved Section 18 emergency uses of sulfoxaflor and even re-registered the pesticide, albeit with restrictions, including a prohibition on use on blooming crops, a requirement of buffer zones near field edges, and limitations on tank mixes. On July 12, 2019, US EPA unconditionally registered sulfoxaflor, removing all restrictions intended to protect pollinators, citing new studies submitted by the registrant.

In my opinion, the newly provided studies are not sufficiently robust to be able to draw the conclusion that no adverse effects will result from use of sulfoxaflor. In fact, the risk assessment data and the peer-

reviewed literature both suggest that adverse effects on pollinators and aquatic insects are highly probable and likely to be cumulative with similar effects caused by neonicotinoid insecticides.

Sulfoxaflor Mode of Action is Sufficiently Similar to Neonicotinoids to Require a Cumulative Impact Assessment

Sulfoxaflor and a variety of other sulfoximine analogs were first patented in 2005 by Dow AgroSciences (now Corteva Agriscience).[11] When Dow AgroSciences first published their work on the mode of action of sulfoxaflor, they made a strong case that this chemical was a new member of the neonicotinoid class of pesticides.[12] The mechanism of action of sulfoxaflor involves the pesticide (an agonist) binding to the nicotinic acetylcholine receptor (nAChR), the same mechanism of action as the neonicotinoids. This binding stabilizes ion channels in the cell membrane in the open state, allowing influx of cations important in nerve impulse transmission and permitting continuous firing of the nerve cell, causing insect death. Cutler describes the symptoms of insect exposure to sulfoxaflor as follows:

> "To further compare sulfoxaflor with neonicotinoids, the effects *in situ* on the exposed aphid nervous system were examined. Sufloxaflor produced a rapid blockade of spontaneous neuronal activity, similar to the blockade produced by both nitenpyram and imidacloprid."

The precise relationship of nAChR receptor binding strength to insecticidal efficacy has been explored at some length and has revealed differences between each neonicotinoid and sulfoxaflor.[13, 14, 15] These differences have been used to justify classification of sulfoxaflor as having a different mode of action from the other neonicotinoids. Work by Watson *et al.* provided data on the relationship between insecticide binding constants to the nAChR receptor protein relative to imidacloprid (K_i) to the toxicity of the chemical to the green peach aphid (GPA), as LC_{90} values (see Table 1 in Reference 13, reproduced below).

Table 1
Comparative GPA toxicity, maximal nAChR currents and [^{3}H]IMI binding data for sulfoxaflor and a set of neonicotinoids.

Compound	GPA Toxicity[a]	I_{max} (% ACh Response)[b]		[^{3}H]IMI Binding	
	LC_{90} (ppm)	Dα2β2	Dα1β2	K_i (nM)[c]	n_H[d]
Sulfoxaflor	0.19 (0.11–0.35)[e]	348 ± 48	27.9 ± 4.7	265 ± 49	0.9
Imidacloprid	0.24 (0.17–0.36)[e]	32.8 ± 2.0	13.2 ± 4.0	5.1 ± 0.7	1.1
Clothianidin	1.2 (0.6–2.3)	273 ± 49	19.3 ± 1.4	24.2 ± 2.3	0.8
Acetamiprid	0.35 (0.2–0.7)[e]	20.5 ± 2.3	11.5 ± 1.5	19.2 ± 5.7	0.9
Thiacloprid	2.8 (1.7–4.7)	12.2 ± 1.3	4.0 ± 0.6	5.4 ± 1.4	1.2
Dinotefuran	6.8 (2.9–29.3)[e]	26.5 ± 4.4	8.6 ± 2.6	2223 ± 712	1.2
Nitenpyram	8.2 (2.5–60)	47.2 ± 3.1	23.4 ± 4.0	7.3 ± 2.8	0.8

[a] LC_{90} value (with 95% fiducial limits).
[b] Mean current induced by 100 μM of each compound expressed as % of an initial response to 100 μM ACh (±S.E.M., $n \geq 4$ replicates per value except nitenpyram on Dα1/β2 where $n = 3$).
[c] Apparent inhibition constants (K_i's) are expressed as mean ± S.E.M. ($n \geq 3$ independent experiments for each value).
[d] Hill slope (n_H) is the mean for each compound.
[e] From Babcock et al., 2011.

The authors state:

> "The high agonist efficacy but relatively weak binding affinity for sulfoxaflor in the systems examined suggests differences between how sulfoxaflor and the current commercial neonicotinoids interact with nAChRs. Given the novel structural elements of sulfoxaflor (CF_3-pyridyl, sulfoximine moiety), a unique interaction at nAChRs from the neonicotinoids might be expected. Clearly, factors in addition to affinity for the IMI binding site contribute to the potent insecticidal activity of sulfoxaflor."

