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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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MEMORANDUM

SUBJECT: **Spirodiclofen:** Environmental Fate and Effects Division's Response to Comments on the Proposed Interim Registration Review Decision

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The United States Department of Agriculture (USDA) and the Florida Fruit and Vegetable Association (FFVA) have submitted comments pertaining to the 2022 Proposed Interim Registration Review Decision for the miticide/insecticide spirodiclofen (PID; Docket Number EPA-HQ-OPP-2014-0262-0039). A summation of the comments and the responses to those comments by the Environmental Fate and Effects Division (EFED) are provided below.

Comments on the Proposed Interim Decision for Registration Review pertaining to the Drinking Water Assessment

1. **Comments:**

USDA Comment

"USDA appreciates EPA's implementation of a well setback to allow continued use of spirodiclofen while ensuring the protection of vulnerable drinking water wells. The need for a 75-foot setback is driven by the highest labeled use rate of 0.594 kg ai/ha on tree nuts and grapes. However, for crops with lower maximum use rates, USDA suggests that shorter well setbacks may be sufficient. As shown in the table below[1], for the uses on citrus (0.370 kg ai/ha), avocado (0.348 kg ai/ha), and pome and stone fruit (0.314 kg ai/ha), a 55-foot setback achieves the same estimated drinking water concentration as the 75-foot setback for tree nuts and grapes. We request, therefore, that well setbacks be differentiated on the label by use and that EPA consider requiring the smaller setback for uses on citrus, avocado, pome fruit and stone fruit. Because all of these labeled uses are perennial crops that are grown for many consecutive years, uncertainties based around annual rotation of fields between these crops would not be a concern."

FFVA Comment

"Drinking water exposure assessments have been an issue for many active ingredients and are often problematic aspects within the PID evaluation processes, and spirodiclofen is no exception in this regard. A proposed mitigation to the drinking water exposure issue includes a 75-foot setback from drinking water wells. It is our understanding that the registrant will be generating some additional data to support the continued registration of this product, and some of this new data should help further refine the spirodiclofen drinking water assessments. We therefore encourage the Agency to evaluate all such information before finalizing the risk assessment, particularly to the extent that new data may facilitate a partial solution to the drinking water safety findings. Additionally, it appears as though these spirodiclofen drinking water assessments for citrus and tropical fruit crops were calculated by incorporating maximum application rates into the modeling that are associated with other spirodiclofen-labeled crops. The outcomes of incorporating these overly high use rates into the modeling results in setback figures that are overexaggerated and excessive for crops such as citrus and tropical fruit that adhere to lower use rates. It would be scientifically appropriate for EPA to mitigate drinking water exposure risks by implementing a reduced, differentiated set of setback numbers, based directly on the application rates appearing on the label."

[1] The USDA provided a table of EDWCs associated with different uses and well setbacks. This table is not included here. EFED independently developed a similar table which is provided in the comments below.

EFED Response:

EFED appreciates the comments on the potential contribution of spirodiclofen residues in groundwater for crops with lower maximum application rates than the highest overall maximum application rate. USDA submitted calculations that well setbacks of 55 feet would adequately mitigate the drinking water cancer risk for citrus, avocado, and pome and stone fruits.

In the PID, the Agency proposed a 75-foot well setback for all spirodiclofen uses, based on a maximum application rate of 0.53 lb ai/A, which is the maximum application rate across all uses of spirodiclofen (allowable on tree nuts and grapes). With the subsurface degradation refinement, the overall maximum application rate, and a well setback distance of 75 feet, the cancer estimated drinking water concentration (EDWC) for tree nuts would be 10 ppb Total Toxic Residues (TTR). Under these conditions, potential cancer dietary risks based on food + water are not of concern.

Citrus, avocado, and pome and stone fruits have lower maximum application rates, and the Agency has confirmed that smaller well setback distances for those crops can adequately mitigate the dietary risks (i.e., result in EDWCs of 10 ppb or less). **Table 1** presents cancer EDWCs for the subject use sites and well setback distances, using the same assumptions and refinements as in USEPA (2022)[2].

Table 1. Spirodiclofen TTR Groundwater Cancer EDWCs (ppb) for Selected Use Scenarios and Well Setback Distances.

Use site	Max. Application Rate (kg ai/ha)	Max. Application Rate (lb ai/A)	Well Setback (ft)	Cancer EDWC (ppb)
Almond, pecan, walnut (tree nuts)	0.594	0.53	75	10.0
Citrus	0.370	0.33	55	10.0
Avocado	0.348	0.31	55	9.4
Pome & Stone Fruit	0.314	0.28	55	8.5

Estimates are based upon the Wisconsin central sands scenario, which yielded the highest EDWCs of the six standard groundwater exposure scenarios.
Assumptions: Velocity = 0.2 ft/day; Aquifer Degradation Rate = 0.0047/day.

