MEMORANDUM

Date: 27 March 2008

Subject: Dietary Exposure Assessments for the Common Triazole Metabolites 1,2,4-Triazole, Triazolylalanine, Triazolylacetic Acid, and Triazolylpyruvic Acid; Updated to Include New Uses of Fenbuconazole, Ipconazole, Metconazole, Tebuconazole, and Uniconazole; and a Change in Plant-back Restriction for Tetraconazole.

DP Numbers: 350314, 350315, 350322, 350323, 350738, 350992

PC Code: 600074 (1,2,4-Triazole), 600011 (Triazolylalanine), 600082 (Triazolylacetic Acid), 625618 (Triazolylpyruvic Acid)

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Background

In February 2006, the HED issued aggregate risk assessments to address the common triazole metabolites 1,2,4-triazole (T), triazolylalanine (TA), and triazolylacetic acid (TAA). Those assessments included all triazole-derivative fungicide compounds and use requests that had been submitted to the Office of Pesticide Programs (OPP) as of 1 September 2005. Recently, OPP updated the triazole metabolite assessments to include new uses of myclobutanil (113961) (W. Cutchin, D347252, 12/19/07). This memorandum further updates the triazole metabolite dietary assessments to address petitions received by OPP for uses of fenbuconazole (PC Code 129011), ipconazole (PC Code 125618), metconazole (PC Code 125619), tebuconazole (PC Code 128997), and uniconazole (PC Code 128676) and a requested revision to the plant-back interval for tetraconazole.

Executive Summary

Acute and chronic aggregate dietary (food and drinking water) exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model DEEM-FCID™, Version 2.03 which use 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 Section 3 requests for the subject-listed fungicides.

Four assessments were conducted: acute and chronic durations for T, and acute and chronic durations for combined residues of TA, TAA, and triazolylpyruvic acid (TP). Residue chemistry databases for most of the subject-listed parent compounds do not include residue measurements for the triazole metabolites; therefore, metabolite residues have been estimated based on metabolism studies and parent compound tolerances. As with the previous triazole metabolite assessments, this assessment includes exposure estimates resulting from direct consumption of T, TA, TAA, and/or TP as well as exposure resulting from consumption of parent fungicides followed by in vivo conversion to the metabolites. For each food form in the acute assessment, the residue used is the maximum estimate from the various food/triazole fungicide combinations combined with the average indirect residue estimate. For the chronic assessments, the residue estimates are the average residue from the food-specific food/triazole combinations combined with the average indirect residue estimates. All four assessments assume 100% crop treated and include conservative estimates for residues of the metabolites in drinking water. The resulting exposure and risk estimates are based on health-protective assumptions and should be characterized as conservative.

For all four analyses, risk estimates are below HED’s level of concern for all population subgroups. There are no dietary exposure considerations for the common triazole metabolites that would preclude granting the registration requests.

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,” 21-JUN-2000, web link: http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061.pdf; or see SOP 99.6 (20-AUG-1999).

The most recent dietary risk assessment for the triazole metabolites was conducted by W. Cutchin (D347252, 12/19/07).

II. Residue Information

These dietary assessments include all of the uses addressed in the February 2006 assessment, previous updates to the assessments for difenoconazole (D341303 and D344298, M. Sahafeyan, 10/30/07) and myclobutanil (D347253, W. Cutchin, 12/19/07), use of other triazoles whose use would not result in metabolite residue estimates that are greater than those used in previous assessments (e.g., cyproconazole, prothioconazole), and the new uses summarized in Table 1.

