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



**OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES**

**MEMORANDUM**

DATE: December 19, 2007

SUBJECT: **Prothioconazole**: Acute and Chronic Aggregate Dietary and Drinking Water Exposure and Risk Assessments for the Section 3 Registration Actions on Sugar Beets (PP# 6F7134) and Soybeans (PP # 6F7073).

PC Code: 113961  
DP Number: 345924

Decision Number: 367564

REVIEWER: Toiya Goodlow, Chemist  
Reregistration Branch 1/Health Effects Division (7509P)

THROUGH: Dennis McNeilly, Chemist  
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and

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TO: Barry O'Keefe, Biologist and Risk Assessor  
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## **Executive Summary**

Acute and chronic dietary risk assessments for food and drinking water were conducted using the Dietary Exposure Evaluation Model (DEEM-FCID™, Version 2.03), which used food consumption data from the U.S. Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. The analyses were performed to support the registration of the proposed Section 3 new uses (soybeans and sugar beets).

### Acute Dietary Exposure Results and Characterization

A moderately refined acute dietary exposure assessment was conducted for prothioconazole. Empirical processing factors (PFs) and livestock maximum residues were incorporated, and 100 percent crop treated (%CT) was assumed for the acute assessment. Average residue levels were also used, since all of the plant commodities included in this assessment are blended food forms. No acute endpoint was identified for the general U.S. population; females 13-49 years of age was the only population subgroup included in the acute assessment. Dietary risk estimates were determined considering exposures from food alone and food plus drinking water using estimated drinking water concentrations (EDWCs) for surface water sources provided by the Environmental Fate and Effects Division (EFED). EDWC values were submitted for both lower and upper bounds for the peanut application scenario, since this crop yielded the highest acute EDWC values. Ground water sources were not included, as the EDWCs for this water source are minimal in comparison to surface water.

The dietary exposure analyses result in acute dietary risk estimates that are below the Agency's level of concern for food only and food and drinking water. At the 95<sup>th</sup> percentile, the food only exposure for females 13-49 years old utilized 8.4% of the acute population adjusted dose (aPAD). The exposure for food plus lower bound drinking water estimates represented 37% of the aPAD at the 95<sup>th</sup> percentile. The exposure for food and upper bound drinking water estimates utilized 76% of the aPAD at the 95<sup>th</sup> percentile.

### Chronic Dietary Exposure Results and Characterization

A moderately refined chronic dietary exposure assessment was also performed. Empirical processing factors, average residues, and livestock maximum residues were incorporated into the chronic assessment; 100% crop treated was also assumed. Dietary risk estimates were determined considering exposures from food alone and food plus upper or lower bound surface water EDWC point estimates based on the sugar beet application scenario, since this crop yielded the highest chronic EDWC values. The dietary exposure analyses result in chronic dietary risk estimates that are below the Agency's level of concern for food alone and food plus drinking water. The highest exposure and risk estimates were for all infants and children 1-2 years old. The food only exposure represented 31% of the chronic population adjusted dose (cPAD) for children 1-2 years old. The highest exposure and risk estimates for food plus drinking water were

for the all infants population subgroup. The exposure for food plus lower drinking water estimates utilized 65% of the cPAD; food plus upper bound drinking water estimates utilized 94% of the cPAD.

Prothioconazole was classified as “Not likely to be carcinogenic to humans”; therefore, a cancer dietary assessment was not performed.

## **I. Introduction**

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which HED has concluded will result in no unreasonable adverse health effects). This dose is referred to as the population adjusted dose (PAD). The PAD is equivalent to point of departure (POD, NOAEL, LOAEL, e.g.) divided by the required uncertainty or safety factors.

For acute and non-cancer chronic exposures, HED is concerned when estimated dietary risk exceeds 100% of the PAD. HED is generally concerned when estimated cancer risk exceeds one in one million. References which discuss the acute and chronic risk assessments in more detail are available on the EPA/pesticides web site: “Available Information on Assessing Exposure from Pesticides, A User’s Guide,” 6/21/2000, web link: <http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061.pdf>; or see SOP 99.6 (8/20/99).

The most recent dietary risk assessment for prothioconazole was conducted by Toiya Goodlow (8/3/06, D331636). This dietary assessment is an update to the 2006 prothioconazole dietary assessment to include the proposed new uses on soybeans and sugar beets and the updated drinking water estimates resulting from these proposed uses.

## **II. Residue Information**

### Prothioconazole Use:

Bayer CropScience has proposed, in PP# 6F7073 (soybeans) and PP# 6F7134 (sugar beets), the establishment of permanent tolerances for combined residues of the fungicide prothioconazole and its desthio metabolite in/on the following raw agricultural commodities: soybean seed, hay and forage and sugar beet roots and tops. HED has determined that the residue chemistry database is sufficient to recommend in favor of a conditional registration, pending the resolution of residue chemistry deficiencies, for this fungicide and establishment of tolerances for prothioconazole on the following: soybean (seed, hay and forage) and sugar beet roots.

Prothioconazole tolerances have recently been published in the Federal Register (FR Vol. 72, No. 49, 3/14/07) and established under 40 CFR §180.626 for various raw agricultural

and livestock commodities. The residues of concern for plant commodities are prothioconazole and the metabolite, desthio-prothioconazole. The residues of concern for livestock commodities are prothioconazole, desthio-prothioconazole and metabolites that can be converted to these two compounds by acid hydrolysis. Water residues of concern include prothioconazole, desthio-prothioconazole, and prothioconazole-S-methyl. The aforementioned residues of concern are included in the tolerance expressions recommended by HED, the prothioconazole drinking water assessment, and in this dietary assessment.