However, sulfoxaflor is not unique in this regard. Comparisons between the individual commercial neonicotinoids indicate differences between them as well. The authors of Reference 13 display a plot of toxicity (as Log GPA LC_{90}) *vs* binding strength (Log K_i), comparing different sulfoximines with different substituents, showing sulfoxaflor being quite different than other sulfoximines (see Figure 8 from Reference 8, reproduced below).

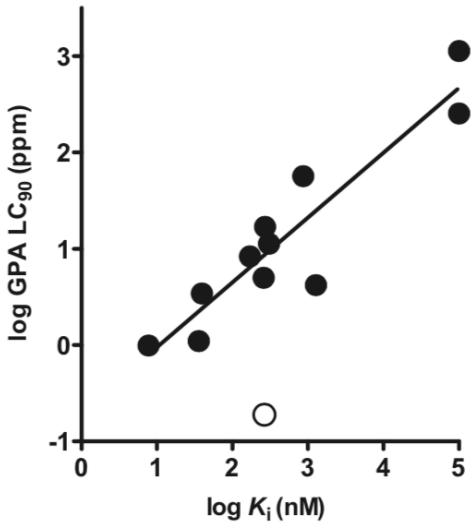

Fig. 8. Correlation of GPA toxicity (LC_{90}) and apparent K_i values for the set of sulfoximines in Table 2. The correlation coefficients (r^2) were 0.68 for all of the compounds ($n = 12$) and 0.85 when sulfoxaflor (○) was excluded ($n = 11$). The regression line shown was fitted excluding sulfoxaflor.

I used the data in Table 1 of Reference 13 to produce a similar plot for the neonicotinoid insecticides, including sulfoxaflor (see Figure 1).

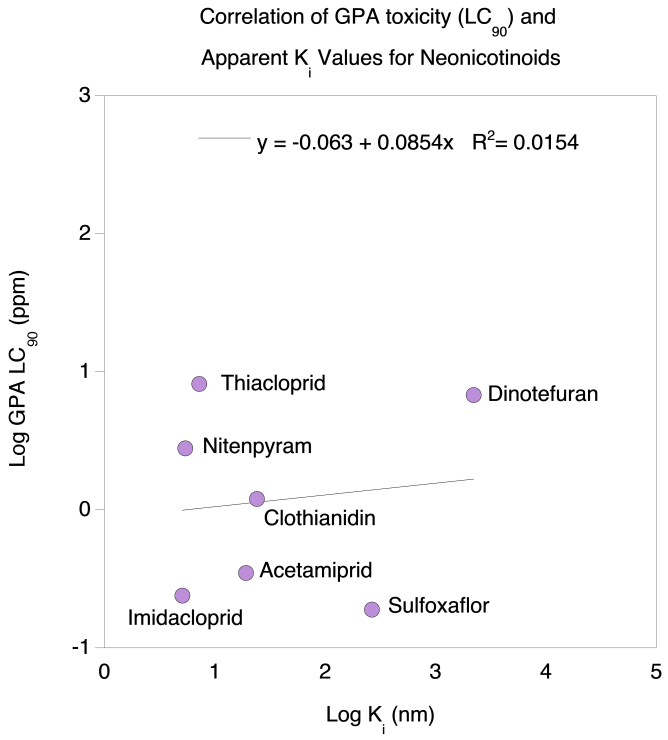

Figure 1: A correlation plot of the toxicity of selected pesticides to green peach aphid (GPA) vs binding ability to the nAChR receptor shows no correlations for either the commercial neonicotinoids or sulfoxaflor.

As is evident from Figure 1, there is no correlation between Log(LC_{90}) values and Log(K_i) values for the existing commercial neonicotinoids, meaning that there is no correlation between strength of binding to the nAChR receptor and toxicity for pesticides currently classified as neonicotinoids. Thus, while the specific details of binding as related to toxicity are not identical between sulfoxaflor and imidacloprid, neither are they identical between imidacloprid and clopyralid or between dinotefuran and acetamiprid or any other neonicotinoid. Yet the neonicotinoid classification is applied similarly to imidacloprid, clopyralid, dinotefuran, thiamethoxam, thiacloprid, and acetamiprid. The proposed separation of sulfoxaflor into its own class by mechanism of action is a false dichotomy. Indeed, comparison of Figure 1 to Figure 8 from Reference 13 indicates that sulfoxaflor is much more comparable to the other neonicotinoids than to other sulfoximines. In addition, like the other neonicotinoids, sulfoxaflor causes identical symptoms of neurological poisoning as a result of interference with ion transport across cell membranes mediated by the nAChR receptor.

