



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460**

**OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION**

May 14, 2021

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Subject: Response to Request for Extension of the Exclusive-Use Period for Fluensulfone
EPA Reg. No. 11678-73
EPA Finding: Extends the Exclusive-Use Data Protection Period by 3 years from
September 11, 2024 to September 11, 2027

Dear Ms. Frugis:

This is the Office of Pesticide Programs' response to your request of September 28, 2020 that data associated with the original registration of the insecticide Fluensulfone 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 September 11, 2014 and ends September 11, 2024. The EPA has reviewed ADAMA's request and finds that ADAMA has provided sufficient evidence to satisfy the criteria for extension of exclusive use data protection for Fluensulfone under FIFRA Section 3(c)(1)(F)(ii) for the minor uses on carrot, sweet potato, okra, bell pepper, watermelon or cantaloupe, sweet cherry, peach, strawberry, kiwi, and macadamia. Therefore, the EPA is granting the request for an exclusive-use extension of three years to end September 11, 2027 for Fluensulfone (EPA Reg. No. 11678-73).

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:

- 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 chemical¹. The registration Fluensulfone Technical (EPA Reg. No. 11678-73) was granted on September 11, 2014 and was the first registration for Fluensulfone. 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 ADAMA'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.

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,

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 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.

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.

Summary of Biological and Economic Analysis Division (BEAD) Review of Justification for Exclusive-Use Extension

ADAMA claims that Fluensulfone satisfies the FIFRA Section 3(c)(1)(F)(ii) requirements for the following 12 uses: carrot, sweet potato, okra, bell pepper, watermelon, cantaloupe, sweet cherry, peach, strawberry, kiwi, macadamia and pecan. All of these crops uses were accepted within 7 years of the onset of the exclusive use data period for fluensulfone (September 11, 2014). While all 12 of these crops are supported by residue data, only a single representative crop residue study was submitted to support watermelon and cantaloupe (subgroup 9A). As a result, 11 of ADAMA's minor use sites for Fluensulfone meet the criteria for extension of exclusive use data protection based upon these criteria.

Per consultation with USDA, EPA relies on the Census of Agriculture for data on crops grown in the United States. For the minor use qualification, fruit and tree nut crops are evaluated for bearing acreage, and vegetable crops are evaluated for harvested acreage. For the 11 sites supported by unique residue data, the total U.S. acreage of 10 sites is less than 300,000 acres, qualifying them as minor crops. The bearing acreage for pecans in 2017 was 461,890 acres, thereby disqualifying it as a minor use crop under FIFRA Section 2(II)(1). Note that the registrant's claimed acreage differs from acreage reported in the Census of Agriculture; this is due to the registrant's use of a different source to determine acreage. As a result, 10 of ADAMA's minor use sites for Fluensulfone meet the criteria for extension of exclusive use data protection based upon these criteria.

For the 10 remaining, applicable minor use sites (carrot, sweet potato, okra, bell pepper, watermelon or cantaloupe, sweet cherry, peach, strawberry, kiwi, macadamia), Fluensulfone satisfies criterion III for its value in managing pest resistance. Fluensulfone has a unique and novel mode of action among nematicides, and it is the first and only nematicide in the fluoroalkenyl chemical class. Plant parasitic nematode resistance to other registered nematicides, such as oxamyl, has been documented and nematodes resistant to carbamates such as oxamyl do not show cross resistance to Fluensulfone. The registrant additionally included letters of support from extension and industry professionals indicating that Fluensulfone's novel mode of action will help in nematicide resistance management. The EPA believes Fluensulfone plays or will play an important role in nematicide resistance management in the crops in which it is registered. The Agency verified that all of these crops uses were accepted within 7 years of the onset of the exclusive use data period for fluensulfone (ending September 11, 2021), and that there are Fluensulfone tolerance citations for the minor use crops (and/or their respective crop groups) in 40 CFR 180.680. While Fluensulfone's mode of action is

not classified and nematode resistance has not been proven, each of the end-use labels contains a resistance management section which supports grower awareness and resistance management efforts.

Determination

The EPA finds the registrant has provided sufficient evidence to satisfy the criteria for extension of exclusive use data protection for Fluensulfone under FIFRA Section 3(c)(1)(F)(ii) for 3 years (extended to September 11, 2027). The EPA found that for the minor uses carrot, sweet potato, okra, bell pepper, watermelon or cantaloupe, sweet cherry, peach, strawberry, kiwi, and macadamia, Fluensulfone provides a novel mode of action to control nematodes and plays or will play an important role in nematocide resistance management. A copy of BEAD's review dated April 6, 2021 is attached.

Sincerely,

**MARIETTA
ECHEVERRIA**

Marietta Echeverria, Acting Director
Registration Division (7505P)
Office of Pesticide Programs

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Enclosure: BEAD Review of ADAMA's Request for an Extension of the Exclusive Use Data for Fluensulfone