Lisa Nisenson
D- 14051
SR- 1,3-Dichloropropene
8PP

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

April 29, 1997

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: 1,3-Dichloropropene (Telone) (029001), Reregistration Case No. 0328 and Special Review, and Chloropicrin (081501), Reregistration Case No. 0040. Conclusions with Regard to Tolerances. CBRS No. 17886, DPBarcode No. D235405, No MRID No.

FROM: John Abbotts, Chemist
Special Review Section I
Chemistry Branch II - Reregistration Support
Health Effects Division [7509C]

THRU: Andrew R. Rathman, Section Head
Special Review Section I
Chemistry Branch II - Reregistration Support
Health Effects Division [7509C]

TO: Christina Scheltema
Special Review and Registration Section
Risk Characterization and Analysis Branch
Health Effects Division [7509C]

A recent memo [undated, but after 1/31/97] from Robert McNally, Special Review Branch, to Randolph Perfetti, CBRS, requested a determination on tolerances for Telone consistent with requirements of the Food Quality and Protection Act (FQPA) of 1996. Conclusions and Recommendations below pertain only to this assignment.

1,3-Dichloropropene (Telone™, 1,3-D) is a List A chemical. The Residue Chemistry Chapter was issued 8/12/85; the Registration Standard (Guidance Document) was issued 9/18/86. An Update to the Residue Chemistry Chapter was not issued. Product Chemistry and Residue Chemistry RED Chapters were issued 12/12/96. Telone is registered on every food crop as a preplant fumigant, and tolerances are not established.

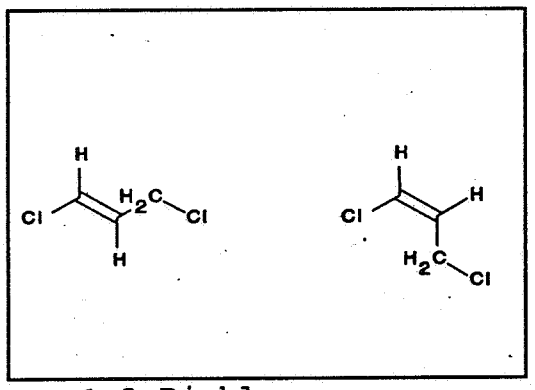
Conclusions/Recommendations

1. Under the requirements of 40 CFR 180.1001 (a), an exemption from tolerances requires a finding of no hazard to the public health. Regardless of the situation with residues in crops, this finding is not appropriate because of the known toxicity of Telone. CBRS therefore recommends against a tolerance exemption.

2. Consistent with the HED determination on use of methyl bromide as a pre-plant fumigant (Memo, 1/31/97, Stephanie Irene, HED to Stephen Johnson, RD), CBRS concludes that specific applications of Telone and Chloropicrin can be declared non-food uses. This determination is limited to uses as a soil fumigant pre-plant. Applications of Telone using drip irrigation are also not covered by this conclusion. It is expected that additional residue chemistry data will be required to support other use patterns.

We recommend that these conclusions be conveyed to applicable registrants.

If you need additional input, please advise.



1,3-Dichloropropene
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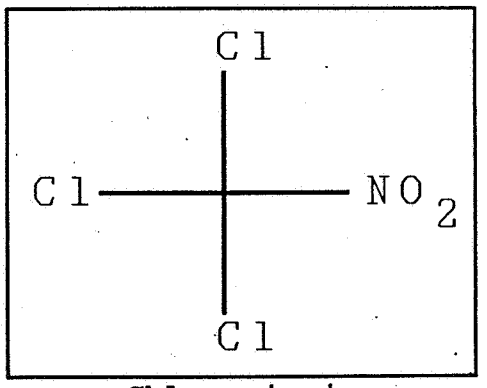

Chloropicrin

Background

CBRS previously recommended that no tolerances were required for Telone for use as a soil fumigant pre-plant (Memo, 8/24/95, D.J. Miller). This recommendation was based on a decision by the Assistant Administrator that tolerances would not be set, even at levels for the limit of detection or quantitation, in cases where data show essentially complete breakdown to non-toxic metabolites and incorporation into natural plant components. This recommendation was reiterated in the Residue Chemistry RED Chapter (CBRS 17671, 12/12/96, J. Abbotts). CBRS has also concluded that because Chloropicrin showed similar characteristics to Telone, including metabolism in plants,

tolerances were not required for this chemical, for use as a soil fumigant pre-plant (Memo, 8/15/96, J. Abbotts).

The current memo from SRB to CBRS describes the opinion of OGC that, under FQPA, a Telone tolerance decision for the RED must fall within one of three categories: (1) tolerances should be established, (2) an exemption from tolerances should be granted, or (3) non-food use should declared. SRB advised that HED had determined that soil fumigation uses of methyl bromide were non-food uses, and attached a memo of 1/31/97 from Stephanie Irene, HED to Stephen Johnson, RD, reporting that determination.

