US EPA ARCHIVE DOCUMENT

Russ Farringer

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

April 6, 1984

MEMORANDUM

Subject: Attendance at meeting on April 27, 1984, and review of data

To: Chief
Toxicology Branch (TS-769)

Chief
Residue Chemistry Branch (TS-769)

Chief
Ecological Effects Branch (TS-769)

(Acc# 252894)

In response to ICI America's letter of April 3, 1984, we are requesting the presence of the following people to attend a meeting on April 27, 1984, 9:00 AM, in the 8th Floor Conference Room:

1. Mr. Russel Farringer, Ecological Effects Branch
2. Mr. Raymond Matheny, Ecological Effects Branch
3. Dr. Clayton Bushong, Ecological Effects Branch
4. Ms. Linda Propst, Residue Chemistry Branch
5. Toxicologist, Toxicology Branch

This meeting will give ICI an opportunity to reply to our October 27, 1983, letter (copy attached), which raised several questions about the fish and wildlife hazards of their Volid Rodenticide Pellets (EPA File Symbol 10182-LI). The meeting will also give the company an opportunity to explain why their third generation anticoagulant, Brodifacoum, should be registered in orchards to control meadow and pine mice.

At the present time, Brodifacoum is basically only registered for control of domestic rats and mice (Norway rat, roof rat, and house mouse) in and around buildings (see attached label).

In preparation for this meeting, the Ecological Effects Branch has requested that the studies on the attached sheet be reviewed by the indicated Branch (Toxicology or Residue Chemistry).

Please let me know by April 11, 1984, who will represent your Branch at this meeting. My telephone number is 557-2600. If the reviewer needs clarification about the requests for data review from the Ecological Effects Branch, please contact Mr. Rus Farringer directly at 557-7560.

We plan to have a pre-conference meeting on April 25, 1984, 10:00 AM, 8th Floor Conference Room, to discuss the status of the reviews and our approach to the April 27, 1984, meeting.

Daniel Peacock

Daniel Peacock, Biologist
Product Manager Team 16
Insecticide-Rodenticide Branch
Registration Division (TS-767)

Attachments:

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ICI Americas Inc.

Agricultural
Chemicals
Division

PUROLATOR COURIER

April 3, 1984

Mr. William H. Miller
Product Management Team 16
Registration Division (TS-767C)
U.S. Environmental Protection Agency
Crystal Mall 2, Room 223
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Mr. Miller:

Re: VOLID™ Rodenticide Pellets
Resubmission to EPA
File Symbol 10182-LI
Application for Conditional
Registration

In connection with our pending application for conditional registration of VOLID rodenticide for control of Microtus in orchards, ICI is herewith submitting the attached document for EPA review. This submission responds to the EPA letter of October 27, 1983, and to the EEB review of August 15, 1983. In addition, this document addresses most of the topics ICI wishes to discuss at the EPA/ICI meeting on April 27.

With regard to the April 27 meeting, I anticipate that in addition to myself, the following personnel will be present:

Dr. Godfrey Teal, Registration Section, ICI, Plant Protection Division, Fernhurst, England;

Dr. C. G. J. Richards, Vertebrate Pesticides and Public Health Insecticides Section, ICI, Plant Protection Division, Fernhurst, England;

Mr. Paul L. Hegdal, U.S. Fish and Wildlife Service, Denver, Colorado;

Mr. Dale E. Kaukeinen, Research and Development Department, ICI Americas, Goldsboro, North Carolina; and

Mr. Robert E. Hawk, Registration and Regulatory Affairs Department, Goldsboro, North Carolina.

Received 4/5/84

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Wilmington, Delaware 19897 Phone (302) 575-3000

ICI respectfully requests that EPA personnel at this meeting include yourself, Daniel Peacock, Russel Farringer, Raymond Matheny and Clayton Bushong.

The items requested in your letter of October 27 are included in this submission document, except for item 6 and the final report on soil persistence of brodifacoum under field conditions. The topic of item 6 is discussed in Section 4.2 of this submission. A final report on soil persistence is not currently available. Please advise me if you require any other information for your review or the upcoming meeting.

