



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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MAY 10 1989

MEMORANDUM

SUBJECT: EPA Registration No. 53201-1 (DEB No. 4998). Methyl Bromide Soil Fumigation Protocols (No Accession Number).

FROM: Nancy Dodd, Chemist *Nancy Dodd*
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THRU: Debra Edwards, Ph.D., Acting Section Head
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TO: Jeff Kempter, PM 32
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The Methyl Bromide Industry Panel (MBIP) submits a letter dated February 10, 1989 concerning a revised protocol for soil fumigation studies in response to DEB's review dated September 2, 1988 and subsequent meetings on November 10, 1988 and December 15-16, 1988.

Summary of Deficiencies in the Protocol that Still Need Resolution

- o For asparagus in California, the label should be revised to allow an application rate of 300 lb ai/A since residue data will be collected at 300 lb ai/A. (The label now allows a maximum of 400 lb ai/A for asparagus in California.)
- o Residue data on asparagus are needed from California, Washington, and either Michigan, New Jersey or Illinois unless regional registration is proposed (with use confined to California and the Pacific Northwest).

- o Lettuce labels must be revised so that the maximum rate on the labels does not exceed the rate at which residue studies are conducted.
- o Rate and site information (from IR-4) is needed for okra.
- o Labels for application of MeBr to alfalfa and clover will be needed.
- o Commodities bearing measurable weathered residues resulting from soil fumigation must be processed, unless the commodity may also be treated postharvest. (Processing studies reflecting only postharvest use would then be required). Data are required for all products identified in the 9/2/88 review (deficiency 4) except those that are the products of processing procedures that require extended drying times or elevated temperatures. (Additional data may be required if the ongoing plant metabolism studies reveal residues of concern other than MeBr.)
- o Revised MeBr labels to conform to the protocol's minimum interval between application and planting are needed.
- o Validation/recovery data for the ion selective electrode method is to be submitted under separate cover.
- o Table I does not propose adequate geographic representation for some crops.
- o Residue data on onions should include data on onions grown from seeds, sets, and transplants if these are allowed on the label since the preharvest intervals (PHIs) are different and, therefore, residue data may differ.
- o For other crops which can be planted as seeds or transplants from or to treated soil, residue data from all scenarios which are allowed on the labels are needed.

Conclusions (Resulting from Review of this Submission)

- 1b. DEB has no objection to the MBIP dropping "sweet corn" from Table I under "miscellaneous" provided no sweet corn soil fumigation use is permitted on any MeBr labels.

- 1c. Upon submission of residue data, DEB will check that maximum residues within a proposed crop group do not vary by more than a factor of 5.
- 1d. A crop group tolerance on leafy vegetables may be appropriate since the proposed use rates are all 300 lb ai/A.

A crop group tolerance on small fruits and berries (except cranberries) may be proposed provided a cranberry soil fumigation use does not appear on the label and residues resulting from the grape treatment (rate = 600 lb ai/A) are not > 5X those resulting from use on the other small fruits (rate = 300 lb ai/A).

- 2a . DEB no longer objects to the MBIP's proposal to keep labels for most crops at 240 lb ai/A but to conduct residue studies for most crops at 300 lb ai/A, since the 300 lb ai/A rate is reasonably close and higher than the label rate of 240 lb ai/A.
- 2bii. DEB has no objection to the 300 lb ai/A application rate for asparagus in Washington since the label rate is lower (maximum 240 lb ai/A).

Since the label now allows application at a maximum rate of 400 lb ai/A in California, however, the label should be revised to allow a maximum rate of 300 lb ai/A in California, since the residue data will be collected at the lower rate of 300 lb ai/A.

The MBIP has previously indicated (see DEB's September 2, 1988 review) that asparagus in Michigan is not grown on MeBr-treated soil.

DEB concludes that the registrant must either conduct residue trials in Michigan, New Jersey or Illinois (in addition to California and Washington); or propose regional registration (confined to California and the Pacific Northwest).

