



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

APR 28 1987

PMSG/ISB
1506B

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No. 359-686. Lindane.
Request for Time Extension.
RCB#: 2184. MRID#: None.

FROM: Maxie Jo Nelson, Chemist
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C) *mjn*

THRU: Robert S. Quick, Section Head
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C) *RSQ*

TO: George LaRocca, Product Manager 15
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

By letter dated April 14, 1987, the law offices of McKenna, Conner & Cuneo, Washington, D.C., on behalf of their client, Centre International d'Etudes du Lindane ("CIEL"), have requested a three month extension (from 4/21/87 to 7/21/87) for submission of the animal metabolism studies required by the data call-in contained in the Lindane Registration Standard, issued by EPA on 9/30/85.

PR Notice 85-5 ("Policy Regarding Time Extensions for Submitting Additional Data to Support Existing Registrations", dated 8/22/85) states that "on a case-by-case basis, consideration will be given to extension requests due to unavoidable analytical problem(s).... However, registrants will be required to demonstrate the validity of the problem(s) and show good faith effort towards resolution."

In compliance with this, the following explanation has been given for requesting the time extension:

"As a result of comments received from EPA after review of the protocol, we repeated the topical

dose experiments in the goat studies to show that, after a topical dose, lindane is extensively metabolized and volatilized on the animal's skin and also in its rumen. These experiments, which were conducted to explain unexpectedly low material balances, required additional research efforts.

"We also conducted an additional experiment on poultry to provide better accountability of the dose in chickens. This experiment was added because, given the total body burden of the hens from the original dosing regiment which were sacrificed at 24-hours, unaccounted-for residues reduced the material balance significantly. We corrected this situation with the repeat groups, but the additional effort added time to the study.

"The analytical work is proceeding well in all studies but we have found polar and bound metabolites in the liver, kidney and urine. This has created the need for additional time-consuming experiments to further isolate, purify and identify these complex residues.

"We have characterized the extractable residues, but we are still attempting confirmation as well as complete quantitation of each metabolite. To do this, we have had to develop capillary gas chromatography techniques that will better resolve the volatile components for adequate separation and quantitation. This is also a time-consuming task and has unexpectedly prolonged the research effort."

Conclusions/Recommendation

The requested time extension of 3 months (until 7/21/87) for submission of the animal metabolism studies required by the data call-in contained in the Lindane Registration Standard (9/30/85) is reasonable from a residue chemistry standpoint, and RCB has no objections to it. However, the granting of time extensions is an administrative decision.

cc: RF, Circ, Reviewer (M. Nelson), PM#15, Lindane Registration Standard file, PMSD/ISB (Eldridge).
TS-769C:RCB:Reviewer(MJN):CM#2:Rm804:557-7484:typist(mjn):4/24/87.
RDI:SectionHead:RSQuick:4/24/87:DeputyChief:RDSchmitt:4/24/87.