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SR-EBDC

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Special Review. DRES Dietary Exposure and Risk Estimates for Proposed Section 18 Use of Formulations Containing Metalaxyl, Maneb, Mancozeb, and Chlorothalonil. DP Barcode: D212400.

FROM: Richard Griffin
Registration Section
Risk Characterization and Analysis Branch
Richard Griffin 3/23/95

THROUGH: Debra Edwards, Chief
Risk Characterization and Analysis Branch
Health Effects Division (7509C)
Debra Edwards 3/23/95

TO: Amy Farrell
Special Review Branch
Special Review and Reregistration Division (7508W)

The Agency has been requested to consider the use of Ridomil MZ58 (metalaxyl/mancozeb), Ridomil Bravo 81W (metalaxyl/chlorothalonil), Maneb Plus Zinc F4 (maneb), and Bravo 720 (chlorothalonil) on turnips, collards, and mustard greens.

CBTS (Susan V. Hummel memo, 2/21/95) has calculated residue estimates which are used along with new percent crop treated estimates to estimate exposure and risk for the three DRES population groups considered in past risk assessments for these crops, namely: the Overall U.S. population, the U.S. Southern Region, and Non-hispanic Blacks.

The following tables contain risk estimates for ETU from maneb, ETU from mancozeb, chlorothalonil, and HCB.

Also attached are carcinogenic risk estimates for all commodities considered during the EBDC PD 4 (based on the revised Q1* for ETU: 6.01×10^{-2} (mg/kg/day)⁻¹) and an exposure/risk assessment for metalaxyl assuming 100 percent crop treated.



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Scenarios for Fungicides used on Georgia Leafy Greens (Collards, Mustard Greens, Turnip Greens)										
Maneb: Assume 100% crop treated			US Population				Southern		Blacks	
	Residues (ppm)		Q* = 0.06	RFD = 0.00008	Q* = 0.06	RFD = 0.00008	Q* = 0.06	RFD = 0.00008	Q* = 0.06	RFD = 0.00008
	maneb	ETU	ETU Risk	ETU %RFD	ETU Risk	ETU %RFD	ETU Risk	ETU %RFD	ETU Risk	ETU %RFD
Turnips-tops										
raw	1.7	0.10	5.9e-08	1.24%	1.3e-07	2.76%	3.1e-07	6.47%		
cooked-nfs	0.17	0.14	3.2e-08	0.67%	8.6e-08	1.78%	1.5e-07	3.09%		
cooked-fresh or canned	0.17	0.14	6.3e-08	1.31%	1.5e-07	3.06%	2.8e-07	5.77%		
total			1.5e-07	3.22%	3.6e-07	7.60%	7.4e-07	15.33%		
Collards-total	0.17	0.14	1.7e-07	3.61%	3.9e-07	8.18%	1.1e-06	22.63%		
Mustard Greens-total	0.17	0.14	1.3e-07	2.77%	3.0e-07	6.26%	7.6e-07	15.74%		
Greens-total			4.6e-07	9.60%	1.1e-06	22.03%	2.6e-06	53.70%		

Maneb: Assume 90% crop treated										
Residues (ppm)			US Population				Southern		Blacks	
	Residues (ppm)		Q* = 0.06	RFD = 0.00008	Q* = 0.06	RFD = 0.00008	Q* = 0.06	RFD = 0.00008	Q* = 0.06	RFD = 0.00008
	maneb	ETU	ETU Risk	ETU %RFD	ETU Risk	ETU %RFD	ETU Risk	ETU %RFD	ETU Risk	ETU %RFD
Turnips-tops										
raw	1.7	0.10	5.4e-08	1.11%	1.2e-07	2.48%	2.8e-07	5.82%		
cooked-nfs	0.17	0.14	2.9e-08	0.60%	7.7e-08	1.61%	1.3e-07	2.78%		
cooked-fresh or canned	0.17	0.14	5.6e-08	1.17%	1.3e-07	2.75%	2.5e-07	5.20%		
total			1.4e-07	2.89%	3.3e-07	6.84%	6.6e-07	13.80%		
Collards-total	0.17	0.14	1.6e-07	3.25%	3.5e-07	7.36%	9.8e-07	20.36%		
Mustard Greens-total	0.17	0.14	1.2e-07	2.50%	2.7e-07	5.63%	6.8e-07	14.17%		
Greens total			4.1e-07	8.64%	9.5e-07	26.67%	2.3e-06	48.33%		

