US Environmental Protection Agency
Office of Pesticide Programs

Etoxazole: Exclusive-use period extension request for data protection

April 20, 2012

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

APR 2 0 2012

Dan Fay
Valent U.S.A. Corporation
1600 Riviera Avenue, Suite 200
Walnut Creek, CA 94596

Subject: **Etoxazole**
Exclusive-use period extension request for data protection from August 22, 2012 to August 22, 2015
Etoxazole Technical; EPA Reg. No. 59639-107

Dear Mr. Fay:

This letter responds to your request dated August 11, 2010 for the active ingredient etoxazole (EPA Reg. No. 59639-107, registration dated August 22, 2002), to receive a three year extension of the original ten year exclusive-use protection period, from August 22, 2012 to **August 22, 2015.**

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). 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 qualifying minor uses registered within the first seven years of an original registration whose data retains exclusive-use protection, with a maximum addition of three years to the original ten year exclusivity period.

The first step in determining whether data qualifies for an extension of its exclusive-use period is to ascertain whether there are exclusive-use data associated with a registration. FIFRA section 3(c)(1)(F)(i) and its implementing regulations specifically describe the set of data that are eligible for exclusive-use protection. A study entitled to exclusive-use protection is defined in 40 C.F.R. 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 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); 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 cited was granted on August 22, 2002 and was the first registration for etoxazole with the product name Etoxazole Technical (EPA Reg. No. 59639-107).

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 Agency will count minor uses supported by IR-4 generated data when determining how many additional years that exclusive-use protection may be extended.

Although EPA has determined that there are exclusive-use protected data associated with this registration, 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 Valent Corporation 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.

After determining that there are exclusive-use data associated with this registration, 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 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

---

1 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 reminder of the original 10-year exclusive-use period. See 49 FR 30884, 30889.

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 Agency determined at least nine of the 14 minor uses submitted by Valent were registered within seven years of the original registration of the Etoxazol Technical. The Agency's benefits review focused on the following nine minor uses due to several publicly accessible information sources as well as peer-reviewed research data that could be used to evaluate the data: (1) pears, (2) cherries (3) plums, (4) peaches, (5) strawberries, (6) hops, (7) walnuts, (8) mint, and (9) muskmelons. All of these crops can be found on the registered end-use label: EPA Reg. No. 59638-138.

As to the criteria mentioned above, Valent submitted information to support claims that etoxazole meets all four criteria for all 14 of the minor crops that it listed in its request. EPA examined information submitted by the registrant, as well as relevant university extension service information, acaricide efficacy trials, USDA Crop Profiles, and Mode of Action and resistance management information available from the Insecticide Resistance Action Committee (IRAC).

Criteria I, III and IV were examined. However, this finding for the extension of the exclusive use period generally relies on Criterion IV, "the minor use pesticide plays or will play a significant part in an integrated pest management program" ("IPM"). The benefits review also acknowledges that for muskmelons etoxazole meets the requirements for Criterion III and that the Agency has granted "reduced risk" status for pome fruits, strawberries and tree nuts, making it eligible for Criterion II as well.

Summary of Findings from the EPA's Benefits Review

Etoxazole is an acaricide which is classified by the Insecticide Resistance Action Committee (a pesticide industry technical organization) in the Mode of Action Group 10B. However, etoxazole has relatively low toxicity to non-mite arthropods that are beneficial to pest control, such as pirate bugs, and poses a low bee-poisoning hazard.

EPA evaluated information on pears, cherries, plums, peaches, strawberries, and walnuts with sources from California (primarily the pest management guidance available through the University of California, Davis, and accessible at http://www.ipm.ucdavis.edu/PMG/crops-agriculture.html), since this state is a major producer of these commodities. For muskmelons, EPA reviewed information from California as well as southeastern U.S. extension sources, since recent pest control advice from these sources was readily available. For hops and mint, EPA reviewed information relevant to Washington and Idaho since those are major producing regions.

Applicability of Criterion IV to etoxazole

Etoxazole is described by University of California extension as one of the top choices for growers of many crops included in the request who may be looking for materials "important to an IPM program." In addition, etoxazole has relatively low toxicity to non-mite arthropods that are beneficial to pest control, such as minute pirate bugs (Ashley et al. 2006), and, as the registrant points out, poses a very low bee-poisoning hazard. The University of California also describes etoxazole as being highly toxic to predatory mites, but low in toxicity to non-mite generalist predators.

While hexythiazox and clofentezine (where registered) also have these characteristics, these chemicals are either primarily ovicides (in the case of hexythiazox) or require precise coverage to achieve effectiveness (in the case of clofentezine). In addition, mites have a well known propensity to develop resistance and each of the pesticides (etoxazole, hexythiazox or clofentezine) have specific IPM/resistance management language on each label. For clofentezine, only one application per crop cycle is recommended, for etoxazole applications are restricted to 1-2 applications per season depending on the crop and for hexythiazoz applications are restricted to once per year. Thus, particularly in situations where mite populations are high, growers may need more than one of these types of pesticides to control mites without disrupting natural control of other pests (a key feature of an effective IPM program). Therefore, EPA concludes that for these crops, criterion IV has been met, in that etoxazole has characteristics that make it a useful component of an IPM program aimed at managing mites along with other key pests.

DETERMINATION

The minor uses of etoxazole set forth in the petition for extension of exclusive use meets benefits-related criterion IV for a three year extension because EPA's review concluded that it does play a useful role in managing mites as part of an IPM program for the nine minor crops reviewed in this document.

After reviewing your petition, the Agency concludes that for at least nine minor uses that etoxazole does play a useful role in managing mites as part of an IPM program. Therefore, the Agency **GRANTS** your request for a three year extension of exclusive-use data protection for selected data under EPA Registration No. 59639-107. Exclusive-use protection for data, which complies with 40 C.F.R. 152.83(c), submitted in support of this registration will expire on August 22, 2015.

Daniel J. Rosenblatt (for) 4/20/12

Lois Rossi, Director
Registration Division
Office of Pesticide Programs

cc: Meredith Laws
Dan Rosenblatt
John Hebert
Autumn Metzger
Nicole Williams
Michele Knorr