

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



OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

March 15, 2018

Amy McCaskill  
Federal Registrations Manager  
Bayer AG  
Bayer CropScience  
2 T.W. Alexander Dr  
Research Triangle Park, NC 27709

Subject: Response to Request for Extension of the Exclusive-Use Period for  
Flupyradifurone TC  
EPA Reg. No. 264-1143  
EPA Finding: Extends the Exclusive-Use Data Protection Period by 3 years from  
January 15, 2025 to January 15, 2028

Dear Ms. McCaskill:

This is the Office of Pesticide Programs' response to your request of October 10, 2016 that data associated with the original registration of the insecticide flupyradifurone receive a three-year extension to the original ten-year exclusive-use protection period pursuant to FIFRA section 3(c)(1)(F)(ii). The original data protection period started on January 15, 2015 and ends January 15, 2025. The registrant's initial petition to extend the exclusive use rights by three years only supported a one-year extension of data exclusivity, given registration for peach, plum and sweet/tart cherry. After being informed of this, the registrant requested to renegotiate this action in order to submit additional information to supplement their initial request. In this subsequent submission, supporting information was submitted for 21 crops. Because three minor uses are required to meet at least one of the criteria for a one-year extension, to receive the maximum three-year extension of data protection, an additional six qualifying minor uses are required. Out of the 21 additional minor crop uses in the petition, the EPA focused on avocado, pomegranate, cucumber, head lettuce, leaf lettuce, and greenhouse tomato, for consideration and determined that the use of flupyradifurone on these crops met the criteria to support the extension of exclusive-use period. Therefore, in conjunction with the prior request, the EPA is granting the request for an exclusive-use extension of three years to end January 15, 2028, under EPA Registration No. 264-1143.

The 1996 Food Quality Protection Act (FQPA) amended section 3(c)(1)(F) to include 3(c)(1)(F)(ii) which the applicant cites as its authority to make this request. 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. 40 CFR section 152.83 defines the study required as part of the application for exclusive-use protection where the following requirements must be met: with a maximum of an additional three years to the exclusivity period.

- 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;
- 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 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.

Second, the data were submitted in support of the first registration of the new chemical<sup>1</sup>. The registration Bayer CropScience LP (Bayer) Flupyradifurone TC (264-1143) was granted on January 15, 2015, and was the first registration for flupyradifurone.

Third, the original data were not submitted to satisfy FIFRA section 3(c)(2)(B). Any data submitted in response to a data call in under section 3(c)(2)(B) associated with this registration will not receive exclusive use protection under FIFRA section 3(c)(1)(F)(ii).

Data generated by IR-4 are not entitled to exclusive use protection (see 40 CFR 152.94(b)). However, the EPA will count minor uses supported, or generated by IR-4 when determining how many additional years that exclusive use protection may be extended.

Although, the EPA has determined that there are exclusive-use protected data associated with this registration, the EPA has not made individual determinations on every study associated with the above referenced registration as to exclusive-use protection. If the EPA receives a me-too application of this pesticide during the extension period citing Bayer's data, the EPA 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.

---

<sup>1</sup> 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 in support of an application of 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 such 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.



After determining that there are exclusive use data associated with this registration, the 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 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 uses 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, and/or
- (II) the alternatives to the minor use pesticide pose greater risks to the environment or human health, and/or
- (III) the minor use pesticide plays or will play a significant part in managing pest resistance, and/or
- (IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The registration of a pesticide for a minor use on a crop grouping established by the Administrator shall be considered for purposes of this clause 1 minor use for each representative crop for which data are provided in the crop grouping.

#### **Analysis of Justification for Exclusive-Use Extension**

The registrant, Bayer, submitted a petition to the EPA requesting that the exclusive-use period be extended for three years (until January 15, 2028) for data submitted in support of the first flupyradifurone registration. The registrant's initial petition to extend the exclusive use rights only supported a one-year extension of data exclusivity, given registration for peach, plum and sweet/tart cherry. Since three minor use crops must meet the criteria for a one-year extension, at least six additional crops must meet at least one of the criteria to receive the maximum three-year extension. Bayer provided additional information for 21 crops for flupyradifurone in order to meet the related criteria for a maximum extension of exclusive-use. This petition includes greenhouse residue trials and these uses are considered distinct from field-grown crop sites in this determination.