It should also be noted that the metabolites 1,2,4-Triazole (1,2,4-T), triazolylalanine (TA), and triazolylacetic acid (TAA) have been identified as residues of toxicological concern for all triazole-derivative fungicides. Separate risk assessments, based on conservative residue estimates, have been completed for 1,2,4-T and TA+TAA (combined) and are updated, as needed, for new triazole fungicide uses. The most recent dietary assessments for these compounds (W. Cutchin, DP Numbers 347252 and 347253) include residue estimates for soybean and sugar beet commodities. Other triazole fungicide uses on these crops result in potentially greater residues of 1,2,4-T, TA, and TAA than are attributable to the proposed uses of prothioconazole. Therefore, an updated assessment is not required to address dietary exposure to 1,2,4-T or to TA+TAA for the soybean and sugar beet petitions.

See D331663 and D335154 dated December 19, 2007, Prothioconazole: Petitions for Establishment of Tolerances for Use on Sugar Beet (PP#6F7134) and Soybean (PP#6F7073). Summary of Analytical Chemistry and Residue Data by Stephen Funk for further details. See DP Barcodes 303508 and 314517, also by S. Funk, for additional information on crops previously registered for prothioconazole use.

#### Residue Data used for Acute and Chronic Assessments:

Moderately refined acute and chronic dietary assessments were performed for prothioconazole. The refinements used for both exposure durations are summarized below.

- Average field trial residues were used for all plant commodities in both the acute and chronic analyses. Mean values used in this assessment can be found in Stephen Funk's Summary of Analytical Chemistry and Residue Data document under 'crop field trials'. Since all of the crops included in this assessment are blended food forms, no residue distribution files (RDFs) were required. See Change in Classification of Food Forms with Respect to "Not Blended," "Partially Blended," and "Blended" Status, HED's ChemSAC memo, 8/20/1999 for further details.
- Maximum residues were used in the assessments for livestock commodities. These values were determined using the submitted ruminant feeding study, poultry metabolism study, and the calculated reasonably balanced dietary burden (RBDB); see D331663, S. Funk for further details. A poultry feeding study was not submitted, but these data have been requested as a condition of registration by HED. The

following calculation was used to determine maximum residues for ruminant commodities:

$$\text{Maximum Residues} = \frac{\text{RBDB}}{\text{Diet in feeding study}} \times \Sigma \text{Residues in feeding study}$$

Example: The maximum residue for milk is calculated below using the RBDB of 9.8 ppm, a diet of 29.5 ppm from the livestock feeding study, and residues of <0.005, <0.005, and <0.005 ppm for milk.

$$\text{Maximum Residue for Milk} = \frac{9.8 \text{ ppm}}{29.5 \text{ ppm}} \times 0.015 \text{ ppm} = 0.005 \text{ ppm}$$

- EFED submitted modeled EDWC values. Point estimates were used in the acute and chronic assessments from the peanut and sugar beet application scenarios. See D341457 and D341458, Drinking Water Assessment for the Section 3 New Use Petitions for the Use of Prothioconazole on Soybeans and Sugar Beets by Cheryl Sutton for additional information.
- Empirical factors generated in processing studies were also included when appropriate in the acute and chronic assessments. Reduction factors were used for canola refined oil, wheat flour, soybean refined oil and sugar beet molasses. Concentration factors were incorporated for wheat bran and germ. A default DEEM 7.81 processing factor was also included for dried beef. A processing factor could not be calculated for peanut butter in the submitted peanut processing study because residues were below the limit of quantification (LOQ) in both the raw agricultural commodity (RAC) and the processed fraction; therefore, no PF was applied for peanut butter.

### III. Drinking Water Data

The drinking water residues used in the dietary risk assessment were provided by the Environmental Fate and Effects Division in the following memorandum: “Drinking Water Assessment for the Section 3 New Use Petitions for the Use of Prothioconazole on Soybeans and Sugar Beets” (D341457 and D341458, 10/10/07) and incorporated directly into this dietary assessment. Water residues were incorporated in DEEM-FCID into the food categories “water, direct, all sources” and “water, indirect, all sources.”

EFED submitted estimated drinking water concentrations, which were determined using the PRZM-EXAMS screening model. EDWC point estimates were submitted for both lower and upper bounds to account for two major uncertainties in the drinking water modeling. First, some prothioconazole residues remained in the bound phase in EFED studies used to characterize persistence. To address this uncertainty, modeling was bounded based on inclusion and exclusion of unextracted residues in half-life

calculations. Secondly, the two major water degradates of prothioconazole formed rapidly after application and have different mobility. To address this uncertainty, modeling was conducted using  $K_{OCs}$  (soil organic carbon-water partitioning coefficients) for desethio-prothioconazole and prothioconazole-S-methyl. The lower bound EDWCs represent the exclusion of unextracted residues and the use of the higher  $K_{oc}$ . Conversely, the higher bound estimates represent the inclusion of unextracted residues and the use of the lower  $K_{oc}$ .

Estimated drinking water concentrations were further refined for peanuts and sugar beets. Regional default Percent Cropped Area factors (PCA) have been applied to estimated concentrations of these crops. Surface water EDWCs used in this assessment are summarized in Table 1 below. DEEM analyses were performed for both the upper and lower bound estimates and the peanut (previous registration) and sugar beet (proposed registration) crop scenarios shown below, since these EDWC values were the highest reported for the respective acute and chronic exposure durations.

DRINKING WATER SOURCE (MODEL USED)	USE SCENARIO (rate modeled)	ESTIMATED DRINKING WATER CONCENTRATION ( ppb)			
		ACUTE		CHRONIC	
		Lower Bound	Upper Bound	Lower Bound	Upper Bound
Surface water (PRZM/EXAMS)	Peanut	13	29	--	--
	Sugar Beet	--	--	8.4	13

#### **IV. DEEM-FCID™ Program and Consumption Information**

Prothioconazole acute and chronic dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03), which incorporates consumption data from USDA’s Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. The 1994-96, 98 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods “as consumed” (e.g., apple pie) are linked to EPA-defined food commodities (e.g. apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. For chronic exposure assessment, consumption data are averaged for the entire U.S. population and within population subgroups, but for acute exposure assessment are retained as individual consumption events. Based on analysis of the 1994-96, 98 CSFII consumption data, which took into account dietary patterns and survey respondents, HED concluded that it is most appropriate to report risk for the following population subgroups: the general U.S.

population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, females 13-49, and adults 50+ years old.

