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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Chlorothalonil and Hexachlorobenzene (HCB) Dietary Exposure Estimates Used in Risk Assessments for the Chlorothalonil Standard (Second Round Review)

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This memo is written in response to questions that arose at the recent Chlorothalonil Policy Group meeting (9/1/88) regarding the use of monitoring data in dietary exposure assessment.

Tolerance levels are used by DEB in developing initial dietary exposure estimates for specific pesticides. Tolerances greatly exaggerate the probable dietary intake because they represent maximum permissible levels that are based on controlled field trials designed to elicit maximum residues following legal use (e.g., maximum rates, shortest PHI, etc.). If use of tolerance levels results in unacceptable risk estimates, DEB attempts to obtain the most realistic estimate of actual consumption possible. Ideally, the data used would be obtained by monitoring residues in the food as consumed (washed, peeled, cooked, etc.). However, such data are seldom available, at least in sufficient quantity for risk assessment. DEB has used a variety of data bases in the past to estimate actual dietary exposure. These include average field residues from controlled field trials, processing and cooking data, percent crop treated data, and monitoring data.

Dietary Exposure to Chlorothalonil:

For chlorothalonil, a substantial data base is available, including some processing data, data depicting residue decline from the field to the grocery, and FDA surveillance monitoring and total diet study (market basket) data. FDA domestic surveillance monitoring data for 1985-1987 and some processing data (for tomatoes and coffee) were used to assess dietary exposure to chlorothalonil for most crops, in conjunction with domestic percent crop treated information. For a few relatively minor crops (e.g., passion fruit, mint), no monitoring data were available and tolerance values were used. Although the number of

domestic surveillance samples collected by FDA for each crop over the 3-year period was highly variable (from 25 samples of papayas to 541 samples of potatoes), for the high risk crops, tomatoes and celery, 479 and 229 samples were collected, respectively. These samples were randomly selected from domestic shipping consignments of the raw agricultural commodity. Additional data submitted by the registrant for tomatoes, celery and cabbage indicate that residues will be reduced further by the time the raw commodity reaches the grocery store. In this regard, no detectable residues of chlorothalonil were found, except in one sample of celery, in the samples collected by FDA in their 1982-1986 total diet studies. Most of the major food commodities on which chlorothalonil is used were collected in the total diet studies and analyzed by methods capable of determining chlorothalonil (e.g., corn, melons, stone fruits, beans, celery, brassica leafy vegetables, tomatoes, onions, carrots, potatoes). These foods were analyzed after normal preparation for consumption (washing, peeling, cooking, etc.) and therefore represent a more realistic estimate of residue intake. Surveillance monitoring data were used in risk assessment instead of the total diet study data, however, because they provide a more conservative estimate of risk and significantly more samples are analyzed in surveillance monitoring.

Determination of the usefulness of monitoring data in dietary exposure assessment must be made on a case-by-case basis. Chlorothalonil was a good candidate for use of FDA monitoring data because (1) two of the commonly used FDA multiresidue methods will measure chlorothalonil residues, (2) data were available for all major food commodities on which chlorothalonil is used, (3) absence of monitoring data for the hydroxy-metabolite (included in the tolerance) was not a problem because the metabolite has not been found to be oncogenic, (4) the field-to-grocery residue dissipation seen in registrant submitted studies support the use of monitoring data over field trial data and (5) chlorothalonil per se does not transfer to meat, milk or eggs.

It should be noted that FDA import surveillance data were not used (except for bananas) in calculating the average dietary exposure to chlorothalonil. The assumption was made that all food consumed that bears chlorothalonil residues is grown in the U.S. While this assumption is not completely correct, it was made in order to permit the use of domestic percent crop treated data in risk assessment. This approach was necessary in this case so that risk numbers could be manipulated by the Special Review Branch as part of the fungicide strategy (EBDCs, captan, and chlorothalonil). Human dietary exposure to chlorothalonil will be recalculated using both domestic and import surveillance monitoring data when the Standard is updated in response to the Second Round Review (SRR).

Dietary Exposure to HCB Resulting from Use of Chlorothalonil:

Although FDA surveillance monitoring and total diet study data are available for HCB, these data are not useful in determining dietary exposure to HCB as a result of chlorothalonil use because HCB is also an impurity in several other pesticides used on food and feed commodities. Therefore, the chlorothalonil monitoring data were used as an indirect indicator of actual HCB residues. Field trial data that were available for a few crops indicated that HCB may be a more persistent residue than chlorothalonil per se. The percent of HCB relative to chlorothalonil at harvest ranged from 0.02-2.86% (mean = 0.35% for 40 samples), while the percent relative to chlorothalonil in the 97% technical product is $\leq$0.05%. Additional data regarding the persistence of HCB relative to chlorothalonil are being requested via the SRR. However, based on the available data, an interim value of 0.5% was selected to calculate the HCB dietary exposure (average dietary exposure for chlorothalonil x 0.5%).

Residues of HCB potentially occurring in meat, milk, and eggs as a result of ingestion by livestock of feed commodities treated with chlorothalonil have not been included in the current HCB dietary risk assessment. Insufficient data are available to determine the dietary intake of HCB by livestock as a result of chlorothalonil use and no HCB feeding studies have been submitted by the registrant. Several published studies and data submitted by registrants for other pesticides show that HCB will transfer to meat and will accumulate in fat. Therefore, the chlorothalonil registrant is being required, via the SRR, to submit data depicting HCB in feed items resulting from chlorothalonil use, and livestock feeding studies depicting residues of HCB in meat, milk and eggs following ingestion of HCB at levels expected to occur in the diet from ingestion of feed items treated with chlorothalonil.

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