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OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Follow-up to Methyl Bromide Registration Standard. Amendment of 2/10/89. MBIP Response to DEB's 11/3/88 Review on Postharvest Protocols, Analytical Methodology and Storage Stability. (DEB # 4999) No MRID No.

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and

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Background

In its review of 11/3/88 (memo of C. Deyrup), DEB had cited a number of problems associated with the postharvest protocols, analytical methodology, and storage stability.

The issues cited below, relating to metabolism studies, the analytical methodology, and the generation of residue data still need to be resolved. More detailed discussions of these issues appear in the main body of the review.

Summary of Remaining Issues

1. In its review of 2/9/89, DEB cautioned that the registrant's approach to determining the contribution that MeBr makes to

the total terminal residue is feasible only if MeBr levels from replicate fumigations show no significant variation; otherwise the metabolism studies would need to be repeated in order to determine the contribution of MeBr to the total radioactive residue.

2. If the metabolism study indicates the presence of 5-BrU, its occurrence should be confirmed by an independent method.
3. Neither RD nor DEB has received the submission explaining the conversion of ppm (v/v) to ppm (w/w). The registrant will need to resubmit the data.
4. The registrant still needs to resolve the issues regarding 1) the use of the standard curves to give the reported residue levels for MeBr and 2) apparent discrepancies in the data of 9/22/88 and 1/20/88.
5. If the registrant elects not to freeze the samples, he should describe the precautions taken to avoid loss of MeBr during maceration.
6. DEB concludes that any method used by the registrant to measure iBr would have to be supported by adequate fortification/recovery data, in order to be considered acceptable.

[The question of iBr methodologies may be rendered moot by the registrant's submission requesting that TOX reconsider the need for regulating residues of iBr.]

7. DEB has concluded that MeBr storage stability studies are not needed, if the samples are to be analyzed within 2-3 hours. However, the samples should be placed in impermeable containers, and the samples should be chilled to <3.7°C as quickly as possible.
8. Although the Methyl Bromide Registration Standard requested storage stability data for iBr, this information would not be needed if TOX should conclude that iBr is not of concern, or if the registrant carries out analyses within 2-3 hours of sampling.
9. As the Registration Standard specified, the fumigations should be conducted at maximum label rates and represent actual commercial fumigation events in all respects, such as MeBr introduction, temperature, humidity, air circulation, packaging, load factor, and aeration and storage conditions.
10. At the 12/15/88 meeting with the MBIP and the USDA/ARS, P. Hartsell, USDA, was uncertain that low load factors would represent the worst case because of conflicting data he had obtained in one trial using a low load factor.

At this meeting, it was agreed that the effect of load factor would need to be checked.

11. Other factors which need to be addressed in generating residue data for the postharvest use are: the fumigation of waxed commodities, the number of applications, potential residues on grain dust, the inclusion of a representative number of bruised fruit, aeration periods, sampling technique, and the aeration temperatures. DEB will judge the adequacy with which these issues are addressed upon receipt of the protocols.
12. MBIP should heed DEB's comments contained in previous memos and in the Registration Standard regarding the conduct of metabolism studies, the analytical methodology, and generation of residue data for postharvest use.

### Recommendations

DEB recommends that the protocols be modified to take into account the issues contained in DEB's Comments/Conclusions in this review. Where appropriate, the registrant should also consider DEB's Comments/Conclusions from previous memos and the Registration Standard.

### Present Consideration

The present amendment contains the Methyl Bromide Industry Panel's (MBIP) response to DEB's reviews of 7/14/88 and 11/3/88.

Although this amendment also contains the revised Table 1, which lists the preplant dosage for many commodities, the registrant is referred to DEB's review of preplant issues (DEB #4998) for a discussion of the revised table.

DEB's previous comments will be cited below under the appropriate heading, followed by the MBIP's response, and DEB's current Comments/Conclusions.

