OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
WASHINGTON, D.C. 20460

April 15, 2026

MEMORANDUM

SUBJECT: A Review of Valent's Petition for Extension of Exclusive Use of Mandestrobin (PC: 036603) (MRID: 52377301; Task Group Number: 00654687)

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SUMMARY

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

Eight crops out of ten use sites claimed by Valent are supported by residue data and meet the criterion for minor crops as each is grown on less than 300,000 acres.

BEAD determined that the registrant submitted sufficient evidence that three minor use sites (sweet potato, lettuce [head], lettuce [leaf]) satisfy a minimum of one criterion under FIFRA Section 3(c)(1)(F)(ii) for a one-year extension of exclusive use of data for mandestrobin.

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 by one year for every 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. In addition, the uses must meet at least one of the following criteria:

(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." 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.

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 cannot evaluate risk 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).

REGISTRANT SUBMISSION

Mandestrobin belongs to code 11 as per the Fungicide Resistance Action Committee group 11 (FRAC, 2025). Mandestrobin was initially registered in 2016 and is effective in controlling fungal diseases in many crops. The registrant claimed that mandestrobin satisfies the FIFRA Section 3(c)(1)(F)(ii) requirements for ten use sites: sweet potato, lettuce (head), lettuce (leaf), strawberry, flaxseed, hardy kiwifruit, green pea, lima bean, snap bean and popcorn (Valent USA LLC, 2025).

The registrant states that all ten crops are individually associated with residue trials (Table 1), are grown on less than 300,000 acres, have insufficient registered alternatives pesticides, and that mandestrobin plays or will play a part in resistance management, and/or an integrated pest management program (criteria I, III, and/or IV) for each of the claimed minor use sites. The claimed criterion for each crop is presented in Table 2.

BEAD ANALYSIS

BEAD first confirms that the residue trial data submitted by the registrant is sufficient such that there is a one-for-one relationship for each claimed use site. In this case, green peas and lima bean were withdrawn for consideration for this request by the registrant as residue studies were done for only soybean in crop group 6, Table 1. 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.

Residue Trial Analysis

Table 1. Proposed crops and representative residue data by crop/ crop subgroup (Valent, 2025).

Minor Use Claimed	Crop Group (subgroup); Date Registered	Residue Data Submitted: MRID # (date)	Maximum Number of Minor Uses Allowed
Sweet Potato	Root and Tuber Vegetables, Crop Group 1D	51689001 (03/08/2023)	1
Lettuce (Head)	Leafy Vegetables, Crop Group 4	51130601 (06/29/2022)	2
Lettuce (Leaf)			
Strawberry	Berry and small Fruit, Crop Group 13-07	49068678 (09/30/2016)	1
Hardy Kiwifruit	Berry and small Fruit, Crop Group 13-07	49068676 (09/30/2016)	1
Flaxseed	Oilseed Group, Crop Group 20	49068671 (06/29/2022)	1
Green Peas*	Crop Group 6	49068674 (07/23/2020)	1
Lima Bean*			
Snap Bean			
Popcorn	Cereal Grains, Crop Group 15	49068673 (07/23/2020)	1

*Registrant withdrew for consideration for this request as only one crop qualifies based on residues studies in soybean in crop group 6 (Valent, 2025b).

Minor Use Analysis

The Environmental Protection Agency (EPA) relies on the USDA Census of Agriculture for data on crops grown in the United States (USDA, NAAS 2022). If a crop is not listed in the Census of Agriculture, per discussion with USDA, the acreage of the crop is 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. Table 2 shows the total U.S. acreage is less than 300,000 acres for each site, qualifying them as minor crops.

Table 2. Acreage of crops and criterion claimed by registrant for extension of exclusive use for mandestrobin.

Minor Use Site	Crop Acres Grown[1]	Criterion Claimed by Registrant
Sweet Potato	168,052	I
Lettuce (Head)	142,488	IV
Lettuce (leaf)	91,745	IV
Strawberry	73,462	III
Hardy Kiwifruit	4,930	III
Flaxseed	262,200	I
Snap Bean	206,030	I
Popcorn	204,412	IV

[1]USDA NASS 2022

BEAD Assessment of Claimed Criteria

Applicability of Criterion I to Mandestrobin (insufficient efficacious alternative registered)
(Sweet Potato, Flaxseed, and Snap Bean)

The registrant claims that there are insufficient efficacious alternative registered pesticides to mandestrobin for application in sweet potato at planting to control black rot disease, and in flaxseed and snap bean to control *Rhizoctonia* diseases. BEAD considers this criterion to be met in sweet potato only as discussed below.

