



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

January 14, 2021

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: A Review of BASF's Petition for Extension of Exclusive Use for Fluxapyroxad (PC: 138009) (DP#455808)

FROM: Jeana Hansel, Plant Pathologist
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TO: Shaja Joyner, Risk Manager
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Product Review Panel Date: December 30, 2020

SUMMARY

Baden Aniline and Soda Factory (BASF) (2019) has petitioned the Environmental Protection Agency (EPA or Agency) to request, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3(c)(1)(F)(ii), that the exclusive use period for data supporting the fungicide fluxapyroxad be extended for three years. BASF claims fluxapyroxad plays a significant part in resistance management and integrated pest management programs, criteria III and IV as defined under FIFRA 3 (c)(1)(F)(ii). BASF (2019) submitted supporting information for sixteen crops. All sixteen crops meet the acreage definition of a minor use, as each crop is grown on less than 300,000 acres nationally, and all sixteen crops are supported by individual residue trial data.

The Biological and Economic Analysis Division (BEAD) determined that at least nine of the sixteen petitioned minor use sites satisfy at least one of the criteria for extension of exclusive use. Fluxapyroxad satisfies criterion III for managing pest resistance in hazelnut, celery, head lettuce, leaf lettuce, spinach, carrot, and radish and satisfies criterion IV for value in integrated pest management programs in peach and sweet cherry.

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 pesticide plays or will play a significant part in an integrated pest management program.*

A minor use is defined in FIFRA Section 2(II) 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.” i.e., the maximum number of eligible distinct minor uses for a crop subgroup is equal to the number of representative crops for which residue data have been submitted. 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.

The Biological and Economic Analysis Division (BEAD) evaluates whether up to nine use sites submitted in BASF’s package met the statutory requirement for an extension of data exclusivity by verifying that each crop is individually associated with a residue trial, verifying minor crop acreage, and validating the claimed criteria.

REGISTRANT SUBMISSION

The registrant claims that fluxapyroxad satisfies the FIFRA Section 3(c)(1)(F)(ii) requirements

for the following 16 use sites: chili pepper, bell pepper, peach, sweet cherry, garden pea, snow pea, cauliflower, flax, safflower, hazelnut, celery, head lettuce, leaf lettuce, spinach, carrot, and radish (BASF 2019). The registrant claims all uses are individually associated with a residue trial, are grown on less than 300,000 acres, and that fluxapyroxad satisfies at least one of the criteria for extension of exclusive use.

BEAD ANALYSIS

BEAD first confirmed that residue trial data are sufficient such that there is a one-for-one relationship for each use site. Then, BEAD confirmed that each crop meets the definition of a minor crop per FIFRA Section 2(l)(1), wherein each crop must be grown on less than 300,000 acres in the U.S. Finally, BEAD evaluated the biological benefits submitted by the registrant to determine if the claimed criteria are met.

Residue Trial Analysis

Of the 16 crops listed in the registrant submission, all 16 are supported by residue data (Table 1). The registrant may claim up to 16 use sites if all are grown on less than 300,000 acres in the U.S. and if the claimed criteria are met.

Table 1. Proposed crops and representative residue data by crop subgroup.

Minor Use Claimed	Crop Group (Subgroup)	Crop Residue Data Submitted for Subgroup (Date; MRID)	Maximum Number of Use Sites Allowed
Chili Pepper	Fruiting Vegetables (8-10B)	Chili Pepper; Bell Pepper (2/24/2010; 47923664)	2
Bell Pepper			
Sweet Cherry	Stone Fruit (12-12A)	Sweet Cherry (2/22/2010; 47923662)	1
Peach	Stone Fruit (12-12B)	Peach (2/22/2010; 47923662)	1
Garden Pea	Legume Vegetables (6B)	Garden Pea (11/11/2009; 47923658)	1
Snow Pea	Legume Vegetables (6A)	Soybean (11/11/2009; 47923658)	1
Cauliflower	Brassica Leafy Vegetables (5A)	Broccoli (5/17/2012; 48812213)	1
Flax	Oilseed (20A)	Canola (2/25/2010; 47923659)	1
Safflower	Oilseed (20B)	Sunflower (2/25/2010; 47923659)	1
Hazelnut	Tree Nut (14-12)	Almond & Pecan (5/1/2012; 48812211)	1
Celery	Leafy Vegetables (4B)	Celery (6/15/2012; 48812219)	1
Head Lettuce	Leafy Vegetables (4A)	Head Lettuce; Leaf Lettuce; Spinach (6/15/2012; 48812219)	3
Leaf Lettuce			
Spinach			
Carrot	Root Vegetables (1B)	Carrot; Radish (2/7/2012; 48812208)	2
Radish			

Minor Use Analysis

EPA relies on the United States Department of Agriculture (USDA) Census of Agriculture for data on crops grown in the United States (EPA 2018, USDA 2017). For the minor use qualification, fruit and tree nut crops are evaluated for bearing acreage, and other crops are evaluated for harvested acreage. The registrant’s claimed acreage differs from acreage reported in the Census of Agriculture; this is due to the registrant’s use of different or older sources to determine acreage (BASF 2019). For each of the 16 sites listed in Table 1, the 2017 annual U.S. acreage is less than 300,000 acres, qualifying them as minor crops, and the registrant may claim up to 16 minor use sites for extension of exclusive use if criteria for extension of exclusive use are met.

