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MEMORANDUM OF CONFERENCE - January 12, 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Mancozeb (014504) 1/12/89 meeting with Rohm and Haas to discuss Ground vs. aerial data, Storage Stability data, Tomato Metabolism Study, and Specific Analytical Methodology for Mancozeb

FROM: Susan V. Hummel, Chemist
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Susan V. Hummel

THRU: Francis B. Suhre, Acting Section Head
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Susan V. Hummel, for

TO: Files

Rohm and Haas requested a meeting to discuss the Residue Chemistry requirements for Ground vs. Aerial data, Storage Stability data, the Tomato Metabolism study in progress, and a specific analytical method for metiram, required by the Mancozeb Registration Standard (4/1/87). The meeting took place January 12, 1989 at 1 pm.

Attendees

BASF
Janet Ollinger
Mark Schweitzer
Stephen Conner
Edwin Carley

EPA
Edward Zager, DEB
Sue Hummel, DEB
Susan Lewis, PM#21

Ground vs. Aerial Trials

Rohm and Haas stated that the Registration Standard did not say that side by side ground and aerial field trials were necessary. I explained that by doing side by side trials, the total number of trials needed would be reduced. Without side by side trials, full geographic representation would be needed for each application method. I explained that side by side trials would be trials conducted in close proximity to each other.

Rohm and Haas then outlined the application methods used for the crops on their label:

Wheat: Only aerial applications are used.

Sweet corn: ground application is used when the plants are small; when the plants are large, only aerial application is used.

Field corn: Grown only for seed. Aerial application only is used.

Apples: Mancozeb is used in W. New York only. Only aerial application is used.

Cucumbers potatoes, and tomatoes. Ground application is used when the plants are small, then aerial application is normally used.

We then discussed crops by crop group, explaining where ground vs. aerial data would be needed. Data are needed for three diverse locations for one crop in each crop group. We would consider combining some crop groups, such as root vegetables and bulb vegetables.

Carrots, representing root and bulb vegetables. Data would be needed from TX and somewhere in the NE or North Central states.

Celery, representing leafy vegetables. Data would be needed from FL and MI/NY.

Tomatoes, representing fruiting vegetables including cucurbits. Only data from ground and hand applications had been submitted. Data would be needed from the west coast, NE, and SE.

Apples, representing pome fruits. Rohm and Haas stated that mancozeb was used in New York only. We agreed to accept ground vs aerial data from New England only if a label restriction (restricting use to New England only were included on the label.

Grapes, representing small fruits. Rohm and Haas stated that aerial application was not used on grapes. A restriction against the use by aerial application would be needed if it were not already on the label.

Cereal Grains. Rohm and Haas stated that aerial application must be used close to harvest because ground equipment could not move through the field. We pointed out that Rohm and Haas had already conducted one side by side ground vs. aerial trial for sweet corn. Additional data for sweet corn would be needed from the west coast and the SE, and three diverse areas for corn forage.

Susan Lewis asked for a suggestion for due dates for these studies. I stated that six months following harvest would be sufficient time to conduct these studies.

Storage Stability Data

Rohm and Haas stated that the requirements in the Registration Standard were conflicting. One part stated that storage stability data for mancozeb and ETU were acceptable, and another part required all new storage stability studies. They stated that they conducted storage stability studies for an older DCI, and now have 24 months of data from those studies. Samples from their residue studies on raw agricultural commodities were all analyzed by the same laboratory (Enviro-Bio-Tech) in the past 5 to 6 years. Some of the samples from processing studies were analyzed by NFPA (National Food Laboratory) and some by EBT. We noted that a recent tomato processing study stated that some of the samples were analyzed in Rohm and Haas laboratories.

We were concerned about differences in the way samples were handled at different times, particularly apples, since the worst storage stability of ETU occurred in apples. We will insist on additional storage stability data for apples. However, for tomatoes, the laboratories used by the other registrants did not report any significant storage stability problems, so we will not require additional storage stability data on tomatoes at this time. Rohm and Haas plans on dropping leafy vegetables (tolerances pending). This makes the requirement for storage stability data on lettuce moot.

Tomato Metabolism study

The tomatoes for the tomato metabolism study have been harvested. Nine applications of 2.4 lb ai/A were made at seven day intervals. Samples were harvested 0 days after the 7th and 8th applications and five days after the 9th application. Rohm and Haas questioned the need for the requirement that samples be collected through 21 days after the last application. I stated that our concern was that residues have sufficient time to metabolize/degrade, and that the multiple applications would allow that.

Rohm and Haas stated that the metabolites were natural products. The natural products were characterized to the level of the individual amino acid, and identified by chromatography of the dansyl derivative. Mass spectrometric identification was done if there was enough activity (generally > 1 ppm). I questioned whether any of the known degradates of mancozeb would dansylate. Dr. Schweitzer stated that ethylene diamine (EDA) would dansylate, but that it would chromatograph differently than other amino acids.

Specific Analytical Method

Rohm and Haas stated that they were having difficulties in developing residue analytical methodology specific for mancozeb. We stated that BASF had suggested that the EBDC's be considered a single active ingredient with different metal stabilizers, analogous to 2,4-D and other phenoxy acids, which are registered as different esters.

I read Rohm and Haas the section of the memorandum of conference from the BASF metiram meeting which dealt with the requirement for a specific analytical method.

"In order for this approach to be considered, the registrants of all of the EBDC's would need to demonstrate that all of the EBDC's were toxicologically equivalent and that a single tolerance should be established for all EBDC's. The registrant's request, including documentation must be submitted in writing. Documentation needed to demonstrate toxicological equivalence would include:

1. A complete discussion of the chemistry of all of the EBDC's, including far more information than we currently have available on product chemistry and metabolism. The registrants would need to demonstrate that the chemistry of all of the EBDC's is equivalent.
2. A complete discussion of all attempts to develop specific residue analytical methodology.
3. Toxicology data and any other information needed by EPA toxicologists.

Ed Zager stated that, until the registrants can demonstrate that the EBDC's are toxicologically equivalent, and that a single tolerance should cover all EBDC's, the data requirement for a specific analytical method would remain.

BASF stated that they would bring these issues up with the newly formed ETU Task Force, and that they would submit their proposal in writing."

Rohm and Haas confirmed that they had discussed this issue with BASF.

cc: R.F., circu, S. Hummel, Metiram S.F., Metiram S.R.F.
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RDI:FBS:03/28/89:EZ:03/30/89
TS-769:RCB:RM810:CM#2:SVH:svh:03/31/89