PMSD/ISB

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

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EXPEDITE

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Mancozeb (014501) Rohm and Haas Response to PD 1; Revised Dietary Exposure to Mancozeb and ETU; Discussion of FDA Monitoring Data [MRID Nos. 403819-14, -17 to -27, and -29, RCB No. 2966]

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The purpose of this memo is to respond to comments made by Rohm and Haas in response to the EBDC PD 1 and to re-estimate residues of mancozeb and ETU in human food items based on available residue and processing data, and livestock feeding studies. The residue estimates will then be used for TAS estimation of dietary exposure and risk. Dietary exposure to mancozeb and ETU had been discussed previously by M. Bradley in her memoranda dated 11/19/86, and 8/25/86. Our previous dietary exposure estimates were based on all available residue data regardless of application rate. In effect, our estimates were governed more by the distribution of the patterns in the field trial data available to the Agency than by the typical application pattern (e.g., rate, number of applications, and PHI). In order to develop a more equitable means of comparison, it was decided to base residue estimates on the maximum registered application rate and the shortest PHI. Our recently completed dietary exposure assessments for maneb and metiram are based on residue data only at the maximum rate, or residues adjusted to the maximum label application rate. Because information on the typical use pattern are not available and residue data reflecting the typical use pattern are not available, and in order to directly compare the available data for the various EBDC fungicides, we are reassessing the dietary exposure to mancozeb and ETU.

Additional residue chemistry data were required by the Mancozeb Registration Standard, 4/1/88). The Residue Chemistry Chapter for the Mancozeb Registration Standard was completed on 9/10/86. An update to the Residue Chemistry Chapter was completed on 1/27/87). A Special Review was initiated for mancozeb and the other EBDC fungicides on 7/10/87. An earlier Special Review (RPAR) of the EBDC fungicides was concluded on 10/14/82 with the publication of the EBDC Decision Document. The EBDC fungicides were being reassessed as part of a settlement agreement negotiated with the National Resources Defense Council (NRDC). Residue Chemistry data necessary for the reassessment were required in Data Call In Notices dated 10/19/84 and 4/30/85.

ROHM AND HAAS RESPONSE TO THE PD 1

Comment 1

Due to the distinctions among the different EBDC's (chemical and use pattern), data regarding one of the EBDC's cannot always be generally extended to the other EBDC's.

EPA Response

We agree that there are differences among the different EBDC's both in terms of the chemical structure and sometimes the use pattern. As a result of the Storage Stability Data Call In Notices of 3/31/87 for maneb and metiram, we now have residue data for maneb and metiram and for ETU derived from maneb and metiram. These data have been used to assess dietary exposure to these chemicals. No residue data were submitted for zineb. Residue estimates for zineb have been based on residue data from other EBDC fungicides.

There are also similarities among the different EBDC's both in terms of chemical structure and use pattern. The EBDC's all degrade to ETU, and can all be determined by analytical methods based on carbon disulfide evolution. The molecular weights for the monomers of all of the EBDC's are similar.

Based on the residue data received, some differences in levels of EBDC parent and ETU are noted.

Rohm And Haas Comment 2

Rohm and Haas made their own estimates of dietary exposure using field trial data and the Tolerance Assessment System (TAS), as available from Technical Assessment Systems, Inc. (TAS, Inc.). Rohm and Haas states that EPA used data from all of the EBDC's. The dietary exposure estimates by Rohm and Haas are based on data for only mancozeb. Rohm and Haas then reduced the mancozeb residue estimates for apples, pears, and tomatoes to correct for

the effect of washing; and reduced the ETU residue estimates to correct for a 1% conversion of EBDC to ETU on analysis.

To support the need for correction for the effects of washing, Rohm and Haas submitted a 1977 survey of homemakers, restaurants, and food processors on food processing (washing, trimming, and peeling). No data were submitted to support the need for a correction for a 1% conversion of EBDC to ETU on analysis. References to several applicator exposure studies were submitted.

EPA Comments

Rohm and Haas appears to have used the same residue field trial data as EPA used, although the EPA Accession Nos. and/or MRID Nos. of the data used by Rohm and Haas were not given as part of their comments.

The percent of crop treated was the only data EPA used from all EBDC's. For the PD 1, the percent of crop treated was not broken down by the individual EBDC chemical. For the PD 2/3, the percent of crop treated has been broken down by chemical. Thus, data from all EBDC's are not being used for the PD 2/3.

The Rohm and Haas residue estimates, before correcting for washing, trimming, and conversion to ETU on analysis are very similar to those of EPA as presented in the PD 1. However, EPA has now revised their residue estimates upwards for several crops (apples, bananas, onions, pears, and tomatoes), because the previous EPA residue estimate was not based on recent residue data at the maximum registered rate.

EPA agrees with Rohm and Haas that many crops are typically washed before consumption. EPA has corrected the residue estimates for the effects of washing, based on conservative washing factors (the minimum reduction shown in washing studies, rather than the average or maximum reduction).

EPA disagrees with Rohm and Haas that the ETU residue estimates should be corrected for a 1% conversion during analysis. The references listed to support such a reduction are for applicator exposure studies, not for residue studies. We agree that there may have been a problem with conversion to ETU during analysis in the past, but we believe the problem is largely corrected. Any recently submitted residue studies are not expected to suffer from the problem of conversion of EBDC to ETU during analysis. In fact, studies submitted by the other registrants (BASF and Pennwalt) do not show any significant conversion of EBDC to ETU during analysis or storage, with the possible exception of tomato commodities. We note that Rohm and Haas residue data on tomatoes from the early 70's showed high

residues of ETU, but that residue data from the mid 80's showed much lower residues of ETU.

The EPA revised residue estimates are presented below in the section, "Summary of Mancozeb Exposure Estimates." A discussion of the differences between these estimates and the earlier mancozeb exposure estimates may be found in the section, "Changes in Residue Estimates."

Rohm and Haas Comment 3

The exposure estimates, as revised by Rohm and Haas should be considered worst case, since the estimates are based on residue data where the crops were not washed, trimmed, or peeled before analysis, except for bananas, and data for the minimum PHI were used. Rohm and Haas points out that both mancozeb and ETU decline rapidly in the field, and that most commodities are stored weeks or months before consumption. Additionally, both mancozeb and ETU are unstable in processed foods and decline rapidly with time.

To support their contention that the exposure estimates are worst case, Rohm and Haas submits market basket studies and table top studies, including analysis of 1000 samples, showing low residues of both EBDC and ETU. The studies report as EBDC, any residue responding to the carbon disulfide evolution methods of analysis. A list of the studies, along with their MRID Nos. is given in Appendix 1.

EPA Comments

The Market Basket studies and the Table Top Studies had been previously submitted to EPA by the EBDC registrants as Dietary Exposure studies submitted in rebuttal to the 1977 RPAR. The studies were discussed in the EBDC Decision Document of 10/14/82. The following documents were submitted.