Table 1. Summary of Compounds and Uses Considered in this Update to the Triazole Metabolite Assessments

<table>
<thead>
<tr>
<th>Compound</th>
<th>Use</th>
<th>Tolerance, ppm</th>
<th>T Update Status</th>
<th>TA/TAA/TP Update Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fenbuconazole</td>
<td>Peppers</td>
<td>0.4</td>
<td>No update required</td>
<td>No update required</td>
</tr>
<tr>
<td>Ipconazole</td>
<td>Cereal grains except rice</td>
<td>0.01</td>
<td>No update required</td>
<td>No update required</td>
</tr>
<tr>
<td></td>
<td>Cotton</td>
<td>0.01</td>
<td>No update required</td>
<td>No update required</td>
</tr>
<tr>
<td></td>
<td>Pea and Bean (Subgroup 6-C)</td>
<td>0.01</td>
<td>No update required</td>
<td>No update required</td>
</tr>
<tr>
<td></td>
<td>Peanut</td>
<td>0.01</td>
<td>No update required</td>
<td>No update required</td>
</tr>
<tr>
<td></td>
<td>Soybean</td>
<td>0.01</td>
<td>No update required</td>
<td>No update required</td>
</tr>
<tr>
<td>Metconazole</td>
<td>Peanut</td>
<td>0.04</td>
<td>No update required</td>
<td>No update required</td>
</tr>
<tr>
<td></td>
<td>Small Grains</td>
<td>2.5</td>
<td>No update required</td>
<td>Assessment updated</td>
</tr>
<tr>
<td></td>
<td>Soybean</td>
<td>0.05</td>
<td>No update required</td>
<td>Assessment updated</td>
</tr>
<tr>
<td></td>
<td>Stone Fruit (Group 12)</td>
<td>0.2</td>
<td>Assessment updated</td>
<td>No update required</td>
</tr>
<tr>
<td></td>
<td>Sugarbeet</td>
<td>0.07</td>
<td>No update required</td>
<td>No update required</td>
</tr>
<tr>
<td></td>
<td>Tree Nuts (Group 14)</td>
<td>0.02</td>
<td>Assessment updated</td>
<td>No update required</td>
</tr>
<tr>
<td>Tebuconazole</td>
<td>Beet (garden), root</td>
<td>0.7</td>
<td>Assessment updated</td>
<td>Assessment updated</td>
</tr>
<tr>
<td></td>
<td>Brassica Veg. (Subgroup 5B)</td>
<td>2.5</td>
<td>Assessment updated</td>
<td>Assessment updated</td>
</tr>
<tr>
<td></td>
<td>Bulb Veg. (Subgroup 3A)</td>
<td>0.1</td>
<td>No update required</td>
<td>No update required</td>
</tr>
<tr>
<td></td>
<td>Bulb Veg. (Subgroup 3B)</td>
<td>1.3</td>
<td>Assessment updated</td>
<td>Assessment updated</td>
</tr>
<tr>
<td>Uniconazole</td>
<td>Fruiting Veg. (Group 8)</td>
<td>0.01</td>
<td>No update required</td>
<td>No update required</td>
</tr>
<tr>
<td>Tetraconazole</td>
<td>Shorter plant-back interval</td>
<td>N/A</td>
<td>Assessment updated</td>
<td>Assessment updated</td>
</tr>
</tbody>
</table>

§ Residue estimates from the previous assessment are unchanged or greater than those that result once this compound/use combination is included in the calculation of anticipated residues.

* HED’s recommended tolerances vary for this group. The maximum value is 2.5 ppm for barley; other entries are 0.25 ppm for oat, 0.25 ppm for rye, and 0.15 ppm for wheat.

† The assessment was updated for stone fruit except cherry.

‡ At this time, Crop Group 3 has not been subdivided into Subgroups 3A and 3B. Group 3B includes green onion, leek, and shallot.

§ The requested change in the plant-back restriction may result in residues of conjugated triazole metabolites in sugarcane. Residues of TA are not expected to exceed 0.17 ppm based on rotational crop data.
The residue estimates, after considering the subject-listed compounds, are summarized in Table 2 for only the affected crops (i.e., cotton is not included in Table 2 since anticipated residues do not indicate that a new assessment is needed based on the new ipconazole use on cotton). These assessments have considered dietary exposure to the triazole metabolites due to the direct consumption of metabolite residues in foods. In addition, indirect exposure resulting from ingestion of parent triazole-derivative fungicides and the subsequent \textit{in vivo} conversion of parent compound to T and/or TA/TAA/TP has been included. As with previous assessments, maximum direct exposure estimates and average indirect exposure estimates were combined to assess acute risks, and average direct and indirect exposure estimates were combined to assess chronic risks. An assumption of 100% crop treated was made for both the free triazole and the conjugated triazole assessments, and both assessments used DEEM 7.81 default processing factors for processed commodities.

