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

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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Review of Justification for Extension of Exclusive Use Period for Prothioconazole (DP#421072)

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Product Review Panel: April 15, 2015

SUMMARY

When pesticides are registered, the original data submitter has a 10-year exclusive use period from the date of registration for the data submitted in support of the original registration. FIFRA allows for an extension of that exclusive use period if certain criteria are met. An extension of one year is provided for every three qualifying minor uses, for a maximum of three years. Bayer submitted a petition to EPA requesting that, under FIFRA Section 3(c)(1)(F)(ii), the exclusive use period be extended for three years with supporting information on 17 crops. BEAD reviewed nine crops and found that the use of prothioconazole on buckwheat, cantaloupe, chickpea, cucumber, loblolly pine (nursery), lowbush blueberry, popcorn, summer squash, and watermelon met at least one of the criteria for extension of the exclusive use period; that is, prothioconazole plays a significant part in integrated pest management or resistance management or there are insufficient efficacious alternative registered fungicides available. In conclusion, the criteria have been met by these nine minor uses to extend the exclusive use period for the maximum three years allowed by FIFRA.

BACKGROUND

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides certain data protection rights to data submitters for their registered pesticides. Section 3(c)(l)(F)(i) states that the original data submitter has a 10-year exclusive use period from the date of registration for the data submitted in support of the original registration. An extension to the exclusive use period may be allowed if certain criteria are met, detailed in Section 3(c)(1)(F)(ii) as the following:

> *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.*

The definition of minor use is described in FIFRA Section 2(ll) as the use of a pesticide on an animal, on a commercial agricultural crop or site, or the protection of public health where (1) the total U.S. acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture, or (2) the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use.

Prothioconazole is a fungicide belonging to a new chemical family, triazolinthiones, which has been only recently classified by the Fungicide Resistance Action Committee (FRAC). Bayer CropScience (Bayer) has submitted a petition to the United States Environmental Protection Agency (EPA) for a three-year extension of the exclusive use period (Bayer, 2014). Since three minor uses must meet one of the criteria for a one-year extension, and the statute limits the extension to a maximum of three years, nine minor uses need to meet at least one of the criteria for a three-year extension.

INTRODUCTION

In this memo, the Biological and Economic Analysis Division (BEAD) evaluates the information submitted to determine whether Criterion I, III, or IV has been met. The purpose of this review is to analyze the information including online publications and photocopied references (Appendices 1-40) submitted by Bayer and to determine whether prothioconazole meets at least one Criterion for at least nine crops.

APPROACH AND METHODOLOGY

In this review, the approach and methodology mainly follows a published online EPA guideline on the exclusive use data protection for minor use registrations (EPA, 2014) described as the following for Criteria I, III, and IV:

> (CRITERION I) ***There are insufficient efficacious alternative registered pesticides available for the use:*** *The registrant must provide documentation that the pesticide is effective and that other pesticides registered are either not effective or otherwise provide inadequate control of the pest. FIFRA Section 18 Emergency Exemptions may provide useful information regarding insufficient efficacious alternatives for certain minor uses. It is helpful to document that the pest in question is actually of concern for crop production. This information is generally available in state extension crop recommendations, Crop Profiles or Pest Management Strategic Plans.*
>
> (CRITERION III) ***The minor use pesticide plays or will play a significant part in managing pest resistance:*** *The registrant must submit documentation that the pest has developed or tends to develop resistance to pesticides and that the minor use pesticide is effective and offers a new mode of action that can be rotated with other pesticides to manage pest resistance. Websites such as the International Survey of Herbicide Resistant Weeds (http://www.weedscience.org/summary/home.aspx) and the Arthropod Pesticide Resistance Database (http://www.pesticideresistance.org/) provide pest resistance information. Consideration for meeting this criterion will be given if the label for the minor use follows the guidance from Pesticide Registration (PR) Notice 2001-5 Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling.*
>
> (CRITERION IV) ***The minor use pesticide plays or will play a significant part in an integrated pest management program****. The registrant must demonstrate that the pesticide is or will be important in integrated pest management (IPM). For example, documentation that an insecticide is relatively safe for beneficial insects may support a finding that it plays a significant role in integrated pest management (IPM) programs. The documentation could also include a reference to a publication, such as a recent Crop Profile, Pest Management Strategic Plan or Cooperative Extension Service recommendation that states the pesticide is a tool in the IPM programs.*

ANALYSIS

Bayer has submitted a petition to EPA for a three-year extension of the exclusive use period with justification for 17 candidate crops in various crop groups (Bayer, 2014). The nine crops focused and analyzed in this memo are buckwheat, cantaloupe, chickpea, cucumber, loblolly pine (nursery), lowbush blueberry, popcorn, summer squash, and watermelon. Their registrations fall within the first seven years of original registration (PPLS, 2015).

