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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: Special Review Action Code 870
Reassessment of Dietary Exposure of Mancozeb and Ethylene thiourea.
Accession Nos. 256370, 259901, 261540-261547, 261999-262003
[No RCB No.]

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The dietary exposure of mancozeb and ethylene thiourea (ETU) has been reassessed (see memo of M. Bradley dated August 25, 1986) to account for the conversion of mancozeb to ETU during the processing of certain raw agricultural commodities (rac). The storage stability of mancozeb and ETU will be discussed in a separate memo.

The residue of ETU in processed products was calculated as follows:

ETU (ppm) in the processed product minus ETU (ppm) in the rac divided by the EBDC (ppm) in the rac times 100 to calculate the percent conversion during the processing. The per cent conversion was then multiplied by the ppm EBDC in the rac from all relevant field trials plus the ppm ETU in the rac (from all relevant field trials) to yield the ppm ETU in the processed product.

The dietary burden for cattle was recalculated because the original diet contained sugarbeet tops which have a feeding restriction as well as a tolerance. Milled byproducts of small grains at 20% of the diet at 8 ppm was substituted for sugarbeet tops for a total of 9.2 ppm EBDC in the diet instead of the originally calculated 10.9 ppm. Expected residues of EBDC and ETU from this diet are:

	PPM	
	EBDC	ETU
muscle	<0.08	0.007
liver	0.06	0.007
kidney	0.014	0.006
fat	0.03	<0.011
thyroid	0.42	0.34
milk	<0.08	<0.011

Our best estimates of the dietary exposure from the use of mancozeb on tolerated crops follows in tabular form, giving the percent of crop treated, the commodity, the percent conversion of EBDC to ETU where applicable and the mean or average residue in ppm and its upper 95% confidence limit (upper 95% C.L.) in ppm with adjustments for the percent of crop treated for both mancozeb and ETU.

Where there were no detectable residues, approximately one fourth of the detection level, 0.02 ppm for EBDC and 0.002 ppm for ETU have been used to emphasize the difference in average residues reported and the various detection limits of the methods used over the course of the residue trials.

Where there is no column entry, the percent of crop treated is unknown, there are no data or there are insufficient data to determine the upper 95% confidence limit. In some cases, the minimum and maximum residue levels found are listed instead of the average and its upper 95% confidence limit.

The percent of crop treated for bananas and cottonseed were not given in the BUD memo of July 7, 1986 and the numbers used are taken from the Ethylene Bisdithiocarbamates Decision Document dated October 14, 1982.

Commodities known to be only animal feed items, such as wheat straw, are not included in the table.

The numbers immediately following the commodity refer to footnotes which contain explanations concerning the available data. In general, from the Registration Standard for mancozeb, for most crops, residue data for aerial application (except bananas) and for the various dust formulations are inadequate to reassess the tolerances although data for the 80% wettable powder formulation are adequate. Other deficiencies noted in the Registration Standard pertaining to the dietary assessment are given in the footnotes.

Storage stability studies have recently been submitted for crops and limited storage stability data for cattle and poultry products have been submitted. Storage conditions and dates from sampling to analysis have also been recently submitted for a number of crops. The storage stability of mancozeb and ETU will be discussed in a separate memo.

