



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

February 14, 2020

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Review of Nichino America's Request for an Extension of the Exclusive Use Period for Pyriproxyfen (DP: 453997)

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Product Review Panel Date:

SUMMARY

Nichino (2019) 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 insecticide pyriproxyfen be extended for three years. Nichino claims pyriproxyfen plays a significant part in resistance management, criterion III as defined under FIFRA 3 (c)(1)(F)(ii). Nichino (2019) submitted supporting information for 25 crops. All 25 crops meet the definition of a minor use as each crop had less than 300,000 acres bearing or harvested. All proposed minor uses are supported with representative crop data of their respective crop group and a maximum of 14 proposed sites are supported on a 1 for 1 basis.

BEAD determined that at least nine of the 25 petitioned minor use sites satisfy Criterion III; pyriproxyfen plays a significant part in resistance management lemon, tangerine, grapefruit, sweet cherry, plum, peach, broccoli, cabbage, and cantaloupe. Therefore, the request for pyriproxyfen satisfies the necessary criteria for a three-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 pesticide plays or will play a significant part in an integrated pest management program.*

A minor use is defined in FIFRA Section 2(11) 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 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.

BEAD evaluated whether at least nine use sites submitted in Nichino’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 necessary number of use sites, verifying minor crop acreage, and validating criteria I, III and/or IV. BEAD may utilize outside sources of information to substantiate registrant claims. Based on the submission, this document evaluates the proposed sites for criterion III only as that was the only criterion identified in the registrant’s submission for consideration.

REGISTRANT CLAIMS

The registrant claims that pyrifluquinazon satisfies the FIFRA Section 3(c)(1)(F)(ii) requirements for the following 25 use sites: arugula, endive, radicchio, spinach, swiss chard, eggplant, bell pepper, non-bell pepper, grapefruit, kumquat, lemon, lime, tangelo, tangerine

(mandarin), sweet cherry, tart cherry, plum, peach, broccoli, Brussel sprouts, cabbage, cauliflower, cantaloupe, watermelon, and squash (See Nichino 2019). The registrant claims all uses are associated with a residue trial, are grown on less than 300,000 acres, and that pyrifluquinazon plays a significant part in resistance management (criterion III).

RESIDUE TRIALS

BEAD first confirms that residue trial data are sufficient such that there is a one-for-one relationship for each of 9 required use sites. Of the 25 crops listed in the registrant submission, a maximum of 14 sites are supported by available residue data on a 1 for 1 basis (Table 1). The registrant may claim up to 9 minor use sites if all sites are cultivated on less than 300,000 acres and if minor use site criterion are met.

Table 1. Proposed crops and representative residue data

Crop Group/ Subgroup	Date, Residue Trial(s)	Crop Data Submitted	Minor Use Represented
Leafy Veg (4-16A)	3.19.2013, 49083769	Lettuce	Endive Radicchio
		Spinach	Spinach
		Celery	Swiss Chard
Leafy Veg (4-16B)	3.19.2013, 49083770	Cabbage	Arugula
Brassica Veg (5A)	3.19.2013, 49083770		Brussel Sprouts
			Cabbage
			Cauliflower
Fruiting Veg (8-10C)	3.19.2013, 49083758	Pepper	Eggplant
Fruiting Veg (8-10B)			Bell Pepper Non-bell Pepper
Citrus Fruit (10-10A)	3.19.2013, 49083763	Orange	Tangerine
Citrus Fruit (10-10B)		Lemon	Kumquat Lemon Lime
		Citrus Fruit (10-10C)	Grapefruit
Stone Fruit (12-12A)			
Stone Fruit (12-12B)	Peach	Peach	
Stone Fruit (12-12C)	Plum	Plum	
Cucurbit Veg (9A)	3.19.2013, 49083771	Muskmelon	Cantaloupe Watermelon
Cucurbit Veg (9B)			Summer Squash

MINOR USE ANALYSIS

Per consultation with USDA, EPA relies on the Census of Agriculture for data on the acreage of crops grown in the United States (EPA 2018). For all 25 sites listed in Table 1 (“Minor Use Represented”), the total U.S. acreage is less than 300,000 acres, qualifying them as minor crops. For the minor use qualification, fruit and tree nut crops are evaluated for bearing acreage, and field crops (e.g. broccoli) are evaluated for acres grown. National acreage reported by Nichino (2019) matches acreage reported by BEAD as both sourced the information from USDA NASS 2017 Census of Agriculture, except for perennial crops (i.e. citrus and stone fruit crops), where Nichino identified acres grown instead of bearing acres, which the Agency uses for determining a minor use in these perennial sites. Since all sites are considered minor uses; any of the sites

within a crop grouping, up to the number of residue trials submitted, may be used to qualify for an extension of data protections.