- 2biii. DEB now concludes that residue data from North Carolina and Kentucky as requested in the Methyl Bromide Registration Standard will be sufficient for tobacco.
- 2biv. The 300 lb ai/A rate in Table 1 for residue studies on pineapple will be acceptable.
- 2bv. Table 1 now proposes a rate of 600 lb ai/A for

grapes, as requested, and a rate of 300 lb ai/A for the other small fruits and berries.

- 2bvi. The 300 lb ai/A rate in Table 1 for residue studies on bulb vegetables will be acceptable.
- 2bvii. Since the use rate on lettuce labels is 400 lb ai/A, residue data must be generated at 400 lb ai/A or those labels must be revised to permit a rate of \leq 300 lb ai/A.
- 2bviii. Residue data at 300 lb ai/A on celery and spinach (Table 1) will be acceptable.
- 2bix. Residue studies on cabbage, mustard greens, and broccoli at 300 lb ai/A (Table 1) will be acceptable.
- 2c. Residue data for the root and tuber vegetable group, the legume vegetables group, and the herbs and spices group at the 300 lb ai/A rate will be acceptable.
- 2d. Since New Mexico, Texas, and Oklahoma are adjacent, peanut data are needed for only one of these states. Therefore, the states of Florida, Texas, and North Carolina (or the regions of Georgia/Alabama/Florida, Virginia/ North Carolina, and Texas/Oklahoma/New Mexico) will be adequate as sites for peanuts.

Deletion of sweet corn from the residue study is acceptable, provided soil fumigation on sweet corn is not permitted.

Rate and site information are needed for okra.

- 2e. Labels for application of MeBr to alfalfa and clover are needed.
- 3. Available residue data on MeBr per se in commodities planted in fumigated soil are limited because tolerances were previously set on inorganic bromide (iBr). Additional residue data on MeBr per se have previously been requested (PP#5F3198, M. Firestone, April 12, 1985 and August 22, 1986 and N. Dodd, May 27, 1987; Methyl Bromide Registration Standard).

DEB cannot conclude at this time that no detectable residues of MeBr per se will be found in crops resulting from soil fumigation. If additional residue data on MeBr per se are available to the MBIP, it should be submitted to EPA for further consideration of this issue.

In any case, residue data reflecting soil fumigation will be needed only for any crops which may be treated by soil fumigation but not by postharvest fumigation. New methyl bromide tolerances will not include iBr (see Recommendations section). Therefore, data reflecting the use likely to result in the majority of the MeBr residues will be required and used in tolerance setting (postharvest fumigation, if registered).

4. As stated above, residue data reflecting soil fumigation will be needed only for those crops that may be treated preharvest but not postharvest. This approach also applies to processing requirements: Commodities bearing measurable weathered residues resulting from soil fumigation must be processed, unless the commodity may also be treated postharvest. (Processing studies reflecting only postharvest use would then be required). Data are required for all products identified in DEB's 9/2/88 review (deficiency 4) except those that are the products of processing procedures that involve extended drying times or elevated temperatures. (Additional data may be required if the ongoing plant metabolism studies reveal residues of concern other than MeBr.)
5. The MBIP must submit revised MeBr labels to conform to the protocol's minimum interval between application and planting.
- 6a. For preplant soil applications only, DEB has no objection to an 18-hour sampling to analysis time since samples are stored in impermeable containers. The concerns related to postharvest fumigation are addressed in C. Deyrup's concurrent review (April 25, 1989).
- 7b. The validation/recovery data and method issues for the ion selective electrode method are being reviewed in another submission (not yet received in DEB).
8. The MBIP should generally follow the "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 Methyl Bromide Registration Standard specifies fewer states or allows selection of one state from states that are adjacent).

The Methyl Bromide Registration Standard concerned registered uses, not those proposed in PP#5F3198. Therefore, the list of requirements in the Standard for residue data for proposed uses is not complete.

9. A tolerance proposal for "legume vegetables (except soybeans)" is acceptable.
10. Onions (small bulb) have been dropped from the revised Table 1, leaving onion (green), onion (large bulb), and garlic as representative crops for the bulb vegetable group.

DEB has no objection to dropping onions (small bulb) from the list since the representative commodities for the bulb vegetables crop group are "onion (green and bulb) and one other commodity."