<table>
<thead>
<tr>
<th>Food Form</th>
<th>1,2,4-Triazole</th>
<th>Triazolylalanine + Triazolylacetic Acid + Triazolylpyruvic Acid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulb Veg. (Group 3B)</td>
<td>0.0583</td>
<td>0.0588</td>
</tr>
<tr>
<td>Brassica Veg. (Group 5B)</td>
<td>0.1122</td>
<td>0.6588</td>
</tr>
<tr>
<td>Garden Beet</td>
<td>0.0314</td>
<td>0.0732</td>
</tr>
<tr>
<td>Peanut</td>
<td>0.0081</td>
<td>0.0478</td>
</tr>
<tr>
<td>Stone Fruit (Group 12)</td>
<td>0.0957</td>
<td>1.2670</td>
</tr>
<tr>
<td>Tree Nuts (Group 14)</td>
<td>0.0040</td>
<td>0.3548</td>
</tr>
</tbody>
</table>

1 Acute = Maximum Direct Exposure Estimate + Average Indirect Exposure Estimate
2 Chronic = Average Direct Exposure Estimate + Average Indirect Exposure Estimate

### III. Drinking Water Data

Residues of 1,2,4-triazole in drinking water were provided to HED by the Environmental Fate and Effects Division (I. Maher, DP 320682). Due to the inter-conversion between 1,2,4-triazole, triazole alanine, and triazole acetic acid that may occur in the environment, the residue estimates used in these assessments are a summation of all three residues and, therefore, represent an overestimate of actual concentrations of 1,2,4-triazole in drinking water. The Tier II PRZM/EXAMS (surface water) and SCiGROW (groundwater) residue estimates are summarized in Table 3. HED notes that there were no detects of 1,2,4-triazole in any of the 271 water samples analyzed by PDP, with a limit of quantification of 730 parts-per-trillion (0.73 ppb).
IV. DEEM-FCID™ Program and Consumption Information

Triazole metabolite 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.

V. Toxicological Information
1,2,4-Triazole is a common metabolite of many triazole-derivative fungicides. As a metabolite, there are no data requirements, \textit{per se}, for this compound. Nevertheless, a significant amount of toxicological data is available and has been reviewed by HED. The following summary table (Table 3) shows the doses selected for assessing dietary exposure and their associated endpoints. Data are insufficient at this time to assign a cancer classification to 1,2,4-triazole. Available data indicate that cancers associated with 1,2,4-triazole are likely to be a threshold effect and that a Q_{10}^{*} approach is not appropriate. An RfD-approach for assessing cancer has been recommended. As such, the chronic exposure assessment is considered to be protective of any potential cancer-related effects.

Table 4. Summary of Toxicological Doses and Endpoints for 1,2,4-Triazole for Use in Dietary Exposure Risk Assessments

