



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 10, 2019

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Subject: Product Name: Fluopyram Technical
EPA Reg. No.: 264-1077
Decision No.: 544124
Application Date: July 31, 2018
EPA Finding: Extend the exclusive use data protection period for fluopyram by 3 years from February 2, 2022 to February 2, 2025.

Dear Ms. Fernandez:

This letter addresses your request that certain data associated with the original registration of fluopyram receive a three-year extension to the ten-year exclusive use protection period. Fluopyram technical (EPA Reg. No. 264-1077) was first registered by the agency on Feb 2, 2012 and the data protection period will expire on February 2, 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
Root and Tuber Vegetables (1C)	Potato	Sweet Potato
Brassica Vegetable (5A)	Broccoli	Broccoli
Brassica Vegetable (5A)	Cabbage	Cabbage
Brassica Vegetable (5A)	Cauliflower	Cauliflower
Cucurbit Vegetables (9)	Cucumber	Cucumber
Cucurbit Vegetables (9)	Summer Squash	Pumpkin
Cucurbit Vegetables (9)	Muskmelon	Watermelon
Cucurbit Vegetables (9)	Muskmelon	Cantaloupe
Citrus Fruit (10-10)	Grapefruit	Grapefruit

Citrus Fruit (10-10)	Lemon	Lemon
Citrus Fruit (10-10)	Orange	Tangerines
Stone Fruit (12-12)	Plums	Apricot
Stone Fruit (12-12)	Peaches	Peach
Stone Fruit (12-12)	Cherries	Sweet Cherry
Berry and Small Fruit (13-07G)	Strawberry	Strawberry
Tree Nuts (14-12)	Almond and Pecan	Pistachio

^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 February 2, 2025 under the EPA Registration No. 264-1077. Bayer Crop Science cited FIFRA section 3(c)(1)(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)(1)(F). FIFRA section 3(c)(1)(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 Feb 2, 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 registration cited was granted on February 2, 2012 and was the first registration for fluopyram. 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 Bayer Crop Science 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;

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 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.

- (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 fluopyram, disease claims, and production practices for the minor crops submitted. The Fungicide Resistance Action Committee (FRAC) has designed a group classification system based on a fungicide's mode of action. Fluopyram is classified as a FRAC Group 7 fungicide. The mode of action of fluopyram for nematodes and fungi is inhibition of succinate dehydrogenase (SDHI) at protein complex II in the mitochondrial respiration chain.

Bayer Crop Science 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 the following nine minor uses met either criterion III or IV. The Agency also determined that the following nine minor uses were registered within seven years of the original registration of Fluopyram Technical: broccoli, cabbage, cucumber, cantaloupe, pumpkin, pistachio, strawberry, sweet cherry, and sweet potato.

Further, the Agency verified there are fluopyram tolerance citations for the nine minor use crops in 40 CFR 180.661. 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 "Emended-Review of Bayer Crop Science's Request for an Extension of the Exclusive Use Period for Fluopyram" dated August 28, 2019 for a more detailed explanation of how each crop meets the standard for extending the exclusive use period.

Applicability of Criterion III to fluopyram:

Cucumber, Cantaloupe, Pumpkin, Pistachio and Strawberry:

Fluopyram controls various fungal pathogens such as *Botrytis*, *Alternaria*, *Didymella*, and powdery mildews. These pathogens have developed resistance to several pesticides thus far, so resistance management is of increasing importance. The registrant has provided information that specifies how growers can utilize fluopyram in the management of resistant fungal populations in several crops. Fluopyram being an SDHI fungicide, has been shown to exhibit efficacy on SDHI-resistant mutant populations that are no longer controlled by other SDHI active ingredients. Fluopyram also fits into a fungicide rotation that will help alleviate selection pressure on other classes of fungicides such as the quinone outside inhibitors or QoI and the Demethylation Inhibitors or DMI type fungicides, of FRAC group 11 and 3 respectively, prolonging their efficacy and staving off the development of resistance

within the target fungal population. Therefore, the agency concludes that fluopyram satisfies criterion III and will play an important role in resistance management of key pathogens in pistachio, strawberry and the cucurbit crops listed above.

Applicability of Criterion IV to fluopyram:

Sweet Potato, Broccoli, Cabbage and Sweet cherry: Fluopyram provides growers with an effective tool to combat problematic species of root knot nematode (*Meloidogyne spp.*). Fluopyram offers increased opportunity for integrated approaches to be used for both pest and soil nutrient management programs when compared to other currently registered alternatives. The registrant also provided discussion on how these newer nematicide products are selective for nematodes relative to older chemistries such as fumigants and oxamyl, which will allow growers increased flexibility in using them and opportunities for increased soil nutrient management and integrated pest management techniques to be practiced. Fluopyram offers a more flexible and selective tool that increases a grower's capacity to practice field management strategies that better promote beneficial bacteria, earthworms, and insect populations contributing to strong IPM programs and more sustainable stewardship practices. Therefore, the Agency finds sweet potato, broccoli, cabbage, and sweet cherry to meet criterion IV for extension of data exclusivity.

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 fluopyram 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.264-1077. Exclusive-use protection for data, which complies with 40 C.F.R. 152.83(c), submitted in support of this registration **will expire on February 2, 2025 for:** broccoli, cabbage, cucumber, cantaloupe, pumpkin, pistachio, strawberry, sweet cherry, and sweet potato. A copy of our review is enclosed.

Sincerely,



Michael L. Goodis,
Director, Registration Division (RD)
Office of Pesticide Programs (OPP)

Enclosure: Emended-Review of Bayer Crop Science's Request for an Extension of the Exclusive Use Period for Fluopyram.