11. Residue data on onions should include data on onions grown from seeds, sets, and transplants if these are allowed by the labels since the PHIs are different and, therefore, residue data may differ.
12. For other crops which can be planted as seeds or transplants from or to treated soil, residue data for all scenarios which are allowed by the labels are needed.

Recommendations

DEB finds the submitted protocol for residue data for MeBr residues to be incomplete for the reasons listed under the "Summary of Deficiencies" above.

The Registrant should note that, since the Toxicology Branch agrees with their contention that iBr residues need not be regulated (D. Ritter memo dated 4/19/89), residue data reflecting soil fumigation will be needed only for those crops on which postharvest fumigation will not be permitted. All DEB conclusions pertaining to this protocol would still apply to those commodities.

Note to PM: DEB recommends that this entire review be sent to the MBIP.

DETAILED CONSIDERATIONS

Deficiencies from DEB's September 2, 1988 review of a protocol for soil fumigation studies are restated below, followed by the MBIP's response and DEB's comments/conclusions.

Deficiency 1b

After the MBIP dropped the cereal grains crop group from Table 1, DEB indicated that residue data for sweet corn (then listed in Table 1 under "Miscellaneous") should be obtained from Florida, California, New York, Texas, Ohio/Pennsylvania, Massachusetts/New Jersey, Oregon/ Washington/Idaho, Michigan/Minnesota/Wisconsin, and Illinois.

Petitioner's Response to Deficiency 1b

"MBIP will delete the cereal grains group including sweet corn from our protocol. Sweet corn is being deleted because fumigation for sweet corn will not justify the need to generate residue data in the nine states as required by DEB."

The MBIP has dropped "sweet corn" from Table 1.

DEB's Comments/Conclusions re: Deficiency 1b

Deficiency 1b is resolved. DEB has no objection to the MBIP dropping the cereal grain uses, including sweet corn.

Deficiency 1c

Crop group tolerances will not be appropriate where maximum residues of iBr or MeBr vary by more than a factor of 5.

Petitioner's Response to Deficiency 1c

No action required.

DEB's Comments/Conclusions re: Deficiency 1c

Feasibility of crop group tolerances will be considered when residue data are submitted. No deficiency is identified at this time.

Deficiency 1d

In the review dated February 2, 1988 (N. Dodd), DEB indicated that for a crop group tolerance on the small fruits and berries crop group to be established, the proposed uses must be similar, as stated in 40 CFR 180.34(f)(3):

"Since a group tolerance reflects maximum residues expected to occur on all individual crops within a group, the proposed or registered patterns of use for all crops in the group must be similar before a group tolerance is

established. The pattern of use consists of the amount of pesticide applied, the number of times applied, the timing of the first application, the interval between applications, and the interval between the last application and harvest. The pattern of use will also include the type of application; for example, soil or foliar application, or application by ground or aerial equipment."

The proposed use on cranberries and the proposed rate on grapes are not the same as for the other representative crops in the small fruits and berries crop group.

In the review dated September 2, 1988 (N. Dodd), DEB indicated that a crop group tolerance for the small fruits and berries group should not be proposed if two representative crops (i.e., cranberries and grapes) would be excluded.

Petitioner's Response to Deficiency 1d

Grapes at an application rate of 600 lb ai/A have been returned to Table 1 as a representative crop for the small fruits and berries (except cranberries) crop group.

"MBIP proposes to change the Small Fruits and Berries group to read: Small Fruits and Berries except Cranberry.

"Cranberries are excluded because cultural practices for cranberries make it impossible to do preplant soil fumigation.

"Grapes are included because even though the dosage rate is higher than for the other berries, it is still similar and therefore the residue level for grapes will not vary by a factor of 5.

"Furthermore, even if the residue level for grapes does vary by a factor of 5 and it has to be excluded from the crop group, 40 CFR 180.34(f)6 does not state that only one crop can be excluded from a crop group.

"Data for the Leafy Vegetables Group will be generated with a 300 lb/A methyl bromide dosage rate and the labels will be revised to reflect this dosage rate change from 400 lb/A to 300 lb/A."