1. Residue Study of EBDC treated fresh tomatoes and processed tomato products (DuPont, 30000/18:33E)

2. Market basket study of tomatoes and tomato products (Rohm and Haas, 30000/18:132D (Confidential))

3. Market basket study of processed foods (DuPont, 30000/18:33E)

4. Market basket study of a few fresh and processed foods (FMC, Supplement, 30000/18:10D)

5. Market basket study of refined sugar and molasses (Alco,, 30000/18:27B (Confidential))

6. Two tabletop studies of 100 ready to eat meals each (Rohm and Haas, 30000/18:132D and 132G (Confidential); also FMC, 30000/18:10D and 10E)

Previous EPA Comments on these studies

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 Agency was concerned about using the limited market basket results in estimating dietary exposure because localized exposure to high residues of EBDC's and ETU could easily have been missed. The Agency did note apparent EBDC and ETU residues in food for which no EBDC tolerances have been established, e.g., milk, sugar, bread, butter, and fish and in drinking water (See review of D. R. Reed, December 5, 1978).

Although the market basket studies were limited and inconsistent, the data were used, along with available residue data to provide a lower limit estimate of chronic dietary exposure. Residue levels equal to the limit of detection of the analytical methods were assumed where no data were available. The upper limit of chronic dietary exposure was estimated using tolerance level residues of EBDC's, corrected for the percentage of crop treated, and assuming 100% stoichiometric conversion of EBDC to ETU.

Current EPA Comments on these studies

Although the analysis of 1000 samples sounds impressive, very few samples of each commodity were analyzed. Only 2 to 30 samples of each commodity were analyzed, generally 10 to 18 samples. 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. A summary of these studies was included as Table III in the MRI Report, and is included as attachment II of this memo. (MRI Report, "Evaluation of the EBDC Fungicides, Final Report," November 10, 1978, done under contract to EPA, EPA Contract No. 68-01-4198, MRI Project No. 4307, RvR Consultants Project No. 91, EPA Contract Officer, Dr. Lionel A. Richardson.)

FDA has also done monitoring for EBDC's and ETU. About 500 samples were analyzed for EBDC and/or ETU by FDA from 1985 to

1988. FDA analyzed about 100 samples for EBDC and/or ETU from 1978 to 1985. Like the market basket studies described above, very few samples of each commodity were analyzed. No USDA data are available for EBDC or ETU. USDA does not monitor for EBDC's or ETU as part of the National Residue Program.

FDA data from 1978 to 1985 for EBDC and ETU residues was summarized by M. Bradley in her memo of 11/19/86. A copy of this memo is included in this memo as attachment III. A summary of the FDA data from 1985 to 1988 is included in this memo as attachment IV.

SUMMARY OF RESIDUE ESTIMATES

Residue estimates to be used in the Special Review are the best available estimates. We have used the average mancozeb residues from residue field trial data from studies closest to the maximum rate and minimum PHI. For ETU residues, we have used the average ETU residue from residue field trial data from studies closest to the maximum rate, minimum PHI, and at least the typical number of applications. The ETU residue estimates have been corrected for loss of ETU residue on sample storage when the loss on storage exceeded 20%.

For mancozeb residues in processed commodities of apples, we have multiplied the best available estimate for the raw agricultural commodity by the concentration factor determined for metiram in the metiram processing studies. For mancozeb residues in processed commodities of sugar beets, tomatoes, snap beans, and grapes, we have multiplied the best available estimate of mancozeb residues for the raw agricultural commodity by the concentration factor determined in the mancozeb processing studies. For potatoes, no processing study was submitted, and no concentration of metiram or conversion to ETU was demonstrated in the metiram potato processing study.

For ETU residue estimates in processed commodities, we have multiplied the mancozeb residue estimate for the raw agricultural commodity by the percent conversion determined in the metiram or mancozeb processing study, and added the ETU residue estimate from the raw agricultural commodity.

Residue estimates in animal commodities were determined by calculating the estimated dietary burden if livestock are fed with animal feed items treated with mancozeb. The average residue from residue field studies was used in the estimation of the dietary burden. The estimated dietary burden was then compared to the residues found in animal commodities in animal feeding studies.

We have made estimates of mancozeb and ETU residues, based on the available residue and processing data. Our residue estimates are tabulated below. These residue estimates and the percent crop treated information from BUD in their memo of 5/27/88 (E. N. Pelletier, SSB; and G. Ballard, EAB) will be used by the TAS staff in estimating dietary exposure. For meat, milk, poultry, and eggs, the residue estimates will be adjusted by the percent crop treated for apples, since mancozeb residues in apple pomace comprise 80-98% of the total dietary burden of mancozeb.

Our best available estimates are tabulated below. The column labeled upper 95% C.L. is either the upper 95th percent confidence limit or the maximum value determined in residue field trials.

SUMMARY OF RESIDUE ESTIMATES

	MANCOZEB			ETHYLENE THIOUREA	
COMMODITY	AVG RES PPM	UPPER 95% C.L. PPM	% CONVERS	AVG RES PPM	UPPER 95% C.L. PPM
APPLES	9.6	17		0.16	0.32
WASHED	6.72	11.9		0.16	0.32
COOKED	0.38.	0.68		0.16	0.32
JUICE	1.5	1.8	0.59%	0.22	0.42
DRY POMACE	85	150			
WET POMACE	19.2	34			
PEARS	29.5	31		0.03	0.06
WASHED	21	22		0.03	0.06
COOKED	21	22	0.45	0.16	0.20
QUINCE	9.6	17		0.16	0.32
CRABAPPLE	9.6	17		0.16	0.32
WASHED & COOKED	SEE APPLES				
ASPARAGUS	0.02	0.09		0.002	
WASHED	0.02	0.0063		0.002	
COOKED	0.02	0.0063	7.6	0.002	
BANANAS	0.14	0.71		0.006	0.006
PULP	0.14	0.71		0.005	
PEEL	0.64	11.91		0.005	0.115
PUREE CAN	0.02			0.002	
SLICES CAN	0.02			0.002	
BARLEY GRAIN	1.08	3.1		0.002	
KERNEL	3.78	10.85	3.70%	0.04	0.11
" W/O HUSK	0.32	0.93	3.70%	0.04	0.11
HUSK	7.78	22.32	19.50%	0.21	0.6
ROUGH	7.24	20.77	8.50%	0.09	0.27
BRAN	0.02		1.80%	0.02	0.06
SHORTS/GERM	0.02		1.80%	0.02	0.06
FLOUR	0.02			0.002	