<table>
<thead>
<tr>
<th>Exposure/Scenario</th>
<th>Point of Departure</th>
<th>Uncertainty/FQPA Safety Factors</th>
<th>RfD, PAD, Level of Concern</th>
<th>Study and Toxicological Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Dietary (females 13-49)</td>
<td>NOAEL = 30 mg/kg</td>
<td>FQPA SF = 1</td>
<td>aPAD = acute RfD FQPA SF = 0.03 mg/kg/day</td>
<td>Developmental Toxicity study in rabbits</td>
</tr>
<tr>
<td></td>
<td>UF = 1000</td>
<td></td>
<td></td>
<td>LOAEL = 45 mg/kg based on urinary tract malformations in fetuses</td>
</tr>
<tr>
<td></td>
<td>Acute RfD = 0.03 mg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute Dietary (general population)</td>
<td>NOAEL = 30 mg/kg</td>
<td>FQPA SF = 1</td>
<td>aPAD = acute RfD FQPA SF = 0.03 mg/kg/day</td>
<td>Developmental Toxicity study in rabbits</td>
</tr>
<tr>
<td></td>
<td>UF = 1000</td>
<td></td>
<td></td>
<td>LOAEL = 45 mg/kg based on clinical signs and mortality in does starting on Gestation Day 6 or 7</td>
</tr>
<tr>
<td></td>
<td>Acute RfD = 0.03 mg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic Dietary (all populations)</td>
<td>LOAEL = 15 mg/kg/day UF = 3000</td>
<td>FQPA SF = 1</td>
<td>cPAD = chronic RfD FQPA SF = 0.005 mg/kg/day</td>
<td>Reproductive Toxicity study in rats</td>
</tr>
<tr>
<td></td>
<td>Chronic RfD = 0.005 mg/kg/day</td>
<td></td>
<td></td>
<td>LOAEL = 15 based on decreased body weight in adult males and on decreased body weight and brain weight in offspring</td>
</tr>
<tr>
<td>Cancer</td>
<td>Insufficient data for a cancer classification. Based on the available information, HED believes that an RfD approach is appropriate and that the cPAD is sufficient to assess cancer risk.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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_{A} = extrapolation from animal to human (intraspecies). UF_{H} = potential variation in sensitivity among members of the human population (interspecies). UF_{L} = use of a LOAEL to extrapolate a NOAEL. UF_{S} = use of a short-term study for long-term risk assessment. UF_{DB} = 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. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

The conjugated triazole metabolites (e.g., triazolylalanine, triazolylacetic acid, triazolylpyruvic acid) are common metabolite of many triazole-derivative fungicides. As a metabolite, there are no data requirements, \textit{per se}, for this compound. Nevertheless, a significant amount of toxicological data is available and has been reviewed by HED. The following summary table (Table 3) shows the doses selected for assessing dietary exposure and their associated endpoints.
Data are insufficient at this time to assign a cancer classification to the conjugated metabolites. Available data indicate that cancers associated with these compounds are likely to be a threshold effect and that a Q<sub>1</sub>* approach is not appropriate. An RfD-approach for assessing cancer has been recommended. As such, the chronic exposure assessment is considered to be protective of any potential cancer-related effects.

Table 5. Summary of Toxicological Doses and Endpoints for the Conjugated Triazole Metabolites for Use in Dietary Exposure Risk Assessments

<table>
<thead>
<tr>
<th>Exposure/Scenario</th>
<th>Point of Departure</th>
<th>Uncertainty/FQPA Safety Factors</th>
<th>RfD, PAD, Level of Concern</th>
<th>Study and Toxicological Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Dietary (females 13-49)</td>
<td>NOAEL = 100 mg/kg</td>
<td>FQPA SF = 1</td>
<td>aPAD = acute RfD</td>
<td>Developmental Toxicity study in rabbits</td>
</tr>
<tr>
<td></td>
<td>UF=1000</td>
<td></td>
<td>RfD SF = 0.1 mg/kg/day</td>
<td>LOAEL=45 mg/kg based on urinary tract malformations in fetuses</td>
</tr>
<tr>
<td>Acute Dietary (general population)</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>No appropriate dose and endpoint could be identified for this population group.</td>
</tr>
<tr>
<td>Chronic Dietary (all populations)</td>
<td>LOAEL = 90 mg/kg/day</td>
<td>FQPA SF = 1</td>
<td>cPAD = chronic RfD</td>
<td>Reproductive Toxicity study in rats</td>
</tr>
<tr>
<td></td>
<td>UF =1000</td>
<td></td>
<td>RfD SF = 0.09 mg/kg/day</td>
<td>LOAEL = 15 based on decreased body weight in adult males and on decreased body weight and brain weight in offspring</td>
</tr>
<tr>
<td>Cancer</td>
<td>Insufficient data for a cancer classification. Based on the available information, HED believes that an RfD approach is appropriate and that the cPAD is sufficient to assess cancer risk.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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>i</sub> = potential variation in sensitivity among members of the human population (interspecies). UF<sub>b</sub> = use of a LOAEL to extrapolate a NOAEL. UF<sub>s</sub> = use of a short-term study for long-term risk assessment. 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. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