Scenarios for Fungicides used on Georgia Leafy Greens (Collards, Mustard Greens, Turnip Greens)

Scenario	Residues (ppm)		US Population		Southern		Blacks	
	maneb	ETU	Q* = 0.06	RFD = 0.00008	Q* = 0.06	RFD = 0.00008	Q* = 0.06	RFD = 0.00008
			ETU Risk	ETU %RFD	ETU Risk	ETU %RFD	ETU Risk	ETU %RFD
Maneb: Assume 22%, 31%, 36% crop treated								
Turnips-tops 22% crop treated								
raw	1.7	0.10	1.3e-08	0.27%	2.9e-08	0.61%	6.8e-08	1.42%
cooked-nfs	0.17	0.14	7.1e-09	0.15%	1.9e-08	0.39%	3.3e-08	0.68%
cooked-fresh or canned	0.17	0.14	1.4e-08	0.29%	3.2e-08	0.67%	6.1e-08	1.27%
total			3.4e-08	0.71%	8.0e-08	1.67%	1.6e-07	3.37%
Collards-total 31% crop treated	0.17	0.14	4.8e-08	1.01%	1.1e-07	2.28%	3.0e-07	6.31%
Mustard Greens-total 36% crop treated	0.17	0.14	4.3e-08	0.90%	9.7e-08	2.03%	2.4e-07	5.10%
Greens total			1.3e-07	2.61%	2.9e-07	5.98%	7.1e-07	14.79%

Scenario	Residues (ppm)		US Population		Southern		Blacks	
	maneb	ETU	Q* = 0.06	RFD = 0.00008	Q* = 0.06	RFD = 0.00008	Q* = 0.06	RFD = 0.00008
			ETU Risk	ETU %RFD	ETU Risk	ETU %RFD	ETU Risk	ETU %RFD
Mancozeb: Assume 100% crop treated								
Turnips-tops								
raw	19	0.08	3.9e-07	8.19%	8.8e-07	18.25%	2.1e-06	42.81%
cooked-nfs	0.19	0.56	1.2e-07	2.53%	3.2e-07	6.70%	5.6e-07	11.60%
cooked-fresh or canned	0.19	0.56	2.4e-07	4.91%	5.5e-07	11.50%	1.0e-06	21.70%
total			7.5e-07	15.63%	1.7e-06	36.45%	3.7e-06	76.11%
Collards-total	0.19	0.56	6.5e-07	13.56%	1.5e-06	30.74%	4.1e-06	85.07%
Mustard Greens-total	0.19	0.56	5.0e-07	10.43%	1.1e-06	23.52%	2.8e-06	59.19%
Greens-total			1.9e-06	39.62%	4.4e-06	90.71%	1.1e-05	220.36%

Mancozeb: Assume 90% crop treated	US Population				Blacks					
	Residues (ppm)		Q* = 0.06	RFD = 0.00008	ETU		Q* = 0.06	RFD = 0.00008	ETU	
	maneb	ETU	ETU Risk	ETU %RFD	ETU Risk	ETU %RFD	ETU Risk	ETU %RFD	ETU Risk	ETU %RFD
Turnips-tops										
raw	19	0.08	3.5e-07	7.38%	7.9e-07	16.42%	1.8e-06	38.53%		
cooked-nfs	0.19	0.56	1.1e-07	2.27%	2.9e-07	6.03%	5.0e-07	10.44%		
cooked-fresh or canned	0.19	0.56	2.1e-07	4.42%	5.0e-07	10.35%	9.4e-07	19.53%		
total			6.8e-07	14.06%	1.6e-06	32.80%	3.3e-06	68.50%		
Collards-total	0.19	0.56	5.9e-07	12.21%	1.3e-06	27.67%	3.7e-06	76.56%		
Mustard Greens-total	0.19	0.56	4.5e-07	9.39%	1.0e-06	21.16%	2.6e-06	53.27%		
Greens total			1.7e-06	35.66%	3.9e-06	114.44%	9.5e-06	198.32%		