SUMMARY OF RESIDUE ESTIMATES, CONTINUED

COMMODITY	MANCOZEB AVG RES PPM	MANCOZEB UPPER 95% C.L. PPM	% CONVERS	ETHYLENE THIOUREA AVG RES PPM	ETHYLENE THIOUREA UPPER 95% C.L. PPM
SWEET CORN	0.07	0.48		0.002	0.02
CORN GRAIN	0.06	1.3		0.002	0.004
MEAL	0.02			0.002	
OIL	0.02			0.002	
FLOUR	0.02			0.002	
GERM	0.02			0.002	
GRITS	0.02			0.002	
HULL	0.02			0.002	
SOAPSTOCK	0.02			0.002	
OATS					
RYE					
WHEAT GRAIN	0.27	1.65		0.002	
BRAN	0.5	3		0.002	
SHORTS	0.3	2		0.002	
FLOUR	0.27	1.65		0.002	
BREAD	0.14	0.83		0.002	
FINES	1.35	8.25		0.002	
OVERS	1.89	11.6		0.002	
CELERY	1.2	3.8		0.005	0.018
TRIMMED	0.792	2.508		0.002	0.007
WASHED	0.49	2.99		0.002	0.007
COOKED	0.49	2.99	12%	0.10	0.32
FENNEL - SEE CELERY					
CARROTS	0.06	0.66		0.002	
WASHED	0.03	0.33		0.002	
COOKED	0.03	0.33	13%	0.01	
POTATOES	0.02	0.1		0.002	0.02
PEELS	0.04	0.18		0.002	
BAKED FLESH	0.02		1.70%	0.0023	0.022
BAKED SKIN	0.02		6.90%	0.003	0.027
FLAKES	0.02		1.70%	0.0023	0.022
BLANCHED	0.02			0.002	
WHOLE BAKED	0.02			0.0024	
F. FRIES	0.02			0.002	
PEELED	0.02			0.002	
CHIPS	0.02			0.002	
GRANULES	0.02			0.002	
SUGARBEETS	0.14	0.6		0.002	0.05
PULP	0.27	1.14		0.002	0.02
MOLASSES	0.02	0.02		0.002	0.002
SUGAR	0.02	0.02		0.002	0.002
SUGARBEET TOPS	16.5	60			

COMMODITY	MANCOZEB AVG RES PPM	MANCOZEB UPPER 95% C.L. PPM	% CONVERS	ETHYLENE THIOUREA AVG RES PPM	ETHYLENE THIOUREA UPPER 95% C.L. PPM
COTTONSEED & PROCESSED PRODUCTS	0.29	1.1		0.03	0.11
CRANBERRY	1.21	8.38		0.01	0.09
WASHED	0.85	5.87		0.01	0.09
COOKED	0.85	5.87	0.45%	0.015	0.128
GRAPES	0.89	11.4		0.002	0.01
WASHED	0.62	7.98		0.01	0.09
COOKED	0.62	7.98	0.45%	0.014	0.141
RAISINS	1.7	21	0.25%	0.004	0.04
STEAMED	0.28	3.6	0.06%	0.003	0.02
DEPECTIN	0.23	3	1.40%	0.015	0.17
WET POMACE	0.28	3.65			
DRY POMACE	0.37	4.79			
RAISIN WASTE	2.54	32.49			
JUICE					
CLEAR	0.02		1.70%	0.017	0.21
THICK	0.07		2.70%	0.03	0.32
PASTEURIZED	0.02		0.50%	0.006	0.07
CANNED	0.02		0.80%	0.009	0.1
JELLY					
BOILED	0.2	2.6	3.10%	0.03	0.37
PULP	0.16	2.1	0.50%	0.006	0.07
JUICE	0.04	0.5	3.60%	0.03	0.42
CL JUICE	0.02		2.10%	0.02	0.24
COOLED	0.02		1.70%	0.017	0.21
RW UJUICE	1.5	19.3	0.02%	0.002	0.01
W WINE	0.02		3.10%	0.03	0.36
WW LEES	3.2	41	3.60%	0.03	0.43
WW UJUICE	0.77	9.9	0.16%	0.003	0.03
RW FWINE	0.02		2.50%	0.02	0.3
RW LEES	1.1	14	1.70%	0.018	0.21
WW FWINE	0.02		4.10%	0.04	0.48
CUCUMBERS	0.37	1.8		0.01	0.08
WASHED	0.26	1.26		0.01	0.08
COOKED	0.26	1.26	4.60%	0.027	0.163
MELONS	1.07	3.49		0.002	0.05
CANTALOUPES					
WATERMELONS					
WASHED	0.75	2.44		0.002	0.05
COOKED	0.75	2.44	4.60%	0.049	0.21
SQUASH, SUMMER	0.28	1.44		0.002	0.02
WASHED	0.20	1.01		0.002	0.02
COOKED	0.20	1.01	4.60%	0.013	0.086

COMMODITY	MANCOZEB AVG RES PPM	MANCOZEB UPPER 95% C.L. PPM	% CONVERS	ETHYLENE THIOUREA AVG RES PPM	ETHYLENE THIOUREA UPPER 95% C.L. PPM
ONION, BULB	0.27	0.48		0.003	0.003
WASHED	0.19	0.34		0.003	0.003
COOKED	0.19	0.34	4.60%	0.012	
PAPAYA	3.02	33.64		0.04	0.4
PULP	0.02				
CANNED	0.02				
PEANUTS	0.02	0.14		0.002	0.005
MEAL	0.02			0.002	
OIL	0.02			0.002	
TOMATOES	0.36	0.44		0.016	0.032
WASHED	0.25	0.31		0.016	0.032
JUICE	0.09		3.20%	0.028	0.030
PASTE	0.60	5.4	38.50%	0.155	0.185
PUREE	0.025	0.39	21.70%	0.094	0.111
CATSUP	0.09	0.39	13.90%	0.066	0.077
CANNED	0.09		1.73%	0.022	0.024
ANIMAL PRODUCTS					
MILK	<0.04	<0.62		0.0063	0.094
BEEF					
MUSCLE	<0.41	2.3		0.018	0.10
LIVER	0.18	1.0		0.036	0.20
KIDNEY	0.09	0.5		0.023	0.13
FAT	0.09	0.2		0.011	0.06
EGGS	0.01	0.02		0.002	0.004
CHICKEN					
LIVER	0.005	0.01		0.005	0.01
BREAST	0.005	0.01		0.01	0.02
KIDNEY	0.005	0.01		0.01	0.02
THIGH	0.005	0.01		0.01	0.02

Detailed Considerations

TOLERANCES

Tolerances have been established for residues of the fungicide mancozeb (coordination product of zinc ion and maneb). calculated as zineb (zinc ethylene bisdithiocarbamate), ranging from 0.1 part per million (ppm) in or on asparagus and corn grain to 65 ppm on sugar beet tops (40 CFR 180.176). Tolerances for liver and kidney have been established. An interim tolerance of 0.5 ppm has been established on potatoes (40 CFR 180.319. Food and feed additive tolerances have been established for processed commodities of barley, oats, rye, wheat, and grapes. (40 CFR 185.6300 [formerly 21 CFR 193.460] and 40 CFR 186.6300 [formerly 21 CFR 561.410]). The tolerances are tabulated below.