As noted in the previous assessment, the current groundwater drinking water exposure estimation process is separate and distinctively different from the surface water exposure process. There are currently only six standard groundwater-specific scenarios which are primarily designed to be representative of areas of the United

[2] **Spirodiclofen:** Addendum to the Drinking Water Assessment for Registration Review" (DP Barcode D465064).

States with vulnerable groundwater supplies. Generally, all standard scenarios are run for a national scale pesticide assessment regardless of the specific uses of the pesticide. The six standard scenarios are not adequate to perform a full crop by crop analysis of exposure with a distribution of estimated exposures across multiples scenarios covering the portions of the United States where a particular crop may be grown. More information on the background and use of the groundwater scenarios is provided in USEPA (2015).[3]

Comments on the Proposed Interim Decision for Registration Review pertaining to the Pollinator Protection Language

1. **Comments:**

USDA Comment

"USDA suggests that EPA consider alternative language for pollinator protection on citrus crops, rather than imposing a ban on application from 'bloom until petal fall.'"

USDA suggested alternative language, based on existing labels for other chemicals:

- *"This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area."*

- *"Following best management practices can help reduce risk to terrestrial pollinators. Examples of best management practices include applying pesticides in the evening and at night when pollinators are not foraging and checking to confirm hive locations before spraying. For additional resources on pollinator best management practices, visit https://www.epa.gov/pollinator-protection/find-best-managementpractices-protect-pollinators."*

- *'Managed pollinator protection plans are developed by states/tribes to promote communication between growers, landowners, farmers, beekeepers, pesticide users, and other pest management professionals to reduce exposure of bees to pesticides. If available, visit state plans for additional information on how to protect pollinators."*

[3] USEPA. 2015. Standard Operating Procedure for Using PRZM-GW to Estimate Pesticide Concentrations in Groundwater for Drinking Water Exposure Assessments. United States Environmental Protection Agency Office of Pesticide Programs, Environmental Fate and Effects Division. Report dated 9/8/2015. Accessed on 8/15/2022 at: https://archive.epa.gov/epa/sites/production/files/2015-11/documents/attachment_2_-_sop_for_przm-gw.pdf.

FFVA Comment

"EPA has shown its forward-thinking capabilities in other PIDs by incorporating alternative language for pollinator protection instead of imposing specific use bans on application from bloom until the completion of petal fall. Label statements are sought that would allow citrus/tropical fruit grower discretion to treat in the late evening or early morning when pollinators are not actively foraging on the crop."

EFED Response:

The Environmental Hazards statement in the current label for spirodiclofen states: "This product is toxic to honeybee larvae through direct contamination of pollen and nectar. Do not apply to blooming, pollen-shedding, or nectar-producing parts of plants if bees forage on the plants." The Agency proposed more direct language (*i.e.*, limiting application until after petal fall) in the 2022 PID, that is consistent with the current hazard statement. EFED further notes that limiting application until after petal fall has already been implemented in the use directions for citrus (except lemon) in California.

EFED notes that spirodiclofen exposure poses a risk to individual honey bees on a chronic oral basis and at the colony level, based on a registrant-submitted semi-field tunnel study, as detailed in the most recent ecological assessment for registration review.[4] The colony level effects of spirodiclofen (e.g., brood development: ↓30% at Day 7, ↓29% at Day 12; colony strength: ↓33% at Day 27) were observed at concentrations approximately 25% (0.13 lb a.i./A) of the maximum registered application rate (0.53 lb a.i./A). The colonies from the tunnel study were likely exposed to spirodiclofen via multiple exposure routes, including direct contact, ingestion of contaminated pollen and nectar, and contact with treated foliage. However, the available data do not enable identification of which of these exposure routes is responsible for the observed colony-level impacts. If the observed colony-level effects largely resulted from oral exposure, as observed for individual bees in the Tier 1 laboratory studies, the label restrictions proposed by the commentors (*e.g.*, application in the evening) would not prevent contamination of pollen and nectar and the subsequent exposure of bees the following day, if applied to blooming crops. Conversely, if the observed colony-level impacts resulted from direct contact with spray droplets, limiting applications to evenings, when bees are less likely to be present, could reduce potential for colony-level risk.

Therefore, based on available data and the most recent risk assessments, limiting spirodiclofen applications until after petal fall is an effective way to decrease exposure and risks to bees. The potential impacts, to individual bees and bees at the colony level, of night-time applications or applications when foraging bees are not present cannot be accurately predicted with the available data. At this time, EFED presumes significant risks of individual and colony-level effects to bees when

[4] USEPA 2021. Spirodiclofen**:** Draft Ecological Risk Assessment for Registration Review. (DP Barcode: 463507)

spirodiclofen is applied to pollinator-attractive crops during bloom. Additional data, such as a tunnel study of applications made with and without bees actively foraging, may facilitate a pollinator risk assessment with a greater level of certainty.