



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

**Response Letter for Extension
of the Exclusive Use
Data Protection Period for
Sulfentrazone Technical**

June 11, 2007



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

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OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Callista O. Chukwunye, Ph.D.
FMC Corporation
1735 Market Street
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re: Request for extension of the period of
exclusive-use data protection for data submitted for
Sulfentrazone Technical (EPA Reg. No. 279-3149)

Dear Dr. Chukwunye:

This is in response to your request dated July 26, 2006¹ that data associated with the original registration of the active ingredient sulfentrazone receive an extension of their exclusive-use protection 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 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 currently 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 C.F.R. 152.83(c).

¹ The Agency sent FMC an interim request for more information on February 27, 2007. This response incorporates the new information FMC submitted to the Agency in response to the interim request.

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.² The registration you cited was granted on February 27, 1997 and was the first registration for sulfentrazone with the product name Sulfentrazone Technical.

Lastly, exclusive-use protection is not available for studies that the Agency requires to maintain registration under FIFRA section 3(c)(2)(B). Therefore, any data associated with this registration that is required by FIFRA section 3(c)(2)(B) will not receive exclusive-use protection under FIFRA section 3(c)(1)(F)(ii).

² 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 exclusive-use 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, or the remainder of the original 10-year exclusive-use period. See 49 FR 30884, 30889.

It is important to note that data generated by IR-4 is not entitled to exclusive use protection (see 40 CFR 152.94(b)). However, the Agency will count minor uses supported by IR-4 generated data when determining how many years exclusive use protection may be extended. IR-4 generated data were submitted for all six minor uses discussed in this letter (asparagus, cabbage, horseradish, peppermint, spearmint and succulent lima bean).

The Agency has not made individual determinations on every study associated with the above-referenced registration as to exclusive use protection. If the Agency receives a me-too application for this pesticide during the extension period citing FMC's data, it 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.

Now that the Agency has determined that studies associated with this registration are exclusive-use studies, 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 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.

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.

After reviewing the Agency's files we have found the following. On September 29, 2003 several minor uses were added to the sulfentrazone technical database. After reviewing the currently-approved uses and data submitted for the sulfentrazone technical, the Agency has determined that the following minor uses qualify toward the request for extension of exclusive-use protection: horseradish, cabbage, peppermint, spearmint, succulent lima bean, and asparagus. As required by statute, the aforementioned minor uses were all registered within the requisite seven-year period. These six minor uses allow for a two-year extension of exclusive-use protection if all other criteria are met.

In addition to meeting the minor use requirements, FIFRA section 3(c)(1)(F)(ii) requires that one of criteria I - IV as stated above be met. FMC submitted information in support of its claims that: (1) there are insufficient efficacious alternatives to sulfentrazone and (2) sulfentrazone plays a significant role in resistance management. The following is our determination on each minor use crop.

Horseradish

The registrant listed a number of problem weeds in horseradish, and stated that limited herbicides are available for this crop (I of the criteria described above). The petition only identified oxyfluorfen, glyphosate, and sethoxydim as the currently used herbicides. The petition also mentioned that sulfentrazone is important for morningglory and nightshade control.

A search of CDMS of herbicides available for use in horseradish included, in addition to the herbicides described by the registrant, carfentrazone, clethodim, DCPA, dimethenamid-p, pyraflufen-ethyl, and paraquat. OPP did not attempt to evaluate all of these alternatives because the search was not weed specific. Rather, OPP refined the CDMS search to include only the weeds morningglory and nightshade. The refined search resulted in only glyphosate, carfentrazone, DCPA, dimethenamid-p, and

pyraflufen-ethyl, and sulfentrazone. Glyphosate may only be applied pre-emergence or to the row middles as contact with the crop may cause injury. In addition, glyphosate will not provide residual control. Carfentrazone is registered for use as a hooded spray to control weeds between the crop rows. Contact with crop will result in crop injury. DCPA and dimethenamid-p are registered to control nightshade but not morningglory. Pyraflufen-ethyl is registered for preplant burndown and must be applied 30 days before planting.

Sulfentrazone is a soil-applied herbicide that may be applied as a preplant or preemergence application or to the row middles once the crop has emerged. Therefore, OPP believes that the registrant may have a case for insufficient registered alternatives for morningglory control based on what is known about the available alternatives.