Mancozeb: Assume 22%, 31%, 36% crop treated	US Population				Blacks					
	Residues (ppm)		Q* = 0.06	RFD = 0.00008	ETU		Q* = 0.06	RFD = 0.00008	ETU	
	maneb	ETU	ETU Risk	ETU %RFD	ETU Risk	ETU %RFD	ETU Risk	ETU %RFD	ETU Risk	ETU %RFD
Turnips-tops 22% crop treated										
raw	19	0.08	8.7e-08	1.80%	1.9e-07	4.01%	4.5e-07	9.42%		
cooked-nfs	0.19	0.56	2.7e-08	0.56%	7.1e-08	1.47%	1.2e-07	2.55%		
cooked-fresh or canned	0.19	0.56	5.2e-08	1.08%	1.2e-07	2.53%	2.3e-07	4.77%		
total			1.7e-07	3.44%	3.8e-07	8.02%	8.0e-07	16.74%		
Collards-total 31% crop treated	0.19	0.56	1.8e-07	3.78%	4.1e-07	8.58%	1.1e-06	23.73%		
Mustard Greens-total 36% crop treated	0.19	0.56	1.6e-07	3.38%	3.7e-07	7.62%	9.2e-07	19.18%		
Greens total			5.1e-07	10.60%	1.2e-06	24.22%	2.9e-06	59.65%		

Scenarios for Fungicides used on Georgia Leafy Greens (Collards, Mustard Greens, Turnip Greens)

Chlorothalonil Risk from Chlorothalonil		Residues (ppm)		US Population		Southern		Blacks	
Assume 100% crop treated	chlorothalonil	HCB	Q* = 0.011	RFD = 0.015	Q* = 0.011	RFD = 0.015	Q* = 0.011	RFD = 0.015	Q* = 0.011
Turnips-tops									
raw	7.2	0.0036	3.4e-07	0.21%	7.7e-07	0.47%	1.8e-06	1.09%	
cooked-nfs	0.79	0.0020	3.1e-08	0.02%	8.1e-08	0.05%	1.4e-07	0.09%	
cooked-fresh or canned	0.79	0.0020	5.9e-08	0.04%	1.4e-07	0.08%	2.6e-07	0.16%	
total			4.3e-07	0.26%	9.9e-07	0.60%	2.2e-06	1.34%	
Collards-total	0.79	0.0020	1.6e-07	0.10%	3.7e-07	0.23%	1.0e-06	0.62%	
Mustard Greens-total	0.79	0.0020	1.3e-07	0.08%	2.8e-07	0.17%	7.2e-07	0.43%	
Greens-total			7.3e-07	0.44%	1.6e-06	1.00%	4.0e-06	2.39%	

Chlorothalonil Risk from Chlorothalonil		Residues (ppm)		US Population		Southern		Blacks	
Assume 90% crop treated	chlorothalonil	HCB	Q* = 0.011	RFD = 0.015	Q* = 0.011	RFD = 0.015	Q* = 0.011	RFD = 0.015	Q* = 0.011
Turnips-tops									
raw	7.2	0.0036	3.1e-07	0.19%	6.9e-07	0.42%	1.6e-06	0.98%	
cooked-nfs	0.79	0.0020	2.8e-08	0.02%	7.3e-08	0.04%	1.3e-07	0.08%	
cooked-fresh or canned	0.79	0.0020	5.3e-08	0.03%	1.3e-07	0.08%	2.4e-07	0.14%	
total			3.9e-07	0.24%	8.9e-07	0.54%	2.0e-06	1.20%	
Collards-total	0.79	0.0020	1.5e-07	0.09%	3.3e-07	0.20%	9.3e-07	0.56%	
Mustard Greens-total	0.79	0.0020	1.1e-07	0.07%	2.6e-07	0.16%	6.4e-07	0.39%	
Greens total			6.5e-07	0.40%	1.5e-06	1.44%	3.6e-06	2.16%	

