



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON D.C., 20460

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OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

**MEMORANDUM**

**SUBJECT:** Review of Request for an Extension of the Exclusive Use Period for Flupyradifurone (DP#436711)

**FROM:** Kara Welch, M.S., Entomologist *K. Welch*  
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**THRU:** Monisha Kaul, Chief *Monisha Kaul*  
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**TO:** Meredith Laws, Chief  
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**PRODUCT REVIEW PANEL DATE:** November 1, 2017

**SUMMARY**

Bayer CropScience AG (2016) submitted a petition to EPA requesting that, under FIFRA Section 3(c)(1)(F)(ii), the exclusive use period for data supporting the insecticide active ingredient flupyradifurone be extended for three years. Supporting information was submitted for 22 crops that the registrant identified as distinct, minor uses. BEAD first established whether there was a one-for-one relationship between residue trial data and each distinct use. Of the 22 crops submitted by the registrant, avocado was submitted as an individual commodity and the other 21 were from the stone fruit crop group associated with three residue trials. Then, BEAD evaluated the available data on the number of acres of production for each of the crops to assess whether the crops meet the definition of minor use per FIFRA Section 2(l)(1) as well as the four criteria in FIFRA Section 3(c)(1)(F)(ii). Information supporting the four criteria were provided by the registrant for stone fruits but not for avocado. After review of the information submitted by the registrant, BEAD concluded that peach, plum, and sweet/tart cherry met the criteria for distinct, minor use sites based on a one-for-one relationship with residue trial data, less than 300,000 acres grown, and submission of information that supports finding that at least one statutory criterion was met. Therefore, the Bayer petition meets the criteria for a one-year extension of data exclusivity allowed by FIFRA as associated with three distinct, minor use sites.

## CHEMICAL BACKGROUND

Flupyradifurone was first registered by EPA on January 15, 2015, under the Reduced Risk Pesticide Program. Flupyradifurone is a systemic insecticide that controls sucking/piercing insect pests such as aphids, fleahoppers, and whiteflies in a wide range of crops as a foliar spray, soil drench, or seed treatment. Flupyradifurone is categorized as a Mode of Action 4 (nicotinic acetylcholine receptor competitive modulator) in Group D (butenolides) by the Insecticide Resistance Action Committee (IRAC).

## REGISTRANT SUBMISSION

The registrant claims that flupyradifurone satisfies criteria III and IV under Section 3(c)(1)(F)(ii) in FIFRA (described above) for the following 22 crops: sweet cherry, tart cherry, peach, apricot, nectarine, plum/prune, American plum, beach plum, Canada plum, cherry plum, Chickasaw plum, damson plum, Japanese plum, Klamath plum, plumcot, capulin, black cherry, nanking cherry, Chinese jujube, Japanese apricot, sloe, and avocado. However, BEAD's analysis supports only peach, plum, sweet/tart cherry for a maximum of a one-year extension of the exclusive use period.

## BACKGROUND

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides certain data protection rights to data submitters for their registered pesticides. Section 3(c)(1)(F)(i) states that the original data submitter has a 10-year exclusive use period from the date of registration for the data submitted in support of the original registration. The period of exclusive use may be extended one year for each three minor uses registered, up to a total of 3 additional years, if within 7 years of the commencement of the exclusive use period the registrant demonstrates that:

- (I) *there are insufficient efficacious alternative registered pesticides available for the use;*
- (II) *the alternatives to the minor use pesticide pose greater risks to the environment or human health;*
- (III) *the minor use pesticide plays or will play a significant part in managing pest resistance; or*
- (IV) *the minor use pesticides plays or will play a significant part in an integrated pest management program*

A minor use is defined in FIFRA Section 2(l) as the use of a pesticide on an animal, on a commercial agricultural crop or site, or the protection of public health where “(1) *the total U.S. acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture, or* (2) *the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use.*”

In the case of crop groupings, FIFRA 3(c)(1)(F)(ii) states that “*the registration of a pesticide for a minor use on a crop grouping . . . shall be considered for one minor use for each*

*representative crop for which data are provided.”* That is, the maximum number of eligible distinct minor uses for a crop group is equal to the number of representative crops for which residue data have been submitted. For instance, if residue data were submitted for oranges and grapefruit as representative crops for citrus, a crop group that contains several minor uses, the data would support two minor uses.

