MEMORANDUM OF CONFERENCE


FROM: Cynthia Deyrup, Ph.D., and Nancy Dodd, Chemists
Residue Chemistry Branch
Tolerance Petition Section 2
Hazard Evaluation Division (TS-769)

THRU: John H. Onley, Ph.D., Section Head
Residue Chemistry Branch
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TO: RCB Files

Attendees
S. Ward USDA/APHIS
J. Pons USDA/APHIS
A. Starrant Agriculture Canada, London
V. White Great Lakes Chemicals
A. Tillman Ameribrom
T. Duafala Trical
M. Pinkerton Ameribrom
R. Liscombe Bolsa Research
J. Ford USDA/APHIS/NMRAL
P. Ochs USDA/APHIS/S & T
L. Wen Ethyl
N. Dodd HED/DEB
W. Francis RD
C. Deyrup HED/DEB

The meeting was convened to discuss deficiencies cited in DEB's reviews concerning preplant and postharvest fumigation protocols (postharvest, C. Deyrup, memo of 11/3/88; preplant, N. Dodd, memo of 9/2/88). The following issues were discussed.

Metabolism

A. Starrant had conducted the metabolism study which was aimed at identifying bound residues only. DEB informed him that the contribution that MeBr and its volatile metabolites make to the total radioactive residue (TRR) should be taken into account. DEB suggested that the commodities be aerated 1-2
hours before analyzing the commodities, since the commodities are generally aerated 1-2 hours commercially. The MBIP (Methyl Bromide Industry Panel, composed of the companies cited on page 1) suggested analysis without aeration, but DEB said that this protocol would place too much emphasis on the parent. A. Starratt said that they would look for 5-bromo-uracil, a potential metabolite and a carcinogen. Dr. Starratt said that 7-methyl guanine occurs naturally in rats; about 1% of the guanine is methylated in the DNA of wheat fumigated with MeBr. The MBIP said that they would send in a protocol covering past and proposed work; two study plans have been lost during transmission.

MBIP said that they had just met with TOX (Dr. Zenzian) and had been told that iBr is not of toxicological concern. TOX, in responding to an earlier DEB deference had concluded that iBr was of concern. Dr. Starratt confirmed that iBr is not of concern in Canada. Canada had concluded that an iBr tolerance is unenforceable because of the levels of naturally occurring iBr. RD told MBIP to marshal its arguments in a submission to TOX.

Proposed Use

The MBIP said that very little of the fumigated commodities would end up in interstate commerce; these commodities are intended for export. They wanted tolerances so that MeBr could be used in case of outbreaks. However, they also were interested in knowing whether a tolerance would be needed if the fumigated commodities were for export only. DEB said that we had already asked the Office of General Counsel for an opinion but had not heard from them.

The MBIP claimed that DEB had told them that residue data reflecting preplant fumigation would be required from 4 areas for major crops, and 2 areas for minor crops. DEB, however, understood that the petitioner was going to start obtaining residue data on obvious states such as CA, and then add states later after submitting a protocol regarding sites.

According to the MBIP, the preplant use is generally limited to the Southern US, where nematodes are a problem. The apparatus used for soil fumigation is a caterpillar tractor almost the size of the conference room (RM 813). These tractors are located primarily in the South and do not travel around the country. If residue data are needed on potatoes grown in Maine, the registrant said that he would need to rent a CSA from the army. DEB told MBIP to document its arguments for generating residue data reflecting a limited geographical data base. [After the meeting, DEB checked the label submitted with PP #5F3300. Instructions are given for soil fumigation with a less elaborate device, namely soil
fumigation underneath a tarp supported by crumpled fertilizer bags.

DEB handed out a Federal Register notice (FR Vol. 51, No. 63, 4/2/86) which described minor crops.

DEB had told MBIP that if it wanted to change the preplant soil fumigation rate from 240 lbs ai/A to 300 lbs ai/A, a revised label should be submitted. MBIP said that it wanted to generate data at the 300 lb rate (1.25X rate), have a tolerance based on this rate, and have the option of increasing the label rate at some later date. DEB responded that tolerances are usually based on data generated at a 1X rate, but DEB would consider this issue.

The registrant said that when a label was finally decided upon, it would be sent to DEB for review; was that OK? DEB said that the label and residue data have to be submitted together; how could we evaluate the residue data if we don't know what the registrant intends to do with the pesticide? MBIP thought that made sense.

