



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

May 5, 2021

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: A Review of FMC Corporation's Petition for Extension of Exclusive Use for Flutriafol (PC: 128940) (DP#458590)

FROM: Jeana Hansel, Plant Pathologist
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THRU: Monisha Kaul, Chief
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TO: Marcel Howard, Risk Manager Reviewer
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Product Review Panel Date: April 14, 2021

SUMMARY

FMC Corporation (2020) (hereafter FMC) has petitioned the Environmental Protection Agency (EPA), under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 3(c)(1)(F)(ii), to extend the exclusive use period for data supporting the fungicide flutriafol for up to three years. FMC claims flutriafol fills a void in current management programs and/or plays or will play a part in risk reduction, resistance management and integrated pest management programs, criteria I, II, III and IV as defined under FIFRA 3(c)(1)(F)(ii) in fourteen crops.

All 14 sites claimed by FMC meet the criterion for minor use designation, i.e., less than 300,000 acres bearing or harvested. However, only 12 sites are supported by residue data.

BEAD finds the registrant submitted sufficient evidence for seven minor use sites to satisfy at least one criterion for extension of exclusive use for flutriafol under FIFRA Section 3(c)(1)(F)(ii). BEAD found that there are insufficient registered alternative fungicides (Criterion

I) for the claimed target pest(s) in strawberry, celery and two fruiting vegetables. BEAD found that for cantaloupe, cucumber, and summer squash, flutriafol plays or will play a role in resistance management (Criterion III) for charcoal rot.

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 the registrant’s petition meet the statutory requirement for an extension of data exclusivity by verifying that residue trials were submitted on a one-for-one basis with use sites, verifying minor crop acreage, and validating the claimed criteria.

REGISTRANT SUBMISSION

The registrant claims that flutriafol satisfies the FIFRA Section 3(c)(1)(F)(ii) requirements for the following 14 use sites: popcorn, mayhaw, peach, nectarine, apricot, cantaloupe, cucumber, summer squash, bell pepper, non-bell pepper, eggplant, strawberry, celery and hops (FMC Corporation 2020). The registrant claims all uses are individually associated with a residue trial, are grown on less than 300,000 acres, and that there are insufficient registered alternative

pesticides, that flutriafol plays or will play a part in risk reduction, resistance management, and/or an integrated pest management program (criteria I, II, III, and/or IV) for each of the claimed minor use sites.

REQUIREMENTS TO QUALIFY FOR THE CLAIMED CRITERIA

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 II, the alternatives to the minor use pesticide pose greater risks to the environment or human health. BEAD cannot evaluate risk and does not provide the registration division with information related to Criterion II.

Requirements for Criterion III, the minor use pesticide plays or will play a significant part in managing pest resistance. EPA 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. EPA 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 ANALYSIS

BEAD first confirms that residue trial data are sufficient such that there is a one-for-one relationship for each use site. Then, BEAD confirms 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. by consulting the most recent Census of Agriculture conducted by the United States Department of Agriculture (USDA) National Agricultural Statistics Service (NASS). Finally, BEAD evaluates the evidence submitted by the registrant to determine if the claimed criteria are met. If BEAD finds nine qualifying use sites meet at least one claimed criterion, the evaluation is complete, as that is the requirement for the maximum three-year extension of data exclusivity.

Residue Trial Analysis

Of the 14 crops listed in the registrant submission, 12 are supported by residue data (Table 1). The registrant may claim peach or nectarine and any two of bell pepper, non-bell pepper, and eggplant, should these uses be cultivated on less than 300,000 acres and if minor use site criteria

are met. The registrant may claim up to 12 minor use sites if all use sites are cultivated on less than 300,000 acres and if minor use site 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
Popcorn	Cereal Grains (15)	Sweet corn (6/23/15; 50450404)	1
Mayhaw	Pome Fruit (11-10)	Apple (2/16/07; 47090446)	1
Peach	Stone Fruit (12-12B)	Peach (4/1/10; 48196905)	1
Nectarine			
Apricot	Stone Fruit (12-12C)	Plum (4/1/10; 48196904)	1
Cantaloupe	Cucurbit Vegetables (9A)	Cantaloupe (6/28/12; 49114804)	1
Cucumber	Cucurbit Vegetables (9B)	Cucumber, summer squash (6/28/12; 49114804)	2
Summer squash			
Bell pepper	Fruiting Vegetables (8-10B)	Bell pepper; Non-bell pepper (6/29/12; 49114803)	2
Non-bell pepper			
Eggplant			
Strawberry	Berry and Small Fruit (13-07G)	Strawberry (2/2/11; 49114802)	1
Celery	Stalk, Stem, and Leaf Petiole Vegetable (22B)	Celery (6/26/13; 49205401)	1
Hops	Miscellaneous	Hops (6/24/14; 49421702)	1

