PMSD/ISB

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

APR 27 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Chlorpyrifos: Impact of Cattle and Sheep Treatments on Dietary Exposure (DEB No. 5146, HED Project No. 9-1186, RD Record No. 242729)

FROM: Debra F. Edwards, Ph.D., Acting Section Chief
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Debra Edwards

THROUGH: Richard D. Schmitt, Ph.D., Acting Chief
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Edward Zager, for

TO: Dennis Edwards, PM-12
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Registration Division (H7505C)

Introduction

According to a 12/29/88 Tolerance Assessment System (TAS) analysis on chlorpyrifos (S. Stanton) conducted in conjunction with the registration standard second round review (SRR), the anticipated residue contribution (ARC) for the overall U.S. population is 141% of the PADI, 200% for non-nursing infants, and 273% for children, 1 to 6 years of age. This analysis utilized percent crop treated data obtained from BEAD and anticipated residue data for citrus fruit, apples, and poultry obtained from DEB. However, due to outstanding data gaps relating to direct treatment of beef and dairy cattle, the analysis assumed that 100% of all meat and milk products would contain residues at current tolerance levels.

Present considerations

Dow Chemical U.S.A. has submitted a letter asking the Agency's thoughts on three potential ways of lowering the anticipated residue contribution for chlorpyrifos such that the ADI is no longer exceeded. Each point will be presented separately, followed by DEB's comments.

Point # 1: If the animal treatment uses were cancelled completely, what would be the Agency's recommendation on the meat tolerance for chlorpyrifos?

DEB Comments re. Point # 1:

This question was raised and addressed previously during the Post Phase II part of SRR development. In a DEB memo dated 3/21/89 (attached), D. Edwards stated, " . . . DEB would be able to recommend the following tolerance levels to cover residues of chlorpyrifos per se in meat and milk, should the direct treatment uses drop out.

cattle fat	0.2 ppm
cattle meat and meat byproducts	0.05 ppm
milk fat	0.25 ppm
whole milk	0.01 ppm"

A revised TAS analysis, conducted using these values for meat and milk resulted in ARCs at 25% of the PADI for the overall U.S. population, 65% for non-nursing infants, and 57% for children, 1 to 6 years of age (3/29/89 TAS memo by S. Stanton).

Point # 2: If the residue studies for the animal treatments were repeated, would the new tolerance for chlorpyrifos in meat be calculated by adding the residue levels from the animal treatments to the residue levels in the animals already incurred from the feed portion of the diet?

DEB Comments re. Point # 2:

Since livestock treated directly may also consume feed items treated with chlorpyrifos, appropriate tolerance levels must be calculated by adding maximum expected residue levels resulting from ingestion of feed items to those resulting from direct treatment of the animal.

Point # 3: As an interim attempt to expedite the lowering of the ADI level, would the Agency consider reducing the % animals treated from the current level of 100% based on use data submitted by the registrant? Although the tolerance would still be maintained at 2 ppm until the data gap is resolved, we are requesting that the Agency consider adjusting the % animals treated to reflect actual market usage.

DEB Comments re. Point # 3:

Meat, fat and meat byproducts: DEB does not recommend the use of % animals treated data in TAS analyses at this time because the available data, upon which the meat tolerances were partially based, reflect residues at posttreatment intervals of $\geq$ 7 days or following use at below maximum rates. Although the labels specify a 14-day preslaughter interval (PSI) for cattle and a 35-day PSI for sheep, PSIs of longer than 3 days are now considered to be impractical. Livestock can change hands quickly and end up with a new owner who is not certain of the date of application or may

even be unaware that an insecticide has been applied. Therefore, current Agency policy is to permit a PSI of no longer than 3 days. In the absence of adequate data reflecting residues in meat within 3 days after treatment, DEB feels that it is prudent to take the conservative approach of assuming 100% animals treated since residues in meat 3 days after treatment may exceed those reported at 7 days. Data depicting residues within 3 days after treatment have been required in the Residue Chemistry Chapter of the SRR. After acceptable data in response to this requirement have been submitted, it may be appropriate to use percent animals treated data in dietary exposure assessments.

Milk: DEB does not recommend the use of % animals treated data in TAS analyses at this time because the available data, upon which milk tolerances were based, reflect residues solely resulting from ingestion of feed items (i.e., the current assessment already assumes 0% of animals directly treated). Established tolerances for whole milk (0.02 ppm) and milkfat (0.5 ppm) include the metabolite, TCP, which is no longer considered to be of toxicological concern. However, until the registrant provides data reflecting additional residues that may occur in milk following direct use or voluntarily cancels such use, DEB recommends against using values other than the current tolerances for whole milk and milkfat.

Attachment: DEB memo by D. Edwards, dated 3/21/89

H7509C:DEB:DFE:4/26/89:CM#2:RM810:x1878
cc: RF:Circ.,Edwards,PP#3F2884,Reg.Standard File (SRR),PMSD/ISB, A.Kocialski (SACB/HED)
RDI:R.Loranger,4/89