



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

**EPA Response to Petition for Spiromesifen**

**September 10, 2009**



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

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OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

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Re: Petition for Extension of the Exclusive Use Period for Data Submitted for Spiromesifen  
Technical (EPA Reg. 264-718)

Dear Dr. Movassaghi:

The Agency **GRANTS** your petition for an extension of exclusive use data protection for EPA Registration No. 264-718 for an additional three (3) years. The initial registration of spiromesifen occurred on May 3, 2005. Exclusive use protection for data submitted in support of this registration which complies with 40 CFR 152.83(c) will expire on May 3, 2018.

This letter is in response to your petition dated November 14, 2007 that data associated with the registration of the active ingredient spiromesifen receive an extension to their exclusive use period. You 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), the section that provides for protection of certain data submitted in support of pesticide registrations. 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 minor uses registered within the first seven years of an original registration whose data retains exclusive use protection, with a maximum of an additional three years of exclusive use protection.

The first step in determining whether data qualifies for an extension of its exclusive use period is to ascertain which data have exclusive use protection. FIFRA section 3(c)(1)(F)(i) and its implementing regulations carefully circumscribe the set of data that are eligible for exclusive use protection. A study entitled to exclusive use protection is defined in 40 CFR 152.83(c).

Pursuant to 40 CFR 152.83(c), the following requirements must be met for a study to be considered an exclusive use study:

- (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; and
- (2) The study was submitted in support of, or 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; and
- (3) The study was not submitted to satisfy a data requirement imposed under FIFRA Section 3(c)(2)(B);

Provided that, a study is an exclusive use study only during the 10-year period following the date of 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 must have been submitted in support of the first registration of the new chemical.<sup>1</sup> The registration you cited was granted May 3, 2005 and was the first registration for spiromesifen with the product name Spiromesifen Technical.

Please note, because exclusive use protection is not available for studies that the Agency requires to maintain registration in effect under 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).

Now that the Agency has determined that studies associated with this registration are exclusive use studies<sup>2</sup>, we must determine whether you have met the criteria for extending the exclusive use protection period 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:

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<sup>1</sup> 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 to support 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 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. See 49 FR 30884, 30889

<sup>2</sup> Because the requestor did not attach a list of data they believe retain exclusive use protection, this response is general in nature. If the Agency receives an application for registering an identical or substantially similar product during the extension period citing your data, it will then address whether those data have the extension of data protection.

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; or
- (II) the alternatives to the minor use pesticide pose a greater risk to the environment of human health; or
- (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.

Bayer CropScience requested 3 years extension of exclusive use data protection based on the registration of 11 minor crops. After reviewing the Agency's files we have found the following: On May 3, 2005 the following minor crops were registered for spiromesifen: strawberries; tuberous and corm vegetables (EPA crop subgroup 1-C); vegetables – leafy greens subgroup (EPA crop subgroup 4-A); vegetables – brassica head and stem subgroup (EPA subgroup 5-B); fruiting vegetables (EPA crop group 8); and cucurbit vegetables and melons (EPA crop group 9). Residue data were generated by Bayer CropScience to support these registrations and were conducted on: strawberries; head lettuce; leaf lettuce; spinach; broccoli; cabbage; mustard greens; peppers; cantaloupe; cucumbers and summer squash. The initial registration of spiromesifen occurred on May 3, 2005 and as required by the statute, the aforementioned minor uses associated with the crop groupings were all registered within the requisite seven-year period.

After reviewing the currently approved label for spiromesifen the Agency has determined that the following 11 minor uses qualify toward the request for extension of exclusive use data protection: strawberries; head lettuce; leaf lettuce; spinach; broccoli; cabbage; mustard greens; peppers; cantaloupe; cucumbers; and summer squash.

In addition to meeting the minor use requirements, FIFRA section 3(c)(1)(F)(ii) requires that one of the criterions I-IV as stated above be met. Bayer CropScience submitted information for all four criteria. The Agency reviewed the information submitted by Bayer CropScience and

elected to evaluate for criterion III, “the minor use pesticide plays or will play a significant part in managing pest resistance”. The Agency concluded that criterion III has been met for all of the crops in the petition and the main target pests, *Bemisia* whiteflies and two-spotted spider mites.

