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MEMORANDUM

SUBJECT: Drinking Water Assessment in Support of the Proposed Prothioconazole Section 3 New Use on Cotton, and New Application Methods on Sugar Beet, Soybean, Dried Shelled Peas and Beans Crop Subgroup 6C, and Corn.

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EXECUTIVE SUMMARY

The Environmental Fate and Effects Division (EFED) has reviewed the proposed labels (EPA Reg. No. 264-825, Proline 480 SC Fungicide; 264-1093, Stratego YLD Fungicide; 264-1122, Evergol Energy; and 264-824, Prothioconazole Technical Fungicide) and information submitted by Bayer CropScience for the proposed new use of prothioconazole on cotton (foliar, in-furrow and seed treatment application); and

new application methods on sugar beet (seed treatment, banded, in-furrow), soybean (in-furrow), dried shelled peas and beans crop subgroup 6C (in-furrow), and corn (in-furrow). No new data were submitted as part of this action.

The proposed application rate for cotton is one application at planting (in furrow) of 0.22 lb a.i./A followed by two foliar applications (14-day intervals) at 0.156 lb a.i./A applied by aerial spray, ground spray or chemigation, for a maximum annual application rate of 0.53 lb a.i./A/yr. While the maximum annual application rate for cotton is not higher than the annual application rates for other uses assessed in previous Drinking Water Assessments (DWA; USEPA 2010; USEPA 2012*a*; USEPA 2012*b*), new modeling was conducted using the currently approved models SWCC and PRZM-GW.

Prothioconazole appears to degrade relatively quickly in the environment; however, its degradates, primarily prothioconazole-desthio and prothioconazole-S-methyl, are more persistent than the parent. As documented in previous prothioconazole assessments, a total toxic residues approach was used for drinking water exposure modeling. Combined residues of concern include the parent and the two aforementioned degradates and were determined using input values that also accounted for unextracted residues.

Surface water modeling with the Surface Water Concentration Calculator (SWCC) indicated that the proposed use on cotton would result in much lower surface water Estimated Drinking Water Concentrations (EDWC) than in the previous DWAs. However, previously reported surface water EDWCs were updated due to changes in the percentage crop area (PCA) adjustment factor (see USEPA 2012b) implemented since those values were reported in the most recent DWA. The surface water acute and chronic EDWCs, based on corn use, have increased slightly (from 99.0 to 108.8 ppb and from 91.1 to 96.8 ppb, respectively). Previous values were based on a corn PCA of 0.91; the values now reflect the current "all agriculture" PCA of 1.0 which is used when a pesticide may be used on multiple crops in the same watershed, as is the case for prothioconazole.

The acute and chronic EDWCs provided for groundwater sources of drinking water, previously determined using the SCI-GROW model based on the maximum application rate for all uses (*i.e*., nursery seedlings), have been updated using the PRZM-GW model. The previously reported cancer EDWC of 91.9 ppb for surface water, determined using the Tier 1 Rice model modified for cranberries (USEPA 2012*b*), has now been replaced with a higher value (based on nursery seedling use) determined using the PRZM-GW model. Because the acute (**188** ppb), chronic (**183** ppb), and cancer (**183** ppb) EDWCs for groundwater are now higher than those for surface water, these groundwater EDWCs are now recommended for use in HED's dietary risk assessment, and are listed in bold in **Table 1.**

Table 1. Maximum Estimated Drinking Water Concentrations for prothioconazole residues of concern in surface water and groundwater.

