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

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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Review of Bayer's Additional Request for an Extension of the Exclusive Use Period for Flupyradifurone (DP#444955)

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THRU: Monisha Kaul, Chief
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PRODUCT REVIEW PANEL DATE: February 14, 2018

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. In BEAD's prior memorandum, it was determined that Bayer's initial petition supported a one-year extension of data exclusivity, given registration for peach, plum, and sweet/tart cherry (Welch 2017).

In Bayer's second submission, supporting information was submitted for 21 crops. All 21 are associated with individual residue trials and meet the definition of minor use. It was determined that at least six of the 21 minor use sites satisfied the data exclusivity criteria as defined under FIFRA 3 (c)(1)(F)(ii). Therefore, in conjunction with the prior request, flupyradifurone is eligible for up the maximum 3-year extension of data exclusivity.

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(ll) 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 lemon and grapefruit as representative crops for citrus, a crop group that contains several minor uses, the data could support multiple minor uses, but a maximum of two uses could support a request for extension of exclusive use. Greenhouse uses are considered separate use sites from field crops in cases where distinct residue data for field-grown crops are submitted to support the registration. This petition includes greenhouse residue trials and these uses are considered distinct from field-grown crop sites.

Previously, Bayer received one year of data exclusivity for the peach, plum, and sweet/tart cherry use sites. Here, BEAD will evaluate whether at least six additional use sites submitted in Bayer's addendum package meet the statutory requirement for an extension of data exclusivity including: verifying residue trials were submitted on a one-for-one basis with use sites, minor crop acreage, and validating criteria I-IV.

REGISTRANT SUBMISSION

The registrant claims that flupyradifurone satisfies the FIFRA Section 3(c)(1)(F)(ii) requirements for an extension of data exclusivity for the following 21 use sites: avocado, pomegranate, cucumber, head lettuce, leaf lettuce, greenhouse pepper, greenhouse tomato, greenhouse cucumber, greenhouse lettuce, grapefruit, lemon, pear, muskmelon, broccoli, cabbage, cauliflower, summer squash, celery, spinach, carrot, and radish (Bayer 2017). The registrant claims all uses are associated with a residue trial, are grown on less than 300,000 acres, and are associated with criteria II and III. Bayer submitted information to qualify for criterion IV but

BEAD did not find this information sufficient and flupyradifurone was not eligible for the maximum extension of data exclusivity without further documentation.

CHEMICAL BACKGROUND

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). Previously, Bayer received one year of data exclusivity for the peach, plum, and sweet/tart cherry use sites.

IDENTIFYING USES FOR CONSIDERATION

Of the 21 crops listed in the registrant submission, all 21 are supported by residue data (Table 1). Therefore, Bayer may claim up to 21 minor use sites if all use sites are cultivated on fewer than 300,000 acres and criteria II and III are met.

MINOR USE ANALYSIS

The USDA Census of Agriculture (USDA 2014a) provides the data on crops grown in the United States. Information was supplemented for greenhouse crops with the USDA Census of Horticultural Specialties (USDA 2014b) where, in Table 1, square footage under protection was converted to acreage. For all sites below, the total U.S. acreage for each crop is less than 300,000 acres (Table 1). Acreage reported by Bayer (2017) may be different from BEAD's analysis because the registrant used USDA NASS information instead of the Census of Agriculture in some cases. See draft PRN on Determination of Minor Use, available at registration.gov, docket EPA-HQ-OPP-2015-0814 for a detailed explanation of appropriate sources for crop acres grown.