MANCOZEP

ETHYLENE THIOUREA

X CROP TREATED	COMMODITY	MANCOZEP				X CONVERS	ETHYLENE THIOUREA			
		AVG RES PPM	ADJUSTED FOR X TREATED	UPPER 95% C.L. PPM	ADJUSTED FOR X TREATED		AVG RES PPM	ADJUSTED FOR X TREATED	UPPER 95% C.L. PPM	ADJUSTED FOR X TREATED
32.00X	APPLES 1	2.6	0.832	11.4	3.648		0.01	0.0032	0.08	0.0256
	PEELED 1a	0.13	0.0416	0.6	0.192		0.002	0.00064	0.002	0.00064
	PEELS 1b	4.4	1.408	19	6.08		0.002	0.00064	0.002	0.00064
	COOKED 1c	0.02	0.0064				0.002	0.00064	0.002	0.00064
	DRIED 1d	0.02	0.0064							
	JUICE	0.4	0.128	1.8	0.576	0.59X	0.03	0.0096	0.15	0.048
41.00X	PEARS 2	5.2	2.132	9.8	4.018		0.01	0.0041	0.11	0.0451
	DRIED 2a	23.4	9.594	44	18.04					
	QUINCE 3	5.2		9.8			0.01		0.11	
	CRABAPPLE 3	5.2		9.8			0.01		0.11	
	ASPARAGUS 4	0.02		0.09			0.002			
100.00X	BANANAS 5	0.35	0.35	0.82	0.82					
	PULP	0.06	0.06	0.31	0.31		0.002	0.002		
	PEEL	0.28	0.28	5.2	5.2		0.002	0.002	0.05	0.05
	PUREE CAN 5a	0.02	0.02				0.002	0.002		
	SLICES CAN 5a	0.02	0.02				0.002	0.002		
4.00X	BARLEY GRAIN 6	1.08	0.0432	3.1	0.124		0.002	0.00008		
	KERNEL	3.78	0.1512	10.85	0.434	3.70X	0.04	0.0016	0.11	0.0044
	W/O HUSK	0.32	0.0128	0.93	0.0372	3.70X	0.04	0.0016	0.11	0.0044
	HUSK	7.78	0.3112	22.32	0.8928	19.50X	0.21	0.0084	0.6	0.024
	ROUGH	7.24	0.2896	20.77	0.8308	8.50X	0.09	0.0036	0.27	0.0108
	BRAN	0.02	0.0008			1.80X	0.02	0.0008	0.06	0.0024
	SHORTS/GERM	0.02	0.0008			1.80X	0.02	0.0008	0.06	0.0024
	FLOUR	0.02	0.0008				0.002	0.00008		
27.00X	SWEET CORN 7	0.07	0.0189	0.48	0.1296		0.002	0.00054	0.02	0.0054
	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	TRANSLATE DATA FROM BARLEY OR WHEAT								
	RYE	TRANSLATE DATA FROM BARLEY OR WHEAT								
1.90X	WHEAT GRAIN 8	0.27	0.00513	1.65	0.03135		0.002	0.000038		
	BRAN	0.5	0.0095	3	0.057		0.002	0.000038		
	SHORTS	0.3	0.0057	2	0.038		0.002	0.000038		
	FLOUR	0.27	0.00513	1.65	0.03135		0.002	0.000038		
	BREAD	0.14	0.00266	0.83	0.01577		0.002	0.000038		
	FINES	1.95	0.02565	8.25	0.15675		0.002	0.000038		
	OVERS	1.89	0.03591	11.6	0.2204		0.002	0.000038		
39.00X	CELERY 9	0.82	0.3198	4.98	1.9422		0.01	0.0039	0.03	0.0117
	FENNEL 10	1.31		8.25			0.01		0.04	
	CARROTS 11	0.06		0.66			0.002			
85.00X	POTATOES 12	0.02	0.017	0.1	0.085		0.002	0.0017	0.02	0.017
	PEELS	0.04	0.034	0.18	0.153		0.002	0.0017		
	BAKED FLESH	0.02	0.017			1.70X	0.0023	0.001935	0.022	0.0187
	BAKED SKIN	0.02	0.017			6.90X	0.003	0.00255	0.027	0.02295
	FLAKES	0.02	0.017			1.70X	0.0023	0.001935	0.022	0.0187
	BLANCHED	0.02	0.017				0.002	0.0017		