DEB's Comments/Conclusions re: Deficiency 1d

A crop group tolerance on leafy vegetables is appropriate since the proposed use rates are all 300 lb ai/A.

The crop group tolerance on small fruits and berries (except cranberries) may be proposed provided a cranberry soil fumigation use does not appear on the label and residues resulting from the grape treatment (rate = 600 lb ai/A) are not > 5X those resulting from use on the other small fruits (rate = 300 lb ai/A).

Deficiency 1d is resolved.

Deficiency #2a

DEB indicated in the review dated 9/2/88 that the rates on labels should be changed from 240 to 300 lb ai/A if the 300 lb ai/A rate was to be used in residue studies.

Petitioner's Response to Deficiency 2a

"MBIP does not understand why the Agency is concerned about the Panel generating residue data at a 300-lb rate when most labels have a 240-lb rate listed. The 300-lb rate builds an extra margin of safety into the residue data. Is it the Agency's policy to not permit the registrant to have a rate on his label lower than that used to generate the residue data? If so, does this mean we can no longer have a dosage range on our labels?"

MBIP generated all residue data at the 300-lb methyl bromide per acre rate for the following reasons:

1. Some crops in MBIP's residue trials need the 300 lb/A rate for disease control. Because all crops were grown in the same plots, it was necessary to treat them all at the same rate.
2. Because the large specialized equipment used for soil application of methyl bromide is difficult to maneuver, it is not possible to treat small plots.

Because the 300 lb/A rate is only a 25 percent increase over the 240 lb/A rate, MBIP believes the increase would not add significantly to methyl bromide residues and consequently would have little or no effect on the ADI. Moreover, risk assessment for the ADI will be based on data generated at 300 lb/A, therefore representing a worse case scenario.

DEB suggested that all labels be changed to reflect the 300 lb/A rate. MBIP is proposing to continue the 240 lb/A rate on its labels except for the crops requiring the higher rate. This should eliminate the concern for expanded geographic areas as expressed by Ms. Dodd (page 26) in her letter of September 9, 1988."

DEB's Comments/Conclusions re: Deficiency 2a

Deficiency 2a is resolved.

DEB no longer objects to the MBIP's proposal to keep labels for most crops at 240 lb ai/A but to conduct residue studies for most crops at 300 lb ai/A, since the 300 lb ai/A rate is reasonably close and higher than the label rate of 240 lb ai/A.

The issue of adequate geographic representation is discussed in Deficiency #8 below.

DEB's Deficiency 2bii

A rate in Table 1 of 400 lb ai/A for asparagus in California and 240 lb ai/A (or 400 lb ai/A) in Washington would be adequate if appropriate labels and residue data are provided. Ideal residue data for asparagus would be from California, New Jersey, Washington, Massachusetts, and Illinois/Michigan. The Methyl Bromide Registration Standard requested data from California, Washington, and Michigan.

Petitioner's Response to Deficiency 2bii

The application rate for asparagus in Table 1 was dropped from 400 to 300 lb ai/A for both California and Washington.

"Because asparagus is a minor crop, MBIP understands that only three geographic areas need to be tested. This is in agreement with Dr. Robert Libby of the IR-4 program (Telecom 1/89). According to Dr. Libby, the IR-4 "Ideal Geographic Representation List" is set up for major crops with minor crops using only 2 to 3 of the areas listed. We propose that California and Washington be the areas for generating asparagus residue data."

DEB's Comments/Conclusions re: Deficiency 2bii

DEB has no objection to the 300 lb ai/A application rate for asparagus in Washington since the label rate is lower (maximum 240 lb ai/A).

Since the label now allows application at a maximum rate of 400 lb ai/A in California, however, the label should be revised to allow a maximum rate of 300 lb ai/A in California, since the residue data will be collected at the lower rate of 300 lb ai/A.

The MBIP has previously indicated (see DEB's September 28, 1988 review) that asparagus in Michigan is not grown on MeBr-treated soil.

