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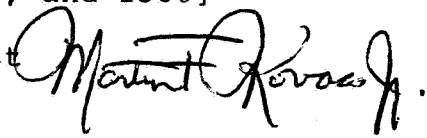
PMSB/TSB
1379

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review and Reassessment of Maneb Residue Data
Relative to the NRDC Lawsuit - EPA Accession Nos.
261550, 261557-261564, 262657-262672, 262674, 262675,
262677, 262821, 262823, 262825-262830, 262872,
263350-263355, 263356-263360, 263911, and 263912
[RCB Nos. 958, 972, 1238, 1239, 1379, and 1380]

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THRU: Charles L. Trichilo, Ph.D., Chief 
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Residue Chemistry Branch (RCB) has reviewed processing studies (submitted July 1, 1986), residue data studies (submitted May 2, 1986), feeding studies (submitted August 29, 1986), and reassessed old data (previously submitted) resulting from total residues of the EBDC fungicide maneb (manganous ethylene bisdithiocarbamate), trade names Manzate and Dithane M-22, including its degradation product (metabolite) ETU (ethylene thiourea) on all raw agricultural commodities (RAC's) for which use is currently registered.

The following residue assessment will be based solely on field residue data for maneb and ETU on RAC's for which use is currently registered together with data for these same residues in processed or cooked commodities derived from some of these RAC's and submitted by the Maneb Task Force as of August 29, 1986. Residue data submitted after August 29, 1986, was not included in this review. Secondary residues of maneb/ETU in meat, milk, poultry and eggs will also be addressed.

Tolerances

Tolerances are currently established in 40 CFR 180.110 for residues of the fungicide maneb (manganous ethylene bisdithiocarbamate) calculated as zinc ethylene bisdithiocarbamate, ranging from 0.1 part per million (ppm) in or on almonds and potatoes to 45 ppm on sugar beet tops, and include the following:

<u>Raw Agricultural Commodity</u>	<u>Tolerance (ppm)</u>
Almonds	0.1
Apples (40 CFR 180.110-1972)	7
(40 CFR 180.110-1974)	2
Apricots	10
Bananas	4
Bananas (pulp without peel)	0.5
Beans (dry form)	7
Beans (succulent form)	10
Broccoli	10
Brussels sprouts	10
Cabbage	10
Carrots	7
Cauliflower	10
Celery	5
Chinese cabbage	10
Collards	10
Corn, sweet (K+CWHR)	5
Cranberries	7
Cucumbers	7
Eggplants	7
Endive (escarole)	10
Figs	7
Grapes	7
Kale	10
Kohlrabi	10
Lettuce	10
Melons	4
Mustard greens	10
Nectarines	10
Onions	7
Papayas	10
Peaches	10
Peppers	7
Potatoes	0.1
Pumpkins	7
Rhubarb	10
Spinach	10
Sugar beet tops	45
Summer squash	4
Tomatoes	4

<u>Raw Agricultural Commodity</u>	<u>Tolerance (ppm)</u>
Turnip roots	7
Turnip tops	10
Winter squash	4

No tolerances are currently pending (40 CFR 180.110) for maneb nor have any food or feed additive tolerances ever been established.

Metabolism

The metabolism of maneb is currently under evaluation as part of the Residue Chemistry Chapter of the Maneb Registration Standard.

In the absence of any metabolism data to the contrary, and for the purpose of this residue assessment only, we consider the residues of concern to include the parent compound maneb and its metabolite/degradation product ETU.

Registered Use Patterns

The sites, application rates, and use practices for maneb are summarized in table 1. This table, which was presented in the July 7, 1986 memorandum (J.D. Hansen, SSB/BUD to E. Zager, RCB/HED) lists only representative crops for which maneb is registered. No tolerances have been established for the commodities asparagus (planting stock treatment) or southern peas as listed in this table. Further details for registered use patterns on the subject commodities can be found in the Maneb Index to Pesticide Chemicals dated April 8, 1982.

Table 1

SITES, APPLICATION RATES, AND USE PRACTICES FOR EBDG

(For representative crops for which MANEB is registered)

CROP	Use Rates AI POUNDS/ACRES	NUMBER SEASONAL APPLICATIONS		DOSAGE RANGE AI (No. appl. x rate, pounds)	PREHARVEST INTERVAL (PHI) AND LIMITATIONS
		MINIMUM	MAXIMUM		
<u>Almonds</u>					
<u>Brown rot</u>	2.3-12.8 lb/A	3	8	6.9 to 102.6	Do not apply later than 5 weeks after petal fall. Apply at 7- to 10-day intervals.
<u>Scab</u>					
<u>Shothole</u>					
<u>Apples</u>					
<u>Fruit rots</u>	0.8-8.0 lb/A	5	12	4.0 to 96	15-day PHI for a few States, 30-day PHI for all others. Delayed dormant and cover sprays.
<u>Leaf spots</u>					
<u>Twig blights</u>					
<u>Apricot</u>					
<u>Brown rot</u>	2.3-12.8 lb/A	3	10	6.9 to 128	14-day PHI. Apply at red bud, early bloom, full bloom, and petal fall, and at 7- to 14-day intervals.
<u>Asparagus (planting stock)</u>					
<u>Crown rot</u>	0.8 lb/100 gal	1		4.0	Dip treatment to crowns. Dip, then drain and plant as soon as possible.
<u>Bananas</u>					
<u>Cercospora leaf spot</u>	1.6-4 lb/A	8	16	12.8 to 64	0-day PHI. Begin when disease first appears and repeat at 2- to 3-week intervals.
<u>Beans, Lima</u>					
<u>Downy mildew</u>	1.6 lb/A	3	6	4.8 to 9.6	4-day PHI. Begin when mildew appears. Repeat at 7-day intervals.

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

(For representative crops for which MANEB is registered)

CROP	Use Rates AI POUNDS/ACRES	NUMBER SEASONAL APPLICATIONS		DOSAGE RANGE AI (No. appl. x rate, pounds)	PREHARVEST INTERVAL (PHI) AND LIMITATIONS
		MINIMUM	MAXIMUM		
<u>Beans, Snap</u> Rust	1.2 to 1.6 lb/A	2	6	2.4 to 9.6	4-day PHI. Apply at first sign of rust and 7 days before harvest (4- to 7-day intervals).
<u>Broccoli</u> <u>Alternaria leaf spot</u> Downy mildew	0.8-3.2 lb/A	6	9	4.8 to 28.8	0-day PHI. Apply when disease threatens. Repeat at 7- to 10-day intervals (for field) or 3 days (plant bed).
<u>Brussels Sprouts</u> <u>Alternaria leaf spot</u> Downy mildew	0.8-2.4 lb/A	6	9	4.8 to 21.6	0-day PHI. Apply when disease threatens. Repeat at 7- to 14-day intervals (for field) or 3 days (plant bed).
<u>Cabbage</u> <u>Alternaria leaf spot</u> Downy mildew	2.4 lb/A	3	9	7.2 to 21.6	7-day PHI. Apply mid to late season with insecticide sprays (7- to 10-day interval).
<u>Carrots</u> Leaf blights	0.8-2.4 lb/A	5	8	7 to 19.2	0-day PHI. Apply when plants are 6 weeks old or at first sign of disease. Repeat at 7- to 10-day intervals.
<u>Cauliflower</u> <u>Alternaria leaf spot</u> Downy mildew	0.8-2.4 lb/A	6	9	4.8 to 21.6	0-day PHI. Apply when disease threatens. Repeat at 7- to 14-day intervals (for field) or 3 days (plant bed).

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

(For representative crops for which MANEB is registered)

CROP	Use Rates AI POUNDS/ACRES	NUMBER SEASONAL APPLICATIONS		DOSAGE RANGE AI (No. appl. x rate, pounds)	PREHARVEST INTERVAL (PHI) AND LIMITATIONS
		MINIMUM	MAXIMUM		
<u>Celery</u> <u>Blights</u>	0.8-2.4 lb/A	5	12	4 to 28.8	14-day PHI. Field application every 7 to 10 days or every 3 to 5 days for plant bed.
<u>Collards</u> <u>Downy mildew</u>	0.76-2.4 lb/A	5	8	3.8 to 19.2	10-day PHI. Apply when disease first appears and repeat at 7- to 10-day intervals.
<u>Cranberries</u> <u>Fruit rots</u> <u>Twig blights</u>	2.4-6.0 lb/A	5	8	12 to 48	30-day PHI. Apply at midbloom. Repeat at 10- to 14-day intervals.
<u>Cucumber</u> <u>Downy mildew</u>	0.8-3.0 lb/A	6	15	4.8 to 45	5-day PHI. Apply when vines begin to run or at first sign of disease, then every 3 to 30 days.
<u>Eggplant</u> <u>Phomopsis</u> <u>blight</u>	0.8-2.4 lb/A	6	10	4.8 to 24	0-day PHI. Begin as fruit forms. Repeat at 7- to 10-day intervals.
<u>Fig (Kadota)</u> <u>Surface molds</u> <u>and rots</u>	0.5-0.6 lb/100 gal	1	1	1.2	10-day PHI. Foliar application. Apply once, 10 to 20 days before harvest.

Table 1

SITES, APPLICATION RATES, AND USE PRACTICES FOR EBDG (cont'd)

(For representative crops for which MANEB is registered)

CROP	Use Rates AI POUNDS/ACRES	NUMBER SEASONAL APPLICATIONS		DOSAGE RANGE AI (No. appl. x rate, pounds)	PREHARVEST INTERVAL (PHI) AND LIMITATIONS
		MINIMUM	MAXIMUM		
<u>Grapes</u> Black rot Bunch rot	1.5-4.0 lb/A	3	10	12 to 15	7-day PHI for the 1.5 lb/A rate or do not apply later than 10 days after bloom for the 4.0 lb/A rate.
<u>Lettuce</u> Downy mildew	0.8-2.4 lb/A	4	6	3.2 to 14.4	10-day PHI. Apply at first sign of disease and repeat every 7 to 10 days.
<u>Melons</u> Anthracnose Downy mildew	0.8-2.4 lb/A	6	9	4.8 to 21.6	5-day PHI. Apply when vines begin to run or when disease first appears. Repeat at 7- to 10-day intervals.
<u>Nectarine</u> Brown rot Scab Shot-hole	4.8-8.0 lb/A	8	10	38.4 to 80	14-day PHI. Apply at red bud, early bloom, full bloom, petal fall, and at 7- to 14-day intervals.
<u>Onion</u> Blotch Downy mildew Blast	2.4 lb/A	6	8	14.4 to 19.2	0-day PHI. Begin when disease first becomes visible.
<u>Papaya</u> Anthracnose Phytophthora fruit rot	1.6-2.4 lb/A	6	14	9.6 to 33.6	0-day PHI. Apply at flowering to crown, blossom area, central column, and developing fruit.

