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

April 6, 2021

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Review of ADAMA USA's Petition for an Extension of the Exclusive Use Period for Fluensulfone (PC#050410) (MRID 51169901)

FROM: Jeana Hansel, Plant Pathologist
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THRU: Monisha Kaul, Chief
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TO: Gene Benbow, Product Manager
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Product Review Panel Date: March 3, 2021

ADAMA USA (2020) has petitioned the EPA 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 nematicide fluensulfone be extended for three years. ADAMA claims fluensulfone plays a significant part in risk reduction, resistance management and integrated pest management programs, criteria II, III and IV as defined under FIFRA 3 (c)(1)(F)(ii). ADAMA USA (2020) submitted supporting information for twelve crops. Residue data were sufficient for eleven crops, ten of which met the criteria for minor use designation (less than 300,000 acres bearing or harvested).

BEAD determined that at least nine of the twelve petitioned use sites satisfy at least Criterion III, and fluensulfone plays or will play a significant role in resistance management for nematodes due to its novel mode of action.

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(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" 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.

BEAD evaluated whether at least nine use sites submitted in ADAMA USA's package met 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.

METHODOLOGY

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(ll)(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. In the case of 9 minor use sites meeting at least one claimed criterion, BEAD

only presents the evaluation for those 9, as that is the requirement for the full 3-year extension of data exclusivity.

REGISTRANT SUBMISSION

The registrant claims that fluensulfone satisfies the FIFRA Section 3(c)(1)(F)(ii) requirements for the following 12 use sites: carrot, sweet potato, okra, bell pepper, watermelon, cantaloupe, sweet cherry, peach, strawberry, kiwi, macadamia and pecan (ADAMA USA 2020). The registrant claims all uses are associated with a residue trial, are grown on less than 300,000 acres, and that fluensulfone plays a significant part in risk reduction, resistance management and integrated pest management for all claimed minor use sites (criteria II, III and IV).

BEAD ANALYSIS

Residue Trial Analysis

Of the 12 crops listed in the registrant submission, all are supported by residue data (Table 1). However, in the case of watermelon and cantaloupe (subgroup 9A), only one representative crop residue study within subgroup 9A was submitted for the two minor uses. The registrant may claim up to 11 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
Carrot	Root and Tuber Vegetables (1B)	Carrot (10/9/15; 49553613)	1
Sweet Potato	Root and Tuber Vegetables (1C)	Potato (10/9/15; 49643601)	1
Okra	Fruiting Vegetables (8-10B)	Bell Pepper; Non-Bell Pepper (3/15/12; 48574804)	2
Bell Pepper			
Watermelon	Cucurbit Vegetables (9A)	Cantaloupe (3/15/2012; 48574806)	1
Cantaloupe			
Sweet Cherry	Stone Fruit (12-12A)	Sweet Cherry (6/26/2017; 50119004)	1
Peach	Stone Fruit (12-12B)	Peach (6/26/2017; 50119004)	1
Strawberry	Berry and Small Fruit (13-07G)	Strawberry (10/9/15; 49553608)	1
Kiwi	Berry and Small Fruit (13-07E)	Kiwi (6/26/17; 50119003)	1
Macadamia	Tree Nuts (14-2)	Almond; Pecan (6/26/17; 50119002)	2
Pecan			

Minor Use Analysis

Per consultation with USDA, EPA relies on the Census of Agriculture for data on crops grown in the United States (EPA 2018). For the minor use qualification, fruit and tree nut crops are evaluated for bearing acreage, and vegetable crops are evaluated for harvested acreage. For the 11 sites supported by unique residue data listed in Table 1, the total U.S. acreage of ten sites is less than 300,000 acres, qualifying them as minor crops. The bearing acreage for pecans in 2017 was 461,890 acres (USDA 2017), thereby disqualifying it as a minor use crop under FIFRA Section 2(ll)(1). The registrant's claimed acreage differs from acreage reported in the Census of Agriculture; this is due to the registrant's use of a different source to determine acreage (ADAMA USA 2020). The registrant may claim up to 10 minor use sites if criteria for extension of exclusive use are met.

Table 2. Acreage of crops considered for extension of exclusive use for fluensulfone.

Minor Use Site	Claimed Acreage[1]	Crop Acres Grown[2]
Carrot	74,513	96,443
Sweet Potato	132,220	172,963
Okra	3,085	3,285
Bell Pepper	43,685	48,801
Watermelon	127,133	129,790
Cantaloupe	71,201	71,436
Sweet Cherry	105,978	93,866
Peach	112,861	94,836
Strawberry	60,162	58,117
Kiwi	4,554	3,707
Macadamia	18,403	17,587
Pecan	155,678	461,890

[1]ADAMA USA 2020.
[2]USDA 2017.

REQUIREMENTS TO QUALIFY FOR THE CLAIMED CRITERIA

ADAMA USA has claimed that fluensulfone qualifies for criteria II, III and IV for all claimed minor use sites.

Requirements for Criterion II, the alternatives to the minor use pesticide pose greater risks to the environment or human health. BEAD does not evaluate Criterion II.

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 such as inclusion of non-chemical pest control strategies (e.g. biological control).

BEAD ASSESSMENT OF CLAIMED CRITERIA

Applicability of Criterion III to fluensulfone.

For ten minor use sites (carrot, sweet potato, okra, bell pepper, watermelon or cantaloupe, sweet cherry, peach, strawberry, kiwi, macadamia), fluensulfone satisfies criterion III for its value in managing pest resistance. Fluensulfone has a unique and novel mode of action among nematicides, and it is the first and only nematicide in the fluoroalkenyl chemical class (IRAC 2019, ADAMA 2020). Plant parasitic nematode resistance to other registered nematicides, such as oxamyl, has been documented (Viglierchio and Brown 1989). Additionally, nematodes resistant to carbamates such as oxamyl do not show cross resistance to fluensulfone (Kearn et al. 2014). The registrant additionally included letters of support from extension and industry professionals indicating that fluensulfone's novel mode of action will help in nematicide resistance management (Westerdahl 2019, Darroch 2019). Fluensulfone plays or will play an important role in nematicide resistance management in the crops in which it is registered.

CONCLUSION

BEAD finds the registrant has provided sufficient evidence to satisfy the criteria for extension of exclusive use for fluensulfone under FIFRA Section 3(c)(1)(F)(ii). BEAD found that for the minor uses carrot, sweet potato, okra, bell pepper, watermelon or cantaloupe, sweet cherry, peach, strawberry, kiwi, and macadamia, fluensulfone provides a novel mode of action to control nematodes and plays or will play an important role in nematicide resistance management.

REFERENCES

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