Minor use

After consulting with the U.S. Department of Agriculture (USDA), BEAD agreed to rely on the most recent Census of Agriculture, conducted every five years by National Agricultural Statistics Service, to determine crop acreage. Crops not listed in the Census of Agriculture are cultivated on fewer than 300,000 acres. For the nine crops on which this memo is focused, the total U.S. acreage for each crop is less than 300,000 acres (Table 1).

Table 1. Nine crops considered by BEAD with U.S. acreage, crop group information, and criterion met through BEAD analysis in this memo.

Crop	U. S. Acreage (acres)		Crop Group	Criterion Met
	Submitted by Bayer	2012 Census of Agriculture		
Buckwheat	24,760 (2007)	33,678	15	IV
Cantaloupe	77,430	71,911	9	I
Chickpea	146,000	(not listed)	6	III
Cucumber	138,000	111,900	9	I
Loblolly pine (nursery)	1,327 (2008)	(not listed)	99	I
Lowbush blueberry	69,610	41,087 (wild blueberries)	13-07	IV
Popcorn	201,623	218,461	15	III
Summer squash	50,200	33,190	9	I
Watermelon	143,400	128,208	9	I

Note: Lowbush blueberry (Vaccinium angustifolium) is also called wild blueberry, mainly grown in parts of Canada and Maine (Markle et al., 1998; USHBC, 2015).

Buckwheat

BEAD finds prothioconazole plays a significant part in an IPM program of buckwheat in a buckwheat-potato rotation based on the information below.

Buckwheat (*Fagopyrum esculentum*) has been grown since the colonial days in North America. Seed treatment by a fungicide improves buckwheat's establishment and uniform stand as a smother crop to suppress problematic weeds, which can also be used as a cover crop and a rotational crop to select Rhizoctonia strains or populations that were nonpathogenic or less pathogenic on potatoes (Larkin et al., 2010; Oplinger et al., 1989; Specht and Leach, 1987).

Two DMI (DeMethylation Inhibitor) fungicides, prothioconazole and ipconazole, are registered for use on buckwheat as a seed treatment (NPIRS, 2015). Three fungal genera causing damping-off are specifically named and targeted by prothioconazole, compared to only one for ipconazole. Usage data on wheat are available in Proprietary Data that confirmed prothioconazole was recently used significantly more than ipconazole. Thus, prothioconazole is preferred to ipconazole for use on buckwheat to improve its establishment, uniform or optimum stand, and vigor as a quick cover and smother crop to reduce pathogen pressure and herbicide use in fields rotated to potato, and to provide a DMI mode of action broadening pest spectrum, all of which are important components in an IPM program (Larkin et al., 2010; Oplinger et al., 1989; SARE, 2007; Specht and Leach, 1987). This cover, smother, and rotational crop can also be used, because of its prolific flowering (Oplinger et al., 1989), as a source of nectar for pollinators, another appealing component in an IPM program. Prothioconazole is not harsh on beneficial organisms, relatively non-toxic to bees (OMAFRA, 2014), an additional asset fitting IPM.

Thus, the prothioconazole use on buckwheat satisfies Criterion IV.

Chickpea

BEAD finds prothioconazole plays a significant part in managing disease resistance for control of Ascochyta blight on chickpea in North Dakota based on the information below.

Ascochyta blight is a severe disease in most chickpea growing regions of the world including North Dakota (NDSU, 2008). Strobilurin fungicides along with protectants were the mainstay of control for this disease, but resistance developed and the most frequently used strobilurin fungicides became ineffective in North Dakota (NDSU, 2008). Prothioconazole is from a different chemical family, triazolinthiones, and is labeled with information on resistance management and its role as a rotational and tank-mixing partner in a resistance management program.