### Metabolism Studies

#### Availability of Study Plan for Review, Memo of 11/3/88

As of 11/3/88, DEB had not been able to find a copy of the proposed metabolism study plan.

#### MBIP's Response, 2/10/89

The study plan has been resubmitted.

#### DEB's Comments/Conclusions

The study plan was resubmitted with the amendment of 11/17/88 along with six interim reports and articles and future study

plans; the issue of the missing protocol is resolved. This amendment was reviewed in great detail in DEB's memo of 2/9/89 (memo of C. Deyrup), and the registrant is referred to this review for a discussion of DEB's conclusions, recommendations, and comments.

Characterization of the Total Radioactive Residue, Memos of 7/14/88, 11/3/88, and 2/9/89

In its 7/14/88, 11/3/88, and 2/9/89 reviews (memo of C. Deyrup), DEB emphasized that metabolism studies should attempt to account for the total radioactive residue (TRR), not just the chemically bound residues. Since the commodities treated with  $^{14}\text{C}$  MeBr had been lyophilized or soxhlet-extracted before counting, only chemically bound  $^{14}\text{C}$  had been investigated. This issue was also discussed with the registrant at the meeting of 11/10/88.

MBIP's Response, 2/10/89

A study plan aimed at delineating the total radioactive residue was submitted under separate cover (also dated 2/10/89).

DEB's Comments/Conclusions

DEB's detailed comments are to be found in its review of the submitted study plan (DEB # 5001).

Briefly, the registrant will treat commodities with unlabeled MeBr so as mimic the labeled metabolism studies. Directly after aeration, levels of MeBr, and possibly methanol and MeCl, will be determined by GC. The levels of the volatile residues will be added to the level of the chemically bound residues determined by radioassay to give an estimate of the total residue, and the contribution of MeBr to the total residue.

In its review of 2/9/89, DEB cautioned that this approach is feasible only if MeBr levels from replicate fumigations show no significant variation; otherwise the metabolism studies may need to be repeated in order to determine the contribution of MeBr to the total radioactive residue.

Is 5-Bromouracil (5-BrU) Present? Memo of 11/3/88

DEB recommended that the registrant determine whether 5-BrU is present chromatographically, by LC/MS, or any other appropriate methodology.

MBIP's Response, 2/10/89

See the study plan submitted with the 2/10/89 amendment.

DEB's Comments/Conclusions

DEB's detailed comments are to be found in its review of the

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submitted study plan (DEB # 5001); DEB considers the protocol to be adequate. If the presence of 5-BrU is indicated, its occurrence should be confirmed by an independent method.

#### Residue Analytical Methods

##### Publication of the Revised MeBr Method in PAM II as a Letter Method, Memos of 7/14/88, 11/3/88

The latest revision of the MeBr analytical method contained modifications which would be useful for a chemist attempting the analysis. DEB recommended that the method be rewritten for the sake of clarity and then published in PAM II as a letter method.

DEB concluded in its 11/3/88 memo that the method had been satisfactorily rewritten.

##### MBIP's Response, 2/10/89

MBIP wants to know how to publish the revised method in PAM II.

##### DEB's Comments/Conclusions

DEB will initiate publication of the revised method in PAM II.

##### Explanation of "Adj ppm," Memo of 11/3/89

A column headed "Concen" had been crossed out, and all the entries, without explanation, were replaced by another column, headed "Adj ppm." Dr. Duafala (Trical) explained in a telecon that the original entries represented MeBr ppm on a v/v basis and were not appropriate for expressing concentrations in solid commodities. He added that a written explanation and recalculation of the "Adj ppm" would be submitted.

##### MBIP's Response

The data were submitted to address this issue.

##### DEB's Comments/Conclusions

DEB has not yet received this submission. DEB checked with W. Francis (RD), who said that he hadn't seen any submissions dealing with the recalculation of residue levels. The registrant will need to resubmit the data.