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Scenarios for Fungicides used on Georgia Leafy Greens (Collards, Mustard Greens, Turnip Greens)

Chlorothalonil Risk from Chlorothalonil		US Population		Southern		Blacks	
Assume 22%, 31%, 36% crop treated	Residues (ppm)	Q* = 0.011	RFD = 0.015	Q* = 0.011	RFD = 0.015	Q* = 0.011	RFD = 0.015
chlorothalonil	HCB	chlorothalonil Risk	Chlorothalonil %RFD	chlorothalonil Risk	Chlorothalonil %RFD	chlorothalonil Risk	Chlorothalonil %RFD
Turnips-tops 22% crop treated							
raw	7.2	7.6e-08	0.05%	1.7e-07	0.10%	4.0e-07	0.24%
cooked-nfs	0.79	6.7e-09	0.00%	1.8e-08	0.01%	3.1e-08	0.02%
cooked-fresh or canned	0.79	1.3e-08	0.01%	3.1e-08	0.02%	5.8e-08	0.04%
total		9.6e-08	0.06%	2.2e-07	0.13%	4.9e-07	0.29%
Collards-total 31% crop treated	0.79	4.6e-08	0.03%	1.0e-07	0.06%	2.9e-07	0.17%
Mustard Greens-total 36% crop treated	0.79	4.1e-08	0.02%	9.2e-08	0.06%	2.3e-07	0.14%
Greens total		1.8e-07	0.11%	4.1e-07	0.25%	1.0e-06	0.61%

HCB Risk from Chlorothalonil		US Population		Southern		Blacks	
Assume 100% crop treated	Residues (ppm)	Q* = 1.7	RFD = 0.0008	Q* = 1.7	RFD = 0.0008	Q* = 1.7	RFD = 0.0008
chlorothalonil	HCB	HCB Risk	HCB %RFD	HCB Risk	HCB %RFD	HCB Risk	HCB %RFD
Turnips-tops							
raw	7.2	2.7e-08	0.002%	5.9e-08	0.036%	1.4e-07	0.084%
cooked-nfs	0.79	1.2e-08	0.001%	3.2e-08	0.019%	5.5e-08	0.033%
cooked-fresh or canned	0.79	2.3e-08	0.002%	5.4e-08	0.033%	1.0e-07	0.062%
total		6.2e-08	0.037%	1.5e-07	0.088%	3.0e-07	0.180%
Collards-total	0.79	6.4e-08	0.039%	1.5e-07	0.088%	4.0e-07	0.244%
Mustard Greens-total	0.79	4.9e-08	0.030%	1.1e-07	0.068%	2.8e-07	0.170%
Greens-total		1.8e-07	0.106%	4.0e-07	0.244%	9.8e-07	0.594%

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Scenarios for Fungicides used on Georgia Leafy Greens (Collards, Mustard Greens, Turnip Greens)

HCB Risk from Chlorothalonil		Residues (ppm)		US Population		Southern		Blacks	
		chlorothalonil	HCB	Q* = 1.7	RFD = 0.0008	HCB Risk	HCB %RFD	Q* = 1.7	RFD = 0.0008
				HCB Risk	HCB %RFD	HCB Risk	HCB %RFD	HCB Risk	HCB %RFD
Assume 90% crop treated									
Turnips-tops									
raw	7.2	0.0036		2.4e-08	0.002%	5.3e-08	0.032%	1.3e-07	0.076%
cooked-nfs	0.79	0.0020		1.1e-08	0.001%	2.9e-08	0.017%	4.9e-08	0.030%
cooked-fresh or canned	0.79	0.0020		2.1e-08	0.002%	4.9e-08	0.030%	9.3e-08	0.056%
total				5.6e-08	0.034%	1.3e-07	0.079%	2.7e-07	0.162%
Collards-total	0.79	0.0020		5.8e-08	0.035%	1.3e-07	0.079%	3.6e-07	0.220%
Mustard Greens-total	0.79	0.0020		4.4e-08	0.027%	1.0e-07	0.061%	2.5e-07	0.153%
Greens total				1.6e-07	0.096%	3.6e-07	0.299%	8.8e-07	0.535%