Drinking Water Source (Model Used)	**Use (Rate Modeled)**	**Maximum Estimated Drinking Water Concentration (EDWC)**		
		Acute (µg/L)	**Chronic (µg/L)**	**Cancer (µg/L)**
Surface water (PRZM/EXAMS; IL corn scenario)	Corn 0.178 1b a.i./A x 4 application/yr at 7-day intervals using aerial spray	108.8[1]	96.8[1]	77.9

Drinking Water Source (Model Used)	Use (Rate Modeled)	Maximum Estimated Drinking Water Concentration (EDWC)		
		Acute (µg/L)	Chronic (µg/L)	Cancer (µg/L)
Groundwater (PRZM-GW)	Nursery seedlings 0.178 1b a.i./A x 5 applications/yr at 14-day intervals	**188**[2]	**183**	**183**

[1]Surface water EDWCs have been updated to reflect the current PCA of 1.0 for "all agriculture." The EDWCs for corn use were estimated previously using EFED's Tier II aquatic models: PRZM (Pesticide Root Zone Model; v3.12.2; 5/15/05) and EXAMS (EXposure Analysis Modeling System; v2.98.04.06; 4/25/05). Calculations for PRZM/EXAMS were carried out with the linkage program shell: PE5 (PRZM EXAMS Model Shell; v5.0; 11/15/06), which incorporates the standard scenarios developed by EFED.
[2] Bolded values indicate the EDWCs recommended for use in HED's dietary risk assessment.

USE CHARACTERIZATION

Prothioconazole is registered for use on a variety of crops, with the majority of usage (total pounds applied to crops basis) on wheat, corn, sugar beets, peanuts, dry beans/peas, soybeans and barley (USEPA 2015*a*). Prothioconazole is also registered for use on alfalfa, beans, bushberries, rice, small grains, crambe, cucurbits, mustard, potatoes, small fruit, cranberries, and nursery stock. It is registered for use as a seed treatment on multiple crops, including cereal grains and potatoes (USEPA, 2015*b*). It is not registered for use on any non-agricultural sites.

The maximum application rate for the proposed new use on cotton is presented in **Table 2**. For comparison purposes, application information is also presented for the uses that result in the maximum EDWCs in surface water and groundwater.

Table 2. Application information for the proposed new use of prothioconazole on cotton and for previously registered uses on corn and nursery seedlings.

Crop	Max. Single Application Rate (lbs. a.i./A)	Max. No. of Applications	Maximum Annual Application Rate (lb a.i./A/yr)	Minimum Application Interval (days)	Application Method(s)
Cotton	1 in-furrow application of 0.22 at planting; 2 foliar applications of 0.156 post-emergence	3	0.53	14	Aerial and ground spray (foliar); Chemigation
Corn	0.178 1b a.i./A	4	0.7125	7	Aerial and ground spray; chemigation
Nursery seedlings[1]	0.178 1b a.i./A	5	0.89	14	Foliar treatment; ground application

[1] Nursery seedlings include shortleaf, loblolly, slash, longleaf pine and other conifers and hardwoods.

EXPOSURE CHARACTERIZATION

Environmental Fate and Transport Characterization

Prothioconazole degrades relatively quickly to two major persistent degradates which are assumed to be of similar toxicity to that of the parent (based on structural similarity), prothioconazole-desthio and prothioconazole-S-methyl, which are both considered residues of concern. Prothioconazole is stable to hydrolysis and degrades by aqueous photolysis ($t_{1/2}$ = 9 d) to prothioconazole-desthio, which appears to resist further photolytic degradation (combined $t_{1/2}$ = 101 d). Prothioconazole and its degradates are not expected to volatilize (vapor pressure < 3 x10^{-9} Torr). Parent prothioconazole rapidly degrades in aerobic soil systems (decreased to 7.9 - 52.1 % of applied by 1 day and was <2.0 - 23.2 % of applied by 7 days). However, based on available data, prothioconazole plus its major degradates (*i.e*., total residues of concern) do not appear to undergo significant microbial degradation in soil ($t_{1/2}$ = 462 – 1386 d) or in water ($t_{1/2}$ = 67 – 433 d). Prothioconazole's mobility is not characterized due to rapid degradation in mobility studies. However, the major degradate that formed in the largest amounts (prothioconazole-desthio) is moderately mobile based on its organic carbon partition coefficient (K_{oc} = 523 – 625 mL/g_{oc}) and the Food and Agriculture Organization soil mobility classification scheme (FAO, 2000). The other major degradate, prothioconazole-S-methyl, which is formed in smaller relative amounts, is slightly mobile (K_{oc} = 1973 – 2993 mL/g_{oc}). Because these two major degradates are considered to be of similar or greater toxicity than the parent (USEPA 2006), they are included in the aquatic exposure estimates as residues of concern. There is potential for the prothioconazole residues of concern to leach to groundwater in vulnerable aquifers, such as those underlying coarse-textured soils low in organic matter.