For chronic dietary exposure assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form to produce a residue intake estimate. The resulting residue intake estimate for each food/food form is summed with the residue intake estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

For acute exposure assessments, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic exposure assessment, or “matched” in multiple random pairings with residue values and then summed in a probabilistic assessment. The resulting distribution of exposures is expressed as a percentage of the aPAD on both a user (i.e., only those who reported eating relevant commodities/food forms) and a per-capita (i.e., those who reported eating the relevant commodities as well as those who did not) basis. In accordance with HED policy, per capita exposure and risk are reported for all tiers of analysis. However, for tiers 1 and 2, any significant differences in user vs. per capita exposure and risk are specifically identified and noted in the risk assessment.

#### IV. Toxicological Information

<b>Table 2. Summary of Toxicological Doses and Endpoints for Prothioconazole for Use in Dietary Exposure Assessment</b>				
<b>Exposure/ Scenario</b>	<b>Point of Departure</b>	<b>Uncertainty/ FQPA Safety Factors</b>	<b>RfD, PAD, Level of Concern for Risk Assessment</b>	<b>Study and Toxicological Effects</b>
Acute Dietary <u>General US population (including infants and children)</u>	An appropriate study was not identified for this population.			
Acute Dietary <u>Females 13-49 years old</u>	NOAEL = 2.0 mg/kg/day	UF <sub>A</sub> =10x UF <sub>H</sub> =10x FQPA SF=10x (UF <sub>DB</sub> )	Acute RfD = 0.002 mg/kg/day  aPAD = 0.002 mg/kg/day	<b>Developmental Toxicity study in rabbits</b> LOAEL = 10 mg/kg/day, based on structural alterations including malformed vertebral body and ribs, arthrogryposis, and multiple malformations.
Chronic Dietary <u>All populations</u>	NOAEL=1.1 mg/kg/day	UF <sub>A</sub> =10x UF <sub>H</sub> =10x FQPA SF=10x (UF <sub>DB</sub> )	Chronic RfD = 0.001 mg/kg/day  cPAD = 0.001 mg/kg/day	<b>Chronic/Oncogenicity study in rats</b> LOAEL = 8.0 mg/kg/day based on liver histopathology (hepatocellular vacuolation and fatty change (single cell, centrilobular, and periportal)).
Cancer	Classification: "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (intraspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (interspecies). UF<sub>DB</sub> = to account for the absence of key data (i.e., lack of a critical study). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose.

The prothioconazole risk assessment team has recommended that the 10X FQPA Safety Factor be retained in the form of an uncertainty factor (UF<sub>DB</sub>) for the lack of data to establish a NOAEL and LOAEL for neurotoxicity (brain morphometry and peripheral nerve lesions) observed in the rat developmental neurotoxicity study. This uncertainty factor is applied to the acute and chronic aggregate dietary risk assessments.

#### VI. Results/Discussion

As stated above, for acute and chronic assessments, HED is concerned when dietary risk exceeds 100% of the PAD. The DEEM-FCID™ analyses estimate the dietary exposure

of the U.S. population and various population subgroups. The results reported in Tables 3 through 6 are for the general U.S. Population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, females 13-49, adults 20-49, and adults 50+ years of age.

Results of Acute Dietary Exposure Analysis

A moderately refined acute dietary exposure assessment was conducted for prothioconazole. Average field trial values, empirical processing factors, and livestock maximum residues were incorporated into the refined acute assessment. The assessment also assumed 100% CT. No acute endpoint was identified for the general U.S. population; females 13-49 years of age was the only population subgroup included in the acute assessment. Dietary risk estimates were determined considering exposures from food alone and food plus water using drinking water exposures for the peanut application scenario. Ground water sources were not included, as the EDWCs for this water source are minimal in comparison to surface water.

The dietary exposure analyses result in acute dietary risk estimates that are below the Agency’s level of concern for food only and food and drinking water. At the 95<sup>th</sup> percentile, the food only exposure for females 13-49 years old was 0.000167 mg/kg/day, which utilized 8.4% of the aPAD (see Table 3). The exposure for food plus lower bound drinking water estimates was 0.000737 mg/kg/day, which utilized 37% of the aPAD at the 95<sup>th</sup> percentile. The exposure for food and upper bound drinking water estimates was 0.001518 mg/kg/day, which utilized 76% of the aPAD at the 95<sup>th</sup> percentile (see Table 4).

<b>Table 3. Results of Acute Dietary Exposure Analysis for Prothioconazole Using DEEM FCID at the 95<sup>th</sup> Percentile – Food Only</b>			
<b>Population Subgroup</b>	<b>aPAD (mg/kg/day)</b>	<b>Exposure (mg/kg/day)</b>	<b>% aPAD</b>
Females 13-49 years old	0.002	0.000167	8.4

<b>Table 4. Results of Acute Dietary Exposure Analysis for Prothioconazole Using DEEM FCID at the 95<sup>th</sup> Percentile – Food and Water (Peanut EDWC value)</b>					
<b>Population Subgroup</b>	<b>aPAD (mg/kg/day)</b>	<b>LOWER BOUND</b>		<b>UPPER BOUND</b>	
		<b>Exposure (mg/kg/day)</b>	<b>% aPAD</b>	<b>Exposure (mg/kg/day)</b>	<b>% aPAD</b>
Females 13-49 years old	0.002	0.000737	37	0.001518	76

Results of Chronic Dietary Exposure Analysis

A moderately refined chronic dietary exposure assessment was also performed. Empirical processing factors, average residues, and livestock maximum residues were

incorporated into the chronic assessment; 100% crop treated was also assumed. Dietary risk estimates were determined considering exposures from food alone and food plus upper or lower bound drinking water EDWC point estimates based on the sugar beet application scenario. The dietary exposure analyses result in chronic dietary risk estimates that are below the Agency’s level of concern for food alone and food plus drinking water. The highest exposure and risk estimates were for all infants and children 1-2 years old. The food only exposure was 0.000338 mg/kg/day, which utilized 31% of the cPAD for children 1-2 years old (see Table 5). The highest exposure and risk estimates for food plus drinking water were for the all infants population subgroup. The exposure for food plus lower drinking water estimates was 0.000712 mg/kg/day, utilizing 65% of the cPAD. The exposure for food plus upper bound drinking water estimates was 0.001030 mg/kg/day, which utilized 94% of the cPAD (see Table 6).