Analytical Methodology

DEB did not consider the methodology used for determining inorganic bromide (iBr) to be adequate because of a wide variation in the recoveries. The registrant said that he would submit a defense of the method. MBIP wants to stick with this method because they've carried out about $100,000 worth of analyses already. DEB replied that we have been asking for recovery data for years, since 1985 as a matter of fact, and had just received the data. APHIS volunteered that they converted iBr to bromoethanol before analysis with GC.

Residue Data

MBIP confirmed that CARAB (CA Raisin Advisory Board) is generating bridging data from a 1 ft\(^3\) chamber to a commercial chamber (885 ft\(^3\)) so that residue data could be generated from the small chamber.

According to MBIP, 3 fumigation runs using 80% load factors would be prohibitively expensive. If 5 apple varieties are tested, it would cost $4,000,000. The Registration Standard had specified that commercial load factors be used. DEB replied that R. Sell (USDA/ARS) had found that low load factors represent the worst case and that load factors of <10% would represent the worst practical commercial case. MBIP then proposed placing bins in various sections of the chamber and compositing samples from these bins. The load factor could be about 1%. DEB suggested that the load factors be <10%, in keeping with Dr. Sell's estimate that 10% represented the worst practical commercial case. The residue data would then reflect the worst average case encountered commercially. DEB thought that this was a practical solution but asked
MBIP to submit the protocol in writing for review.

MBIP wanted to know how they could generate preplant residue data on apple trees from the North when apples up North are not grown in fumigated soil. DEB said that it may be necessary to add the residue levels from preplant treatments to those from postharvest fumigation in order to establish a tolerance. DEB told the petitioner that residue data from several varieties of the major crops would be needed. APHIS wanted to know if they had to generate data for its use if the US imports only Granny Smith apples. [APHIS fumigates imported commodities, often at higher rates than the domestic label] DEB told them to document that only Granny Smith apples are imported. DEB suggested that they use the 1 ft³ chamber for bridging studies; if residue levels are the same for various types of apples, they could generate data on one variety only. DEB informed APHIS that Dr. H. Moffitt (USDA/ARS) may already have investigated residue levels in different apples; Dr. Moffitt had told DEB that residue levels were the same in different kinds of apples bearing closed and open calyxes (the part opposite the stem).

DEB emphasized that the temperatures of the commodity, the chamber, and during aeration are crucial in generating the residue data. MBIP argued that fumigation chambers are not temperature controlled. DEB insisted that the temperature be taken into account for establishing tolerances. Work published by the USDA had shown that not only is the temperature a factor during fumigation but it is the only parameter affecting desorption. DEB told the petitioner to consult with growers and fumigators, find out when fumigations occur, take into account the temperature variations during these seasons, establish and document the worst case expected commercially, and then generate the appropriate residue data. The label should then restrict application to the worst case. In this way the temperature restriction would be practical.

Since the APHIS use is so much higher than the label use, APHIS and MBIP wanted to know how we were going to regulate residues. DEB responded that setting two different tolerances because of the different application rates was out of the question. The FDA wouldn't know where the crop originated. APHIS requires higher rates because all the insects must be killed, and the capra beetle, which doesn't occur in the US, is a very tough bug to kill. DEB suggested that APHIS investigate the practicality of using higher temperatures and/or longer aeration periods to bring levels down to the domestic tolerance level.

DEB asked whether crops would be transplanted into fumigated soil. MBIP said that crops could be transplanted from fumigated soil into untreated soil and that that should be a non-food use. Crops would not normally be transplanted into fumigated soil. DEB said that we would need to check the non-food use status of transplanting.
MBIP argued that residue data should be generated on perfect specimens only; bruised specimens would rot after fumigation. MBIP had thought that DEB wanted residue data on bruised or stemless fruit so that tolerances could be set on that basis. DEB explained that the USDA tolerances for US #1 crops usually allowed up to 10% bruised or 12% stemless items. Therefore, samples taken for analysis should include these percentages of bruised/stemless items. APHIS considered that to be reasonable.

Referring to Table 2 of N. Dodd's review of 9/2/88, the MBIP said that processing data would be generated on commodities which had been preplant treated, postharvest treated, then processed.

MBIP invited N. Dodd and C. Deyrup to travel to California to see how MeBr is applied, because they and the NAS thought that it would be worthwhile for DEB to get some real world exposure to application techniques. DEB said that we would contact Dr. White to tell him how such a cultural practice trip could be initiated through the correct channels.

The meeting finally ended after more than 2 and a half hours. The registrant (V. White) thanked us for meeting with them and said he couldn't believe the amount of work which went into DEB reviews.

cc: Circu, SF, RP, Reg. Std File-Boodee, N.Dodd, C.Deyrup
TS-769:CM#2:RM810:X7484:C.Deyrup:cd:12/7/88