Because high levels of unextracted material in laboratory metabolism studies precluded an accurate determination of the biotic degradation rates for parent prothioconazole, a total toxic residues (TTR) method, including unextracted material and the residues of concern, was utilized for exposure modeling. Additional details on this, and on the environmental fate and transport of prothioconazole and its degradates can be found in the June 1, 2006 Ecological Risk Assessment (USEPA, 2006) and in the Registration Review Problem Formulation (USEPA 2015*c*). Also presented in those documents and in USEPA 2010*a* are detailed summary tables of physical/chemical and environmental fate/transport properties of prothioconazole's combined residues of concern, as well as summaries of the major degradation products formed by each degradation process in the submitted fate studies.

Measures of Aquatic Exposure

Models

Surface Water

Preliminary modeling for the proposed use on cotton was conducted using the Surface Water Concentration Calculator (SWCC, v 1.106, May, 2014). The SWCC is used to generate EDWCs that may occur in surface water used as drinking water. The SWCC simulates pesticide transformation on and runoff from an agricultural field (in addition to loadings from spray drift), following applications to crops. The model then simulates resulting concentrations in an adjacent surface water body. Standard assumptions for drinking water assessment are a surface water watershed of 172.8 ha that drains into a drinking water "index" reservoir of 5.26 ha surface area, and average depth 2.74 m. A more detailed description of the index reservoir and its watershed can be found in (USEPA 2010*b*).

Although preliminary modeling was conducted using SWCC for the new use on cotton to determine whether the EDWCs for cotton use were lower than previous maximum EDWCs, the maximum surface water acute and chronic EDWCs are still based on corn use and were estimated previously using EFED's

Tier II aquatic models: PRZM (Pesticide Root Zone Model; v3.12.2; 5/15/05) and EXAMS (EXposure Analysis Modeling System; v2.98.04.06; 4/25/05). Calculations for PRZM/EXAMS were carried out with the linkage program shell: PE5 (PRZM EXAMS Model Shell; v5.0; 11/15/06), which incorporates the standard scenarios developed by EFED. Details of the determination of the EDWCs for corn use can be found in USEPA 2009 and USEPA 2012*a*. While new modeling was not conducted for the corn use, the surface water EDWCs were updated (in post-processing) based on current guidance.

Groundwater

Groundwater EDWCs for prothioconazole were derived using the PRZM-GW model (Pesticide Root Zone Model for Groundwater, version 1.07, Nov., 2014), with the GW-GUI (Graphical User Interface, version 1.0, August 31, 2012). PRZM-GW is a one-dimensional leaching model that estimates the concentrations of pesticides in groundwater. It accounts for pesticide fate in the crop root zone by simulating pesticide transport and degradation through the soil profile after a pesticide is applied to an agricultural field. PRZM-GW permits the assessment of multiple years of pesticide application (up to 100 years) on a single site. Six standard scenarios, each representing a different region known to be vulnerable to groundwater contamination, are available for use with PRZM-GW for risk assessment purposes. In PRZM-GW simulations, each of these standard scenarios was used with 30 years of pesticide application. PRZM-GW output represents pesticide concentrations in vulnerable groundwater located directly beneath an agricultural field, following many years of pesticide application (USEPA 2012a, 2012b).

