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

November 23, 2020

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Review of Landis America's Request for an Extension of the Exclusive Use Period for Pyroxasulfone (DP: 63588-91)

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THRU: Monisha Kaul, Chief
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Product Review Panel Date: July 29, 2020

SUMMARY

Landis International (registrant) 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 herbicide pyroxasulfone be extended for three years. Landis (2019) claims pyroxasulfone plays a significant part of herbicide resistance management, criterion III as defined under FIFRA 3 (c)(1)(F)(ii) and/or will play a significant role in integrated pest management, criterion IV as defined under FIFRA 3 (c)(1)(F)(ii). Landis (2019) submitted supporting information for 11 crops. All 11 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 11 proposed sites are supported on a 1 for 1 basis.

BEAD determined that nine uses supported by residue data satisfy either Criterion III or Criterion IV. Pyroxasulfone will play a significant role in resistance management and/or integrated pest management for: faba bean, fescue, orchardgrass, perennial ryegrass, peppermint, spearmint, popcorn, onions, and leeks.

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 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 Landis'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 utilized outside sources of information to substantiate registrant claims. Determinations of Criterion II are handled by the Registration Division and thus not addressed herein. This document evaluates the proposed sites for criterion III and IV as identified in the registrant's submission (Landis, 2019) for consideration.

REGISTRANT CLAIMS

The registrant claims that pyroxasulfone satisfies the FIFRA Section 3(c)(1)(F)(ii) requirements for the following 11 use sites: onion bulb; leeks; Faba (broad) beans; fescue; perennial ryegrass; bluegrass; sunflower; celery; peppermint; spearmint; and corn (See Landis, 2019). The registrant claims all uses are associated with a residue trial, are grown on less than 300,000 acres, and that pyroxasulfone plays a significant part in either resistance management (criterion III) and/or integrated pest management (criterion IV) for these 11 crops.

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 11 crops listed in the registrant submission, a maximum of 11 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. Several sites are supported by IR-4 generated data, which can be used to count toward qualifying for an extension of exclusive use period. However, the data itself is not eligible for extended protections as explained in EPA's "Questions and Answers-Exclusive Use Data Protection for Minor Use Registrations", Revised February, 2018[1].

Table 1. Proposed crops and representative residue data

No.	**Crop Group**	**Proposed Minor Crop**	**Supporting Residue Data** (Crop, MRID, Date submitted)	**Data Produced By**
1	Onion, bulb, subgroup (Crop subgroup 3-07A)	Onion bulb	Onion bulb, 50025801, 5/24/2018	Landis
2	Onion, green, subgroup (Crop subgroup 3-07B)	Leek	Onion greens, 50025801, 5/24/2018	Landis
3	Dried shelled pea and bean (except soybean) subgroup (Crop Subgroup 6C)	Faba (Broad) bean	Dry beans, 49639201, 4/25/2018	Landis
4	Grass Forage, Fodder, and Hay Group (Crop Group 17)	Fescue	Tall fescue, 50188401, 11/16/2018	IR-4
5	Grass Forage, Fodder, and Hay Group (Crop Group 17)	Perennial ryegrass	Perennial ryegrass, 50188401, 11/16/2018	IR-4
6	Grass Forage, Fodder, and Hay Group (Crop Group 17)	Orchard grass	Bluegrass, 50188401, 11/16/2018	IR-4
7	Sunflower subgroup (Crop subgroup 20B)	Safflower	Sunflower, 49792501, 4/25/2018	IR-4

[1] https://www.epa.gov/sites/production/files/2018-02/documents/exclusive-use-questions-feb2018.pdf

8	Leaf petiole vegetable subgroup (Crop Subgroup 22B)	Celery	Celery, 50281101, 11/16/2018	IR-4
	Mint, Peppermint	Peppermint	Peppermint, 50188403; 50251102, 11/16/2018	IR-4
10	Mint, Spearmint	Spearmint	Spearmint, 50188403; 50251102, 11/16/2018	IR-4
11	Corn (field, pop and sweet)	Popcorn	Corn, 48430011, 2/15/2012	Landis

