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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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EXPEDITE

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Special Review Action Code 870
Maneb Frozen Storage Stability/Request for Time
Extension. No Accession No. [RCB No.1703]
and
Registration Review Action Code 400
Maneb Data Call-In Requirements re: Storage Stability
Data; RD #014505, No Accession No. [RCB No.1716]

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This EBDC data package was submitted in connection with the NRDC suit. It is being expedited at the request of the HED Deputy Director.

At the verbal request of the DCI staff this memorandum will also address the frozen storage stability requirements of metiram/ETU.

I. Maneb and Ethylene thiourea

In response to data call-in notices, the Maneb Task Force has submitted frozen storage stability data (No Accession Nos., RCB #1703) on three crops (tomatoes, lettuce and apples) to support residue data previously submitted on 13 crops. However, no frozen storage stability data to support their dairy cattle and poultry feeding studies nor processed commodities derived from their processing studies have been submitted.

In the submitted frozen storage stability studies, untreated apple, tomato, and lettuce control samples from the Maneb Task Force (MTF) 1985 crop residue program were ground, respectively fortified (separately) at 2, 4 and 10 ppm each with maneb and ETU and then blended. All samples were frozen (5° to 10°F) in glass containers and subsequently analyzed in duplicate for maneb at 0 time, 4 and 12 weeks and for ETU at 0 time, and 8 and 12 weeks for apples, 7 and 17 weeks for tomatoes and 9 and 17 weeks for lettuce.

Reported maneb recoveries from apple, tomato and lettuce samples after 4 and 12 weeks frozen storage averaged (35% and 10%), (64% and 24%), and (36% and 12%) respectively. ETU recoveries from apple (after 8 and 12 weeks), tomato (after 7 and 17 weeks) and lettuce (after 9 and 17 weeks) samples averaged (0.1% and 0.4%), (58% and 49%) and (6% and 0.8%) respectively. Essentially all of the ETU residues in apples and lettuce could not be accounted for and approximately 50% of the ETU residues in tomatoes could not be accounted for within 3 months of frozen storage.

To obtain comparative frozen storage stability data on field samples, the MTF reanalyzed samples remaining in frozen storage, each containing finite residues of both maneb and ETU from the 1985 crop residue program. Recoveries were calculated by comparison of residue results from reanalyzed samples to those obtained from the original analyses. Reported maneb recoveries and storage intervals were; corn forage 82% @ 8.5 mos., black-eyed beans 113% @ 7.5 mos., black-eyed bean vines 34% @ 8.5 mos., lettuce 97% @ 9.5 mos., and sugar beet tops 114% @ 8.5 mos. ETU recoveries on the same respective crop samples were; 136% @ 8 mos., 64% @ 7.5 mos., 105% @ 8.5 mos., 24% @ 10 mos., and 24% @ 8 mos.

Based on the conflicting recovery results obtained from the fortified control samples versus reanalysis of treated and stored field samples which indicated greater storage stability for both maneb and ETU in the latter samples, the MTF considered that the design of the fortification studies were flawed in that grinding these crops prior to fortification with either maneb or ETU, including the use of glass containers, accelerated their enzymatic and physical breakdown. Therefore, the MTF now proposes to undertake a new frozen storage stability study utilizing field crops treated with maneb and sampled periodically beginning on the day the samples arrive at the lab. Samples will be frozen without grinding and portions analyzed at one month, three months, six months and one year. At the same time untreated control samples of the same crops will be sprayed with maneb, stored frozen and analyzed over the same period of time.

Comments and Conclusions

1. The submitted residue stability data on ground and macerated tomato, lettuce and apple samples each fortified with maneb and ETU, clearly indicated that the stability of maneb and ETU declined rapidly during frozen storage intervals of up to 17 weeks. No data were provided demonstrating possible conversion of maneb to ETU during storage of field treated samples; these data would be informative. RCB takes issue with the contention of the MTF that sample grinding and maceration alone enhanced the decomposition of ETU in the rac's examined since ETU has been observed in studies submitted by other laboratories to be significantly more stable in these same ground, macerated, and frozen (raw agricultural commodities) rac's. Thus, the MTF should carefully look at all parameters including temperature, time lapse between each step, etc. The MTF should also be advised as to the difficulty of uniformly spiking whole or unmacerated samples as part of their proposed storage stability study and additionally be advised that field treated samples are unacceptable for determining the storage stability of ETU residues since it is not clear as to how much maneb could be converted to ETU during storage.