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

(For representative crops for which MANEB is registered)

CROP	Use Rates AI POUNDS/ACRES	NUMBER SEASONAL APPLICATIONS		DOSAGE RANGE AI (No. appl. x rate, pounds)	PREHARVEST INTERVAL (PHI) AND LIMITATIONS
		MINIMUM	MAXIMUM		
<u>Southern Peas</u>	0.6-1.8 lb/A	4	6	2.4 to 10.8	4-day PHI. Cleared only on southern peas. 7-day interval.
<u>Rust</u>					
<u>Anthracnose</u>					
<u>Downy mildew</u>					
<u>Peach</u>					
<u>Brown rot</u>	4.8-8.0 lb/A	8	10	38.4 to 80	2-day PHI. Apply at red bud, early bloom, full bloom, petal fall, and at 7- to 14-day intervals.
<u>Scab</u>					
<u>Shot-hole</u>					
<u>Peppers</u>					
<u>Anthracnose</u>	0.8-3.0 lb/A	4	8	3.2 to 24	0-day PHI. 7- to 10-day intervals.
<u>Cercospora leaf spot</u>					
<u>Potato</u>					
<u>Blights</u>	0.8-2.0 lb/A	6	15	4.8 to 30	0-day PHI. Begin using 0.8 lb rate when plants are 2 to 6 inches high.
<u>Pumpkins</u>					
<u>Angular leaf spot</u>	2.28-2.4 lb/A	6	12	13.7 to 28.8	0-day PHI. Begin when disease threatens and repeat at 7- to 10-day intervals as needed.
<u>Downy mildew</u>					
<u>Spinach</u>					
<u>Downy mildew</u>	0.8-2.4 lb/A	8	12	6.4 to 28.8	10-day PHI. 7- to 10-day intervals beginning at first true leaf.

Table 1 SITES, APPLICATION RATES, AND USE PRACTICES FOR EBDIC'S (Cont'd)

(For representative crops for which MANEB is registered)

CROP	Use Rates AI POUNDS/ACRES	NUMBER SEASONAL APPLICATIONS		DOSAGE RANGE AI (No. appl. x rate, pounds)	PREHARVEST INTERVAL (PHI) AND LIMITATIONS
		MINIMUM	MAXIMUM		
Squash	0.8-2.8 lb/A	6	9	4.8 to 25.2	5-day PHI. Apply when vines begin to run or when disease first appears. Repeat at 7- 10-day intervals.
Anthracnose					
Downy mildew					
Sugar Beet					
Cercospora leaf spot	0.8-2.56 lb/A	4	12	3.2 to 30.7	14-day PHI. Apply at first sign of disease. Repeat at 7- to 10-day intervals.
Sweet Corn					
Helminthosporium	1.6-2.4 lb/A	10	18	16 to 43.2	0-day PHI. 3- to 7-day intervals beginning at 6 inches in height.
Tomato					
Blights	0.8-2.5 lb/A	8	13	6.4 to 32.5	5-day PHI. Apply when seedlings emerge or when transplants set and repeat at 7- to 10-day intervals.
Turnips					
Downy mildew	0.76-2.4 lb/A	6	10	4.5 to 24	10-day PHI. Apply when disease first appears and repeat at 7- to 10-day intervals.
Leaf spot					
Watermelons					
Downy mildew	0.8-2.4 lb/A	8	12	6.4 to 28.8	5-day PHI. Apply at 7- to 10-day intervals. Start when vines begin to run.

Analytical MethodsEBDC (Maneb)

Methods for determining residues of EBDC fungicides were developed in the early 1950's (Clark, Baum, Stanley, and Hester, Anal. Chem. 23, 1842 [1951]). These methods were modified by various investigators (Lowen, Anal. Chem. 23, 1846-1850, [1951]; J.A.O.A.C. 36, 484-492 [1953]; Pease, 40, 1113-1118 [1957]; Cullen, T.E., Anal. Chem. 36, 221-224 [1964]; Gordon et al., J.A.O.A.C., 50, 1102-1108 [1967]). Each method is based on the simple principle of the liberation of carbon disulfide from the EBDC moiety by digestion followed by colorimetric determination of the quantity of carbon disulfide produced. The methods currently in use today are all modifications of the basic dithiocarbamate method described by Pease (see reference above). It should be noted that these methods are not specific for the individual EBDC's analyzed and that because of substrate interferences from some crops method sensitivity may range from 0.1 to 0.5 ppm.

Petition Data

One or more of the aforementioned methodologies were utilized to generate residue data for maneb on the following commodities:

<u>Commodity</u>	<u>Pesticide Petition No.</u>
Apples	21
Bananas (whole)	1257
Bananas (pulp)	1257
Beans (lima)	156
Beans (snap)	21/156
Cabbage	156
Carrots	21
Celery	21/156
Cucumbers	21
Figs	21
Lettuce	21/156
Papayas	485
Peaches	156
Peppers	21
Potatoes	21
Pumpkins	321
Rhubarb	225
Spinach	156
Squash	21
Sugar beet (roots)	439
Sugar beet (tops)	439

<u>Commodity (cont'd)</u>	<u>Pesticide Petition No.</u>
Sweet corn (kernels)	156
Sweet corn (husks)	156
Tomatoes	21
Watermelon	321

Company Studies

Subsequent maneb residue data reported by E.I. du Pont de Nemours & Co., Inc., on tomatoes, potatoes, cucumbers, cantaloupe, and summer squash as a status report to EPA dated November 1, 1972 and later published by Pease, H.L. and Holt, R.F. in J. Agr. Food Chem. 25:561-567 (1977) were generated with the modified carbon disulfide evolution method of Keppel, G.D., J. Assoc. Off. Anal. Chem. 54:528 (1971).

Residue Trials Conducted by Maneb Task Force in Response to EPA's Data Call-In Notice of October 19, 1984

Maneb residue data reported by the Maneb Task Force on the following 13 crops were generated by the method of McLeod, H.A. and McCully, K.A., Head Space Gas Procedure for Screening Food Samples for Dithiocarbamate Pesticide Residues in J.A.O.A.C. Vol. 52, No. 6, p. 1226 (1969): almonds, apples, bananas, beans (dry, succulent, hay, vines, and cannery waste), cabbage, cantaloupe, cucumbers, grapes, lettuce (head and leaf), potatoes, sugar beets (tops and roots), sweet corn (kernels and forage), and tomatoes.

Process Conversion Data Submitted by Maneb Task Force in Response to EPA's Data Call-In Notice of October 19, 1984

Maneb residue data reported by the Maneb Task Force on processed converted products derived from the following crops were also generated by the method of H.A. McLeod and K.A. McCully above: apples, green snap beans, grapes, potatoes, and tomatoes.

ETU

Residue methods for ETU have been extensively reviewed in the February 20, 1973 memorandum of Donald J. Reed and are summarized in table 2 of that document.

Table 2

I. Gas-Liquid Chromatography

<u>Cleanup</u>	<u>Derivative</u>	<u>Detection</u>	<u>Reference</u>
Cellulose column	S-butyl	Thermionic	Yip/Onley, FDA (JAOAC, 1971)
Liquid-liquid partitioning	S-butyl	Thermionic or FPD	Onley, EPA (ACS, NY, 1972)
Alumina column	S-butyl	FPD	Haines/Adler, R&H (unpublished)
Gel permeation	S-butyl	FPD	Holt/Pease, DuPont (unpublished)
Liquid-liquid partitioning	Trifluoro- acetyl + S-benzyl	EC	Newsome (<u>J. Ag. & Food Chem.</u> , 1972)
Silica gel column	Diaethyl	FPD	R&H (unpublished)
None (for formula- tions only)	None	Thermal conductivity	Bonteyan (JAOAC, 1972)

II. Liquid-Liquid Chromatography

Florisil column	None	UV	Cook/Lepper, FMC (ACS, NY, 1972)
Charcoal column	None	UV	Ives, EPA (unpublished)

III. Thin-Layer Chromatography

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Alumina column	S-butyl (or none)	Grote's reagent	Yip/Onley, FDA (JAOAC, 1971)
Not detailed	None	Iodine + starch	Blasquez/Plummer (ACS, NY, 1972)

Petition Data

None of the aforementioned Pesticide Petition Numbers 21 through 1257 contained ETU residue data.

Company Studies

ETU residue data were initially reported by E.I. du Pont de Nemours & Co., Inc., on tomatoes, potatoes, cantaloupes, cucumbers, and summer squash as a status report to EPA dated November 1, 1972 and later published by Pease, H.L. and Holt, R.F. in J. Agr. Food Chem. 25:561-567 (1977). The methodology used in these studies was entitled Procedure for the Determination

of Ethylene Thiourea Residues Using Flame Photometric Gas Chromatography and was a modification of the original method published by Onley, J. and Yip, G., J.A.O.A.C., Vol. 54, No. 1 (1971) pp. 165-169. The method modification involved a partitioning step into water from the chloroform phase for added cleanup and a gel filtration column used to purify the extracts. ETU is measured as the S-butyl derivative, after reaction of ETU with 1-bromobutane, by sulfur-sensitive flame photometric gas chromatography.

Residue Trials Conducted by Maneb Task Force in Response to EPA's Data Call-In (DCI) Notice of October 19, 1984

ETU residue data reported by the Maneb Task Force on the same commodities (crops) described above were generated by the method of Onley, J.H. et al., Gas-Liquid Chromatography and Liquid Chromatography of Ethylene Thiourea in Fresh Vegetable Crops, Fruits, Milk, and Cooked Foods in J.A.O.A.C., Vol. 60, No. 5, p. 1107 (1977). In this method the crop-methanol extract is cleaned up by adsorbing the sample onto gas-chrom S, desorbing ETU, and eluting ETU from aluminum oxide with chloroform containing ethanol. ETU is converted to the S-butyl derivative for gas-liquid chromatography (GLC) and flame photometric detection (FPD) (sulfur mode). For liquid chromatography (LC), ETU is cleaned up on another aluminum oxide column and injected directly. LC and GLC results are confirmed by thin-layer chromatography (TLC).

Process Conversion Data Submitted by Maneb Task Force in Response to EPA's DCI Notice of October 19, 1984

ETU residue data were reported by the Maneb Task Force in processed converted products derived from the following crops: apples, green snap beans, grapes, potatoes, and tomatoes. Data were also generated by the method of J.H. Onley et al. cited above.

The evaluation of the analytical methodology for residues of maneb and ETU is currently being assessed as part of the Residue Chemistry Chapter of the Maneb Registration Standard. Therefore, for the purpose of this residue assessment only, we consider that the submitted analytical methods are adequate to measure residues of both maneb and ETU only on the specific commodities for which these analyses were performed.

Residue Data

The residue data utilized in this residue assessment were obtained from three sources:

- [1] Residue data utilized from field studies submitted with tolerance petitions. These data reflected residues of maneb only.

- [2] Company data submitted by E.I. du Pont de Nemours & Co., Inc., for residues of both maneb and ETU on tomatoes, potatoes, cantaloupe, cucumbers, and summer squash.
- [3] Residue data submitted by the Maneb Task Force in response to EPA's DCI Notice of October 19, 1984. These residue trials were conducted on 13 crops: almonds, apples, bananas, beans, cabbage, cantaloupe, cucumbers, grapes, lettuce, potatoes, sugar beets, sweet corn, and tomatoes. For all of the studies, trials were conducted at various agricultural locations using Maneb 80% Wettable Powder at the maximum recommended rate based on the EPA Compendium or Index, two times the maximum rate, and an untreated check. In most cases samples were harvested at or near the minimum PHI recommended on the label and in all cases residues of both maneb and ETU were determined.

Residue data for each commodity were tabulated below only if the reported use approximated the maximum registered rate described in table 1. All exaggerated rate data reported in petitions including the 2X rate employed in the Maneb Task Force residue trials were not tabulated. The source of the residue data is indicated as [1], [2], or [3] below to correspond to the source described above.

Almonds

- [3] Residue studies reflect three to four applications of Maneb 80% Wettable Powder at 1.6 lb ai/A with a 96- to 182-day PHI for California (registered PHI = no later than 5 weeks after petal fall). On nutmeats, residues of maneb ranged from < 0.050 to 0.580 and averaged 0.111 ppm for 23 samples. Residues of ETU were all reported at < 0.010 for 20 samples. On hulls, residues of maneb ranged from 0.093 to 91.900 and averaged 29.3 ppm for 22 samples. Residues of ETU ranged from < 0.02 to 0.026 ppm and averaged < 0.02 ppm for 19 samples. RCB estimates the minimum PHI of "not later than 5 weeks after petal fall" to represent 50 to 65 days. ETU residues were reported at actual PHI's of 96 to 144 days.