## IDENTIFYING USES FOR CONSIDERATION

FIFRA 3(c)(1)(F)(ii) states that *“the registration of a pesticide for a minor use on a crop grouping . . . shall be considered for one minor use for each representative crop for which data are provided.”* That is, the maximum number of eligible minor uses is equal to the number of representative crops for which residue data have been submitted. The 22 crops listed in the registrant submission are supported only by residue data submitted for the stone fruit crop group (12-12) on the representative crops, peach, plum, sweet/sour cherry, as well as avocado registered as an individual commodity.

More information on crop groups and representative commodities can be found in the Code of Federal Regulations Part 40 Section 180.41.

## MINOR USE

The USDA Census of Agriculture (USDA 2014) provides the data on crops grown in the United States. Crops not listed in the Census of Agriculture are presumed to be cultivated on fewer than 300,000 acres. For the four distinct use sites above, the total U.S. acreage for each crop is less than 300,000 acres (Table 1). Note, sweet and sour (tart) cherry are considered one representative commodity by Code of Federal Regulations Part 40 Section 180.41 and do not represent distinct use sites.

**Table 1.** Acreage of crops considered for extension of exclusive use for flupyradifurone

Crop	Acreage
Peach	128,480
Plum/prune	88,122
Sweet cherry	105,244
Tart cherry	49,785
Avocado	73,535

Source: USDA 2014

## SUPPORT TO QUALIFY FOR CRITERIA

*Requirements for Criterion III, Pesticide Plays a Significant Part in a Resistance Management Program.* BEAD considers that Criterion III has been met in situations where there is reliable information that the chemical being evaluated is used 1) to delay the development of pest resistance to other chemicals with different Modes of Action, or 2) where one or more of the target pests have already developed resistance in the U.S. to alternative chemicals.

*Requirements for Criterion IV, Pesticide Plays a Significant Part in an Integrated Pest Management Program.* Integrated Pest Management (IPM) is an important set of tactics for

growers to maintain the productivity of cropland while potentially reducing the overall input and environmental impact of pest management tools such as pesticides. Among other things, IPM strategies can help minimize the impact of pesticides on beneficial organisms (such as pollinating insects, predators, and parasites). BEAD would consider that Criterion IV had been met in situations where there was reliable information that flupyradifurone is a significant tool in managing target pests as a part of a larger IPM program that is intended to control a range of key pests in a crop.

## **ASSESSMENT OF CRITERIA**

The registrant only submitted data supporting the criteria outlined above for the stone fruit group. As there are no supporting data for avocado, BEAD concludes that avocado does not meet the biological criteria counting towards an extension of data exclusivity. BEAD examined information submitted by the registrant as well as other publicly available information, and descriptions of insecticide Modes of Action (MoA) available through the Insecticide Resistance Action Committee (IRAC), to evaluate whether flupyradifurone plays, or will play a significant part in managing pest resistance (criterion III) and/or if the minor use pesticide plays, or will play, a significant part in an integrated pest management program (criterion IV) for the stone fruit crop group.

### *Applicability of Criterion III to flupyradifurone*

The registrant claims flupyradifurone controls sucking pests, namely San Jose scale, on stone fruit and is a new mode of action contributing to strong insect resistance management strategies (Bayer 2016). San Jose scale is a key pest in nearly all fruit producing regions of the United States (Hoyt 1993). Flupyradifurone is the only insecticide in sub group 4D of butenolides belonging to the larger class of nicotinic acetylcholine receptor competitive modulators (IRAC 2017). Per Market Research Data (MRD), leading active ingredients targeting San Jose scale include chlorpyrifos, pyriproxyfen, and esfenvalerate across peaches, plums, and cherries combined (MRD 2011-2015). BEAD identified references for San Jose scale insecticide resistance to lime sulfur (APRD 2017) and organophosphates (Buzzetti et al. 2015). BEAD concludes that flupyradifurone represents a unique subgroup MoA available to growers for San Jose scale and confirmed that none of the grower-preferred insecticides are in the same class of chemistry.

### *Applicability of Criterion IV to flupyradifurone*

The registrant claimed flupyradifurone has minimal impact on beneficial insects such as ladybird beetles and predatory mites as well as low acute toxicity for pollinators (Bayer 2017). BEAD concurs with the registrant that flupyradifurone is known to be a soft chemistry for beneficial insects and pollinators, therefore it is a good fit for IPM programs (EPA 2017).



## CONCLUSION

BEAD determined that the registrant's request meets the data requirement, minor use designation, as well as both criteria III and IV for peach, plum/prune, and sweet/tart cherry crops.

## REFERENCES

Arthropod Pesticide Resistance Database (APRD). 2017. Insecticide Resistance Action Committee and Michigan State University. <https://www.pesticideresistance.org/> [Accessed August 2017]

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