The Agency concluded that spiromesifen is a new active ingredient that belongs to the chemical class of cyclic tetrone acid derivatives discovered by Bayer CropScience during the 1990s (Nauen and Bretschneider, 2002; Bretschneider, et al., 2003). Spiromesifen inhibits lipid biosynthesis (Toapanta et al., 2003; Prabhaker and Toscano, 2007). According to Brust (2006), spiromesifen exhibits a translaminar activity that allows it to penetrate the leaf surface and move through the leaf cells. Spiromesifen shows no cross-resistance to currently available insecticides and acaricides (Toapanta et al., 2003; Prabhaker and Toscano, 2007). Spiromesifen is registered for control of two-spotted spider mites and whiteflies on strawberries, mustard greens, peppers, cantaloupe, cucumbers and summer squash. On leaf and head lettuce, spinach, broccoli and cabbage it is labeled only for whitefly control.

In the Agency’s analysis, the two species of *Bemisia*, *B. tabaci* (sweet potato whitefly) and *B. argentifolii* (silverleaf whitefly) are treated as a single species since, until recently, the silverleaf whitefly was considered the “B” biotype of the sweet potato whitefly and not a separate species (Baker, 2006). Reportedly, the silverleaf whitefly has displaced the sweet potato whitefly in most of its former range (UC Pest Management Guidelines, 2005). Although *Bemisia* whiteflies are found throughout the southern United States, they appear to be especially damaging in the hot, desert areas of California, Arizona and Texas (USDA-Crop Profile for broccoli in California, 1999). The host range of the silverleaf whitefly is known to extend to 500 species of plants (Fasulo, 2007).

The Agency used the Michigan State University’s Arthropod Pesticide Resistance Database to evaluate the resistance incidences of the two species of *Bemisia* whiteflies and two-spotted spider mites. The Database indicates that these pests have developed resistance to numerous active ingredients and chemistries worldwide. In the U.S., two-spotted spider mites and *Bemisia* whiteflies have developed resistance to 28 and 18 insecticidal active ingredients, respectively. On a worldwide basis, the corresponding numbers are 86 and 45, respectively. At present, pesticide resistance in *Bemisia* whiteflies appears to be limited to California, Arizona and Hawaii. Resistant populations of two-spotted spider mite are found primarily in the eastern half of the U.S., as well as in California and Washington.

The two-spotted spider mite is a serious pest of strawberries in California and Arizona and on peppers in the western United States. *Bemisia* whiteflies are serious pests of head and leaf lettuce in Arizona and California where they cause direct damage to plants as well as vector plant viruses. *Bemisia* whiteflies are also serious pests in Arizona spinach, western peppers and brassicas and cucurbit crops in the southeast and western United States.

These pests have demonstrated a history of resistance to pesticides in the U.S. and worldwide. The classic method for slowing the development of pest resistance to pesticides is to rotate different classes of chemistry during the spray season. This works only when there are several different and effective pesticide products available for control of the resistance-prone pests which have different modes of action. Spiromesifen has a unique mode of action and is

effective in controlling *Bemisia* whiteflies and two-spotted spider mite. The Agency concluded that spiromesifen is a novel chemistry that can be rotated with the few available and effective chemistries for control of *Bemisia* whiteflies and two-spotted spider mites to slow the development of resistance to pesticides by these pests.

The Agency concluded that all 11 of the requested uses meet criteria III. The uses are strawberries, head lettuce, leaf lettuce, spinach, broccoli, cabbage, mustard greens, peppers, cantaloupe, cucumbers, and summer squash. The Agency, therefore, **GRANTS** your request for an extension of exclusive use data protection under EPA registration No. 264-718 for an additional three (3) years. Exclusive use protection for data submitted in support of this registration which complies with 40 CFR 152.83(c) will expire on May 3, 2018.



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cc: Meredith Laws  
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