Prothioconazole was classified as “Not likely to be carcinogenic to humans”; therefore, a cancer assessment was not performed.

<b>Table 5. Results of Chronic Dietary Exposure Analysis for Prothioconazole Using DEEM FCID-Food Only</b>			
<b>Population Subgroup</b>	<b>cPAD (mg/kg/day)</b>	<b>Refined Assessment</b>	
		<b>Exposure (mg/kg/day)</b>	<b>% cPAD</b>
General U.S. Population	0.0011	0.000105	9.5
All Infants (< 1 year old)	0.0011	0.000132	12
<b>Children 1-2 years old</b>	0.0011	<b>0.000338</b>	<b>31</b>
Children 3-5 years old	0.0011	0.000275	25
Children 6-12 years old	0.0011	0.000180	16
Youth 13-19 years old	0.0011	0.000095	8.7
Adults 20-49 years old	0.0011	0.000077	7.0
Adults 50+ years old	0.0011	0.000064	5.9
Females 13-49 years old	0.0011	0.000070	6.3

<b>Table 6. Results of DEEM-FCID Chronic Dietary Exposure Analysis for Prothioconazole Using Lower and Upper Bound EDWC Values for Sugar Beets– Food and Water</b>					
<b>Population Subgroup</b>	<b>cPAD (mg/kg/day)</b>	<b>LOWER BOUND</b>		<b>UPPER BOUND</b>	
		<b>Exposure (mg/kg/day)</b>	<b>% cPAD</b>	<b>Exposure (mg/kg/day)</b>	<b>% cPAD</b>
General U.S. Population	0.0011	0.000282	26	0.000379	34
<b>All Infants (&lt; 1 year old)</b>	0.0011	<b>0.000712</b>	<b>65</b>	<b>0.001030</b>	<b>94</b>
Children 1-2 years old	0.0011	0.000601	55	0.000745	68
Children 3-5 years old	0.0011	0.000521	47	0.000656	60
Children 6-12 years old	0.0011	0.000350	32	0.000443	40
Youth 13-19 years old	0.0011	0.000223	20	0.000294	27
Adults 20-49 years old	0.0011	0.000242	22	0.000333	30
Adults 50+ years old	0.0011	0.000238	22	0.000334	30
Females 13-49 years old	0.0011	0.000234	21	0.000325	30

## VII. Characterization of Inputs/Outputs

In the course of conducting a refined dietary exposure analysis, decisions are made regarding the following: the residue data used in the analysis (e.g. monitoring data, field trial data, etc.), refinements incorporated in DEEM-FCID™ such as %CT and processing factors, sensitivity analyses, and a variety of other issues which may be chemical- or crop-specific. Characterization of this assessment and associated uncertainties include:

- Average field trial residues were used for all plant commodities in both the acute and chronic analyses because all of the crops included in this assessment are blended food forms. The use of crop field trial data usually overstates the residue levels that consumers are exposed to since residue levels are measured at harvest time and do not reflect any degradation of the pesticide. Moreover, crop field trials are performed using maximum application rates and minimum pre-harvest intervals. No monitoring data are available for prothioconazole, as it is a new chemical.
- Maximum residues were used in the assessments for livestock commodities. These values were determined using the submitted ruminant feeding study and poultry metabolism study, and reflect the maximum level of pesticide likely to be present in livestock commodities. These livestock estimates are considered to be conservative because limit of quantification values were used for residues below LOQ and 100% CT was used to calculate these values.

- Empirical factors generated in processing studies were included in the acute and chronic assessments. Reduction factors were used for canola refined oil, wheat flour, soybean refined oil and sugar beet molasses. Concentration factors were incorporated for wheat bran and germ. A default DEEM 7.81 processing factor was included for dried beef. A processing factor could not be calculated for peanut butter in the submitted peanut processing study because residues were below the LOQ in both the RAC and the processed fraction; therefore, no PF was applied for peanut butter.
- Since there are no water monitoring data available for prothioconazole, drinking water exposure estimates were based on PRZM-EXAMS surface water modeling results. The drinking water inputs may be considered conservative for the following reasons. The model results assume that applications will be made at maximum application rates every year for 30 years. The PRZM-EXAMS models are based on an actual reservoir/watershed system in Illinois which is known to be a highly vulnerable configuration. Based on these considerations, it is likely that actual exposure to prothioconazole from drinking water is somewhat lower than the estimates provided in this assessment.

## **VIII. Conclusions**

Refined acute and chronic dietary risk assessments were conducted for prothioconazole. Average residues, empirical PFs, livestock maximum residues, and drinking water residue estimates were incorporated, and 100% CT was assumed for both assessments. The dietary exposure analyses result in acute and chronic dietary risk estimates that are below the Agency's level of concern.

## **IX. List of Attachments**

1. Tabular Summary of Data and Residue Estimates Used in the Dietary Analyses.
2. Acute and Chronic Food Only Input File.
3. Acute Food Only Results File.
4. Acute Food and Water Results File- Peanuts, Lower Bound.
5. Acute Food and Water Results File- Peanuts, Upper Bound.
6. Chronic Food Only Results File.
7. Chronic Food and Water Results File- Sugar Beets, Lower Bound.
8. Chronic Food and Water Results File- Sugar Beets, Upper Bound.

cc: T.Goodlow/HED/RRB1. M. Metzger/HED/RRB1. B. O'Keefe/HED/RAB3.