The EPA confirmed, based on the USDA Census of Agriculture (USDA 2014a) for all 21 submitted crops, the total U.S. acreage for each crop is less than 300,000 acres<sup>2</sup>. Therefore, each of these crops is determined to be a minor use. The EPA also verified there are flupyradifurone registrations allowing use on the 21 submitted minor use crops (Crop Group (CG)): carrot (CG1); radish (CG 1); head lettuce (CG 4); leaf lettuce (CG 4); greenhouse lettuce (CG 4-16A); celery (CG 4); spinach (CG 4); broccoli (CG 5-16); cabbage (CG 5-16); cauliflower (CG 5-16); greenhouse pepper (CG 8-10B); greenhouse tomato (CG 8-10A); greenhouse cucumber (CG

---

<sup>2</sup> Crops not listed in the USDA Census of Agriculture are presumed to be cultivated on less than 300,000 acres.

9B); cucumber (CG 9); summer squash (CG 9); muskmelon (CG 9); grapefruit (CG 10-10); lemon (CG 10-10); pear (CG 11-10); avocado (CG 24B); pomegranate (CG 24B), and that these 21 minor uses were each registered within 7 years of the initial registration of January 15, 2015. As per FIRFA § 3(c)(1)(F)(ii), the EPA will consider one minor use for each representative crop for which data are provided in the crop grouping.

The EPA has confirmed that the end use product labels currently listing these minor uses (EPA Reg. No. 264-1141) carry the resistance-management labeling statements as described by PR Notice 2017-1. The EPA has verified that the labels for EPA Reg. No. 264-1141 (Sivanto 200 SL, Sivanto Prime 200 SL, Sivanto Prime) are currently being marketed, are publically available on the Pesticide Product Label System (PPLS), and contain these minor uses.

Once it was determined that nine qualifying minor uses (i.e., supported by data) were submitted, the EPA applied the statutory criteria to its evaluation of the information submitted by the registrant to determine if at least one criterion has been met for each of these distinct minor uses. The EPA evaluated, under Criterion II, that the pesticide was registered recently under reduced risk status presuming that alternative pesticides pose greater risks. The EPA evaluated, under Criterion III, the information submitted by the registrant as well as publicly available information, including descriptions of insecticide Modes of Action (MoA) available through the Insecticide Resistance Action Committee (IRAC), to determine whether flupyradifurone will play a significant part in managing pest resistance for the submitted crop groups. The EPA considers that Criterion III is met in situations where there is reliable information that the insecticide being evaluated is used 1) to delay the development of pest resistance to other insecticides with different MoA, or 2) where one or more of the target pests have already developed resistance in the U.S. to alternative insecticides.

### **Summary of Findings**

Flupyradifurone received reduced risk status for citrus, cucurbit vegetables, fruiting vegetables, and pome fruit in March 2013. Reduced risk status was also granted for avocado and greenhouse tomatoes in May 2016. For purposes of exclusive use extension determinations under Criterion II, EPA believes that reduced risk determinations are most relevant within two years of their submissions. Since 2016 is within this two-year time frame, it was determined that avocado and greenhouse tomato represent two eligible minor use sites that can be claimed under Criterion II.

Bayer claims that flupyradifurone is the only insecticide in IRAC subgroup 4D and contributes to a strong insect resistance management program for aphids and whiteflies that are pests of avocado, pomegranate, head lettuce, leaf lettuce, cucumber, and greenhouse tomato. The EPA has verified that flupyradifurone is labeled for all of the sites subject to this determination and is the only butenolide (4D) insecticide. Having a unique mode of action, flupyradifurone is an important rotation partner to delay the development of pesticide resistance. Because avocado and greenhouse tomatoes were eligible for Criterion II, these uses were not considered under the Criterion III. Therefore, flupyradifurone is eligible for cucumber, pomegranate, head lettuce, and leaf lettuce under Criterion III. Peach, plum, and sweet/tart cherry meet both Criterion III and IV. Thus, flupyradifurone is eligible for a total of nine minor use sites between Criterion II III and IV.



## **Determination**

EPA concludes that Bayer has satisfied the requirements necessary to extend the period of exclusive-use data for three years. The EPA has determined that flupyradifurone satisfies Criterion II, III and IV for at least nine additional minor uses registered within seven years of the original registration. Therefore, the EPA **GRANTS** your request for a three-year extension of exclusive-use data protection for selected data under EPA Registration Number 264-1143. Exclusive-use protection for data, which complies with 40 CFR 152.83(c), submitted in support of this registration, **will expire on January 15, 2028**. A copy of our reviews are enclosed.

Sincerely,



Michael L. Goodis, P.E.  
Director, Registration Division (7505P)  
Office of Pesticide Programs

Enclosures:

Review of Request for an Extension of the Exclusive Use Period for Flupyradifurone

Review of Bayer's Additional Request for an Extension of the Exclusive Use Period for Flupyradifurone