Due to strobilurin resistance, the university extension recommended that no applications of strobilurin fungicides be applied to chickpea in North Dakota in 2007 and that preventative applications of chlorothalonil be applied prior to flowering, followed by a rotation of the fungicides boscalid (SDHI) and prothioconazole (DMI) at flowering, or if conditions were favorable for disease development (Wise et al., 2009). Prothioconazole has consistently provided excellent control of Ascochyta blight of chickpeas in field trials and is the sole DMI fungicide recommended in the resistance management program (Wunsch, 2014).

In addition, the Western Forum on Pest Management confirmed that resistance to strobilurin fungicides had been identified in the *Ascochyta rabiei* pathogen in Saskatchewan, Alberta, and North Dakota, and prothioconazole was the only recommended DMI fungicide (WFPM, 2014).

Thus, the prothioconazole use on chickpea satisfies Criterion III.

Loblolly pine

BEAD finds prothioconazole is effective and there are insufficient efficacious alternative registered pesticides available for control of pitch canker on nursery seeds and seedlings of loblolly pine based on the information below.

The U.S. pine nursery industry produces nursery-grown bare root seedlings used for reforestation (Enebak, 2012). Loblolly pine is listed on the Proline 480 SC label of prothioconazole, submitted as a candidate crop (*Pinus taeda*) by Bayer in the application package, and accounted for approximately 75% of the pine nursery acreage (Boyer and South, 1984). One of key diseases is pitch canker caused by *Fusarium circinatum*. No fungicides registered for pitch canker or canker caused by Fusarium on loblolly pine (nursery) are found in the National Pesticide Information Retrieval System (NPIRS).

In 2008, a FIFRA Section 24(c) was requested by the Georgia Forestry Commission for prothioconazole because 1) forest tree nurseries faced the loss of a number of fungicides that make growing tree seedlings increasingly difficult; 2) there were no registered fungicides for pitch canker control in nurseries; and 3) prothioconazole had been thoroughly researched by the Auburn University Nursery Management Cooperative and had proven to be effective (GFC, 2008). In 2011, laboratory, greenhouse, and field trials continued to show prothioconazole was efficacious against important fungal pathogens including pitch canker that cause damage and seedling mortality in forest seedling nurseries (Starkey and Enebak, 2011). With a FIFRA Section 3 registration, prothioconazole is available for control of pitch canker and other diseases in nurseries including loblolly pine (Bayer, 2014).

Thus, the prothioconazole use on loblolly pine (nursery) satisfies Criterion I.

Lowbush blueberry

BEAD finds prothioconazole plays a significant part in the IPM program of Valdensinia leaf spot on lowbush blueberries in Maine based on the information below.

Valdensinia leaf spot (*Valdensinia heterodoxa*) causes early leaf drop or complete leaf drop of infected plants so that no flower buds are produced (Percival, 2009; Percival et al., 2009; Woolley, 2012). It is an invasive disease spreading to Maine from Canada in 2009 (Annis et al., 2009). Hildebrand and Renderos (2010) confirmed that it became a serious disease of lowbush blueberry spreading throughout Nova Scotia, New Brunswick, and Prince Edward Island with new observations occurring in Quebec and Maine.

Information on this new fungal disease in the U.S. is limited and lowbush (wild) blueberries are mainly grown in Northern Maine and parts of Canada (USHBC, 2015). No information on Valdensinia and its control are found in the Crop Data Management System (CDMS) or NPIRS. No fungicides were recommended when this disease was first reported in Maine (Annis et al., 2009; Mack, 2009). Prothioconazole has been registered in the U.S. for Valdensinia leaf spot and is the only recommended fungicide against Valdensinia leaf spot (Annis and Yarborough, 2015). The IPM components in Maine include 1) prothioconazole to suppress and 2) hard burn of all leaf litter and infected plants to eradicate.

Thus, the prothioconazole use on lowbush blueberries satisfies Criterion IV.

Popcorn

BEAD finds 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 based on the information below.

Popcorn can be grown under the same conditions that favor field corn, and the largest acreages of popcorn often coincide with areas for large field corn acreages (Carter et al., 1989). QoI (Quinone outside Inhibitor) fungicides are used most frequently on corn and, to manage resistance, DMI fungicides are often used together with them. Several generations of Group 3 DMI fungicides have been developed, and there are differences in the activity spectra of different DMI active ingredients (FERA, 2009; Mueller and Bradley, 2015). Prothioconazole is the new generation of the DMI mode of action. It is the only active ingredient in a new chemical family, triazolinthiones, classified by FRAC recently, and its labels display resistance management information and its role as a partner in a resistance management program.

