



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

**Petition for the Extension of the  
Exclusive Use Period for  
Carfentrazone Technical**

**October 4, 2011**



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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Ms. Shannon Yanocha  
FMC Corporation  
1735 Market St.  
Philadelphia, PA 19103

OCT - 4 2011

Re: Petition for Extension of the Exclusive Use Data Protection Period for  
Carfentrazone-ethyl Technical (EPA Reg. No. 279-3181) Under FIFRA section 3(c)(1)(F)(ii)

Dear Ms. Yanocha:

This is in response to your request, dated May, 2010, that data associated with the registration of the active ingredient carfentrazone-ethyl receive extensions for the exclusive use period protection. 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 new 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 to the exclusivity period.

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 is 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;
- (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 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 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 must have been submitted in support of the first registration of the new chemical.<sup>1</sup> The registration you cited was granted on September 30, 1998, and was the first registration with the product name Carfentrazone-ethyl (F8426) Technical.

Lastly, 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 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:

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 uses 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.

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.

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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> This response is general in nature. If the Agency receives a me-too application for this pesticide during the extension period citing FMC data, it will then address whether those data have the extension of protection.



After reviewing the Agency's files and FMC's letter dated August 5, 2010, we have confirmed the following: In April, 2008, FMC petitioned the Agency for a three-year extension of the exclusive-use period for data submitted in support of the carfentrazone-ethyl registration. This request was based on consideration of 12 minor uses which were added to the Carfentrazone-ethyl Technical label within seven years of the initial registration. Seven of these met at least one of the criteria for the extension of the exclusive use period. Therefore, in September, 2009, the Agency granted a two-year extension of the exclusive-use period for data submitted in support of the carfentrazone-ethyl registration. Two more minor uses are needed for carfentrazone-ethyl to be qualified for an extension of the exclusive use period one more year, for a total of 3 years. In May, 2010 FMC submitted information on 5 more minor crops, all of which were registered in 2004: raspberries, peaches, okra, garlic and peppers, and requested an extension of the exclusive data use period for an additional year. After reviewing the currently approved label for Carfentrazone-ethyl Technical, the Agency has determined that the following minor uses qualify toward the request for extension of exclusive use protection<sup>3</sup>: garlic and okra. As required by statute, the aforementioned minor uses associated with the crop groupings were all registered within the requisite seven year period.

In addition to meeting the minor use requirements, as stated above FIFRA section 3(c)(1)(F)(ii) requires that one of the criteria I - IV be met. The Agency determined that carfentrazone-ethyl plays a role in managing resistant weed biotypes in garlic and okra, meeting the requirements of criterion III, above. The justification for this is as follows (excerpted from the memorandum, "Review of Justification for the Extension of Exclusive Data Use Period for Carfentrazone-ethyl (DP #380972)," dated November 10, 2010:

Garlic: According to the USDA census of Agriculture (2007), California ranks first in both the number of farms growing garlic and in harvested garlic acres. Garlic is a weak competitor and does not thrive in weedy fields. Currently, 23 different biotypes of herbicide-resistant weed species are present in California (WSSA, 2010). Some of these weeds are resistant to modes of action of widely used herbicides, such as: glycines (glyphosate), synthetic auxins (quinclorac), bipyridiliums (paraquat), ACCase (fenoxaprop), and ALS inhibitors (halosulfuron) (WSSA, 2010). Paraquat, glyphosate, and metam sodium are used as pre-plant treatments to control established weeds prior to planting garlic. Carfentrazone-ethyl is a PPO-inhibitor, and is applied as a post-emergence burndown treatment to control broadleaf weeds in middle rows of garlic fields. Applications of herbicide formulations with different modes of action help in minimizing the development of herbicide resistance in weeds. Carfentrazone-ethyl is available as a stand-alone product, or a premix with many other herbicides, such as 2,4D, MCPP-P, quinclorac, glyphosate, dicamba, and halosulfuron (CDMS, 2010). Use of premixed herbicides with differing modes of action minimized development of herbicide-resistant weeds in garlic production. Additionally, application of herbicides with longer residual activity also plays a major role in enhancing the development of herbicide resistance in weed species. Compared to many available alternatives, at recommended rates, carfentrazone-ethyl has little or no residual activity (New York Department of Environmental Conservation, 1999). Carfentrazone-ethyl can be considered a highly useful tool available for garlic growers to manage the development of herbicide resistance in weeds found in garlic fields. Therefore, under FIFRA § 3(c)(1)(F)(ii), carfentrazone-ethyl meets Criterion III considered for the extension of the exclusive use data period.

Okra: Many herbicides are recommended as pre-emergence and pre-plant treatments in okra; however, only a few are recommended as post-emergence treatments: sethoxydim, glyphosate, and carfentrazone-ethyl. Of these, sethoxydim only controls grass weed species, and has a 14-day preharvest

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<sup>3</sup> Because the statute sets a maximum of a three year extension for exclusive use protection provided that 9 minor uses are added within the seven year period after registration, the Agency did not list more than nine eligible minor uses. There may be additional uses not listed in this document that also count toward exclusive use protection. The agency will evaluate those uses for eligibility should the registrant decide to voluntarily cancel or stop marketing any of the 9 uses currently forming the basis of the extension.

interval. A large number of weed species have developed resistance to glyphosate (WSSA, 2010), and it also has a 14-day preharvest interval in okra. Carfentrazone-ethyl has a 0-day preharvest interval, and therefore has greater application flexibility in okra production. In addition, only two weed species, tall waterhemp (*Amaranthus tuberculatus*) and common ragweed (*Ambrosia artemisiifolia*), have developed resistance to carfentrazone-ethyl in the United States (WSSA, 2010). Furthermore, carfentrazone-ethyl has little or no residual activity, and with its unique mode of action, it can be used as a stand-alone or tank mixed product to manage the development of herbicide resistance in weeds found in okra production fields. Therefore, under FIFRA § 3(c)(1)(F)(ii), carfentrazone-ethyl meets Criterion III considered for the extension of the exclusive use data period.

Garlic and okra qualify as minor-use crops, and also fulfill Criterion III under FIFRA § 3(c)(1)(F)(ii). This fulfills the requirement for two additional crops necessary to extend the exclusive use period for an additional year. The Agency, therefore, **grants** your request for an extension of exclusive use data protection under EPA Registration No. 279-3181 for an additional one (1) year. Exclusive use protection for data submitted in support of this registration which complies with 40 CFR §152.83(c) expired on **September 30, 2011**.

A handwritten signature in black ink, appearing to read "Lois Rossi" with a stylized flourish at the end.

Lois Rossi, Director  
Registration Division  
Office of Pesticide Programs