Cabbage

The registrant stated that because sulfentrazone was a Priority A project³ in IR-4, and the Priority A requirements are similar to those in FIFRA Section 3(c)(1)(F)(ii)(I-IV), this use site meets the criteria described above. The fact that a pesticide is listed as a Priority A project does not automatically mean it meets the FIFRA criteria, however, it is important information to aid OPP in making its determination. As with all other information, OPP evaluates all available information when making its determinations.

In addition, the registrant stated that sulfentrazone poses a lower risk to the environment or human health when compared to the alternative, paraquat (see FIFRA Section 3(c)(1)(F)(ii)(II)). Although paraquat also controls broadleaf weeds, OPP does not believe it is the most likely alternative to sulfentrazone due to relatively low usage, pests targeted, and lack of residual control (EPA proprietary data).

The registrant also described how sulfentrazone controls a broader spectrum of weeds than many of the other alternatives and specifically mentions the weeds nightshade and waterhemp. As the registrant points out, before sulfentrazone was registered, it was identified as an herbicide that may control these weeds "in some situations" in cabbage (PMSP, 2002). According to the label, a few nightshade species, common waterhemp and tall waterhemp are controlled by sulfentrazone.

³ A Priority A project in IR-4 is a high priority project. Only select projects receive this designation. Factors that are considered when determining Priority A projects include availability and efficacy of alternatives, IPM compatibility, and the potential impact from the target pest (Baron, 2007).

OPP notes that oxyfluorfen is described as providing good nightshade control but can only be applied before transplanting (and not used on direct seeded crops) (Crop Profile in MN, 2001). Sulfentrazone may be applied preplant or preemergence and used for transplanted or direct seeded cabbage.

The PMSP describes waterhemp as an emerging weed problem and as being more difficult to control than other pigweeds species (PMSP for MN and WI Cabbage, 2002; Crop Profile in Wisconsin, 2003). Since waterhemp appears to be a difficult weed to control in cabbage, OPP searched the Crop Data Management System (CDMS) for other herbicides registered for use on cabbage to control waterhemp in order to determine whether there may be efficacious alternatives. In addition to sulfentrazone, carfentrazone, glyphosate and pyraflufen are registered. BEAD investigated further and found that carfentrazone may only be applied as a hooded spray between the crop rows. Glyphosate may only be applied before the crop emerges or to the row middles and will not provide residual control. Pyraflufen may be used for preplant burndown. Given the limitations with the alternative herbicides, OPP believes that there are insufficient efficacious alternatives to control waterhemp in cabbage.

Mint (Peppermint and Spearmint)

The registrant focused on the limited availability of alternatives for mint, and the need for sulfentrazone as a resistance management tool due to the development of resistant weeds in mint (I and III of the criteria described above).

OPP confirmed that there is terbacyl-resistant Powell amaranth in mint in Washington, and terbacyl-resistant redroot pigweed in Oregon (Heap, 2007). In Oregon, bromoxynil resistant common groundsel has also been documented (Heap, 2007).

In the PMSP for the Midwestern states, an herbicide efficacy table shows that sulfentrazone provides good control of pigweed species, terbacyl provides good to excellent control, and that pyridate provides excellent control (PMSP for IN, WI, and MI Mint, 2002). Other herbicides also have good efficacy but are not used much due to limitations, such as the potential to cause crop injury (PMSP for IN, WI, and MI Mint, 2002; PMSP for PNW Mint, 2002). Since pyridate is not available for use, and terbacyl resistant pigweeds have been documented in mint, OPP believes sulfentrazone may play an important role in resistance management, thus meeting the resistance management criteria (CDMS search; PMSP for PNW Mint, 2002).

The label lists mint as one crop but as noted in the FMC letter to OPP (Chukwunye, 2006) there are two separate tolerances for peppermint and spearmint in 40 CFR 180.498. Therefore, the two mint crops will be considered as two separate crops.

Succulent Lima Bean

Tennessee was granted an emergency exemption use for sulfentrazone on lima bean to control hophornbeam copperleaf because of a lack of effective alternatives. The registrant submitted additional information describing the difficulty

controlling hophornbeam copperleaf in lima beans. The registrant also described how sulfentrazone will play a role in managing weeds, specifically marestalk and pigweed species, that have developed resistance to glyphosate.