DMI fungicides are needed for control of anthracnose leaf blight and only two of them, prothioconazole and tetraconazole, are recommended (Wise, 2014). Proprietary Data (2013) confirmed that prothioconazole was the top DMI fungicide used by corn growers to control anthracnose leaf blight.

Research data also showed that Stratego YLD had the highest yield among fungicides tested in field trials against common rust and gray leaf spot (Schleicher and Jackson, 2011). It is a combination product consisting of the DMI fungicide prothioconazole and the QoI fungicide trifloxystrobin, which has a high risk of developing resistance (FRAC, 2014). Its use has been increasing and Proprietary Data (2013) confirmed it was the top product to control anthracnose leaf blight and the second most-applied product to control common rust and gray leaf spot. Prothioconazole offers a new and highly active DMI alternative to older-generation DMI fungicides and commonly used QoI fungicides in order to preserve the effectiveness of both of these groups against popcorn diseases.

Thus, the prothioconazole use on popcorn satisfies Criterion III.

Cantaloupe, cucumber, summer squash, and watermelon (4 crops)

BEAD finds prothioconazole is effective and there are insufficient efficacious alternative registered pesticides available for control of Fusarium wilt on cantaloupe, cucumber, summer squash, and watermelon based on the information below.

Fusarium wilt is an important vascular disease and is specifically different from Fusarium root rots, Fusarium leaf spots, and other Fusarium rots (ANR, 2014; Egel and Martyn, 2007; Zitter et al., 1996). There are fungicides registered for control of non-specific *Fusarium* spp. such as non-vascular Fusarium rots. However, no fungicides were labeled for Fusarium wilt of watermelon (Egel and Hoke, 2007). Currently, very few pesticides are labeled specifically for Fusarium wilt on melons and cucurbits, with 1,3-D and 1-2 inorganic chemicals found in CDMS, and 1-5 biologicals, 1-4 inorganic chemicals, 1,3-D, chloropicrin, triflumizole (greenhouse cucumber), and thiophanate-methyl (FIFRA Section 24(c)) found in NPIRS.

In 2008 and 2009, the Inter-Regional Research Project Number 4 (IR-4 Project aka the Minor Crop Pest Management Program) conducted major researches to screen for fungicides for control of Fusarium wilt on cucurbits and melons. IR-4 project 10813 (prothioconazole) was requested by PCR (project clearance request) (IR-4, 2008). Prothioconazole was effective against Fusarium wilt (Zhou et al., 2009). Some other non-fumigant control options such as Garlic GP Fungicide did not result in an effective control (Zhou et al., 2009). Many data from the IR-4 coordinated research trials indicated that prothioconazole was the only registered efficacious non-fumigant alternative.

A non-fumigant alternative is often preferred to fumigants if it is only a Fusarium wilt problem. If fumigants are used, 1,3-D and chloropicrin are preferred to others for control of Fusarium wilt because Fusarium wilt is on their labels. Fumigants are often recommended when fields have nematode problems, and for example in Texas on watermelon, they are only recommended for nematode control (USDA, 2012b). Fumigant products registered for Fusarium wilt consist of a single active ingredient product of 1,3-D and several combination products of chloropicrin and 1,3-D (NPIRS, 2015). Therefore, they are limited due to 50 foot well setbacks in all states, township caps in California, and restrictions near karst formations in Florida on the use of 1,3-D. Both prothioconazole and fumigants are needed so that there are sufficient efficacious control options available in those large melon/cucurbit production states.

Thus, the prothioconazole use on cantaloupe, cucumber, summer squash, and watermelon satisfies Criterion I.

CONCLUSION

BEAD has found prothioconazole is an important IPM or resistance management tool on buckwheat, chickpea, lowbush blueberry, and popcorn, and there are insufficient efficacious registered fungicide alternatives available on cantaloupe, cucumber, summer squash, watermelon, and loblolly pine (nursery) for control of certain diseases. BEAD concludes that adequate criteria have been met by the prothioconazole use on buckwheat, cantaloupe, chickpea, cucumber, loblolly pine, lowbush blueberry, popcorn, summer squash, and watermelon to support an extension of the exclusive use period for three years.

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