Recent work by Ulens *et al.* using a modified acetylcholine binding protein (AChBP), demonstrated that the sulfoxaflor molecule binds through receptor interactions that are "virtually identical" to neonicotinoids, indicating that the commercialized neonicotinoids and sulfoxaflor share a common mechanism of action.[16]

Degradation pathways between sulfoxaflor and the other neonicotinoids do appear to be substantially different, which would affect resistance.[15, 17] But mode of insecticidal action and the mechanism by which insects develop resistance are two different, and in this case, unrelated, characteristics of a pesticide.

In my opinion, the available data indicate that sulfoxaflor is sufficiently similar to the neonicotinoids in its mode of action to be grouped with them and classified as a neonicotinoid. The hazards associated with

their use must be assessed as a group to ensure that cumulative impacts are accounted for, as CEQA requires.

Current Exposure to nAChR-Agonist Insecticides in California is Extensive

Since the registration of the first neonicotinoid in the U.S. in 1994, use of these pesticides has increased over time, with neonicotinoids now among the highest use insecticides in the U.S.[18] In California, where use data exist, the number of acres treated and pounds used have steadily increased over the years. In 2016, over three million acres were treated with neonicotinoids, with nearly 800,000 pounds released to the environment (see Figure 2).[19] In 2016, imidacloprid alone was the 3rd highest use insecticide in California in terms of acres treated.

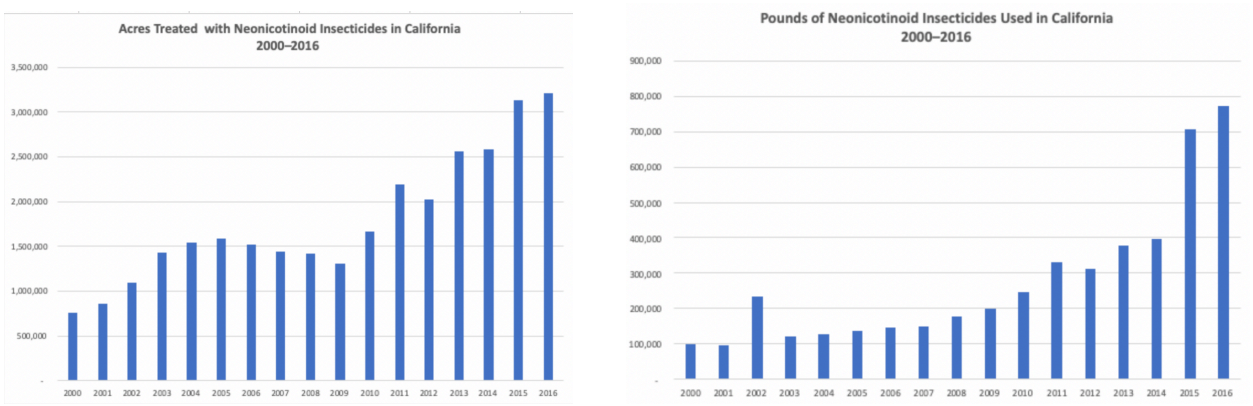

Figure 2: Neonicotinoid use in California has increased substantially over time, in terms of acres treated and pounds applied.

DPR is currently re-evaluating the neonicotinoids based on its own 2009 assessment of the potential for significant adverse effects on pollinators. Since 2009, the number of acres treated with neonicotinoids has more than doubled, and pounds applied has increased by a factor of 3.9. Introduction of sulfoxaflor, yet another neonicotinoid insecticide with low cross-resistance with others in the same class, will result in even more acres treated and pounds applied. The similarity of sulfoxaflor to the neonicotinoids indicates that potential for significant adverse effects on pollinators will increase unless DPR takes steps to reduce use or change use patterns and restrictions for this class of chemicals.

Assessment of Beneficial Insect Exposure Through Surface Water and Guttation is Missing

Exposure through drinking water and guttation water was not assessed by US EPA or DPR, but has the potential to be a major exposure pathway for pollinators and other beneficial insects. In 2015, neonicotinoids were reported to be found in 63% of 48 streams sampled waters across the U.S.[20] which are used by pollinators as a source of drinking water.[21] Sulfoxaflor's long half-life in water and high water solubility indicate potential for toxic runoff to surface waters. A comprehensive risk assessment should include pollinator exposures through surface waters.

Concentrations of other neonicotinoids in guttation water have been measured at very high levels, much higher than that observed in pollen and nectar, yet both EPA and DPR risk assessments do not account for this exposure route. For example, Hoffmann *et al* measured imidacloprid in guttation water from cantaloupe plants at up to 37,000 ppb, up to 10 times the LC_{50} for sensitive insect species.[22] Girolami, *et al.* demonstrated that leaf guttation drops of corn plants germinated from neonicotinoid-coated seeds contained amounts of insecticide consistently higher than 10,000 ppb, with maxima up to 100,000 ppb for thiamethoxam and clothianidin, and up to 200,000 ppb for imidacloprid. These concentrations are close to those in applied sprays and are rapidly lethal to bees.[23] There have been no comparable studies for sulfoxaflor, but because sulfoxaflor is highly water soluble and is readily taken up through the roots of

plants into the xylem, it will be expressed in the guttation water. This exposure pathway was not taken into account in US EPA's risk assessment, and remains as a data gap for the California registration.