MINOR USE ANALYSIS

EPA relies on the Census of Agriculture to determine the acreage of crops grown in the United States (EPA, 2018). For all 11 sites listed in Table 1 ("Minor Use Represented"), the total U.S. acreage is less than 300,000 acres, qualifying them as minor crops. National acreage reported by Landis (2019) matches acreage reported by BEAD for most sites as both sourced the information primarily from USDA NASS 2017 Census of Agriculture, however sites such as leeks and faba beans were not reported there and are thus assumed to be less than 500 acres. Since all 11 sites are considered minor uses any nine may be counted toward qualifying for an extension of data protections if each meets one of the four criterions assessed below.

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

Site	Landis's Reported Crop Acreage	Crop Acres Grown [a]	Criteria Claimed
Onion bulb	163,982	163,982	I/IV
Leek	149	NA	I/IV
Faba (Broad) bean	3,300	NA	I/III
Fescue	170,284	170,284	III
Perennial ryegrass	232,139	232,139	III
Orchard grass	12,807	12,807	III
Safflower	144,027	144,027	I/ III/ IV
Celery	36,587	36,587	I/ III/ IV
Peppermint	62,071	62,071	I/ III/ IV
Spearmint	23,264	23,264	I/ III/ IV
Popcorn	221,264	221,264	III

[a] Acreage derived from the 2017 Census of Agriculture. 2019. United States Department of Agriculture publication AC-17- A-51, unless otherwise noted.

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.

Requirements for Criterion IV, pesticide plays or will play a significant part in an Integrated Pest Management Program. BEAD considers Criterion IV has been met in situations where there is information that the chemical being evaluated is useful in managing target pests with low-to- no impact on other aspects of integrated pest management or IPM such as inclusion of non- chemical pest control tactics.

Applicability of Criterion III to pyroxasulfone

Landis (2019) claims that within in 9 of their 11 proposed sites pyroxasulfone plays a significant role in herbicide resistance management (faba bean, fescue, orchardgrass, perennial ryegrass, peppermint, spearmint, safflower, celery, and popcorn). Pyroxasulfone is from a new chemical family, according to WSSA, however its mode of action, mitochondrial disruption, is not new and is shared among other herbicides such as the acetochlor, metolachlor, s-metolachlor and more. Whether cross resistance occurs between other chemical families in this MOA group and pyroxasulfone's has not yet been well studied.

Faba (broad) Bean

Landis (2019) provided supporting information from North Dakota State University (NDSU) extension around the use of pyroxasulfone to control a number of weed species exhibiting resistance to varying classes of herbicides including ALS inhibitors, ACCase inhibitors, photosystem II inhibitors, and EPSP synthase inhibitors. According to NDSU, pyroxasulfone has played a strong role in the management of resistant weed bio-types and has been observed outperforming chemistries within the same MOA classification, such as s-metolachlor, making it the preferred choice for controlling pre-emerged resistant weed populations in faba bean production. Based on the supporting information BEAD agrees that pyroxasulfone satisfies criteria III in faba bean production.

Fescue, Perennial Ryegrass, and Orchardgrass (grown for seed)

The registrant's submission contained supporting evidence around the use of pyroxasulfone for resistance management of several key chemistries in grass seed production such as diuron, ethofumesate, and flufenacet in addition to others (Landis, 2019). According to information from Oregon State University extension submitted by Landis (2019) pyroxasulfone is becoming a frequently used tool for dealing with populations of annual bluegrass, rough-stalk bluegrass, and annual ryegrass exhibiting resistance to multiple herbicides in grass grown for seed production. Based on this information BEAD agrees that pyroxasulfone satisfies criteria III and will play a significant role in resistance managment in fescue, orchardgrass, and perennial ryegrass grown for seed.