Table 2. Acreage of crops and criteria considered for extension of exclusive use for fluxapyroxad.

Minor Use Site	Claimed Acreage ¹	Crop Acres Grown ²	Criteria Claimed
Bell Pepper	43,300	48,801	III, IV
Chili Pepper	18,900	24,165	III, IV
Sweet Cherry	91,700	93,866	III, IV
Peach	92,750	94,836	III, IV
Snow Peas	228,500 ³	10,598 ⁴	III, IV
Garden Peas		147,791 ⁵	III, IV
Cauliflower	38,000	50,331	III, IV
Flax	168,000	283,586	I
Safflower	167,500	144,027	I
Hazelnut	70,000	43,965	III, IV
Celery	29,300	36,587	I, III, IV
Head Lettuce	127,000	147,369	I, III, IV
Leaf Lettuce	60,000	74,399	I, III, IV
Spinach	42,000	69,969	I, III, IV
Carrot	76,000	96,443	I, III, IV
Radish	-- ⁶	14,328	I, III, IV

¹BASF 2019.

²USDA 2017.

³Registrant combined crop acreage (BASF 2019).

⁴Acres Harvested, Chinese Peas (Sugar & Snow)

⁵Acres Harvested, Green Peas (excl. Southern)

⁶“An accurate acreage assessment was not readily available.” (BASF 2019).

REQUIREMENTS TO QUALIFY FOR THE CLAIMED CRITERIA

Bayer has claimed that fluxapyroxad qualifies for criteria I, III, and/or IV for 16 minor crops. Here, BEAD reviews the claims for nine minor crops: hazelnut, celery, head lettuce, leaf lettuce, spinach, carrot, radish, peach, and sweet cherry, for the full 3-year extension of exclusive use.

Requirements for Criterion I, there are insufficient efficacious alternative registered pesticides for the use site. EPA considers Criterion I to be met in situations where the pesticide: 1) fills a void in the current program (e.g., unique timing window); 2) controls a broader spectrum of pests than currently registered alternatives; 3) controls a different life stage for the pest; or 4) provides a crucial timing advantage (e.g. shorter pre-harvest interval or re-entry interval).

Requirements for Criterion III, the minor use pesticide plays or will play a significant part in managing pest resistance. BEAD considers Criterion III to be met in situations where there is reliable information that the chemical being evaluated is used either to delay the development of pest resistance to other chemicals with different modes of action or where one or more of the target pests have already developed resistance in the U.S. to alternative chemicals.

Requirements for Criterion IV, the minor use pesticide plays or will play a significant part in an integrated pest management program. BEAD considers Criterion IV to be met in situations where there is reliable information that the chemical being evaluated is useful in managing target pests while having low-to-no impact on other aspects of integrated pest management (IPM), such as inclusion of non-chemical pest control strategies (e.g. biological control).

BEAD ASSESSMENT OF CLAIMED CRITERIA

Applicability of Criterion III to fluxapyroxad. The registrant claims that fluxapyroxad plays or will play a significant part in managing pest resistance in bell pepper, chili pepper, peach, sweet cherry, garden pea, snow pea, cauliflower, hazelnut, celery, head lettuce, leaf lettuce, spinach, carrot, and radish. BEAD considers this criterion to be met in hazelnut, celery, head lettuce, leaf lettuce, spinach, carrot, and radish and discusses below.

For hazelnut, the registrant claims that fluxapyroxad plays a role in managing fungicide resistance in Eastern Filbert Blight (EFB). The registrant supported these claims with references to the EFB help page maintained by Oregon State University, which explicitly recommends Merivon (pyraclostrobin plus fluxapyroxad) for management of EFB; furthermore, Oregon State University indicates that fluxapyroxad is the only Fungicide Resistance Action Committee (FRAC) group 7 fungicide that provides control of EFB (Pscheidt 2020). As fluxapyroxad is the only group 7 fungicide providing adequate control for EFB, it is a helpful tool for growers to include in fungicide rotations in order to reduce or delay the emergence and spread of fungicide resistant isolates of EFB (Pscheidt et al. 2017, Pscheidt et al. 2018). According to the FRAC, availability of different chemical modes of action is important to prevent or overcome resistance problems (Brent & Holloman 2007). BEAD concludes that fluxapyroxad, as the only known efficacious FRAC group 7 fungicide for EFB, has value in managing fungicide resistance in EFB in hazelnut, thus satisfying criterion III.