RCB concludes that the MTF should repeat the frozen crop storage stability studies for field treated samples looking at only the parent compound maneb. Additionally, RCB concludes that fortified frozen storage stability studies for each maneb and ETU (i.e., samples will be fortified each with maneb or ETU but not in combination) be conducted over a one year time interval only on the following four crops; apples, lettuce, spinach and tomatoes.

2. 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.

3. RCB concludes that frozen storage stability data for both maneb and ETU are needed as soon as possible for all commodities, rac's plus processed commodities derived from possible processing studies, at the approximate time intervals that these commodities are held in frozen storage prior to analysis. It would probably be more advantageous if processed commodities be analyzed as quickly as possible following their preparation.

4. To support previously submitted dairy cattle and poultry feeding studies, RCB concludes that frozen storage stability studies for both maneb and ETU are needed for all animal commodities (i.e., tissues, milk and eggs) examined at the approximate time intervals that these commodities were held in frozen storage prior to analysis. Depending upon the outcome of the requested frozen storage stability studies, additional dairy cattle and poultry feeding studies may be needed.

5. The Pesticide Assessment Guidelines Subdivision O Residue Chemistry §171-4(c) Magnitude of the Residue (1) General Considerations (ii) Sampling para. 4 provides general guidance to the registrant re: frozen storage stability data requirements.

6. For more specific guidance re: suggested protocols and procedures, the registrant is referred to the Data Reporting Guidelines on Storage Stability Study published by the National Technical Information Service (NTIS) and available as Document #PB86-248192.

Recommendations on Maneb Requirements

RCB recommends that the MTF read carefully the Comments and Conclusions (1 to 6) above and submit protocols to the Agency for review prior to the initiation of any of the foregoing frozen storage stability studies to be submitted in conjunction with field residue, processing and feeding studies. Approximately 13 months would be needed for completion and write up of the appropriate storage stability studies and approximately 18 months may be needed for generating and compiling the necessary residue data. In any case RCB recommends that a quarterly progress report be sent to the Agency.

II. Metiram and Ethylene thiourea

In response to the Data Call-In Notices, FMC Corp. has not submitted frozen storage stability studies for metiram and ETU either to support their previously submitted residue and processing data on apples and potatoes or to support their previously submitted dairy cattle and poultry feeding studies.

Comments and Conclusions

1. To support residue data submitted on apples and potatoes, RCB concludes that frozen storage stability studies for both metiram and ETU be conducted on both apples and potatoes for at least 6 months but no longer than one year for each of these commodities. Depending upon the outcome of these requested frozen storage stability studies, additional residue data may be needed.

2. Frozen storage stability data for both metiram and ETU are needed as soon as possible for all commodities, including raw's plus processed commodities derived from possible processing studies, at the approximate time intervals that these commodities are held in frozen storage prior to analysis. It would probably be more advantageous if processed commodities be analyzed as quickly as possible following their preparation.

3. To support the previously submitted dairy cattle and poultry feeding studies, RCB concludes that frozen storage stability studies for both metiram and ETU are needed for all animal commodities (i.e., tissues, milk and eggs) examined at the approximate time intervals that these commodities were held in frozen storage prior to analysis. Depending upon the outcome of these requested frozen storage stability studies, additional dairy cattle and poultry feeding studies may be needed.

4. The Pesticide Assessment Guidelines Subdivision 0 Residue Chemistry §171-4(c) Magnitude of the Residue (1) General Considerations (ii) Sampling para. 4 provides general guidance to the registrant re: frozen storage stability data requirements.

5. For more specific guidance re: suggested protocols and procedures, the registrant is referred to the Data Reporting Guidelines on Storage Stability Study published by the National Technical Information Service (NTIS) and available as Document #PB86-248192.

Recommendations on Metiram Requirements

RCB recommends that the Registrant read the Comments and Conclusions listed above then submit protocols to the Agency for review prior to the initiation of any of the foregoing frozen storage stability studies to be submitted in conjunction with field residue, processing and feeding studies.

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