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OFFICE OF
PREVENTION, PESTICIDES, AND
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MEMORANDUM

December 12, 2006

SUBJECT: Response to Comments on the "Prothioconazole Tier II Drinking Water Exposure Assessment."

TO: Tony Kish, Product Manager
Lana Coppolino, Reviewer
FB/RD (7505P)

FROM: Greg Orrick, Environmental Scientist Greg Orrick 12-14-06
ERB4/EFED (7507P)

THRU: Betsy Behl, Chief
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This memo is EFED's response to comments received from Bayer CropScience (BCS) regarding the Prothioconazole Tier II Drinking Water Exposure Assessment conducted in support of human health risk assessment. BCS organized their comments under four major points for consideration by EPA. The conclusions of each major point are italicized below and followed by EFED's response.

Overall, EFED responses to BCS comments indicate that the Prothioconazole Tier II Drinking Water Exposure Assessment was conducted appropriately and does not require revision.

Comment 1: Exclusion of bound, non-extractable residues as a part of the total toxic residues.

BCS: *The soil extraction methods employed in the environmental fate studies included refluxing with acetonitrile:water (80:20) solvent at elevated temperatures. If the bound residues are not desorbed in an organic solvent at elevated temperatures, it can be concluded with high certainty that environmental impact of these*

residues will be mitigated by the strong or irreversible binding, and the bound residues cannot and should not be considered as environmentally available.

EFED response: Subdivision N guidelines require that environmental fate studies include a reasonable attempt to identify the parent and all major degradates, including rates of their formation and decline. When greater than 10% of applied residues are not extracted after extraction attempts with one solvent, the use of multiple solvent systems is reasonable. EFED disagrees that use of one organic solvent at elevated temperatures is a reasonable extraction effort when non-extracted residues are greater than 10% of the applied. Organic matter fractionation of non-extracted residues does not address whether the extraction effort was reasonable.

Comment 2: Use of aerobic soil degradation studies conducted on the major metabolites, prothioconazole-desthio and prothioconazole-S-methyl, in the exposure assessment.

BCS: *Studies submitted to EPA clearly show that prothioconazole-desthio and prothiconazole-S-methyl degrade readily in aerobic soil, contrary to the observations from the parent study. As a part of exposure refinement, information and results from these studies should be considered.*

EFED response: The total toxic residues (TTR) approach used in the prothioconazole risk assessment requires degradate information from studies on the parent compound. The data from the submitted studies concerning prothioconazole-desthio and prothiconazole-S-methyl (MRID 46246513 and 46246514) were considered and could not be applied to the TTR approach. Furthermore, reasonable extraction efforts were not made in the submitted degradate studies. The degradation rates of the degradates in the parent study and the degradate studies are not clearly different when non-extracted residues are included in the calculations.

Comment 3: Evaluation of parent and metabolites individually in the exposure assessment tools (PRZM and EXAMS) and combine them if needed, applying molecular equivalence.

BCS: *Instead of treating the prothioconazole and its major metabolites as a lumped constituent, utilizing the formation-degradation kinetics ability of PRZM and EXAMS to calculate the exposure concentrations of the individual residues, the exposure assessment can be substantially refined. This method provides a more realistic, yet conservative, exposure estimate.*

EFED response: Quality assurance has not been conducted for PRZM's routines concerning the calculation of individual toxic residue exposure estimates. Therefore, this refinement of the TTR approach for the exposure assessment of prothioconazole provides no assessment benefit.

Comment 4: Use of refined rice exposure assessment.

BCS: *By using a higher tier rice exposure assessment model, accounting for chemical degradation, precise existing cultural practices and site-specific weather data, the calculated EDWC were about 10 times lower that the screening level method used by EPA. Considering several conservative assumptions such as conservative the environmental fate parameters and percent cropped area estimate, used in the refined exposure assessment, the actual drinking water concentrations resulting from prothioconazole use on rice are not expected be higher than the estimated values.*

EFED response: The Interim Rice Model, as opposed to the RICEWQ and other rice models, is the only model that has been through QA/QC by OPP, and therefore is approved for use in pesticide risk assessment. Exposure estimates calculated for pesticide applications on rice should not be refined with models not approved for use in pesticide risk assessment. Furthermore, although the EFED rice model includes a number of conservative assumptions it has been found to yield concentrations that are not unreasonably conservative for several compounds for which monitoring data are available.