PMSD 1594

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

JUN 3 1987

EXPEDITE

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Anticipated residues for Tilt (propiconazole) on several commodities. PP#'s 4F3007, 4E3026, and 4F3074.

FROM: Karl H. Arne, Ph.D.
Residue Chemistry Branch

THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: Lois Rossi, PM # 21
Registration Division

The following anticipated residues were calculated for use in assessing the dietary exposure of Tilt resulting from pending uses on bananas and small grains. Ciba-Geigy has submitted their version of anticipated residues, and any differences between their estimates and RCB's estimates are discussed below.

Bananas (PP#4F3026)

The tolerance proposed is 0.2 ppm. The anticipated residue used for TAS calculations was 0.05 ppm, which is the average residue from field trial data incorporating the maximum proposed use. Ciba-Geigy's anticipated residue is also given as 0.05 ppm but for reasons not explained the value 0.025 was used in their TAS analysis.

Barley, Rice, Wheat, and Rye (PP#4F3074)

The tolerance proposed is 0.1 ppm for these grains. Since no residues were detected above the sensitivity of the method, 0.05 ppm, this level was used as the anticipated residue. Ciba-Geigy used 0.025 ppm because they felt that 0.025 ppm would have been detected, if present. RCB does not feel that 0.025 ppm is supported by available chromatograms, which have many peaks near the analyte peak. Submission of additional chromatograms may support the registrant's value.

The residue values for wheat were further reduced by the percent of crop treated, 2 per cent. This is the maximum per cent of wheat that has been treated with fungicide for the past several years. Personal communication with Bernard Smale of BUD confirmed this figure.

Residues in wheat flour were also reduced by a processing factor. Field incurred residues of 0.27 and 0.44 ppm were obtained in wheat grain from exaggerated rates. Milling reduced the residues in flour to <0.05 ppm in both cases. Since reduction of residues at lower levels in the grain may not be exactly proportional, a reduction factor of 5x was used. This resulted in an anticipated residue for flour of 0.01 ppm before applying the per cent of crop treated.

Meat, Milk, Poultry, and Eggs (PP#4F3074)

The tolerances proposed are: Milk, 0.05 ppm; meat and fat of beef, sheep, horses, goats, and pigs, 0.1 ppm; liver and kidney of beef, sheep, horses, goats, and pigs, 0.2 ppm; meat and fat of poultry, 0.1 ppm; liver of poultry, 0.2 ppm; eggs, 0.1 ppm. Anticipated residues for meat, milk, poultry, and eggs were determined by using the theoretical diets described in S. Malak's memo of 5/14. These diets predicted exposure to livestock of 0.35 ppm in the feed for beef cattle, 0.2 ppm in the feed for dairy cows, and 0.07 ppm in the feed for poultry. RCB (S. Malak, personal communication) extrapolated the results of the three feeding levels in the feeding studies (15, 75, and 150 ppm) to the low levels expected in the diet, then multiplied the results by a factor of about 10 to account for the error that may be involved in extrapolating from high doses to low doses. This resulted in estimated residues in meat and milk of 0.01 ppm except for liver and kidney, for which residues remained at the tolerance level, 0.2 ppm. A similar process for poultry resulted in anticipated residues of 0.01 ppm for eggs and tissues.

Ciba-Geigy used average residues in animal feed from field trial data as a basis for determining anticipated residues in meat, milk, poultry, and eggs. They then presumed linearity between the worst case feeding study (that diet that produced the highest proportional residues) and the diet at the anticipated level (0.075 ppm for all livestock) to estimate secondary residues from the lower feeding level.

RCB does not agree with Ciba-Geigy's linear extrapolation from high feeding levels to estimate residues that might result from very low feeding levels. The lowest feeding level for cows was 15 pm, and the lowest feeding level for poultry was 7.5 ppm; While the feeding studies showed some linearity, it is impossible to know with any accuracy what residues will result from very low feeding levels. Results from a lower level feeding study along with more sensitive methodology are required to more accurately determine secondary residues that might result from the proposed uses.

Conclusions

The above estimated anticipated residues represent the best estimate that RCB can make with available data. Additional data that would be useful include: cooking and baking studies

corresponding to the food factors used in TAS, additional feeding studies at lower levels, and more sensitive methodology.

cc: TAS file
Reading File
K. Arne
PP#'s 4F3007, 4E3026, 4F3074
TOX
PMSD
Circ.
Subject file