For leafy vegetables (celery, head lettuce, leaf lettuce, and spinach), the registrant claims that fluxapyroxad plays a significant part in managing fungicide resistance in seedborne and seedling diseases, including diseases caused by *Rhizoctonia solani*, *Phoma lingam*, *Aspergillus* spp., *Penicillium* spp., *Fusarium solani*, *Stemphylium* spp., *Botrytis* spp., and *Alternaria* spp. (BASF 2019). Fluxapyroxad is currently the only registered seed treatment fungicide in FRAC group 7 for these use sites. Use of seed treatment fungicides and availability of diverse seed treatment fungicides are important in managing fungicide resistance as seedborne and seedling diseases have a high risk of developing resistance (Lamichhane et al. 2017; Lamichhane et al. 2020). This risk of resistance is reduced when using seed treatments compared to using post-plant sprays or drenches (Lamichhane et al. 2020). According to the FRAC, availability of different chemical modes of action is important to prevent or overcome resistance problems (Brent & Holloman 2007). BEAD concludes that fluxapyroxad, having a unique mode of action for seed treatment of leafy vegetables (celery, head lettuce, leaf lettuce, and spinach), plays or will play a significant part in managing fungicide resistance in seedborne and seedling diseases and satisfies criterion III for extension of exclusive use in these sites.

For carrot and radish, the registrant claims that fluxapyroxad plays a significant part in managing resistance in several seedborne diseases, including damping-off. According to the 2020 Utah State University Extension guide for vegetables, fluxapyroxad is the only fungicide in FRAC group 7 with efficacy on damping-off of carrot and radish (Volesky et al. 2020). Pathogens causing seedling diseases, such as damping-off, have a high risk of developing fungicide resistance (Lamichhane et al. 2017). This risk of resistance is reduced when using seed treatments compared to using post-plant sprays or drenches (Lamichhane et al. 2020). According to the FRAC, availability of different chemical modes of action is important to prevent or overcome resistance problems (Brent & Holloman 2007). BEAD concludes that fluxapyroxad, having a unique mode of action for seed treatment of carrot and radish, plays or will play a significant part in managing fungicide resistance in seedborne and seedling diseases and satisfies criterion III for extension of exclusive use in these sites.

Applicability of Criterion IV to fluxapyroxad. The registrant claims that fluxapyroxad plays or will play a significant part in an integrated pest management program for bell pepper, chili pepper, peach, sweet cherry, garden pea, snow pea, cauliflower, hazelnut, celery, head lettuce, leaf lettuce, spinach, carrot, and radish. BEAD considers this criterion to be met for peach and sweet cherry and discusses below.

In peach and sweet cherry, the registrant claims that fluxapyroxad plays a role in an integrated pest management program for various fungal diseases of stone fruits, including brown rot. The registrant supports these claims by referring to the University of California (UC) IPM page for peach and cherry fungicide recommendations. The only listed product with comparable efficacy to Merivon (fluxapyroxad and pyraclostrobin; FRAC group 7 and 11) for all listed diseases in both crops is Luna Sensation (fluopyram and trifloxystrobin; FRAC group 7 and 11) (UC IPM 2017a, UC IPM 2017b). Luna Sensation has a longer pre-harvest interval (1 day versus 0 days) than Merivon. It is important that growers spray for brown rot as close to harvest as possible as it is an important postharvest disease in stone fruits and spraying closely before harvest, especially with succinate dehydrogenase inhibitor (SDHI) fungicides with long residual activity, such as fluxapyroxad, will reduce disease incidence and severity, consequently reducing the need for additional postharvest fungicide applications (Cox & Villani 2016, Sundin & Rothwell 2014). Merivon is also highly recommended to control brown rot by Michigan State University Extension and Penn State Extension (Sundin & Rothwell 2014; Peter 2017). The use of in-field fungicide applications to reduce post-harvest disease incidence and severity is a form of disease prevention, which is a key tenet of integrated pest management (EPA, no date). Therefore, BEAD concludes that fluxapyroxad has unique value and plays or will play an important role in an integrated pest management program for fungal diseases in peach and sweet cherry.

CONCLUSION

BEAD finds the registrant has provided sufficient evidence fluxapyroxad under FIFRA Section 3(c)(1)(F)(ii). BEAD concludes that for hazelnut, celery, head lettuce, leaf lettuce, spinach, carrot, and radish, fluxapyroxad provides an alternative mode of action to control fungal diseases, thereby reducing the risk of fungicide resistance in these sites, satisfying criterion III (the minor use pesticide plays or will play a role in managing pest resistance). BEAD concludes that for peach and sweet cherry, fluxapyroxad provides long residual activity with a 0-day

postharvest interval, theoretically reducing postharvest fungicide applications to these crops, satisfying criterion IV (the minor use pesticide plays or will play a role in an integrated pest management program). Therefore, BEAD finds that a minimum of nine crops meet at least one of the criteria under FIFRA Section 3(c)(1)(F)(i), qualifying fluxapyroxad for a three-year extension of exclusive use of data.

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