



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

February 5, 2020

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Review of Bayer CropScience's Request for an Extension of the Exclusive Use Period for Indaziflam

FROM: Jeana Hansel, Plant Pathologist
Biological Analysis Branch

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THRU: Monisha Kaul, Chief
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A handwritten signature in blue ink, appearing to read "Monisha Kaul".

TO: Emily Schmid, Product Manager
Sarah Meadows, Risk Manager Reviewer
Registration Division (7505P)

Product Review Panel Date: January 22, 2020

SUMMARY

Bayer CropScience (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 herbicide indaziflam be extended for three years. Bayer claims indaziflam 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). Bayer (2019) submitted supporting information for twelve crops. All twelve crops meet the definition of a minor use as each crop had less than 300,000 acres bearing or harvested, and residue data were sufficient for eleven crops.

BEAD determined that at least nine of the twelve petitioned minor use sites satisfy at least Criterion III. Indaziflam plays a significant role in resistance management in lemon or lime, pear, sweet cherry, apricot, raspberry, pistachio, olive, coffee, and hop. Therefore, the request for indaziflam satisfies the necessary criteria for the nine necessary minor use sites 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(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.

BEAD evaluated whether at least nine use sites submitted in Bayer’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.

REGISTRANT SUBMISSION

The registrant claims that indaziflam satisfies the FIFRA Section 3(c)(1)(F)(ii) requirements for the following 12 use sites: lemon, lime, pear, sweet cherry, tart cherry, apricot, raspberry, blueberry (highbush), pistachio, olive, coffee, and hop (Bayer 2019). The registrant claims all uses are associated with a residue trial, are grown on less than 300,000 acres, and that indaziflam plays a significant part in resistance management and integrated pest management for all claimed minor use sites (criteria III and IV).

BEAD ANALYSIS

Residue Trial 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. Finally, BEAD evaluates the biological benefits submitted by the registrant to determine if the claimed criteria are met. Of the 12 crops listed in the registrant submission, all are supported by residue data (Table 1). However, in the case of citrus fruits, the registrant proposed more minor use sites than supporting representative crop residue data provided for the crop subgroup; therefore, only one proposed minor use site in citrus is eligible for qualification of extension of exclusive use. 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
Lemon	Citrus Fruit (10-10B)	Lemon (4/7/2011; 47743405)	1 (Lemon or Lime)
Lime			
Pear	Pome Fruit (11-10)	Pear (4/7/2011; 47743402)	1
Sweet Cherry	Stone Fruit (12-12A)	Sweet Cherry & Tart Cherry (4/7/2011; 47743403)	2
Tart Cherry			
Apricot	Stone Fruit (12-12C)	Peach (4/7/2011; 47743403)	1
Raspberry	Berry & Small Fruit (13-07A)	Raspberry (7/5/2017; 49752803)	1
Blueberry (highbush)	Berry & Small Fruit (13-07B)	Blueberry (highbush) (7/5/2017; 49752802)	1
Pistachio	Tree Nut (14-12)	Almond (4/7/2011; 47743404)	1
Olive	Tropical & Subtropical Fruit; Edible Peel (23A)	Olive (4/7/2011; 47743407)	1
Coffee	Miscellaneous	Coffee (7/5/2017; 49752801)	1
Hop	Miscellaneous	Hop (7/5/2019; 49752804)	1

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 all 12 sites listed in Table 1, 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. hop) are evaluated for harvested acreage. The national acreage reported by Bayer (2019) matches acreage reported by BEAD due to use of the same source. Both lemon and lime are considered minor uses; therefore, either may be used to qualify for an extension of data protections.

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

Minor Use Site	Claimed Acreage	Crop Acres Grown
Lemon	59,001	59,001
Lime	1,051	1,051
Pear	51,435	51,435
Sweet Cherry	93,866	93,866
Tart Cherry	35,944	35,944
Apricot	12,179	12,179
Raspberry	20,646	20,646
Blueberry (highbush)	97,515	97,515
Pistachio	247,872	247,872
Olive	40,915	40,915
Coffee	8,441	8,441
Hop	59,429	59,429

Source: USDA 2017.

REQUIREMENTS TO QUALIFY FOR THE CLAIMED CRITERIA

Bayer has claimed that indaziflam qualifies for criteria III and IV for all claimed minor use sites.

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 indaziflam

The registrant claims that indaziflam plays an important role in control of weeds resistant to glyphosate, triazines, acetolactate synthase (ALS) inhibitors, and growth regulators for all identified minor use sites. Indaziflam is one of few herbicides classified as a cellulose biosynthesis inhibitor and is the only registered herbicide in the alkylazine group (L/29) (WSSA, 2019). The registrant notes that field resistance to this group of herbicides has not been detected in any weed species (Brabham et al. 2014; Heap 2014; see Bayer 2019). The registrant states that indaziflam is commonly applied in tank mixtures and/or in rotation with other herbicides to prevent development and spread of herbicide-resistant weed populations (Green 2014; Jhala et al. 2013; see Bayer 2019).

For citrus fruits (lemon or lime), pear, sweet cherry, apricot, raspberry, pistachio, olive, and hop, the registrant claims that indaziflam manages herbicide-resistant weeds commonly found within and adjacent to plantings, such as glyphosate-resistant rigid ryegrass, horseweed, junglerice, and amaranth, and weeds resistant to multiple herbicides, such as hairy fleabane and Italian ryegrass (Hanson 2014; Heap 2014; see Bayer 2019). The registrant provided evidence of herbicide resistance in these weeds in states that produce these crops (Heap 2014; USDA 2017; see Bayer 2019). Additionally, the registrant provided evidence of indaziflam's ability to control the specified weeds (Jhala et al. 2013; Sebastian et al. 2017; see Bayer 2019).

For coffee, the registrant claims that indaziflam manages metribuzin-resistant goosegrass, which is commonly found within and adjacent to orchards in Hawaii, the principal producer of coffee in the United States (Heap 2014; USDA 2017; see Bayer 2019). The registrant provided evidence that indaziflam effectively controls populations of goosegrass with documented herbicide resistance (McCullough et al. 2013; McElroy et al. 2017; see Bayer 2019). Indaziflam will help to manage herbicide resistance in herbicide-resistant goosegrass populations in coffee plantations as there is no documented resistance to indaziflam in any weed species (Brabham et al. 2014; Heap 2014; see Bayer 2019).

BEAD concludes that for the nine qualifying sites listed above (lemon or lime, pear, sweet cherry, apricot, raspberry, pistachio, olive, coffee, and hop), indaziflam satisfies criterion III and will play an important role in herbicide resistance management for specified weeds in these crops. Therefore, nine distinct minor use sites qualify for extension of exclusive use of indaziflam under criterion III, and indaziflam qualifies for the full three-year extension of exclusive use. BEAD did not evaluate whether indaziflam use in the remaining sites, blueberry and tart cherry, would also play a significant role in resistance management. Furthermore, BEAD did not evaluate the applicability of criterion IV to indaziflam, as it qualifies for the maximum three-year extension of exclusive use under criterion III.

CONCLUSION

BEAD finds the registrant has provided sufficient evidence to support a three-year extension of exclusive use of data for indaziflam under FIFRA Section 3(c)(1)(F)(ii). BEAD found that for lemon or lime, pear, sweet cherry, apricot, raspberry, pistachio, olive, coffee, and hop, indaziflam provides an alternative mode of action to control weeds resistant to other herbicides and therefore satisfies criterion III and plays a significant role in herbicide resistance management.

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