



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

May 8, 2023

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: A Review of Syngenta's Petition for Extension of Exclusive Use for Benzovindiflupyr (PC: 122305) (DP#465161)

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Product Review Panel Date: April 5, 2023

SUMMARY

Syngenta Crop Protection, LLC (Syngenta) 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 benzovindiflupyr fungicide for three years. Syngenta claims benzovindiflupyr fills a void in current fungal disease control programs and/or plays or will play a part in risk reduction, fungicide resistance management, and integrated pest management programs, thus satisfying criteria I, II, III and IV as defined under FIFRA 3(c)(1)(F)(ii) in all claimed crops.

BEAD finds that all twenty crop use sites claimed by Syngenta meet the criterion for minor use designation, i.e., less than 300,000 acres of each crop are grown or harvested in the United States and are supported by residue data.

BEAD finds the registrant submitted sufficient evidence for nine minor use sites (blueberry, sweet potatoes, triticale, garlic, bell peppers, non-bell peppers, watermelon, cucumber, and squash) to satisfy a minimum of one criterion for each use site for extension of exclusive use for benzovindiflupyr under FIFRA Section 3(c)(1)(F)(ii).

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 registered within 7 years of the commencement of the exclusive use period and 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.” Therefore, 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

Benzovindiflupyr fungicide belongs to code 7 as per fungicide Resistance Action Committee (FRAC, 2022). Benzovindiflupyr was initially registered in 2015 and is effective in controlling fungal pests in many crops. The registrant claimed that benzovindiflupyr satisfies the FIFRA Section 3(c)(1)(F)(ii) requirements for twenty use sites: blueberry [low bush], sweet potatoes, triticale, garlic, onion [green], ginseng, dry lima bean, dry Southern pea, bell pepper, non-bell peppers, eggplant, tomatillo, cucumber, watermelon, squash, pear, quince, kiwifruit, sesame, and fescue grass (Syngenta, 2022). The registrant claims all uses are individually associated with residue trial, are grown on less than 300,000 acres, there are insufficient registered alternatives pesticides, that benzovindiflupyr 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. The claimed criterion for each crop is presented in Table 2.

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 pest control 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 does not determine risks 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 (such as biological control, cultural practices).

BEAD ANALYSIS

BEAD first confirms that residue trial data are sufficient such that there is a one-for-one relationship for each claimed 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 claimed evidence submitted by the registrant to determine if the claimed criteria are met. Nine qualifying use sites must satisfy a minimum of one criterion for three-year extension of exclusive use for benzovindiflupyr under FIFRA Section 3(c)(1)(F)(ii).

Residue Trial Analysis

The registrant's submission showed that all crops are supported by residue data (Table 1). The registrant can claim all crops as minor use as each crop is cultivated on less than 300,000 acres (Table 2).

Table 1. Benzovindiflupyr* proposed crops and representative residue data by crop/ crop subgroup.

Minor Use Claimed	Crop Group (subgroup); Date Registered	Residue Data Submitted: MRID # and date **	Maximum Number of Minor Use Sites Allowed
Blueberry (low bush)	Crop Subgroup 13B; 12/17/20	48604597 (1), 50803801 (10/24/19)	1
Sweet Potatoes	Crop Group 1C; 8/28/15	48604575 (1)	1
Triticale	Cereal Grains, CG 15; 8/28/15	48604476 (1) 48604592 (1) 48604482 (1)	1
Garlic	Crop Group 3-07A; 12/21/17	49929801 (6/3/16)	1
Onion, green	Crop Group 3-07B; 12/21/17	49929801 (6/3/16)	1
Ginseng	Crop Subgroup 1-B; 12/17/20	50803802 (10/24/19)	1
Dry Lima Bean	Crop Subgroup 6C; 8/28/15	48604573 (1) 48604487 (1) 48604488 (1)	2
Dry Southern Peas			
Bell Peppers	Fruiting Vegetables CG 8-10; 8/28/15	48604574 (1)	4
Non-bell Peppers			
Eggplant			
Tomatillo			
Cucumbers	Crop Group 9; 8/28/15	48604576 (1)	3
Watermelon			
Squash			
Pear	Crop Group 11-10; 8/28/15	48604479 (1) 48604484 (1) 48604485 (1)	2
Quince			
Kiwifruit	Grape and small fruit vine 13-07F; 8/28/15	48604481 (1) 48604594 (1)	1

Minor Use Claimed	Crop Group (subgroup); Date Registered	Residue Data Submitted: MRID # and date **	Maximum Number of Minor Use Sites Allowed
Sesame	Rapeseed Crop Group 20A; 8/28/15	48604486 (1)	1
Fescue Grass	Grasses Grown for Seed-Cool Season, Crop Group-17; 6/14/18	50101701 (12/22/16)	1

*Initial registration date was August 28, 2015.

