



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

**Flumioxazin EPA Petition
Response for the Extension
of the Exclusive Use Data**

December 16, 2008



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

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OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Daniel P. Fay
Valent U.S.A. Corporation
1600 Riviera Avenue
PO Box 8025
Walnut Creek, CA 94596-8025

Dear Mr. Fay:

Subject: Request for Extension of the Period of Exclusive Data Use for the Active Ingredient Flumioxazin
Flumioxazin Technical (EPA Registration No. 59639-97)

This is in response to James Pensyl's Letter Dated April 15, 2008 that requested that data associated with the registration of the active ingredient flumioxazin receive an extension of their exclusive-use protection period. FIFRA section 3(c)(1)(F)(ii) was cited 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 with a maximum of an additional three years to the exclusivity period. At the time the petition for extension is received, there must be an active exclusive use period.

The first step in determining whether data qualifies for an extension of its exclusive-use period is to ascertain if there are exclusive use data supporting the original registration. FIFRA section 3(c)(1)(F)(i) carefully circumscribes the set of data that are eligible for exclusive-use protection. Additionally, the implementing regulations define what qualifies a study for exclusive-use protection.

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;

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(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 there is exclusive use protected data associated with the original registration.

First, the data submitted in support of 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.¹ The registration you cited was granted on April 12, 2001 and was the first registration for flumioxazin with the product name Flumioxazin Technical. Data submitted to obtain the original registration are entitled to exclusive use protection.

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) does not receive exclusive-use protection under FIFRA section 3(c)(1)(F)(ii).

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 additional years exclusive use protection may be extended.

After reviewing this registration file, EPA has determined that there are exclusive-use studies associated with the original registration. The Agency, however, has not made individual exclusive use determinations for every study associated with the above-referenced registration.

¹Data 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.

If the Agency receives a me-too application for this pesticide during the extension period citing Valent'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 the original registration will receive the determined extension of exclusive use protection.

Next, we must determine whether: (1) minor uses have been registered within seven years of the original registration and (2) 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 one 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 August 25, 2004, May 15, 2006 and March 20, 2008 thirteen minor uses were added to the Flumioxazin Technical registration. The registration of these uses occurred within seven years of the original registration.

After reviewing registrant's petition, the currently-approved uses and data submitted for the Flumioxazin Technical, the Agency has determined that the following minor uses qualify toward the request for extension of exclusive-use protection: asparagus, blueberry, cherry, mint, melon, mint, onion, pepper, peach, pear, plum and strawberry. As required by statute, the aforementioned minor uses were all registered within the requisite seven-year period and meet at least one criterion set forth in FIFRA section 3(c)(1)(F)(ii).

As is further described in the enclosed assessment, the Agency determined that there are insufficient efficacious alternative registered pesticides available for the use on the minor crops: cherry, melon, onion, pepper, peach, pear, plum and strawberry. Therefore, these minor uses meet criterion I.

Additionally, the Agency determined that flumioxazin end-use products are an integral part of pest resistance management programs in minor crops. Because the Agency determined that flumioxazin contributes significantly to an effective sustainable pesticide resistance management strategy which will delay the onset of resistance, as well as slow the development and subsequent buildup of resistance, with resorting to increased rates and frequency of application, and ultimately, will prolong the useful life of many pesticides in the minor crops: asparagus, blueberry, cherry, mint, peach, pear, and plum. Therefore, these minor uses satisfy criterion III. See enclosed assessment for a more detailed analysis.

The Agency, therefore, GRANTS your request for an extension of exclusive-use protection for an additional three (3) years. Exclusive-use protection for data, which complies with 40 C.F.R. 152.83(c), submitted in support of this registration will expire on April 12, 2014.

If you have any questions concerning this letter, please contact Ms. Joanne Miller at 703-305-6224. For your information attached is a copy of the Biological and Economic Analysis Division (BEAD) review.

Sincerely yours,



Lois Rossi, Director
Registration Division (7505P)
Office of Pesticide Programs

Enclosure
cc: Michele L. Knorr

ATTACHMENT to GRANT LETTER

FLUMIOXAZIN MINOR CROP REVIEW and REFERENCES

Asparagus

Flumioxazin is used to manage pest resistance in asparagus (Criterion III). Bernard Zandstra (2008), Michigan State Univ., stated that flumioxazin gives 4-6 weeks control of horseweed (*Conyza canadensis*), which is any increasing problem in many crops such as asparagus because of its propensity for resistance to glyphosate. It is also very effective against common lambsquarters (*Chenopodium album*), nightshades (*Solanum spp.*), and pigweeds (*Amaranthus spp.*), which have developed resistance to most other classes of residual herbicides. Flumioxazin

is thus an important herbicide in resistance management and Dr. Zandstra considers it part of an integrated weed management system. Flumioxazin can control triazine resistant common groundsel which has been verified in asparagus fields in California (Heap 2008). BEAD finds that flumioxazin's use in asparagus meets criteria III for the extension of exclusive use because it can control resistant weeds in asparagus.

