



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 1, 2016

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Subject: Response to Request for an Extension of the Exclusive Use Period for Spinetoram Technical
EPA Registration Number: 62719-539
EPA Finding: Extends the exclusive-use data protection period by 3 years from September 28, 2017 to September 28, 2020

Dear Ms. Hughes:

This is the Office of Pesticide Programs' response to your petition dated December 1, 2015 (additional addendum dated February 29, 2016), requesting to extend the period of exclusive data use for the insecticide spinetoram by three years.

The 1996 Food Quality Protection Act (FQPA) amended FIFRA 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 the 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 retain 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 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 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.

Second, the data were submitted in support of the first registration of the new chemical.¹ The registration of Dow AgroSciences (DAS) Spinetoram Technical (62719-539) was granted September 28, 2007, and was the first registration for spinetoram.

Third, the data were not submitted to satisfy FIFRA section 3(c)(2)(B), any such data 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 determination 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 DAS'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 of FIFRA section 3(c)(1)(F)(ii), and if so, by how many years.

FIFRA § 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, and/or
- (II) the alternatives to the minor use pesticide pose greater risks to the environment or human health, and/or

¹ Data are not protected solely because they pertain to a 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 the data that pertain solely to the new use. Thus, for example, if the new use is approved after eight years of first registration, the data supporting that use would gain exclusive use protection for only two years.

- (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 (IPM) program.

Analysis of Justification for Exclusive Use Extension

The registrant, DAS, submitted a petition to the Agency requesting that the exclusive-use period be extended for three years (until September 28, 2020) for data submitted in support of the spinetoram registration. Since three crops must meet the criteria for a one-year extension, at least nine crops need to meet at least one of the criteria to receive the maximum three-year extension. DAS claimed to have registered more than 25 minor uses on spinetoram products, and that spinetoram met all benefits related criteria for an extension. In addition, DAS emphasized the reduced-risk status of this chemical as a basis for being less risky than available alternatives.

The Agency verified there are spinetoram tolerance citations in 40 CFR 180.635 for the following nine listed minor use crops and crop groupings: avocado, blueberries, bulb onion, cranberries, green onion, head lettuce, peppers (bell and other), raspberries and strawberries. Additionally, based on EPA's label data base it appears that growers have access to end use products, including EPA registration numbers 62719-541 and 62719-545 for each crop use in this finding. Furthermore, each of these labels contain a resistance management section and IRAC code for this chemical. Additionally, these nine minor uses were each registered within 7 years of the initial application of September 28, 2007. Therefore, the first condition of exclusive use extension has been met.

Next, during the course of its review the Agency applies 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 the minor uses. EPA evaluated the information under Criterion III. The Agency 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 Modes of Action, or 2) where one or more of the target pests have already developed resistance in the U.S. to alternative insecticides.

The Agency first examined the list of registered minor acreage crops to determine whether or not spinetoram is the only available representative of its Mode of Action grouping. Spinosad, which is closely related to spinetoram, is the only other insecticide with IRAC Mode of Action 5. However, spinosad has numerous instances of confirmed resistance across insect families such as hemiptera, diptera, lepidoptera, and coleoptera. The following table shows nine minor crops, along with the pests listed on their labels, for which spinetoram is registered. Note there may be additional minor crops that have only spinosad and spinetoram as Mode of Action 5 chemistry; however, the Agency did not assess more than the nine below. Rotating insecticides with as many different Modes of Action as possible is key to resistance management. Since spinetoram is relatively new to many U.S. crops, and according to available databases, these pests have not yet developed resistance to it. This increases spinetoram's importance as a resistance management tool in crops where most of the alternatives are older chemistries (i.e., organophosphates and pyrethroids).

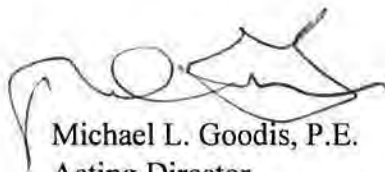
Crop	Target Pest
Avocado	Avocado Thrips (<i>Scirothrips perseaes</i>)
Blueberries	Spotted wing drosophila (<i>Drosophila suzukii</i>)
Bulb Onion	Onion Thrips (<i>Thrips tobaci</i>)
Cranberries	Blackheaded fireworm (<i>Phopobota naevana</i>)
Green Onion	Onion Thrips (<i>Thrips tobaci</i>)
Head Lettuce	Western Flower Thrips (<i>Frankliniella occidentalis</i>)
Peppers (bell and other)	Western Flower Thrips (<i>Frankliniella occidentalis</i>)
Raspberries	Spotted wing drosophila (<i>Drosophila suzukii</i>)
Strawberries	Western Flower Thrips (<i>Frankliniella occidentalis</i>)

The Agency determined that spinetoram is currently one of two insecticides in its specific MoA group (5) that is currently registered for at least nine minor uses that are included in the registrant's submission. Therefore, for these crops, the Agency concludes that spinetoram plays or will play a significant part in managing pest resistance. These crops are: avocado, blueberries, bulb onion, cranberries, green onion, head lettuce, peppers (bell and other), raspberries and strawberries.

Determination

EPA concludes that DAS has satisfied the requirements necessary to extend the period of exclusive use data. EPA determined that spinetoram satisfies Criterion III for at least nine minor uses that were registered within seven years of the original registration. Therefore, EPA grants your request for a three-year extension of exclusive-use-data protection for selected data under EPA Registration Number 62719-539. Exclusive-use protection for data, which complies with 40 CFR 152.83(c), submitted in support of this registration, will expire on September 28, 2020.

Sincerely,



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