Data Gaps Exist for Sublethal Effects of Sulfoxaflor on Beneficial Insects

Sulfoxaflor has high acute toxicity to honey bees, as indicated by the contact LD_{50} of 0.379 µg/bee for technical grade active ingredient (TGAI) and between 0.130 and 0.224 µg/bee for the formulated products. The oral LD_{50} of the TGAI is 0.146 µg/bee, and for the formulated product 0.0515 µg/bee.

Sulfoxaflor also has adverse impacts on honey bee brood maturation, noted in the US EPA risk assessment, with a dose of 2.0 µg a.i./bee resulting in 0% of brood surviving and a dose of 0.2 µg a.i./bee resulting in 35% of brood surviving, and a dose of 0.2 µg a.i./bee resulting in a survival rate of 46.7%.[24]

Similarly, in the peer-reviewed literature, Siviter noted adverse effects of sulfoxaflor on bumblebee reproduction.[25, 26] The study showed that chronic exposure of bumblebees to sulfoxaflor at realistic field concentrations resulted in fewer male workers and a 54% reduction in the number of offspring compared to an unexposed control. He *et al.* found that pupation, adult emergence, and egg counts of the predatory Asian lady beetle, *Harmonia axyridis*, were reduced after sulfoxaflor treatments.[27] Jian *et al.* found adverse impacts of sulfoxaflor on *Trichogramma* parasitoid wasps at sublethal concentrations in sulfoxaflor-treated host eggs, with adult emergence compromised at doses more than 30 times lower than typical field application rates.[28] These studies all provide evidence that sulfoxaflor interferes in insect reproduction, similar to a result observed for thiamethoxam.[29]

The Tier 2 studies described in the EPA risk assessment do not provide credible data on sublethal effects, either because colony health was not assessed over a sufficiently long time period, or the study conditions were compromised by inadequate controls and/or flawed study design.

In sum, the available data on sublethal effects is insufficient for DPR to draw a conclusion that no adverse effects on beneficial insects will occur with the registration of sulfoxaflor. Existing data suggest that adverse effects are likely.

DPR Proposed Registration of Sulfoxaflor Threatens Commercial Beekeeping Operations, Native Pollinators, and Growers Dependent on Pollinators

Nationwide, pollinators are struggling. Over the last 10–15 years, commercial beekeepers have experienced extensive colony losses, both during the overwintering period, and in more recent years, during the summer as well[30] Beekeepers are currently mitigating these colony losses at significant cost in resources and staff time,[31] which strains the sustainability of commercial beekeeping operations in the U.S. The stresses experienced by honey bees affect not only managed bees and the beekeepers who rely on them for their livelihood, but also wild pollinators, and farmers that depend on pollinators for economically viable yields. The approval of sulfoxaflor for use in California will only increase toxic exposure potential for commercial honey bees, further damaging the commercial beekeeping industry and the agricultural operations it supports.

DPR is proposing to approve sulfoxaflor for use on almonds, pistachios, stonefruit crops, berries, and grapes—crops occupying close to three million acres of agricultural land in California. Nearly the entire U.S. bee supply spends several months foraging either on these crops directly or on blooming weeds or cover crops growing between the rows of trees or vines. Assuming growers adopt sulfoxaflor (and there is no reason to believe they will not, if it is approved), use of sulfoxaflor will increase over time. In conjunction with the high use in California of other neonicotinoids with a similar mechanism of action, the entire U.S. bee supply will likely suffer high cumulative exposure and subsequent adverse effects to this group of insecticides. DPR did not evaluate this cumulative exposure risk and therefore cannot conclude that no significant impacts will occur.

Data Presented by DPR are Insufficient for Registration

DPR's *Public Report in Support of Proposed Decision* to register sulfoxaflor does not provide sufficient information on the data DPR evaluated to reach the decision to approve registration. The public cannot evaluate information that is not included in the report. Supplemental information provided in response to requests suggests that there was a more substantive analysis, but it is not part of the decision document.

DPR Cannot Conclude That No Unreasonable Adverse Effects Will Occur

The information provided by DPR as the basis for the decision to register sulfoxaflor is not sufficient to draw a definitive conclusion that there will be no unreasonable adverse effects. To the contrary, information available from the US EPA, EU's EFSA, and Canada's PMRA risk assessments as well as the peer-reviewed literature suggests that sulfoxaflor is likely to be highly problematic for bees, with high acute toxicity and indications of reproductive toxicity for pollinators and other beneficial insects. In addition, there appears to be sufficient persistence of sulfoxaflor in water and plant tissue to allow pollinator exposures through drinking runoff or guttation water from treated areas and from ingestion of nectar and pollen from treated plants.