Respectfully submitted,

James M. Wagner
Manager, EPA Registration

JMW/bmw

Enclosure (One Volume)

Submitted in Triplicate

171/11 97022/1

27 OCT 1983

ICI Americas Inc.
Agricultural Chemicals Division
Wilmington, DE 19897

Gentlemen:

Subject: Volid Rodenticide Pellets
EPA File Symbol 10182-LI
Your Letters of April 29 and May 18, 1983

We have completed our risk assessment of the proposed use of brodifacoum (BFC) in orchards and have concluded that the proposed use could produce serious hazards and significant population reductions to non-target organisms in and, around orchards. Such hazards include a potential 60% to 80% reduction of screech owl populations and on quantified avian and mammalian mortality. BFC is highly toxic, both primarily and secondarily, and very persistent in the environment. A complete copy of our review has been previously submitted to your company. If you wish to pursue this or other field uses of BFC, we would suggest that you schedule a conference with us to discuss the problems associated with these uses.

If you elect to have a meeting, please submit the following information prior to the meeting:

1) Readable and complete copy of Reference 11-T (Hegdall, et al, 1983), Acc. No. 250077.

2) Readable and complete copy of Reference 14-T (North, 1983), Acc. No. 250077.

3) Final reports for any preliminary reports submitted in Acc. No. 250077.

4) List of specific questions that you wish to discuss.

5) Complete text of computer program used for your population model.

6) Complete details on the Gram 2/1 HDLC Technique, including modifications alluded to in ABC, Inc. Report 10I. Copy of all available recovery data for Gram 2/1 Technique.

CONCURRENCES								
SYMBOL ▶								
SURNAME ▶								
DATE ▶								

EPA Form 1320-1 (4-81) OFFICIAL FILE COPY

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Submit a copy of the final report of the study "Persistence of Brodifacoum in Soil Under Field Conditions."

Sincerely yours,

William H. Miller
Product Manager (16)
Insecticide-Rodenticide Branch
Registration Division (TS-767)

DCR-40306:MILLER:10/24/83:RD-1:tar:de-11/2/83

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NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated
May 1982

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION

MAY BE HARMFUL OR FATAL IF SWALLOWED. KEEP AWAY FROM HUMANS, DOMESTIC ANIMALS, AND PETS. WASH HANDS AFTER HANDLING BAIT.

IF BAIT IS EATEN BY HUMANS, CALL A PHYSICIAN AT ONCE. For 24-hour emergency assistance, call 302/575-3000.

IF BAIT IS EATEN BY ANIMALS OR PETS, CALL 217/333-3611 or 302/575-3000 for 24-hour emergency assistance.

In case of significant spill, call CHEMTREC 800/424-9300.

NOTE TO PHYSICIAN OR VETERINARIAN
This product may reduce the clotting ability of the blood and cause hemorrhaging. If this occurs, intramuscular and oral administration of vitamin K_1 combined with blood transfusions are indicated as in the case of hemorrhage caused by overdoses of bishydroxycoumarin. Vitamin K_1 is antidotal at doses of 10 to 20 mg (not mg/kg) and should be given and repeated as necessary (based on monitoring of prothrombin times).

ENVIRONMENTAL HAZARDS
This product is toxic to fish, birds and wildlife. This product can pose a secondary hazard to birds of prey and mammals. Keep out of any body of water.

NOTICE TO BUYER AND USER: Seller warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions, or under conditions not reasonably foreseeable to Seller and Buyer and User assumes the risk of any such use. SELLER DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF FITNESS OR MERCHANTABILITY. SELLER SHALL NOT BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT AND SELLER'S SOLE LIABILITY AND BUYER'S AND USER'S EXCLUSIVE REMEDY SHALL BE LIMITED TO THE REFUND OF THE PURCHASE PRICE.

HAVOC™

RODENTICIDE
MINI-PELLETS

KILLS RATS & MICE

Kills warfarin-resistant Norway Rats and House Mice.

Rodents may consume a lethal dose in one feeding with first dead rodents appearing four or five days after treatment begins.

Active Ingredient:	
Brodifacoum- 3-[3-(4'-bromo-[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2H-1-benzopyran-2-one	**0.005%**
Inert Ingredients	**99.995%**
Total	**100.000%**

KEEP OUT OF REACH OF CHILDREN

CAUTION

May Be Harmful or Fatal If Swallowed.
Read Additional Precautionary Statements on Side Panel.

