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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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MEMORANDUM

SUBJECT: Review of a Request for an Extension of the Exclusive Use Period for Spinetoram

FROM: Caleb Hawkins, Biologist
Biological Analysis Branch
Biological and Economic Analysis Division (7503P)

THRU: Monisha Kaul, Chief
Biological Analysis Branch
Biological and Economic Analysis Division (7503P)

TO: Carlyn Petrella, Biologist
Invertebrate Branch II (IVB2)
Registration Division (7505P)

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SUMMARY

When a new pesticide active ingredient is registered, the original data submitter has a 10-year period following the date of registration during which they retain exclusive use of the data. FIFRA allows for an extension of that exclusive-use period for up to three years if minor uses that meet certain criteria are registered. A one-year extension is allowed for every three qualifying minor uses.

Dow AgroSciences submitted a petition to EPA requesting that, under FIFRA Section 3(c)(1)(F)(ii), the exclusive use period for data supporting the active ingredient spinetoram be extended for three years. Because three minor uses must meet the criteria for each one-year extension, nine registered minor uses are required to meet the criteria for a three-year extension. Supporting information was submitted for nine crops that the registrant identified as minor uses meeting the criteria established for extension of exclusive use. BEAD evaluated the available data on the number of acres of production for each of the crops listed by the registrant to assess whether the crops meet the definition of minor use per FIFRA Section 2(ll)(1) and then applied the benefits-related criteria for extension of exclusive use expressed in FIFRA Section 3(c)(1)(F)(ii) to the crops proposed by the registrant. It was determined that the use of spinetoram on blueberries, raspberries, strawberries, cranberries, avocado, peppers, green onion, bulb onion, and head lettuce met the criteria for extension of the exclusive-use period. Spinetoram plays a significant part in managing pest resistance and/or plays a significant role in integrated pest management (IPM) for these minor uses. Therefore, the extension of exclusive use criteria have been met for nine minor uses to extend the exclusive use period for the maximum three years allowed by FIFRA.

BACKGROUND

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides certain data protection rights to data submitters for their registered pesticides. Section 3(c)(l)(F)(i) states that the original data submitter has a 10-year exclusive use period from the date of registration for the data submitted in support of the original registration. An extension to the exclusive use period may be allowed if certain criteria are met, detailed in Section 3(c)(1)(F)(ii) as the following:

> *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 –*
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> *(I) there are insufficient efficacious alternative registered pesticides available for the use;*
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> *(II) the alternatives to the minor use pesticide pose greater risks to the environment or human health;*
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> *(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.

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. Any additional exclusive use period under this clause shall be modified as appropriate or terminated if the registrant voluntarily cancels the product or deletes from the registration the minor uses which formed the basis for the extension of the additional exclusive use period or if the Administrator determines that the registrant is not actually marketing the product for such minor uses.

The definition of minor use is described in FIFRA Section 2(ll) as the use of a pesticide on an animal, on a commercial agricultural crop or site, or the protection of public health where (1) the total U.S. acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture, or (2) the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use.

PRODUCT BACKGROUND

Spinetoram was first registered by EPA on September 28, 2007, under the Reduced Risk Pesticide Program. Spinetoram is a broad-spectrum insecticide that controls lepidopteran pests, leaf miners, and thrips in a variety of crops. Spinetoram is categorized as Mode of Action 5 (nicotinic acetylcholine receptor allosteric modulators) by the Insecticide Resistance Action Committee (IRAC). Spinetoram is derived from the naturally occurring soil bacterium *Saccharopolyspora spinosa.*

REGISTRANT SUBMISSION

The registrant claims that spinetoram satisfies criteria II, III, and VI under Section 3(c)(1)(F)(ii) in FIFRA (described above) for blueberries, raspberries, strawberries, cranberries, avocado, peppers, green onion, bulb onion, and head lettuce. Specifically, the registrant claims that spinetoram products are registered on over 25 minor uses. However, BEAD's analysis only focuses on 9 of these crops for which the registrant submitted data, as this number of use sites is sufficient for the maximum extension of exclusive use-period.