**Residue data submitted (1) on 11/26/2012 or date indicated in parenthesis

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 20 use sites listed in Table 1, the total U.S. acreage is less than 300,000 acres for each site qualifying them as minor crops (Table 2).

Table 2. Acreage of crops and criteria claimed by registrant for extension of exclusive use for benzovindiflupyr.

Minor Use Site	Crop Acres Grown ¹	Criteria Claimed
Blueberry (Lowbush)	89,200	IV
Sweet Potatoes	172,983	I, III
Triticale	81,475	I, III
Garlic	43,903	I, III, IV
Onion, Green	6,792	I, III, IV
Ginseng	1,050	III, IV
Dry Lima Beans	21,557	I, III
Dry Southern Peas	32,312	I, III
Bell peppers	48,801	III, IV
Non-bell peppers	24,165	III, IV
Eggplant	5,365	I, III, IV
Tomatillo	Not in Census ²	I, III, IV
Cucumbers	119,655	III, IV
Watermelon	129,790	III, IV
Squash	70,190	III, IV
Pear	56,719	I, II, III
Quince	Not in Census ²	I, II, III
Kiwifruit	4,354	II, IV
Sesame	55,178	III, IV
Fescue Grass	170,284	III, IV

¹USDA NASS 2017.

²The USDA NASS does not survey tomatillo and quince, indicating that crop acreage is below 300,000 acres.

BEAD Assessment of Claimed Criteria for Minor Crops

BEAD reviewed claimed criteria for benzovindiflupyr to determine if nine or more minor crops meet at least one claimed criterion. The evaluation is complete if nine qualifying use sites meet at least one claimed criterion for eligibility of a three-year extension of exclusive use for benzovindiflupyr.

Blueberry (lowbush):

Syngenta (2022) claimed that benzovindiflupyr will play an important role in integrated management of rust disease in blueberry as the pathogen can survive on alternate host (hemlock) that can result in rust disease epidemic (UGA, 2015). Benzovindiflupyr is effective in controlling rust disease (Syngenta, 2022). BEAD finds that the fungicides dominantly used for controlling rust disease in blueberry (lowbush) include strobilurins (e.g., azoxystrobin, pyraclostrobin) and triazoles (e.g., propiconazole, metconazole and prothioconazole) (Burrack, 2021; Brannen, 2017). Benzovindiflupyr is effective in controlling rust disease on blueberry (Brannen, 2017) and its mode of action is different than commonly used fungicides for controlling the disease (Brannen, 2017) and therefore can play a role in resistance management. Also, BEAD finds that benzovindiflupyr can play an important role in an integrated pest management program for controlling rust disease in blueberry (lowbush) when used with cultural practices (such as removal of alternate host [hemlock]) to reduce pathogen inoculum and with fungicides having different mode of action. Based on submitted and available information, BEAD finds that claimed criteria III and IV are met.

Sweet Potatoes:

Syngenta (2022) claimed that *Rhizoctonia* disease of sweet potatoes can severely affect crop yields and quality. Azoxystrobin (a strobilurin fungicide, code 11 [FRAC, 2022]) is widely used fungicide for controlling *Rhizoctonia* disease due to its high efficacy (Noor and Khan, 2018; Syngenta, 2022) but resistance development in the pest is a major concern for growers (Syngenta, 2022) as it has single site mode of action (FRAC, 2022). The submitted data show that benzovindiflupyr fungicide has high efficacy in controlling *Rhizoctonia* (Syngenta, 2022) and belongs to another class of fungicides (SDHI fungicides, code 7) [FRAC, 2022]. BEAD finds that there are inadequate number of effective registered alternatives in controlling *Rhizoctonia* in sweet potatoes. BEAD also finds that benzovindiflupyr can play a role in fungicide resistance management as its mode of action is different than azoxystrobin. Based on submitted and available information, BEAD finds that claimed criteria I and III are met.