CBRS Comments

40 CFR 180.1001 (a) notes that "An exemption from a tolerance shall be granted when it appears that the total quantity of the pesticide chemical in or on all raw agricultural commodities for which it is useful under conditions of use currently prevailing or proposed will involve no hazard to the public health." These considerations lead to the following comment:

Conclusion 1: Under the requirements of 40 CFR 180.1001 (a), an exemption from tolerances requires a finding of no hazard to the public health. Regardless of the situation with residues in crops, this finding is not appropriate because of the known toxicity of Telone. CBRS therefore recommends against a tolerance exemption.

With regard to other options consistent with FQPA, the previous instructions of the Assistant Administrator would argue against the setting of tolerances, unless this option is absolutely necessary.

The non-food use finding for methyl bromide does seem relevant to Telone. The HED finding was based on no reasonable expectation of methyl bromide residues in crops planted and grown in fumigated soil. Futhermore, seeds or plants cannot be placed in the soil for a specific interval following application due to phytotoxicity. The non-food use determination for methyl bromide was limited to soil-fumigation pre-plant; tolerances were required for post-harvest use.

Similar considerations apply to the use of Telone pre-plant: As noted above, the previous determination that tolerances were not required was based on data demonstrating that Telone was extensively metabolized and then reincorporated into natural plant components. SRB also advises that planting intervals after Telone fumigation are typically one week to ten days because of phytotoxicity.

The previous determination that tolerances were not required for Chloropicrin use as a soil fumigant pre-plant was based on chemical characteristics similar to those of Telone, including extensive metabolism and reincorporation into natural plant components (Memo, 8/15/96, J. Abbotts). Use directions for Chloropricin also specify an interval of 14 days or more between soil fumigation and planting because of phytotoxicity concerns. The determination that tolerances were not needed was limited to pre-plant soil fumigation. Reregistration of other Chloropicrin uses would require additional residue chemistry data, including but not limited to metabolism studies. The considerations above lead to the following comment:

Conclusion 2: Consistent with the HED determination on use of methyl bromide as a pre-plant fumigant (Memo, 1/31/97, Stephanie Irene, HED to Stephen Johnson, RD), CBRS concludes that specific applications of Telone and Chloropicrin can be declared non-food uses. This determination is limited to uses as a soil fumigant pre-plant. Applications of Telone using drip irrigation are also not covered by this conclusion. It is expected that additional residue chemistry data will be required to support other use patterns.

Attachment: Memo requesting determination from SRB to CBRS

cc (w/o Attachment):Abbotts, RF, Telone List A File,
Chloropicrin List A File
cc (w/ Attachment):Circ, Telone SF, Chloropicrin SF,
Lisa Nisenson (SRRD)
RDI:ARRathman:4/18/97:RBPerfetti:4/21/97
7509C:CBII-RS:JAbbotts:CM-2:Rm805A:305-6230:4/29/97
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Tolerance Decision for 1,3-Dichloropropene (Telone) under the Food Quality Protection Act of 1996 (FQPA)

TO: Randolph Perfetti, Acting Chief
Chemistry Branch II

FROM: Robert McNally, Chief
Special Review Branch

The purpose of this memo is to request that the Health Effects Division reexamine its position that Telone does not require a tolerance without specifically granting an exemption. In order to be consistent with the Food Quality Protection Act of 1996, a Telone tolerance decision for the RED must fall within one of three categories: (1) tolerances required, (2) exemption from tolerances, or (3) non-food use.

Since the tolerance decision for Telone was pre-FQPA and does not fit into any of these three categories, SRRD is requesting that HED reassess this decision.

Background

During the Reinventing Tolerance Workgroup briefing, held on July 14, 1995, the Assistant Administrator decided that, in general, tolerances would not be set in cases where data show essentially complete breakdown to non-toxic degradates and subsequent reincorporation into natural plant constituents. This decision affects Telone, as well as the soil fumigant uses of chloropicrin and phosphide.

The Special Review Branch informally sought advice from the Telone Special Review and Reregistration team members as to whether this decision was still valid given the new requirements of the FQPA. John Abbotts of the Chemistry Branch II said that he did not interpret the AA's decision to mean a formal exemption from the requirements of a tolerance and that we should consult with OGC and pursue this through HED management.

In addition, HED recently determined that the soil fumigation uses of methyl bromide should be considered non-food uses (see attached memo from Stephanie Irene to Steve Johnson, dated January 31, 1997). Given the factors used in making this determination and the similarities in the application and degradation of the two fumigants, would Telone also meet the criteria for re-classification as a non-food use chemical?

OGC's Opinion

SRB asked OGC's opinion on this matter. The key points which emerged from the discussions were:

- Under FQPA, not setting a tolerance is the same as setting a tolerance of zero.

