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RECORD NO.

SHAUGHNESSEY NO.

REVIEW NO.

EEB REVIEW

DATE: IN 5-30-86 OUT 13 JUN 1986

FILE OR REG. NO 359-686

PETITION OR EXP. NO. _____

DATE OF SUBMISSION 5-21-86

DATE RECEIVED BY HED 5-27-86

RD REQUESTED COMPLETION DATE 7-28-86

EEB ESTIMATED COMPLETION DATE 7-21-86

RD ACTION CODE/TYPE OF REVIEW 650

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

DATA ACCESSION NO(S). _____

PRODUCT MANAGER NO. G. LaRocca (15)

PRODUCT NAME(S) Lindane

COMPANY NAME Centre International d' Etudes do Lindane (CIEL)

SUBMISSION PURPOSE Registrant request for waiver of 7-day
feeding study with bobwhite quail and
red-winged blackbirds

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

EEB REVIEW

Pesticide Name: Lindane

100.0 Submission Purpose and Label Information

Registrant request for waiver of 7-day forced feeding study with bobwhite quail and red-winged blackbirds.

101.0 Hazard Assessment

101.1 Discussion

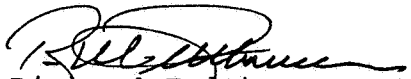
(In addition to the following discussion see previous review by Dick Felthousen, dated 4-25-86)

The Ecological Effects Branch (EEB) has reviewed the registrants (CIEL) request of waiver from conducting a 7-day dietary forced feeding study with Lindane on red-winged blackbirds and bobwhite quail and concurs with the request for the following reasons:

1. The registrant has agreed to conduct a 14-day free choice dietary toxicity study on bobwhite quail and red-winged blackbirds, as per protocol recommendations set forth in EEB's review of 4-25-86;
 2. The 14-day free choice dietary toxicity study is more representative of environmental exposure conditions and, as such, more likely generate useful data for a hazard assessment;
- and
3. No additional useful information would be obtained from the forced feeding study that could not be obtained from the 14-day free choice study.

103.0 Conclusion

EEB concurs with the registrant's request of waiver from conducting 7-day forced feeding studies on bobwhite quail and red-winged blackbirds.



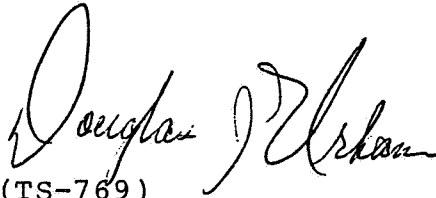
Richard Feithousen, Wildlife Biologist
Ecological Effects Branch
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Norman J. Cook 6.12.86

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13 JUN 1986



107 REFERENCE - AVIAN TOXICITY STUDIE

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

25 APR 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: CIEL/Lindane Registration Standard - Protocol Review

FROM: Richard Felthousen, Wildlife Biologist
Ecological Effects Branch
Hazard Evaluation Division (TS-769-C)

THRU: Harry Craven, Head-Section 4
Ecological Effects Branch
Hazard Evaluation Division (TS-769-C)

THRU: *jc* Michael W. Slimak, Chief
Ecological Effects Branch
Hazard Evaluation Division (TS-769-C)

TO: George LaRocca, PM 15
Insecticide/Rodenticide
Registration Division (TS-767-C)

Background Summary

The Registrant has submitted 5 test protocols, for scientific review, in response to data requests made by the Ecological Effects Branch (EEB) as a result of EEBs review of the Lindane Registration Standard. The EEB, after extensively analyzing the Lindane data base, determined that earlier reviews may have underestimated the potential hazards of Lindane for use in seed treatments and, as such, requested that additional tests be undertaken. In addition, it was estimated that the use of Lindane on pecans could produce residues in aquatic ecosystems greater than 1/2 the fish and aquatic invertebrate LC₅₀ values. However, because these exposure levels were only estimates, the EEB felt that aquatic residue monitoring studies and spray drift studies were required to determine if RPAR risk criterion were exceeded under actual use patterns (Stavola, Memo dated: 7-25-85).

Discussion

The EEB had originally assumed that it was unlikely that a bird could consume enough treated seeds under field conditions to get a lethal dose. However, subsequent calculations by Stavola (see Lindane Registration Standard) showed that based on a seed treatment rate of 2 oz a.i./100 lbs. of seed (corn), a red-winged blackbird would only have to consume 9 seeds to get a lethal dose. Ingesting 9 seeds would be equivalent to about 3 grams of food. The daily average food consumption for a red-winged blackbird is 5-6 grams/day. Therefore, ingestion of 3 grams, at one time, is possible for these species. Complimenting this assessment is the fact that necropses of birds caught in agricultural fields revealed that their crops were full of seeds (R. Balcomb, pers. comm.).

In addition to toxicity, a major factor complicating the question of hazard from Lindane treated seeds to avian species is repellancy. Earlier avian studies indicate that Lindane appears to act as a repellent to birds. Obviously, if it is a repellent, birds may not be at risk from the seed treatment use. Therefore, in order to address the toxicity and repellancy questions, the EEB requested that forced and free-choice dietary studies, using red-winged blackbirds and bobwhite quail, be undertaken.

Another area of concern involved the use of Lindane on pecans. The initial hazard assessment determined that such use could "produce residues in aquatic ecosystems greater than 1/2 the LC50 values of risk and aquatic invertebrates, thereby exceeding the RPAR risk criteria". However, there were insufficient environmental fate and exposure data to fully support this initial estimate. Therefore, the EEB requested that aquatic residue monitoring and spray drift studies be conducted to determine if RPAR risk criterion were met or exceeded under actual use.

Recommendations regarding the submitted protocols

14^{day}-free-choice dietary toxicity studies - bobwhite and red-winged blackbirds

The EEB finds these studies acceptable provided the following study design changes are made:

Food Consumption

1. Food consumption is to be measured daily.
2. Feed hoppers are to be randomized daily to prevent conditioning.

Treatment Design

Treatment design will consist of the following:

1. Control Group - 2 feed hoppers with untreated seeds.
2. Treatment 1 - 2 feed hoppers with treated seeds.
3. Treatment 2 - 2 feed hoppers, 1 with treated seeds and 1 with untreated seeds.

7-day forced dietary toxicity studies - bobwhite quail and red-winged blackbirds

The EEB finds the submitted protocols for these studies to be acceptable provided the following design changes are made.

Food Consumption

1. Food consumption is to be measured daily.

Lindane Aquatic Residue Monitoring Study

As proposed, the Draft Protocol for the aquatic residue monitoring study is unacceptable for the following reasons:

1. It does not provide a full description of the study site(s).
2. It does not explain whether it is a single or multiple site study.
3. It does not specifically address, when, where, or how often residue levels are to be monitored.
4. It does not specifically mention what type of vegetation or aquatic organisms are to be monitored.

Because of these deficiencies and others, the EEB suggests the registrant contact EEB and arrange to discuss specifics on how the study should be conducted to determine if there is a risk to non-target organisms from the use of Lindane on pecans.