PMSD/TSB

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

AUG 25 1988

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Maneb (014505) and Metiram (014601)
Registrant Compliance with the Storage Stability Data Call In Notice of 3/31/87
[No MRID No., No RCB No.]

FROM: Susan V. Hummel, Chemist
Special Registration Section II
Dietary Exposure Branch
Health Effects Division (TS-769C)

Susan V. Hummel

THRU: Edward Zager, Section Head
Special Registration Section II
Dietary Exposure Branch
Health Effects Division (TS-769C)

TO: Valerie Bael, PM#77
Special Review Branch
Special Review and Reregistration Division (TS-767C)

This memo discusses registrant compliance with the Maneb and Metiram Storage Stability Data Call In Notices of 3/31/87.

The Maneb Storage Stability Data Call In Notice of 3/31/87 required residue data on all crops having tolerances for maneb under 40 CFR 180.110. Process conversion residue studies were required for all processed fractions of apples, green beans, potatoes, tomatoes, grapes and sugar beets. New animal feeding studies were required. Storage stability data were required on four crops (apples, lettuce, spinach, and tomatoes); all processed commodities; and all meat/poultry commodities. Fortified storage stability studies were required. Additionally, storage stability data for weathered samples were required for the parent compound, maneb. All studies were required to be submitted by 3/1/88. Additional residue chemistry data were required by the Maneb Comprehensive Data Call In Notice of 4/1/87.

The Metiram Storage Stability Data Call In Notice of 3/31/87 required residue data on all crops having tolerances for metiram under 40 CFR 180.217 and 40 CFR 180.319. Process conversion studies were required for all processed fractions of apples and potatoes. No processing studies were required for tomato, sugar beet, or peanut processed commodities because BASF had previously indicated that they would not be supporting uses on

these crops. New animal feeding studies were required. Storage stability data were required on apples and potatoes; all processed commodities; and all meat/poultry commodities. Fortified storage stability studies were required. Storage stability data for weathered samples was required for the parent compound, metiram on apples and potatoes. Conversion in storage and process conversion data were required to measure conversion of metiram to ETU during frozen storage and processing. All studies were required to be submitted by 3/1/88. Additional residue chemistry data were required by the Metiram Comprehensive Data Call In Notice of 4/1/87.

CONCLUSIONS

In general, the residue chemistry data (residue data, storage stability data, and processing data) submitted by the registrants were supplied as required by the 3/31/87 DCI. Exceptions were that data were not supplied for all crops having tolerances or all processed commodities and some data were late.

The following deficiencies in the submitted residue data were noted.

For metiram, rac samples were stored for a longer period of time than any of the storage stability samples were stored.

For maneb, serious omissions were the lack of apple and potato processing studies, and failure to analyze the apple rac samples in a reasonable length of time, considering the known problem with storage stability of ETU in apples. Due to ETU instability, the apple study is invalid and will not be accepted as fulfilling the requirements of any other DCI.

The storage stability data showed that ETU was not stable in frozen storage. The results were variable, and found to be dependent on a number of factors discussed below. Because of the differences in the results obtained by the various registrants, we require storage stability studies for EBDC's and ETU conducted concurrently with residue analyses for each crop group, for each growing season, and for each laboratory conducting residue studies. Because of the variable results in the submitted storage stability studies, the residue data submitted by the registrants for the 3/31/87 DCI will not necessarily be accepted as fulfilling the requirements of any other DCI.

The residue data submitted in response to the Storage Stability Data Call In Notices of 3/31/87 were used to conduct a dietary exposure analysis because these data were the best available data. The data were not fully reviewed for compliance with the Comprehensive Data Call In Notices of 4/1/87, and will not necessarily be accepted for that purpose.

2

The Product Manager should be aware that the registrants did not meet the requirements of the 3c(2)(B) for the crops for which data were not provided, taking into account the translation of data from other commodities as described in the body of this memo (Maneb only), and any time extensions which have been granted.