Attachment 1: Tabular Summary of Data and Residue Estimates Used in the Dietary Analyses.

<b>Table 11. Summary of Data and Residue Estimates Used in the Dietary Analyses</b>							
RAC	Food Forms	Classification <sup>1</sup>	Data Source <sup>2</sup>	No. of Samples; Average Residues	LOD	PFs	Anticipated Residue Estimates <sup>3</sup>
<b>Crop Group 1: Root and Tuber Vegetables</b>							
Beet, sugar	All	B	FT, 46974608	24; 0.07	0.05	None	0.07
Beet, sugar, molasses	All	B	FT, 46974608	24; 0.07	0.05	0.1	0.07
<b>Crop Group 6: Legume Vegetables</b>							
Bean, dried, shelled	All	B	FT, 46246200	20; 0.062	0.01	None	0.062
Pea, dry, shelled	All	B	FT, 46246221	26; 0.156	0.05	None	0.156
Soybean, seed	All	B	FT, 46841001	42; 0.05	0.05	None	0.05
Soybean, flour	All	B	FT, 46841001	42; 0.05	0.05	None	0.05
Soybean, soy milk	All	B	FT, 46841001	42; 0.05	0.05	None	0.05
Soybean, oil	All	B	FT, 46841001	42; 0.05	0.05	0.2	0.05
<b>Crop Group 15: Cereal Grains</b>							
Barley	All	B	FT, 46246200	49; 0.040	0.02	None	0.040
Wheat, grain	All	B	FT, 46246219	66; 0.014	0.02	None	0.014
Wheat, flour	All	B	FT, 46246219	66; 0.014	0.02	0.4	0.014
Wheat, germ	All	B	FT, 46246219	66; 0.014	0.02	2.0	0.014
Wheat, bran	All	B	FT, 46246219	66; 0.014	0.02	2.4	0.014
<b>Crop Group 20: Oilseeds</b>							
Rapeseed, oil	All	B	FT, 46246215	44; 0.015	0.020	0.7	0.015
<b>Miscellaneous Commodities</b>							
Peanut	All	B	FT, 46246217	24; 0.01	0.02	None	0.01
<b>Meat</b>							
Beef, meat	All except dried beef	--	Ruminant feeding study	3; 0.01	0.01	None	0.010
	Dried beef	--	Ruminant feeding study	3; 0.01	0.01	1.92	0.010
Beef, meat byproducts	All	--	Ruminant feeding study	3; 0.104	0.01	None	0.104
Beef, fat	All	--	Ruminant feeding study	3; 0.005	0.01	None	0.05
Beef, kidney	All	--	Ruminant feeding study	3; 0.083	0.01	None	0.083
Beef, liver	All	--	Ruminant feeding study	3; 0.104	0.01	None	0.104
Goat, meat	All	--	Ruminant feeding study	3; 0.01	0.01	None	0.010
Goat, meat byproducts	All	--	Ruminant feeding study	3; 0.104	0.01	None	0.104

Goat, fat	All	--	Ruminant feeding study	3; 0.005	0.01	None	0.05
Goat, kidney	All	--	Ruminant feeding study	3; 0.083	0.01	None	0.083
Goat, liver	All	--	Ruminant feeding study	3; 0.104	0.01	None	0.104
Horse, meat	All	--	Ruminant feeding study	3; 0.01	0.01	None	0.010
Pork, meat byproducts	All	--	Ruminant feeding study	3; 0.104	0.01	None	0.104
Pork, kidney	All	--	Ruminant feeding study	3; 0.083	0.01	None	0.083
Pork, liver	All	--	Ruminant feeding study	3; 0.104	0.01	None	0.104
Sheep, meat	All	--	Ruminant feeding study	3; 0.01	0.01	None	0.010
Sheep, meat byproducts	All	--	Ruminant feeding study	3; 0.01	0.01	None	0.104
Sheep, fat	All	--	Ruminant feeding study	3; 0.005	0.01	None	0.05
Sheep, kidney	All	--	Ruminant feeding study	3; 0.083	0.01	None	0.083
<b>Poultry</b>							
Chicken, liver	All	--	Poultry metabolism study	NA	NA	None	0.005
Poultry, other, liver	All	--	Poultry metabolism study	NA	NA	None	0.005
Turkey, liver	All	--	Poultry metabolism study	NA	NA	None	0.005
<b>Dairy Products</b>							
Milk	All	--	Ruminant feeding study	3; 0.005	0.01	None	0.005

<sup>1</sup> Classification of blended (B), partially blended (PB) or not blended (NB).

<sup>2</sup> FT = field trial data; MRIDs are listed for crop field trial studies.

<sup>3</sup> Acute and Chronic ARs are equivalent. Since all of the food forms included are blended commodities, average residues were used for both assessments.

Attachment 2. Acute and Chronic Food Only Input File.

U.S. Environmental Protection Agency Ver. 2.02  
 DEEM-FCID Acute analysis for PROTHIOCONAZOLE  
 Residue file name: C:\Documents and Settings\tgoodlow\My  
 Documents\2004DEEMFCID\Prothioconazole\2007 DA\dietary  
 assessment\prothioconazole\_food only.R98  
 Analysis Date 10-22-2007 Residue file dated: 10-22-2007/10:34:44/8  
 Reference dose: aRfD = 0.002 mg/kg bw/day NOEL = 2 mg/kg bw/day  
 Comment: New uses and water numbers