The label restrictions proposed by DPR include no applications during bloom, 12-foot buffer zones near areas with blooming weeds or wildflowers near field edges, and advisory language suggesting that applicators apply the products when bees are not likely to be flying (early or late in the day). The label does not prohibit tank mixing, which has been shown to amplify the toxicity[32] or enhance the persistence[33] of sulfoxaflor, nor does it protect surface waters used by pollinators as drinking water sources from contamination. The advisory language recommending early morning or late afternoon applications is unenforceable. The imposition of a 12-foot buffer zone is wholly inadequate to protect against spray drift, even for a non-volatile pesticide. As a contrary example, consider ARB/DPR monitoring of an application of bifenthrin (log (Vp) = -6.74, application rate 0.1 lbs/acre, wind speeds 3-6 mph) in 2001 that showed spray drift 76 feet from the field edge at measured concentrations of 270 ng/m^3.[34] In short, the label restrictions are unlikely to protect pollinators and other terrestrial or aquatic insects.

Less Toxic Alternatives Are Available

DPR only considered the options of approval, approval with restrictions, or denial of registration. EPA's risk assessment only considered other toxic alternatives, with the decision document comparing sulfoxaflor with some of the most toxic pesticides on the market. However, there are other alternatives to registering a new neonicotinoid insecticide besides those explored. Numerous biopesticides and low-toxicity inorganic insecticides are commercially available, with most having a reduced risk profile compared to sulfoxaflor. Non-toxic cultural methods used for insect control in organic production systems are also available and include preservation of beneficial insect populations by providing habitat, controlling pest populations by timing planting to minimize pest pressure, intercropping to prevent pests from getting a foothold, and avoiding the use of toxic insecticides that will kill beneficial organisms. None of these alternatives were explored by DPR.

Sincerely,

Susan E. Kegley, PhD
Principal and CEO

CDPR Registration.Comments

From: susan bartow <sznb58@gmail.com>
Sent: Tuesday, December 31, 2019 1:01 PM
To: CDPR Registration.Comments
Subject: possible registration of sulfoxaflor

Categories: Negative Letter

EXTERNAL:

Dear Pesticide Registration Branch, Department of Pesticide Regulation,

I teach 11 and 12-year-old children simple basics of planting seeds and growing food. My students sometimes keep counts of the bees that visit our plants. Even at their young age, they understand the importance of bees to the food supply. What is harder, I think, for a very young person to grasp, is the potential of a chain reaction effect upon all who will suffer from the use of a pesticide such as sulfoxaflor, whether they be the pollinators of our food supply or the mammals, such as the bats, whose pups have been shown to have muscle contractions to exposure in utero so strong as to bend their bones even before they are born. These children I teach will have to live with the decisions that we make today.

I do not know how to explain to 11 and 12-year-old children that in California it may become ok to use of a pesticide that the EPA's own tests have shown significantly reduce larval emergence and survival rates for individual bees that were exposed to little bits of this pesticide at a time. That is what would happen to bees as they foraged about and did the work of pollinating our food. How do I explain to these children that in July of 2019, the EPA waived the more usual process of field testing for Dow Dupont? I am hoping that in California, we can do better. That is why, as a teacher of over 30 years in the state of California, with its rich agricultural heritage, I am writing to you today to voice my tremendous concern about the possible use of sulfoxaflor on the crops in California. I am concerned that this pesticide will have the same disastrous effects on the already declining populations of bees and other pollinators that the first generation of neonicotinoid pesticides have had.

The EPA's testing has clearly shown the toxicity of sulfoxaflor to the already declining honeybee population. The many, many , species of native California bees that inhabit the soil would likely be adversely affected as well as this pesticide is deposited in the soil.

But also to be considered are the parasitic wasps that are effective biocontrol agents of many pests. For example, a study published in *Biological Control* in July 2019 showed negative impacts on the parasitism ability of the Trichogramma species, as well as progeny emergence. Similarly, sulfoxaflor has been shown to have harmful effects on lady bugs, a predator of the aphids sulfoxaflor is used to kill. So, it would appear to me that managing pests with sulfoxaflor limits the effectiveness of important biological controls.

The EPA has determined sulfoxaflor to have what they call "suggested evidence for carcinogenic potential" based upon tumor frequency studies. This is the pesticide that would end up in California waterways if it is approved for use, and since it doesn't break down quickly in water, it seems to me this toxic chemical could build up in our waterways.