MANCOZEB

ETHYLENE THIOUREA

X CROP TREATED	COMMODITY	ADJUSTED		UPPER		X CONVERS	ADJUSTED		UPPER		ADJUSTED	UPPER	ADJUSTED
		AVG RES PPM	FOR X TREATED	95% C.L. PPM	FOR X TREATED		AVG RES PPM	FOR X TREATED	95% C.L. PPM	FOR X TREATED			
	(POTATO CONT)												
	F. FRIES	0.02	0.017				0.002	0.0017					
	PEELED	0.02	0.017				0.002	0.0017					
	CHIPS	0.02	0.017				0.002	0.0017					
	GRANULES	0.02	0.017				0.002	0.0017					
1.00X	SUGARBEETS 13	0.14	0.0014	0.6	0.006		0.002	0.00002	0.05	0.0005			
	PULP 13a	0.27	0.0027	1.14	0.0114		0.002	0.00002	0.02	0.0002			
	MOLASSES	0.02	0.0002	0.02	0.0002		0.002	0.00002	0.002	0.00002			
	SUGAR	0.02	0.0002	0.02	0.0002		0.002	0.00002	0.002	0.00002			
0.06X	COTTONSEED 14	0.29	0.000174	1.1	0.00066		0.03	0.000018	0.11	0.000066			
	OIL												
			NO DATA ARE AVAILABLE										
	CRANBERRY 15	1.21		8.38			0.01		0.09				
1.00X	GRAPES 16	0.89	0.0089	11.4	0.114		0.002	0.00002	0.01	0.0001			
	RAISINS	1.7	0.017	21	0.21	0.25X	0.004	0.00004	0.04	0.0004			
	STEAMED	0.28	0.0028	3.6	0.036	0.06X	0.003	0.00003	0.02	0.0002			
	DEPECTIN	0.23	0.0023	3	0.03	1.40X	0.015	0.00015	0.17	0.0017			
	JUICE												
	CLEAR	0.02	0.0002			1.70X	0.017	0.00017	0.21	0.0021			
	THICK	0.07	0.0007			2.70X	0.03	0.0003	0.32	0.0032			
	PASTURIZED	0.02	0.0002			0.50X	0.006	0.00006	0.07	0.0007			
	CANNED	0.02	0.0002			0.80X	0.009	0.00009	0.1	0.001			
	JELLY												
	BOILED	0.2	0.002	2.6	0.026	3.10X	0.03	0.0003	0.37	0.0037			
	PULP	0.16	0.0016	2.1	0.021	0.50X	0.006	0.00006	0.07	0.0007			
	JUICE	0.04	0.0004	0.5	0.005	3.60X	0.03	0.0003	0.42	0.0042			
	CL JUICE	0.02	0.0002			2.10X	0.02	0.0002	0.24	0.0024			
	COOLED	0.02	0.0002			1.70X	0.017	0.00017	0.21	0.0021			
	RW UJUICE 16a	1.5	0.015	19.3	0.193	0.02X	0.002	0.00002	0.01	0.0001			
	W WINE	0.02	0.0002			3.10X	0.03	0.0003	0.36	0.0036			
	WV LEES	3.2	0.032	41	0.41	3.60X	0.03	0.0003	0.43	0.0043			
	WV UJUICE	0.77	0.0077	9.9	0.099	0.16X	0.003	0.00003	0.03	0.0003			
	RW FWINE	0.02	0.0002			2.50X	0.02	0.0002	0.3	0.003			
	RW LEES	1.1	0.011	14	0.14	1.70X	0.018	0.00018	0.21	0.0021			
	WV FWINE	0.02	0.0002			4.10X	0.04	0.0004	0.48	0.0048			
68.00X	CUCUMBERS 17	0.37	0.2516	1.8	1.224		0.01	0.00068	0.08	0.0544			
	MELONS 18	1.07		3.49			0.002		0.05				
19.00X	CANTALOUPE		0.2033		0.6631			0.00038		0.0095			
77.00X	WATERMELONS		0.8239		2.6873			0.00154		0.0285			
	SQUASH, S 19	0.28		1.44			0.002		0.02				
41.00X	ONION, BULB 20	0.07	0.0287	0.36	0.1476		0.002	0.00002					
	PAPAYA 21	3.02		33.64			0.04		0.4				
	PULP	0.02											
	CANNED 21b	0.02											
19.00X	PEANUTS 22	0.02	0.0038	0.14	0.0266		0.002	0.00038	0.005	0.00095			
	NEAL	0.02	0.0038				0.002	0.00038					
	OIL	0.02	0.0038				0.002	0.00038					