Apples

- [1] (PP#21) Residue studies reflected four to eight applications of Manzate 70% at 8 to 12 lb ai/A

with PHI's of 54 to 100 days. Maneb residues ranged from < 0.2 to 0.2 ppm and averaged 0.11 ppm for nine samples.

- [3] Residue studies reflect 4 to 14 applications of Maneb 80% Wettable Powder at 6.4 lb ai/A with PHI's of 15 days for Michigan, Pennsylvania, and New York and 30 days for California and Washington. Registered PHI = 15 days northeast, 30 days west. Maneb residues ranged from 1.04 to 23.7 ppm and averaged 10.7 ppm for 26 samples. ETU residues ranged from < 0.010 at 30 days PHI to 0.057 to 0.091 ppm at 15 days PHI and averaged 0.240 ppm for 11 samples over a 15- to 30-day PHI range.

Bananas

- [1] (PP#2F1257) Residue studies (Honduras) reflected 3 to 10 applications of Maneb 80% Wettable Powder at 2.4 to 5.0 lb ai/A with PHI's of 0 to 12 days. Maneb residues in whole bananas ranged from 0.4 to 1.6 ppm and averaged 1.09 ppm for nine samples; banana pulp ranged from 0.3 to 0.6 ppm and averaged 0.45 ppm for four samples.
- [3] Residue studies reflect 10 applications of Maneb 80% Wettable Powder at 4.0 lb ai/A (Honduras) with a PHI of 14 days (registered PHI = 0 days).
- Maneb residues ranged from < 0.05 to 0.224 ppm and averaged 0.07 ppm for six whole banana samples and reported at < 0.05 ppm for six banana pulp samples.
- ETU residues ranged from < 0.0125 to 0.0230 ppm and averaged 0.016 ppm for seven whole banana samples and for seven banana pulp samples ranged from < 0.0125 to 0.0304 ppm and averaged 0.0182 ppm.

Beans

Dry-Blackeye

- [3] Residue studies reflect eight to nine applications of Maneb 80% Wettable Powder at 3.2 lb ai/A with a PHI of 7 days for California. Registered PHI = 0 days.
- Maneb residues ranged from 1.25 to 1.58 ppm and averaged 1.38 ppm for three samples.

ETU residues ranged from 0.013 to 0.323 ppm and averaged 0.128 ppm for three samples.

Green Snap Beans

- [1] (PP#21 and PP#156) Residue studies reflect one to seven applications of Maneb 70% Wettable Powder at 2 lb ai/A with PHI's of 0 and 4 days for Florida. Registered PHI = 4 days.

Maneb residues ranged from 1.4 to 5.7 ppm and averaged 3.5 ppm for 10 samples.

- [3] Residue studies reflect eight to nine applications of Maneb 80% Wettable Powder at 3.2 lb ai/A with a PHI of 7 days for California.

Maneb residues ranged from 4.87 to 31.40 ppm and averaged 19.69 ppm for three samples.

ETU residues ranged from 0.010 to 0.078 ppm and averaged 0.051 ppm for three samples.

Lima Beans

- [1] (PP#156) Residue studies reflect one to six applications of Maneb 70% Wettable Powder at 2 lb ai/A with PHI's of 0 and 7 days for Florida.

Maneb residues ranged from 0.00 to 0.14 ppm and averaged 0.06 ppm for 10 samples.

- [3] Residue studies reflect eight to nine applications of Maneb 80% Wettable Powder at 3.2 lb ai/A with a PHI of 7 days for California. Registered PHI = 4 days.

Maneb residues ranged from 0.114 to 0.118 ppm and averaged 0.116 ppm for three samples.

ETU residues were reported at < 0.010 ppm for three samples.

Bean Hay

- [3] Residue studies reflect eight to nine applications of Maneb 80% Wettable Powder at 3.2 lb ai/A with a PHI of 7 days for California. Registered PHI = 4 days.

Maneb residues ranged from 1.53 to 69.40 ppm and averaged 25.36 ppm for six samples.

Beans (cont'd)

ETU residues ranged from < 0.010 to 0.601 ppm and averaged 0.184 ppm for six samples.

Bean Vines

[3] Use pattern same as [3] under Bean Hay above.

Maneb residues ranged from 83.1 to 208.0 ppm and averaged 150.7 ppm for three samples.

ETU residues ranged from 0.448 to 1.207 ppm and averaged 0.812 ppm for three samples.

Broccoli

[1] (PP#183) Residue studies reflect two to eight applications of Maneb 70% Wettable Powder at 2.8 lb ai/A with PHI's of 0 to 16 days for New York. Registered PHI = 0 days.

For unwashed and untrimmed broccoli, maneb residues ranged from 0.56 to 25.0 ppm and averaged 6.86 ppm for 18 samples.

For washed and trimmed broccoli, maneb residues ranged from 2.7 to 7.3 ppm and averaged 4.1 ppm for seven samples.

Cabbage (head)

[3] Residue studies reflect six to seven applications of Maneb 80% Wettable Powder at 2 lb ai/A with a PHI of 7 days for California. Registered PHI = 7 days (heads field trimmed).

Maneb residues ranged from 0.59 to 2.83 ppm and averaged 1.16 ppm for nine samples.

ETU residues were all reported at < 0.010 ppm for nine samples.

Carrots

[1] (PP#21) Residue studies reflect three to seven applications of Maneb 70% Wettable Powder at 1 to 1.4 lb ai/A with PHI's of 14 to 30 days. Registered PHI = 0 days.

Maneb residues reported at < 0.1 ppm for three samples.

Cantaloupe

- [2] (DuPont Study) Residue studies reflect 8 to 12 applications of Maneb 80% Wettable Powder at 2.4 lb ai/A with PHI's of 1, 3, and 5 days for Georgia.

Maneb residues ranged from 0.9 to 2.3 ppm and averaged 1.6 ppm for three samples.

ETU residues were all reported at < 0.05 ppm for three samples.

- [3] Residue studies reflect five to seven applications of Maneb 80% Wettable Powder at 3 lb ai/A with a PHI of 5 days for California. Registered PHI = 5 days.

Maneb residues ranged from 1.06 to 4.10 ppm and averaged 2.31 ppm for six samples.

ETU residues were reported at < 0.010 ppm for six samples.

Celery

- [1] (PP#21 and PP#156) Residue studies reflect 7 to 20 applications of Maneb 70% Wettable Powder at 1 to 1.4 lb ai/A with PHI's of 0, 1, 7, and 11 days for Delaware and Florida. Registered PHI = 14 days.

For unwashed and untrimmed celery samples (five) maneb residues ranged from 1.75 to 20.60 ppm and averaged 9.25 ppm. For washed and trimmed celery samples (six) maneb residues ranged from 1.75 to 5.90 ppm and averaged 3.91 ppm.

Cucumber

- [1] (PP#21) Residue studies reflect four to seven applications of Maneb 70% Wettable Powder at 1.4 lb ai/A with PHI's of 0 and 7 days for Florida.

Maneb residues ranged from 0.0 to 0.2 ppm and averaged 0.03 ppm for six samples.

Cucumber (cont'd)

- [2] (DuPont Study) Residue studies reflect four to five applications of Maneb 80% Wettable Powder at 2.4 lb ai/A with PHI's of 1, 3, 5, and 7 days for Florida, South Carolina, and Michigan.

Maneb residues ranged from < 0.1 to 0.68 ppm and averaged 0.36 ppm for nine samples.

ETU residues were all reported at < 0.05 ppm for nine samples.

- [3] Residue studies reflect seven applications of Maneb 80% Wettable Powder at 3 lb ai/A with a PHI of 5 days for Indiana and New York. Registered PHI = 5 days.

Maneb residues ranged from 0.08 to 0.29 ppm and averaged 0.20 ppm for nine samples.

ETU residues ranged from < 0.005 to 0.009 ppm and averaged 0.004 ppm for two samples.

Figs

- [1] (PP#21) Residue studies reflect one application of Maneb 70% Wettable Powder at 0.525 lb/100 gal with a PHI of 0 days for California. Registered PHI = 10 days.

A maneb residue of 0.9 ppm was reported for one sample.

Grapes

- [3] Residue studies reflect seven applications of Maneb 80% Wettable Powder at 4 lb ai/A with a PHI of 7 days for California. Registered PHI = 7 days.

Maneb residues ranged from 8.89 to 13.50 ppm and averaged 11.93 ppm for three samples.

ETU residues were all reported at < 0.010 ppm for three samples.

LettuceHead

- [1] (PP#21 and PP#156) Residue studies reflect one to three applications of Maneb 70% Wettable Powder at 1.4 lb ai/A with PHI's of 2, 5, 9, and 23 days for California. Heads stripped and trimmed.

Maneb residues ranged from 0.6 to 14.8 ppm and averaged 5.0 ppm for four samples.

- [3] Residue studies reflect four to seven applications of Maneb 80% Wettable Powder at 3.2 lb ai/A with a PHI of 10 days for California and Florida. Heads stripped and trimmed. Registered PHI = 10 days.

Maneb residues ranged from 0.06 to 14.9 ppm and averaged 5.46 ppm for 10 samples.

ETU residues ranged from < 0.010 to 0.059 ppm and averaged 0.023 ppm for five samples.

Leaf

- [1] (PP#156) Residue studies reflect 15 applications of Maneb 70% Wettable Powder at 1.05 lb ai/A with PHI of 7 days for Florida.

Maneb residues reported at 2.4 ppm for one sample (washed).

- [3] Residue studies reflect four to seven applications of Maneb 80% Wettable Powder at 3.2 lb ai/A with a PHI of 10 days for California, New York, and Michigan. Registered PHI = 10 days.

Maneb residues ranged from 4.1 to 119.0 ppm and averaged 28.2 ppm for six (washed) samples.

ETU residues ranged from 0.169 to 0.357 ppm and averaged 0.255 ppm for 11 (washed) samples.

Papaya

- [1] (PP#485) Residue studies reflect 2 to 13 applications of Maneb 80% Wettable Powder at 1.6 and 2.4 lb ai/A with PHI's of 3, 4, 5, 7, 20, and 22 days PHI for Hawaii. Registered PHI = 0 days.

Papaya (cont'd)

Maneb residues ranged from 1.0 to 5.2 ppm and averaged 2.8 ppm for 15 samples.

Peach

- [1] (PP#156) Residue studies reflect one application of Maneb 70% Wettable Powder at 4 to 8 lb ai/A with PHI's of 0 to 33 days for California and Washington. Registered PHI = 2 days.

Maneb residues ranged from 1.5 to 23 ppm and averaged 11.1 ppm for 20 samples.

Peppers

- [1] (PP#21) Residue studies reflect three to seven applications of Maneb 70% Wettable Powder at 2.4 to 3.2 lb ai/A with PHI's of 0, 4, 7, 14, and 30 days for Florida, Connecticut, and New Jersey. Registered PHI = 0 days.

Maneb residues ranged from < 0.1 to 5.2 ppm and averaged 1.3 ppm for nine samples.

Potatoes

- [1] (PP#21) Residue studies reflect nine applications of Maneb 70% Wettable Powder at 0.9 lb ai/A with a PHI of 25 days for Delaware.

Maneb residues were reported at < 0.50 ppm for eight samples.

