SHAUGHNESSEY NO.
098301

REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 5/11/83 OUT 7/5/83

FILE OR REG. NO. 264-EUP-AT

PETITION OR EXP. PERMIT NO.

DATE OF SUBMISSION 5/6/83

DATE RECEIVED BY HED 5/10/83

RD REQUESTED COMPLETION DATE 8/1/83

EEB ESTIMATED COMPLETION DATE 7/25/83

RD ACTION CODE/TYPE OF REVIEW 751/EUP

TYPE PRODUCT(S): I, D, H, F, N, R, S Insecticide/Nematicide

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. J. Ellenberger (12)

PRODUCT NAME(S) Temik

COMPANY NAME Union Carbide

SUBMISSION PURPOSE Submission of avian/mammalian protocol for review

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.

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

MEMORANDUM

JUL 05 1983

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: Jay Ellenberger
Product Manager No. 21
Registration Division (TS-767)

THRU: Raymond W. Matheny RWM
Head, Review Section No. 1
Ecological Effects Branch
Hazard Evaluation Division (TS-769)

Clayton Bushong, Chief CB
Ecological Effects Branch
Hazard Evaluation Division (TS-769)

SUBJECT: Revised protocol for determining the impact of Temik (EPA Reg. #264-330/264-331) on non-target organisms.

Background to Memorandom

The Registrant (Union Carbide Agricultural Corporation) has submitted a revised protocol for assessing the impact of Temik (aldicarb) on non-target birds and mammals. Protocols accompanying an earlier request were reviewed and found to be unacceptable (see memo by Bowen 04/21/83). The studies in question are needed to support the conditional registration of Temik on sorghum and field corn. The Registrant was informed in July of 1982 that non-target field monitoring would be required (Bowen 7/26/82). On November 15, 1982 Union Carbide agreed in writing to conduct the non-target testing needed to support the proposed registration (Assession # 83516/83517).

Response

The revised protocol submitted by William B. Jackson and A.D. Ashton has been reviewed and found to be deficient in the following areas:

1. Details on plot locations and characterization, residue determination, application methods and equipment were not provided.

2. The vita of the principle on site investigator did not accompany the testing protocol.

3. The subject protocol was initiated prior to EEB's review.

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While the revised protocol corrects some of the deficiencies cited in our April 21, 1983 memo, it still lacks the detailed description needed to assess the merits of the proposed field study. EEB's policy of reviewing protocols prior to initiating costly end use field studies was implemented so that registrants could avoid conducting research that did not adequately address Agency concerns. In this instance, this safeguard has been circumvented and the registrant will have to bear the burden of responsibility for the applicability of this research. No mention was made of the proposed study to monitor tile drainage waters for Temik residues.

Summary

The revised protocol has been reviewed and determined to be lacking in its experimental design. In as much as the protocol was submitted after the study was initiated, EEB does not expect a formal reply to the deficiencies cited earlier. To our knowledge, a revised protocol for assessing Temik residues in tile drainage waters was never submitted.

This correspondence should not be interpreted as a concurrence with the protocol, EEB will defer its decision on the acceptability of this study after we review the final draft.

Charles Bowen II
Fishery Biologist
Ecological Effects Branch
Hazard Evaluation Division TS-769

Attachment: Revised non-target monitoring protocol

cc: Richard Balcomb

ECOLOGICAL EFFECTS BRANCH ALDICARB REVIEW dated 7-5-83

Page _____ is not included in this copy.

Pages 4 through 5 are not included in this copy.

The material not included contains the following type of information:

___ Identity of product inert ingredients

___ Identity of product impurities

___ Description of the product manufacturing process

___ Description of product quality control procedures

___ Identity of the source of product ingredients

___ Sales or other commercial/financial information

___ A draft product label

___ The product confidential statement of formula

___ Information about a pending registration action

X FIFRA registration data

___ The document is a duplicate of page(s) _____

___ The document is not responsive to the request

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