DEB concludes that the registrant must either conduct residue trials in Michigan, New Jersey, or Illinois (in addition to California and Washington); or propose regional registration (confined to California and the Pacific Northwest).

Deficiency 2bii remains outstanding.

Deficiency 2biii

DEB indicated (review of September 2, 1988) that residue data for tobacco should be obtained from North Carolina, Kentucky, Georgia, Maryland/Pennsylvania, and Wisconsin.

Petitioner's Response to Deficiency 2biii

"The Methyl Bromide Registration Standard proposes that tobacco residue data be generated in North Carolina and Kentucky. Therefore, MBIP proposes to generate the tobacco residue data in North Carolina and Kentucky."

DEB's Comments/Conclusions re: Deficiency 2biii

DEB now concludes that residue data from North Carolina and Kentucky as requested in the Methyl Bromide Registration Standard will be sufficient.

Deficiency 2biii is resolved.

Deficiency 2biv

The rate for pineapples should be 240 lb ai/A.

Petitioner's Response to Deficiency 2biv

See Petitioner's Response to Deficiency 2a.

DEB's Comments/Conclusions re: Deficiency 2biv

Deficiency 2biv is resolved. The 300 lb ai/A rate for residue studies is acceptable.

Deficiency 2bv

The rate for grapes should be 600 lb ai/A. The rate for Rubus spp., blueberry, and cranberry should be 240 lb ai/A since the rate which is proposed for small fruits and berries in PP#5F3198 is apparently up to 240 lb ai/A.

Petitioner's Response to Deficiency 2bv

See Petitioner's Response to Deficiency 2a.

DEB's Comments/Conclusions re: Deficiency 2bv

Table 1 now proposes a rate of 600 lb ai/A for grapes, as requested, and a rate of 300 lb ai/A for the other small fruits and berries.

Deficiency 2bv is resolved. The proposed rates are acceptable.

Deficiency 2bvi

DEB requested revised labels for bulb vegetables if residue data were to be obtained at 300 instead of 240 lb ai/A.

Petitioner's Response to Deficiency 2bvi

See Petitioner's Response to Deficiency 2a.

DEB's Comments/Conclusions re: Deficiency 2bvi

Deficiency 2bvi is resolved. The 300 lb ai/A rate for residue studies is acceptable without label changes.

Deficiency 2bvii

DEB indicated (review dated September 2, 1988) that the proposed rate for lettuce in California, Arizona, and Florida was adequate. The MBIP subsequently revised Table 1 to list a rate of 300 lb ai/A for lettuce in California, Florida, and Texas.

Petitioner's Response to Deficiency 2bvii

See Petitioner's Response to Deficiency 2a.

DEB's Comments/Conclusions re: Deficiency 2bvii

Since the use rate on lettuce labels is 400 lb ai/A, residue data must be generated at 400 lb ai/A or those labels must be revised to permit a rate of \leq 300 lb ai/A.

Deficiency 2bvii is not resolved.

Deficiency 2bviii

Proposed label rates of 240 lb ai/A for celery and spinach should be revised to 300 lb ai/A if residue data is to be obtained at the higher rate.

Petitioner's Response to Deficiency 2bviii

See Petitioner's Response to Deficiency 2a.

DEB's Comments/Conclusions re: Deficiency 2bviii

Deficiency 2bviii is resolved. Residue studies at the higher rate of 300 lb ai/A are acceptable.

Deficiency 2bix

Proposed label rates of 240 lb ai/A for cabbage, mustard greens, and broccoli should be revised to 300 lb ai/A if residue data are to be obtained at the 300 lb ai/A rate.

Petitioner's Response to Deficiency 2bix

See Petitioner's Response to Deficiency 2a.

DEB's Comments/Conclusions re: Deficiency 2bix

Deficiency 2bix is resolved. Residue studies at the higher rate of 300 lb ai/A are acceptable without label changes.

Deficiency 2c

Proposed label rates for the root and tuber vegetables group, the legume vegetables group, and the herbs and spices group should be revised to 300 lb ai/A if residue data are to be obtained at the 300 lb ai/A rate.

Petitioner's Response to Deficiency 2c

See Petitioner's Response to Deficiency 2a.