Each day when I go to work, I will look into the eyes of children who will inherit the consequences of the decisions made today. Decisions that will affect their food security and the viability of the water that they share with all of the magnificent creatures that live in California. I hope that for the children, for the agricultural economy, for the waterways, and for all of the pollinators and predators and magnificent creatures large and tiny, that in California, a model will be set that makes reasonable interpretation of scientific studies and sets a model for the rest of the nation.

Please do not register sulfoxaflor for use in California.

Respectfully submitted,
Susan Bartow, Middle School Science Teacher, Pasadena, CA

In case you are interested in reading just a bit of the information I read, I will provide you with some reference information here.

EPA-HQ-OPP-2010-0889-0565.pdf *July 2019 letter from EPA waiving field testing for Dow Dupont*

EPA-HQ-OPP-2010-0889-0011.pdf page 29 of 176. *EPA Carcinogenic rating for sulfoxaflor*
Also p 18 and 91-92 for information about bats/mammals.

https://www.journals.elsevier.com/biological-control *Biological Control volume 134 July 2019.*
Study of parasitic wasps.

https://shareok.org/bitstream/handle/11244/33448/Robideau_okstate_0664M_13744.pdf?sequence=1 *Master's thesis Oklahoma State University regarding the harmful effects of sulfoxaflor on lady bugs.*

CDPR Registration.Comments

From: SALLY BARTOW <sallybartow@comcast.net>
Sent: Tuesday, December 31, 2019 1:20 PM
To: CDPR Registration.Comments
Subject: vote NO on pesticides!

Categories: Negative Letter

EXTERNAL:

Dear Sir and Madam,

Please encourage all the legislators to vote NO on registering sulfoxaflor in CA. Our Earth is already struggling to sustain us, so why register a pesticide that would harm insects? We need insects to maintain a steady food supply. We also need a healthy water supply, and there is insufficient proof that sulfoxaflor is reliably safe for the water supply.

Please, think short and long term; protect us now and in the future by prohibiting sulfoxaflor in California.

Thank you,
Sally Bartow

1716 North Dillon St
Los Angeles, CA 90026

CDPR Registration.Comments

From: Kathryn Wild <Kathryn.Wild.15291958@p2a.co>
Sent: Sunday, December 29, 2019 6:51 AM
To: CDPR Registration.Comments
Subject: Comments on proposed decision to register pesticides products containing sulfoxaflor

Categories: Negative Letter

EXTERNAL:

Dear California Department of Pesticide Regulation,

I have a lovely garden in San Diego and 2 yrs ago we had very close to a thousand blossoms on our peach and plum trees. But, NO BEES that year. Consequently, we ended up with only a dozen peaches and 4 plums out of nearly 1000 blossoms. We have since planted year round flowering native plants In order to help balance our local bee population. We need bees!

I am writing to urge the California Department of Pesticide Regulation NOT to register sulfoxaflor for use in California.

Regards,
Kathryn Wild
7275 Canyon Breeze Rd
San Diego, CA 92126

CDPR Registration.Comments

From: Eric Dynamic <Eric.Dynamic.107838508@p2a.co>
Sent: Monday, December 23, 2019 10:27 PM
To: CDPR Registration.Comments
Subject: Comments on proposed decision to register pesticides products containing sulfoxaflor

Categories: Negative Letter

EXTERNAL:

Dear California Department of Pesticide Regulation,

The California Department of Pesticide Regulation should not register sulfoxaflor for use in California. It is a neonicotinoid and harmful to bees, which are threatened. The California Department of Pesticide Regulation should not need to be reminded of this in the first place and the public should not need to petition for the rejection of this substance. That should have been automatic.

Regards,
Eric Dynamic
1833 berkeley way
Berkeley, CA 94703

CDPR Registration.Comments

From: Mary Schmidt <Mary.Schmidt.46336576@p2a.co>
Sent: Friday, December 20, 2019 2:56 PM
To: CDPR Registration.Comments
Subject: Comments on proposed decision to register pesticides products containing sulfoxaflor

EXTERNAL:

Dear California Department of Pesticide Regulation,

Hi, my name is Mary and I live in San Francisco. I am writing to urge the California Department of Pesticide Regulation not to register sulfoxaflor for use in California.

Honey bees and other pollinators are facing many challenges, and pesticide exposure is at the top of the list. There is now overwhelming scientific evidence that widespread use of insecticides — including sulfoxaflor and similar neonicotinoids — are a key factor in bee decline.

According to the 9th U.S. Circuit Court of Appeals' landmark opinion in Pollinator Stewardship Council v. U.S. Envt'l Prot. Agency, 806 F.3d 520, 523 (9th Cir. 2015):

Neonicotinoids, including sulfoxaflor, are "systemic" insecticides, which means that they are sprayed onto plants, which then absorb the chemicals and distribute them throughout the plant, into the tissues, pollen, and nectar. Sulfoxaflor and other systemic insecticides therefore kill insects in two different ways: insects die when they come into contact with the pesticide, as when they are sprayed with it, and also when they ingest the plant which has absorbed the pesticide.