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 4 and 5 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. Cancer risk is determined for the general U.S. population only.

Acute and chronic dietary exposure estimates are below HED’s level of concern for all population subgroups, including those of infants and children, for both 1,2,4-triazole as well as the conjugated triazole metabolites.
Table 4. Summary of Dietary (Food and Drinking Water) Exposure and Risk for the Common Triazole Metabolites

<table>
<thead>
<tr>
<th>Population Subgroup</th>
<th>1,2,4-Triazole</th>
<th>Triazolylalanine + Triazolylacetic Acid + Triazolylpyruvic Acid</th>
</tr>
</thead>
<tbody>
<tr>
<td>General U.S. Population</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All Infants (&lt; 1 year old)</td>
<td>0.003927</td>
<td>0.008085</td>
</tr>
<tr>
<td>Children 1-2 years old</td>
<td>0.009308</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Children 3-5 years old</td>
<td>0.006180</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Children 6-12 years old</td>
<td>0.001447</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Youth 13-19 years old</td>
<td>0.002985</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Adults 20-49 years old</td>
<td>0.002347</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Adults 50+ years old</td>
<td>0.002393</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Females 13-49 years old</td>
<td>0.003268</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dietary Exposure (mg/kg/day)</th>
<th>% aPAD*</th>
<th>Dietary Exposure (mg/kg/day)</th>
<th>% cPAD*</th>
<th>Dietary Exposure (mg/kg/day)</th>
<th>Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Dietary (95th Percentile)</td>
<td></td>
<td>Chronic Dietary</td>
<td></td>
<td>Cancer</td>
<td></td>
</tr>
<tr>
<td>0.000884</td>
<td>18</td>
<td>0.001616</td>
<td>32</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>0.003168</td>
<td>26</td>
<td>0.001088</td>
<td>25</td>
<td>Not Applicable</td>
<td></td>
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<tr>
<td>0.001088</td>
<td>22</td>
<td>0.000728</td>
<td>15</td>
<td>Not Applicable</td>
<td></td>
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<tr>
<td>0.000728</td>
<td>15</td>
<td>0.000750</td>
<td>15</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>0.000728</td>
<td>15</td>
<td>0.000750</td>
<td>15</td>
<td>Not Applicable</td>
<td></td>
</tr>
</tbody>
</table>

* %PADs are reported to 2 significant figures. The values for the highest exposed population for each type of risk assessment are bolded.

VII. Characterization of Inputs/Outputs

Although these dietary exposure assessments are principally based on anticipated residues, the data, selection criteria, and assumptions that serve as the source of those residues are conservative in nature. Most residue estimates used in the assessments are derived from tolerance-level residues and it was assumed that 100% of foods with a triazole-derivative-fungicide tolerance have residues of the triazole metabolites. Overall, this assessment is considered to be conservative and likely overestimates actual direct and indirect dietary exposure to the triazole metabolites.

