



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

DEC 19 2014

Ms. Amy McCaskill
Bayer CropScience
2 T. W. Alexander Drive
P. O. Box 12014
Research Triangle Park, NC 27709

Dear Ms. McCaskill:

Subject: Spirotetramat Technical
EPA Registration Number 264-1049
Extension of Exclusive Data Use Period Granted
Your submission dated September 23, 2013
OPP Decision Number D484893

This is the Office of Pesticide Programs' response to the petition, dated Sept. 23, 2013, filed by Bayer CropScience requesting to extend the period of exclusive data use for the insecticide spirotetramat. Spirotetramat is an insecticide inhibiting acetyl CoA carboxylase (Group 23) (Insecticide Resistance Action Committee (IRAC), 2014). Bayer CropScience submitted a petition to the United States Environmental Protection Agency (EPA) for a three-year extension of the exclusive use period. Since three minor uses must meet one of the criteria for a one-year extension, and the statute limits the extension to a maximum of three years, nine minor uses need to meet at least one of the criteria for a three-year extension.

You have cited Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 3(c)(1)(F)(ii) as the authority for the Agency 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 sets forth the criteria for extending the period of exclusive use protection. The period of exclusivity shall be extended one year for each three qualifying minor uses registered within the first seven years of the commencement of the exclusive use period when the Agency makes certain determinations, discussed in detail below. First, however, a study must meet the definition of "exclusive use study" as defined in the Code of Federal Regulation Title 40 (40 CFR) section 152.83:

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; and
3. The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(7)(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 qualifies under the definition of exclusive use.

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 you cited was initially granted on June 30, 2008 and was the first registration for spirotetramat with the product name Spirotetramat Technical. A legal challenge to the registration resulted in the registration being vacated for a period and the registration was reissued on Oct. 15, 2010. In a previous communication dated May 24, 2012 (attached), the Agency determined that the exclusive use period commenced on February 4, 2009.

Third, the data were not submitted to satisfy FIFRA section 3(c)(2)(B).

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

The EPA has determined that the three criteria defining an exclusive use study have been met for data association with this registration, although, 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 for this pesticide during the extension period citing Bayer CropScience 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.

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 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 such protection, but the protection is limited to the data that pertain solely to the new use.

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 § 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.

Three minor uses must meet one of the criteria for a one-year extension and the statute limits the extension to a maximum of three years. Therefore, in order the grant an extension for three years are requested by Bayer, nine minor uses need to meet at least one of the criteria.

Analysis of Justification for Exclusive Use Extension

Bayer submitted information on the role of spirotetramat in Criteria I to IV of FIFRA § 3(c)(1)(F)(ii), to support their petition for extension of the exclusive use period, which is evaluated in this analysis.

The EPA determined that the minor crops were registered within seven years of the original registration of Spirotetramat Technical. Spirotetramat was first registered on June 30, 2008, and additional minor uses were registered on May 6, 2011 and May 2, 2013.

Criterion I is that there are insufficient efficacious alternative registered pesticides available for the use. To meet Criterion I, it must be documented that a pesticide is effective and other pesticides registered are either not effective or otherwise provide inadequate control of the pest. FIFRA Section 18 Emergency Exemptions may provide useful information regarding Criterion I for certain minor uses.

Criterion IV is that the minor use pesticide plays or will play a significant part in an integrated pest management program. To meet Criterion IV, it must be documented a pesticide is

relatively safe for beneficial insects and is an IPM tool, which may support a finding that it plays a significant role in IPM programs.

Integrated Pest Management (IPM) is an important strategy 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) and delay pests developing resistance to some pesticides. Insecticides that are relatively nontoxic to beneficial insects are well suited for incorporation into IPM programs. EPA would consider that Criterion IV had been met in situations where there was compelling information that spirotetramat was important in managing insects as part of a larger IPM program used for control of key pests in a given crop.

Information Sources

EPA examined information submitted by the registrant, as well as relevant university extension service information, United States Department of Agriculture (USDA) Crop Profiles, and Mode of Action and resistance management information available from university publications. These additional sources were only consulted to confirm or supplement the information submitted by the registrant. It is EPA policy not to substantiate exclusive use criteria if the data submitted is lacking or completely inadequate.

Minor Crop Assessments

Bayer submitted information in support of 53 candidate crops in various crop groups. It is EPA's policy to stop evaluating crops once nine of the submitted crops have been found to meet the exclusive use criteria. The remaining crops will not be analyzed or reviewed. EPA focused its review on dry bulb onion, grapefruit, lemon, lime, kumquat, pummelo, tangerine, tangelo, and Satsuma mandarin. EPA verified that these crops met the acreage requirement for minor crops (less than 300,000 acres cultivated) under FIFRA section 2(II)(1) using USDA data.

Summary of Findings

- **Dry bulb onion**

For Criterion I, it must be documented that a pesticide is effective and other pesticides registered are either not effective or otherwise provide inadequate control of the pest.

Spirotetramat has been reported as an effective insecticide to control onion thrips. Multiple Section 18 exemption requests were granted for use on dry bulb onion to control thrips in more than 10 states. The BEAD review of recent Section 18 emergency exemptions for spirotetramat use on dry bulb onion to control thrips found that spirotetramat was necessary to ensure thrips control. These previous Section 18 exemptions provide strong evidence that the use of spirotetramat is critical for season-long thrips control on onions in multiple locations in

the United States. In summary, Criterion I has been met because there are insufficient efficacious alternative registered insecticides available for the dry bulb onion use.

- **Grapefruit, Lemon, Lime, Kumquat, Pummelo, Tangerine, Tangelo, and Satsuma mandarin (8 crops)**

For Criterion IV, it must be documented a pesticide is relatively safe for beneficial insects and is an IPM tool, which may support a finding that it plays a significant role in IPM programs. Bayer submitted information and references including publically available sources to support that spirotetramat has a very low impact on beneficial predators and parasites and is an ideal fit in IPM programs.

The compatibility of spirotetramat with biological control and beneficial insects including *Aphytis melinus* has been documented. A study found that spirotetramat was considered harmless to *A. melinus*. The augmentative release of this parasitoid is one of control strategies in citrus against a key insect pest - the California red scale, *Aonidiella aurantia*. Spirotetramat is an important tool to help integrate *A. melinus* release within an IPM program for citrus in which pesticides are still used. Spirotetramat has been recommended for citrus use in the California statewide IPM program with a special reference on its nontoxic effect on *Aphytis* and vedalia beetles. In addition, the toxicity of spirotetramat residues is also reported to be low or relatively non-persistent for another beneficial insect, *Tamarixia radiata*, a parasitoid of the Asian citrus psyllid.

Grapefruit, lemon, lime, kumquat, pummelo, tangerine, tangelo, and Satsuma mandarin are grown in California and some of these crops are also grown elsewhere in the United States, including Florida, Texas, and Louisiana. These eight crops have been specifically named in a FIFRA Section 2(ee) recommendation for the use of spirotetramat in citrus to control bud mite, rust mite (silver mite), and red mite with a rate of 10 fluid ounces per acre in California. Spirotetramat use is recommended in the California statewide IPM program and in other states.

In summary, Criterion IV has been met with the use of spirotetramat on grapefruit, lemon, lime, kumquat, pummelo, tangerine, tangelo, and Satsuma mandarin.

Determination

EPA concludes that spirotetramat is an effective alternative for control of certain insect pests on dry bulb onion; and an important IPM tool for grapefruit, lemon, lime, kumquat, pummelo, tangerine, tangelo, and Satsuma mandarin. Therefore, EPA finds that spirotetramat satisfies at least one criteria for an extension of the period of exclusive use for at least nine minor uses: dry bulb onion, grapefruit, lemon, lime, kumquat, pummelo, tangerine, tangelo, and Satsuma mandarin.

Therefore, EPA grants your request for a three-year extension of exclusive use data protection for selected data under EPA Registration Number 264-1049.

As indicated in a letter dated May 24, 2012 from then RD Director Lois Rossi to your legal counsel Anthony L. Michaels of Beveridge & Diamond, the exclusive use period for spirotetramat is February 4, 2009 – February 4, 2019. A copy of this letter is enclosed. With this three-year extension, exclusive use protection for applicable data, submitted in support of this registration, will expire on February 4, 2022.

Sincerely,

A handwritten signature in cursive script that reads "Susan Lewis".

Susan Lewis
Director, Registration Division
Office of Pesticide Programs

Enclosure: Letter from Lois Rossi to Anthony Michaels, Esq. of Beveridge and Diamond