Mancozeb Tolerances

Raw Agricultural Commodity	Tolerance (ppm)
Apples	7
Asparagus	0.1 (N)
Bananas	4
Bananas (pulp without peel)	0.5
Barley, Bran	20 (FA)
Barley, Flour	1 (FA)
Barley, Grain	5
Barley, Milled Feed	20
Barley, Straw	25
Carrots	2
Celery	5
Corn, Fodder	5
Corn, Forage	5
Corn, Grain	0.1
Corn, sweet (K+CWHR)	0.5
Cottonseed	0.5
Crabapples	10
Cranberries	7
Cucumbers	4
Fennel	10
Grapes	7
Kidney	0.5
Liver	0.5
Melons	4
Oats, Bran	20 (FA)
Oats, Flour	1 (FA)
Oats, Grain	5
Oats, Milled Feed	20
Oats, Straw	25
Onions (dry bulb)	0.5
Papayas, whole fruit	10

Mancozeb Tolerances, continued

Raw Agricultural Commodity	Tolerance (ppm)
Papayas, edible pulp	NONE
Peanuts	0.5
Peanut Vine Hay	65
Pears	10
Popcorn, grain	0.5
Potatoes	0.5 (I)
Quinces	10
Raisins	28 (FA)
Rye, Bran	20 (FA)
Rye, Flour	1 (FA)
Rye, Grain	5
Rye, Milled Feed	20
Rye, Straw	25
Squash, Summer	4
Sugar Beets	2
Sugar beet tops	65
Tomatoes	4
Wheat, Bran	20 (FA)
Wheat, Flour	1 (FA)
Wheat, Grain	5
Wheat, Milled Feed	20
Wheat, Straw	25

Several tolerances for residues of mancozeb are pending. Pesticide petitions 3F2949 and 3F2888 are currently in reject status.

REGISTERED USES

The use patterns for mancozeb are summarized below in Table 1. Only crops which have registered uses are listed. This information was received from the Benefits and Use Division in their memorandum of 5/27/88 (E. N. Pelletier, SSB and G. Ballard, EAB). Information on the average number of applications used for apples and potatoes was received from BUD in their memo of 6/7/88 (G. L. Ballard and E. N. Pelletier). Information on the maximum number of applications for other crops was received from BUD in their memo of 7/6/86 (J. D. Hansen, SSB). Additional information on these uses may be found in the Residue Chemistry Chapter for the Mancozeb Registration Standard. (dated 9/10/86) or in the Mancozeb index.

Table 1 SITES, APPLICATION RATES, AND USE PRACTICES FOR MANCOZEB

CROP	Use Rates AI POUNDS/ACRES	NUMBER SEASONAL APPLICATIONS TYPICAL	MAXIMUM	PREHARVEST INTERVAL (PHI) AND LIMITATIONS
Apples Fruit rots Leaf spots Twig blights	0.8-1.7 lb/100g 6.4-8.0 lb/A	1-6	12	15-day PHI for a few States, 30-day PHI for all others. Delayed dormant and cover sprays.
Asparagus	1.6 lb /A	1	-	Apply to field after harvest.
Bananas Cercospora leaf	1.6-3.2 lb/A	15	16	0-day PHI. Begin when disease first appears and spot-repeat at 2- to 3-week intervals.
Barley, Oats, Rye, and Wheat	1.6 lb/A	1-2	-	26 day PHI.
Caprifigs	3.3 lb / 100 gal		1	Post harvest dip.
Carrots Leaf blights	1.2-1.6 lb/A	3	12	7-day PHI. Begin at first sign of disease Repeat at 7- to 10-day intervals.
Corn, field	1.2 lb/A	-	-	40 day PHI.
Crabapples/Quinces	0.8-1/7 lb/100gal (200-500 gal/A) (1.4-8.0 lb/A)	2	12	15 day PHI through 8.4 lb/A. Delayed dormant and foliar applications.
Cranberries	2.4-4.8 lb/A	1	12	30 day PHI.
Cucumber Downy mildew	1.6-2.4 lb/A	2	15	5-day PHI. Begin when first true leaf emerges, or at first disease occurrence, then every 5 to 14 days.
Fennel	1.6 lb/A	7 min.	12	7 day PHI. Apply at emergence and at 7 day intervals.

Table 1 SITES, APPLICATION RATES, AND USE PRACTICES FOR MANCOZEB (cont'd)

CROP	Use Rates AI POUNDS/ACRES	NUMBER SEASONAL APPLICATIONS TYPICAL	MAXIMUM	PREHARVEST INTERVAL (PHI) AND LIMITATIONS
Grapes Black rot Bunch rot	1.2-3.2 lb/A	2-3	6	66-day PHI for all states except CA. In CA, do not apply after fruit set.
Melons Downy mildew	1.6-2.4 lb/A	2	9	5 day PHI. 5- to 7- day intervals.
Onion Blotch Downy Mildew Blast	2.4 lb/A	4	8	7-day PHI. Begin when disease first becomes visible.
Papaya Anthracnose Phytophthora fruit rot	1.6-2.0 lb/A	6 min.	14	0-day PHI. Apply at flowering to crown, blossom area, central column, and developing fruit.
Peanuts Cercospora leaf spot	0.8-1.6 lb/A	3-5	14	14 day PHI. 7 to 10 day interval.
Pears Fruit rot Leaf spot	0.8-1.7 lb/100 gal (200-500 gal/A) (6.4-8.0 lb/A)	1-2	12	15 day PHI through 8.4 lb/A. Delayed dormant and foliar applications.
Pineapple	25.2-27 lb/100 gal at planting			Preplant dip for treatment of planting material.
Potato Blights	0.8-1.6 lb/A	4	9	0-day PHI. Begin using when plants are 4 to 6 inches tall.
Squash, summer Downy mildew	0.8-2.4 lb/A	2	9	5 day PHI. Begin when disease first appears or when first true leaf emerges. Repeat at 5- to 14- day intervals.
Sugar Beet Cercospora leaf spot	1.2-1.6 lb/A	1	12	14-day PHI. Apply at first sign of disease. Repeat at 7- to 10-day intervals.
Sweet Corn Helminthosporium	1.2 lb/A	2-10	18	5-day PHI. 4- to 14-day intervals.

Table 1 SITES, APPLICATION RATES, AND USE PRACTICES FOR MANCOZEB (cont'd)

CROP	Use Rates AI POUNDS/ACRES	NUMBER SEASONAL APPLICATIONS TYPICAL	MAXIMUM	PREHARVEST INTERVAL (PHI) AND LIMITATIONS
Tomato Blights	1.6-2.4 lb/A	7	15	5-day PHI. Begin application when the first fruit clusters are visible and continue every 7 to 12 days.
Watermelons Downy mildew	1.6-2.4 lb/A	2-7	12	5-day PHI. Apply at 5- to 7-day intervals.

PLANT AND ANIMAL METABOLISM

The metabolism of mancozeb was discussed in the Residue Chemistry Chapter of the Mancozeb Registration Standard (9/86). The metabolism of mancozeb is not adequately understood. Additional metabolism data have been required via the Mancozeb Registration Standard (4/1/87). Some additional information on mancozeb metabolism is currently under review in the Residue Chemistry Branch. (S. Hummel). For the purposes of the Special Review, the residue of concern will be considered to be the parent compound, mancozeb, and ethylenethiourea (ETU).

ANALYTICAL METHODS

Since no new residue data have been submitted, analytical methods will not be discussed in this memo.

STORAGE STABILITY DATA

Storage Stability data were submitted for mancozeb on apples and tomatoes and were discussed in Mancozeb Registration Standard Residue Chemistry Chapter. Mancozeb was reported to be stable in frozen storage for up to one year. ETU was reported to be stable in frozen storage for up to 6 months. ETU residues in apples declined to 46% when stored frozen for one year.