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X CROP TREATED	COMMODITY	MANCOZEB				X CONVERS	ETHYLENE THIOUREA			
		AVG RES PPH	ADJUSTED FOR X TREATED	UPPER 95% C.L. PPH	ADJUSTED FOR X TREATED		AVG RES PPH	ADJUSTED FOR X TREATED	UPPER 95% C.L. PPH	ADJUSTED FOR X TREATED
34.00X	TOMATOES 23	0.79	0.2686	3.89	1.3226		0.02	0.0068	0.15	0.051
	JUICE	0.02	0.0068			3.20X	0.05	0.017	0.28	0.0952
	PASTE 23a	1.1	0.374	5.4	1.836	38.50X	0.32	0.1088	1.65	0.561
	PUREE	0.08	0.0272	0.39	0.1326	21.70X	0.19	0.0646	1	0.34
	CATSUP	0.08	0.0272	0.39	0.1326	13.90X	0.13	0.0442	0.69	0.2346
	CANNED						0.03	0.0102		
	SOUP					4.00X	0.05	0.017	0.31	0.1054
	DRIED						0.01	0.0034		
	BOILED 23b	3.43	1.1662			8.80X	0.09	0.0306	0.49	0.1666
ANIMAL PRODUCTS 24										
	MILK	0.02					0.002			
	BEEF									
	MUSCLE	0.02					0.007			
	LIVER	0.059					0.007			
	KIDNEY	0.014					0.006			
	FAT	0.034					0.002			
	THYROID	0.42					0.34			
	EGGS	0.02					0.0004			
	CHICKEN									
	LIVER	0.004					0.002			
	HEART	0.072					0.002			
	BREAST	0.006					0.002			
	KIDNEY	0.02					0.002			
	THIGH	0.02					0.002			
	GIZZARD	0.025					0.002			
	FAT	0.094					0.002			

1 Apples. Reg. Std. requires data for dust formulations and for all formulations, data for the maximum rate, No. of applications and PHI. The geographical representation and processing studies are considered adequate. Data used for the dietary assessment consisted of a wide range of treatment rates, little data for the maximum rate and data for which the raw data were not resubmitted.

1a peeled, sliced, cored raw apples

1b peels, cores and slices

1c includes applesauce, blanched slices, canned slices and jelly

1d very limited data for parent only

2 Pears. Reg. Std. requires data for dust formulations, aerial application and for all formulations, data for the maximum rate; geographic representation is adequate. Data used for the dietary assessment was limited; only two studies contained ETU analyses and no data for the maximum use are available.

2a very limited data for parent only

3 Quince, Crabapple. Data are translated from pear data.

4 Asparagus. Reg. Std. requires data for dust formulations and aerial application; the geographic representation is marginally adequate (no CA data). This is a dormant use.

5 Bananas. Reg. Std. requires additional data reflecting maximum rate for final application, geographical representation including HI, more data for whole fruit and for use of ground equipment. Recoveries of ETU were very low.

5a 18 samples of 2 lots of canned puree and 6 samples of canned slices (treatment history unknown) had no detectable EBDC and ETU residues.

6 Barley. Reg. Std. requires data for dust formulations, aerial application and geographic representation, however such data required for wheat can be translated to barley. The processing study is adequate provided ETU is not tolerated. If ETU is tolerated, additional processing data will be needed.

7 Corn. Reg. Std. requires data for dust formulations, aerial application and geographical representation. A processing study is required for corn bearing measurable weathered residues as well as data for sweet corn cannery waste. The current processing studies were conducted with corn treated at 1X and 2X with a 21 day PHI instead of a 40 day PHI required for corn grain. No residues or EBDC or ETU were detected on the rac or any processing products.

8 Wheat. Reg. Std. requires data for dust formulations, aerial application and KS/MO area for geographical representation. Data are required for 1.7 lb ai/A instead of 1.6 lb ai/A used in the current studies. The processing study is tentatively adequate.

9 Celery. Reg. Std. requires data for dust formulation, aerial application and 1.7 lb ai/A instead of 1.6 lb ai/A used in the current studies. Geographical representation is adequate.