- [2] (DuPont Study) Residue studies reflect four to six applications of Maneb 80% Wettable Powder at 1.6 lb ai/A with PHI's of 1, 6, and 9 days for Florida, Maine, and Indiana.

Maneb residues were reported at < 0.1 ppm for four samples.

ETU residues were reported at < 0.05 ppm for four samples.

- [3] Residue studies reflect 6 to 16 applications of Maneb 80% Wettable Powder at 1.6 lb ai/A with PHI's of 0, 5, and 7 days for California, Washington, New York, Wisconsin, and Maine. Registered PHI = 0 days.

Potatoes (cont'd)

Maneb residues ranged from < 0.050 to 0.099 ppm and averaged 0.077 ppm for 19 samples.

ETU residues were all reported at < 0.0125 ppm for 13 samples.

Pumpkins

- [1] (PP#321) Residue studies reflect one to five applications of Maneb 80% Wettable Powder at 1.2 to 2.4 lb ai/A with PHI's of 0, 3, and 7 days for Illinois and Wisconsin. Registered PHI = 0 days.

Maneb residues ranged from 0.03 to 0.39 ppm and averaged 0.16 ppm for five samples.

Rhubarb (Greenhouse Use)

- [1] (PP#225) Residue studies reflect four applications of Maneb 80% Wettable Powder at 1.6 lb ai/100 gal with PHI's of 0, 3, and 5 days for Michigan. Registered PHI = 0 days.

Maneb residues ranged from 6.3 to 26.0 ppm and averaged 13.8 ppm for four samples.

Spinach

- [1] (PP#156) Residue studies reflect two to three applications of Maneb 5.6% Dust at 1.68 lb ai/A with PHI's of 0 and 7 days for Tennessee. Registered PHI = 10 days.

Maneb residues reported at 18 and 43 ppm average 30.5 ppm (unwashed) and 3 and 4 ppm average 3.5 ppm (washed).

Squash

- [1] (PP#21) Residue studies reflect three to seven applications of Maneb 70% Wettable Powder at 2.8 lb ai/A with PHI's of 0 and 7 days for Florida. Registered PHI = 5 days.

Maneb residues ranged from 0.06 to 0.5 ppm and averaged 0.21 ppm for eight samples.

- [2] (DuPont Study) Residue studies reflect three to four applications of Maneb 80% Wettable Powder at 2.4 lb ai/A with PHI's of 1, 3, 5, and 7 days for South Carolina and Florida. Registered PHI = 5 days.

Maneb residues ranged from < 0.1 to 0.51 ppm and averaged 0.23 ppm for six samples.

ETU residues were reported to be < 0.05 ppm for six samples.

Sugar Beets

Roots

- [1] (PP#439) Residue studies reflect three to six applications of Maneb 80% Wettable Powder at 1.2 and 1.6 lb ai/A with PHI's of 0, 1, and 14 days for Minnesota, Iowa, and Ohio. Minimum label PHI = 10 days without feeding restriction and 14 days with feeding restriction.

Maneb residues were reported at < 0.1 ppm for seven samples.

- [3] Residue studies reflect five applications of Maneb 80% Wettable Powder at 2.4 lb ai/A with PHI of 10 days for California and Michigan. Registered PHI = 14 days without feeding restriction, 10 days with feeding restriction.

Maneb residues ranged from 0.06 to 0.81 ppm and averaged 0.27 ppm for 22 samples.

ETU residues were all reported at < 0.0125 ppm for 13 samples.

Tops

- [1] (PP#439) Same use pattern as reported above for Roots except PHI's 0 to 22 days.

Maneb residues ranged from 1.6 to 104 ppm and averaged 28 ppm for 17 samples.

- [3] Same use pattern as Roots above.

Maneb residues ranged from 5.7 to 54.0 ppm and averaged 26.1 ppm for 20 samples.

Tops (cont'd)

ETU residues ranged from 0.033 to 0.594 ppm and averaged 0.170 ppm for 14 samples.

Sweet CornKernels

- [1] (PP#156) Residue studies reflect 5 to 13 applications of Maneb 70% Wettable Powder at 2.1 and 2.8 lb ai/A with PHI's of 0, 5, and 21 days for Florida. Registered PHI = 0 days.

Maneb residues were all reported at < 0.2 ppm for five samples.

- [3] Residue studies reflect 7 to 14 applications of Maneb 80% Wettable Powder at 2.0 lb ai/A with PHI's of 0 and 7 days for California, New York, Wisconsin, and Florida.

Maneb residues ranged from < 0.05 to 1.86 ppm and averaged 0.30 ppm for 24 samples.

ETU residues were all reported at < 0.0156 ppm for 14 samples.

Forage

- [3] Same use pattern as reported above for Sweet Corn Kernels except all ETU data obtained at 7 days PHI.

Maneb residues ranged from 2.1 to 93.2 ppm and averaged 42.4 ppm for 18 samples.

ETU residues ranged from 0.028 to 0.235 ppm and averaged 0.105 ppm for nine samples.

Tomatoes

- [1] (PP#21) Residue studies reflected 1 to 20 applications of Maneb 70% Wettable Powder at 2.1 and 3.4 lb ai/A at PHI's of 0, 5, 6, and 7 days for Texas and Florida. Registered PHI = 5 days.

Maneb residues ranged from 0.08 to 1.3 ppm and averaged 0.55 ppm for 10 samples.

- [2] (DuPont Study) Residue studies reflect 3 to 10 applications of Maneb 80% Wettable Powder at 2.4 lb ai/A at PHI's of 1, 3, and 5 days for Florida, Michigan, Maryland, Delaware, and California.

Maneb residues ranged from 0.61 to 4.0 ppm and averaged 1.48 ppm for 17 samples. ETU residues were all reported at < 0.05 ppm for 16 samples.

- [3] Residue studies reflect 5 to 10 applications of Maneb 80% Wettable Powder at 2.4 lb ai/A at PHI's of 5 and 7 days for California, Florida, Indiana, and Michigan.

Maneb residues ranged from 0.56 to 12.20 ppm and averaged 4.25 ppm for 21 samples.

ETU residues were all reported at < 0.0250 ppm for 13 samples.

Watermelons

- [1] (PP#0321) Residue studies reflect four to eight applications of Maneb 80% Wettable Powder at 1.2 lb ai/A at PHI's of 3 and 23 days for Florida. Registered PHI = 5 days.

Maneb residues were reported at < 0.1 ppm for two samples.

Discussion of Residue Data

For the purpose of this residue assessment RCB considers the residues of concern to include the parent compound maneb plus its metabolite/degradation product ETU. Accordingly, ETU residue data are available only for the following crops: almonds, bananas, beans (dry, snap, lima), cabbage, cantaloupe, cucumbers, grapes, lettuce (leaf and head), potatoes, sugar beets, sweet corn, tomatoes, and apples. No ETU residue assessment can therefore be made for the remaining RAC's for which maneb is registered for use and for which no ETU residue data are available. Of the aforementioned RAC's no sample history information or sample storage information are provided for cucumbers, apples grown in Michigan, New York, and Pennsylvania, or tomatoes grown in Florida, Indiana, and Michigan. The following RAC's were stored under unspecified conditions at the following intervals prior to analysis: bananas (2 months), beans (3 1/2 to 7 months), cabbage (1 to 4 1/2 months), head lettuce - Florida, leaf lettuce - Michigan and New York (7 to 10 1/2 months), and sugar beets (3 1/2 to 7 months). The following RAC's were stored under frozen conditions at the

following intervals prior to analysis: almonds (128 to 195 days), cantaloupe (4 months), grapes (4 1/2 to 6/12 months), head lettuce - California (4 to 6 months), leaf lettuce - California (6 months), potatoes (3 to 5 months), sweet corn (3 to 8 1/2 months), tomatoes - California (4 to 6 months), and apples - California (205 days).

The residue data summarized above have not been adequately validated and therefore must be considered extremely questionable. Adequate sample history data are not available and unacceptable storage stability data (see RCB's M.F. Kovacs, Jr., January 21, 1987 memorandum re: The Maneb Task Force's submitted storage stability data) have been submitted which cannot be used to validate the summarized residue data on the 13 crops that the registrant shows present concern for. In fact, in the aforementioned memorandum RCB recommended that:

"Residue data previously submitted on 13 crops which were held in frozen storage for varying periods of time are invalid since many of the field treated samples were macerated and stored under the same conditions that resulted in extensive decomposition in the submitted storage stability samples. Accordingly, new field trials generating the appropriate data are necessary for these same 13 crops."

Until adequate storage stability data are provided, the residue levels on RAC's discussed in this review should be regarded as minimum estimates. Residue levels could be much higher if residues decayed significantly in storage.

The repeated residue studies must be validated with new frozen storage stability data for both mane and ETU conducted on representative crops (see Maneb DCI Notice for Storage Stability Data for details of this requirement).

Table 3Crops For Which Tolerances Are Established But No Residue Data Available

<u>Crop</u>	<u>Tol.</u>	<u>Petition Est. Tol.</u>	<u>40 CFR 180.34(f) Commodity Group</u>	<u>Rep. Crop Residue Data Available</u>
Apricots	10	156	Stone Fruit	Peaches
Nectarines	10	156	Stone Fruit	Peaches
Brussels Sprouts	10	183	Brassica Leafy Veggies.	Cabbage/Broccoli
Cauliflower	10	183	Brassica Leafy Veggies.	Cabbage/Broccoli
Collards	10	183	Brassica Leafy Veggies.	Cabbage/Broccoli
Kale	10	156	Brassica Leafy Veggies.	Cabbage/Broccoli
Cranberries	7	21	Small Fruits & Berries	Grapes
Eggplant	7	21	Fruiting Veggies./Except Cucurbits	Tomatoes Peppers
Onions	7	21	Bulb Vegetables	None* *Onion Rep. Crop
Turnips (Tops)	10	156	Roots & Tuber Veggies.	Carrots Potatoes Sugar Beets
Turnips (Roots)	7	156	Roots & Tuber Veggies.	

In the M.J. Bradley (RCB) January 17, 1986 memorandum to H. Jacoby (RD) and J. Lewis (RD) re: the Maneb DCI request for time extension for crop residue data, letter of December 27, 1985, comments, requirements related to residue data for the aforementioned crops were made as follows: Specific residue data, maneb and ETU, were requested for apricots and nectarines. Specific residue data, maneb and ETU, was requested for brussels sprouts, cauliflower, kale, and collards. Due to the range of application rates and PHI's the representative crops (cabbage, broccoli) may not be sufficient for translation to other members of the crop group brassica leafy vegetables. Specific residue data on maneb and ETU were requested for cranberries and turnips (tops and roots) and especially for onions since they are a representative commodity of their commodity group bulb vegetables. Due to the range of application rates and PHI's the representative crops (tomatoes and peppers) may not be sufficient for translation to other members of the crop group fruiting vegetables, except cucurbits (i.e., eggplants).

Therefore, in the absence of these residue data, the existing maneb tolerance for each of these crops will be used to estimate maneb residues.

Table 4

Maneb Residues
Derived from Existing Tolerances

<u>Crop</u>	<u>Tolerance ppm</u>	<u>% Crop¹/ Treated</u>	<u>Adj. for % Crop²/ (ppm)</u>
Apricots	10.0	2	0.20
Brussels Sprouts	10.0	-	10.0
Cauliflower	10.0	-	10.0
Collards	10.0	-	10.0
Cranberries	7.0	-	7.0
Eggplant	7.0	-	7.0
Kale	10.0	-	10.0
Nectarines	10.0	1	0.10
Onions	7.0	41	2.87
Turnips (Tops)	10.0	-	10.0
Turnips (Roots)	7.0	-	7.0

1/These percentages were presented in the July 17, 1986 memorandum of J.D. Hanson SSB/BUD to E. Zager RCB/HED.