Recommendations

The registrants of maneb and metiram should be informed of our conclusions and should receive a full copy of this memo, including the attachment. The Product Manager should be aware that the registrants did not meet the requirements of the 3c(2)(B) for the crops for which data were not provided, taking into account the translation of data from other commodities as described in the body of this memo (Maneb only), and any time extensions which have been granted.

Detailed Considerations

Variable Storage Stability

Differing results were obtained by the various registrants of the EBDC fungicides for the stability of ETU in frozen storage. It is obvious that ETU stability is dependent upon many factors, including the identity of the commodity, storage conditions, and sample handling, including analysis and analyst familiarity with the analytical methodology. We believe that the storage stability data submitted by each registrant reasonably reflect the storage conditions and sample handling done by that registrant (or contract laboratory conducting the study).

Maneb

For the studies conducted by Morse Laboratories under contract to Pennwalt or the Maneb Task Force for the 1987 growing season, we can conclude that maneb is reasonably stable in raw agricultural commodities for up to six months in frozen storage. ETU is stable in tomatoes, leafy vegetables, and root crops for up to three months in frozen storage. ETU residues in apples are stable for up to one month in frozen storage. Maneb and ETU are reasonably stable in processed commodities for up to three months in frozen storage. Most of the rac samples an processed commodity samples were analyzed within three months except apples (>6 months), sugar beets (4 months) and beans and corn (3-1/2 months). Due to ETU instability, the apple study is invalid and will not be accepted as fulfilling the requirements of any other DCI.

No maneb residue data were submitted for carrots, dry bulb onions, celery, rhubarb, apricots, peaches, nectarines, cranberries, almonds, asparagus, bananas, figs, and papayas. No

residue data were required by the 3/31/87 Special Review Data Call In Notice for corn forage and silage; the use on tobacco; or the seed, seed piece, and planting stock treatments on barley, corn, cotton, flax, oats, peanuts, pineapple, rice, rye, sorghum, soybeans, sunflowers, and wheat, since there are no tolerances to cover residues resulting from these uses. Residue data for turnips, turnip tops, endive, collards, mustard greens, kohlrabi, brussels sprouts, cauliflower, chinese cabbage, eggplant, squash, and pumpkin may be translated from other commodities as described in the 4/1/87 Comprehensive Data Call In Notice. No processing data were received for apple and potato processed fractions.

Metiram

For the studies conducted by Enviro-Bio-Tech under contract to BASF and the Metiram Task Force in the 1987 growing season, we can conclude that metiram is reasonably stable in raw agricultural commodities and processed apple and potato commodities frozen for up to three months. ETU is reasonably stable in apple processed commodities frozen for three months; and is unstable in raw agricultural commodities and potato processed commodities stored one month or less under the storage and analysis conditions used by the registrant (or contractor).

For metiram, all rac samples were stored longer than the ETU remains stable, thus, although the submitted studies were used to estimate dietary exposure, the studies submitted under the 3/31/87 DCI are invalid, and cannot be accepted as fulfilling the requirements of any other DCI. Additionally, the animal feeding studies are not supported by storage stability data, since the storage stability data were not conducted by the same laboratory conducting the feeding studies. These studies must be repeated.

Discussion

Although the 3/31/87 Storage Stability Data Call In Notice did not explicitly require residue data at the maximum rate, maximum number of applications, and the minimum PHI, these requirements are discussed in the Residue Chemistry Guidelines (Subdivision O, Pesticide Assessment Guidelines). Although not explicitly stated in the Data Call In Notice, residue data for different rates and PHI's are helpful for comparison purposes, and to determine dissipation of residues in the field. The Residue Chemistry Guidelines specify that data should be gathered from differing PHI's and that data on the decline of residues after harvest are also desirable.

Below, we have excerpted some relevant portions of the Residue Chemistry Guidelines and addenda, which should be emphasized to the registrants.