HCB Risk from Chlorothalonil		Residues (ppm)		US Population		Southern		Blacks	
		chlorothalonil	HCB	Q* = 1.7	RFD = 0.0008	HCB Risk	HCB %RFD	Q* = 1.7	RFD = 0.0008
				HCB Risk	HCB %RFD	HCB Risk	HCB %RFD	HCB Risk	HCB %RFD
Assume 22%, 31%, 36% crop treated									
Turnips-tops 22% crop treated									
raw	7.2	0.0036		5.9e-09	0.000%	1.3e-08	0.008%	3.1e-08	0.019%
cooked-nfs	0.79	0.0020		2.6e-09	0.000%	7.0e-09	0.004%	1.2e-08	0.007%
cooked-fresh or canned	0.79	0.0020		5.1e-09	0.000%	1.2e-08	0.007%	2.3e-08	0.014%
total				1.4e-08	0.008%	3.2e-08	0.019%	6.5e-08	0.040%
Collards-total 31% crop treated	0.79	0.0020		1.8e-08	0.011%	4.1e-08	0.025%	1.1e-07	0.068%
Mustard Greens-total 36% crop treated	0.79	0.0020		1.6e-08	0.010%	3.6e-08	0.022%	9.1e-08	0.055%
Greens total				4.8e-08	0.029%	1.1e-07	0.066%	2.7e-07	0.163%

CHEMICAL INFORMATION FOR CASWELL NUMBER 375AA

DATE: 03/15/95 PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Metalaxyl Caswell #375AA CAS No. 57837-19-1 A.I. CODE: 113501 CFR No. 180.408 185.4000	6mo feeding- dog NOEL= 7.8000 mg/kg 250.00 ppm LEL= 30.6300 mg/kg 1000.00 ppm ONCO: E (HED NOTE)	Increased alkaline phos- phatase activity, incr relative liver weights. No evidence of carcinog- enicity in rats or mice.	ADI UF -->100 OPP Rfd= 0.080000 EPA Rfd= 0.060000	No data gaps.	WHO last reviewed 1982 HED complete 05/23/86 EPA verified 07/08/86 Rfd/PR reviewed 03/03/94 On IRIS.

FOOD CODE	FOOD NAME	TOLERANCE (PPM)		
		PETITION NUMBER	NEW	PUBLISHED
13009AA	COLLARDS			5.000000
13021AA	MUSTARD GREENS			5.000000
13026AA	TURNIPS-TOPS			15.000000
14019AA	TURNIPS-ROOTS			0.050000

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CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Metaxyl Caswell #375AA CAS No. 57837-19-1 A.I. CODE: 113501 CFR No. 180.408 185.4000	6mo feeding- dog NOEL= 7.8000 mg/kg 250.00 ppm LEL= 30.6300 mg/kg 1000.00 ppm ONCO: E (HED NOTE)	Increased alkaline phosphatase activity, increased relative liver weights. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP Rfd= 0.080000 EPA Rfd= 0.060000	No data gaps.	WHO last reviewed 1982 HED complete 05/23/86 EPA verified 07/08/86 Rfd/PR reviewed 03/03/94 On IRIS.