EPA Code	Crop Grp	Food Name	Def Res (ppm)	Adj.Factors #1	Adj.Factors #2	Comment
15000250	15	Barley, pearled barley	0.040000	1.000	1.000	
15000251	15	Barley, pearled barley-babyfood	0.040000	1.000	1.000	
15000260	15	Barley, flour	0.040000	1.000	1.000	
15000261	15	Barley, flour-babyfood	0.040000	1.000	1.000	
15000270	15	Barley, bran	0.040000	1.000	1.000	
06030300	6C	Bean, black, seed	0.062000	1.000	1.000	
06030320	6C	Bean, broad, seed	0.062000	1.000	1.000	
06030340	6C	Bean, cowpea, seed	0.062000	1.000	1.000	
06030350	6C	Bean, great northern, seed	0.062000	1.000	1.000	
06030360	6C	Bean, kidney, seed	0.062000	1.000	1.000	
06030380	6C	Bean, lima, seed	0.062000	1.000	1.000	
06030390	6C	Bean, mung, seed	0.062000	1.000	1.000	
06030400	6C	Bean, navy, seed	0.062000	1.000	1.000	
06030410	6C	Bean, pink, seed	0.062000	1.000	1.000	
06030420	6C	Bean, pinto, seed	0.062000	1.000	1.000	
21000440	M	Beef, meat	0.010000	1.000	1.000	
21000441	M	Beef, meat-babyfood	0.010000	1.000	1.000	
21000450	M	Beef, meat, dried	0.010000	1.920	1.000	
21000460	M	Beef, meat byproducts	0.104000	1.000	1.000	
21000461	M	Beef, meat byproducts-babyfood	0.104000	1.000	1.000	
21000470	M	Beef, fat	0.050000	1.000	1.000	
21000471	M	Beef, fat-babyfood	0.050000	1.000	1.000	
21000480	M	Beef, kidney	0.083000	1.000	1.000	
21000490	M	Beef, liver	0.104000	1.000	1.000	
21000491	M	Beef, liver-babyfood	0.104000	1.000	1.000	
01010520	1A	Beet, sugar	0.070000	1.000	1.000	
01010521	1A	Beet, sugar-babyfood	0.070000	1.000	1.000	
01010530	1A	Beet, sugar, molasses	0.070000	0.100	1.000	
01010531	1A	Beet, sugar, molasses-babyfood	0.070000	0.100	1.000	
40000940	P	Chicken, liver	0.005000	1.000	1.000	
06030980	6C	Chickpea, seed	0.062000	1.000	1.000	
06030981	6C	Chickpea, seed-babyfood	0.062000	1.000	1.000	
06030990	6C	Chickpea, flour	0.062000	1.000	1.000	
23001690	M	Goat, meat	0.010000	1.000	1.000	
23001700	M	Goat, meat byproducts	0.104000	1.000	1.000	
23001710	M	Goat, fat	0.050000	1.000	1.000	
23001720	M	Goat, kidney	0.083000	1.000	1.000	
23001730	M	Goat, liver	0.104000	1.000	1.000	
06031820	6C	Guar, seed	0.062000	1.000	1.000	
06031821	6C	Guar, seed-babyfood	0.062000	1.000	1.000	
24001890	M	Horse, meat	0.010000	1.000	1.000	
06032030	6C	Lentil, seed	0.062000	1.000	1.000	
27002220	D	Milk, fat	0.005000	1.000	1.000	
27002221	D	Milk, fat - baby food/infant for	0.005000	1.000	1.000	
27012230	D	Milk, nonfat solids	0.005000	1.000	1.000	
27012231	D	Milk, nonfat solids-baby food/in	0.005000	1.000	1.000	
27022240	D	Milk, water	0.005000	1.000	1.000	
27022241	D	Milk, water-babyfood/infant form	0.005000	1.000	1.000	
27032251	D	Milk, sugar (lactose)-baby food/	0.005000	1.000	1.000	
06032560	6C	Pea, dry	0.156000	1.000	1.000	
06032561	6C	Pea, dry-babyfood	0.156000	1.000	1.000	
06032580	6C	Pea, pigeon, seed	0.156000	1.000	1.000	
95002630	O	Peanut	0.010000	1.000	1.000	
95002640	O	Peanut, butter	0.010000	1.000	1.000	
95002650	O	Peanut, oil	0.010000	1.000	1.000	

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25002920	M	Pork, meat byproducts	0.104000	1.000	1.000
25002921	M	Pork, meat byproducts-babyfood	0.104000	1.000	1.000
25002940	M	Pork, kidney	0.083000	1.000	1.000
25002950	M	Pork, liver	0.104000	1.000	1.000
60003020	P	Poultry, other, liver	0.005000	1.000	1.000
20003190	20	Rapeseed, oil	0.015000	0.700	1.000
20003191	20	Rapeseed, oil-babyfood	0.015000	0.700	1.000
26003390	M	Sheep, meat	0.010000	1.000	1.000
26003391	M	Sheep, meat-babyfood	0.010000	1.000	1.000
26003400	M	Sheep, meat byproducts	0.104000	1.000	1.000
26003410	M	Sheep, fat	0.050000	1.000	1.000
26003411	M	Sheep, fat-babyfood	0.050000	1.000	1.000
26003420	M	Sheep, kidney	0.083000	1.000	1.000
26003430	M	Sheep, liver	0.104000	1.000	1.000
06003470	6	Soybean, seed	0.050000	1.000	1.000
06003480	6	Soybean, flour	0.050000	1.000	1.000
06003481	6	Soybean, flour-babyfood	0.050000	1.000	1.000
06003490	6	Soybean, soy milk	0.050000	1.000	1.000
06003491	6	Soybean, soy milk-babyfood or in	0.050000	1.000	1.000
06003500	6	Soybean, oil	0.050000	0.200	1.000
06003501	6	Soybean, oil-babyfood	0.050000	0.200	1.000
50003830	P	Turkey, liver	0.005000	1.000	1.000
50003831	P	Turkey, liver-babyfood	0.005000	1.000	1.000
15004010	15	Wheat, grain	0.014000	1.000	1.000
15004011	15	Wheat, grain-babyfood	0.014000	1.000	1.000
15004020	15	Wheat, flour	0.014000	0.400	1.000
15004021	15	Wheat, flour-babyfood	0.014000	0.400	1.000
15004030	15	Wheat, germ	0.014000	2.000	1.000
15004040	15	Wheat, bran	0.014000	2.400	1.000

Attachment 3. Acute Food Only Results File.