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

Crop Group	Residue Trial*	Acreage
Root and Tuber Vegetables (1)	Carrot	99,293
Root and Tuber Vegetables (1)	Radish	14,867
Leafy Vegetables (4)	Head Lettuce	154,968
Leafy Vegetables (4)	Leaf Lettuce	69,973
Leafy Vegetables (4-16A)	Lettuce (GH)**	10***
Leafy Vegetables (4)	Celery	32,577
Leafy Vegetables (4)	Spinach	46,377
Brassica Head and Stem Vegetable (5-16)	Broccoli	128,938
Brassica Head and Stem Vegetable (5-16)	Cabbage	66,035
Brassica Head and Stem Vegetable (5-16)	Cauliflower	42,081
Fruiting Vegetables (8-10B)	Pepper (GH)**	80***
Fruiting Vegetables (8-10A)	Tomato (GH)**	1,000***
Cucurbit Vegetables (9B)	Cucumber (GH)**	252
Cucurbit Vegetables (9)	Cucumber	111,900
Cucurbit Vegetables (9)	Summer Squash	58,486

Cucurbit Vegetables (9)	Muskmelon	71,911
Citrus Fruit (10-10)	Grapefruit	88,393
Citrus Fruit (10-10)	Lemon	62,324
Pome Fruit (11-10)	Pear	56,749
Tropical and Subtropical Fruit (24B)	Avocado	73,534
Tropical and Subtropical Fruit (24B)	Pomegranate	32,887

Source: USDA 2014a
* Residue trials were conducted for these representative crops
** GH, greenhouse
*** Converted from square footage listed in USDA 2014b

SUPPORT TO QUALIFY FOR CRITERIA

Requirements for Criterion II, Alternatives Pose Greater Risks to Environment or Human Health. If a pesticide was registered recently under reduced risk status, EPA presumes that the alternative pesticides pose greater risks than the active ingredient being considered for an extension of data exclusivity.

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.

ASSESSMENT OF CRITERIA

Applicability of Criterion II to flupyradifurone
Flupyradifurone received reduced risk status for citrus, cucurbit vegetables, fruiting vegetables, pome fruit in March 2013 (Bayer 2017). Additionally, reduced risk status for flupyradifurone was granted for the following use sites avocado and greenhouse vegetables in May 2016 (Bayer 2017). Because 2016 is within the two-year timeframe during which registrants can claim criterion II towards an extension of data exclusivity, BEAD determined that avocado and greenhouse vegetables (cucumber, lettuce, pepper, and tomato) represent five eligible minor use sites. However, the use sites that received reduced risk status in 2013 are considered to be out-of-date. This qualifies flupyradifurone for an additional year of data exclusivity.

Applicability of Criterion III to flupyradifurone
The registrant claims flupyradifurone is the only insecticide in IRAC subgroup 4D and contributes to a strong insect resistance management program for aphids and whiteflies that are pests of avocado, pomegranate, head lettuce, leaf lettuce, cucumber, cucumber (GH), lettuce (GH), pepper (GH), and tomato (GH) (Bayer 2017). BEAD verified flupyradifurone is the only butenolide (4D) insecticide (IRAC 2018). As a unique mode of action, flupyradifurone is an important rotation partner to delay the development of pesticide resistance. Because avocado and greenhouse vegetables were eligible for criterion II, these uses will not be considered again for criterion III which would result in a double counting for eligible use sites. Flupyradifurone is eligible for field-grown cucumber, pomegranate, head lettuce, and leaf lettuce, which, in addition

to the five crops that qualify under criterion II, flupyradifurone is eligible for a total of nine minor use sites between criteria II and III.

CONCLUSION

The registrant has provided sufficient information to support extension of exclusive use under FIFRA Section 3(c)(1)(F)(ii) for more than the six required use sites required to attain two additional years of data exclusivity in addition to their original submission which was eligible for a one-year extension. The addendum package summarized nine additional eligible use sites including: avocado, pomegranate, cucumber, head lettuce, leaf lettuce, greenhouse pepper, greenhouse tomato, greenhouse cucumber, and greenhouse lettuce.

REFERENCES

Bayer CropSciences. 2016. Amended Petition for a Three-Year Extension of Exclusive Use Data Protection for Flupyradifurone as Provided Under FIFRA Section 3(c)(1)(F)(ii). (50471501)

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