Modeling Approach and Input Parameters

The two major degradates (prothioconazole-desthio and prothioconazole-S-methyl) were detected in all fate laboratory studies (except hydrolysis, and aqueous and soil photolysis for prothioconazole-S-methyl) and it is therefore assumed that these degradates could be formed in significant environmental concentrations. In addition, prothioconazole-desthio and prothioconazole-S-methyl have been considered likely to exhibit equal or greater toxicity than the parent prothioconazole, based on submitted toxicity studies conducted on aquatic organisms (USEPA 2006; USEPA 2008). HED has also identified concern regarding the mammalian hazard associated with these environmental metabolites. Therefore, as in past EFED assessments, the EDWCs are based on total toxic residues (TTR) which include the parent compound plus the degradates prothioconazole-desthio and prothioconazole-S-methyl. The input values were determined using half-lives which accounted for unextracted residues, as discussed in USEPA 2006.

Because the two major degradates of prothioconazole that are formed rapidly after application have different mobilities, the lower mean K_{oc} (indicating higher mobility), for prothioconazole-desthio, was used with the PRZM-GW. A K_{oc} is not available for the parent compound. Prothioconazole-desthio is more mobile than other degradates, is persistent, and is the major degradate observed in the fate studies. The K_{oc} for prothioconazole-desthio in four soil types ranged from 523 to 625 mL/g, with negligible differences in adsorption among soil types.

Modeling for groundwater EDWCs was conducted using the highest application rate on the labels, which is for nursery seedlings. All inputs used for modeling with PRZM-GW are listed in **Table 3**.

Table 3. Input values for the PRZM-GW model for prothioconazole for the overall maximum label rate.

Variable Name	Data Value	Data Source/ MRID(s)	Comment
Application Method	Above Canopy Application	Proline® 480 SC Fungicide label (41% a.i.).	Foliar application to nursery seedlings, post-emergence.
Application Date	April 1 (FL) May 1 (Delmarva) May 15 (GA) June 1 (NC, WI)	Crop Scenarios; Label	Based on timing of disease pressure and preventative application.
Application Rate (lbs. a.i./acre) [kg/ha]	0.178 1b a.i./A [0.199 kg/ha]	Label	Highest label rate overall; based on nursery seedlings use.
Application Frequency (per year)	5X	Label	–
Application Interval (days)	14	Label	–
Hydrolysis Half-life (days; pH 7)	0 (stable)[1]	46246505 46246506	Both prothioconazole and prothioconazole-desthio are stable to hydrolysis at all pHs. No degradation occurred at 50 ºC.
Aerobic Soil Metabolism Half-life (days; 25ºC)	1052[1]	46246511 46246512	The 90 percent upper confidence bound on the mean of six values for prothioconazole TTR, including unextracted residues.
K_{oc} (mL/g)	575 mL/g[1]	46246450	Mean of 4 K_{oc} values for prothioconazole-desthio.

[1]EFED input parameter guidance: http://www.epa.gov/oppefed1/models/water/przm_gw/wqtt_przm_gw_input_guidance.htm.

Modeling Results

Surface Water

Because preliminary SWCC modeling results indicated that the proposed use on cotton would result in much lower surface water EDWCs than in the previous DWAs, SWCC modeling results for cotton are not presented here. However, previously reported surface water EDWCs were updated due to changes in the percentage crop area (PCA) factor (see USEPA 2014) implemented since those values were determined. The surface water 1-in-10-year acute and chronic EDWCs, based on corn use, have increased slightly due to a higher PCA, from 99.0 to **108.8** ppb for acute and from 91.1 to **96.8** ppb for chronic. Previous values were based on a corn PCA of 0.91; the values now reflect the current "all agriculture" PCA of 1.0 which is used when a pesticide may be used on multiple crops in the same watershed, as is the case for prothioconazole. The previously reported cancer EDWC of 91.9 ppb for surface water, determined using the Tier 1 Rice model modified for cranberries (USEPA 2012*b*), has now been replaced with a higher value of 183 ppb (based on nursery seedling use) determined using the PRZM-GW model.

Groundwater

Groundwater EDWC modeling results are presented in **Table 4**. The highest EDWC values are in bold, are associated with the NC Eastern Coastal Plain scenario, and were determined using the overall highest label application rate (*i.e*., the application rate for nursery seedlings).

