



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 26, 2021

Lauren Seabrook
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Subject: Product Name: Xemium Fungicide Technical
EPA Reg. No.: 7969-312
Decision No.: 557738
Application Date: November 21, 2019
EPA Finding: Extend the exclusive use data protection period for fluxapyroxad on minor crops by 3 years from May 11, 2022 to May 11, 2025.

Dear Ms. Seabrook:

This letter addresses your request that certain data associated with the original registration of fluxapyroxad receive a three-year extension to the ten-year exclusive use protection period. Xemium Fungicide Technical (EPA Reg. No. 7969-312) was first registered by the agency on May 11, 2012 and the data protection period will expire on May 11, 2022. Though only nine registered minor crops are needed to support the request, the following sixteen were cited:

| Crop Group/Subgroup | Crop Data Submitted ^a | Minor Use Represented ^b |
|---|----------------------------------|------------------------------------|
| Fruiting Vegetables; Pepper/Eggplant Subgroup (8-10B) | Chili Pepper; Bell Pepper | Chili Pepper; Bell Pepper |
| Stone Fruit; Cherry Subgroup (12-12A) | Sweet Cherry | Sweet Cherry |
| Stone Fruit; Peach Subgroup (12-12B) | Peach | Peach |
| Legume Vegetables; Edible-Podded Subgroup (6A) | Soybean | Snow Pea |
| Legume Vegetables; Succulent Shelled Pea and Bean Subgroup (6B) | Garden Pea | Garden Pea |
| Brassica; Leafy Vegetables Subgroup (5A) | Broccoli | Cauliflower |
| Oilseed; Rapeseed Subgroup (20A) | Canola | Flax |
| Oilseed; Sunflower Subgroup (20B) | Sunflower | Safflower |
| Tree Nut Group (14-12) | Almond and Pecan | Hazelnut |

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| Leafy Vegetables; Leafy Greens Subgroup (4A) | Head lettuce; Leaf Lettuce; Spinach | Head Lettuce; Leaf Lettuce; Spinach |
| Leafy Vegetables; Leaf Petioles Subgroup (4B) | Celery | Celery |
| Root Vegetables Except Sugar Beet Subgroup (1B) | Carrot; Radish | Carrot; Raddish |

^a All residue data submitted by registrant were conducted on representative crops listed in this column

^b Minor use sites proposed by the registrant

EPA is granting the request for an exclusive use extension of three additional years to end on May 11, 2025 under the EPA Registration No. 7969-312. BASF Corporation cited FIFRA section 3(c)(l)(F)(ii) as the authority for EPA to make such a determination. The 1996 Food Quality Protection Act ("FQPA") amendments to FIFRA incorporated this subsection under 3(c)(l)(F). FIFRA section 3(c)(l)(F)(ii) sets forth the criteria for extending the period of exclusive use protection. The period of exclusivity can be extended one year for every three qualifying minor uses registered within the first seven years of an original registration whose data retains exclusive use protection, with a maximum addition of three years to the original ten-year exclusivity period. All of the minor use crop candidates were registered within the requisite seven years period, prior to May 11, 2019, and are grown on less than 300,000 acres per year.

The first step in determining whether data qualifies for an extension of its exclusive use period is to ascertain whether there are any exclusive use data associated with a registration. FIFRA section 3(c)(1)(F)(i) and its implementing regulations specifically describe the set of data that are eligible for exclusive use protection. A study entitled to exclusive use protection is defined in 40 C.F.R. 152.83(c), and the following requirements must be met:

- (1) The study pertains to a new active ingredient new chemical or new combination of active ingredients (new combination) first registered after September 30, 1978;
- (2) The study was submitted in support of, or as a condition of approval of the application, resulting in the first registration of a product containing such new chemical or new combination (first registration), or an application to amend such registration to add a new use; and
- (3) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B); and a study is an exclusive use study only during the 10-year period following the date of the first registration.

The following is our analysis for determining whether the data associated with the registration you have cited contains exclusive use data. First, the data associated with this registration do pertain to, or have been derived from testing on, a new active ingredient that was first registered after September 30, 1978. Second, the data were submitted in support of the first registration of the new chemical¹. The

¹ Data are not protected solely because they pertain to the new chemical, but because they are submitted in support of a particular product registration of a new chemical. Thus, data submitted to support an application for the second (and later) registrations, by whatever applicant, of a product containing the same new chemical acquire no exclusive use protection. Additionally, data submitted in support of subsequent amendments to add new uses

registration cited was granted on May 11, 2012 and was the first registration for fluxapyroxad. Third, the data were not submitted to satisfy FIFRA section 3(c)(2)(B). Data generated by IR-4 are not entitled to exclusive use protection (see 40 CFR I 52.94(b)). However, the Agency will count minor uses supported by IR-4 generated data when determining how many additional years that exclusive use protection may be extended.

Although, EPA has determined that there is exclusive use protected data associated with this registration, the Agency has not made individual determinations on every study associated with the above referenced registration as to exclusive use protection. If the Agency receives a me-too application for this pesticide during the extension period citing BASF Corporation data, it will then address which of those data have the extension of protection. Therefore, this response is a general determination that the exclusive use studies associated with this registration will receive the determined extension of exclusive use protection.