Minor Use Analysis

The Environmental Protection Agency (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). If a crop is not listed in the Census of Agriculture, per discussion with USDA, the acreage of the crop can be assumed to be less than 300,000. For the minor use qualification, fruit and tree nut crops are evaluated for bearing acreage, and other crops are evaluated for harvested acreage. For each of the 14 sites listed in Table 1, the total U.S. acreage is less than 300,000 acres, qualifying them as minor crops. However, due to insufficient representative residue data in stone fruits and fruiting vegetables (Table 1), the registrant may claim up to 12 minor use sites if criteria for extension of exclusive use are met.

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

Minor Use Site	Crop Acres Grown ¹	Criteria Claimed
Popcorn	221,264	I
Mayhaw	Not surveyed ²	I
Peach	94,836	I, II
Nectarine	18,204	I, II
Apricot	12,179	I, II
Cantaloupe	71,436	I, II, III, IV
Cucumber	119,655	I, II, III, IV
Summer squash	70,190	I, II, III, IV
Bell pepper	48,801	I, II, III, IV
Non-bell pepper	24,165	I, II, III, IV
Eggplant	5,365	I, II, III, IV
Strawberry	58,117	I, II, III, IV
Celery	36,587	I
Hops	59,429	I, II

¹USDA NASS 2017.

²The USDA NASS does not survey mayhaw, indicating that crop acreage is well below 300,000 acres. There are no available recent estimates of national mayhaw acreage online.

BEAD Assessment of Claimed Criteria

Applicability of Criterion I to flutriafol. The registrant claims that there are insufficient efficacious alternative registered pesticides to flutriafol in popcorn, mayhaw, peach, nectarine, apricot, cantaloupe, cucumber, summer squash, bell pepper, non-bell pepper, eggplant, strawberry, celery and hops. BEAD considers this criterion to be met in bell pepper, non-bell pepper, eggplant, strawberry, and celery, and discusses below.

In bell pepper, non-bell pepper, and eggplant, flutriafol is the only fungicide labeled for control of charcoal rot. Charcoal rot has become more prevalent following the ban of methyl bromide (FMC 2020, Rapp 2018). While other fumigants are still used, they do not control the disease as well as methyl bromide did, and they cannot be used when plants are in the field (FMC 2020, Rapp 2018). Solanaceous vegetables, such as peppers and eggplant, are major hosts for charcoal rot (Partridge, undated). Flutriafol is the only fungicide labeled for control of charcoal rot in fruiting vegetables, therefore criterion I is satisfied for bell pepper, non-bell pepper, and eggplant. Due to insufficient residue data, only two out of three of these minor use sites can be claimed for extension of exclusive use of flutriafol (Table 1).

In strawberry, flutriafol is the only fungicide labeled for control of charcoal rot. Charcoal rot is a universal problem in strawberry production and has become more severe since the ban of methyl bromide (Kloosterman 2019, FMC 2020). While other fumigants are still used, they do not control the disease as well as methyl bromide did, and they cannot be used when strawberries are in the field (Kloosterman 2019, FMC 2020). Flutriafol is the only fungicide labeled for control of charcoal rot when strawberries are in the field, therefore criterion I is satisfied for strawberry.

In celery, flutriafol is the only non-seed treatment fungicide labeled for control of *Fusarium* sp. *Fusarium* sp. is a soilborne disease that has become more prevalent in celery since the ban of

methyl bromide (Quiros 2020, FMC 2020). Because flutriafol is the only in-field fungicide registered for control of *Fusarium* sp. in celery, it satisfies criterion I for celery.

Applicability of Criterion III to flutriafol. The registrant claims that flutriafol plays or will play a significant part in managing pest resistance in cantaloupe, cucumber, summer squash, bell pepper, non-bell pepper, eggplant, and strawberry. BEAD considers this criterion to be met in cantaloupe, cucumber, and summer squash, and discusses below.

In cantaloupe, cucumber, and summer squash, flutriafol is the only fungicide in the Fungicide Resistance Action Committee (FRAC) group 3 labeled for control of charcoal rot. The only other fungicide labeled for this disease is thiophanate-methyl, which is a FRAC group 1 fungicide. Charcoal rot is an emerging disease that has been increasing in severity since the ban of methyl bromide (FMC 2020, Egel 2018, Egel et al. 2020). While no resistance to either fungicide has been documented yet in this pathogen, FRAC indicates that group 1 fungicides including thiophanate-methyl have a high risk of resistance, whereas group 3 fungicides including flutriafol have a medium risk of resistance (FRAC 2021). Given its unique mode of action for the disease and a generally lower risk of resistance than the alternative, flutriafol satisfies criterion III for cantaloupe, cucumber, and summer squash, and will play a role in managing fungicide resistance in *Macrophomina phaseoli*, the causal pathogen of charcoal rot.