VIII. Conclusions

Based on conservative estimates of direct and indirect dietary exposure, acute and chronic risk estimates for the general U.S. population and all representative population subgroups, including those of infants and children, are well below HED’s level of concern for both 1,2,4-triazole and the conjugated triazole metabolites. There are no dietary exposure considerations for the common triazole metabolites that would preclude granting the requested uses of the triazole fungicides fenbuconazole, ipconazole, metconazole, tebuconazole, and uniconazole.
IX. List of Attachments
Attachment 1. Residue inputs and assumptions used in the acute assessment of free triazole.
Attachment 2. Residue inputs and assumptions used in the acute assessment of the conjugated triazole metabolites.
Attachment 3. Residue inputs and assumptions used in the chronic assessment of free triazole.
Attachment 4. Residue inputs and assumptions used in the chronic assessment of the conjugated triazole metabolites.
Attachment 5. Summary of the results of the acute assessment of free triazole.
Attachment 6. Summary of the results of the acute assessment of the conjugated triazole metabolites.
Attachment 7. Summary of the results of the chronic assessment of free triazole.
Attachment 8. Summary of the results of the chronic assessment of the conjugated triazole metabolites.
Attachment 1. Residue inputs and assumptions used in the acute assessment of free triazole.

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Attachment 2. Residue inputs and assumptions used in the acute assessment of the conjugated triazole metabolites.

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Attachment 3. Residue inputs and assumptions used in the chronic assessment of free triazole.

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EPA Code | Crop | Commodity Name | Def Res (ppm) | Adj.Factors #1 | Adj.Factors #2 | Comment |
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EPA Code | Crop | Commodity Name | Def Res (ppm) | Adj.Factors #1 | Adj.Factors #2 | Comment |
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EPA Code | Crop | Commodity Name | Def Res (ppm) | Adj.Factors #1 | Adj.Factors #2 | Comment |
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EPA Code | Crop | Commodity Name | Def Res (ppm) | Adj.Factors #1 | Adj.Factors #2 | Comment |
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Attachment 4. Residue inputs and assumptions used in the chronic assessment of the conjugated triazole metabolites.

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<tr>
<td>15004020 15</td>
<td>Wheat, flour</td>
<td>0.061000</td>
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</tr>
<tr>
<td>15004021 15</td>
<td>Wheat, flour-babyfood</td>
<td>0.061000</td>
<td>1.000</td>
<td>1.000</td>
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<tr>
<td>15004030 15</td>
<td>Wheat, germ</td>
<td>0.061000</td>
<td>1.000</td>
<td>1.000</td>
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<tr>
<td>15004040 15</td>
<td>Wheat, bran</td>
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<td>Wild rice</td>
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<td>Yam, true</td>
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<td>Yam bean</td>
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Attachment 5. Summary of the results of the acute assessment of free triazole.

<table>
<thead>
<tr>
<th></th>
<th>95th Percentile Exposure</th>
<th>% aRfD</th>
<th>99th Percentile Exposure</th>
<th>% aRfD</th>
<th>99.9th Percentile Exposure</th>
<th>% aRfD</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. Population:</td>
<td>0.003927</td>
<td>13.09</td>
<td>0.006319</td>
<td>21.06</td>
<td>0.011242</td>
<td>37.47</td>
</tr>
<tr>
<td>All infants:</td>
<td>0.009308</td>
<td>31.03</td>
<td>0.012990</td>
<td>43.30</td>
<td>0.021310</td>
<td>71.03</td>
</tr>
<tr>
<td>Children 1-2 yrs:</td>
<td>0.007684</td>
<td>25.61</td>
<td>0.011223</td>
<td>37.41</td>
<td>0.016115</td>
<td>53.72</td>
</tr>
<tr>
<td>Children 3-5 yrs:</td>
<td>0.006180</td>
<td>20.60</td>
<td>0.008767</td>
<td>29.22</td>
<td>0.013921</td>
<td>46.40</td>
</tr>
<tr>
<td>Children 6-12 yrs:</td>
<td>0.004147</td>
<td>13.82</td>
<td>0.005922</td>
<td>19.74</td>
<td>0.009063</td>
<td>30.21</td>
</tr>
<tr>
<td>Youth 13-19 yrs:</td>
<td>0.002985</td>
<td>9.95</td>
<td>0.004826</td>
<td>16.09</td>
<td>0.008445</td>
<td>28.15</td>
</tr>
<tr>
<td>Adults 20-49 yrs:</td>
<td>0.003247</td>
<td>10.82</td>
<td>0.004757</td>
<td>15.86</td>
<td>0.007519</td>
<td>25.06</td>
</tr>
<tr>
<td>Adults 50+ yrs:</td>
<td>0.002930</td>
<td>9.77</td>
<td>0.004213</td>
<td>14.04</td>
<td>0.006535</td>
<td>21.78</td>
</tr>
<tr>
<td>Females 13-49 yrs:</td>
<td>0.003268</td>
<td>10.89</td>
<td>0.004690</td>
<td>15.63</td>
<td>0.008146</td>
<td>27.15</td>
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</tbody>
</table>
Attachment 6. Summary of the results of the acute assessment of the conjugated triazole metabolites.