10 Fennel. Reg. Std. requires all pertinent data for fennel. The predicted residue levels are translated from celery data.

11 Carrots. Reg. Std. requires data for dust formulations and 1.7 lb ai/A instead of 1.6 lb ai/A used in the current studies. Geographical representation is adequate.

12 Potatoes. Reg. Std. requires data for dust formulations and data for the exact maximum use including maximum dose per treatment, minimum treatment intervals and 0 day PHI. A processing study is required with field weathered residues on the rac. One processing study was conducted on treated potatoes having no detectable residues, however these potatoes were sprayed with mancozeb prior to processing. Conversion to ETU was shown in baked and flaked potatoes. Residue levels for the rac are the minimum and maximum, respectively, reported.

13 Sugarbeets. Reg. Std. requires data for dust formulations and data for the maximum use including the maximum dose, intervals and 0 day PHI. A processing study is required on sugarbeets bearing field weathered residues. The geographical representation is adequate, however there are no data for the maximum use.

14 Cottonseed. Reg. Std. requires data for dust formulations, aerial application and geographic representation. A processing study is also required.

15 Cranberry. Reg. Std. requires data for dust formulations, aerial application and geographic representation. There are no data for the maximum No. of applications.

16 Grapes. Reg. Std. requires data for dust formulations and aerial applications. The geographic representation and processing studies are adequate.

16a Definitions are: red wine unfermented juice, white wine, white wine lees, white wine unfermented juice, red wine filtered wine, and red wine lees.

17 Cucumber. Reg. Std. requires data for dust formulations, aerial application and geographic representation.

18 Melons. Reg. Std. requires data for dust formulations and aerial application. Geographic representation is adequate.

19 Squash, summer. Reg. Std. requires data for aerial application. Geographic representation is adequate. There are no data for the maximum No. of applications.

20 Onion, dry bulb. Reg. Std. requires data for dust formulations, aerial application and data for the exact maximum use including 0 day PHI. There are no data for the maximum No. of applications. The geographic representation is adequate.

21 Papaya. Reg. Std. requires data for dust formulations, aerial application and additional data for pulp. Pulp was analyzed in only two of eleven studies and only three studies were conducted for ETU analysis. The geographical representation is adequate.

7

21a Twenty four cans of commercially processed products were analyzed for EBDC only. Some of the processed products had been treated with mancozeb.

22 Peanuts. Reg. Std. requires data for dust formulations, aerial application and 0 day PHI. Geographic representation is inadequate for vine hay. A processing study is required for nutmeats bearing field weathered residues. ETU recoveries were unacceptably low in some tests. The ETU data are the minimum and maximum, respectively, reported and for 7 day PHI instead of 0 day PHI at 1X and 1.4 X treatment.

23 Tomatoes. Reg. Std. requires data for dust formulations and aerial application. The geographic representation and processing studies are adequate.

23a The calculated conversion ranges from 58-217% although no greater than 100% conversion is possible. No explanation was given for these results.

23b In eight studies, tomatoes were boiled in water for 15 minutes and showed an average of 8.8% conversion from EBDC to ETU.

24 We have reservations about the livestock feeding studies in that the mancozeb weathered residues may have contained a large proportion of degradates that would not be converted to ETU. ETU residues in cattle tissues are comparable to those from the maneb study, however ETU residues in both studies are less than those reported in the metiram study all at comparable feeding levels. Residues of EBDC (CS₂) in cattle tissues are not significantly different at comparable feeding levels for all three chemicals. The Reg. Std. defers evaluation of the feeding studies until the metabolism questions are answered and better residue data for feed items are submitted. Rohm and Haas is redoing the storage stability data for animal tissues.

cc: Reviewer, Mancozeb SF, R F, circu, PM 21, PMSD/ISB
RDI:Section Head:Date:E. Zager:11/17/86:RDS:11/17/86 ; RSG:11/17/86
TS-769:RCB:Reviewer:MJBradley:MJB:CM#2:RM:810:557-1521:10/09/86