There is ample scientific evidence that exposure to miniscule amounts of sulfoxaflor can impair bees' brain functions and suppress their immune systems, making them more susceptible to diseases, pests, and other stressors.

The department's proposal to register sulfoxaflor for the first time in California follows the worst year on record for honey bees. According to the most recent survey of winter honey bee loses:

Beekeepers across the United States lost 40.7 percent of their honey bee colonies from April 2018 to April 2019, according to preliminary results of the latest annual nationwide survey conducted by the University of Maryland-led nonprofit Bee Informed Partnership. The survey results indicate winter losses of 37.7 percent, which is the highest winter loss reported since the survey began 13 years ago and 8.9 percentage points higher than the survey average.

See Science Daily, July 19, 2019, https://www.sciencedaily.com/releases/2019/06/190619142532.htm.

DPR's proposed decision to allow use of sulfoxaflor in California poses a direct threat to sustainable agriculture of healthy food in California. I urge DPR to withdraw its proposed decision, follow the science, and decline to register sulfoxaflor.

Regards,

Mary Schmidt
134 8th Ave
San Francisco, CA 94118

CDPR Registration.Comments

From: C. Leavell <C.Leavell.40985761@p2a.co>
Sent: Sunday, December 29, 2019 2:04 PM
To: CDPR Registration.Comments
Subject: Comments on proposed decision to register pesticides products containing sulfoxaflor

Categories: Negative Letter

EXTERNAL:

Dear California Department of Pesticide Regulation,

My name is Chuck and I live in Anaheim CA. I am writing to urge the California Department of Pesticide Regulation not to register sulfoxaflor for use in California. This chemical acts on the insects nervous system which functions exactly the same our nervous system. So if it kills an insect attacking a food product it will also have a negative affect on our nerves. How do you spray this on an infected field to kill unwanted pest and not have it drift into the surrounding ecosystem? or water supply, or ground water, or air one is breathing? This chemical is especially dangerous for children both the living and those in utero. We do NOT need this to be allowed to be sprayed nor coated on seeds in California. Please don't let it be sold or used here!

Honey bees and other pollinators are facing many challenges, and pesticide exposure is at the top of the list. There is now overwhelming scientific evidence that widespread use of insecticides — including sulfoxaflor and similar neonicotinoids — are a key factor in bee decline.

Regards,
C. Leavell
2788 E Verde Ave
Anaheim, CA 92806

Duran, Amy@CDPR

From: leslie colyer <leslieatlan@msn.com>
Sent: Sunday, December 29, 2019 10:52 AM
To: CDPR PRECComments@CDPR
Subject: Pesticides

EXTERNAL:

One in every three bites of food depends on bees for pollination. From cherries to almonds to blueberries, bees and other pollinators are essential for our diets; and for growers, bees are important for business.

However, earlier this month, the California Department of Pesticide Regulation proposed approving the powerful bee-killing pesticide sulfoxaflor for use in the Golden State.

Scientists have long said that pesticides like sulfoxaflor are causing unprecedented colony collapse. Described as a "next-generation neonicotinoid," sulfoxaflor is toxic to bees and other pollinators, and its approval poses a direct threat to California's agricultural economy.

At a time when honey bees and other pollinators are dying in greater numbers than ever before, introducing this bee-killing pesticide for general use in California is the wrong move.

Thank you.

Leslie Colyer
San Rafael, CA

COMMENT PERIOD ENDS JUNE 28, 2020

NOTICE OF FINAL DECISIONS TO DENY PESTICIDE PRODUCTS

Pursuant to Title 3, California Code of Regulations section 6255, the Director of the Department of Pesticide Regulation (DPR) files this Notice of Final Decisions to Deny Pesticide Products with the Secretary of the Resources Agency for posting. Unless specified, the reason for denial is that the required data was not submitted, was determined to be inadequate, or there was a likelihood of a significant adverse environmental effect anticipated from the use of these products in a manner consistent with its label. This action will not have a significant adverse impact on the environment. This notice must remain posted for a period of 30 days for public inspection. For information about submitting a request for any documents related to this notice, please visit https://www.cdpr.ca.gov/public_r.htm.

