



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

APR 30 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Special Review Action Code 870 - Maneb Data Screen
for Apples and Processed Apples, Beans and Processed
Beans, Bananas and Processed Bananas, Potatoes and
Processed Potatoes, and Sugar Beets and Processed
Sugar Beets - MRID Nos. 401087-01 through 401087-05
[RCB No. 2123]

FROM: Martin F. Kovacs, Jr., Ph.D., Chemist
Tolerance Petition Section II
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J. Orley for

TO: Joan Warshawsky
Special Review Branch
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and

Henry F. Jacoby
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THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
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RCB has been asked by the DCI staff to screen/review
this EBDC data package for use in maneb reassessment per
NRDC/Data Call-In requirements.

RCB has screened the maneb and ethylene thiourea (ETU)
residue data contained in MRID Nos. 401087-01 through
401087-05.

Apples and Processed Apple Products (MRID No. 401087-01)

Included in this submission were:

1. ETU residue data on apples from previously submitted residue study MTF No. 85-41 from Michigan, dated April 18, 1986.
2. ETU residue data on apples from previously submitted residue study MTF No. 85-42 from New York, dated April 18, 1986.
3. Reanalysis of ETU residues in apples from previously submitted residue study MTF No. 85-43 from Pennsylvania, dated April 12, 1986.
4. Processed apple products study coordinated by Healy and Associates, Crown Point, Indiana on apples grown in Michigan during the 1985 growing season and dated February 2, 1987.

Beans and Processed Bean Products (MRID No. 401087-02)

Included in this submission were:

1. New maneb and ETU residue data on dry beans and bean hay from Michigan, MTF No. 85-06 dated April 18, 1986.
2. New maneb residue data on succulent beans and maneb and ETU residue data on bean hay from New York, MTF No. 85-07 dated April 18, 1986.
3. New maneb residue data on succulent beans and maneb and ETU residue data on bean hay from Wisconsin, MTF No. 85-08 dated April 18, 1986.
4. Processed bean products coordinated by Healy and Associates, Crown Point, Indiana on succulent beans grown in Wisconsin during the 1985 growing season and dated January 29, 1987.

Bananas and Processed Banana Products (MRID No. 401087-03)

Included in this submission were:

1. ETU residue data on whole bananas and banana pulp from previously submitted Honduras study MTF No. 85-51, dated January 28, 1987.

2. Maneb and ETU residue data on whole bananas and banana pulp from Costa Rica, MTF Nos. 86-52 through 86-56 dated January 28, 1987.
3. Processed banana products study coordinated by Healy and Associates, Crown Point, Indiana on bananas grown in Honduras and Costa Rica during the 1985 growing season and dated January 28, 1987.

Potatoes and Processed Potato Products (MRID No. 401087-04)

Included in this submission were:

1. ETU residue data on potatoes from previously submitted residue study MTF No. 85-16 from Maine, dated February 2, 1987.
2. ETU residue data on potatoes from previously submitted residue study MTF No. 85-17 from New York, dated February 2, 1987.
3. ETU residue data on potatoes from previously submitted residue study MTF No. 85-18 from Wisconsin, dated February 2, 1987.
4. Processed potato products study coordinated by Healy and Associates, Crown Point, Indiana on potatoes grown in Maine during the 1985 growing season and dated February 2, 1987.

Sugar Beets and Processed Sugar Beet Products (MRID No. 401087-05)

Included in this submission were:

1. ETU residue data on sugar beets from previously submitted residue study MTF No. 85-11 from Michigan, dated February 2, 1987.
2. ETU residue data on sugar beets from previously submitted residue study MTF No. 85-12 from Minnesota, dated February 2, 1987.
3. ETU residue data on sugar beets from previously submitted residue study MTF No. 85-13 from Nebraska, dated February 2, 1987.
4. Processed sugar beet products study coordinated by Healy and Associates, Crown Point, Indiana on sugar beets grown in Minnesota during the 1985 growing season and dated February 2, 1987.