Storage stability data have not been submitted for mancozeb and ETU in animal commodities.

RESIDUE DATA AND PROCESSING STUDIES

No additional residue data for mancozeb have been received. Residue data in response to the Mancozeb Registration Standard are due in October, 1988. Residue estimates for mancozeb and ETU had previously been made, based on existing residue data. (See

memo of M. Bradley, 11/19/86.) However, some adjustments are being made in our residue estimates to account for differences between the available residue data and the maximum registered rate. Corrections to the residue estimates are also being made to account for the effects of washing and cooking. The changes are discussed below by crop. Wherever possible, residue data are taken from a single recent field trial study.

Apples

Commodity Source	Rate (lb ai/A)	#Appli-cations	PHI (days)	Max. Storage (days)	Residue (ppm) Mancozeb Ave.	Mancozeb Max.	ETU Ave.	ETU Max.
Apples								
1984	5.1-6.0	10-15	6-7	600	6.9	15	0.04	0.08
			14-21	600	6.6	12	0.025	0.05
ETU corrected for storage time			14-21		6.6	12	0.11	0.22
Correct for difference in rate (*8/5.5)			14-21		9.6	17	0.16	0.32

Rohm and Haas also cites a washing study for apples conducted by the National Food Laboratory. The average reduction reported for washing was a factor of 0.60. The range of washing factors was 0.48-0.73x. The maximum factor (minimum reduction) was approximately the same as the washing factor used by EPA (0.7x)

Bananas

Commodity Source	Rate (lb ai/A)	#Appli-cations	PHI (days)	Max. Storage (days)	Residue (ppm) Mancozeb Ave.	Mancozeb Max.	ETU Ave.	ETU Max.
Bananas								
1971-72	1.2-1.8	3-8	0-48	-	0.06	0.31	<0.01	<0.01
Correct for difference in rate (3.2/1.4)					0.14	0.71	<0.023	<0.023

Celery

Commodity Source	Rate (lb ai/A)	#Appli-cations	PHI (days)	Max. Storage (days)	Residue (ppm) Mancozeb Ave.	Mancozeb Max.	ETU Ave.	ETU Max.
Celery								
1984	01.3-1.6	7-17	14	-	1.2	3.8	0.005	0.018
correcting for trimming					0.79	2.5	0.002	0.007

Rohm and Haas reported an average trimming factor for mancozeb on celery of 0.66x, and for ETU on celery of 0.41x. The residues have been corrected for these factors.

Onions

Commodity Source	Rate (lb ai/A)	#Applications	PHI (days)	Max. Storage (days)	Residue (ppm) Mancozeb Ave.	Mancozeb Max.	ETU Ave.	ETU Max.
Onions								
1985	1.6	6	7	-	0.18	0.32	0.002	0.002
			14		0.11	0.19	0.002	0.002
	2.4	6-10	7		0.05	0.068	0.002	0.002
			14		0.02	0.02	0.002	0.002
adjust for difference in maximum rate (2.4/1.6)					0.27	0.48	0.003	0.003

The maximum residue for mancozeb was found in the study at 1.6 lb ai/.A. The residue was then corrected for the difference between the 1.6 lb/A rate and the maximum 2.4 lb/A rate.

Pears

Commodity Source	Rate (lb ai/A)	#Applications	PHI (days)	Max. Storage (days)	Residue (ppm) Mancozeb Ave.	Mancozeb Max.	ETU Ave.	ETU Max.
Pears								
1985	1.6	6	7-8	-	9.8	10	0.018	0.030
			14		5.9	6.2	0.006	0.012
			21		3.8	4.6	0.002	0.002
adjust for difference in maximum rate (8.0/1.6) at 14 day PHI					29.5	31	0.030	0.060

Tomatoes

Commodity Source	Rate (lb ai/A)	#Applications	PHI (days)	Max. Storage (days)	Residue (ppm) Mancozeb Ave.	Mancozeb Max.	ETU Ave.	ETU Max.
Tomatoes								
1985	2.1	6	2	-	0.78	0.87	0.013	0.019
			5		0.32	0.39	0.014	0.029
			9		0.13	0.18	0.013	0.014
adjust for difference in maximum rate (2.4/2.1)					0.36	0.44	0.016	0.032

Washing studies on tomatoes were cited by Rohm and Haas. The average reduction on washing was a factor of 0.32x. The range of washing factors was 0.06-0.67x. The maximum factor (minimum reduction on washing is about the same as the conservative washing factor used by EPA.

Grapes

The residue data available for grapes used less than the maximum registered rate. However, the registered PHI is much longer than reflected in any of the residue data. Therefore, no correction will be made to the grape residue estimate for the difference in the maximum application rate.

Washing and Cooking Studies

Several washing and cooking studies have been conducted. One study was done under contract to EPA (W. F. Phillips and M. D. Grady, April, 1977, "Effects of Food Processing on Residues of Two Ethylenebisdithiocarbamate (EBDC) Fungicides and Ethylene-thiourea (ETU)," EPA-600/1-77-021). Tomatoes, spinach, and carrots were treated with EBDC fungicides and analyzed before and after washing and cooking. An earlier study was conducted by an EPA laboratory. (R. R. Watts, R. W. Storherr, J. H. Onley, "Effects of Cooking on Ethylenebisdithiocarbamate Degradation to Ethylene Thiourea," Bull. Environ. Contam. Toxicol., 12(2), 1974, 224-226). Samples of spinach, potato, and carrot were spiked with EBDC fungicides either before or after cooking, and analyzed after cooking. The percent conversion to ETU was calculated.

These washing and cooking studies were discussed in our memo on maneb dietary exposure (S. Hummel, 6/30/88). The results of these studies will be used to correct residue estimates for the effects of washing and cooking, since the Tolerance Assessment System has categories for both raw and cooked commodities. Tomato EBDC residues and EBDC residues in other fruits and fruiting vegetables will be multiplied by a factor of 0.7 to correct for washing. Tomato ETU residues will be corrected using a 4.6% conversion factor for EBDC to ETU. This same factor will be used for other fruiting vegetables. Apple and other fruit ETU residues will be corrected by a 0.45% conversion factor for EBDC to ETU. This factor is the EBDC to ETU conversion factor from the metiram processing study for applesauce. EBDC residues in spinach and other leafy vegetables will be multiplied by 0.6 to correct for the effects of washing. ETU residues in spinach and other leafy vegetables will be corrected for 12% conversion of EBDC to ETU on cooking. The 12% figure is the average of the conversion factors determined in the Phillips study and the Watts study discussed above. EBDC residues in carrots and other

root crops will be multiplied by 0.5% to correct for the effects of washing. ETU residues in carrots and other root crops will be corrected for 13% conversion of EBDC to ETU on cooking. The 13% figure is the average of the % conversion determined in the Watts study for carrots and potatoes. The percent conversion from EBDC to ETU for cooking is calculated using the EBDC residue in the raw agricultural commodity since the conversion factors were calculated from cooking and processing studies using unwashed raw agricultural commodities. Residues in baked whole potatoes have been estimated by assuming that baked whole potatoes contain 10% baked skins and 90% baked flesh. The corrected residue estimates are tabulated below. Non-detectable residues have been included as one-fourth the limit of detection.