The Residue Chemistry Guidelines state the following on the

rate, mode, number, and timing of applications:

> Field experiments must reflect the proposed use with respect to the rate and mode of application, number and timing of applications, and formulations proposed. Because of differences observed in residue levels resulting from ultra low volume (ULV) and aerial applications, these too should be represented unless the proposed label specifically prohibits such application methods. The label should contain a restriction against the use on irrigated crops unless data are provided for crops grown under these conditions.

On geographical representation:

> Field trials should represent <u>all</u> of the principal growing regions of the crop as indicated in the USDA publication, <u>Agricultural Statistics</u>, and all of the seasonal variations. Several varieties should be represented. The number of field trials required is not specified in the Guidelines, although the Guidelines state that more important crops require more field trials and more toxic pesticides need more field trials.

On residue decline studies:

> Residue decline studies are also required. Samples from a single location should be harvested with differing PHI's to indicate residue decline. Data on the decline of residues after harvest are also desirable.

On storage stability data:

> Accepted procedure for maintaining sample integrity should be followed after taking the sample. Normally, samples should be kept frozen until analyzed. Information should be furnished on how samples are shipped and stored until analyzed. If samples are likely to be held in storage, storage stability data should be obtained by fortifying control samples, storing them under the same conditions as the treated samples, and analyzing at the end of the storage period. It is always advisable to have spiked storage stability samples available to allow for unforeseen delays in analysis of check samples should reanalysis be necessary to verify possibly aberrant results.

Residue Field Trials are also discussed in the Addendum to the Residue Chemistry Guidelines: Standard Evaluation procedure - Field trials (published 6/85):

> A sufficient number of field trials is needed. All types of applications must be represented: broadcast/soil/

aerial, concentrate/dilute/ULV. Studies must be conducted at the maximum rate and minimum PHI specified on the label. Generally several locations per geographical area are needed. Side by side field trials are needed for evaluation of ground vs. aerial and concentrate vs dilute vs ULV types of application.

Storage Stability data are also discussed in OPP's Position Document, "Effects of Storage (Storage Stability) on Validity of Pesticide Residue Data." August, 1987.

Samples used in storage stability studies should be stored exactly like the field incurred residue samples; e.g., same form of sample (whole, blended, or raw sample extract), in the same freezer, in the same types of containers, and for the same lengths of time. Deviations from this may result in the treated samples being considered invalid due to lack of appropriate supporting storage stability data.

If limited decline of the residue is shown to occur during the storage period, correction factors may be applied to the supervised trial residue results to determine the appropriate level at which the proposed tolerance should be established. If extensive decline of the residue is shown to occur, storage of field trial samples prior to analyses should be avoided. For those compounds known to be labile or volatile, storage stability data are even more important. These samples should be analyzed as soon as possible (within several days of collection).

After a series of appropriate storage stability studies on unrelated commodities have been submitted that show similar results, future petitions on related commodities can reference previously accepted studies in lieu of conducting additional storage stability studies. Translating a storage stability study from one commodity to another will be considered appropriate only if both commodities are related (e.g., in the same crop group), and if the experimental design is considered appropriate to current considerations.

In the limited amount of time the registrants were given to conduct residue field trials for the 3/31/87 Storage Stability Data Call In Notice (11 months), studies should have been conducted at the maximum rate, maximum number of applications, and minimum PHI, with studies conducted in at least the major growing areas.

Attachment: Position Document on Storage Stability: Attached to copies to addressee for forwarding to the registrants

cc: R.F., circu, S. Hummel, Maneb S.F., Maneb S.R.F. (Hummel), Maneb R.S.F. (Boodee), V. Bael - 3 copies (SRB/RD), S. Lewis (PM#21), PMSD/ISB
RDI:EZ:08/25/88:RDS:08/25/88
TS-769:RCB:RM810:CM#2:SVH:svh:08/25/88