Comments1. Apples and Processed Apple Products

Reanalyzed and/or additional ETU residue data obtained from previously submitted 1985 apple field trials (MI, NY, and PA) were not supported by sample storage information and frozen storage stability data reflecting the extended sample storage intervals reported. Sample harvest to analysis intervals ranged from 9 to 12 months.

Of the nine apple processed fractions (total samples 21) derived from the submitted apple processing study, some were held at room temperature, some were frozen, and some were held at room temperature and then frozen for total storage intervals of 8 to 9 months prior to residue analysis. Storage stability data to support these processed fraction storage conditions were not provided.

2. Beans and Processed Bean Products

New maneb and ETU residue data for dry beans and bean hay from a Michigan field trial and succulent beans and bean hay from New York and Wisconsin field trials were not supported by sample storage information and frozen storage stability data. Sample harvest to analysis intervals ranged up to 12 months.

The three bean processed fractions (total 6 samples) derived from the submitted bean processing study were held in a frozen condition following processing for approximately 9 1/2 months prior to residue analysis. Storage stability data to support these processed fraction storage conditions were not provided.

3. Bananas and Processed Banana Products

New maneb and ETU residue data for bananas and banana pulp from Costa Rica including new ETU residue data obtained from a previously submitted 1985 Honduras study were not supported by sample storage information and frozen storage stability data reflecting the extended sample storage intervals reported. Sample harvest to analysis intervals ranged up to 2 months.

The processed banana (baby food), total 2 samples, derived from the submitted banana processing study were held for 2 months under unspecified conditions

following processing them under an additional 2 1/2 months under frozen conditions for a total of 4 1/2 months prior to residue analysis. Storage stability data to support these processed fraction storage conditions were not provided.

4. Potatoes and Processed Potato Products

New ETU residue data on potatoes from previously submitted residue studies (ME, NY, and WI) were not supported by sample storage information and frozen storage stability data reflecting the extended sample storage intervals reported. Sample harvest to analysis intervals ranged up to 12 months.

The two potato processed fractions (total 6 samples) derived from the submitted potato processing study could have been held for a maximum of approximately 9 to 10 months in a frozen condition prior to residue analysis. Information on processing data or storage stability data to support these processed fraction storage conditions were not provided.

5. Sugar Beets and Processed Sugar Beet Products

New ETU residue data on sugar beets (roots only) from previously submitted residue studies (MI, MN, and NE) were not supported by sample storage information and frozen storage stability data reflecting the extended sample storage intervals reported. Sample harvest to analysis intervals ranged from 8 1/2 to 12 months. The three sugar beet processed fractions (total 6 samples) derived from the submitted sugar beet processing study did not reflect ETU analysis due to analytical methodology problems. In addition, processed samples were held for approximately 8 months prior to analysis under unspecified conditions and storage stability data were not provided.

Conclusions

1. The currently reanalyzed (apples) including new residue studies (apples, beans, bananas, potatoes, and sugar beets) are all deficient because none of the residue studies were supported by frozen storage stability data although residue samples obtained from these studies could have been held in frozen storage for up to 3 months for bananas and up to 12 months for apples, potatoes, beans, and sugar beets. Therefore, RCB concludes that the submitted residue data

are not even adequate for dietary exposure assessment, and thus do not pass the screen. These studies must be repeated to comply with the NRDC reassessment and DCI requirements.

2. All of the submitted processing studies for apples, bananas, beans, potatoes, and sugar beets were not supported by adequate sample storage information and/or frozen storage stability data; they are not even adequate for a dietary exposure assessment, and thus do not pass the screen. These studies must be repeated to comply with the NRDC reassessment and DCI requirements.
3. Although we have identified only the obvious deficiencies in this screen, additional data deficiencies for the currently submitted residue and processing studies may be noted upon completion of a full RCB review.

cc: W. Boodee, E. Zager, Reviewer: M. Kovacs, A. Barton: S.F.:
R.F.:Ellenberger:SRB/RD:PMSD/ISB, Circ.

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