Blueberry

Flumioxazin is used to manage herbicide resistant horseweed in Michigan blueberry (Criterion III). Bernard Zandstra (2008), Michigan State Univ., stated that flumioxazin gives 4-6 weeks control of horseweed, which is an increasing problem in many crops such as blueberry because of its propensity for resistance to several herbicide families including glyphosate. It is also very effective against common lambsquarters, nightshades, and pigweeds, which have developed resistance to most other classes of residual herbicides. Pelargonic acid is the only postemergence herbicide available for bearing blueberries and does not provide any residual control. In Michigan horseweed has shown resistance to ALS inhibitors (B/2), photosystem II inhibitors (C1/5), and ureas and amides (C2/7) (Heap 2008). Flumioxazin is thus an important herbicide in resistance management and he considers it as a part of an integrated weed management system. BEAD finds that flumioxazin's use in blueberry meets Criterion III for the extension of exclusive use because it can control resistant weeds.

Mint

Flumioxazin is used to manage resistant prickly lettuce (*Lactuca serriola*) and common groundsel (*Senecio vulgaris*) in mint in Washington (Criterion III). Rick Boydston and R. Baker (2003), in Washington, showed that flumioxazin and sulfentrazone, when applied as a split application to dormant mint in the fall and spring, controlled prickly lettuce and common groundsel. In Washington prickly lettuce has shown resistance to ALS inhibitors (B/2) and synthetic auxins (O/4) and common groundsel has shown resistance to photosystem II inhibitors (C1/5) (Heap 2008). BEAD finds that flumioxazin's use in asparagus meets criteria III for the extension of exclusive use because it can control resistant weeds in mint.

Muskmelon

Flumioxazin is used in muskmelon because there are insufficient efficacious alternative registered pesticides available for this use (Criterion I). Kai Umeda and N. Lund (2002), Univ. of Arizona, demonstrated good crop safety and control of two difficult to control weeds: narrowleaf lambsquarters (*Chenopodium denticatum*) and Wright's groundcherry (*Physalis wrightii*). BEAD finds that flumioxazin's use in muskmelon meets criteria I for the extension of exclusive use because it can control weeds where efficacious alternatives do not exist.

Onion

Flumioxazin is used in onion because there are insufficient efficacious alternative registered pesticides available for this use (Criterion I). Clarence Swanton (2008), University of Guelph, stated that flumioxazin can provide superior control of some problem weed species such as hairy galinsoga (*Calinsoga ciliata*) compared to pendimethalin. Pendimethalin is the only alternative residual herbicide used by dry bulb onion producers on muck soils and it must be used at relatively high dosage (3 kg ai/ha). BEAD finds that flumioxazin's use in onions meets criteria I

for the extension of exclusive use because it can control weeds where efficacious alternatives do not exist.

Pepper (bell and non-bell)

Flumioxazin is used in pepper because there are insufficient efficacious alternative registered pesticides available for weed control in peppers (Criterion I). Jill Schroeder (2008), New Mexico State University, stated that growers have great difficulty managing annual broadleaf weeds in pepper. In an email Dr. Schroeder states, "This difficulty is due partly from a lack of registered, efficacious options and partly from the fact that broadleaf weeds emerge throughout the growing season. I would say that a groundcherry species (*Physalis wrightii*) and morningglories (*Ipomoea purpurea* and *Ipomoea hederacea*) pose the greatest late season challenge to our growers. Furthermore, because of the growth habit of pepper and the season-long weed pressure, this treatment would need to be part of an integrated approach for weed management. We lack viable herbicide alternatives for broadleaf weed control early in the season (late March through May, prior to thinning) due to the fact that our peppers are mostly direct seeded and seem to lack tolerance to most broadleaf herbicides we have tested. Therefore, other weed management strategies need to be practiced early in the season and in conjunction with the use of post-directed herbicides. Finally, we are just now facing our first issues with suspected herbicide resistant weeds, so the more tools we have to deal with them, the better off our growers will be." BEAD finds that flumioxazin's use in peppers meets criteria I for the extension of exclusive use because it can control weeds where efficacious alternatives do not exist.

Fruit Trees – Cherry, Peach, Pear, Plum

Flumioxazin is used in fruit tree orchards such as cherry, peach, pear, and plum because there are insufficient efficacious alternative registered pesticides available for this use (Criterion I) and because it can play a significant part in managing herbicide resistant weeds (Criterion III). Tom Lanini (2008), Univ. of California at Davis states that flumioxazin controls many of the glyphosate resistant or tolerant weeds: marehail, hairy fleabane (*Conyza bonariensis*), lambsquarters, malva, and common purselane. Some of these weeds are resistant to other herbicides families: hairy fleabane is resistant to glycines (G/9), lambsquarters is resistant to photosystem II inhibitors (C1/5) and ALS inhibitors (B/2), and common purselane is resistant to photosystem II inhibitors (C1/5) (Heap 2008). Joe Masabni (2008), Texas A&M and previously with Univ. of Kentucky, states that flumioxazin is one of the only herbicides that can be applied in the fall in Kentucky and provide several months of weed control. This allows fewer herbicide applications and more time for other orchard practices in the spring: spraying insects, pruning, scouting, and thinning. BEAD finds that flumioxazin's use in fruit tree orchards meets criteria I and III for the extension of exclusive use because it can control weeds where efficacious alternatives do not exist and controls resistant weeds.

Strawberry

Flumioxazin is used in strawberry because there are insufficient efficacious alternative registered pesticides available for this use (Criterion I). Steve Fennimore (2008), Univ. of California at Davis, stated that flumioxazin is the only herbicide that can provide effective control of clover (*Medicago polymorpha*) in strawberry. Even fumigation with methyl bromide and chloropicrin does not control clover. BEAD finds that flumioxazin's use in strawberry meets criteria I for the

extension of exclusive use because it can control weeds where efficacious alternatives do not exist.

REFERENCES

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