MEAT, MILK, POULTRY, AND EGGS

No additional livestock feeding studies have been submitted. The residue estimates for animal commodities, however, are being revised due to changes in the residue estimates for livestock feeds.

The results of the livestock feeding studies were summarized by Rohm and Haas and are tabulated below. The slope of the plot of residue in tissue (ppm mancozeb) vs. ppm mancozeb in the feed is reported.

Residues in Animal Commodities from Livestock Feeding Studies

Commodity	Residue (ppm) per ppm mancozeb in feed Mancozeb	 ETU
Cattle		
Milk	<0.0016	0.00024
Beef Muscle	<0.009	0.00040
Beef Liver	0.004	0.00078
Beef Kidney	0.002	0.00049
Fat	0.002	0.00024
Poultry		
Eggs	0.002	0.0004
Poultry Liver	0.001	0.001
Poultry Kidney	0.001	0.002
Poultry Breast	0.001	0.002
Poultry Thigh	0.001	0.002

Livestock Diets

A typical livestock diet for beef and dairy cattle and poultry would be as shown below in the calculation of the livestock dietary burden.

Mancozeb Dietary Burden for Cattle Using Average Residues

Beef Cattle Mancozeb	% in Diet	Mean Residue (ppm) Mancozeb	Dietary Burden (ppm)
Apple pomace (dry)	50	85	42.5
Barley straw/hay	25	6.2	1.6
Grain milled byproducts	25	7.8	2.0
		Total = 46	
Dairy Cattle			
Apple pomace (dry)	25	85	21.2
Barley straw/hay	50	6.2	3.1
Grain milled byproducts	25	7.8	2.0
		Total = 26	
Poultry			
Apple pomace (dry)	5	85	4.25
Wheat milled byproducts	10	1.9	0.19
Cottonseed meal	10	0.29	0.03
Barley Grain	50	1.1	0.55
Wheat Grain	25	0.27	0.07
		Total = 5.1	

The dietary burden of mancozeb was calculated using the mean residue of mancozeb in the animal feed, because it is unlikely that a livestock grower would treat all crops used for animal feed with mancozeb and would feed only treated animal feed items.

Expected residues of mancozeb and ETU resulting in tissue and milk from these diets are as follows:

Expected Residues in Beef Tissues and Milk from Average Residues in Animal Feed Items

	Residue (ppm) Mancozeb	ETU
Milk	<0.04	0.0063
Liver	0.18	0.036
Muscle	<0.41	0.018
Kidney	0.09	0.023
Fat	0.09	0.011

Expected residues of mancozeb and ETU resulting in poultry tissue and eggs from this diet are as follows:

Expected Residues in Poultry Tissues and Eggs from Average Residues in Animal Feed Items

	Residue (ppm) Mancozeb	ETU
Whole eggs	0.010	0.002
Liver	0.005	0.005
Kidney	0.005	0.010
Muscle	0.005	0.010

Residues in Meat, Milk, Poultry, and Eggs for Acute Exposure

For use in assessing the acute exposure to ETU from mancozeb, residues in livestock tissues, milk and eggs are estimated from diets of maximum mancozeb residues.

Mancozeb Dietary Burden for Cattle Using Maximum Residues

Beef Cattle Mancozeb	% in Diet	Mean Residue (ppm) Mancozeb	Dietary Burden (ppm)
Apple pomace (dry)	50	150	75
Barley straw/hay	25	700	175
Grain milled byproducts	25	22	5.5
		Total =	256
Dairy Cattle			
Apple pomace (dry)	25	150	37.5
Barley straw/hay	50	700	350
Grain milled byproducts	25	22	5.5
		Total =	393

Poultry	% in Diet	Mean Residue (ppm) Mancozeb	Dietary Burden (ppm) Mancozeb
Apple pomace (dry)	5	150	7.5
Wheat milled byproducts	10	12	1.2
Cottonseed meal	10	1.1	0.1
Barley Grain	50	3.1	1.6
Wheat Grain	25	1.6	0.4
		Total =	10.7

Expected residues of mancozeb and ETU resulting in tissue and milk from these diets are as follows:

Expected Residues in Beef Tissues and Milk from Maximum Residues in Animal Feed Items

	Residue (ppm)	
	Mancozeb	ETU
Milk	<0.62	0.094
Liver	1.0	0.20
Muscle	2.3	0.10
Kidney	0.5	0.13
Fat	0.5	0.06

Expected residues of mancozeb and ETU resulting in poultry tissue and eggs from this diet are as follows:

Expected Residues in Poultry Tissues and Eggs from Maximum Residues in Animal Feed Items

	Residue (ppm)	
	Mancozeb	ETU
Whole eggs	0.02	0.004
Liver	0.01	0.01
Kidney	0.01	0.02
Muscle	0.01	0.02

Discussion of Residues in Meat, Milk, Poultry, and Eggs

Storage Stability data for animal commodities have not been submitted. Without storage stability data reflecting the storage conditions, including the length of sample storage, the results of the livestock feeding studies cannot be validated. Although the results of the livestock feeding studies have not been validated, the studies are being used to estimate residues in animal commodities for the purposes of the Special Review.

The livestock dietary burdens (and the anticipated residues for livestock commodities, adjusted for percent of crop treated) calculated by Rohm and Haas are 2 to 4 times less than the dietary burdens calculated by EPA, due to a difference in the residue estimate for apple pomace. The Rohm and Haas anticipated residue for apple pomace is based on apple field trials at less than the maximum registered rate. Additionally, Rohm and Haas

used a different processing factor for apple pomace, based on a different interpretation of the same apple processing data. We do note that Rohm and Haas corrected the livestock dietary burdens for the percent of crop treated for each livestock feed, and then labeled the resulting anticipated residue for livestock commodities as "worst case."

Attachment I: Table of available residue data attached to all copies

Attachment II: Table III-21 from MRI Report, summarizing Registrant Market basket surveys

Attachment III: M. Bradley memo of 11/19/86, summarizing FDA Monitoring Data from 1978 to 1985 attached to all copies

Attachment IV: Summary of FDA Monitoring data from 1985 to 1988 attached to all copies

cc: R.F., circu, S. Hummel, Mancozeb S.F., Mancozeb S.R.F. (Hummel), Mancozeb R.S.F. (Hazel), TAS (RCB), E. Saito (SIS), V. Bael (SRB/RD), S. Lewis (PM#21), PMSD/ISB
RDI:EZ:07/12/88:RDS:07/12/88
TS-769:RCB:RM810:CM#2:SVH:svh:07/12/88

ATTACHMENT I. MANCOZEB STUDIES SUBMITTED IN RESPONSE TO PD 1

40381900 Rohm and Haas Co. (1987) Submission of Data in Response to Agency's Notice of Special Review of EBDC Fungicide. (Docket No. 30000/53.) Transmittal of 31 studies.

40381901 Ollinger, J. (1987) Comments of the Rohm and Haas Co. on the Special Review of EBDC Fungicides. (Docket No. 30000/53.) Unpublished compilation prepared by Rohm and Haas Co. 33 p.