2/The adjustment for percent crop treated is obtained by multiplying the tolerance level by the percent crop treated.

Process/Conversion Studies

Maneb and ETU residue data reported by the Maneb Task Force on processed converted products derived from apples, green snap beans, grapes, potatoes, and tomatoes are summarized below, and estimates of average concentration/reduction factors for maneb and percent conversion of maneb to ETU residues in processed and cooked food and feed commodities are calculated from these summarized data.

Apples

Fresh apple fruit was commercially processed following application of Maneb 80 percent WP to apple orchards in California and Washington at 6.4 lb/ai (1X) and 12.8 lb/ai (2X)/A with a 30-day PHI. Fresh apples used in these processing studies were derived from three sources: Porterville, CA, Delano, CA, and Wenatchee, WA. The Porterville, CA apple samples were placed in frozen storage until processing, and washed and peeled prior to processing into cooked/canned applesauce, juice, and sliced apples. Washed but unpeeled apples from Porterville, CA, Delano, CA, and Wenatchee, WA were also processed into wet pomace, dry pomace, and fresh juice, and into cooked, processed, strained applesauce (baby food) for the Wenatchee, WA apples.

Residue analyses of processed commodities are summarized below.

	<u>#</u> <u>Samples</u>	<u>Avg.</u> <u>(ppm)</u>	<u>Range</u> <u>(ppm)</u>	<u>Avg.</u> <u>Conc./Reduc.</u> <u>Factor</u>	<u>Avg.</u> <u>% Conversion</u>
<u>Processed Subset 1</u>					
<u>Porterville, Delano, CA</u>					
<u>Wenatchee, WA</u>					
Fresh Fruit					
Maneb	6	8.128	(2.107-20.892)	-	-
ETU	6	< 0.010	< 0.010	-	-
Wet Pomace					
Maneb	6	8.238	(2.415-20.580)	1.1	-
ETU	6	< 0.020	< 0.020	-	0
Dry Pomace (8% Moisture)					
Maneb	6	29.037	(11.385-71.415)	3.57	-
ETU	6	0.041	(0.020-0.112)	-	0.50
<u>Processed Subset 1</u>					
<u>Porterville, Delano, CA</u>					
<u>Wenatchee, WA</u>					
Fresh Juice					
Maneb	6	14.312	(3.226-43.008)	1.76	-
ETU	6	0.011	(< 0.010-0.029)	-	0.14
<u>Processed Subset 2</u>					
<u>Porterville, CA</u>					
Fresh Fruit					
Maneb	1	3.368	3.368	-	-
ETU	1	< 0.010	< 0.010	-	-

	<u>#</u>	<u>Avg.</u>	<u>Range</u>	<u>Avg.</u>	<u>Avg.</u>
	<u>Samples</u>	<u>(ppm)</u>	<u>(ppm)</u>	<u>Conc./Reduc.</u>	<u>% Conversion</u>
				<u>Factor</u>	
<u>Processed Subset 2</u>					
<u>Porterville, CA (cont'd)</u>					
Washed Apples					
Maneb	1	< 0.050	< 0.050	< 0.01	-
ETU	1	< 0.010	< 0.010	-	0
Peeled/Cored					
Maneb	1	< 0.050	< 0.050	< 0.01	-
ETU	1	< 0.010	< 0.010	-	0
Cooked/Canned Applesauce					
Maneb	1	< 0.050	< 0.050	< 0.01	-
ETU	1	< 0.010	< 0.010	-	0
Cooked/Canned Apple Juice					
Maneb	1	0.078	0.078	0.02	-
ETU	1	< 0.010	< 0.010	-	0
Canned Apple Slices					
Maneb	1	< 0.050	< 0.050	< 0.01	-
ETU	1	< 0.010	< 0.010	-	0
<u>Processed Subset 3</u>					
<u>Wenatchee, WA</u>					
Fresh Fruit					
Maneb	1	2.107	2.107	-	-
ETU	1	< 0.010	< 0.010	-	-
Washed Apples					
Maneb	1	1.598	1.598	0.76	-
ETU	1	< 0.010	< 0.010	-	0
Processed, Strained					
Applesauce	Maneb	1	0.195	0.195	0.09
(Baby Food)	ETU	1	0.240	0.240	-
					11.4

Discussion of Apple Processing Study

The calculations for average concentration/reduction of maneb and percent conversion of maneb to ETU in wet and dry pomace and fresh juice were derived from the fresh fruit samples (6) in Processed Subset 1. These same calculations applied to washed apples, peeled and cored apples, and cooked/canned applesauce, apple juice, and apple slices, which were derived from the fresh fruit sample (1) in Processed Subset 2. Processed, strained applesauce (baby food) was derived from the fresh fruit sample (1) in Processed Subset 3.

Washing apples tends to reduce maneb residues; however, the degree of removal was markedly different between apples in Subsets 2 and 3. No explanation was offered for the discrepancy. Because washed apples contained < 0.05 ppm maneb, the processed commodities derived from those apples contained little if any maneb and no ETU whereas the washed apples in Subset 3 contained 1.598 ppm maneb which resulted in considerable ETU residues (0.240 ppm) in processed strained applesauce (baby food). Additionally, the baby food processing conditions were much more rigorous than that for the cooked/canned apple sauce and juice, i.e., 20-minute steaming at 200 °F followed by processing at 215 °F at pH 4.0 maximum for 16 minutes for baby food compared to approximately 4-minute heating at 190 to 210 °F for applesauce and juice.

Because of the discrepancies in the data cited above between cooked canned applesauce and processed strained applesauce (baby food) we recommend that ETU residue data derived from the latter commodity be used in lieu of the former for the purpose of residue assessment. Additionally, the raw fresh apple juice data should be used in lieu of the cooked canned apple juice data.

For the above reasons and additionally due to the limited number of processed samples in this study together with the lack of information on storage stability studies and sample history, RCB concludes that for the purpose of residue assessment the apple processing study should be repeated. To validate the repeated apple processing study, frozen storage stability data for both maneb and ETU are needed for the approximate time intervals that these processed commodities are held in frozen storage prior to analyses (see Maneb DCI Notice for Storage Stability Data for details of this requirement).

Green Snap Beans

Fresh green whole snap beans were commercially processed following application of Maneb 80% WP to beans in California at 3.2 lb (1X) and 6.4 lb (2X) ai/A with a 7-day PHI.

All of the green whole snap beans used in these processing studies were derived from one field trial conducted in Porterville, California. Samples were held in frozen storage for an unspecified period of time prior to processing. Cooked/frozen green beans were graded, washed, and steam blanched at 205 to 212 °F (3 minutes) prior to freezing. Cooked/canned green beans were graded, washed, steam blanched at 205 to 212 °F (3 minutes), salt and sugar added at 200 °F, cans sealed at 180 °F, retorted at 240 °F for 25 minutes, and cooled in cold water to 95 to 105 °F. Cooked/pureed baby food was graded, washed, steam blanched at

205 to 212 °F (3 minutes), pureed, heated to 180 °F, canned, cans sealed at 180 °F, retorted at 240 °F for 25 minutes, and cooled to 95 to 105 °F.

Residue analyses of processed commodities are summarized below.

	<u># Samples</u>	<u>Avg. (ppm)</u>	<u>Range (ppm)</u>	<u>Avg. Conc./Reduc. Factor</u>	<u>Avg. % Conversion</u>
<u>Processed Subset 1</u> (1X and 2X Appl. Rate)					
Whole Beans					
Maneb	2	32.54	(19.89-45.19)	-	-
ETU	2	0.087	(0.057-0.117)	-	-
Cannery Waste					
Maneb	2	7.10	(5.15-9.05)	0.22	-
ETU	2	0.006	0.006	-	-
Cooked/Frozen					
Maneb	2	0.853	(0.537-1.170)	0.03	-
ETU	2	0.233	(0.139-0.328)	-	0.45
<u>Processed Subset 2</u> (1X Appl. Rate)					
Whole Beans					
Maneb	1	19.89	19.89	-	-
ETU	1	0.057	0.057	-	-
Cooked/Canned					
Maneb	1	0.038	0.038	0.002	-
ETU	1	0.145	0.145	-	0.44
Cooked/Pureed (Baby Food)					
Maneb	1	0.060	0.060	0.003	-
ETU	1	0.391	0.391	-	1.68

Discussion of Bean Processing Study

The calculations for average concentration/reduction of maneb and ETU in cannery waste and cooked frozen beans and percent conversion of maneb to ETU in cooked frozen beans were derived from whole bean samples (2) in Processed Subset 1.

These same calculations applied to cooked/canned beans and cooked/pureed beans (baby food) derived from whole bean sample (1) in Processed Subset 2.

Overall, cooking increases the formation of ETU in this commodity, with the degree of ETU formation generally proportional to the extent and duration of cooking/processing as evidenced by the highest ETU conversion percentage (1.68) for the extensively processed and cooked pureed baby food.

Due to the limited number of processed samples in this study together with the lack of information on storage stability studies and sample history, RCB concludes that for the purpose of residue assessment the green bean processing study should be repeated. To validate the repeated green bean processing study, frozen storage stability data for both maneb and ETU are needed at the approximate time intervals that these processed commodities are held in frozen storage prior to analyses (see Maneb DCI Notice for Storage Stability Data for details of this requirement).

Grapes

Grapes were commercially processed following application of Maneb 80% WP to grapes in California at 4.0 lb (1X) and 8.0 lb (2X) ai/A with a 7-day PHI. The grape samples used in these processing studies were derived from field trials conducted at two locations: Terra Bella and Porterville, CA. Grapes from these locations were frozen prior to processing; however, no storage stability or sample history data were provided. The grapes were thawed and juiced in a commercial-type juicer, separating the juice from the wet pomace. The wet pomace was then split into two subsamples. One was bagged, labeled as wet pomace, and refrozen. The other was weighed and dried to 8 percent moisture, bagged, labeled as dry pomace, and refrozen until analysis.

Residue analyses of processed commodities are summarized below.

	<u>#</u> <u>Samples</u>	<u>Avg.</u> <u>(ppm)</u>	<u>Range</u> <u>(ppm)</u>	<u>Avg.</u> <u>Conc./Reduc.</u> <u>Factor</u>	<u>Avg.</u> <u>% Conversion</u>
<u>Processed Subset 1</u>					
(1X and 2X Appl. Rate)					
Terra Bella, Porterville, CA					
Whole Fruit					
Maneb	4	11.633	(1.584-30.118)	-	-
ETU	4	0.008	(< 0.010-0.016)	-	-
Wet Pomace					
Maneb	4	16.865	(1.926-49.862)	1.45	-
ETU	4	0.015	(< 0.020-0.028)	-	0.06
Dry Pomace					
Maneb	4	77.954	(3.545-236.742)	6.70	-
ETU	4	0.200	(< 0.020-0.551)	-	1.65
Fresh Juice					
Maneb	4	22.654	(4.389-75.705)	1.95	-
ETU	4	0.020	(< 0.010-0.064)	-	0.10
<u>Processed Subset 2</u>					
(2X Appl. Rate)					
Terra Bella, CA					
Whole Fruit					
Maneb	1	3.139	3.139	-	-
ETU	1	< 0.010	< 0.010	-	-
Raisins					
Maneb	1	5.939	5.939	1.9	-
ETU	1	0.021	0.021	-	0.67
Raisin Waste					
Maneb	1	7.828	7.828	2.5	-
ETU	1	< 0.020	< 0.020	-	0

Discussion of Grape Processing Study

The calculations for average concentration/reduction of maneb and percent conversion of maneb to ETU in wet and dry pomace were derived from the whole fruit samples (4) in Processed Subset 1. These same calculations applied to raisins and raisin waste were derived from the whole fruit sample (1) in Processed Subset 2.