##### The Use of Log-Log Paper to Plot Standard Curves, Memo of 11/3/89

DEB objected to the use of log-log paper to plot standard curves. It is not standard procedure to use log-log paper because it is not possible to tell whether the values reflect the range of the most sensitive instrument response; this range corresponds to the linear region of standard curves plotted on regular paper.

MBIP's Response, 2/10/89

This issue was discussed at the 12/16/88 meeting and is resolved.

DEB's Comments/Conclusions

DEB has discussed the use of log-log paper with Dr. Duafala in a telecon as well as at the 12/16/88 meeting. Log-log paper will not be used in future submissions. The issue is resolved.

Use of Standard Curves to Determine Residue Levels and Reported MeBr Residue Levels, Memo of 11/3/88

In addition to questioning the standard curve for walnuts which essentially appeared to consist of two points on log-log paper, DEB had also asked the registrant to explain how the standard curves were used to obtain the reported residue levels for MeBr. DEB's estimates differed from the registrant's; DEB had used the submitted standard curves to arrive at its estimates.

The registrant had submitted a study comparing MeBr levels in commodities fumigated under tarps, in a fumigation room, in a vault, and in a vacuum fumigation chamber. DEB wanted to know why the levels reported in the 9/22/88 amendment appeared to be at variance with those reported in the 1/20/88 submission.

MBIP's Response

These issues will be discussed in a separate submission from Bolsa Labs, which conducted the studies.

DEB's Comments/Conclusions

These issues are still outstanding.

Possible Loss of Analyte during Maceration, Memo of 11/3/88

DEB wanted to know what precautions had been taken during maceration to prevent loss of the volatile analyte.

MBIP's Response, 2/10/89

Samples are received at the lab on dry ice. The frozen samples are fractured with a mallet, and quickly subdivided into blending jars to minimize residue loss.

DEB's Comments/Conclusions

DEB is no longer concerned that MeBr may diffuse from samples before the determinative step, if the samples are handled as described above.

When DEB met with the MBIP on 12/16/88, DEB was informed that

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the sampling to analysis time would be 2-3 hours, rather than several days. DEB was not concerned that the levels of the analyte would decline significantly during the trip to the lab, provided that the commodities were chilled as quickly as possible to  $<3.7^{\circ}\text{C}$  (the boiling point of MeBr). DEB told the registrant that freezing would not be necessary for the trip to the lab. As the registrant pointed out, the samples would be analyzed before they would have a chance to freeze--even if they were placed on dry ice.

If the registrant elects not to freeze the samples, he should describe the precautions taken to avoid loss of MeBr. In meetings with the registrant, DEB has explained that problems have arisen during this step with other volatile pesticides.

#### Erratic iBr Analyses, Memo of 11/3/88

DEB concluded that the ion selective electrode (ISE) method was too unreliable to be used to generate residue data.

#### MBIP's Response, 2/10/89

At the meeting of 12/16/88, the registrant agreed to submit additional data and equations.

#### DEB's Comments/Conclusions

DEB's account of the ISE discussion, taken from the memo of the 12/16/88 conference, is repeated below.

"Bolsa had assembled a package including the resumes of the lab personnel and a defense of the ISE (ion selective electrode) method of analysis. Bolsa had originally programmed the instrument so that ppm iBr could be read directly from the machine. Bolsa found that if millivolts were recorded, then plotted vs concentration iBr, and the slope of the resulting line was plugged into the relevant equation, reasonable recoveries resulted. Reading the ppm iBr from the meter had led to recoveries ranging up to 187%. Bolsa could not explain why this difference resulted as they were simply carrying out the same operations as the meter. They reasoned that there must be some sort of electrical bias built into the machine. DEB told them that plots of mV vs concentration would need to be submitted before DEB could judge the adequacy of the ISE method. DEB noted that the results for strawberries were even worse than when ppm were read directly from the machine, i.e., the recoveries exceeded 100% by a still larger percentage. Since the originally submitted strawberry data contained recoveries ranging from 89-187% as well as a level of almost 22,000 ppm from one anomalous run, DEB concluded that the ISE method does not appear applicable to strawberries.