Peppermint and Spearmint

Landis (2019) identified in their submission that pyroxasulfone is the first WSSA group 15, Very Long Chain Fatty Acid, or VLCFA inhibitor available to peppermint and spearmint growers. According to extension sources from Washington State University (WSU) and North Dakota State University (NDSU) submitted by Landis (2019), pyroxasulfone provides comparable or superior control compared to registered alternatives of several common weed species in mint production. According to WSU, pyroxasulfone has been a key tool in managing terbacil resistant populations of redroot pigweed, lambsquarters, and ACCase resistant grass species since registered for use in these crops. Based on the supporting evidence provided by the registrant BEAD agrees that pyroxasulfone satisfies criterion III in peppermint and spearmint.

Popcorn
Landis (2019) submitted letters of support from the Ohio State University, Ohio Agricultural Research and Development Center outlining how pyroxasulfone is used as a tank mix partner in a sequence of herbicide rotations to control a variety of resistant weeds species such as pigweeds, nightshades and various annual grasses. Extension professionals indicated that in popcorn pyroxasulfone provided good residual control of waterhemp biotypes resistant to other herbicide active ingredients, while also exhibiting excellent crop safety which is a major concern of herbicide use in popcorn production (Landis, 2019). Based on the supporting evidence provided by the registrant BEAD agrees that pryroxasulfone plays a significant role in resistance management in popcorn production.

Applicability of Criterion IV to pyroxasulfone
Landis (2019) claims pyroxasulfone meets criteria IV and will play a significant role in integrated pest management (IPM) within production of the following crops dry bulb onions, leeks, celery, safflower, peppermint and spearmint. According to Landis (2019), pyroxasulfone's ability to perform on muck soils and to provide lasting residual control beyond currently registered alternatives makes it useful in an IPM plan, as it allows for reduced herbicide applications.

Dry Bulb Onions and Leeks
Supporting evidence provided by Landis (2019) out of the Michigan State University (MSU) detailed the benefits pyroxasuflone provides when used in muck soil production of dry bulb onions and leeks. According to MSU, pyroxasulfone use in in these crops allows for not only reduced herbicide applications but when timed properly can eliminate the need for manual weed removal which translates to a significant labor cost savings. Additional supporting information provided by the University of Wisconsin at Madison (UWM) indicated that the residual control provided by pyroxasulfone was far superior to registered alternatives. According to extension at UWM, integration of pyroxasulfone into weed management programs in dry bulb onions and leeks in muck soils has resulted in a reduction from 10-13 herbicide applications per year to just 4 applications, while providing superior weed control in onions and leeks. Based on the supporting evidence provided BEAD agrees that pyroxasulfone satisfies criteria IV in onions and leeks.

CONCLUSION

BEAD finds the registrant has provided sufficient evidence to support consideration for a three-year extension of exclusive use of data for pyroxasulfone under FIFRA Section 3(c)(1)(F)(ii). BEAD found that for faba beans, fescue, orchardgrass, perennial ryegrass, peppermint, spearmint and popcorn pyroxasulfone provides an alternative MOA to control weeds exhibiting herbicidal resistance to other herbicide active ingredients and therefore satisfies criterion III, it will play a significant role in resistance management. In onions and leeks, Landis (2019) claimed that pyroxasulfone would play a significant role in integrated pest management programs. Based on the supporting evidence in the registrant's submission BEAD determined that pyroxasulfone did meet criteria IV as according various extension sources helps reduce overall herbicide usage and pest management efforts within these two crops. The information submitted by Landis meets the criteria established under FIFRA (3)(c)(1)(F)(ii) Criterion III or Criterion IV for 9 of the 11 petitioned minor use sites. Pyroxasulfone likely will play a significant role in either resistance management and/or integrated pest management for: faba bean, fescue, orchardgrass, perennial ryegrass, peppermint, spearmint, popcorn, onions and leek.

REFERENCES

EPA, 2018. Pesticide Registration Notice 2018-1. https://www.epa.gov/pesticides/epa-updates-method-establishing-economic-minor-use

Landis. 2019. Petition for 3 Years Extension of Exclusive Data Use for Pyroxasulfone as Provided for Under FIFRA Section 3(c) (1) (F) (ii). Landis International, Inc. (MRID 51028901)

United States Department of Agriculture (USDA). 2017. Census of Agriculture. National Agricultural Statistics Services (NASS). Available online at https://agcensus.usda.gov/Publications/2017/. July 2020.