Due to the limited number of processed samples in this study together with the lack of information on storage stability studies and sample history, RCB concludes that for the purpose of residue assessment the grape processing study should be repeated. To validate the repeated grape processing study, frozen storage stability data for both maneb and ETU are needed at the approximate time intervals that these processed commodities are held in frozen storage prior to analyses (see Maneb DCI Notice for Storage Stability Data for details of this requirement).

Potatoes

Potatoes were commercially processed following application of Maneb 80% WP to potatoes in California and Washington at 1.6 lb (1X) and 3.2 lb (2X) ai/A with a 7-day PHI. Although potato samples were obtained from three locations: Porterville, CA, Bakersfield, CA, and Wenatchee, WA, only the potato samples from Bakersfield, CA were used in the processing studies. No storage stability or sample history data were provided for these samples. Potatoes processed into potato flakes were washed, steam peeled, scrubbed, trimmed, sliced, spray washed to remove starch at 120 to 130 °F, precooked at 160 to 165 °F for 20 minutes, steam cooked at 202 to 212 °F for 45 minutes, then dried to 7 percent moisture content in a drum dryer at 100 to 125 psi steam (335 to 350 °F). Additives such as sodium bisulfite, sodium acid pyrophosphate, and citrus acid were added. Potatoes processed into chips were washed, abrasion peeled, trimmed, sliced, washed to remove starch at 120 to 130 °F, fried at 185 °C for 60 to 70 seconds in vegetable oil, then deoiled and salted to 2 to 3 percent moisture content. Residue analyses of processed commodities are summarized below.

		<u>#</u>	<u>Avg.</u>	<u>Range</u>	<u>Avg.</u>	<u>Avg.</u>
		<u>Samples</u>	<u>(ppm)</u>	<u>(ppm)</u>	<u>Conc./Reduc.</u>	<u>% Conversion</u>
					<u>Factor</u>	
Bakersfield, CA						
(1X and 2X Appl. Rate)						
Fresh Potatoes	Maneb	2	0.052	(< 0.050-0.079)	-	
	ETU	2	< 0.010	< 0.010		-
Cooked/Boiled Dehydrated (Flakes)	Maneb	2	< 0.050	< 0.050	< 1	
	ETU	2	0.157	(0.142-0.172)	-	> 100
Cooked/Fried Dehydrated (Chips)	Maneb	2	< 0.050	< 0.050	< 1	-
	ETU	2	0.169	(0.096-0.242)	-	> 100

Discussion of Potato Processing Study

The calculations for average concentration/reduction of maneb and percent conversion of maneb to ETU in both cooked/boiled/dehydrated (flakes) and cooked/fried/dehydrated (chips) were derived from fresh potato samples in the Bakersfield, CA trial.

This processing study was conducted on fresh potato samples containing essentially no detectable residues of either maneb or ETU. Nevertheless, more ETU was generated in processed potato flakes and chips than could have been converted from the original maneb present on the fresh potatoes (i.e. > 100% conversion).

The Maneb Task Force did not discuss the results obtained in the study report or the possibility of sample contamination or analytical error.

For the above reasons and additionally due to the limited number of processed samples in this study together with the lack of information on storage stability studies and sample history, RCB concludes that for the purpose of residue assessment the potato processing study should be repeated. To validate the repeated potato processing study, frozen storage stability data for both maneb and ETU are needed at the approximate time intervals that these processed commodities are held in frozen storage prior to analysis (see Maneb DCI Notice for Storage Stability Data for details of this requirement).

Tomatoes

Tomatoes were commercially processed following application of Maneb 80% WP in California at 2.4 lb (1X) and 4.8 lb (2X) ai/A with a 5-day PHI. The fresh tomato samples used in those processing studies were derived from field trials conducted at three locations: King City, Porterville, and Lost Hills, CA. Tomato samples from the King City and Lost Hills locations were previously frozen; therefore, the fresh tomatoes were not washed prior to processing into wet and dry pomace and fresh juice. Additional fresh tomatoes from the Porterville, CA location were washed prior to processing into wet and dry pomace, peeled tomatoes, and various canned products such as stewed, puree, juice, sauce, paste, and catsup. Samples were held in frozen storage for an unspecified period of time prior to processing and no storage stability data were provided. Fresh tomatoes processed into fresh juice and wet and dry pomace are normally washed first in water at 130 °F for 3 minutes prior to rinsing, sorting, trimming, crushing to separate the juice from the pulp and

the pulp dried to 8 percent moisture for dry pomace. Fresh tomatoes processed into canned stewed tomatoes were washed, rinsed, sorted, trimmed, peeled (live steam at 208 to 220 °F for 30 seconds) then stewed and canned at 194 °F. For canned puree tomatoes (10% solids), peeled tomatoes are pulped, pureed at 140 °F and canned at 190 °F. Canned tomato paste is prepared from puree by cooking at 140 °F and canning at 194 °F. Canned tomato juice (6.2% solids), is prepared from puree by heating at 140 °F with added salt and sorbic acid, canning at 194 °F, and retorting with steam at 212 °F for 15 to 20 minutes. Canned tomato sauce is prepared from puree by cooking at 140 °F with added salt, sugar, onions, garlic, and spices, canning at 194 °F, and retorting with steam at 212 °F for 15 to 20 minutes. Catsup is prepared from puree by adding sugar, salt, vinegar, onions, cloves, cinnamon, allspice, cayenne, and garlic, pressure cooking at 90 to 120 psi (33% solids) and canning at 194 °F.

Residue analyses of processed commodities are summarized below.

	<u>#</u> <u>Samples</u>	<u>Avg.</u> <u>(ppm)</u>	<u>Range</u> <u>(ppm)</u>	<u>Avg.</u> <u>Conc./Reduc.</u> <u>Factor</u>	<u>Avg.</u> <u>% Conversion</u>
<u>Processed Subset 1</u>					
(1X and 2X Appl. Rate)					
King City, Lost Hills, California					
Fresh Tomatoes (Unwashed)					
Maneb	4	3.714	(1.805-7.687)	-	-
ETU	4	0.035	(0.002-0.005)	-	-
Wet Pomace					
Maneb	4	2.171	(0.927-5.651)	0.6	-
ETU	4	< 0.02	< 0.02	-	0
Dry Pomace					
Maneb	4	7.595	(2.453-18.450)	2.0	-
ETU	4	0.031	(0.001-0.059)	-	0.74
Fresh Juice					
Maneb	4	6.697	(3.682-9.340)	1.8	-
ETU	4	0.011	(0.005-0.016)	-	0.20

	<u>#</u> <u>Samples</u>	<u>Avg.</u> <u>(ppm)</u>	<u>Range</u> <u>(ppm)</u>	<u>Avg.</u> <u>Conc./Reduc.</u> <u>Factor</u>	<u>Avg.</u> <u>% Conversion</u>
<u>Processed Subset 2</u>					
(1X and 2X Appl. Rate)					
Porterville, California					
Fresh Tomatoes					
(Unwashed)					
Maneb	2	3.168	(1.919-4.418)	-	-
ETU	2	0.0045	(0.004-0.005)	-	-
Fresh Tomatoes					
(Washed)					
Maneb	1	0.146	0.146	0.05	-
ETU	1	0.004	0.004	-	0
Wet Pomace					
Maneb	2	0.038	(< 0.05-0.051)	0.01	-
ETU	2	< 0.02	< 0.02	-	0
Dry Pomace					
Maneb	2	< 0.05	< 0.05	< 0.01	-
ETU	2	0.02	(< 0.02-0.029)	-	0.49
Fresh Tomatoes					
(Peeled)					
Maneb	1	0.017	0.017	0.01	-
ETU	1	0.004	0.004	-	0
Canned/Stewed Tomatoes					
(Cooked)					
Maneb	1	< 0.05	< 0.05	< 0.01	-
ETU	1	0.016	0.016	-	0.63
Canned/Puree Tomatoes					
(Cooked)					
Maneb	2	< 0.05	< 0.05	< 0.01	-
ETU	2	0.074	(0.050-0.098)	-	2.19
Canned Tomato Juice					
(Cooked)					
Maneb	2	< 0.05	< 0.05	< 0.01	-
ETU	2	0.030	(0.006-0.054)	-	0.80
Canned Tomato Sauce					
(Cooked)					
Maneb	1	< 0.05	< 0.05	< 0.01	-
ETU	1	0.047	0.047	-	2.24

	<u>#</u> <u>Samples</u>	<u>Avg.</u> <u>(ppm)</u>	<u>Range</u> <u>(ppm)</u>	<u>Avg.</u> <u>Conc./Reduc.</u> <u>Factor</u>	<u>Avg.</u> <u>% Conversion</u>
<u>Processed Subset 2</u>					
(1X and 2X Appl. Rate)					
(cont'd)					
Canned Tomato Paste					
(Cooked)					
Maneb	1	< 0.05	< 0.05	< 0.01	-
ETU	1	0.075	0.075	-	3.70
Canned Tomato Catsup					
(Cooked)					
Maneb	2	< 0.05	< 0.05	< 0.01	-
ETU	2	0.078	(0.065-0.091)	-	2.32

Discussion of Tomato Processing Study

The calculations for average concentration/reduction of maneb and percent conversion of maneb to ETU in wet and dry pomace and fresh juice were derived from fresh tomatoes (4) in Processed Subset 1. These same calculations applied to peeled tomatoes, cooked/canned stewed tomatoes, cooked/canned puree tomatoes, cooked/canned tomato juice, cooked/canned tomato sauce, cooked/canned tomato paste, and cooked/canned tomato catsup derived from fresh tomato samples (2) in Processed Subset 2.

Based on the very limited data presented, it appears that maneb is removed from tomatoes by washing followed by peeling, and cooking and processing of tomatoes may cause additional reduction of maneb residues. Overall, the degree of ETU generation from maneb is generally proportional to the extent and duration of cooking/processing as evidenced by the highest conversion rates for the highly processed canned and cooked puree, sauce, catsup, and paste.

Due to the limited number of processed samples in this study together with the lack of information on storage stability studies and sample history, RCB concludes that for the purpose of residue assessment that the tomato processing study should be repeated. To validate the repeated tomato processing study, frozen storage stability data for both maneb and ETU are needed at the approximate time intervals that these processed commodities are held in frozen storage prior to analyses (see Maneb DCI Notice for Storage Stability Data for details of this requirement).

Meat, Milk, Poultry and Eggs

There are no established or proposed tolerances for residues of maneb per se in meat, milk, poultry, and eggs.