The ISE method uses a standard addition; therefore each determination generates recovery data. DEB suggested that the GC method should be used whenever it becomes apparent that the ISE method

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isn't working with a particular commodity. By incorporating flexibility into the iBr analyses, Trical would generally be able to use the faster, simpler ISE method and reserve the GC method for recalcitrant matrices. DEB explained that either method would be acceptable, as long as it was supported by adequate fortification/recovery data."

DEB has not yet received the Bolsa submission. However, DEB still concludes that any method used by the registrant would have to be supported by adequate fortification/recovery data, in order to be considered acceptable.

[The question of iBr methodologies may be rendered moot by the registrant's submission requesting that TOX reconsider the need for regulating residues of iBr.]

#### Storage Stability Data

##### Methodology Used to Generate Storage Stability Data, Memo of 11/3/88

DEB had concluded that inadequate methodologies were used to determine levels of MeBr and iBr in the storage stability studies.

##### MBIP's Response, 2/10/89

Bolsa will submit additional data.

##### DEB's Comments/Conclusions

DEB has concluded that MeBr storage stability studies are not needed, if the samples are to be analyzed within 2-3 hours. Therefore, additional data would not be needed, unless the sampling to storage period approaches 10-12 hours.

Although the Methyl Bromide Registration Standard requested storage stability data for iBr, this information would not be needed, if TOX should conclude that iBr is not a residue of concern or if the registrant conducts analyses within 2-3 hours of sampling.

##### Storage Stability Data to Cover the Sampling to Analysis Period, Memos of 7/14/88 and 11/3/88

Storage stability data are needed to cover the sampling to analysis period for each commodity. Since commodities may be analyzed by the FDA as soon as they enter interstate commerce, DEB must be able to estimate the residue level of the commodities at that point.

##### MBIP's Response, 2/10/89

"Samples are analyzed as quickly as possible and in many cases

within 45 minutes. In every case, they are analyzed as quickly as possible. How can we analyze for residues earlier than 'as soon as possible'? We believe the extraordinary precautions in handling these samples will result in shortening of time between sampling and analyses. Furthermore the sampling and analysis will be accomplished before the RAC enter into interstate commerce for monitoring by FDA."

#### DEB's Comments/Conclusions

The Methyl Bromide Registration Standard cited data indicating that up to 85% of the MeBr was lost from frozen commodities stored in plastic bags after 0-7 days. The Standard therefore "strongly suggested" that spiked commodities be carried through the sampling, storage, and analysis steps.

According to the MBIP's previous response (amendment of 9/22/88), analyses would be conducted within 24 hours of sampling, a period described as "as soon as physically possible." Given the significant decline in some samples after 0-7 days storage, this information did not allay DEB's concerns that a substantial amount of the volatile MeBr might be lost during storage.

The registrant has found that it is possible to significantly reduce the storage period so that samples will be analyzed within 2-3 hours (meeting of 12/16/88), with many analyses being completed within 45 minutes of sampling. Provided that this revised protocol is followed, DEB is not concerned about the loss of MeBr residues during this short period; it will not be necessary to submit storage stability data for each commodity. However, the samples should be placed in impermeable containers, and the samples should be chilled to <3.7°C as quickly as possible.

The Registration Standard had cited the need for storage stability data for iBr residues. However, the registrant has submitted an amendment questioning the need to regulate iBr residues. Storage stability data for iBr would not be needed, if TOX should conclude that iBr is not a residue of concern or if the registrant conducts analyses within 2-3 hours of sampling.

#### Use of an FID Detector for the Storage Stability Study, Memo of 11/3/88

Although the registrant explained that the previous submission had expressed MeBr levels in terms of ppm (v/v) instead of (w/w), DEB needed to know how these different representations of concentration are mathematically related.

#### MBIP's Response, 2/10/89

This issue has already been addressed in a previous submission.