TOTAL TMRC (MG/KG BODY WEIGHT/DAY)

POPULATION SUBGROUP	CURRENT TMRC*	NEW TMRC**	NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES
U.S. POPULATION - 48 STATES	0.000388	0.000388	0.485254	0.000000	
U.S. POPULATION - SPRING SEASON	0.000419	0.000419	0.524299	0.000000	
U.S. POPULATION - SUMMER SEASON	0.000210	0.000210	0.262151	0.000000	
U.S. POPULATION - FALL SEASON	0.000531	0.000531	0.663840	0.000000	
U.S. POPULATION - WINTER SEASON	0.000392	0.000392	0.489579	0.000000	
NORTHEAST REGION	0.000088	0.000088	0.110099	0.000000	
NORTH CENTRAL REGION	0.000241	0.000241	0.300785	0.000000	
SOUTHERN REGION	0.000905	0.000905	1.130923	0.000000	
WESTERN REGION	0.000113	0.000113	0.140946	0.000000	
HISPANICS	0.000013	0.000013	0.015908	0.000000	
NON-HISPANIC WHITES	0.000161	0.000161	0.201663	0.000000	
NON-HISPANIC BLACKS	0.002043	0.002043	2.553580	0.000000	
NON-HISPANIC OTHERS	0.000275	0.000275	0.343819	0.000000	
NURSING INFANTS (< 1 YEAR OLD)	0.000000	0.000000	0.000000	0.000000	
NON-NURSING INFANTS (< 1 YEAR OLD)	0.000079	0.000079	0.099169	0.000000	
FEMALES (13+ YEARS, PREGNANT)	0.000247	0.000247	0.309325	0.000000	
FEMALES 13+ YEARS, NURSING CHILDREN (1-6 YEARS OLD)	0.000001	0.000001	0.001027	0.000000	
CHILDREN (7-12 YEARS OLD)	0.000527	0.000527	0.658815	0.000000	
CHILDREN (13-19 YEARS OLD)	0.000534	0.000534	0.667099	0.000000	
MALES (13-19 YEARS OLD)	0.000362	0.000362	0.451894	0.000000	
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000405	0.000405	0.506849	0.000000	
MALES (20 YEARS AND OLDER)	0.000323	0.000323	0.403566	0.000000	
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000379	0.000379	0.473176	0.000000	

*Current TMRC does not include new or pending tolerances.
 **New TMRC includes new, pending, and published tolerances.

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

FEB 24 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Subject: ETU (Ethylene Thiourea) Revised Q_1^* , (3/4's Interspecies
Scaling Factor), NTP $B_6C_3F_1$ Mouse Dietary Study

Caswell No.443AA

From: Bernice Fisher, Biostatistician
and
Hugh Pettigrew, Section Head
Statistics Section
Science Analysis Branch/HED (7509C)

Bernice Fisher
Hugh Pettigrew

To: Debra Edwards, Chief
Chemical Coordination Branch/HED (7509C)

Thru: William L. Burnam, Chief
Science Analysis Branch/HED (7509C)

W. Burnam

The revised unit risk, Q_1^* (mg/kg/day)⁻¹ of ETU, based upon female (F_1) mouse liver (adenoma and/or carcinoma) tumor rates is 6.01×10^{-2} in human equivalents (converted from animals to humans by use of the 3/4's scaling factor-1994, Tox_Risk, 3.5-K.Crump)^a. The dose levels used in the mouse study were 0, 100, and 330 ppm of ETU. The corresponding tumor rates in female mice were 9/98, 4/27 and 136/150. These doses and rates were obtained from the memorandum "Ethylene Thiourea (ETU) - Q_1^* Calculation Based on Female Mouse Liver Tumors (Pooled Data) from NTP Study, H.Pettigrew, 11/13/91)."

^a See Memo - Deriving Q_1^* 's Using the Unified Interspecies Scaling Factor, P.A. Fenner-Crisp, Director-HED, 7/1/94.

cc: Caswell file
B.Doyle

R.F.Griffin
L.Dorsey



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Dose-Response Analysis

Since the female mice did not have significant differential mortality with incremental doses of ETU, the estimate of unit risk, Q_1^* , was obtained by the application of the Multi-Stage model (Tox_Risk program, version 3.5 - K.Crump).