Table 4. Groundwater Estimated Drinking Water Concentrations for prothioconazole based on use on nursery seedlings.

Model	Crop Use Modeled[1]	Scenario (Tier 1)	Highest Daily Value (µg/L)	Post Breakthrough Average (µg/L)	Time to Breakthrough (days)
PRZM-GW	Nursery Seedlings	WI Central Sands/Corn (30-yr simulation)	156	138	10,071
PRZM-GW	Nursery Seedlings	DELMARVA Sweet Corn - Evesboro Loamy Sand	140	117	7842
PRZM-GW	Nursery Seedlings	Florida Citrus - FL Central Ridge, Polk County/Astatula sand	158	151	6503
PRZM-GW	Nursery Seedlings	FLORIDA - potato - Jacksonville	16.8	incomplete	incomplete
PRZM-GW	Nursery Seedlings	GA - Southern Coastal Plain, Tifton loamy sand - Peanuts	35.4	34.5	10,746
PRZM-GW	Nursery Seedlings	NC Eastern Coastal Plain - Norfolk loamy sand - Cotton	**188**	**183**	7273

[1]In this context, crop refers to the use modeled in terms of time of application, type of application, and application rates. PRZM-GW standard scenarios were developed based on specific crop use areas, so the crop identified for each may differ from the crop use pattern modeled.

The PRZM-GW concentrations represent groundwater concentrations that might be expected in shallow, unconfined aquifers under sandy soils. The output file associated with the highest groundwater EDWCs is included as **Appendix A**.

UNCERTAINTIES

The major uncertainties in this assessment are associated with the high levels of unextracted residues observed in lab studies and the fact that a K_{oc} for the parent cannot be determined.

The large amounts of unextracted and unidentified residues add considerable uncertainty with respect to the biotic degradation half-lives used in modeling the corn use. This is discussed in further detail in USEPA 2006.

Because the mobility of prothioconazole cannot be determined due to its instability, modeling was conducted using the K_{oc} data for the most mobile degradate, prothioconazole-desthio. This is discussed in further detail in USEPA 2006. This moderate uncertainty affects all of the reported surface water and groundwater EDWCs.

REFERENCES

Food and Agriculture Organization of the United Nations. 2000. FAO PESTICIDE DISPOSAL SERIES 8. Assessing Soil Contamination: A Reference Manual. Appendix 2. Parameters of pesticides that influence processes in the soil. Editorial Group, FAO Information Division: Rome. http://www.fao.org/DOCREP/003/X2570E/X2570E00.htmU.S. EPA. 2006. Environmental Fate and Ecological Risk Assessment for the Registration of Prothioconazole (DP Barcode: 324660). Office of Pesticide Programs, Environmental Fate and Effects Division. June 2006.

U.S. EPA. 2006*c*. Prothioconazole Tier II Estimated Drinking Water Concentrations (EDWCs) for Use in the Human Health Risk Assessment. [Second Revision]. DP Barcode: 320265. Office of Pesticide Programs, Environmental Fate and Effects Division. June 2006.

U.S. EPA. 2009. Drinking Water Assessment in Support of the New Use of Prothioconazole on Crop Groups 15 and 16 (Cereal Grains and Forage, Fodder and Straw of the Cereal Grains Group Except Sweet Corn, Sorghum and Rice) and Sweet Corn (DP Barcode: 369343). Office of Pesticide Programs, Environmental Fate and Effects Division. December 2009.

U.S. EPA. 2010*a*. Drinking Water Assessment in Support of the New Use of Prothioconazole on Nursery Seed and Seedlings of Conifers and Hardwoods; Foliar Use on Rice and Rice Hulls; and Seed Treatment Use on Dried Shelled Pea and Bean Subgroup 6C (Except Soybean), Rice and Soybean" (DP Barcodes: D373683, D378621, D378998). Office of Pesticide Programs, Environmental Fate and Effects Division. October 2010.