#### DEB's Comments/Conclusions

DEB has not been able to find this submission in its files.

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The registrant will need to resubmit the calculations which translate MeBr ppm (v/v) to MeBr ppm (w/w). The information should include the definition of MeBr ppm (v/v) as it applies to solid commodities and an explanation of the correction factors used in the mathematical conversion.

#### Residue data

In its memo of 7/14/88, DEB cited a number of factors which should be considered in generating residue data. The issues discussed below follow the numbering of the residue data factors listed in the 7/14/88 memo.

#### Other Factors in Generating the Residue Data (Memo of 7/14/88)

1. RCB's guidelines as put forth in its review of the almond protocol (memo of W. Hazel, 11/3/87), apply to all residue tests. The tests should be conducted at maximum label rates and represent actual commercial fumigation events in all respects, such as MeBr introduction, temperature, humidity, air circulation, packaging, load factor, and aeration and storage conditions. For example, grapes may be packaged in lugs containing wood shavings, which, according to the APHIS plant protection manual, are highly sorbent. Also, many commodities are stored cold after fumigation. Moreover, the residue data should reflect the range of temperatures expected during fumigation, or MBIP should demonstrate that the fumigation temperatures chosen represent the worst case. RCB notes that the APHIS manual uses lower rates with higher fumigation temperatures, but there is no tie-in of the rate and the fumigation temperature on the label submitted PP #5F3300.

#### MBIP's Response, 2/10/89

Each applicable issue will be addressed specifically in the protocol.

#### DEB's Comments/Conclusions

The adequacy of the proposed protocols will depend, on part, on the thoroughness with which the above issues are addressed. In its memo of 4/10/89, DEB concluded that the registrant will need to generate residue data reflecting the fumigation of bagged and unbagged commodities.

Since the revised protocols have not yet been received, these issues are not yet resolved.

#### Other Factors in Generating the Residue Data (Memos of 7/14/88 and 11/3/89)

The registrant needn't monitor levels of MeBr in the chamber, provided that:

1. The load factors employed are relatively low (C.R. Sell,

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USDA/ARS, recommends <10%, using the APHIS definition of load factor), and

2. Samples are taken from all areas of the chamber and are composited before analysis. The samples should also be drawn from the top, middle, and bottom of the containers.

MBIP's Response, 2/10/89

Each protocol will take the above factors into consideration when applicable.

DEB's Comments/Conclusions

At the 12/15/88 meeting with the MBIP and the USDA/ARS, P. Hartsell, USDA, was uncertain that low load factors would represent the worst case because of conflicting data he had obtained in one trial using a low load factor. At this meeting, it was agreed that the effect of load factor would need to be checked.

Since the revised protocols have not yet been received, and the effect of load factor has not yet been explored, these issues are not yet resolved.

Other Factors in Generating Residue Data (Memo of 7/14/88)

3. Many commodities are waxed. Where appropriate, residue data should be generated on waxed and unwaxed commodities.

MBIP's Response, 2/10/89

If commodities are waxed, then waxed commodities will be fumigated as practiced by the industry. The issue will be addressed in the protocol for each commodity.

DEB's Comments/Conclusions

The issue of waxing will need to be addressed in each protocol. If the registrant does not believe that residue data on a particular waxed commodity are necessary, he will need to support this position by citing experts from the appropriate industry.

For instance, in its memo of the 11/10/88 conference, the registrant states that only apples intended for export to Japan are fumigated. The registrant does not need a domestic tolerance for apples going to Japan, provided that precautions are taken to ensure that these apples do not enter the domestic market. But if the registrant seeks to establish a MeBr tolerance on apples for the domestic market, he will need to demonstrate that it is commercially practical to restrict fumigation to unwaxed apples.

Currently the citrus industry fumigates waxed citrus. The MBIP has information that the citrus industry intends to change its

fumigation procedure so that only unwaxed citrus would be fumigated. Again, this change in procedure would need to be supported by documentation.

