112701
SHAUGHNESSY NO.

REVIEW NO.

EEB REVIEW

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PETITION OR EXP. NO.

DATE OF SUBMISSION 6-18-85

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RD REQUESTED COMPLETION DATE 9-11-85

EEB ESTIMATED COMPLETION DATE 9-4-85

RD ACTION CODE/TYPE OF REVIEW 740/EUP

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

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. W. Miller (16)

PRODUCT NAME(S) Volid Rodenticide Pellets

COMPANY NAME ICI Americas, Inc.

SUBMISSION PURPOSE Proposed EUP for continued evaluation of secondary hazards to screech owls

SHAUGHNESSY NO.	CHEMICAL, & FORMULATION	% A.I.
112701	Brodifacoum	0.00108%

EXPERIMENTAL USE PERMIT

BRANCH REVIEW

Brodifacoum

100 Experimental Use Label Information

100.1 Pesticide Use

Brodifacoum is the active ingredient of Volid. It is an anticoagulant for the control of pine and meadow voles in apple orchards.

100.2 Formulation Information

Volid is 0.001 percent Brodifacoum. This is 10 parts per million (ppm). There is 0.00001 lbs ai in 1 lb of Volid.

100.3 Application Methods, Directions, Rates

Apply bait after harvest while orchard is in the nonbearing phase. For best results, apply only when daytime temperatures exceed 40 °F. Do not apply if rain is expected within 3 days. Where herbicides are used (land is cleared under trees), apply volid in adjacent ground cover.

Hand Baiting: Apply at 5 to 15 lb/acre (0.00005 to 0.00015 lb ai per acre). Cover all baiting points with tire sections, shingles, boards or other cover. Do not exceed 15 lb/acre/season. To help prevent invasion, application to noncrop border areas such as ditch banks, hedgerows, and fence lines may also be made.

Broadcast Baiting: Hand or machine broadcast bait evenly and penetrate vegetative cover. Do not treat bare ground. Apply at 5 to 15 lb/acre (0.00005 to 0.00015 lb ai/acre). If vole activity remains high at 2 weeks, make a second application. Do not exceed 15 lb/acre/season. Be sure to pick up pellet spills promptly.

100.4 Target Organism

Pine voles and meadow voles.

100.5 Precautionary Labeling

ENVIRONMENTAL HAZARDS

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

100.6 Proposed EUP Program

100.6.1 Objectives

To evaluate the secondary hazards to screech owls (Otus asio) resulting from the use of Volid rodenticide (containing 10 ppm brodifacoum) for control of Microtus species in dormant orchards.

100.6.2 Date, Duration

It is proposed that the permit be effective for 36 months beginning September 1985.

100.6.3 Amount Shipped, Geographical Distribution

Seventy-five thousand lbs of Volid rodenticide is required. It is proposed that 5000 acres would be treated in any of three States, New York, Virginia, or West Virginia. It could be that the areas overlap State boundaries so it could be in both Virginia and West Virginia. Part of the proposed field work includes finding appropriate study areas for a treatment, control and residue analysis site.

1001 Hazard Assessment

101.1 Discussion

Volid would be applied at up to 15 lbs of bait per acre in and around orchards. This is equivalent to 0.00015 lb ai per acre. If the pellets are placed by hand, they would be under some protective cover such as a cut tire or a board. If broadcast, they would be in grass or other vegetation. The label recommends application to noncrop border areas such as ditch banks, hedgerows, and fencelines to prevent reinvasion.

Brodifacoum Toxicity

Some selected toxicity test results show that brodifacoum is very highly toxic to fish, birds, and mammals.

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Species	T.M.	Test Type	Results
Bluegill	92.5%	96-hr LC_{50}	89 ppb measured
Rainbow trout	92.5%	96-hr LC_{50}	45 ppb measured
Daphnia magna	93.3%	48-hr LC_{50}	890 ppb measured

The use rate and method of application precludes unreasonable adverse effects to aquatic organisms.

Primary Consumers

Mallard	Tech.	Acute Oral LD_{50}	2 mg/kg 10% mort. at 0.3 mg/kg
Pheasant	**	Acute Oral LD_{50}	10 mg/kg
Opossum	**	Acute Oral LD_{50}	0.17 mg/kg
Rabbit	**	Acute Oral LD_{50}	0.2 mg/kg 0.29 mg/kg
Mallard	94%	40-day LC_{50} (5-day feeding 35-day obs.)	2.7 ppm 30% mort. at 1 ppm
Bobwhite	94%	40-day LC_{50} (5-day feeding 35-day obs.)	0.8 ppm* 80% mort. at 1.78 ppm 20% mort. at 1 ppm
Rat, albino	98%	5-day LC_{50} (19 days obs.)	0.57 ppm 1.0 ppm

* Raw mortality data were not provided in review, study shows 40-day LC_{50} is probably between 1 ppm and 1.78 ppm.
** Assumed technical.