The estimate of unit risk, Q_1^* , was based upon liver (adenoma and/or carcinoma) tumor rates observed in female mice.

The resulting estimate of unit risk, Q_1^* , is as follows:

Species, Strain, Sex	Tumor	Q_1^* (mg/kg/day) ⁻¹ in Human Equivalents ^a
Mouse, B ₆ C ₃ F ₁ , Female	Liver (Ad &/or Ca)	6.01x10 ⁻²

For the conversion to human equivalents, weights of .0343 kg for the mouse, 70 kg for humans and the 3/4's scaling factor were used. Food consumption was 5.7 g/day as presented in the study.

It is to be noted that Q_1^* (mg/kg/day)⁻¹ is an estimate of the upper bound on risk and that (as stated in the EPA Risk Assessment Guidelines) "the true value of the risk is unknown, and may be as low as zero."

CARCINOGENIC RISK ESTIMATES BASED ON THE REVISED UNIT RISK,
 Q_1 *(MG/KG/DAY)⁻¹ OF ETU (6.01X10⁻²) AND PD4 EXPOSURE ESTIMATES

Almonds.....	7.2 E-10	Kohlrabi.....	<1.0 E-10
Apples w 77 day PHI..	1.8 E-07	Lettuce, head.....	1.3 E-08
* Apricots.....	2.5 E-07	Lettuce, leaf.....	7.6 E-08
Bananas.....	3.6 E-08	* Mustard greens.....	1.1 E-06
Barley.....	1.2 E-10	* Nectarines.....	4.2 E-08
Beans, Dry.....	7.3 E-09	Oats.....	1.8 E-10
* Beans, Suc.....	2.0 E-06	Onions.....	1.4 E-08
Broccoli.....	1.2 E-08	Papaya.....	1.3 E-08
Brussels sprout.....	1.8 E-09	* Peaches.....	1.4 E-06
Cabbage.....	2.8 E-08	Peanuts.....	1.1 E-09
Cantaloupes.....	4.7 E-09	Pears w 77 day PHI...	9.6 E-09
* Carrots.....	2.1 E-07	Pecans.....	<1.0 E-10
Cauliflower.....	5.9 E-09	Peppers.....	5.0 E-09
* Celery.....	4.8 E-07	Pineapple.....	<1.0 E-10
* Collards.....	6.9 E-07	Potatoes.....	1.2 E-07
Corn, pop.....	<1.0 E-10	Pumpkins.....	2.4 E-10
Corn, sweet.....	1.5 E-08	* Rhubarb.....	1.5 E-07
Corn, grain.....	7.2 E-10	Rye.....	<1.0 E-10
Cotton.....	1.2 E-10	* Spinach.....	1.2 E-06
Crabapples.....	1.2 E-10	Squash, summer.....	6.0 E-09
Cranberries.....	2.7 E-09	Squash, winter.....	6.0 E-09
Cucumbers.....	1.8 E-08	Sugarbeets.....	2.1 E-08
Eggplant.....	1.1 E-09	Tomatoes.....	1.5 E-07
Endive.....	1.7 E-08	* Turnip, tops.....	1.1 E-06
Fennel.....	2.4 E-10	* Turnip, roots.....	5.9 E-08
Figs.....	<1.0 E-10	Watermelon.....	6.0 E-09
Grapes.....	3.9 E-08	Wheat.....	1.0 E-09
Kale.....	5.4 E-08	Meat, red.....	1.0 E-09
		Milk.....	1.1 E-08

* cancelled uses



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

December 7, 1995

MEMORANDUM

SUBJECT: Maneb (014505) on Collards, Mustard Greens, and Turnip Tops in Georgia and Tennessee. Use of Maneb 80 WP formulation. [No MRID No.; CB 16476; DP BARCODE D220408]

FROM: Edward Zager, Chief
Chemistry Branch II - Reregistration Support
Health Effects Division [7509C] *Edward Zager*

TO: Jack Housenger, Chief
Special Review Branch
Special Review & Reregistration Division [7508W]

Elf Atochem has stated that they are discontinuing production of the Maneb Plus Zinc F4 Flowable formulation of maneb, which has been proposed for use on collards, mustard greens, and turnip tops in GA and TN, in connection with a ~~Sub Part D~~ hearing request. Elf Atochem has submitted bridging data from two EBDC (maneb) formulations on other crops and requests that the data be considered in support of the use of Maneb 80, a wettable powder formulation on collards, mustard greens, and turnip tops.