U.S. Environmental Protection Agency Ver. 2.02  
DEEM-FCID ACUTE Analysis for PROTHIOCONAZOLE (1994-98 data)  
Residue file: prothioconazole\_food only.R98 Adjustment factor #2 NOT used.  
Analysis Date: 10-22-2007/11:54:26 Residue file dated: 10-22-2007/10:34:44/8  
NOEL (Acute) = 2.000000 mg/kg body-wt/day  
Daily totals for food and foodform consumption used.  
Run Comment: "New uses and water numbers"  
=====

Summary calculations (per capita):

95th Percentile			99th Percentile			99.9th Percentile		
Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE
-----								
Females 13-49 yrs:								
0.000167	8.35	11977	0.000265	13.25	7549	0.000418	20.90	4785

Attachment 4: Acute Food and Water Results File- Peanuts, Lower Bound.

U.S. Environmental Protection Agency Ver. 2.02  
DEEM-FCID ACUTE Analysis for PROTHIOCONAZOLE (1994-98 data)  
Residue file: prothioconazole\_acute\_NU&peanutlowSW.R98  
Adjustment factor #2 NOT used.  
Analysis Date: 10-22-2007/12:00:12 Residue file dated: 10-22-2007/10:29:03/8  
NOEL (Acute) = 2.000000 mg/kg body-wt/day  
Daily totals for food and foodform consumption used.  
Run Comment: "New uses and water numbers"  
=====

Summary calculations (per capita):

95th Percentile			99th Percentile			99.9th Percentile		
Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE
-----								
Females 13-49 yrs:								
0.000737	36.84	2714	0.001161	58.04	1722	0.001983	99.13	1008

Attachment 5: Acute Food and Water Results File- Peanuts, Upper Bound.

U.S. Environmental Protection Agency Ver. 2.02  
DEEM-FCID ACUTE Analysis for PROTHIOCONAZOLE (1994-98 data)  
Residue file: prothioconazole\_acute\_NU&peanuthighSW.R98  
Adjustment factor #2 NOT used.  
Analysis Date: 10-22-2007/12:03:30 Residue file dated: 10-22-2007/10:30:14/8  
NOEL (Acute) = 2.000000 mg/kg body-wt/day  
Daily totals for food and foodform consumption used.  
Run Comment: "New uses and water numbers"  
=====

Summary calculations (per capita):

95th Percentile			99th Percentile			99.9th Percentile		
Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE
-----								
Females 13-49 yrs:								
0.001518	75.90	1317	0.002430	121.49	823	0.004289	214.45	466

Attachment 6: Chronic Food Only Results File.

U.S. Environmental Protection Agency  
DEEM-FCID Chronic analysis for PROTHIOCONAZOLE  
Residue file name: C:\Documents and Settings\tgoodlow\My Documents\2004DEEMFCID\Prothioconazole\2007 DA\dietary assessment\prothioconazole\_food only.R98

Ver. 2.00  
(1994-98 data)

Adjustment factor #2 NOT used.

Analysis Date 10-22-2007/12:11:07 Residue file dated: 10-22-2007/10:34:44/8  
Reference dose (RfD, Chronic) = .0011 mg/kg bw/day  
NOEL (Chronic) = 1.1 mg/kg bw/day  
COMMENT 1: New uses and water numbers

-----  
Total exposure by population subgroup  
-----

Population Subgroup	Total Exposure		
	mg/kg body wt/day	Margin of Exposure 1/	Percent of RfD
U.S. Population (total)	0.000105	10,518	9.5%
U.S. Population (spring season)	0.000105	10,427	9.6%
U.S. Population (summer season)	0.000102	10,767	9.3%
U.S. Population (autumn season)	0.000106	10,352	9.7%
U.S. Population (winter season)	0.000104	10,541	9.5%
Northeast region	0.000100	10,968	9.1%
Midwest region	0.000109	10,057	9.9%
Southern region	0.000099	11,112	9.0%
Western region	0.000112	9,811	10.2%
Hispanics	0.000124	8,853	11.3%
Non-hispanic whites	0.000101	10,904	9.2%
Non-hispanic blacks	0.000106	10,411	9.6%
Non-hisp/non-white/non-black	0.000115	9,553	10.5%
All infants (< 1 year)	0.000132	8,354	12.0%
Nursing infants	0.000043	25,336	3.9%
Non-nursing infants	0.000165	6,659	15.0%
Children 1-6 yrs	0.000290	3,798	26.3%
Children 7-12 yrs	0.000170	6,467	15.5%
Females 13-19 (not preg or nursing)	0.000082	13,374	7.5%
Females 20+ (not preg or nursing)	0.000063	17,521	5.7%
Females 13-50 yrs	0.000079	13,856	7.2%
Females 13+ (preg/not nursing)	0.000096	11,425	8.8%
Females 13+ (nursing)	0.000096	11,475	8.7%
Males 13-19 yrs	0.000108	10,196	9.8%
Males 20+ yrs	0.000082	13,446	7.4%
Seniors 55+	0.000064	17,277	5.8%
Children 1-2 yrs	0.000338	3,252	30.8%
Children 3-5 yrs	0.000275	4,004	25.0%
Children 6-12 yrs	0.000180	6,101	16.4%
Youth 13-19 yrs	0.000095	11,521	8.7%
Adults 20-49 yrs	0.000077	14,300	7.0%
Adults 50+ yrs	0.000064	17,085	5.9%
Females 13-49 yrs	0.000070	15,749	6.3%

-----

Attachment 7: Chronic Food and Water Results File- Sugar Beets, Lower Bound.