According to a former Technical Sales Representative for the registrant, lima beans are often rotated with glyphosate-tolerant crops such as corn, soybeans, and cotton (Crumby, 2007). As stated in a Tennessee extension publication, "The advent of no-till row crop production along with Roundup Ready" [glyphosate-tolerant] crops has become a good niche environment for this weed [hophornbeam copperleaf]. The reduction in the use of cultivation and applications of soil applied residual herbicides has helped this weed become more established in Tennessee" (Steckel, no date). In addition, as pointed out by Crumby, glyphosate-resistant weeds are becoming an increasing problem. Glyphosate-resistant horseweed (marestalk) has been documented in Tennessee and glyphosate-resistant horseweed and pigweed species have been documented in nearby states (Heap, 2007). "Hophornbeam copperleaf also has some tolerance to glyphosate" (Steckel, no date). According to the label, sulfentrazone will control hophornbeam copperleaf and pigweed species.

The information submitted supports two of the four criteria. There are insufficient efficacious alternatives to sulfentrazone, as demonstrated by the emergency exemption use prior to sulfentrazone registration. Sulfentrazone also plays a significant role in resistance management by controlling weeds that are resistant to glyphosate and by being an alternative chemistry to use in rotation with glyphosate when lima beans are rotated with glyphosate-tolerant crops.

Asparagus

The registrant provided sufficient information data demonstrating that sulfentrazone is used on asparagus and that use of this pesticide is necessary, due to insufficient efficacious alternatives to control certain pests, including morningglory.

The registrant submitted information on the lack of herbicides for the control of morningglory. The Agency reviewed the Crop Profile for Asparagus in New Jersey (2003) and confirmed that morningglory is difficult to control, that there are few alternatives available for control, and that hand weeding may be

necessary. The Agency found that there are four alternative herbicides that are registered for control of morningglory in asparagus: 2,4-D, glyphosate, halosulfuron and norflurazon. Two of these alternatives, halosulfuron and norflurazon, only suppress morningglory. Both glyphosate and 2,4-D must be applied after weeds emerge. Sulfentrazone is used before the crop and weeds emerge. Therefore, based on the description of morningglory in the Crop Profile and that there are no other herbicides that may be applied before weeds emerge to control morningglory, the Agency finds that for morningglory in asparagus there is a lack of efficacious alternatives to sulfentrazone.

After consulting with USDA, the Agency agrees with FMC that (1) there are insufficient efficacious alternatives to sulfentrazone and (2) sulfentrazone plays a significant role in resistance management. Therefore, after consulting with USDA, the Agency **GRANTS** your request for an extension of exclusive-use data protection for selected data under EPA Registration No. 279-3149 for an additional two (2) years. Exclusive-use protection for data, which complies with 40 C.F.R. 152.83(c), submitted in support of these registrations will expire on February 27, 2009.



Lois Rossi, Director
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cc: Joanne Miller
Michele Knorr

REFERENCES

- A Pest Management Strategic Plan (PMSP) for the Indiana, Wisconsin, and Michigan Mint Industries, 2002, Web address: <http://www.ipmcenters.org/pmsp/pdf/MidwestMintpmsp.pdf>
- Baron, J., Executive Director, IR-4 Project, Memorandum to A. Jennings, USDA, March 6, 2007 [submitted with petition]
- Chukwunenye, C.O., Manager, Product Registrations, FMC Corporation, Correspondence with J. Miller, USEPA Office of Pesticide Programs, July 26, 2006.
- Crop Data Management System (CDMS) search, Web address: <https://premier.cdms.net/webapls/>
- Crop Profile for Asparagus in New Jersey, 2003, Web address: <http://www.ipmcenters.org/CropProfiles/docs/NJasparagus.html>
- Crop Profile for Cabbage in Minnesota, 2001, Web address: <http://www.ipmcenters.org/CropProfiles/docs/MNCabbage.html>
- Crop Profile for Cabbage in Wisconsin, Revised 2003, Web address: <http://www.ipmcenters.org/CropProfiles/docs/wicabbage.html>
- Crumby, T., former Technical Service Representative, FMC Corporation, Sulfentrazone Utilization in Lima Bean and Cowpeas statement, March 15, 2007 [submitted with petition]
- Heap, I., The International Survey of Herbicide Resistant Weeds, Online, Internet, January 26, 2007 and March 29, 2007, Web address: <http://www.weedscience.org>
- Pest Management in the Future, A Strategic Plan for the Minnesota and Wisconsin Cabbage Industry (PMSP), 2002, Web address: <http://www.ipmcenters.org/pmsp/pdf/MICabbage.pdf>
- Pest Management Strategic Plan (PMSP) for Pacific Northwest (PNW) Mint Production, 2002, Web address: <http://www.ipmcenters.org/pmsp/pdf/PNWMintPMSP.pdf>
- Steckel, L., Hophornbeam Copperleaf, W120, University of Tennessee Extension [submitted with petition]