6-23-86
RCB

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

JUN 23 1986

3352

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EUP and temporary tolerances of 0.01 ppm of 1,3-dichloropropene (Telone II) in or on cottonseed and soybeans.
PP # 6G 3352 ; 464-EUP-91
Accession No. 261122 Caswell No. 324 A

TO: Henry M. Jacoby, PM #21
Registration Division (TS-769C)

FROM: Quang Q. Bui, Ph.D., Quang Q Bui 6/18/86
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THRU: Laurence D. Chitlik, D.A.B.T.
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and
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LDC 6/19/86
6/22/86

Registrant: Dow Chemical Co.,
Midland, Michigan 48640

Related Petition: 6G-3352

1,3-Dichloropropene (Telone II) is curr ently registered as a preplant soil nematicidal fumigant. The registered uses were previously considered as nonfood uses since Telone II was applied to the soil prior to planting and residues in the crops were not expected. Thus, there are currently no tolerances established for 1,3-Dichloropropene.

However, available residue data suggest that as a result of its use, residues of 1,3-Dichloropropene and its metabolite 3-Chloroallyl alcohol may exist in raw agricultural commodities.

In this action (PP #6G3352), the registrant submitted an EUP to evaluate Telone II soil fumigant under commercial conditions. Use would occur in the following States: Alabama, Florida, Georgia, Maryland, North Carolina, South Carolina, and Texas. The maximum acreage to be treated will be 1810 and the maximum gallons of Telone II to be used will be 7240 (maximum 4 gallons per acre). Tolerances requested are 0.01 ppm for combined residues of the 1,3-Dichloropropene and its metabolite 3-Chloroallyl alcohol in or on cottonseed and soybeans.

RECOMMENDATION:

This action is not toxicologically supported due to the lack of several toxicity studies as required by § 112-4 of the Pesticide Assessment Guidelines, Subdivision I, Experimental Use Permits (USEPA 10/82; see "Toxicity Data Gaps" below). The calculated oncogenic risk for the proposed tolerances in or on cottonseed and soybeans at 0.01 ppm is 4.68×10^{-7}.

1. Calculated oncogenic risk for Telone II

Data from two oncogenic studies in rats and mice with Telone II conducted by the National Toxicology Program (NTP Project NTPTR269, NIH Publication No. 85-2525, May 1985) revealed positive carcinogenic potential in both species and sexes. From these results, an oncogenic risk Q* of 1.75×10^{-1} (mg/kg/day) has been determined by Toxicology Branch (memo of B. Fischer to H. Jacoby, dated 2/21/86).

The calculated oncogenic risk for the proposed tolerance at 0.01 ppm in or on cottonseed and soybeans is:

Crop	Food Factor	Tolerance	Telone II consumed mg/kg/day(a)	Risk(b)
Cottonseed (oil) and soybean (oil)	1.07	0.01 ppm	2.675×10^{-6}	4.68×10^{-7}

(a) $\frac{1.5 \text{ kg food/day} \times 1.07\% \times 0.01 \text{ ppm}}{60 \text{ kg person}}$ = Telone consumed (mg/kg body weight/day)

(b) Telone consumed (mg/kg/day) x risk [1.75×10^{-1} (mg/kg/day)]

2. Toxicity data gaps:

a. Subchronic feeding studies (2 studies required)
b. Chromosomal aberration study
c. Acute dermal and inhalation studies
d. Data from the first generation of an ongoing reproduction study

It should be noted that all the above data are required for all EUPs accompanied by temporary tolerances.

3. Residue chemistry branch's issue

RCB had recommended against this petition due to inadequate analytical information (see memo of J. Worthington to H. Jacoby, dated 5/1/86).