

PMSD/ISB



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

APR 27 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Registration No. 53201-1 (DEB No. 5000). Methyl Bromide Protocols for Pre- and Post-harvest Applications - Issues discussed in the November 10, 1988 Meeting (No Accession Number).

FROM: Nancy Dodd, Chemist and Cindy Deyrup, Ph.D., Chemist
Tolerance Petition Section II *Nancy Dodd*
Dietary Exposure Branch
Health Effects Division (H7509C) *C. Deyrup*

THRU: Debra Edwards, Ph.D., Acting Section Head
Tolerance Petition Section II
Dietary Exposure Branch
Health Effects Division (H7509C) *Debra Edwards*

TO: Jeff Kempter, PM #32
Antimicrobial Program Branch
Registration Division (H7509C)

and

Dave Ritter, Toxicologist
Toxicology Branch II - Herbicide, Fungicide, and
Antimicrobial Support
Health Effects Division (H7509C)

The Methyl Bromide Industry Panel (MPIP) has submitted a discussion for the Dietary Exposure Branch (DEB) response to some of the issues discussed at the November 10, 1988 meeting. The meeting covered numerous issues relating to

1

preplant and postharvest protocols. The MBIP's recollection of the meeting will be restated below, followed by DEB's comments. All preplant issues will be discussed first, followed by postharvest issues. Comments enclosed in brackets were made after the meeting.

The registrant may be interested in DEB's account of the meeting of November 10, 1988, a copy of which is attached to this memorandum. Also, a copy of this entire review should be sent to the MBIP.

PREPLANT STUDIES

Issue #1: Rate to be Used in Residue Trials

The MBIP wants to keep labels at 240 lb ai/A for most uses but use 300 lb ai/A in most residue studies. Since most crops are being grown in the same plots and the soil is being treated with large specialized equipment, use of the same rate will be necessary.

DEB's Discussion - #1

DEB previously indicated that the field studies should be conducted at the maximum label rate of 240 lb ai/A.

[However, DEB has no objection to the MBIP use of 300 lb ai/A since that rate is reasonably close and higher than the label rate of 240 lb ai/A.]

Issue #2: Test Sites

The MBIP wants to conduct residue studies in two or three States for most crops.

DEB's Discussion - #2

The MBIP should generally follow Table A's "Ideal Geographic Representation from IR-4 Memorandum or RCB Files," which is included in DEB's review dated September 2, 1988 (N. Dodd). Exceptions may be possible if the MBIP provides adequate documentation of the reasons.

[For example, the MeBr Registration Standard specifies fewer States or States that are adjacent.]

Issue #3: Selection of Cultivars for Use in Residue Trials

The MBIP believes that differences in residues among cultivars would not exceed the fivefold residue level differences allowed in crop groups. Dr. Moffitt (USDA/ARS)

2

has indicated that the residue differences in Red Delicious vs. Golden Delicious apples are not significant.

DEB's Discussion - #3

Cultivars were discussed in connection with postharvest fumigation of almonds (memorandum of W. Hazel, March 24, 1988). DEB requested that the almond cultivar with the highest oil content be used. DEB also indicated that any almond cultivar could be used if the oil content was similar.

DEB is not concerned with apple cultivars, based on the statement of Dr. Moffitt (USDA/ARS) that the residue differences in Red Delicious vs. Golden Delicious are not significant.

DEB requires data on both large (i.e., regular) and cherry tomatoes because of the difference in the surface/volume ratio.

DEB indicated in a meeting on December 15, 1988 that residue data on walnuts should include some on Eureka walnuts since they have a higher oil content than other walnuts.

[For preplant soil applications, cultivars are not of concern except for nuts and tomatoes. For nuts, the "worst case" cultivar of the representative crop should be used in the residue studies. For tomatoes, residue data are needed on both large (i.e., regular) tomatoes and cherry tomatoes.]

POSTHARVEST STUDIES

The following postharvest issues were discussed at the November 10, 1988 meeting.

Issue #1: Effect of Fruit Size on Residue Levels

This topic was discussed in detail under the preplant section of this memorandum.

Issue #2: Chamber Temperature

DEB recommended that all fumigations be done at the temperature which resulted in the highest residue levels. MBIP presented USDA data which show that lower temperatures result in higher methyl bromide (MeBr) residue levels. MBIP will specify a minimum fumigation temperature on the label for each commodity.