Secondary Consumers

Beagle Dogs	Assumed tech.	LD_{50}	> 0.25 < 1 mg/kg
Mink	?	LD_{50}	9 mg/kg
Cats	Assumed tech.	LD_{50}	approx. 25 mg/kg
American kestrel	?	LC_{50}	6 ppm
Laughing gull	?	LC_{50}	0.72 ppm

101.2 Likelihood of Adverse Effects to Nontarget Organisms

It is likely that there would be adverse effects to nontarget mammals and birds if this EUP were permitted. However, the limited acreage would preclude unreasonable adverse effects. Besides, the purpose of the EUP would be to conduct a field study to show what adverse effects could be expected if brodifacoum were registered on apple orchards. Any such field study must necessarily affect the animals observed, if any effects occur.

However, the issue is whether the EUP is necessary in light of the inadequacy of the proposed field study. See the attached field study DER. The EEB considers the proposed field study not adequate to support registration of brodifacoum. Therefore, we recommend that no EUP be issued.

101.3 Endangered Species

It is unlikely that any endangered species would be adversely affected by the proposed EUP if it were issued.

101.4 Adequacy of Toxicity Data

The data are adequate to assess the hazards of this proposed EUP.

The proposed field study protocol is entirely inadequate.

Protocol Evaluation: The three problems with the study protocol as it is presented are:

a. The results will not provide us with an index of population turnover as the study is supposed to do.

b. Successfully reaching the stated objective, i.e., obtaining an index of population turnover, will not answer the question of whether a screech owl population is resilient enough to experience the individual losses from secondary poisoning and not suffer a substantial decline. Note that previous field work and laboratory data show beyond a reasonable doubt that individual owls will die from secondary exposure to brodifacoum.

c. If any field study successfully showed that screech owl populations were resilient enough to overcome losses from the use of brodifacoum, it would not show that other populations of birds and mammals would not suffer from secondary poisoning. The registrant and its consultants readily admit the screech owl is very resilient.

See the attached field study protocol review for details.

103 Conclusions

The EEB has reviewed both the proposed EUP and the proposed field study protocol. The EUP is not expected to result in unreasonable adverse effects to nontarget organisms. However, the purpose of the EUP was for ICI, Americas to conduct a field study. Since the proposed field study protocol is inadequate we recommend that the EUP not be issued and that ICI not plan to conduct the study as proposed.

EEB has reviewed the protocol and found it to be inadequate. Any study that would address the concerns EEB has for nontarget birds and mammals would likely be extremely long and expensive. Besides involving more than 3 years, we would expect it to include numerous bird and mammal species in various habitats. Based on laboratory data and previous field work, EEB would anticipate any study, no matter how long and involved, to support the contention that brodifacoum is too toxic to be registered on a large acreage crop like apples.

EEB would welcome a meeting with ICI, Americas personnel to discuss these issues.

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Attachment

112701
Shaughnessy No.

FIELD STUDY PROTOCOL REVIEW

1. Pesticide Name: Brodifacoum

2. Study Type: Predatory Bird Field Study

3. Pesticide Use: Rodenticide in Apple Orchards

4. Study Purpose: To evaluate the secondary hazards to screech owls (Otus asio) resulting from the use of VOLID rodenticide (containing 10 ppm or 0.001 percent ai brodifacoum) for control of Microtus species in dormant apple orchards. This study is supposed to monitor screech owl populations over a long period (several years) to determine if typical use of Volid rodenticide will reduce these populations. The registrant, ICI, claims that because screech owl populations are resilient the demonstrated hazard to individuals will not adversely affect local populations. See also discussion below on resilience.

   The mark-recapture effort is to determine if Volid treatment increases turnover within screech owl populations associated with apple orchards.

   The residue collection effort, separated spatially from the mark-recapture effort, is intended to determine brodifacoum residues in owls feeding in treated areas.

   Resilience in this context is assumed to mean that screech owl populations can make up for poisoning losses by reproduction and increased survival of those remaining individuals. Presumably, with those poisoned owls out of the population, there are more resources available to the remaining birds so proportionately more young per pair will survive and live longer than if no poisonings had occurred. This resilience cannot include maintaining a particular population by immigration from populations in unaffected areas.

5. Site Description: The actual site has not been selected, as ICI is waiting our approval of the protocol before performing the baseline surveys to determine what areas would be appropriate. The potential sites would be the Shenandoah Valley in Virginia or West Virginia or else in upstate New York.

Three separate areas would be used.

I. Treatment Site: The treated site is proposed to be 3000 acres. In a telephone conversation with Dale Kaukeinen of ICI, it was clarified that this meant an area with 3000 acres of orchards. It is estimated that orchards make up 30 percent of the land so the actual acreage would be 10,000 acres or 15.6 mi^2. If this protocol is approved, it will specifically note that the study area must be 10,000 acres with at least 3000 acres of orchards.

II. Control Site: Similar to the treatment site in vole and screech owl populations and size. It would be an intermix of deciduous woods, pasture, and row crops.

III. Residue Collection Site: Again, an area similar to the treatment and control sites, only somewhat smaller (2000 acres of apple orchards; probably 6666 acres total, or 10.4 mi^2).

6. Exposure Regime: In the Treatment Site and the Residue Collection Site apple orchards would be treated according to label recommendations. This would mean an application of bait after harvest while the orchard is in a nonbearing phase. This would probably be in November. No rodenticides could be used in the control area except possibly zinc phosphide.