DEB's Comments/Conclusions re: Deficiency 2c

Deficiency 2c is resolved. Residue studies at the higher rate of 300 lb ai/A are acceptable without label changes.

Deficiency 2d

Rate and site information (from IR-4) are needed for okra. Adequate geographic representation is not proposed for sweet corn and peanuts.

Petitioner's Response to Deficiency 2d

"MBIP now proposes to eliminate sweet corn from its residue study and proposes to do the residue work for peanuts

in the following regions: Georgia/Alabama/Florida; Virginia/North Carolina; Texas/Oklahoma/New Mexico."

DEB's Comments/Conclusions re: Deficiency 2d

The proposed residue sites in Table 1 for peanuts are now Florida, Texas, and North Carolina.

The ideal geographic representation (from Agricultural Statistics 1986 or DEB files) for peanuts was previously given as Georgia/Alabama/Florida, Virginia/North Carolina, Texas/Oklahoma, and New Mexico.

Since New Mexico, Texas, and Oklahoma are adjacent, data are needed for only one of those states.

DEB concludes that Deficiency 2d concerning sweet corn and peanuts is resolved by deletion of sweet corn from the residue study and by identifying the states of Florida, Texas, and North Carolina (or the regions of Georgia/Alabama/Florida, Virginia/North Carolina, and Texas/Oklahoma/New Mexico) as sites for peanuts.

Deficiency 2d concerning okra remains outstanding.

Deficiency 2e

Labels for application of MeBr to alfalfa and clover will be needed.

Petitioner's Response to Deficiency 2e

None.

DEB's Comments/Conclusions re: Deficiency 2e

Deficiency 2e remains outstanding. Labels for application of MeBr to alfalfa and clover will be needed.

Deficiency 3

Any new iBr or MeBr tolerances must be adequate to cover both the proposed preplant use and any registered postharvest applications. Crop samples grown on fumigated soil must also be fumigated postharvest when both preplant soil treatment and postharvest fumigation are to be registered. MBIP's Table 2 (see Deficiency 4 below) is not a complete list of raw agricultural commodities (RACs) to be treated both preplant and postharvest and then processed.

Petitioner's Response to Deficiency 3

"MBIP has petitioned the Agency for deletion of iBr residue tolerances. Should this petition be granted then iBr accumulation will not be an issue in the RACs which are postharvest fumigated. To date no MeBr residues have been found in crops grown on preplant fumigated soil. Therefore, only MeBr residues resulting from postharvest fumigation will be an issue in postharvest fumigated commodities. MBIP will hold their response to this issue in abeyance until the Agency makes a decision on iBr tolerances.

MeBr is a volatile compound with a boiling point of 37 F. Therefore, any processing of RACs will result in a dissipation rather than a concentration of residue."

DEB's Comments/Conclusions re: Deficiency 3

Available residue data on MeBr per se in commodities planted in fumigated soil are limited because tolerances were previously set on iBr. Additional residue data on MeBr per se have previously been requested (PP#5F3198, M. Firestone, April 12, 1985 and August 22, 1986 and N. Dodd, May 27, 1987; MeBr Registration Standard).

DEB cannot conclude at this time that no detectable residues of MeBr per se will be found in crops resulting from soil fumigation.

If additional residue data on MeBr per se are available to the MBIP, it should be submitted to EPA for further consideration of this issue.

In any case, residue data reflecting soil fumigation will be needed only for any crops which may be treated by soil fumigation but not by postharvest fumigation. New methyl bromide tolerances will not include iBr. Therefore, data reflecting the use likely to result in the majority of the MeBr residues will be required and used in tolerance setting (postharvest fumigation, if registered).

Deficiency 3 is resolved.

Deficiency 4

The MBIP has submitted a table (Table 2 below) which lists those RACs which will be fumigated both preplant and postharvest, and then processed to see if residues concentrate during processing operations.