DEB reminds the registrant that different kinds of waxes are used. For instance, two types of waxes are used on apples. The two waxes, carnauba and shellac, may affect residue levels differently (Dr H. Moffitt, USDA/ARS).

Other Factors in Generating Residue Data (Memo of 7/14/88)

4. The residue data should encompass a range of sizes of a commodity. For example, data on both tomatoes and cherry tomatoes should be generated.

MBIP's Response, 2/10/89

The MBIP will generate residue data on both the cherry tomatoes and regular tomatoes.

DEB's Comments/Conclusions

In the protocols submitted thus far, tomatoes were the only commodity which would encompass a wide range of sizes. DEB had been especially concerned about tomatoes because cherry tomatoes and regular tomatoes travel separately through interstate commerce. This issue is resolved.

Other Factors in Generating Residue Data (Memos of 7/14/88 and 11/3/88)

5. Residue data reflecting multiple applications are required when appropriate. MBIP will need to explain how it determined the number of applications for each commodity and should support its protocol with documentation.

MBIP's Response, 2/10/89

The number of fumigations will be determined by industry practices and confirmed by letters from experts.

DEB's Comments/Conclusions

The adequacy of this aspect of the protocols will be assessed upon receipt of the protocols.

[Issues 6 and 7 were resolved (see memo of 11/3/88)]

Other Factors in Generating Residue Data (Memo of 7/14/88)

8. The use of MeBr in grain elevators could lead to higher residue levels in grain dust than in the grain itself. Grain dust is a cattle feed item. Therefore residue data on grain dust are also required.

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MBIP's Response, 2/10/89

This issue will be addressed in the protocol.

DEB's Comments/Conclusions

DEB can't comment on the protocol, since it has not yet been received. However, the registrant should note the comments contained in DEB's memo of 11/3/88, in which D. Krejci (Grain Elevators and Processing Society or GEAPS) and T. Klevay (Miller's National Federation) pointed out that MeBr may be used in silos and in at least one milling company. DEB also noted in this 11/3/89 review that the use of oil to decrease grain dust concentrations may have an effect on MeBr levels in grain dust.

Pending the receipt of a revised protocol, the problems associated with the wheat grain protocol remain outstanding.

Other Factors in Generating Residue Data (Memos of 7/14/88 and 11/3/88)

9. The residue data should reflect the analyses of a representative proportion of bruised or stemless commodities. Data in RCB's files indicate that certain fumigant levels are higher in such fruit. According to USDA Marketing Inspection, Fresh Products Branch, in the absence of other defects, 10% of fruit (apples and peaches) may be bruised, and 12% of table grapes may be stemless.

MBIP's Response, 2/10/89

The registrant will attempt to include some damaged and stemless fruit, although they will not be able to document the percentage of damaged fruit analyzed.

DEB's Comments/Conclusions

DEB was concerned that only produce in pristine condition might be selected, a practice which could lead to lower residue levels, according to data in DEB's files. DEB could consider the sampling procedure as adequate, as long as the registrant includes some damaged fruit and doesn't specifically exclude such fruit from the analyses.

The adequacy of this aspect of the protocols will be assessed upon receipt of the protocols.

Other Factors in Generating Residue Data (Memos of 7/14/88 and 11/3/88)

10. If tolerances are proposed on the basis of residue levels following a period of aeration, MBIP will need to demonstrate that the aeration period is appropriate (i.e., that the commodity will not be available for sampling by the FDA before the aeration period has elapsed). In its 11/3/88 memo, DEB pointed out that

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the commodities shouldn't be bagged before the aeration period has elapsed.

MBIP's Response, 2/10/89

The protocol will reflect appropriate aeration periods for each industry.

DEB's Comments/Conclusions

At the meeting of 11/10/88, the registrant said that the USDA would prepare information assessing at what point after fumigation the FDA inspectors could sample the commodities. This information would be crucial in designing the protocols.

DEB, of course, cannot draw any conclusions on the adequacy on the proposed protocols until they have been received and reviewed.

