



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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Larry Zang
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re: Request for extension of the period of exclusive-use data protection for data submitted for Fludioxonil Technical (EPA Reg. No. 100-759), Maxim 4FS (EPA Reg. No. 100-758), and Switch 62.5WG (EPA Reg. No. 100-953)

Dear Mr. Zang:

This is in response to your request dated January 29, 2004 that data associated with the registration of the active ingredient fludioxonil 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).

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.¹ The registration you cited was granted on October 5, 1995 and was the first registration for fludioxonil with the product name Fludioxonil 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).

Now that the Agency has determined that studies associated with this registration are exclusive-use studies², we must determine whether you have met the criteria for

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

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.³ On September 30, 1998 and August 21, 2001 several minor uses were added to the Fludioxonil Technical

pesticide during the extension period citing Syngenta data, it will then address which of those data have the extension of protection.

³ Syngenta argues that the crops caneberry, pistachio, and watercress should be counted toward the extension of exclusive-use protection. Those uses were registered on March 13, 2003. Because the uses were not registered within seven years of the original registration, those uses have not been counted toward the total.

database. After reviewing the currently-approved uses and data submitted for the fludioxonil technical, the Agency has determined that the following minor uses qualify toward the request for extension of exclusive-use protection: lettuce, radish, cucumber, garden pea, strawberry, and onion. 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. Syngenta submitted the following responses to two of these criteria. First, EPA designated fludioxonil as a reduced-risk pesticide in a letter dated April 23, 1997. As a reduced-risk pesticide, fludioxonil is able to provide effective control while displacing or replacing other chemicals posing greater risk to humans and non-target organisms.

Second, fludioxonil end-use products are an integral part of pest resistance management programs in minor crops. In support of the pest management programs, Syngenta provided information concerning the pest management programs for minor crops stating that fludioxonil is a key component in developing and managing any pesticide resistance because it has a different mode of action than other available products.

The Agency recognizes that pesticides are important pest management tools. The Agency agrees that fludioxonil's designation as a reduced-risk pesticide shows that it poses lesser risks to the environment or human health than alternative pesticides some of which have a greater carcinogenic and teratogenic potential. The Agency also agrees that fludioxonil 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, without resorting to increased rates and frequency of application, and ultimately, will prolong the useful life of many pesticides.

The Agency, therefore, **GRANTS IN PART** your request for an extension of exclusive-use data protection for selected data under EPA Registration Nos. 100-758, 100-759 and 100-953 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 October 5, 2007.

Lois Rossi

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cc: Cynthia Giles-Parker
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