40381914 Larkin, R. (1987) Response to EPA's PD 1 Dietary Exposure Estimate for Mancozeb and ETU. (Docket No. 30000/53.) Unpublished review prepared by Rohm and Haas Co. October 15, 1987. 87 p.

40381917 Chilton Research Services (1977) An Investigation of the Normal Preparation Practices for Fruits and Vegetables Before Eating or Processing: PD 1 Dietary Exposure Rept. #003. (Docket No. 30000/53.) Unpublished study. 63 p.

40381918 Petersen, B.; Chaisson, C.; Eickhoff, J. (1987) Anticipated Residues and Chronic Dietary Exposure Analysis for Mancozeb and ETU: PD 1 Dietary Exposure #004. (Docket No. 30000/53.) Unpublished study prepared by Technical Assessment Systems. Sept 21, 1987. 237 p.

40381919 Han, J. C-Y. (1977) Stability of :Carbon 14:-ETU and :Carbon 14:-Maneb Residues in Canned Vegetables: PD 1 Dietary Exposure Rept. #005. (Docket No. 30000/53.) Unpublished study prepared by E.I. du Pont de Nemours and Co. 21 p.

40381920 Phillips, W.; Grady, M.; Gordon, C. (1982) A Nationwide Market Basket Sampling for Residues of Ethylenebisdithiocarbamate Fungicides: PD 1 Dietary Exposure Rept. #006. (Docket No. 30000/53.) Unpublished study prepared by Technological Resources, Inc. December 23, 1977, 21 p. Also submitted as Rohm and Haas Rebuttal of RPAR Docket No. 30000/18:132D, submitted 12/23/87.

40381921 Phillips, W.; Grady, M. (1978) A Market Basket Survey for Residues of Ethylenebisdithiocarbamates (EBDC) and Ethylenethiourea (ETU): PD 1 Dietary Exposure Rept. #007. (Docket No. 30000/53.) Unpublished study prepared by Technological Resources, Inc. May, 1978 and June, 1978. 15 p. Also submitted earlier by FMC, Docket No. 30000/18:10D.

40381922 Holt, R. (1977) Market Basket Survey, Ethylenethiourea and EBDC Residues: PD 1 Dietary Exposure Rept. #008. (Docket No. 30000/53.) Unpublished study prepared by E.I. du Pont de Nemours and Co. 2 p. Also submitted earlier by DuPont Docket No. 10000/18:33E.

40381923 Phillips, W.; Grady, M. (1978) A Nationwide Market Basket Survey for Residues of Ethylenebisdithiocarbamates and Ethylenethiourea in Tomatoes and Tomato Products: PD 1 Dietary Exposure Rept. #009. (Docket No. 30000/53.) Unpublished study prepared by Technological Resources, Inc. August 10, 1978. 21 p. Also submitted earlier by Rohm and Haas, Docket No. 30000/18:132G.

40381924 Phillips, W.; Grady, M.; Gordon, C.; et al. (1977) Table Top Study of Fungicide Residues in Meals prepared in Homes and Restaurants: PD 1 Dietary Exposure Rept. #010. (Docket No. 30000/53.) Unpublished study prepared by Technological Resources, Inc. and Rohm and Haas Co. 22 p. Also submitted earlier by Rohm and Haas, December 23, 1987, Docket No. 30000/18:132D.

40381925 Phillips, W.; Grady, M. (1978) Final Report: Table Top Survey I - Supplement I: EBDC Fungicide Residues: PD 1 Dietary Exposure Rept. #011. (Docket No. 30000/53.) Unpublished study prepared by Technological Resources, Inc., July 27, 1978, 10 p. Also submitted earlier by Rohm and Haas and FMC, Docket Nos. 30000/18:132G and 30000/18:10E.

40381926 Technological Resources, Inc. (1978) Table Top Study II of Fungicide Residues in Meals Prepared in Homes and Restaurants: PD 1 Dietary Exposure Rept. #012. (Docket No. 30000/53.) Unpublished study., June 5, 1978, 30 p. Submitted earlier by Rohm and Haas and FMC, Docket Nos. 30000/18:132G and 30000/18:10D.

40381927 Heldman, D. (1987) Testimony of Dr. Dennis R. Heldman Before the Subcommittee on Health and Environment for the House of Representatives: June 8, 1987, PD 1 Dietary Exposure Rept. #013. (Docket No. 30000/53.) Unpublished compilation. 46 p.

40381929 Johnson, R.; Hafer, J. (1987) ETU Content in Commercial Dithane: Lab. Proj. ID RWN-87-131. (Docket No. 30000/53.) Unpublished study prepared by Rohm and Haas Co. 12 p.

Mancozeb residue chemistry review

Page _____ is not included in this copy.

Pages 26 through 29 are not included in this copy.

The material not included contains the following type of information:

___ Identity of product inert ingredients

___ Identity of product impurities

___ Description of the product manufacturing process

___ Description of product quality control procedures

___ Identity of the source of product ingredients

___ Sales or other commercial/financial information

___ A draft product label

___ The product confidential statement of formula

___ Information about a pending registration action

X FIFRA registration data

___ The document is a duplicate of page(s) _____

___ The document is not responsive to the request

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Attachment III

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

AUG 27 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: Special Review Action Code 870
Dietary Exposure Assessment of EBDCs and Ethylene thiourea.
FDA Surveillance and Registrant's Market Basket and Tabletop Surveys. No Accession No. [No RCB No.]

From: Martha J. Bradley, Chemist MJ Bradley
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

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

To: Ester Saito, SIS
Hazard Evaluation Division (TS-769)

H. Jacoby, PM 21
Registration Division (TS-767C)

Toxicology Branch
Hazard Evaluation Division (TS-769)

We have been requested to include available residue data from samples with no treatment history in the dietary risk assessment for the EBDCs and ETU resulting from several Data Call In notices for these chemicals.

Residue data determined by the dithiocarbamate, carbon disulfide evolution, method on samples of unknown treatment history cannot be related to any of these individual pesticides without additional tests. When ETU is also present or the parent compound is converted to ETU, the presence of ethylenebisdithiocarbamates is confirmed. The following data are being reported separately from the mancozeb, maneb and metiram dietary exposure assessments since the source of the residue is unknown.

FDA Monitoring Data

Surveillance and Compliance data have been received from FDA covering the years 1978 to 1985 for both domestic and import samples. For each commodity analyzed, the total number of samples, per cent of positive (+) samples, average residue and maximum residue for both EBDC and ETU are given. The 95% confidence limit (95% C.L.) of an individual value (assuming a log-normal distribution), 95 percentile, is also given if more than two positive samples were found. The FDA reports the EBDC residues as zineb,

maneb or mancozeb, however the source of the residue is unknown and all have been calculated as zineb as in 40 CFR 180.110 (maneb), 180.114 (ferbam), 180.116 (ziram), 180.176 (mancozeb) and 180.217 (metiram).