ICI Americas Inc.
Wilmington, Delaware 19897

EPA Reg. No. 10182-75
EPA Est. No. 523-IL-1
Net Contents: 45 lb (20.4 kg)

STORAGE AND DISPOSAL

STORAGE: Do not contaminate water, food or feed by storage o disposal. Open dumping is prohibited. Do not reuse empt container.
DISPOSAL: Bait that cannot be used according to label instruc tions must be disposed of according to applicable Federal State, or local procedures. Dispose of bait container in a sanitar landfill or by incineration if allowed by State and local authorities

DIRECTIONS FOR USE

GENERAL CLASSIFICATION

It is a violation of Federal law to use this product in a manne inconsistent with its labeling.

USE RESTRICTIONS: For control of Norway Rats, Roof rats an House mice in and around homes, industrial, commercial, agri cultural and public buildings. HAVOC may also be used in an around transport vehicles (ships, trains, aircraft) and related por or terminal buildings. Do not use in sewers. This product must b placed in tamper-proof bait boxes or in locations not accessibl to children, pets, domestic animals or wildlife. Do not place bai in areas where there is a possibility of contaminating food o surfaces that come in direct contact with food.

SELECTION OF TREATMENT AREAS: Determine areas where rats and/or mice will most likely find and consume the bai Generally, these areas are along walls, by gnawed openings, i or beside burrows, in corners and concealed places, betwee floors and walls, or in locations where rodents or their signs hav been observed. Remove as much food as possible.

APPLICATION DIRECTIONS

Norway and Roof Rats:
Apply 4 to 16 ounces of bait (usually at intervals of 15 to 3 feet) per placement. Maintain an uninterrupted supply of fres bait for 10 days or until signs of rat activity cease.

House Mice:
Apply ¼ to ½ ounce of bait at intervals of 8 to 12 feet pe placement. Larger placements (up to 2 ounces) may be neede at points of very high mouse activity. Maintain an uninterrupte supply of fresh bait for 15 days or until signs of mouse activi cease.

Rats & Mice:
Replace contaminated or spoiled bait immediately. Colle and dispose of all dead animals and unconsumed bait accordin to "Disposal" paragraph. To prevent reinfestation, eliminat food, water, and harborage as much as possible. If reinfestatio does occur, repeat treatment. Where a continuous source infestation is present, establish permanent bait stations ar replenish bait as needed.

List of Data that EEB[1] has Requested other HED Branches to Review:

Accession #	Study No.	To Be Reviewed By: Tox Br	Res. Chem.
245704	10	YES	YES
	11		YES
	12		YES
	13		YES
	18	YES	
	19	YES	
	20	YES	
	21	YES	
	22	YES	
	23	YES	
	24	YES	
	25	YES	YES
	26	YES	
250077	3I	YES	
	9I		YES
	10I		YES

[1] Review of 8-15-83

EEB has requested the bracketed studies be reviewed by other HED Branches.

will need the following information in hand at least six weeks prior to such a meeting.

1. All previously submitted Fish and Wildlife Packages (Data Submissions).

2. Copies of all minutes of previous meetings and any correspondence in regards to all BFC registration actions.

3. Fully readible and complete copies of all references in EPA Acc. #250077 for the following studies:

   Reference 11-T, Hegdall, et al., 1983
   Reference 14-I, North, 1983.

   In addition, final (not preliminary) reports for all references in Acc. #250077.

4. The following studies are to be deferred to the respective Branches for review. The copies of their reports for these studies should be in EEB's possession at least four weeks before the meeting.

   (Note: Studies marked with an (*) were previously deferred to the respective Branches but were never transmitted from RD to them.)

Tox Br → <u>Toxicology Branch/HED</u>

Accession #245704

Study #'s - 10*, 18, 19*, 20*, 21*, 22, 23*, 24*, 25, 26

Accession #250077

Study # - 3I

Res Chem → <u>Residue Chemistry Branch/HED</u>

Accession #245704

Study #'s - 10*, 11*, 12, 13*, 25

Accession #250077

Study # - 9I, 10I

In addition, the complete Gram 2/1, HPLC technique should be supplied to them. The modifications of this technique alluded to in ABC, Inc. report (10I) to ICI should be delineated completely. All recovery data that are available for the Gram 2/1 technique,

that ICI and/or its contractors' subsidiaries have, should be made available to the Residue Chemistry Branch.

5. The registrant should submit in writing specific questions and/or points that they wish to discuss at least six weeks prior to the meeting.

6. The registrant should submit the complete text of the computer program they used for their population model. EEB requires this program in order to utilize the data as we see it in an identical computer print-out for comparison to Dr. North's printouts.