U.S. EPA. 2010*b*. Development and Use of the Index Reservoir in Drinking Water Exposure Assessments. Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances, Office of Pesticide Programs, Environmental Fate and Effects Division. (http://www.epa.gov/oppefed1/models/water/index_reservoir_dwa.html)

U.S. EPA. 2012*a*. Drinking Water Assessment in Support of the Proposed Prothioconazole Section 3 Seed Treatment Uses on Seeds of Cereal Grains Crop Groups 15 & 16 (Except Sorghum and Rice (DP Barcode 398128). Office of Pesticide Programs, Environmental Fate and Effects Division. February 2012.

U.S. EPA. 2012*b*. Drinking Water Assessment in Support of the Proposed Prothioconazole Section 3 New Uses on Bushberry (Crop Subgroup 13-07B), Low Growing Berry Subgroup, Except Strawberry (Crop Subgroup 13-07H) and Cucurbit Vegetables (Crop Group 9). (DP Barcode: D405409). Office of Pesticide Programs, Environmental Fate and Effects Division. November 2012.

U.S. EPA. 2014. Guidance on Development and Use of Community Water System Drinking Water Intake Percent Cropped Area Adjustment Factors for use in Drinking Water Exposure Assessments: 2014 Update. Office of Pesticide Programs, Environmental Fate and Effects Division. Sept. 9, 2014.

U.S. EPA. 2015a. Screening Level Estimates of Agricultural Uses of Prothioconazole (113961). United States Environmental Protection Agency (USEPA). Biological and Economic Analysis Division. Office of Pesticide Programs. May 11, 2015.

U.S. EPA. 2015*b*. BEAD Chemical Profile (BCP) for Registration Review: Prothioconazole (113961). United States Environmental Protection Agency (USEPA). Biological and Economic Analysis Division. Office of Pesticide Programs. September, 2015.

U.S. EPA. 2015*c*. Registration Review: Preliminary Problem Formulation for Environmental Fate, Ecological Risk, Endangered Species, and Human Health Drinking Water Exposure Assessments for Prothioconazole. Office of Pesticide Programs, Environmental Fate and Effects Division. December 7, 2015.

APPENDIX A – Groundwater Modeling Output File for the Maximum Groundwater EDWCs

Groundwater Analysis for Prothioconazole and the NC Eastern Coastal Plain - Norfolk Loamy Sand - Cotton Scenario (Application Input Values Based on Nursery Seedlings Use Pattern)

Estimated groundwater concentrations and breakthrough times for prothioconazole are presented in Table 1 for the NC Eastern Coastal Plain - Norfolk loamy sand - Cotton groundwater scenario. A graphical presentation of the daily concentrations in the aquifer is presented in Figure 1. These values were generated with the PRZM-GW (Version 1.07). Critical input values for the model are summarized in Tables 2 and 3.

Table 1. Groundwater Results for Prothioconazole and the NC Eastern Coastal Plain - Norfolk loamy sand - Cotton Scenario with Nursery Seedlings Use Pattern.

Peak Concentration (ppb)	188
Post-Breakthrough Mean Concentration (ppb)	183
Entire Simulation Mean Concentration (ppb)	80
Average Breakthrough Time (days)	7273.045
Throughputs	1.506934

Table 2. Chemical Properties for Groundwater Modeling of Prothioconazole.

K_{oc} (ml/g)	575
Surface Soil Half Life (days)	1052
Hydrolysis Half Life (days)	0
Diffusion Coefficint Air (cm2/day)	0.0
Henry's Constant	0.0
Enthalpy (kcal/mol)	0.0

Table 3. Pesticide Application Scheme Used for Prothioconazole. (This application scheme was applied every year of the simulation.)

Application Date (Month/Day)	Application Method	Application Rate (kg/ha)
6/1	Above canopy application	0.199
6/15	Above canopy application	0.199
6/29	Above canopy application	0.199
7/13	Above canopy application	0.199
7/27	Above canopy application	0.199

Figure 1. Aquifer Breakthrough Curve for prothioconazole and the NC Eastern Coastal Plain - Norfolk Loamy Sand - Cotton Scenario with Nursery Seedlings Use Pattern