- A tolerance is required if Telone or its identifiable degradates or metabolites are expected to be present in crops grown in treated soils. This tolerance must be established even if the residues are not of toxicological concern. Put another way - are the residues distinct from commonly occurring substances?

  According to a August 24, 1995 memo from David Miller to Lisa Nisenson and Christina Scheltema, radiolabelled 1,3-D was found in fatty acids, carbohydrates and other natural biochemical molecules. DowElanco submitted, and HED accepted, a proposed metabolic pathway (emphasis added).

  HED reviews have stated that Telone and its degradates of toxicological concern (namely 3-chloroacrylic acid (CA) and 3-chloroallylalcohol (CAA) are not found in plants. Further degradation takes place in the plant to yield acetic acid and malonic acid, which is further metabolized through the fatty acid and acetic acid cycles. The memo did not go into detail as to the time span of this process.

- Under FQPA, there are three options: (1) declare Telone a non-food use; (2) declare Telone a food-use chemical, but formally exempt it from the requirement of a tolerance; or (3) establish a tolerance.

  - OGC questioned the appropriateness of granting an exemption from a tolerance for a chemical of Telone's toxicity (Toxicity Class II). Are there issues related to granting an exemption for a chemical classified in Toxicity Class II?

- In summary, the question of a tolerance hinges on whether the residues are distinctly "Telone," not in the sense of the parent compound, but as in parent, metabolite(s) or degradate(s) that are identifiable with the parent and distinct from commonly occurring substances. If so, tolerances are needed. If not, either an exemption is needed or Telone should be declared a non-food use chemical.

HED's Recent Decision on Methyl Bromide

HED recently reclassified methyl bromide's soil fumigation uses as non-food uses, thereby lifting the requirement that tolerances be set for any residues that may appear from soil fumigation. It should be noted that there are tolerances set for commodity fumigation uses. In general, HED cited several reasons for reaching this decision, namely:

- There is no reasonable expectation that methyl bromide residues would be found in crops grown in methyl bromide-treated soils;
- Planting cannot occur in treated soils for up to 14 days after fumigation due to phytotoxicity;
- Though some methyl bromide is available for uptake by plants, the chemical is reactive enough to have degraded by the time of harvest. HED has numerous studies to demonstrate this.

Each of these points can also be made when looking at Telone's data base (except for the interval related to phytotoxicity, which for Telone is typically one week to ten days).

Conclusion

SRB requests that HED make a determination on the following questions:

(1) Given OGC's advice on FQPA, are tolerances required for Telone?

(2) If not, should Telone be classified as a non-food use chemical, or should Telone be formally issued an exemption from tolerances?

(3) Does the decision to classify methyl bromide as a non-food use chemical have any bearing on a decision for Telone?

We request that a determination be made to coincide with development of the Telone HED Chapter, which is scheduled for completion by the end of April.

Attachment

cc: Nancy Zahedi, SRRD\SRB
Lisa Nisenson, SRRD\SRB
Christina Scheltema, HED\RCAB
John Abbotts, HED\CBII

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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JAN 31 1997

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: Methyl Bromide. Food vs. Non-Food Use Status for Soil Fumigation Uses.

From: Stephanie R. Irene, Ph.D., Associate Director
Health Effects Division (7509C)

1/31/97

To: Stephen L. Johnson, Director
Registration Division (7505C)

HED has reexamined the soil fumigation use of methyl bromide with respect to the need for a tolerance or exemption from tolerance for residues in crops grown in the treated soil. We now conclude that the soil fumigation applications should be considered non-food uses and not require the establishment of a tolerance or exemption from a tolerance.

This decision is based upon there being no reasonable expectation of methyl bromide residues in crops planted and grown in the fumigated soil. In addition, seeds or plants can not be placed in the soil for a certain time period due to phytotoxicity. The interval depends in part on whether or not the soil is covered by a tarp after application. At a typical interval of 14 days after treatment, maximum methyl bromide residues in the top 12" of soil are down to about 3 ppm (see 10/27/92 L. Cheng review, CBRS# 8829). Although some methyl bromide is thus available for uptake by plants, this chemical is very reactive and could not reasonably be expected to survive intact in plant tissues until time of harvest. The reactivity is confirmed by radiolabeled studies reflecting post-harvest fumigation which show extensive methylation of natural plant constituents such as proteins, amino acids and purines (see 6/21/91 Reg. Std. Update). Numerous crop field trials conducted on a wide assortment of crops all showed no detectable residues of methyl bromide per se, which has been determined to be the only residue of concern (see L. Cheng memo for discussion of field trials).

Considering all the above factors, HED concludes that the soil fumigation uses of methyl bromide should be considered non-food uses. This decision does not apply to post-harvest

Forest 7505C 6th file

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