



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

MAY 18 1990

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Methyl Bromide Reregistration Letter from the Methyl Bromide Industry Panel (MBIP) dated 12/29/89

FROM: Nancy Dodd, Chemist *Nancy Dodd*
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Health Effects Division (H7509C)

THRU: Michael T. Flood, Ph.D., Acting Section Head *Stephanie Willett for*
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TO: Walter Francis, Acting Product Manager #32
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Registration Division (H7505C)

and

Larry Schnaubelt
Reregistration Branch
Special Review and Reregistration Division (H7508C)

The MBIP has submitted a letter dated 12/29/89 which raises several issues regarding methyl bromide protocols and reregistration. The protocols were submitted in response to the Methyl Bromide Registration Standard. The MBIP's issues will be repeated below, followed by DEB's conclusions:

MBIP's Issue #1

Possibility of requesting a temporary exemption from the requirement for inorganic bromide tolerance for pre-plant soil fumigation uses. The request will be based on the lack of HED's toxicological concern with inorganic bromide; the recent E.P.A. decision to delete inorganic bromide tolerances; and the large volume of data showing no residue of methyl bromide per se resulting from pre-plant soil fumigations.

DEB's Conclusion re: Issue #1

Assuming concurrence from Toxicology Branch, DEB has no objection to a temporary exemption from the requirement for inorganic bromide tolerances for pre-plant soil fumigation uses. However, this is an administrative decision.

DEB notes that an exemption from a tolerance for a toxic chemical like methyl bromide per se (as opposed to inorganic bromide) will not be granted.

MBIP's Issue #2a

Will the submitted pre-plant/post-harvest protocol cover pre-plant uses of methyl bromide?

DEB's Conclusion re: Issue #2a

Residue data from postharvest applications will cover pre-plant soil fumigation uses for plant parts which are treated postharvest. Residue data for plant parts which are not treated postharvest (for example, forage, fodder, and silage of corn) would have to be provided from soil fumigation studies. Alternatively for crop parts which DEB now considers to be under grower control, grazing and feeding restrictions on the label would be possible. (Crops under grower control are identified in Table II of the Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry (Oct. 1982) and revised in DEB's "Overview of Guidance, Pesticide Assessment Guidelines, Subdivision O-Residue Chemistry" by R. Loranger, 8/30/89.

MBIP'S Issue #2b

Will the bridging studies developed by U.S.D.A. and submitted with the Dried Fruit and Nut protocol be applicable to the enclosed pre-plant/post-harvest fumigation protocol? These bridging studies investigated chamber size, fumigation temperature, packaging, etc.

DEB's Conclusion re: Issue #2b

Studies which identified "worst case" conditions and which were accepted in connection with the Dried Fruit and Nut protocol are acceptable for this protocol. Additional bridging data on chamber size are needed. Residue data should be provided for each individual commodity or for the representative crops of the crop groups. (Bridging data for dried fruit as suggested by the MBIP are not acceptable).

MBIP's Issue #2c

Is the risk assessment that is a part of the enclosed pre-plant/post-harvest protocol an acceptable method of risk assessment?

DEB's Conclusion re: Issue #2c

DEB defers to the Dietary Risk Evaluation System (Jim Kariya) concerning Part I, Appendix I of the submission.

MBIP'S Issue #2d

Can the general term "processed foods" be used on a pesticide label or would specific processed foods have to be listed on the label?

DEB's Conclusion re: Issue #2d

Each specific processed food which is to be fumigated must be listed because each must have a tolerance.

MBIP's Issue #2e

In light of E.P.A.'s memo dated 7/7/89, are we now correct that inorganic bromide residue data is not required to meet the re-registration standard requirements?

DEB's Conclusion re: Issue #2e

Based on memos from HFASB/HED (Dave Ritter, Toxicologist, 4/19/89) and from Anne Lindsay, Director, Registration Division (5/19/89), DEB is no longer requiring residue data for inorganic bromide to meet registration standard requirements.

MBIP's Issue #2f

If the statement in (e) above is correct and data to date show no residues of methyl bromide per se from pre-plant fumigation, do we still need to generate methyl bromide per se residue data in all of the states listed in previous DEB communications?

DEB's Conclusion re: Issue #2f

Previous DEB memos requested adequate geographic representation for soil fumigation uses. Any data reflecting soil fumigations must include adequate geographic representation. The issue of adequate geographic representation does not apply to postharvest fumigations.

DEB notes that pre-plant soil fumigation data previously submitted (PP#5F3198) indicate that residues of methyl bromide per se may be detectable at the method sensitivity of the King et al. headspace method in PAM II (0.01 ppm).

cc: RF, SF, Circulation (6), PP#5F3300, PP#5F3198, N. Dodd (DEB), Methyl Bromide Registration Standard File - W. Boodee, R. Schmitt (DEB), Larry Schnaubelt (SRRD), PM#32, C. Furlow (PIB/FOD, H7506C)

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