Non-Qualifying Minor Use Sites

While BEAD found that seven claimed minor use sites satisfy criteria I, III, and/or IV for extension of exclusive use, BEAD cannot make a determination on whether popcorn, mayhaw, peach, nectarine, apricot, and hops satisfy their respective claimed criteria from the evidence the registrant provided. These crops are discussed below.

Popcorn. FMC (2020) claims that there are insufficient fungicides registered to control tar spot in popcorn. A review of registered fungicides indicates that there are multiple alternatives to flutriafol for this use. These alternatives encompass multiple FRAC groups, including several in FRAC group 3 (e.g. prothioconazole, tetraconazole), the same group flutriafol is in. Due to sufficient alternative fungicides registered for the use, popcorn does not satisfy the claimed criterion for extension of exclusive use.

Mayhaw. FMC (2020) claims that there are insufficient fungicides registered to control quince rust in mayhaw. A review of registered fungicides indicates that there are multiple alternatives to flutriafol for this use. These alternatives encompass multiple FRAC groups, including several in FRAC group 3 (e.g. mefentrifluconazole, difenoconazole), the same group flutriafol is in. Due to sufficient alternative fungicides registered for the use, mayhaw does not satisfy the claimed criterion for extension of exclusive use.

Peach, Nectarine, Apricot. FMC (2020) claims the stone fruit satisfy criterion I (there are insufficient efficacious alternative registered pesticides available for the use) and II (the alternatives to the minor use pesticide pose greater risks to the environment or human health). For criterion I, FMC claims that there are insufficient efficacious alternatives for rusty spot (in peach). A review of registered fungicides indicates that there are multiple alternatives to

flutriafol for this use. These alternatives encompass multiple FRAC groups, including one in FRAC group 3 (tebuconazole), the same group flutriafol is in.

Additionally, FMC (2020) claims that there are insufficient efficacious alternatives registered for control of powdery mildew in peach, nectarine, and apricot via drip irrigation. A review of registered fungicides indicates that there are multiple alternatives to flutriafol for control of powdery mildew in the stone fruits. These alternatives encompass multiple FRAC groups, including several in FRAC group 3 (e.g. tebuconazole, propiconazole), the same group flutriafol is in. Due to sufficient alternative fungicides registered for the claimed uses, the stone fruit do not satisfy criterion I for extension of exclusive use.

With regard to FMC's claim that flutriafol satisfies criterion II (the alternatives to the minor use pesticide pose greater risks to the environment or human health) in the stone fruit, BEAD cannot evaluate risk and does not provide the registering division with information related to criterion II and therefore cannot make a determination on whether flutriafol satisfies this criterion.

Hops. FMC (2020) claims hops satisfies criterion I (there are insufficient efficacious alternative registered pesticides available for the use) and II (the alternatives to the minor use pesticide pose greater risks to the environment or human health). For criterion I, FMC claims that there are insufficient efficacious alternatives registered for control of powdery mildew via drip irrigation. For consideration of insufficient efficacious alternatives, BEAD evaluates if there are effective registered alternatives for the use, including all available application methods. A review of registered fungicides indicates that there are multiple alternatives to flutriafol for control of powdery mildew. These alternatives encompass multiple FRAC groups, including several in FRAC group 3 (e.g. tebuconazole, triflumizole), the same group flutriafol is in. Due to sufficient alternative fungicides registered for the use, hops does not satisfy criterion I for extension of exclusive use.

With regard to FMC's claim that flutriafol satisfies criterion II (the alternatives to the minor use pesticide pose greater risks to the environment or human health) in hops, BEAD cannot evaluate risk and does not provide the registering division with information related to criterion II and therefore cannot make a determination on whether flutriafol satisfies this criterion.

CONCLUSION

BEAD finds the registrant has provided sufficient evidence that seven minor use sites satisfy the criteria necessary for a two-year extension of exclusive use for flutriafol under FIFRA Section 3(c)(1)(F)(ii). BEAD found that for the minor uses bell pepper, non-bell pepper, eggplant, strawberry, and celery, there are insufficient registered alternative fungicides for the claimed target pests in those crops; however, due to insufficient residue data, only two minor use sites can be claimed for the fruiting vegetables crop group (8-10B) that encompasses bell pepper, non-bell pepper, and eggplant. BEAD found that for cantaloupe, cucumber, and summer squash, flutriafol plays or will play a role in resistance management for charcoal rot.

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