Table 2
Sampling of Crops

<u>RAC</u>	<u>Processed Into</u>
Potato	Granules, Chips, Dried
*Soybean	Meal, Soapstock, Crude Oil, Refined Oil
Tomato	Wet Pomace, Dry Pomace, Catsup, Juice
Orange	Dry Pulp, Peel, Wet Pomace, Dry Pomace, Juice
Grape	Raisin, Juice, Wet Pomace, Dry Pomace
Peanut	Meal, Soapstock, Crude Oil, Refined Oil
Pineapple	Bran, Juice
Apple	Juice, Applesauce, Wet and Dry Pomace
Spices	Ground Spice

However, the MBIP has not adequately indicated what processed commodities and animal feeds it intends to analyze along with the RACs. Residue data will also be needed for the following processed commodities/feeds after both soil treatment and postharvest fumigation:

RACs

Potatoes - Add wet peel, dry peel, and processed potato waste.

Soybeans - Add hulls.

Tomatoes - Add puree.

Orange - Add wet pulp, molasses, and oil.

Add plums - Add prunes.

Add almonds - Add hulls.

Add sugar beets - Add molasses, dehydrated pulp, and refined sugar.

Add mustard greens - Add seeds.

Add beans (succulent and dry) - Add cannery residues.

Grapes - Add raisin waste.

Add sweet corn - Add cannery waste.

Spices - Add dried spice. (For spices, the RAC is fresh spice and the processed commodity is dried spice.)

*Note: If a tolerance is not being sought for soybeans (see Table 1 of this submission), then a processing study on soybeans is not needed.

Note: DEB understands that clover is not to be treated postharvest. However, residues in both fresh clover and clover hay should be determined in connection with the soil fumigation use.

Petitioner's Response to Deficiency 4

MBIP refers to the discussion of Deficiency 3.

DEB's Comments/Conclusions re: Deficiency 4

As stated above, residue data reflecting soil fumigation will be needed only for those crops that may be treated preharvest but not postharvest. This approach also applies to processing requirements: Commodities bearing measurable weathered residues resulting from soil fumigation must be processed, unless the commodity may also be treated postharvest. (Processing studies reflecting only postharvest use would then be required). Data are required for all products identified in DEB's 9/2/88 review (deficiency 4) except those that are the products of processing procedures that involve extended drying times or elevated temperatures. (Additional data may be required if the ongoing plant metabolism studies reveal residues of concern other than MeBr.)

Deficiency 4 remains outstanding.

Deficiency 5

Some proposed/established uses do not specify a minimum interval between application and planting. The labels should be changed to conform to the protocol or the protocol should be changed.

Petitioner's Response to Deficiency 5

A revised label will be submitted.

DEB's Comments/Conclusions re: Deficiency 5

Deficiency 5 remains outstanding pending submission of revised MeBr labels to conform to the protocol's minimum interval between application and planting.

Deficiency 6a

DEB has previously indicated that residues of MeBr per se should be analyzed "as soon as possible (perhaps within 12 hours) after sampling and/or that samples must be stored in impermeable containers" since storage stability data show that MeBr can be lost significantly from fumigated raw and processed crop products. (See the MeBr Registration Standard and also RCB's February 19, 1986 review of PP#5F3300.) If the petitioner finds that he needs 18 hours between harvest and analyses, he should investigate how much MeBr per se would be lost during that time period.

Petitioner's Response to Deficiency 6a

"MBIP believes that sample storage stability should not be an issue for the following reasons:

- a. Samples were analyzed as soon as they arrived at the laboratory. Samples were not stored in the lab. When samples were shipped to the lab, they were placed in closed glass canning jars and shipped on dry ice. Upon receipt in the lab they were immediately analyzed. All out-of-town samples were shipped to the lab by overnight express which could result in a harvest to analyses time of 18 hours. Of the 40+ crops analyzed thus far, no detectable level of MeBr has been found. Approximately 25 percent of the samples were analyzed within 45 minutes after harvest. Because MeBr was nondetectable at the time of analyses, the generation of percent loss data would have no meaning, e.g., 10 percent of 0 is still zero. Therefore, the only way to assess MeBr loss during shipment is to do the analysis immediately after harvest. This means having the lab next to the field where the crops are grown. This is not possible to do in most cases.