Tracking Number – (EPA Registration Number)
Applicant
Brand Name

294059 - (1677 - 237)
ECOLAB INC.
OXYCIDE DAILY DISINFECTANT CLEANER
USE: DISINFECTANT, VIRUCIDE - FOR THE CONTROL OF ORGANISMS SUCH AS STAPHYLOCOCCUS AUREUS, SALMONELLA ENTERICA, AND NOROVIRUS ON HARD, NON-POROUS SURFACES IN SITES SUCH AS HEALTHCARE FACILITIES, OFFICE BUILDINGS, RETAIL ESTABLISHMENTS, ACADEMIC FACILITIES, DIETARY AREAS, AND WHOLESALE ESTABLISHMENTS
TYPE: SECTION 3 LABEL AMENDMENT - TO REVISE THE MARKETING CLAIMS, FIRST AID SECTION, AND PRECAUTIONARY STATEMENTS; AND TO ADD A CLAIM FOR CANDIDA AURIS TO THE LABEL
ACTIVE INGREDIENT(S):
HYDROGEN PEROXIDE
PEROXYACETIC ACID
CAS NUMBER(S): 7722-84-1 , 79-21-0

290594 - (228 - 633)
NUFARM AMERICAS, INC.
LESCO SPECTATOR TURF AND ORNAMENTAL FUNGICIDE
USE: FUNGICIDE - FOR THE CONTROL OF DISEASES SUCH AS GRAY LEAFSPOT, DOLLAR SPOT, AND RUST ON CROPS SUCH AS TURFGRASSES, ORNAMENTALS, AND NON-BEARING FRUIT AND NUT TREES IN NURSERY AND LANDSCAPE PLANTINGS
TYPE: SECTION 3 REGISTRATION -
ACTIVE INGREDIENT(S):
PROPICONAZOLE
CAS NUMBER(S): 60207-90-1

268283* - (NO NUMBER ASSIGNED)
ISAGRO USA, INC
IRF135 EUP
USE: FUNGICIDE, HERBICIDE, INSECTICIDE, MOLLUSCICIDE, NEMATICIDE - FOR THE EPA-APPROVED EXPERIMENTAL USE PROGRAM, FOR THE CONTROL OF WEEDS, INSECTS, NEMATODES, AND FUNGI ON BAREGROUND, PRE-PLANT SOILS IN SITES SUCH AS TURFS, LAWNS, AND NURSERIES, INCLUDING FOREST TREE SEEDLINGS AND CONIFER TREES
TYPE: SECTION 5 EXPER. USE PERMIT -
ACTIVE INGREDIENT(S):
ALLYL ISOTHIOCYANATE
CAS NUMBER(S): 57-06-7
*Application for registration of tracking #268283 withdrawn at the request of the registrant

268282* - (NO NUMBER ASSIGNED)
ISAGRO USA, INC
IRF166 EUP
USE: FUNGICIDE, HERBICIDE, INSECTICIDE, MOLLUSCICIDE, NEMATICIDE - FOR THE EPA-APPROVED EXPERIMENTAL USE PROGRAM, FOR THE CONTROL OF WEEDS, INSECTS, NEMATODES, AND FUNGI ON BAREGROUND, PRE-PLANT SOILS IN SITES SUCH AS TURFS, LAWNS, AND NURSERIES, INCLUDING FOREST TREE SEEDLINGS AND CONIFER TREES
TYPE: SECTION 5 EXPER. USE PERMIT -
ACTIVE INGREDIENT(S):
ALLYL ISOTHIOCYANATE
CAS NUMBER(S): 57-06-7
*Application for registration of tracking #268282 withdrawn at the request of the registrant

274053* - (100 - 1608)
SYNGENTA CROP PROTECTION, LLC
PICATINA
USE: FUNGICIDE - FOR THE CONTROL OF DISEASES SUCH AS LATE BLIGHT, POWDERY MILDEW, AND BASAL ROT IN SITES SUCH AS ORNAMENTAL PLANTS, CHRISTMAS TREES, AND VEGETABLE PLANTS GROWN FOR RETAIL SALE
TYPE: SECTION 3 REGISTRATION -
ACTIVE INGREDIENT(S):
PYDIFLUMETOFEN
CAS NUMBER(S): 1228284-64-7
*Application for registration of tracking #274053 withdrawn at the request of the registrant

274059* - (100 - 1607)
SYNGENTA CROP PROTECTION, LLC
PICATINA GOLD
USE: FUNGICIDE - FOR THE CONTROL OF DISEASES SUCH AS LATE BLIGHT, POWDERY MILDEW, AND BASAL ROT IN SITES SUCH AS ORNAMENTAL PLANTS, CHRISTMAS TREES, AND CONTAINER GROWN PLANTS GROWN IN SHADE HOUSES
TYPE: SECTION 3 REGISTRATION -
ACTIVE INGREDIENT(S):
AZOXYSTROBIN
PROPICONAZOLE
PYDIFLUMETOFEN
CAS NUMBER(S): 131860-33-8 , 60207-90-1 , 1228284-64-7
*Application for registration of tracking #274059 withdrawn at the request of the registrant

Tulio Macedo

Tulio Macedo, Chief
Pesticide Registration Branch

05/29/2020
Dated