The Chemistry Branch II has reviewed the October 18, 1995 Elf Atochem submission addressed to Barbara D. Linney which compares residue data from two separate maneb formulations on 14 crops. These comparisons are intended to demonstrate the similarity in resulting residues from the use of Maneb 4 pound per gallon flowable formulation (Maneb Plus Zinc F4) and Maneb 80 percent by weight wettable powder formulation (Maneb 80.) This is being done in an effort to obtain Georgia and Tennessee registrations for Maneb 80 use on collards, mustard greens, and turnip tops using Maneb Plus Zinc F4 residue data.

Utilizing residue data from maneb liquid flowable (Maneb Plus Zinc F4) and maneb 80% by weight wettable powder (Maneb 80%), an analysis was done to compare the residue levels on 14 crops, adjusting for differences in application rates.

Conclusions

The amount of data available on each formulation for use on leafy crops were limited but sufficient for minor crops such as collards, mustard greens and turnip tops. Residues on 14 crops from the two maneb formulations (liquid flowable Maneb Plus Zinc F4 and wettable powder Maneb 80) were analyzed and no clear bias for consistently higher or lower residue levels from either formulation were observed. We are satisfied with the

quantity and quality of existing data available and will not require additional data to support Georgia and Tennessee registration of collards, mustard greens, and turnips tops for Maneb 80.

Based on this analysis and past assessments, CBRS believes that the use of Maneb 80 on collards, mustard greens, and turnip tops in Georgia and Tennessee at 3, 2, and 1 applications (respectively) of 1.2 lbs active ingredient per acre, with 14 day intervals and a 14 day PHI, will not result in a higher exposure than previously determined to be acceptable.

cc:RF, circu, Mancozeb RSF, Mancozeb SF
RDI:EZ:12/07/95
7509C:RM:804:CM#2:AF/SH:12/07/95

JAN 24 1995

**Supplemental Information to the 12/7/95 Memorandum from E. Zager to J. Housenger
Regarding Maneb Use on Leafy Greens**

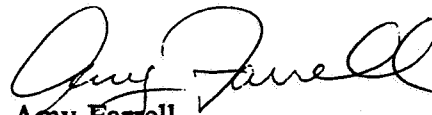
Supplemental Information:

The December 7, 1995 memorandum explains HED's support of using Maneb Plus Zinc F4 residue data to support the registration of Maneb 80 on collards, mustard greens, and turnip tops. (See memo for exact provisions.) This determination was made because residue data is not routinely translated between these two types of formulations.

The Pesticide Rejection Rate Analysis for Residue Chemistry provides guidance on the formulations for which data are routinely translated. It explains that data from wettable powders is routinely translated to/from data from dry flowables. Because Maneb 80 is a wettable powder and Maneb 75DF is a dry flowable, translation of the data from one to the other is acceptable.

Correction:

The December 7, 1995 Memo erroneously refers to the leafy greens hearing as a Subpart D Hearing.



Amy Farrell
Special Review and Reregistration Division

DOCKET FILE ENTRY
DOCUMENT COVER SHEET

CBI: Appendix In-Text No CBI

Docket No 30000/18F Chemical EBDO

Pre-SR PD1 PD2/3 PD4 Reg Std

POST
SR

Document Title Special Review - DRES dietary exposure and Risk Estimates for Proposed Section 18 Use of Formulations Containing Metaxyl... Doc Date 3/23/95

Author/Affiliation Richard Griffin | HED/EPA

Submitter/Affiliation _____ | _____

Doc Distributed in Meeting Meeting Date / /

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