Meat and MilkPreviously Submitted Feeding Studies

E.I. du Pont de Nemours and Company (PP#5F0439) submitted a study in which eight dairy cows, in two treatments, were fed maneb in a grain concentrate hay diet at levels of 0, 25, 50, and 100 ppm (w/w) for 30 days. Cows in each treatment group were sacrificed on the first or seventh day after treatment. Following dosing of cows with 100 ppm maneb, residues in milk samples were quantified. The milk sampling procedure used was not described. Average residues of maneb from eight milk samples from animals in the 25 and 30 ppm treatment group were ≤ 0.05 ppm. Nine milk samples from animals in the 100 ppm treatment group contained ≤ 0.05 to 0.14 ppm. An aberrant value in the data was noted as possible contamination but was not reported. Control milk samples contained ≤ 0.05 ppm. Maneb residues in milk declined from 0.09 ppm on the final day of feeding to 0.06 and ≤ 0.05 ppm by 24 and 44 to 116 hours posttreatment, respectively. Residues in lean muscle, subcutaneous fat, and kidney from cows sacrificed 1 day posttreatment in the 50 and 100 ppm treatment groups and one cow sacrificed 7 days posttreatment at the 100 ppm level were ≤ 0.20 ppm. Residues in the liver of one cow treated with 100 ppm and sacrificed 1 day posttreatment were 0.2 ppm. A CS₂ method developed by Pease (1957, JAOAC 40:1113-1118) was used to determine all residues. No limit of detection was provided for any of the tissues tested. Recovery efficiencies for milk were 44 to 63 percent at fortifications of 0.0475 to 0.2835 ppm. Recovery efficiencies for meat tissues were 54 to 66 percent at fortifications of 0.176 to 0.744 ppm.

Rohm & Haas Company submitted data reflecting maneb residues in tissues of dairy cattle following a 30-day feeding trial. Doses of the 80% WP formulation were encapsulated and administered to the animals by stomach intubation using a bolus gun. Treatment levels were 0, 5, 15, and 45 ppm of maneb per day based on total feed provided each animal. One cow was treated at each dose level. On the twentieth day of the feeding trial, the cow treated with 45 ppm of maneb per day collapsed and died. This cow was necropsied, and tissue samples were taken and analyzed for maneb residues. Uncorrected residues were < 0.016 ppm (nondetectable) in one sample of tongue, brain, striated and smooth muscle, and fat and two kidney samples. The following residues were detected in

tissues from animals treated at 5 and 15 ppm maneb, respectively, and sacrificed 30 days posttreatment: 0.022 and 0.042 ppm in liver, and 0.010 and 0.023 ppm in kidney. Control residues were < 0.01 ppm (nondetectable) in three liver and kidney samples. Other tissues (e.g., muscle, fat, brain) from the 5 and 15 ppm treated animals were not analyzed because no detectable residues were found in these tissues from the cow treated at 45 ppm per day. Unidentified colorimetric methods were used to determine maneb residues in milk and tissues. The respective limits of detection were 0.01 and 0.016 ppm. Recoveries were 75 to 150 percent (103.1 + 20.6 average + standard deviation) from 14 samples of milk fortified with maneb at 1.6 to 32 mmg. Recoveries were 95 to 116.8 percent from 16 samples including the liver, kidney, smooth muscle, striated muscle, tongue, fat, and brain fortified with maneb at 2.4 to 16.0 ppm. Milk samples in this trial were collected, frozen, and analyzed, but data are not discussed since only raw absorbance values were provided.

New Feeding Study Submitted August 29, 1986, Accession No. 263912

Protocol

Lactating dairy cattle were dosed with DITHANE® Special, M-22 with zinc (80% maneb). The daily doses were given in gelatin capsules by gavage. Dose levels included the equivalent to 10, 30, and 100 ppm maneb in the diet. Control animals were given empty capsules. Samples of milk, urine, and feces were collected periodically. Dosing continued for 28 days. After 28 days, dosing was discontinued, and two control animals and three animals from each of the dose groups were sacrificed. Samples of liver, kidney, muscle, and fat were collected for analysis. The remaining animals (one control and three 100 ppm animals) were held for a 7-day withdrawal period. These last four were then sacrificed, and the same tissues were collected for analysis.

Analytical Methods

Maneb

A modified procedure of Keppel (1971, JAOAC 54:528-532), was used to determine maneb residues in animal tissues, urine, feces, milk, fat, and eggs. In this method "Determination of Maneb and/or CS₂ Generators by Carbon Disulfide Evolution Method" Hazleton Laboratories America, Inc. method TR 36F-82-14, maneb is quantitatively decomposed to carbon disulfide (CS₂) by refluxing the sample in dilute hydrochloric acid in the presence of stannous chloride. The liberated CS₂ was swept by an air stream through a series of purification traps and was absorbed in ethanol at the temperature of dry ice. The

CS₂ was measured by gas chromatography (GC) using a flame photometric detector in the sulfur mode.

At overall fortification levels of 0.02 to 1.25 ppm, average recoveries and limits of detection, respectively, for maneb in liver, kidney, milk, muscle, heart, fat, and thyroid were: (100%, 0.066 ppm), (94%, 0.25 ppm), (95%, 0.02 ppm), (97%, 0.05 ppm), (92%, 0.05 ppm), (95%, 0.05 ppm), and (95% 0.25 ppm).

ETU

Method TR 36F-82-15 entitled "An Analytical Method for Determining ETU in Chicken Tissues, Eggs, and Excreta" (Hazleton Laboratories America, Inc.), was used to determine ETU residues in animal tissues, urine, feces, milk, fat, and eggs.

The ETU content in this method is determined by extracting an aliquot of the sample with methanol. After filtration, an aliquot of the extract was cleaned by eluting it through a column of three sections: silicic acid (top section), Florisil, and alumina. The collected effluent was held at the dry ice and acetone temperature for 5 minutes and further purified by filtering it through a 0.5 μ Millipore[®] membrane. After evaporation of the filtrate, the ETU content is derivatized with 1-bromobutane in the presence of dimethylformamide and sodium borohydride. The resulting s-butyl derivative is measured by GC using a flame photometric detector in the sulfur mode.

At overall fortification levels of 0.008 to 0.080 ppm, average recoveries and limits of detection, respectively, for ETU in liver, kidney, milk, muscle, and fat were: (102%, 0.016 ppm), (110%, 0.008 ppm), (93%, 0.008 ppm), (81%, 0.008 ppm) and (92%, 0.008 ppm).

Residues in Milk

Residues of maneb and ETU in milk did not differ significantly from control values at both the 10 and 30 ppm dosages for maneb and at the 10 ppm dosage for ETU. At the 100 ppm dosage level maneb reached a peak residue of 0.156 ppm at day 7 of treatment. At the 30 ppm dosage level ETU reached a peak residue of 0.017 ppm at day 27 of treatment. At the 100 ppm dosage level, ETU reached a peak residue of 0.109 ppm at day 17 of treatment. During a 7-day withdrawal period, average ETU residues in milk at day 27 (0.063 ppm) declined to < 0.008 ppm.

Residues in TissueManeb

Residues of maneb in liver averaged 0.12, < 0.07, and 0.19 ppm at the 10, 30, and 100 ppm feeding levels. Residues in control liver were higher than the 30 ppm group. For kidney; 0, 0.11, and 0.08 ppm, respectively; muscle, 0.01, 0.02, and 0.06 ppm, respectively; heart, < 0.01, < 0.01, and < 0.01 ppm, respectively; thyroid, < 0.25, 0.45, and < 0.25 ppm, respectively; renal fat, 0.08, 0.09, and 0.10 ppm, respectively; and omental fat, 0.05, 0.08, and 0.04 ppm, respectively.

ETU

Comparable residues of ETU in liver were: < 0.016, 0.025, and 0.056 ppm; kidney, < 0.008, 0.008, and 0.053 ppm; muscle, < 0.008, 0.01, and 0.025 ppm; and fat, < 0.008, < 0.008, and 0.008 ppm. Thyroid tissues was not examined for ETU.

Cattle feed items for which residue data are available and for which no feeding restriction exists are apple pomace, green bean cannery waste, dry grape pomace, raisin waste, cull potatoes, sugar beet leaves, sweet corn cannery waste and dry tomato pomace. A typical diet utilizing these feed items for beef and dairy cattle would be as follows:

<u>Beef Cattle</u>	<u>% in Diet</u>	<u>Mean Residue (ppm) Maneb</u>	<u>Dietary Burden (ppm) Maneb</u>
Apple pomace (dry)	50	53.4	26.7
Sugar beet leaves	20	11.6	2.3
Raisin waste	10	29.8	3.0
Other feeds	20	--	--

Total = 32.0

Dairy Cattle

Apple pomace (dry)	25	53.4	13.4
Sugar beet leaves	20	11.6	2.3
Green bean cannery waste	20	1.1	0.2
Raisin waste	10	29.8	3.0
Other feeds	25	--	--

Total = 18.9

The mean residue for maneb was used because the cattle of a grower whose crops are all treated with maneb and whose livestock are fed with these treated items consume only plant products from that particular farm.

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

	<u>Maneb</u>	ppm	<u>ETU</u>
Milk	0.01		0.01
Liver	0.13		0.025
Muscle	0.02		0.01
Kidney	0.11		0.008
Fat	0.08		0.004
Thyroid	0.45		ND

ND = Not analyzed.

Poultry and Eggs

Previously Submitted Feeding Studies

Rohm & Haas Company submitted a study in which White Leghorn chickens (10 per treatment level) were fed maneb at levels of 0, 5, 15, and 45 ppm (w/w) for 28 days. Residue data were collected from eggs (albumen and yolk), muscle, gizzard, heart, and liver. Approximately four eggs were collected daily for each treatment group during the final 2 weeks of the experiment, although 38 samples were lost before analysis. Residues of maneb, corrected for apparent residues in controls, were nondetectable (≤ 0.01 ppm) in 148 albumen and yolk samples. Control values in 36 albumen and yolk samples were nondetectable (the limit of detection was unspecified): 0.03 ppm, and nondetectable (the limit of detection was unspecified): 0.04 ppm, respectively. Corrected residues in 10 muscle samples, 7 gizzard samples, 5 heart samples, and 6 liver samples were nondetectable (limit of detection was unspecified). Residues on 13 unspecified control tissues were 0.04 to 0.11 ppm. An adequate colorimetric method was used to determine maneb residues as CS_2 . Recovery efficiency from four albumen and yolk samples collected daily for 8 days (32 total) were 78 to 104 percent and 76 to 98 percent, respectively; recoveries from 14 unspecified meat tissue samples were 71 to 105 percent. Fortification levels were not provided. All recoveries were corrected for apparent residues. Egg samples were stored for 2 weeks at 13 °C prior to analysis. At 1 day posttreatment, animals were sacrificed and meat tissues collected, separated, and promptly frozen. Limits of detection were not clearly defined.

New Feeding Study Submitted August 29, 1986, Accession No. 263911Protocol

Single-comb White Leghorn laying hens were dosed with DITHANE Special M-22 with zinc (80% maneb). The daily doses were given in gelatin capsules. Dose levels included the equivalent of 10, 30, and 100 ppm maneb in the diet. Control animals were given empty capsules. Egg samples were collected periodically. Dosing continued for 28 days. After 28 days, dosing was discontinued, and five control animals and five or ten animals from each of the dose groups were sacrificed. Samples of liver, kidney, abdominal fat, heart, and muscle were collected for analysis. The remaining animals (five control and five 100 ppm animals) were held for a 7-day withdrawal period. These remaining animals were then sacrificed and the same tissues collected for analysis.

Analytical MethodsManeb

Same method utilized as described above under Meat and Milk.

At overall fortification levels of 0.02 to 1.25 ppm, average recoveries and limits of detection, respectively, for maneb in muscle, liver, heart, kidney, fat, whole egg, egg white, and egg yolk were: (99%, 0.05 ppm), (96%, 0.066 ppm), (92%, 0.05 ppm), (109%, 0.25 ppm), (104%, 0.05 ppm), (84%, 0.02 ppm), (91%, 0.02 ppm), and (98%, 0.02 ppm).

ETU

Same method utilized as described above under Meat and Milk.

