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

NOV 28 1995

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Lindane: Waiver request for several toxicity studies.

FROM: Marion Copley, DVM Marion Copley 11/14/95
Acting Chief, TB1
HED (7509C)

TO: Larry Schnaubelt (7508W)
Special Review and Reregistration Division

THRU John Doherty, PhD 11/14/95
Acting Section Head
Sect 4, TB1, HED (7509C)

PC Code: 009001
DP Barcode: D212372
Submission: S482265
Reregist. Case #: 0315

CONCLUSIONS

The waiver request for the studies, listed below, with lindane are not supported. Chemistry, in a memorandum dated 10/31/95 from Stephen Funk to Larry Schnaubelt, had determined that lindane, when used as a seed treatment, requires tolerances and is considered a food use. Therefore the complete battery of toxicity studies is required.

ACTION REQUESTED

CIEL has requested data waivers (see letter dated April 25, 1994) for the following studies:

81-3 - acute inhalation study (Standard)
81-8ss - acute rat neurotoxicity study (requested in a 1991 DCI)
82-5b[1] - 90-day neurotox mammal (requested in a 1991 DCI)
83-2b - oncogenicity mouse (no DCI as yet, recommended by the HED RfD Peer Review Committee)
83-6 - developmental neurotoxicity (no DCI as yet, recommended by the HED RfD Peer Review Committee)

---

1 Should this actually be 82-5b or 82-7 (90-day subchronic neurotoxicity screening battery).

Their justification (letter dated 2/12/93) for this request is that they are proposing to cancel all uses except for seed treatment and (letter dated 4/25/94)

> "CIEL proposes to voluntarily cancel all remaining lindane uses other than the seed treatments for crops, drastically reduce lindane use and exposure, and eliminate the triggers for any further data requirements. In 1991, EPA issued a Data Call-In, and in response, CIEL requested data waivers except for the requirement of an acute and a 90-day neurotoxicity battery. In light of the substantial further curtailment which CIEL now proposes for the use of lindane, this neurotoxicity battery is unnecessary and CIEL further requests that EPA waive this requirement to lindane's reregistration. The exposures contemplated from the very low application rate of the seed treatment use are minuscule . . . and will not result in meaningful residues on edible commodities."

DISCUSSION

Chemistry Branch 2 stated in their memorandum of 0/31/95 from Stephen Funk to Larry Schnaubelt, **"measurable radiolabeled residues of a non-biological compound type are found, the use is deemed a food/feed use and tolerances are required."**

A complete study battery is therefore required as it would be for any other food use chemical requiring tolerances.

The RfD Committee requested (mouse oncogenicity (83-2b) and developmental neurotoxicity (83-6) studies.

1) "The mouse carcinogenicity data (83-2b) were considered insufficient because of major deficiencies associated with all studies available. The Committee concluded that another carcinogenicity study in a commonly used strain of mice should be submitted and the Agency should be consulted on the protocol of the study before initiation." This request is consistent with that of the WHO (No. 124, page 20) which concluded that "long-term carcinogenicity tests conducted according to present-day standards should be conducted".

2) ". . . because of neurotoxicity signs observed in several species and because Lindane, like other organochlorines, is known to cross the placenta, the Committee concluded that a developmental neurotoxicity study in rats (83-6) must be submitted to further evaluate any potential developmental neurotoxicity of this chemical."

CIEL only presented broad generalizations when requesting the waivers ie, "exposures contemplated . . . are minuscule . . not result in meaningful residues." This does not appear supported with quantification. In fact, as noted above Chemistry Branch 2 has determined that tolerances are necessary.

The above studies and the acute and subchronic neurotoxicity studies (81-8 and 82-5b[2]) are still required based on the remaining food use and potential for neurotoxicity potential of lindane.

There has been no direct justification received in TB1 for waiving the acute inhalation study (81-3). SRRD needs to confirm that this study is actually a data gap. It should be noted that there is a study (acc # 263946) in the toxicology data base classified as GUIDELINES in a review in 1987. However, the study indicates that the particles were described as being 50% less than 7 microns. It is unlikely that this would meet the current acceptance criteria of MMAD being 1-4 microns.

---

[2] Should this be an 82-7 rather than an 82-5b)?