SUPPORT TO QUALIFY FOR CRITERIA

Requirements for Criterion II, the Alternatives to the Pesticide Use Pose Greater Risks to the Environment of Human Health. BEAD does not evaluate this criterion. Evaluation of this criterion is conducted by the Environmental Fate and Effects Division or the Health Effects Division.

Requirements for Criterion III, Pesticide Plays a Significant Part in a Resistance Management Program. BEAD considers that Criterion III has been met in situations where there is reliable information that the chemical being evaluated is used 1) to delay the development of pest

resistance to other chemicals 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 chemicals.

Requirements for Criterion IV, Pesticide Plays a Significant Part in an Integrated Pest Management Program: Integrated Pest Management (IPM) is an important set of tactics for growers to maintain the productivity of crop land while potentially reducing the overall input and environmental impact of pest management tools such as pesticides. Among other things, IPM strategies can help minimize the impact of pesticides on beneficial organisms (such as pollinating insects, predators, and parasites). BEAD would consider that Criterion IV had been met in situations where there was reliable information that spinetoram is a significant tool in managing target pests as a part of a larger IPM program that is intended to control a range of key pests in a given crop.

ASSESSMENT

BEAD examined information submitted by the registrant as well as other publicly available information, and descriptions of insecticide Modes of Action (MoA) available through the Insecticide Resistance Action Committee (IRAC), to evaluate whether spinetoram plays, or will play, a significant part in managing pest resistance (criterion III) and/or if the minor use pesticide plays, or will play, a significant part in an integrated pest management program (criterion IV).

MINOR USE

The USDA Census of Agriculture (USDA, 2014) provides the data on crops grown in the US. Crops not listed in the Census of Agriculture are presumed to be cultivated on fewer than 300,000 acres. For the nine crops on which this memo is focused, the total U.S. acreage for each crop is less than 300,000 acres (Table 1). The nine crops are blueberries, raspberries, strawberries, cranberries, avocado, peppers, green onion, bulb onion, and head lettuce.

Table 1: Acreage of crops considered for extension of exclusive use for spinetoram

CROP	Acreage
Blueberries	96,169
Raspberries	23,104
Strawberries	67,467
Cranberries	43,918
Avocado	73,534
Peppers (bell and other)	81,616
Green Onion	5,624
Bulb Onion	149,960
Head Lettuce	154,968

Source: USDA, 2014

Applicability of Criterion III to spinetoram

BEAD first examined the list of registered minor acreage crops to determine whether or not spinetoram is the only available insecticide of its Mode of Action grouping. Spinosad, which is closely related to spinetoram, is the only other insecticide with IRAC Mode of Action 5. Spinosad has numerous instances of confirmed resistance across insect families such as hemiptera, diptera, lepidoptera, and coleoptera.

Most of the pests listed in Table 2 have shown resistance (or some potential to develop it) for different chemistries, based on the database of research publications maintained by Michigan State University (MSU) and available at www.pesticideresistance.com. Rotating insecticides with as many different Modes of Action as possible is a key resistance management principle that is generally applicable for insect pest control. Since spinetoram is a relatively new insecticide in many U.S crops (including the crops listed in Table 2) pests have not yet developed resistance to it in this country (according to the database available at www.pesticideresistance.com). This increases its importance as a resistance management option in crops where the majority of alternatives are older chemistries such as organophosphate and pyrethroids, since insects have had exposure to older chemistries for decades. Most other MoAs have active ingredients with documented resistance to the pests discussed in this analysis.

Table 2: Major pests controlled by spinetoram as cited by the registrant and insecticides that have shown resistance in the target pest

CROP	Target Pest	Insecticides to which observed resistance is documented
Blueberries°	Spotted wing drosophila (*Drosophila suzukii*)	aldrin, chlorpyrifos, cyromazine, DDT, lindane, lufenuron, malathion, methoprene, parathion, propoxur
Raspberries	Spotted wing drosophila (*Drosophila suzukii*)	See blueberry
Strawberries	Western Flower Thrips (*Frankliniella occidentalis*)	Abamectin, acephate, Acetamiprid, acrinathrin, bendiocarb, bifenthrin, chlorpyrifos, cyantranilliprole, cypermethrin, cypermethrin-alpha, deltamethrin, diazinon, dicholrvos, endosulfan, esfenvalerate, firponil, formetanate, imidacloprid, malathion, methamidophos, methiocarb, mehomyl, permethrin, pyriproxyfen, spinetoram, spinosad, tau-fluvalinate, thiamethoxam, toxaphene
Cranberries	Blackheaded fireworm (*Phopobota naevana*)	No instances of confirmed resistance found
Avocado*	Avocado Thrips (*Scirothrips perseaes)*	Aldrin, bendiocarb, bifenthrin, cyfluthrin, cypermethrins, DDT, dieldrin, dimethoate, esfenvalerate, fenpropathrin, flucythrinate, formetanate, malathion, parathion,