Table 2. Acreage of crops and Criterion considered for extension of exclusive use for pyrifluquinazon.

Site	Crop Acres Grown ¹	Criteria Claimed
Arugula	Not listed	III
Endive	2,432	III
Radicchio	Not listed	III
Spinach	69,969	III
Swiss Chard	Not listed	III
Eggplant	5,365	III
Bell Pepper	48,801	III
Non-bell Pepper	24,165	III
Grapefruit	64,790	III
Kumquat	258	III
Lemon	59,001	III
Lime	1,051	III
Tangelo	7,222	III
Tangerine	56,883	III
Tart Cherry	35,994	III
Sweet Cherry	93,866	III
Peach	94,836	III
Plum and Prune	61,273	III
Broccoli	135,185	III
Brussel Sprouts	9,445	III
Cabbage	72,296	III
Cauliflower	50,331	III
Cantaloupe	71,436	III
Squash	70,190	III
Watermelon	129,790	III

Source: USDA 2017. Acres grown for annual crop; bearing acres for perennial crops (i.e. tree or orchard crops). Crops not listed in the Census can be presumed to be grown on less than 300,000 acres.

SUPPORT TO QUALIFY FOR CRITERIA

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 (MOA) or where one or more of the target pests have already developed resistance in the U.S. to alternative chemicals.

Applicability of Criterion III to pyrifluquinazon

The registrant claims that pyrifluquinazon plays an important role in control of insect resistance management (IRM), in pests such as whitefly, aphids, thrips, and scale, for all identified minor use sites. Nichino claims pyrifluquinazon is one of only two insecticides classified as an Insecticide Resistance Action Committee (IRAC) Group 9B chordotonal organ channel modulator and that it is the only registered insecticide from this group for use in certain proposed crop groups such as stone fruit and citrus (IRAC, 2019; See Nichino, 2019). For other minor use sites proposed, such as leafy brassica (arugula) and cucurbit vegetables (cantaloupe, squash, and watermelon), Nichino claims pyrifluquinazon is the only insecticide with a Group 9B MOA registered for control of key pests such as whitefly and thus provides a unique MOA and tool in resistance management scenarios targeting populations of whitefly.

For orchard crops (minor use sites; lemon, grapefruit, tangerine, sweet cherry, peach, and plum), the registrant claims that pyrifluquinazon manages insecticide-resistant populations of aphids, citrus thrips and red scale. Pyrifluquinazon would be the only chordotonal organ modulator (IRAC Group 9B) registered in these crops and therefore provides a unique MOA for targeting the identified pests within these crops and would be valuable to growers in situations where insecticidal resistance has developed to available alternatives (CDMS, 2019; IRAC, 2019; See Nichino, 2019).

For crop such as broccoli, cabbage, and cantaloupe, the registrant claims that pyrifluquinazon will play a significant role in resistance management of aphids and whitefly, which are commonly found within each of the identified crops. The registrant cited extension materials outlining the importance of whitefly control and the resistance management issues whitefly pose in multiple vegetable cropping systems (Palumbo, 2018b; Palumbo, 2019a; See Nichino, 2019). Nichino provided evidence from Arizona state extension professionals that pyrifluquinazon provides excellent control of whitefly making it a potential resistance management partner in these three crops. Despite another IRAC 9B insecticide, pymetrozine, also being registered in these sites, Nichino provided information showing how this active ingredient is not appropriate for IRM as it is only labelled to provide suppression of whitefly (CDMS, 2019; Palumbo, 2018ab; Palumbo, 2019abc; See Nichino, 2019).

BEAD concludes that for at least nine of 25 minor use sites, pyrifluquinazon satisfies Criterion III, that is, it will play an important role in insecticide resistance management for specified pests in these minor use sites.

CONCLUSION

BEAD finds the registrant has provided sufficient evidence to support a three-year extension of exclusive use of data for pyrifluquinazon under FIFRA Section 3(c)(1)(F)(ii). BEAD found that for lemon, tangerine, grapefruit, sweet cherry, peach, plum, broccoli, cabbage, and cantaloupe pyrifluquinazon provides an alternative MOA to control insects resistant to other insecticides and therefore satisfies criterion III, it will play a significant role in resistance management.

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