



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 6, 2021

Paula Bodey
FMC Corporation
2929 Walnut Street
Philadelphia, PA 19104

Subject: Cheminova Flutriafol Technical
EPA Reg. No. 4787-55
Decision Numbers: 562806
Application dated 04/23/2020
Extension of Exclusive Use Period data protection period **PARTIALLY GRANTED** from
April 29, 2020 to April 29, 2022

Dear Ms. Bodey:

This letter addresses your request that data associated with the original registration of flutriafol receive a three-year extension to the original ten-year exclusive use protection period. The original data protection period started April 29, 2010 and ended April 29, 2020. EPA received the request to extend the exclusive use period on April 23, 2020 before the period expired, therefore, consistent with the Agency's policy (2018 Questions and Answers – Exclusive Use Data Protection for Minor Use Registration), EPA is considering this action as if the exclusive use period had not expired. EPA also can confirm that it has not issued any me-too registrations between the time the exclusive use period expired and the date of this response. Though only nine registered minor crops are needed to support the request, the following fourteen were cited:

- Strawberry
- Cucumber
- Summer squash
- Cantaloupe
- Celery
- Bell pepper
- Non-bell pepper
- Eggplant
- Mayhaw
- Peach
- Apricot
- Nectarine
- Popcorn
- Hops

FMC (279) purchased Cheminova (4787) in 2015. Based on this acquisition, FMC maintains ownership of Cheminova and all its assets, including all the data and studies filed with EPA supporting

the referenced Flutriafol Technical (4787-55). FMC submitted the request to extend the exclusive-use period for flutriafol on behalf of Cheminova.

EPA determined that 7 of the uses qualify to be counted toward an exclusive use extension of two additional years to end April 29, 2022 under EPA Reg. No. 4787-55. FMC 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 minor uses registered within the first seven years of an original registration whose data retains exclusive-use protection, with a maximum of an additional three years to the original ten-year exclusivity period.

The first step in determining whether data qualifies for an extension of its exclusive-use period is to ascertain which data currently have exclusive-use protection. FIFRA section 3(c)(1)(F)(i) and its implementing regulations specifically describe the set of data that is 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 must have been submitted in support of the first registration of the new chemical¹. The registration you cited, Cheminova Flutriafol Technical, EPA Registration No. 4787-55 was granted on April 29, 2010 and was the first registration for flutriafol. 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 152.94(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.

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.

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 FMC 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

All 14 minor crops uses were registered within the required 7 years following the initial registration and included the following:

Claimed Minor Use Crops	Claimed Criterion Met	Agency Determination of Criterion Satisfied/ Failed	
		Agency Consideration for Criterion	
Popcorn	I	Failed	Sufficient alternatives fungicide registered for this use
Mayhaw	I	Failed	Sufficient alternatives fungicide registered for this use
Apricot	I, II	Failed	Sufficient alternatives fungicide registered for this use and labeling not approved for the specified application method (drip irrigation)
Nectarine		Failed	
Peach		Failed	
Cantaloupe	I, II, III, IV	Satisfied (I, III)	Insufficient registered alternative and flutriafol will play a role in fungicide resistant management of pest.
Cucumber		Satisfied (I, III)	
Summer squash		Satisfied (I, III)	
Eggplant	I, II, III, IV	Failed	Insufficient residue data

Bell pepper		Satisfied (I)	Insufficient registered alternative
Non-bell pepper		Satisfied (I)	Insufficient registered alternative
strawberry	I, II, III, IV	Satisfied (I)	Insufficient registered alternative
Celery	I	Satisfied (I)	Insufficient registered alternative
Hops	I, II	Failed	Sufficient alternatives fungicide registered for this use and labeling not approved for the specified application method (drip irrigation)

All fourteen crops meet the definition of a minor use as each crop had less than 300,000 acres bearing or harvested. Based on the analysis and attached review, a review of FMC Corporations petition for Exclusive Use , the following seven minor use crops will support a two year extension of the exclusive use period (strawberry, celery, cantaloupe, cucumber, summer squash, fruiting vegetable crop group 8-10B (bell pepper, non-bell pepper, eggplant). Due to insufficient residue data, only two crops in the fruiting vegetable crop group 8-10B can be claimed to support the extension. The following criteria were reviewed to support the exclusive use determination listed below.

- Criterion (I) the agency determined there are insufficient efficacious alternative pesticides available for the targeted pests on strawberry, celery, fruiting vegetable crop group 8-10 B (bell pepper, non-bell pepper, eggplant).
- Criterion (II) the alternatives to the minor use pesticide pose greater risks to the environment or human health. The registrant provided 2(ee) labels for alternative application methods to support this criterion. Although the 2(ee) statue allows for the use of any application method that is not prohibited on the labeling, the Agency determined that that the evaluation process for extension of exclusive use period relies upon the most recently approved Section 3 labeling and the application method(s) permitted on those labels. The flutriafol Section 3 labels do not specifically allow for drip irrigation as an application method on apricot, hops, nectarine, and peach minor uses. Therefore, insufficient evidence was provided to satisfy criterion (II) for extension of the exclusive use.
- Criterion (III) the minor use pesticide plays or will play a significant part in managing pest resistance in cantaloupe, cucumber, and summer squash.
- Criterion (IV), the Agency determined that criterion I or III were met for the minor uses bell pepper, cantaloupe, cucumber, non-bell pepper, strawberry, eggplant and summer squash minor uses; therefore, an analysis was not performed for criterion (IV).

Therefore, seven distinct minor use sites qualify for extension of exclusive use of flutriafol under criterion I and III, and flutriafol qualifies for a two-year extension of exclusive use.

The Agency verified there are flutriafol tolerance citations for the minor use crops in 40 CFR 180.629. Additionally, each of the end-use labels contains a resistance management section and FRAC group number code which supports grower awareness and fungicide resistance management efforts.

DETERMINATION

The Agency concludes that the uses listed above are minor uses and were registered within seven years of the original flutriafol registration. These minor uses were found to meet at least one of the four criteria listed above. The Agency, therefore, **GRANTS IN PART** your request for an extension of exclusive-use data protection for selected data under EPA Registration Nos. 4787-55 for an additional

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two (2) years. Exclusive-use protection for data, which complies with 40 C.F.R 152.83 (c), submitted in support of this **registration will expire on April 29, 2022**. A copy of review is enclosed.

Sincerely,

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

Enclosures: Review of FMC's Request for an Extension of the Exclusive Use Period for Flutriafol