3

DEB's Discussion - #2

Actually, at this meeting, DEB gave an article by C.R. Sell, USDA, to the MBIP.

Fumigations reflecting the worst case are needed in order to establish tolerance levels.

[Calculating the dietary exposure from worst case situations could lead to an unrealistic and toxicologically unacceptable estimate. Therefore, data reflecting more common commercial practices are also needed.]

Issue #3: Aeration Temperature

DEB was concerned that the temperature of aeration could affect the commodity residue level. The MBIP argued that commodities are either fumigated at ambient temperatures or at pre-fumigation storage temperatures. The fumigation chamber temperature and the temperature during the short forced aeration period are generally not controlled. The MBIP maintains that the commodity temperature itself would not change significantly during the short fumigation and aeration period. MBIP proposed to write postharvest protocols to duplicate actual field conditions.

DEB's Discussion - #3

DEB pointed out that the effect of temperature would have to be taken into account; according to the R. Sell article, temperature was the only parameter affecting desorption. The post-harvest protocols should reflect temperatures expected during commercial fumigations, as stated above by the MBIP. Some data representing the worst case are needed.

Issue #4: Chamber Size

DEB has stipulated that all test fumigations must be undertaken in commercial size atmospheric chambers or in vacuum chambers. Vacuum chambers will be used only for walnuts, and this will be specified on the label. DEB has been given data from the USDA/ARS lab in Fresno; the data prove that small chambers can provide data comparable to that obtained in commercial chambers.

DEB's Discussion - #4

DEB was informed that bridging data linking a 1 ft³ chamber to a commercial chamber (885 ft³) were being generated in California.

4

[The actual data were given to DEB at the meeting of December 15, 1988 and were therefore not discussed at this meeting.]

Issue #5: Effect of Packaging on Residue Levels - MBIP Memorandum of Conference

DEB asked that different types of packaging be tested to determine which one represents the worst case. The MBIP maintains that most fumigation takes place in wooden bins and is not packaged; commodities fumigated in packages would contain lower residues of MeBr because the packaging absorbs some of the available MeBr.

DEB's Discussion - #5

[At the December 15, 1988 meeting with the MBIP, DEB asserted that data were needed to support MBIP's contentions if packaged commodities are fumigated.]

Issue #6: Intervals Between Multiple Treatments and Number of Applications

DEB wanted to know if, in commercial practice, commodities may be refumigated before they have been thoroughly aerated; if so, the test fumigations should reflect this practice. Also, the number of fumigations depends upon the commodity and can range from 1 to 10 treatments. The MBIP said that industrial practices for each commodity will be considered in determining the protocol. Information regarding multiple fumigations and the number required will be documented by an official source from a company marketing the commodity in commerce.

DEB's Discussion - #6

MBIP's account agrees with DEB's recollection; all sources of information on commercial practices should be cited.

Issue #7: Load Factor

Using an 80 percent load factor for commercial chambers would place a prohibitive burden on the registrant. DEB agreed that a 10 percent load factor would be a more severe test and would be acceptable.

DEB's Discussion - #7

An article by C.R. Sell, USDA, indicated that lower load factors lead to higher residue levels of MeBr. Dr. Sell had estimated that a 10 percent load factor represented the worst practical commercial case. MBIP proposed placing bins in various sections of the chamber and compositing samples from

these bins. DEB thought that this was a practical solution to the problem of maintaining a low load factor and compositing samples from different sections of the chamber; MBIP was advised to submit the final protocol for review.

[At the December 15, 1988 meeting with the MBIP, Preston Hartsell, USDA/ARS questioned whether low load factors lead to higher residue levels of MeBr.]

Issue #8: Sampling of Chamber Air During Fumigation and Aeration

DEB recommended sampling the chamber air during fumigation and aeration to ensure that some samples are taken from areas where the gas concentration is greatest. MBIP believes that the circulating equipment adequately distributes the gas, and samples will be gathered from different parts of the chamber.

DEB's Discussion - #8

This issue had been addressed in the amendment of September 22, 1988. DEB agreed that compositing samples from various locations within the chamber would ensure that representative samples are analyzed (C. Deyrup, memorandum of November 3, 1988).