7. Study Methods:

Baseline: This would be a 2 to 3 week effort to find appropriate study sites. This would take place in likely areas in Virginia, West Virginia, or New York. The following are some of the criteria for site choices:

a. Cooperative landowners
b. Adequate population of screech owls
c. Adequate population of voles
d. All three sites must be separated by adequate distance to prevent movement of owls from one site to another.

Information to choose these sites would be obtained through site visits, some trapping effort, and talking to residents. This would take place during a 2 to 3 week effort in the spring prior to the test initiation. This baseline effort would also serve to familiarize the researchers with the study area.

The baseline study will not include any mark-recapture work, so no "index of population" will be available.

The actual study would begin the October following the spring baseline effort. It would take place initially in the treatment site and control site. A minimum of 30 screech owls would be captured by using tape-recorded calls and mist nets in the treatment site. Thirty owls would also be captured thus in the control site. The captured owls would be marked by individually identified leg bands.

Then in November, application of Volid would take place according to the EUP label in both the "Treatment Site" and the "Residue Collection Site."

In January, or 2 months following treatment, the "residue collection" effort would begin on the the Residue Collection Site. A minimum of 20 screech owls will be captured. Half of these owls will be sacrificed immediately and analyzed for residues of brodifacoum. The remaining owls will be maintained in an isolated flight cage with appropriate food and cover (e.g., nest boxes). Any mortalities of these remaining owls will be autopsied and analyzed for residue. Surviving owls will be killed 12 months posttreatment, necropsied, and analyzed for residues.

According to the proposed uses of this residue collection effort:

> Multi-year effects could be anticipated by extrapolation of brodifacoum residue kinetics from the one-season exposed birds. Successive-year accumulation effects could also be partially addressed by additional selective collection of owls recaptured in the mark-recapture study area. However, advisability and nature of such collections would need to be established based on first year banding and recapture results and available residue data, since such collections might compromise the mark-recapture study.

Then in late February or March, a second trapping effort would take place at the "Treatment Site" and "Control Site" similar to the one in October. All screech owls would be identified as to whether they had been marked in October. These and any raptors caught would be banded (if not already banded) and released.

Seasonal and annual changes of the proportion of screech owls marked:unmarked will be compared between treated and control areas.

This study would be conducted for 3 years.

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On October 11, 1985, I had a conference telephone conversation with Bruce Colvin and Dale Kaukeinen. Some additional information was obtained concerning the proposed study, its purposes and uses for the results.

The study is intended to provide an index of turnover by the capture-mark-recapture effort at the treatment and control site. Put simply, if exactly 30 owls were captured at both sites in October and then fewer marked animals were caught at the treatment site than the control site in the spring, it would suggest a greater turnover in the treatment site.

Example: This suggests a greater turnover in the treatment site.

	Treatment	Control
October	30 captured and marked	30 captured and marked
February/March	30 captured 10 of these had been marked in October	30 captured 15 of these had been marked in October

There are no plans for an immediate recapture effort in October to develop a pretreatment index of population size in the treatment and control site. The determination of similarity between the treatment population and control population would be strictly qualitative, based on sightings, some cursory trapping and discussions with residents.

Bruce Colvin estimated that if 30 owls were captured, that would represent over half the immediate screech owl population.

8. Protocol Evaluation: The three problems with the study protocol as it is presented are:

   a. The results will not provide us with an index of population turnover as the study is supposed to do.

   b. Successfully reaching the stated objective, i.e., obtaining an index of population turnover, will not answer the question of whether a screech owl population is resilient enough to experience the individual losses from secondary poisoning and not suffer a substantial decline. Note that previous field work and laboratory data show beyond a reasonable doubt that individual owls will die from secondary exposure to brodifacoum.

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c. If any field study successfully showed that screech owl populations were resilient enough to overcome losses from the use of brodifacoum, it would not show that other populations of birds and mammals would not suffer from secondary poisoning. The registrant and its consultants readily admit the screech owl is very resilient.

Rationale for (a): There are two reasons why I do not believe this study will provide an index of population turnover.

1. Since there would be no quantitative estimate of screech owl populations at either the treatment site or the control site, there would be no way of determining if differences in the ratios marked:unmarked in the spring capture between the treatment site and control site were caused by turnover or simply differences in population size. If the treatment site had a bigger population than the control site, any recapturing effort would automatically turn up fewer marked birds. This unknown could result in an apparent turnover when none occurred and more importantly, it could mask a turnover if the control population happened to be greater than the treatment population.

2. Random sample variation would make meaningful interpretation virtually impossible. It is unlikely, with so few birds, that this randomness can be accommodated. When an apparent turnover occurred because fewer marked birds were captured at the treatment site, it would not be possible to prove it was not just due to sampling error.

   Likewise, equal ratios of marked:unmarked at both sites would not convince me that turnover had not occurred and was not masked by sample error. Previous field data convinces me that turnover will occur.

Rationale for (b): An index of population turnover obtained between October and March will have nothing to do with internal population resilience. