



**US Environmental Protection Agency
Office of Pesticide Programs**

**Exclusive Use Extension Request
Response Letter for Spirodiclofen**

July 19, 2013



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

JUL 19 2013

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

Dear Ms. Movassaghi:

Subject: Spirodiclofen Technical
EPA Registration Number 264-830
Extension of Exclusive Data Use Period Granted
Your submission dated October 17, 2012
OPP Decision Number D471910

This is in response to your request, dated Oct. 17, 2012, the Office of Pesticide Programs' preliminary response to your petition requesting to extend the period of exclusive data use for the insecticide spirodiclofen by 3 years.

You have cited 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 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. A study entitled to exclusive use protection is defined in 40 CFR section 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 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 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 you cited was granted on June 30, 2005, and was the first registration for spirodiclofen with the product name Spirodiclofen Technical.

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 EPA will count minor uses supported by IR-4 generated data 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 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.

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

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. 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.

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.

Analysis of Justification for Exclusive Use Extension

Bayer submitted information on the role of spiroadiclofen in integrated pest management, Criterion 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 Spiroadiclofen Technical. Spiroadiclofen was first registered on June 30, 2005, and additional minor uses were registered on June 18, 2008 and April 29, 2010.

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 spiroadiclofen was important in managing insects as part of a larger IPM program used for control of key pests in a given crop.

Spiroadiclofen is a foliar miticide that is classified by Insecticide Resistance Action Committee (IRAC, 2013) as a Group 23 insecticide, which are lipid biosynthesis inhibitors. Spiroadiclofen is registered for use on a variety of crops such as citrus, grapes, stone fruit, pome fruit, and mango. According to Bayer and confirmed by the Office of Pesticide Programs, spiroadiclofen is the only miticide registered for use on perennial crops within IRAC Group 23 and is one of a few miticides that are active on eggs, nymphs, and adult growth stages. In addition, spiroadiclofen targets important mite pests while having low to moderate effects on predatory mites. Spiroadiclofen may be used once per season.

Information Sources

EPA examined information submitted by the registrant, as well as relevant university extension service information, USDA Crop Profiles, and Mode of Action and resistance management information available from IRAC. 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 17 representative minor crops: grapefruit, lemon, lime, key lime, kumquat, pummelo, tangerine, avocado, cherry, nectarine, peach, pear, filbert, pistachio, mango, papaya, and hops. It is BEAD'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 grapefruit, lemon, lime, key lime, kumquat, pummel, tangerine, avocado, and peach. 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 (NASS, 2008).

Summary of Findings

- **Citrus:** The information submitted by Bayer to support criterion IV for **grapefruit, lemon, lime, key lime, kumquat, pummel, and tangerine** was primarily based on citrus management guidelines from California and Florida. According to this information, spirotetramat targets important citrus pests such as citrus rust mite and spider mites. Spirotetramat is recommended for management of the citrus rust mite in California as part of an IPM program in citrus (UC IPM, 2009). It is the only IRAC Group 23 insecticide listed by UC IPM (2009). Florida recommends the use of spirotetramat as an effective control of citrus rust mites and spider mites and lists it as one of a few insecticides with minimal effects on natural enemies that has a short pre-harvest interval (UF IFAS, 2012). In addition, there are documented resistance issues related to other insecticides used for control of citrus rust mite in the U.S. (APRD, 2013). California and Florida have recent FIFRA Section 2(ee) recommendations for use of spirotetramat (IRAC Group 23) to control citrus rust mites, which is an indication that additional miticides are needed for control of citrus rust mites. Based on the review of the submitted information, EPA concludes that spirotetramat satisfies criteria III and IV for grapefruit, lemon, lime, key lime, kumquat, pummel, and tangerine.
- **Avocado:** Avocados are primarily grown in California with some production in Florida. There are relatively few miticides available for use in avocados. Spirotetramat is the only Group 23 miticide listed by UC IPM (2011a) for mite control, including the key pest the perse mite. In addition, UC IPM (2011b) lists spirotetramat as a selective insecticide with low impacts to predatory mites. Based on the review of the submitted information, EPA concludes that spirotetramat satisfies criterion IV for avocado.
- **Peach:** California is a major producer of U.S. peaches. Spirotetramat is listed as the only IRAC Group 23 miticide for control of brown mite and European red mite for use in an IPM program in peaches (UC IPM, 2010a; UC IPM, 2010b). UC IPM management options consider efficacy and impact to beneficials thus supporting Bayer's claim that spirotetramat plays a useful role in IPM. Based on the review of the submitted information, EPA concludes that spirotetramat satisfies criterion IV for peaches.

Determination

EPA concludes that Bayer has satisfied the requirements necessary to extend the period of exclusive use data for the nine crops listed above. EPA finds that spirodiclofen satisfies criteria III and IV for an extension of the period of exclusive use for grapefruit, lemon, lime, key lime, kumquat, pummel, and tangerine. In addition, EPA finds that spirodiclofen satisfies criterion IV for an extension of the period of exclusive use for avocado and peach. Therefore, EPA grants your request for a three year extension of exclusive use data protection for selected data under EPA Registration Number 264-830. Exclusive use protection for data, which complies with 40 CFR 152.83(c), submitted in support of this registration, will expire on June 30, 2018.

Sincerely,

A handwritten signature in black ink that reads "Lois Rossi". The signature is written in a cursive, flowing style.

Lois Rossi, Director
Registration Division
Office of Pesticide Programs