Domestic

	ppm EBDC					ppm ETU				
Commodity	Samples	% + Samples	Avg	Max	95% C.L.	Samples	% + Samples	Avg	Max	95% C.L.
spinach	32	53	15.75	81.9	212	27	11*	0.12	1.2	0.12
tomatoes	24	9.09	0.05	0.6		22	4.76	trace	trace	
cabbage	20	90	1.46	9.08	11	2	50	0.04	0.08	
mushrooms	7	14.3	0.74	5.2		14	36	0.05	0.188	0.36
potatoes	3	33.3	0.43	1.3		0	-	-	-	
lettuce	9	55.6	0.13	0.42	0.73	8	0	-	-	
celery	3	100	0.92	2.33	29	0	-	-	-	
cucumbers	3	100	0.42	0.43	0.44	0	-	-	-	
collard greens	1	0	-	-		0	-	-	-	
artichokes	1	100	0.5	0.5		0	-	-	-	
fish	2	100	0.08	0.125		0	-	-	-	
whole grain oats	1	100	0.04	0.04		0	-	-	-	
soybean meal	1	100	trace	trace		0	-	-	-	
animal feed	2	100	0.77	1.48		0	-	-	-	
Import										
oranges	1	100	trace	trace		0	-	-	-	
nuts	1	100	0.47	0.47		0	-	-	-	

* 20 samples on original analysis had ETU residues from 0.08 - 1.76 ppm, however, these residues were not confirmed as ETU by mass spectroscopy analysis and are not included as positive samples.

Registrant's Market Basket and Tabletop Surveys

RCB's comments on these studies are incorporated in the EBDC Decision Document dated October 14, 1982 on pages II-37 through II-39. The data from these studies are tabulated in the MRI Report, Evaluation of the EBDC Fungicides dated Novermer 10, 1978 pages III-54 through III-57. A copy of the tabulated data is attached to this review as Attachment I.

Processing Studies

Two additional processing studies, the Phillips and duPont studies, not included in the mancozeb or maneb dietary assessment reviews, were also discussed and tabulated in the MRI Report. Copies of these data are also attached to this review as Attachments II and III.

Attachments: I (4 pages) Table III-21. EBDC and ETU residues in raw and processed foods collected in market basket studies
II Table III-17. Effect of processing on EBDC and ETU residues on tomatoes, carrots, and spinach
III Table III-19. Effect of processing on EBDC and ETU residues on tomatoes
IV (7 pages) Statistical Worksheets

cc without attachments: Reviewer, Mancozeb SF, R F, circu, PM 21, PMSD/ISB, EBDC SR
RDI:Section Head:RSQuick by MJN:Date:08/25/86:E. Zager:08/25/86:RDS:08/27/86
TS-769:RCB:Reviewer:MJBradley:MJB:CM#2:RM:810:557-1521:08/21/86

ATTACHMENT IV SUMMARY OF FDA MONITORING DATA

FDA Total Diet Studies: Of the 234 items in the revised Total Diet Study market baskets, none are analyzed by methods known to determine EBDCs or ETU.

FDA Domestic and Import Surveillance Data: The commodity and food items sampled in domestic and import surveys (FY 78 through January 21, 1988) were analyzed by methods known to detect EBDCs (calculated as zineb) and ETU. The analytical method used (CS_2 evolution) is incapable of distinguishing among the different EBDC's and other CS_2 generating compounds. EBDC residues are calculated as zineb regardless of the source of the residue. Domestic and import surveillance data collected from 1985 through January 21, 1988 are summarized in Table 1. A total of 456 samples were analyzed for EBDC's and/or ETU from 1985 to 1988. For several spinach samples, the sample history was known; and the samples were known to have been treated with maneb. These samples were reported as maneb.

Table 1. Samples of food items bearing residues of EBDCs (unspecified) or ETU from domestic and import surveillance.

Commodity	Samples tested	Samples with residues	Residues (ppm) EBDC min	EBDC max	EBDC mean[a]	ETU min	ETU max	ETU mean[a]
apples	8	7	nd	nd	nd	0.01	0.12	0.04
apples	1	0	--[b]	--	--	nd	nd	nd
apple juice	2	0	nd	nd	nd	--	--	--
apricots	1	0	nd	nd	nd	--	--	--
bananas	54	2	0.15	1.6	0.88	--	--	--
broccoli (frozen)	12	11	0.1	3.08	0.63	--	--	--
broccoli	10	0	nd	nd	nd	--	--	--
Brussels sprouts	5	1		0.193		--	--	--
cabbage	5	1		0.24		--	--	--
cantaloupes	13	1		1.03		--	--	--
carrots	9	0	nd	nd	nd	--	--	--
cauliflower	3	0	nd	nd	nd	--	--	--
coriander	1	0	nd	nd	nd	--	--	--
corn salad	1	0	nd	nd	nd	nd	nd	nd
corn salad	4	1		4.46		--	--	--
cucumbers	15	0	nd	nd	nd	--	--	--
dandelions	1	0	nd	nd	nd	--	--	--
eggplant	1	0	nd	nd	nd	--	--	--
endive	1	0	nd	nd	nd	--	--	--
grapefruit	1	0	nd	nd	nd	--	--	--
grapes	1	0	nd	nd	nd	--	--	--
honeydew melon	4	0	nd	nd	nd	--	--	--
honeydew	2	0	--	--	--	nd	nd	nd
honeydew	9	2	0.7	2.5	1.6	--	--	--
kale	2	0	nd	nd	nd	--	--	--
kiwi	2	0	nd	nd	nd	--	--	--
kohlrabi	1	0	nd	nd	nd	--	--	--
lettuce	40	1		0.45		--	--	--
mushrooms	7	5	--	--	--	0.062	0.188	0.139

mustard greens	4	1		2.37		--	--	--
okra	2	0	nd	nd	nd	--	--	--
onions	2	0	nd	nd	nd	--	--	--
orange concentrate	3	0	--	--	--	nd	nd	nd
orange concentrate	1	0	nd	nd	nd	--	--	--
orange	3	0	nd	nd	nd	--	--	--
papayas	1	0	nd	nd	nd	--	--	--
peas	1	0	nd	nd	nd	--	--	--
peppers	22	0	nd	nd	nd	--	--	--
pigeon peas	24	14	--	--	--	0.03	0.21	0.08
pineapples	1	0	nd	nd	nd	--	--	--
potatoes	3	0	--	--	--	nd	nd	nd
spinach	19	7	0.23	41.3	10.1	--	--	--
spinach (maneb)	4	4	--	--	--	3.32	7.85	5.08
spinach	5	5	--	--	--	1.58	9.22	4.46
spinach, canned	3	0	--	--	--	nd	nd	nd
squash	24	0	nd	nd	nd	--	--	--
strawberries	8	1	nd	nd	nd		0.06	
tangerines	9	0	nd	nd	nd	--	--	--
tomato paste	9	2	--	--	--	0.05	0.05	0.05
tomatoes	57	8	0.1	0.54	0.26	--	--	--
tomatoes	10	0	--	--	--	nd	nd	nd
tomatoes (canned)	20	1		1.4		--	--	--
turnip greens	4	1		5.66		--	--	--
turnips	1	0	nd	nd	nd	--	--	--

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[a] Mean residue level of the samples bearing detectable residues.

[b] -- = These samples were not analyzed for residues.