At overall fortification levels of 0.008 to 0.080 ppm, average recoveries and limits of detection, respectively, for ETU in muscle, liver, kidney, fat, and whole egg were: (78%, 0.008 ppm); (91%, 0.016 ppm); (94%, 0.008 ppm); (80%, 0.008 ppm); and (96%, 0.008 ppm).

Residues in Eggs

Residues of maneb in whole eggs did not differ significantly from control values at both the 10 and 30 ppm dosage levels. At the 100 ppm dosage level, maneb reached a peak residue of 0.072 ppm at day 4 of treatment. Residues of maneb in egg yolk did not differ significantly from control values at the 10 ppm dosage level. At the 30 and 100 ppm dosage level,

maneb reached a peak residue of 0.262 and 0.186 ppm at day 6, respectively.

Residues of maneb in egg white did not differ significantly from controls at both the 10 and 30 ppm dosage levels. At the 100 ppm dosage level, maneb reached a peak residue of 0.048 ppm at day 20 of treatment. Residues of ETU in whole eggs did not differ significantly from control values at the 10 ppm dosage level. At the 30 and 100 ppm dosage level, residues of ETU peaked at (0.019 ppm; 2 days of treatment) and (0.060 ppm; 7 days of treatment), respectively. Residues of ETU in both egg yolk and egg white were not determined.

Residues in Tissue

Maneb

Residues of maneb in heart tissue did not differ significantly from controls at all treatment levels and in liver and kidney at the 10 ppm treatment level. Residues in liver averaged 0.214 and 0.102 ppm at the 30 and 100 ppm feeding levels and in kidney 0.068 and 0.349 ppm, respectively. Residues in abdominal fat averaged 0.284, 0.378, and 0.265 ppm at the 10, 30, and 100 ppm treatment levels and for muscle were 0.013, 0.048, and 0.131 ppm, respectively.

ETU

Residues of ETU in fat did not differ significantly from controls at all treatment levels. Residues in liver averaged 0.009, 0.037, and 0.081 ppm at the 10, 30, and 100 ppm treatment levels. For muscle: 0.010, 0.012, and 0.038 ppm, respectively, and kidney, 0.009, 0.027, and 0.060 ppm, respectively.

Poultry feed items for which residue data are available and for which no feeding restriction exists are apple pomace, grape pomace, cull potatoes, and wet tomato pomace. A typical diet utilizing these feed items for poultry would be as follows:

<u>Poultry</u>	<u>% in Diet</u>	<u>Mean Residue (ppm) Maneb</u>	<u>Dietary Burden (ppm) Maneb</u>
Cull potatoes	20	< 0.1	0.01
Apple pomace (dry)	5	53.4	2.7
Grape pomace (dry)	5	52.5	2.6
Tomato pomace (wet)	2	2.1	0.04
Other feed items	68		

Total = 5.35

The mean residue for maneb was used because poultry of a grower whose crops are all treated with maneb and whose poultry are fed with these treated items consume only plant products from that particular farm.

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

	ppm	
	<u>Maneb</u>	<u>ETU</u>
Whole eggs	< 0.02	< 0.008
Egg yolk	< 0.02	ND
Egg white	< 0.02	ND
Liver	< 0.066	0.008
Kidney	< 0.25	0.008
Muscle*	0.01	0.008
Heart	< 0.05	ND
Fat	0.15	< 0.008

 ND = Not analyzed.

* = 50% breast, 50% thigh.

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

RCB cannot arrive at a final conclusion regarding the adequacy of the submitted dairy cattle and poultry feeding studies to assess secondary residues of maneb and ETU in meat, milk, poultry, and eggs in the absence of frozen storage stability data for these commodities. In the dairy cattle study, milk, muscle, fat, (kidney, thyroid, and heart) analyzed for maneb were held in frozen storage for up to 28, 57, 22, and 22 days, respectively, and when analyzed for ETU were held in frozen storage at (43 to 77), (70 to 77), (79 to 86), and (72 to 84) days, respectively. Liver was held for ETU analysis for 93 to 100 days. In the poultry study, whole eggs (including egg whites and yolks), heart, liver, kidney, muscle, and fat analyzed for maneb were held in frozen storage for up to 4 weeks prior to analysis. Egg and tissue samples were held in frozen storage for 2 to 2 1/2 months and 3 months, respectively, prior to ETU analysis. Therefore, to validate both the dairy cattle and poultry feeding studies, frozen storage stability data for both maneb and ETU are needed for the approximate time that these animal commodities were held in frozen storage prior to analyses (see Maneb DCI Notice for Storage Stability Data for details of this requirement). Depending upon the outcome of the requested frozen storage stability studies, additional dairy cattle and poultry feeding studies may be needed.

Until adequate storage stability data are provided, the residue levels on animal commodities discussed in this review should be regarded as minimum estimates. Residue levels could be much higher if residues decayed significantly in storage.

A complete residue assessment regarding secondary residues of maneb and ETU in meat, milk, poultry, and eggs cannot be made in the absence of a sugar beet processing study to ascertain the transfer of maneb and ETU residues to dehydrated sugar beet pulp and sugar beet molasses.

Conclusions

Field Residue Data

1. For the purpose of this residue assessment, RCB considers the residues of concern to include the parent compound maneb plus its metabolite/degradation product ETU. Accordingly, ETU residue data are available only for the following crops: almonds, bananas, beans (dry, snap, lima), cabbage, cantaloupe, cucumbers, grapes, lettuce (leaf and head), potatoes, sugar beets, sweet corn, tomatoes, and apples. No ETU residue assessment estimate can therefore be made for the remaining RAC's for which maneb is registered for use and for which no ETU residue data are available.
2. Of the aforementioned RAC's no sample history information or sample storage information are provided for cucumbers, apples grown in Michigan, New York, and Pennsylvania, or tomatoes grown in Florida, Indiana, and Michigan. The following RAC's were stored under unspecified conditions at the following intervals prior to analysis: bananas (2 months), beans (3 1/2 to 7 months) cabbage (1 to 4 1/2 months), head lettuce - Florida, leaf lettuce - Michigan and New York (7 to 10 1/2 months), and sugar beets (3 1/2 to 7 months). The following RAC's were stored under frozen conditions at the following intervals prior to analysis: almonds (128 to 195 days), cantaloupe (4 months), grapes (4 1/2 to 6 1/2 months), head lettuce - California (4 to 6 months), leaf lettuce - California (6 months), potatoes (3 to 5 months), sweet corn (3 to 8 1/2 months), tomatoes - California (4 to 6 months), and apples - California (205 days).
3. The Maneb Task Force has submitted unacceptable storage stability data (see RCB's M.F. Kovacs Jr., January 21, 1987, memorandum re: The Maneb Task Force's submitted frozen storage stability data) which cannot be used to validate the residue data on the 13 crops that the registrant shows present concern for. In fact, in the aforementioned memorandum RCB recommended that:

"Residue data previously submitted on 13 crops which were held in frozen storage for varying periods of time are invalid since many of the field treated samples were

macerated and stored under the same conditions that resulted in extensive decomposition in the submitted storage stability samples. Accordingly, new field trials generating the appropriate data are necessary for these same 13 crops."

4. Until adequate storage stability data are provided, the residue levels on RAC's discussed in this review should be regarded as minimum estimates. Residue levels could be much higher if residues decayed significantly in storage
5. The repeated residue studies must be validated with new frozen storage stability data for both maneb and ETU conducted on representative crops (see Maneb DCI Notice for Storage Stability Data for details of this requirement).
6. For each of the 13 crops described above, the Maneb Registration Standard concludes that the available residue data are inadequate to support the established tolerances for residues of maneb for various reasons including deficiencies related to the type of formulation used (WP vs. dust) or method of application (aerial vs. ground) and in the case of potatoes, sugar beet (roots and tops), cabbage, beans (succulent/dry), cucumbers, apples, sweet corn, and bananas lack of adequate geographical representation.

Processing Studies

1. Overall, for all processing studies submitted, a very limited number (1 to 6) samples for each processed commodity were analyzed for maneb and ETU. None of the processing studies provided complete documentation on dates of sample harvest, dates of shipment and subsequent processing of commodities, and how long or under what conditions processed samples were held prior to analysis. The following time intervals between sample harvest and when processed fractions were analyzed in the laboratory were calculated by the reviewer for the following frozen commodities: apples (8 to 11 1/2 months), beans (4 1/2 months), grapes (4 months), and tomatoes (6 months). Potatoes were held under unspecified storage conditions for 7 1/2 months between harvest and sample analysis.
2. Additional processing study-specific deficiencies are discussed under both the apple and potato processing studies.
3. For the reasons given in item 1 above and where applicable in item 2, RCB concludes that for the purpose of residue assessment the apple, green bean, grape, tomato, and potato processing studies should be repeated.
4. Until adequate storage stability data are provided, the residue levels on processed commodities discussed in this review should be regarded as minimum estimates. Residue levels could be much higher if residues decayed significantly in storage.

5. To validate these repeated processing studies frozen storage stability data for both maneb and ETU are needed for each processed commodity derived from the submitted processing studies at the approximate time intervals that these processed commodities are held in frozen storage prior to analysis (see Maneb DCI Notice for Storage Stability Data for details of this requirement).
6. Due to numerous data deficiencies cited in the submitted apple, potato, tomato, green bean, and grape processing studies, the Maneb Registration Standard concludes that additional processing studies are required for each of these commodities.
7. An additional processing study is also needed on sugar beets to ascertain the transfer of maneb and ETU residues to crystalline beet sugar and to the important livestock feed items dehydrated sugar beet pulp and sugar beet molasses.

Animal Feeding Studies

1. RCB cannot arrive at a final conclusion regarding the adequacy of the submitted dairy cattle and poultry feeding studies to assess secondary residues of maneb and ETU in meat, milk, poultry, and eggs in the absence of frozen storage stability data for these commodities.

In the dairy cattle study, milk, muscle, fat, (kidney, thyroid, and heart) analyzed for maneb were held in frozen storage for up to 28, 57, 22, and 22 days respectively and when analyzed for ETU were held in frozen storage at (43 to 77), (70 to 77), (79 to 86), and (72 to 84) days, respectively. Liver was held for ETU analysis for 93 to 100 days. In the poultry study, whole eggs (including egg whites and yolks), heart, liver, kidney, muscle and fat analyzed for maneb were held in frozen storage for up to 4 weeks prior to analysis. Egg and tissue samples were held in frozen storage for 2 to 2 1/2 months and 3 months, respectively, prior to ETU analysis. Therefore, to validate both the dairy cattle and poultry feeding studies, frozen storage stability data for both maneb and ETU are needed for the approximate time that these animal commodities were held in frozen storage prior to analyses (see Maneb DCI Notice for Storage Stability Data for details of this requirement). Depending upon the outcome of the requested frozen storage stability studies, additional dairy cattle and poultry feeding studies may be needed.

2. A complete residue assessment regarding secondary residues of maneb and ETU in meat, milk, poultry, and eggs cannot be made in the absence of a sugar beet processing study to ascertain the transfer of maneb and ETU residues to dehydrated sugar beet pulp and sugar beet molasses.

3. Until adequate storage stability data are provided, the residue levels on animal commodities discussed in this review should be regarded as minimum estimates. Residue levels could be much higher if residues decayed significantly in storage.

Recommendations

RCB recommends that the registrant read carefully the above conclusions, the Maneb DCI Notice for Storage Stability Data, and initiate the appropriate protocols to resolve all outstanding issues.

cc: Maneb S.F., R.F., Special Review S.F., Circu., M. Kovacs, TOX,
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