Triticale:

Syngenta (2022) claimed that benzovindiflupyr is highly effective in controlling rust and glume blotch diseases of cereals including triticale (Bond, 2015). Strobilurins (e.g., azoxystrobin and pyraclostrobin) and triazoles (such as propiconazole and tebuconazole) fungicides are dominantly used in controlling rust and glume blotch diseases in triticale (Syngenta, 2022). The efficacy of strobilurins and triazole fungicides in controlling cereals diseases is declining, after many years of continuous use, due to tolerance or resistance in fungal pests (Syngenta, 2022; Sukut and Koycu, 2019). Benzovindiflupyr has different mode of action (code 7) than strobilurins (code 11) and triazoles (code 3) as per Fungicide Resistance Action Committee (FRAC, 2022). In 2020, Syngenta registered a combination of benzovindiflupyr, azoxystrobin and propiconazole (Trivapro®) for more effective control of rust and glume blotch disease in triticale and resistance management (Syngenta, 2022). Based on submitted and available information, BEAD finds that claimed criterion III is met.

Garlic:

Syngenta (2022) claimed that benzovindiflupyr is more efficacious than its widely used alternatives (tebuconazole, azoxystrobin) in controlling rust disease, and plays a role in fungicide resistance management and IPM. Review of publicly available information showed that tebuconazole (FRAC code 3), azoxystrobin (FRAC code 11) and mancozeb (FRAC code M03) are recommended and used for controlling garlic rust (Swett *et al.*, 2019). Benzovindiflupyr has different mode of action (FRAC Code 7) than these fungicides and therefore benzovindiflupyr fungicide plays a role in fungicide resistance management when used in combination and/or rotation with fungicides having different mode of action. The registrant did not elaborate on the role of benzovindiflupyr in IPM, therefore EPA did not assess their claims under criterion IV. Based on submitted and available information, BEAD finds that claimed criterion III is met.

Bell peppers, non-bell peppers, Watermelon, Cucumber and Squash:

Syngenta (2022) claimed that anthracnose disease (caused by *Colletotrichum gloeosporioides* and *C. acutatum*) in bell-pepper and non-bell peppers is highly destructive and can cause high yield losses (Wyenandt, 2016; Syngenta, 2022). Syngenta (2022) also claims that anthracnose disease (caused by *C. orbiculare*) in cucurbits (watermelon, cucumber, and squash) is an aggressive and highly destructive disease that can result in heavy yield losses (McGrath and Zittler, 2022). To control anthracnose disease there are registered alternatives available to growers (azoxystrobin, pyraclostrobin, trifloxystrobin, difenoconazole, famoxadone, mancozeb, copper, fluopyram, fluxapyroxad, penthiopyrad). Among the registered alternatives, FRAC code 7 fungicides are either not effective (fluopyram and fluxapyroxad) or weakly effective (penthiopyrad) in controlling the pest (Syngenta, 2022) whereas benzovindiflupyr is highly effective in controlling the pest (*C. gloeosporioides*, *C. acutatum* and *C. orbiculare*) ((Ishii, *et al.*, 2016; Ishii, *et al.*, 2022; Liang *et al.*, 2022; Syngenta, 2022). Therefore, benzovindiflupyr can be used by growers in combination and/or rotation with other fungicides having different mode of action for resistance management. Based on submitted and available information, BEAD finds that claimed criterion III is met for bell peppers, non-bell peppers, watermelon, cucumber, and squash.

Green onions, Ginseng, Dry lima beans, Dry Southern peas, Eggplant, Tomatillo, Pear, Quince, Kiwifruit, Sesame and Fescue grass

BEAD did not evaluate these crops to determine if they meet at least one claimed criterion for extension of exclusive because nine crops have already met the criterion for maximum eligibility of a three-year extension of exclusive use for benzovindiflupyr.

CONCLUSION

BEAD finds that the registrant submitted sufficient evidence for nine minor use sites (blueberry [lowbush]), sweet potatoes, triticale, garlic, bell peppers, non-bell peppers, watermelon, cucumber, and squash) to satisfy one or more criteria for extension of exclusive use for benzovindiflupyr under FIFRA Section 3(c)(1)(F)(ii).

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