		pyrethroids (unspecified), tartar emetic, tau-fluvalinate
Peppers (bell and other)	Western Flower Thrips (*Frankliniella occidentalis*)	See Strawberry
Green Onion	Onion Thrips (*Thrips tobaci*)	Aldrin, carbosulfan, cyhalothrin-lambda, cypermethrins, cypermetrhin-alpha, DDT, deltamethrin, diazinon, dicholrvos, dieldrin, dimethoate, enamectin benzoate, endosulfan, imidacloprid, methidathion, methomyl, permethrin, profenofos, spinosad
Bulb Onion	Onion Thrips (*Thrips tobaci*)	See Green Onion
Head Lettuce	Western Flower Thrips (*Frankliniella occidentalis*)	See Strawberries

°A related species, *Drosophila melanogaster*, was used as reference for resistance
*A related species, *Scirothrips citri*, was used as reference for resistance
Sources: Dow AgroSciences, 2016 and Michigan State University, 2016

Applicability of Criterion IV to spinetoram

BEAD examined recent peer-reviewed research publications which confirmed that spinetoram is one of a set of relatively new chemistries that have low negative impacts on predatory and parasitic insects that can be used as natural pest control within an IPM program in most crops. Natural enemies for which the impacts of spinetoram on mortality and/or fecundity have been evaluated include the minute pirate bug (*Orius armitus*), the seven-spotted ladybug (*Coccinella septempunctata*), and the convergent ladybeetle (*Hippodamia convergens*) (Broughton et al., 2014; Roubos et al., 2014; Sabry, Hassan, and Abd-El Rahman, 2014). All are natural enemies of a variety of common insect pests in many small acreage crops.

In addition, the University of California Statewide IPM Program, which provides detailed insecticide recommendations for dozens of minor crops included in spinetoram's labels, often mentions this insecticide as an option for commercial growers (see individual crops listing at http://ipm.ucanr.edu/PMG/crops-agriculture.html) (Table 3). UC-IPM ranks pesticides having the greatest IPM value listed first, meaning that the most effective and least harmful to natural enemies, honey bees, and the environment are listed at the top.

Table 3: Spinetoram's rank in IPM programs sorted by crop and pest.

Crop	**Pest**	**UC-IPM Rank of Spinetoram in IPM Program**
Blueberry	Spotted Wing Drosophila	1 out of 7
Raspberry (represented by caneberry in the database)	Spotted Wing Drosophila	3 out of 5
Strawberry	Western Flower Thrips	2 out of 6

Avocado	Avocado Thrips	2 out of 6
Peppers (bell and other)	Thrips	3 out of 8
Onions (Green and bulb onion)	Thrips	2 out of 6
Lettuce	Western Flower Thrips	1 out of 5

Source: UC-IPM, 2016. http://ipm.ucanr.edu/PMG/crops-agriculture.html

Cranberry is not found in the UC-IPM database, but the 2016 Cranberry Chart Book developed by University of Massachusetts recommends spinetoram as part of an IPM program in Cranberries (Ghantous, Sylvia, and Gauvin, 2016).

While spinetoram is not unique in the qualities described above, BEAD concludes there is sufficient acceptable evidence that it is a significant component of IPM programs intended to control a range of pests in many crops.

CONCLUSION

BEAD determined that the registrant's request meets Criterion III (utility as a resistance management tool) in at least 9 crops where spinetoram is the one of the two currently registered representative of its biochemical mode of action, and that it also meets Criterion IV (utility in IPM programs for a range of pests) in several minor acreage crops. Thus, the request meets these two benefits related criteria for an extension of exclusive data use.

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