Sweet Potato: Black rot disease is caused by *Ceratocystis fimbriata*. Fungal infection commonly occurs from infected parent planting material (slips) or infested soil/equipment. The pathogen can also survive for many years in the soil (Valent, 2025a). Disease symptoms (dry firm rot of dark color) on tuberous root are observed at harvest and/or during storage (Valent, 2025a). Mandestrobin is applied as in-furrow treatment at planting for controlling the disease. The registrant claimed that mandestrobin alternatives are a premix of azoxystrobin+fludioxonil (FRAC 11 + 7), azoxystrobin+fludioxonil+difenoconazole (FRAC 11+7+3), and polyoxin D zinc salt (FRAC 19).

BEAD determined that a premix of azoxystrobin+fludioxonil (FRAC 11+7) and azoxystrobin+fludioxonil+difenoconazole (FRAC 11+7+3) are labeled as postharvest treatment of sweet potato to control black rot in storage, not at the time of planting. Polyoxin is not labeled for controlling black rot disease (caused by *Ceratocystis fimbriata*) in sweet potato. BEAD finds that thiabendazole and metconazole are registered for treating sweet potato and are not labeled for application as in-furrow treatment at planting to control the disease. Therefore, BEAD concludes that claimed criterion is met because only mandestrobin is available to growers that can be applied as in-furrow treatment at planting to control black rot disease.

Flaxseed and Snap Bean*: Rhizoctonia solani* causes damping-off and seedling diseases in both crops (Valent, 2025a).

The registrant claimed that for treating flaxseed, registered alternatives include fludioxonil (FRAC code 12), penflufen (FRAC code 7), sedaxane (FRAC code 7), and a combination of fluxapyroxad (FRAC code 7)+pyraclostrobin (FRAC code 11)+metalaxyl (FRAC code 4) (Valent, 2025a).

BEAD finds that in addition to registrant's claimed alternatives, inpyrfluxam (FRAC code 7) and pyraclostrobin are registered for controlling *R. solani* disease in flaxseed. BEAD concluded that there are multiple alternatives available for controlling *R. solani* in flaxseed and these are considered effective in controlling *R. solani* diseases (Holzapfel, 2018). Therefore, the submitted information does not support claimed criterion.

For snap bean, the registrant claimed that only trifloxystrobin is registered for seed treatment to control *R. solani* and is insufficient in controlling *R. solani* disease in snap bean.

BEAD found that in addition to mandestrobin and trifloxystrobin other alternatives fungicides [azoxystrobin (FRAC code 11), pyraclostrobin (FRAC code 11), trifloxystrobin (FRAC code 11), fludioxonil (FRAC code 12) and penthiopyrad (FRAC code 7)] are registered for seed treatments to control *R. solani* diseases in snap bean. Registered alternatives are considered effective in controlling the pathogen (Egel, 2021). Therefore, the submitted information does not support claimed criterion.

Applicability of Criterion III to Mandestrobin (role in resistance management):
(Strawberry and Hardy Kiwifruit)

Strawberry*:* The registrant claimed that gray mold, caused by *Botrytis cinerea*, in strawberries is an important disease that affects above ground plant parts including leaves, flowers, and fruits. Gray mold can cause yield losses of 50 percent or higher (Mertely, et al., 2022). The registered fungicide alternatives for controlling gray mold in strawberries include: cyprodinil+fludioxonil (FRAC code 9+12), pyraclostrobin+fluxapyroxad (FRAC code 11+7), pyraclostrobin+boscalid (FRAC code 11+7), penthiopyrad (FRAC code 7), isofetamid (FRAC code 7), fluopyram+trifloxystrobin (FRAC code 7+11), fluopyram (FRAC code 7), captan (FRAC code M4), thiram (FRAC code M3), fenhexamid (FRAC code 17), iprodione (FRAC code 2), and thiophanate-methyl (FRAC code 1). The registrant

claimed that mandestrobin serves as an option for *Botrytis* control in strawberry with no reported fungicide resistance issue in the fungal pathogen and will play a role in resistance management.

BEAD agrees with the registrant that multiple fungicides having different modes of action (MOA) are registered in controlling gray mold disease in strawberries. Botrytis in strawberries has developed resistance to many fungicides (UC IPM, 2024) and to manage the disease frequent application of mixtures of various fungicides are recommended (Koike, et al 2018). Mandestrobin has been reported to have limited and/or erratic or low efficacy in controlling gray mold in strawberry (Blauer and Holmes, 2019) due to resistance in the pathogen (UC IPM, 2024). A fungicide is unlikely to play a significant part in managing pest resistance if the pest has already developed resistance against it. Therefore, the submitted information does not support criterion III. The registrant withdrew strawberry for consideration for this request because of documented resistance in *Botrytis cinerea* to mandestrobin and strobilurin fungicides (2025b).

