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

August 30, 1988

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: EBDC's (014505), Chlorothalonil (081901), and Captan (081301); Comparison of Dietary Exposure Analyses [No MRID No., RCB Nos. 4273, 4274, and 4275]

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TO: Kathy Pearce and Valerie Bael, PM#67
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Special Review and Reregistration Division (TS-767C)

Dietary Exposure Branch has been requested to provide a description of the data used to estimate the anticipated residues used in the dietary exposure assessments for EBDC's, chlorothalonil, and captan.

EBDC's and ETU

The dietary exposure analyses for the EBDC's and ETU were based on average residues from residue data (field trial data) at the maximum application rate. No information was available on the typical application rate. These residue estimates most accurately describe residues "at the farm gate." To make the residue estimates better approximate residues in foods as eaten, washing and cooking factors were applied. The washing and cooking factors were determined in washing and cooking studies. Washing reduces EBDC residue levels, but has little effect on ETU residue levels. Cooking converts a percentage of EBDC residues to ETU residues. No data were available on the reduction of EBDC residues on cooking, so it was assumed that the reduction of EBDC residue in cooking would not exceed the reduction of EBDC residue from washing. Residue estimates from field trials were also adjusted for the effects of commercial processing by multiplying the residue estimates by processing factors. The residue estimates were also adjusted for percent of crop treated using figures provided by BUD.

Although some monitoring data were available, these data were not used to estimate dietary exposure. The available monitoring data were a limited amount of registrant summaries of registrant studies conducted in the 1970's, and a limited amount of FDA monitoring data. These data were not used for a number of reasons. In the registrant studies, very few samples of each commodity were analyzed. Generally 10 to 18 (always less than 30) samples of each commodity were analyzed. This number of samples is unlikely to be statistically representative of the United States Food supply. Furthermore, the studies were not done under approved EPA protocols, and the studies are summaries of data, with no raw data included. The studies were conducted in the late 1970's, and no sample history was included for any of the samples. This is a major deficiency, considering the storage stability problems that have become apparent subsequently. The registrant studies had been submitted and reviewed for the earlier EBDC RPAR. These studies were reviewed and discussed in the EBDC Decision Document (10/14/82). At that time, the studies were found to be inconsistent, deficient, and of questionable value in determining representative exposure. The market basket studies were highly variable in terms of percentage of samples found to contain ETU and levels of ETU reported.

The FDA monitoring data were not used because, like the registrant generated market basket studies described above, very few samples of each commodity were analyzed. No more than 36 samples of any commodity were analyzed for ETU. EBDC's and ETU are not determined by the multiresidue methods used by FDA for monitoring. Special analytical methods must be used to determine EBDC's and ETU. No data on animal commodities were available for EBDC's or ETU. USDA does not monitor for EBDC's or ETU.

Captan

The dietary exposure analysis for captan was based primarily on FDA monitoring data from FY 78 to FY 84. A much greater number of samples were analyzed by FDA for captan than for EBDC's and ETU because captan is determined by the Luke multiresidue method which is routinely used by FDA for monitoring. For most major commodities, 100-300 samples were analyzed in that time period; >300 samples of strawberries, tomatoes, peaches, cherries, and apples were analyzed; and <50 samples of small berries, broccoli, eggplant, and peppers were analyzed. For the dietary exposure analysis, the average residue in all analyzed samples, from the year having the highest residue, was used as the residue estimate. Because the average residue in all samples from a given year was used, it was therefore assumed to already reflect the percent of crop treated, and the residue estimate was not further corrected for percent of crop treated.

Where monitoring data were not available, or insufficient monitoring data were available, the captan dietary exposure

assessment was based on residue data from field studies. Residue data were available for captan and its metabolite TPTI (tetrahydrophthalimide). Residue estimates for the raw agricultural commodities from the field studies were corrected for the effects of washing, cooking, and peeling, based on factors determined in special processing studies. The corrected residue estimates were then multiplied by the percent of crop treated. Correction factors for washing, peeling, and cooking were not applied to the monitoring study results.

Chlorothalonil

The dietary exposure analysis for chlorothalonil was based primarily on FDA monitoring data from FY 85 to FY 87. A much greater number of samples were analyzed by FDA for chlorothalonil than for EBDC's and ETU because captan is determined by FDA multiresidue protocols I and III, which are routinely used by FDA for monitoring. For most major commodities, 100-500 samples were analyzed in that time period; >500 samples of potatoes were analyzed; and <50 samples of apricots, dry beans, brussels sprouts, cranberries, leeks, papayas, parsnips, and soybeans were analyzed. For the dietary exposure analysis, the average residue in all analyzed samples was used as the residue estimate. Because the percent of crop treated was much greater than the percent of positive samples in the monitoring study, the monitoring results were corrected to account for this difference. This adjusted estimate based on monitoring data included correction for percent crop treated, therefore, no further correction for percent crop treated was made.

The percent crop treated data from BUD were used to permit assignment of values to samples in which no residues were detected; however, percent crop treated values less than 10% were not used, except for soybeans. For example, if 25 out of a total of 100 samples analyzed over the three year period bore measurable residues and the percent crop treated is 40%, the 60 samples were assigned a value of 0.00 ppm and 15 assigned a value of 0.005 ppm (1/2 the limit of detection). This assumes that 40% of the collected samples were treated with chlorothalonil, 25% bearing detectable residues and 15% bearing some residue level below the limit of detection. The following formula was used in calculation of average dietary residues:

$$[(\%CT * TSC - TPC) * 0.005 \text{ ppm} + APS * TPC] / TSC$$

%CT = percent crop treated
 TSC = total sample counts (total number of samples analyzed using methods that detect chlorothalonil)
 TPC = total positive counts (total number of samples bearing measurable residues of chlorothalonil)
 0.005 ppm = 1/2 the limit of detection
 APS = average residue in positive samples (ppm)

Due to the absence of monitoring data for green onions, passion fruit, shallots, mint, and cocoa beans, the tolerance level was used as the residue estimate; and processing data were used for the residue estimate for coffee. These figures were not corrected for percent of crop treated because percent of crop treated information was unavailable for these crops.

Chlorothalonil derived Hexachlorobenzene (HCB)

Residue estimates for HCB were obtained by multiplying the residue estimate for chlorothalonil (average residue from FDA monitoring studies, tolerance level, or average residue from processing studies) by 0.5%. The 0.5% adjustment value was obtained by comparing available HCB and chlorothalonil residue levels from controlled field trial studies for crops which had detectable residues of HCB. The average HCB residue as a percent of chlorothalonil ranged from 0.07 to 0.26%, except for cucumbers, which was 1.48%. Additional data on HCB residues relative to chlorothalonil residues are being requested via the Registration Standard (FRSTR).

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TS-769C:DEB:SVH:svh:RM:810:CM#2:x77324:8/30/88