We are finding it difficult to design a study that will give meaningful and useful data.

- b. The time interval between fumigation of the soil and harvest would be 90 days plus for most crops. Twenty-five percent of the samples were analyzed within 45 minutes of harvest and none of the samples were found to contain MeBr. The MBIP contends that any potential

residue that is lost in the time up to 18 hours from a sealed glass jar packed in dry ice is of little consequence, especially considering the time from application to harvest."

DEB's Comments/Conclusions re: Deficiency 6a

For preplant soil applications only, DEB has no objection to an 18-hour sampling to analysis time since samples are stored in impermeable containers.

The concerns related to postharvest fumigation are addressed in C. Deyrup's concurrent review (April 25, 1989).

Deficiency 6a has been resolved.

Deficiency 7b

Concerning the ion selective electrode method, DEB will need the validation/recovery data requested in the Residue Chemistry Chapter (dated March 28, 1986) of the MeBr Registration Standard and answers to the method issues raised in DEB's July 14, 1988 review of the follow-up to the Methyl Bromide Registration Standard.

Petitioner's Response re: Deficiency 7b

Data were submitted to EPA under separate cover.

DEB's Comments/Conclusions re: Deficiency 7b

These data have not yet been received for review in DEB.

Deficiency 8

DEB concludes that the geographical representations as proposed by the MBIP with the March 11, 1988 letter are adequate for the following crops: celery, basil, chives, marjoram, sage, avocados, pineapples, pistachio nuts, radish, garlic, lemon, almond, oranges, and grapefruit.

However, Deficiency No. 8 is not resolved. DEB suggests that the MBIP follow the "Ideal Geographic Representation from IR-4 Memorandum or RCB Files" for the remainder of the crops not listed above.

Petitioner's Response to Deficiency 8

"MBIP proposed to generate the residue data at 300 lb MeBr/A as discussed in 2. However, the label will reflect the 240 lb MeBr/A usage rate. Since the label rate is identical to the residue data reviewed previously by the Agency, we

believe no additional residues are required other than those required in the Registration Standard.

Furthermore, IR-4's "Ideal Geographic Representation" is an ideal list and not a required list."

DEB's Comments/Conclusions re: Deficiency 8

The MBIP should generally follow the "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 allows selection of one state from states that are adjacent).

The MeBr Registration Standard concerned registered uses, not those proposed in PP#5F3198. Therefore, its list of requirements for residue data for proposed uses is not complete.

Other Deficiency

The petitioner has deleted soybeans from the crop group "legume vegetables" on the revised Table 1 submitted on March 11, 1988. Since soybeans are a representative crop, DEB recommends that the individual remaining commodities from the legume vegetables group be listed under "Miscellaneous".

The revised Table 1 lists "legume vegetables (except soybeans)."

Petitioner's Response to "Other Deficiency"

"MBIP does not wish to support the development of data in soybeans because there is no economic basis to do so.

It is our understanding from the Agency that a representative crop within a crop group may be deleted specifically if the use is not supported by the registrant. We propose, therefore, to establish a tolerance for legume vegetables except soybeans."

DEB's Comments/Conclusions re: "Other Deficiency"

DEB concludes that a tolerance proposal for "legume vegetables (except soybeans)" is acceptable.

This deficiency is resolved.

Other Considerations

1. Onions (small bulb) have been dropped from the revised Table 1, leaving onion (green), onion (large bulb), and garlic as representative crops for the bulb vegetables group.

DEB has no objection to dropping onions (small bulb) from the list since the representative commodities for the bulb vegetables crop group are "onion (green and bulb) and one other commodity."

2. Residue data on onions should include data on onions grown from seeds, sets, and transplants since the PHI's are different and, therefore, residue data may differ.
3. For other crops which can be planted as seeds or transplants from or to treated soil, residue data for all scenarios are needed.

cc: N. Dodd (DEB), PP#5F3198, E. Eldredge (ISB/PMSD),
Circulation (6), RF, MeBr Registration Standard File - W.
Boodee

RDI:D. Edwards:4/27/89:R.Loranger:4/27/89

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