



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

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

April 21 , 2010



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

John Abbott
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P.O. Box 18300
Greensboro, North Carolina 27419-8300

APR 21 2010

Subject: Petition for Extension of the Exclusive Use Data Protection Period for
Cyprodinil, Cyprodinil Technical-EPA Registration Number 100-811, under
FIFRA § 3(c)(1)(F)(ii)

Dear Mr. Abbott:

This letter is in response to Syngenta's petition for extension of the exclusive use data period for cyprodinil dated February 1, 2008. The initial registration date for cyprodinil occurred on April 10, 1998. The Agency **grants** Syngenta's petition for extension of exclusive use data protection for cyprodinil for **two years**. The new expiration date for cyprodinil exclusive use data is **April 10, 2010**.

The 1996 Food Quality Protection Act (FQPA) amendments to FIFRA incorporated provisions under 3(c)(1)(F), the section that provides certain data protection, to provide additional data protection for minor use registrations. FIFRA section 3(c)(1)(F)(ii) sets forth criteria for extending the period of exclusive-use protection. If the Administrator determines that one of four criterion are met, the period of exclusivity can be extended one year for every three minor uses registered within the first seven years of the exclusive use period of the original registration. The maximum number of years the exclusivity period may be extended is three years.

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.

Pursuant to the 40 CFR 152.83 definition of exclusive use study, 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 describes our analysis for determining whether the data associated with Cyprodinil Technical, EPA Registration Number 100-811, contains exclusive use data. First, we determine whether there are data associated with this registration that pertain to, or have been derived from testing on, a new active ingredient. We have determined that there are data associated with this registration that pertain to 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 10, 1998 and was the first registration for cyprodinil with the product name Cyprodinil Technical.

Please note, exclusive use protection is not available for studies that the Agency requires under FIFRA section 3(c)(2)(B) to maintain registration in effect. 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 there are studies associated with this registration that are exclusive use studies², we must determine whether you have met the criteria for extending the exclusive use protection period 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:

¹ Data are not protected solely because they pertain to a 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.

² This response is general in nature. For purposes of this petition, EPA did not determine which data associated with this registration have/had exclusive use data protection, only that at least some data are entitled to exclusive use data protection.

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.

Syngenta Crop Protection, Inc. requested 3 years extension of exclusive use data protection, until April 10, 2011, for registration of nine crops; basil, blueberry, broccoli, cabbage, chives, lychee, mustard greens, pistachio and raspberry. All of these crops are minor uses as defined in FIFRA Section 2(ii).

The Agency determined that the initial registration of cyprodinil, Cyprodinil Technical – EPA Registration Number 100-811, occurred on April 10, 1998. On March 13, 2003, FIFRA Section 3 registrations were granted for cyprodinil on blueberry, pistachio and raspberry and on October 14, 2004 for basil, broccoli, cabbage, chives, lychee, and mustard greens. As required by statute, the aforementioned nine minor crop uses were all registered within the requisite seven-year period.

Next, EPA analyzed whether the nine minor use crops met any of the statutory criteria for extending exclusive use protection. Syngenta provided information to support criteria (I) “there are insufficient efficacious alternative registered pesticides available for the use” and (III) “the minor use pesticide plays or will play a significant part in managing pest resistance” for all nine of the minor use crops. Syngenta also provided information to support criterion (IV) “the minor

use pesticide plays or will play a significant part in an integrated pest management program (IPM)” for blueberry, lychee and raspberry.

The Agency evaluated information provided by Syngenta to support criterion (I) for basil, chives and lychee. The Agency determined that the alternatives to cyprodinil for control of Alternaria leaf spot and Botrytis leaf blight in basil and chives provide limited efficacy. Therefore, criterion (I) is supported for basil and chives. Copper fungicides are alternatives to cyprodinil for control of Alternaria and Botrytis fruit rots in lychee. However, copper is the only alternative and repeated applications are phytotoxic to lychee. Therefore, the Agency determined that there are insufficient efficacious alternative registered pesticides available for control of Alternaria and Botrytis fruit rots in lychee. Criterion (I) has been met for basil, chives and lychee.