After determining that there are exclusive use data associated with this registration, EPA analyzed whether: (1) minor uses have been registered within seven years of the original registration and (2) at least one of the following required criteria were satisfied for extending the exclusive use protection pursuant to FIFRA section 3(c)(1)(F)(ii), and if so, by how many years. FIFRA section 3(c)(1)(F)(ii) states, in pertinent part:

“The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after the date of enactment of this clause, and within 7 years of the commencement of the exclusive-use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, 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.”

SUMMARY OF FINDINGS

EPA evaluated information about characteristics of fluxapyroxad, disease management claims, and production practices for the minor crops submitted. The Fungicide Resistance Action Committee (FRAC)

to the first registration of a product containing the new chemical gain exclusive use protection, but the protection is limited to data that pertain solely to the new use. Thus, for example, if the new use is approved after eight years of registration, the data supporting that use would gain exclusive use protection for only two years, or the remainder of the original 10-year exclusive use period. See 49 FR 30884, 30889.

has designed a group classification system based on a fungicide's mode of action (MOA). Fluxapyroxad is classified as a FRAC Group 7 fungicide.

BASF Corporation identified sixteen qualifying minor crops and submitted information to substantiate that each crop met at least one of the four criteria above. The Agency determined hazelnut, celery, head lettuce, leaf lettuce, spinach, carrot, and radish satisfy criterion III and peach and sweet cherry satisfy criterion IV. The Agency also determined that the nine minor uses were registered within seven years of the original registration of Xemium Fungicide Technical.

Further, the Agency verified there are fluxapyroxad tolerance citations for the nine minor use crops in 40 CFR 180.666. Additionally, each of the end-use labels contains a resistance management section and FRAC code and resistance management information. The following is a summary of each crop and the criterion that was met to count towards extending the exclusive use period. This summary was based upon the information provided by the registrant and reviewed by EPA. Please review the supporting document "Review of BASF's Petition for Extension of Exclusive Use for Fluxapyroxad" dated December 30, 2020 for a more detailed explanation of how each crop meets the standard for extending the exclusive use period.

Applicability of Criterion III to fluxapyroxad:

Hazelnut: Fluxapyroxad is the only known efficacious FRAC group 7 fungicide for control of Eastern Filbert Blight in hazelnut. Including fluxapyroxad in fungicide rotations reduces or delays the emergence and spread of fungicide resistant isolates of EFB. This satisfies criterion III for hazelnut.

Leafy Vegetables (Celery, Head Lettuce, Leaf Lettuce, and Spinach); For leafy vegetables, fluxapyroxad plays a significant part in managing several seedborne and seedling diseases. Seedborne and seedling diseases have a high risk of developing resistance, but this risk is reduced when using seed treatments compared to post-plant sprays or drenches. Fluxapyroxad has a unique MOA when used as a seed treatment on leafy vegetables and plays or will play a significant part in managing fungicide resistance in seedborne or seedling diseases which satisfies criterion III.

Carrot and Radish: For carrot and radish, fluxapyroxad plays a significant part in managing resistance several seedborne diseases including damping-off. Fluxapyroxad is the only FRAC group 7 with efficacy on damping-off of carrot and radish. Pathogens causing seedling diseases have a high risk of developing resistance, but this risk is reduced when using seed treatments compared to post-plant sprays or drenches. Fluxapyroxad has a unique MOA when used as a seed treatment on carrot and radish plays or will play a significant part in managing fungicide resistance in seedborne or seedling diseases which satisfies criterion III.

Applicability of Criterion IV to fluxapyroxad:

Dry Bulb Onions and Leeks: The use of in-field fungicide application to reduce post-harvest disease incident and severity is a key tenet of integrated pest management. FRAC group 7 fungicides, including fluxapyroxad, need to be sprayed as close to harvest as possible to reduce disease intensity and severity. There is only one product with comparable efficacy that has all the listed disease control claims in both

sweet cherry and peach as the fluxapyroxad product that is a co-formulation with pyraclostrobin. The fluxapyroxad [product has a shorter pre-harvest interval. Therefore, fluxapyroxad has unique value and plays or will play an important role in integrated pest management programs which satisfies criterion IV.

DETERMINATION

The Agency concludes that you have provided sufficient evidence to support extension of exclusive use of data under FIFRA Section 3(c)(1)(F)(ii) for at least nine minor use sites required to attain three additional years of data exclusivity under criterion III and IV and these uses were registered within seven years of the original fluxapyroxad registration. Therefore, the Agency **GRANTS** your request for a three-year extension of the original exclusive-use data protection period for data submitted to support EPA Registration No. 7969-312. Exclusive-use protection for data, which complies with 40 C.F.R. I 52.83(c), submitted in support of this registration **will expire on May 11, 2025**. A copy of our review is enclosed.

Sincerely,

Marietta Echeverria,
Acting Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

Enclosure: Review of BASF's Request for an Extension of the Exclusive Use Period for Fluxapyroxad.