Hardy Kiwifruit: Gray mold, caused by *Botrytis cinerea*, infects stem ends and sepals of kiwi fruits resulting in fruit rotting in storage. The registered alternatives to control this disease include azoxystrobin (FRAC code 11), azoxystrobin+difenoconazole (FRAC code 11+3), trifloxystrobin (FRAC code 11), difenoconazole+cyprodinil (FRAC code 3+9), cyprodonil+fludioxonil (FRAC code 9+12), and isofetamid (FRAC code7). The registrant claimed that mandestrobin serves as an option for *Botrytis* control on hardy kiwifruit with no reported fungicide resistance issue in the fungal pathogen and will play a role in resistance management.

BEAD determined that multiple fungicides having different MOAs are registered for controlling the disease and managing resistance in the pathogen. BEAD determined that fungicide resistance and cross resistance is present in the pathogen to strobilurin fungicides including mandestrobin (FRAC, 2025). A fungicide is unlikely to play a significant part in managing pest resistance if the pest has developed resistance against it. Therefore, the submitted information does not support criterion III. The registrant withdrew hardy kiwifruit crop for consideration for this request due to resistance in *Botrytis cinerea* to strobilurin fungicides (2025b).

Applicability of Criterion IV to Mandestrobin (role in IPM):
(Lettuce (Head), Lettuce (Leaf) and Popcorn)

Integrated pest management (IPM) programs use current information on the life cycles of pests and their interaction with the environment. This information, in combination with available pest control methods, is used to manage pests with the most economical means and while considering relative risks of various methods, thus minimizing risk to people, property, and the environment. IPM takes advantage of all appropriate pest management options. In other words, pesticides are a component of an IPM program, but IPM does not rely solely on pesticides (EPA, 2025).

Lettuce (Head) and Lettuce (Leaf): *Sclerotinia sclerotium* and *S. minor* infect lower leaves and stems of lettuce (head) and lettuce (leaf) in contact with soil, leading to a soft brown decay that can kill the crown and cause the plants to collapse near harvest time and is called lettuce

drop. Pathogens can be windborne or soilborne and survive in soil for two to three years (Valent 2025). Registered alternatives for both types of lettuce include: fluopyram (FRAC code 7), pydiflumetofen+fludioxonil (FRAC code 7+12), cyprodinil+fludioxonil, (FRAC code 9+12), trifloxystrobin+fluopyram (FRAC code 11+7), isofetamid (FRAC code 7), boscalid (FRAC code 7), pyraclostrobin+fluxapyroxad (FRAC code 11+7), penthiopyrad (FRAC code 7), and pyrclostrobin+boscalid (FRAC code 11+7). These fungicides are applied immediately after plant emergence or at transplanting in the field and have limited efficacy in reducing disease incidence (about 50-70 percent) (Matherson and Porchas, 2019). The registrant claimed that mandestrobin is effective in controlling the disease (Kuack, 2023), can be applied up to 10 days after transplant and will serve as a rotational partner in IPM programs.

BEAD finds that mandestrobin is effective in inhibiting *Sclerotinia* spp. and controlling the disease (Hirotomi et al., 2016). *Sclerotinia* spp. are difficult to control, and integrated management of this pest is recommended (Matheron and Porchas, 2019, Koike and Turini, 2017; Mersha, 2016). BEAD determined that mandestrobin can play a significant role in integrated pest management in both types of lettuce when used in combination with cultural practices such as depth of seed planting, soil moisture management, plant row spacing, and/or sanitation. Therefore, criterion IV is met.

Popcorn: *Rhizoctonia solani* damping off and seedling blight diseases are common problems in popcorn resulting is seedling death and yield losses (Valent, 2025a). The registrant mentioned that many fungicides are registered for use in popcorn as seed treatment that are in FRAC groups 1, 3, 4, 7, 11, and 12 for controlling this pathogen and mandestrobin will add another option for growers.

BEAD agrees that many fungicides are registered for popcorn seed treatment that are in FRAC code 1 (thiabendazole), 3 (ipconazole), 7 (sedaxane), 11 (azoxystrobin, pyraclostrobin, trifloxystrobin) and 12 (fludioxonil). The registrant did not elaborate on how mandestrobin will play a role in IPM. Therefore, the submitted information does not support criterion IV.

CONCLUSION

In conclusion, BEAD finds that three minor crop use sites (sweet potato, lettuce (head), and lettuce (leaf) claimed by the registrant meet the criterion for extension of exclusive use. Other use sites (strawberry, hardy kiwifruit, flaxseed, snap bean and popcorn) did not meet the claimed criterion for extension of exclusive use. Strawberry and hardy kiwifruit were withdrawn for consideration for this request by the registrant as resistance in the claimed pathogen (*Botrytis cinerae*) has been reported to strobilurin fungicides.

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