Criterion (III) “the minor use pesticide plays or will play a significant part in managing pest resistance“ has been met for broccoli, cabbage and mustard green minor crop uses. The alternatives to cyprodinil include QoI-fungicides like pyraclostrobin and azoxystrobin which are commonly used on Brassica crops (includes broccoli, cabbage and mustard greens). The Fungicide Resistance Action Committee (FRAC) has classified QoI-fungicides as group 11 fungicides. Group 11 fungicides are known to be high risk for resistance development and cross resistance occurs between all members of group 11 fungicides. Cyprodinil has a different mode of action than QoI-fungicides and is classified as a group 9 fungicide. The University of California IPM extension program recommends alternating cyprodinil with QoI-fungicides for resistance management in these crops. Cyprodinil is available for disease control in Brassica crops in a combination product, Switch 62.5 WG, which also includes fludioxonil. Even though cyprodinil is only available in a combination product for Brassica crops, the Agency determined that cyprodinil on its own is a resistance management fungicide for these crops as it has a different mode of action than QoI-fungicides. The addition of fludioxonil, a group 12 fungicide with a different mode of action than cyprodinil and QoI-fungicides, to cyprodinil in the combination product Switch 62.5 WG increases the spectrum of disease control for brassica crops in a single product and adds another measure of resistance management. Additionally, the label for an end-use product containing cyprodinil, Switch 62.5 WG, includes resistance management labeling in the “General Use” section of the label as recommended by Pesticide Registration (PR) Notice 2001-5 “Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling” as follows:

General Use Precautions:

RESISTANCE MANAGEMENT

GROUP 9 | 12 FUNGICIDES

Switch 62.5 WG contains two fungicides with different modes of action. Cyprodinil is an anilino-pyrimidine in Group 9. Fludioxonil is a phenylpyrrole in Group 12. A disease management program that includes alternation of tank mixes between Switch 62.5 WG and other labeled fungicides that have a different mode of action is essential to prevent pathogen populations from developing resistance to Switch 62.5 WG. Do not alternate or tank mix this product with fungicides to which resistance has already developed. Switch 62.5 WG may be applied in an alternating or blocking program.

The Switch 62.5 WG label also contains resistance management labeling for Brassica crops as follows:

USE DIRECTIONS - Brassica Vegetables:

Resistance Management: After 2 applications of Switch 62.5 WG, alternate with another fungicide with a different mode of action for 2 applications.

Syngenta's use of the voluntary resistance management labeling from PR Notice 2001-5 and mandatory Brassica crop use-specific labeling supports their case for criterion (III).

The Agency determined that criterion (IV) "the minor use pesticide plays or will play a significant part in an integrated pest management program" has been met for blueberry and raspberry. Cyprodinil is referenced for use in IPM programs in USDA Pest Management Strategic Plans (PMSP) for blueberries produced in Michigan, Oregon and Washington, and New England states. The PMSPs indicate that growers are using IPM programs that include cultural, biological and chemical controls for disease management. Similarly, the PMSP for raspberries produced in Oregon and Washington indicates that growers are using IPM programs that include cyprodinil for disease management.

The Agency did not have sufficient information to determine if cyprodinil use in pistachios met criteria (I) or (III). With regard to criterion (I), there are several alternatives to cyprodinil for control of *Alternaria* and *Botrytis* in pistachios and no efficacy data were submitted to compare cyprodinil to its alternatives. For criterion (III), no specific information was submitted in the petition or found during Agency analysis for determining if the pistachio use meets this criterion. If Syngenta wants EPA to reconsider the pistachio use, you may provide the Agency with further details on why this use meets either criterion (I) or (III).

In summary, eight of the nine minor crop uses in the petition met one of the four criteria and are eligible to be considered towards extension of the exclusive use period for cyprodinil. Basil, chives and lychee met criterion (I); broccoli, cabbage and mustard greens met criterion (II) and blueberry and raspberry met criterion (IV).

The Agency determined that eight of the nine minor use crops submitted in the petition met the requirements for extension of the exclusive use period for cyprodinil. The eight minor use crops are: basil, blueberry, broccoli, cabbage, chives, lychee, mustard greens and raspberries. The Agency **grants** Syngenta's petition for extension of the exclusive use period for cyprodinil for **two years**. The **new exclusive use expiration** date for cyprodinil is **April 10, 2010**.

Sincerely,


Lois Rossi, Director
Registration Division
Office of Pesticide Programs

cc: Cynthia Giles-Parker
Shaja Joyner
Nicole Williams
Michele Knorr
Pat Cimino