U.S. Environmental Protection Agency
DEEM-FCID ACUTE Analysis for TA/TAA
(1994-98 data)
Residue file: TA+TAA Acute-3-08.R98
Analysis Date: 03-27-2008/13:39:06
Daily totals for food and foodform consumption used.
Run Comment: "RfDs are PADs. aPAD for Females 13-49 only"

===============================================================================
Summary calculations (per capita):

<table>
<thead>
<tr>
<th></th>
<th>95th Percentile</th>
<th>99th Percentile</th>
<th>99.9th Percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure % aRfD</td>
<td>Exposure % aRfD</td>
<td>Exposure % aRfD</td>
</tr>
<tr>
<td>Females 13-49 yrs:</td>
<td>0.028598</td>
<td>0.043254</td>
<td>0.079130</td>
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<tr>
<td></td>
<td>28.60</td>
<td>43.25</td>
<td>79.13</td>
</tr>
</tbody>
</table>

Page 39 of 41
Attachment 7. Summary of the results of the chronic assessment of free triazole.

<table>
<thead>
<tr>
<th>Population Subgroup</th>
<th>Total Exposure</th>
<th>Percent of Rfd</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. Population (total)</td>
<td>0.000884</td>
<td>17.7%</td>
</tr>
<tr>
<td>U.S. Population (spring season)</td>
<td>0.000893</td>
<td>17.9%</td>
</tr>
<tr>
<td>U.S. Population (summer season)</td>
<td>0.000900</td>
<td>18.0%</td>
</tr>
<tr>
<td>U.S. Population (autumn season)</td>
<td>0.000865</td>
<td>17.3%</td>
</tr>
<tr>
<td>U.S. Population (winter season)</td>
<td>0.000879</td>
<td>17.6%</td>
</tr>
<tr>
<td>Northeast region</td>
<td>0.000920</td>
<td>18.4%</td>
</tr>
<tr>
<td>Midwest region</td>
<td>0.000884</td>
<td>17.7%</td>
</tr>
<tr>
<td>Southern region</td>
<td>0.000805</td>
<td>16.1%</td>
</tr>
<tr>
<td>Western region</td>
<td>0.000979</td>
<td>19.6%</td>
</tr>
<tr>
<td>Hispanics</td>
<td>0.001015</td>
<td>20.3%</td>
</tr>
<tr>
<td>Non-hispanic whites</td>
<td>0.000860</td>
<td>17.2%</td>
</tr>
<tr>
<td>Non-hispanic blacks</td>
<td>0.000834</td>
<td>16.7%</td>
</tr>
<tr>
<td>Non-hisp/non-white/non-black</td>
<td>0.001115</td>
<td>22.3%</td>
</tr>
<tr>
<td>All infants (&lt; 1 year)</td>
<td>0.001616</td>
<td>32.3%</td>
</tr>
<tr>
<td>Nursing infants</td>
<td>0.000724</td>
<td>14.5%</td>
</tr>
<tr>
<td>Non-nursing infants</td>
<td>0.001955</td>
<td>39.1%</td>
</tr>
<tr>
<td>Children 1-6 yrs</td>
<td>0.001820</td>
<td>36.4%</td>
</tr>
<tr>
<td>Children 7-12 yrs</td>
<td>0.001031</td>
<td>20.6%</td>
</tr>
<tr>
<td>Females 13-19 (not preg or nursing)</td>
<td>0.000696</td>
<td>13.9%</td>
</tr>
<tr>
<td>Females 20+ (not preg or nursing)</td>
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</tr>
<tr>
<td>Females 13-50 yrs</td>
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<tr>
<td>Females 13+ (preg/not nursing)</td>
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</tr>
<tr>
<td>Males 13-19 yrs</td>
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</tr>
<tr>
<td>Males 20+ yrs</td>
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</tr>
<tr>
<td>Seniors 55+</td>
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</tr>
<tr>
<td>Children 1-2 yrs</td>
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<tr>
<td>Children 3-5 yrs</td>
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<tr>
<td>Children 6-12 yrs</td>
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<tr>
<td>Youth 13-19 yrs</td>
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</tr>
<tr>
<td>Adults 20-49 yrs</td>
<td>0.000760</td>
<td>15.2%</td>
</tr>
<tr>
<td>Adults 50+ yrs</td>
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<tr>
<td>Females 13-49 yrs</td>
<td>0.000750</td>
<td>15.0%</td>
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Attachment 8. Summary of the results of the chronic assessment of the conjugated triazole metabolites.