U.S. Environmental Protection Agency Ver. 2.00  
 DEEM-FCID Chronic analysis for PROTHIOCONAZOLE (1994-98 data)  
 Residue file name: C:\Documents and Settings\tgoodlow\My  
 Documents\2004DEEMFCID\Prothioconazole\2007 DA\dietary  
 assessment\prothioconazole\_chronic\_NU&SugarBeetlowSW.R98  
 Adjustment factor #2 NOT used.  
 Analysis Date 10-22-2007/12:13:21 Residue file dated: 10-22-2007/10:31:28/8  
 Reference dose (RfD, Chronic) = .0011 mg/kg bw/day  
 NOEL (Chronic) = 1.1 mg/kg bw/day  
 COMMENT 1: New uses and water numbers

=====  
 Total exposure by population subgroup  
 =====

Population Subgroup	Total Exposure		
	mg/kg body wt/day	Margin of Exposure 1/	Percent of RfD
U.S. Population (total)	0.000282	3,906	25.6%
U.S. Population (spring season)	0.000281	3,915	25.5%
U.S. Population (summer season)	0.000292	3,763	26.6%
U.S. Population (autumn season)	0.000277	3,965	25.2%
U.S. Population (winter season)	0.000276	3,992	25.0%
Northeast region	0.000262	4,202	23.8%
Midwest region	0.000288	3,814	26.2%
Southern region	0.000267	4,115	24.3%
Western region	0.000315	3,492	28.6%
Hispanics	0.000325	3,382	29.6%
Non-hispanic whites	0.000274	4,020	24.9%
Non-hispanic blacks	0.000274	4,019	24.9%
Non-hisp/non-white/non-black	0.000332	3,311	30.2%
All infants (< 1 year)	0.000712	1,545	64.7%
Nursing infants	0.000259	4,252	23.5%
Non-nursing infants	0.000884	1,244	80.4%
Children 1-6 yrs	0.000537	2,048	48.8%
Children 7-12 yrs	0.000331	3,324	30.1%
Females 13-19 (not preg or nursing)	0.000207	5,318	18.8%
Females 20+ (not preg or nursing)	0.000240	4,593	21.8%
Females 13-50 yrs	0.000251	4,388	22.8%
Females 13+ (preg/not nursing)	0.000268	4,098	24.4%
Females 13+ (nursing)	0.000341	3,224	31.0%
Males 13-19 yrs	0.000238	4,619	21.7%
Males 20+ yrs	0.000240	4,575	21.9%
Seniors 55+	0.000237	4,632	21.6%
Children 1-2 yrs	0.000601	1,830	54.7%
Children 3-5 yrs	0.000521	2,112	47.3%
Children 6-12 yrs	0.000350	3,142	31.8%
Youth 13-19 yrs	0.000223	4,923	20.3%
Adults 20-49 yrs	0.000242	4,541	22.0%
Adults 50+ yrs	0.000238	4,616	21.7%
Females 13-49 yrs	0.000234	4,691	21.3%

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Attachment 8: Chronic Food and Water Results File- Sugar Beets, Upper Bound.

U.S. Environmental Protection Agency  
DEEM-FCID Chronic analysis for PROTHIOCONAZOLE  
Residue file name: C:\Documents and Settings\tgoodlow\My Documents\2004DEEMFCID\Prothioconazole\2007 DA\dietary assessment\prothioconazole\_chronic\_NU&SugarBeethighSW.R98  
Adjustment factor #2 NOT used.  
Analysis Date 10-22-2007/12:14:36 Residue file dated: 10-22-2007/10:32:34/8  
Reference dose (RfD, Chronic) = .0011 mg/kg bw/day  
NOEL (Chronic) = 1.1 mg/kg bw/day  
COMMENT 1: New uses and water numbers

Ver. 2.00  
(1994-98 data)

=====  
Total exposure by population subgroup  
=====

Population Subgroup	Total Exposure		
	mg/kg body wt/day	Margin of Exposure 1/	Percent of RfD
U.S. Population (total)	0.000379	2,906	34.4%
U.S. Population (spring season)	0.000377	2,917	34.3%
U.S. Population (summer season)	0.000396	2,774	36.0%
U.S. Population (autumn season)	0.000371	2,964	33.7%
U.S. Population (winter season)	0.000369	2,979	33.6%
Northeast region	0.000350	3,141	31.8%
Midwest region	0.000386	2,847	35.1%
Southern region	0.000359	3,060	32.7%
Western region	0.000426	2,582	38.7%
Hispanics	0.000435	2,527	39.6%
Non-hispanic whites	0.000368	2,987	33.5%
Non-hispanic blacks	0.000366	3,008	33.3%
Non-hisp/non-white/non-black	0.000451	2,439	41.0%
All infants (< 1 year)	0.001030	1,068	93.6%
Nursing infants	0.000377	2,921	34.2%
Non-nursing infants	0.001278	861	116.2%
Children 1-6 yrs	0.000672	1,636	61.1%
Children 7-12 yrs	0.000419	2,625	38.1%
Females 13-19 (not preg or nursing)	0.000275	3,999	25.0%
Females 20+ (not preg or nursing)	0.000336	3,271	30.6%
Females 13-50 yrs	0.000344	3,193	31.3%
Females 13+ (preg/not nursing)	0.000363	3,033	33.0%
Females 13+ (nursing)	0.000475	2,313	43.2%
Males 13-19 yrs	0.000309	3,554	28.1%
Males 20+ yrs	0.000327	3,361	29.8%
Seniors 55+	0.000333	3,307	30.2%
Children 1-2 yrs	0.000745	1,476	67.7%
Children 3-5 yrs	0.000656	1,678	59.6%
Children 6-12 yrs	0.000443	2,483	40.3%
Youth 13-19 yrs	0.000294	3,747	26.7%
Adults 20-49 yrs	0.000333	3,306	30.3%
Adults 50+ yrs	0.000334	3,298	30.3%
Females 13-49 yrs	0.000325	3,389	29.5%

=====