Issue #9: FDA Inspections

If proposed tolerances are based on an aeration period, the commodity should not be available for testing by FDA inspectors before this period has elapsed. DEB questioned where in the shipment their samples would be collected. The USDA will prepare information assessing at what point after fumigation the commodities could be sampled by FDA inspectors.

DEB's Discussion - #9

DEB had contacted the FDA and had been informed that the FDA would not sample commodities as they emerge from fumigation. The information to be furnished by the USDA is of crucial importance in establishing tolerances for postharvest uses.

[DEB was aware that the FDA would select samples randomly from a shipment and had informed MBIP that the sample selection used to generate residue data should mimic the FDA sample selection process as much as possible (memorandum of September 23, 1988).]

Issue #10: Waxed Commodities

It has been demonstrated that waxed commodities absorb and release MeBr residues more slowly than unwaxed commodities. MBIP's protocols will be based on commercial practices. In the case of apples, the only product being fumigated is that which will be exported to Japan. There is no commercial use of MeBr on domestic apples, and apples exported to Japan are not waxed before fumigation. MBIP does not propose to fumigate apples that have been waxed.

Although the citrus industry currently fumigates waxed citrus, it would like to change this procedure and fumigate unwaxed citrus. The issue will be addressed when the protocols are revised.

DEB's Discussion - #10

Besides apples, MBIP maintained that several other commodities are to be fumigated for export use only and therefore wanted to find out if tolerances were needed for commodities intended for export.

[DEB checked with the Office of General Counsel and found that tolerances are not needed for commodities to be exported, provided that certain precautions are taken to ensure that the commodities are not released to the domestic market. This information was conveyed to the registrant.]

[Until seeing MBIP's memorandum of conference, DEB was unaware of proposed changes in citrus fumigation.]

Issue #11: Grain Dust

MBIP's memorandum of the November 10, 1988 conference included the following discussion on grain dust:

DEB is concerned that the use of MeBr on stored grain could lead to higher residues in grain dust than in the grain itself. DEB is correct in its comment that stored grain is usually treated with aluminum phosphide, not MeBr.

When MeBr is used in silos, the grain is not cleaned directly after fumigation. Dust is only collected as the grain moves through the elevator system. If oil is used to reduce dust levels, the amount of dust collected by dust collectors would be a minuscule amount in the total volume of grain dust used for animal feed.

If grain is fumigated and milled in the same facility, the dust is removed before the grain is milled; this dust is sold then as animal feed. Since the removal of the dust involves aeration with huge quantities of air, the aeration of the dust is more thorough than the aeration of the grain itself.

The milling industry generally uses MeBr as a space fumigant; that is, the grain itself would not be fumigated.

DEB's Discussion - #11

According to DEB's memorandum of conference, this subject was not discussed in detail at the November 10, 1988 meeting, because the memorandum dealing with grain dust (C. Deyrup memorandum of November 3, 1988) had been handed to the registrant on the day of the meeting.

[DEB may not agree with MBIP's viewpoint.]

Attachment 1: DEB Memorandum of November 10, 1988 Conference

cc: C. Deyrup (DEB), N. Dodd (DEB), R. Schmitt, PP#5F3198, Methyl Bromide Registration Standard File, W. Boodee, E. Eldredge (ISB/PMSD), Circulation (6), RF,

RDI: D. Edwards:4/20/89:R. Loranger:4/20/89
H7509C:DEB:CM#2:Rm 800D:X1681:N.Dodd:Kenco:nd:4/24/89

8



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

DEC 8 1988

OFFICE OF
PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM OF CONFERENCE

SUBJECT: Meeting of 11/10/88. Protocols for Postharvest and Preplant MeBr Fumigations.

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

THRU: John H. Onley, Ph.D., Section Head
Residue Chemistry Branch
Tolerance Petition Section 2
Hazard Evaluation Division (TS-769) *John H. Onley*

TO: RCB Files

Attendees

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

9

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-bromouracil, 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 C5A 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 ft³ chamber to a commercial chamber (885 ft³) 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

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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, RF, Reg. Std File-Boodee, N.Dodd, C.Deyrup
RDI: J.Onley:11/15/88:R.D.Schmitt:11/16/88
TS-769:CM#2:RM810:X7484:C.Deyrup:cd:12/7/88

13