U.S. Environmental Protection Agency
DEEM-FCID Chronic analysis for TA/TAA (1994-98 data)
Residue file name: C:\Documents and Settings\mdoherty\My Documents\Chemistry Reviews\DEEM Runs\Triazoles\TA+TAA Chronic-3-08.R98
Adjustment factor #2 NOT used.
Reference dose (RfD, Chronic) = .09 mg/kg bw/day
COMMENT 1: RfDs are PADs. aPAD for Females 13-49 only

<table>
<thead>
<tr>
<th>Population Subgroup</th>
<th>Total Exposure</th>
<th>Percent of Rfd</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. Population (total)</td>
<td>0.008085</td>
<td>9.0%</td>
</tr>
<tr>
<td>U.S. Population (spring season)</td>
<td>0.008174</td>
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<tr>
<td>U.S. Population (summer season)</td>
<td>0.008208</td>
<td>9.1%</td>
</tr>
<tr>
<td>U.S. Population (autumn season)</td>
<td>0.007925</td>
<td>8.8%</td>
</tr>
<tr>
<td>U.S. Population (winter season)</td>
<td>0.008039</td>
<td>8.9%</td>
</tr>
<tr>
<td>Northeast region</td>
<td>0.008265</td>
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</tr>
<tr>
<td>Midwest region</td>
<td>0.008219</td>
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<tr>
<td>Southern region</td>
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<td>Western region</td>
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<tr>
<td>Hispanics</td>
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<tr>
<td>Non-hispanic whites</td>
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<td>Non-hispanic blacks</td>
<td>0.007846</td>
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<tr>
<td>Non-hisp/non-white/non-black</td>
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<tr>
<td>All infants (&lt; 1 year)</td>
<td>0.014844</td>
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<td>Nursing infants</td>
<td>0.006628</td>
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<tr>
<td>Non-nursing infants</td>
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<tr>
<td>Children 1-6 yrs</td>
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<td>Children 7-12 yrs</td>
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<td>Males 13-19 yrs</td>
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<tr>
<td>Males 20+ yrs</td>
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<tr>
<td>Seniors 55+</td>
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</tr>
<tr>
<td>Children 1-2 yrs</td>
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<tr>
<td>Children 3-5 yrs</td>
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</tr>
<tr>
<td>Children 6-12 yrs</td>
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<td>12.7%</td>
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<tr>
<td>Youth 13-19 yrs</td>
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<tr>
<td>Adults 20-49 yrs</td>
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<tr>
<td>Adults 50+ yrs</td>
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<tr>
<td>Females 13-49 yrs</td>
<td>0.006407</td>
<td>7.1%</td>
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Page 41 of 41