UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 3, 2015

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Registration Manager
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Subject: **Product Name: Prothioconazole Technical**
EPA Reg. No. 264-824; Decision: 491207; Application Dated 5/5/2014
EPA Finding: Extends the exclusive-use data protection period by 3 years from March 27, 2017 to March 27, 2020

Dear Ms. Fernandez:

This letter addresses your request that data associated with the original registration of Prothioconazole receive a three year extension to the original ten year exclusive-use protection period. The original data protection period started March 27, 2007 and ends March 27, 2017. Though only nine registered minor crops are needed to support the request, the following seventeen were cited: watermelon, summer squash, cucumber, cantaloupe, pumpkin, lowbush blueberry, cranberry, currant, gooseberry, loblolly pine, slash pine, longleaf pine, hardwoods, chickpea, crambe, buckwheat, and popcorn. EPA is granting the request for an exclusive use extension of three additional years to end March 27, 2020 under EPA Registration No 264-824.

Bayer CropScience cited FIFRA section 3(c)(1)(F)(ii) as the authority for EPA 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 any 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 that was first registered after September 30, 1978.

Second, the data were submitted in support of the first registration of the new chemical.[1] The registration cited was granted on March 27, 2007 and was the first registration for prothioconazole with the product name "Prothioconazole Technical".

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 Bayer CropScience 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:

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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.

> "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;
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> (II) the alternatives to the minor use pesticide pose greater risks to the environment or human health;
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> (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."

SUMMARY OF FINDINGS

EPA evaluated information about characteristics of prothioconazole, disease claims, and production practices for the nine minor crops. The Fungicide Resistance Action Committee (FRAC) has designed a group classification system based on a fungicide's mode of action. Prothioconazole is classified as a triazole fungicide (FRAC Group 3), which acts as a demthylation inhibitor (DMI) that inhibits sterol biosynthesis in fungi. DMI fungicides are the most widely used fungicides due to their effectiveness in managing many diseases caused by numerous fungal pathogens. Prothioconazole is the new generation of the DMI mode of action. It is the only active ingredient in a new chemical family, thiazolinthiones, classified by FRAC.

Bayer CropScience identified 17 qualifying minor crops and submitted information to substantiate that each crop met at least one of the four criteria above. The Agency determined the following nine minor uses met criteria I, III and IV. The Agency also determined that the following nine minor uses were registered within seven years of the original registration of Prothioconazole Technical: buckwheat, cantaloupe, chickpea, cucumber, loblolly pine (nursery), lowbush blueberry, popcorn, summer squash, and watermelon.

The Agency verified there are prothioconazole tolerance citations for the nine minor use crops in 40 CFR 180.626. Additionally, each of the labels contains a resistance management section and FRAC code and resistance management information as a partner in a resistance management program. The following is a summary of each crop and the criterion that was met to count towards extending the exclusive use period. This summary was based upon the information provided by the registrant and reviewed by EPA. Please review the supporting document "Review of Justification for Extension Use Period for Prothioconazole" dated May 4, 2015 for a more detailed explanation of how each crop meets the standard for extending the exclusive use period.

Buckwheat: Prothioconazole plays a significant part in an IPM program of buckwheat in a buckwheat-potato rotation. Prothioconazole use on buckwheat satisfies Criterion IV.

Cantaloupe, cucumber, summer squash, and watermelon: Prothioconazole is effective and there are insufficient efficacious alternative registered pesticides available for control of Fusarium wilt on cantaloupe, cucumber, summer squash, and watermelon. Prothioconazole use on cantaloupe, cucumber, summer squash, and watermelon satisfies Criterion I.

Chickpea: Prothioconazole plays a significant part in managing disease resistance for control of Ascochyta blight on chickpea in North Dakota. Prothioconazole use on chickpea satisfies Criterion III.

Loblolly pine: Prothioconazole is the only efficacious registered pesticide for control of canker or pitch canker on the minor use loblolly pine (nursery) and it is also used to control other fungal pathogens in forest seedling nurseries. Prothioconazole use on loblolly pine (nursery) satisfies Criterion I.

Lowbush blueberry: Prothioconazole plays a significant part in the IPM program of Valdensinia leaf spot on lowbush blueberries in Maine. Prothioconazole use on lowbush blueberries satisfies Criterion IV

Popcorn: Prothioconazole plays a significant part in managing resistance and prolonging lifespan of resistance-prone but highly valuable fungicides for control of anthracnose leaf blight and other diseases on popcorn. Prothioconazole use on popcorn satisfies Criterion III.

DETERMINATION

The Agency concludes that the nine uses listed above are minor uses and were registered within seven years of the original prothioconazole registration. These minor uses were found to meet at least one of the four criteria listed above. Therefore, the Agency **GRANTS** your request for a three year extension of the original exclusive-use data protection period for data submitted to support EPA Registration No.264-824. Exclusive-use protection for data, which complies with 40 C.F.R. 152.83(c), submitted in support of this registration **will expire on March 27, 2020**. A copy of our review is enclosed.

Sincerely,

Susan T. Lewis

Susan Lewis, Director
Registration Division (7505P)
Office of Pesticide Programs

Enclosure: Review of Justification for Extension Use Period for Prothioconazole