Other Factors in Generating Residue Data (Memos of 7/14/88 and 11/3/88)

11. Samples to be analyzed should be taken from different sections of the container. In its 11/3/88 memo, DEB cautioned the registrant to sample from the bottom of the container, since MeBr is heavier than air.

MBIP's Response

Each protocol will address this issue.

DEB's Comments/Conclusions

The registrant addressed this issue in the amendment of 9/22/88. DEB's conclusion on the adequacy of the protocols must await receipt of the protocols.

Other Factors in Generating Residue Data (Memos of 7/14/88 and 11/3/88)

12. The aeration temperatures should be specified. RCB suggests that the coolest feasible temperatures for each commodity be investigated. MBIP has the option of revising the label to specify a minimum aeration temperature if it can demonstrate that such a label restriction is practical.

In its 11/3/88 review, DEB reiterated that the temperature must be taken into account for each protocol. The aerations should be conducted at the coldest temperatures used commercially; the choice of aeration temperatures should be supported by documentation.

For example, if it is necessary to aerate cherries for 2 days at 60°F, the registrant will need to demonstrate that this

would not adversely affect the shelf life to the point of impracticality. If it is necessary to aerate a commodity for 10 days at 36°F, the registrant will need to demonstrate that it is feasible to withhold the commodity from interstate commerce for this period. If aeration is generally carried out at ambient temperatures, the registrant will need to consider the coldest likely temperatures for the aeration of each crop.

If the registrant should propose temperature ranges for the aerations, he would need to document that these aeration temperature restrictions are practical in commercial practice.

DEB is convinced that the factors involved in the aeration process are critical in determining MeBr residue levels.

MBIP's Response, 2/10/89

Aeration temperature cannot be controlled under commercial fumigation conditions. Specific aeration conditions will be recorded and made available to the Agency in the data submission.

DEB's Comments/Conclusions

The MBIP contends that aeration and fumigation are often carried out at ambient temperatures and the temperatures are not controlled.

In devising protocols to address these issues, DEB suggests the following:

1. If fumigation and aeration take place under ambient conditions, the registrant should determine what the worst case temperatures would be. For instance, when DEB visited packing plants on December 19, 1988, the users conceded that the California weather was so awful that day (i.e., cold), that fumigation represented a borderline situation; some users said that they would fumigate on such a day and other said that they wouldn't. Those that would fumigate said that if it were any colder, it would not be possible to fumigate because of problems involving both efficacy and the distribution of the gas. Once the worst case temperature for fumigation and aeration have been defined, the registrant should generate residue data reflecting the worst case.
2. Residue data reflecting more common commercial practice are also needed so that estimates of dietary exposure will not be unrealistically high. The small fumigation chambers may be used to generate bridging data.
3. If some chilled commodities are fumigated, DEB would need data reflecting that particular use. Again, the aeration temperature should reflect the worst case expected in commercial practice.

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4. If commodities are stored chilled, but are not fumigated while chilled, the registrant should document this practice. For instance, Dr. E. Nickerson of the Florida Department of Agriculture, Consumer Services, instructs the citrus industry not to bring chilled fruit for fumigation because he would need to let the truck content warm up before fumigating.
5. As DEB explained to the registrant at the 11/10/88 meeting, it may be possible to estimate the time needed for MeBr to decline to acceptable levels at various temperatures, if the desorption of MeBr follows first order kinetics throughout the decline.

If this approach is followed, DEB recommends that the validity of extrapolating first order decline curves to the no-detect level should be checked by allowing at least one study for each crop to continue to the no-detect level. Extrapolation from initial decline rates to the no-detect level may not be valid if other reactions of MeBr (besides desorption) become predominant at low MeBr levels.

At low levels of MeBr, the decline of MeBr could actually be faster than would be predicted by first order kinetics. If that is the case, the registrant, extrapolating on the basis of first order kinetics, could be burdened by a prolonged and unnecessary aeration period.

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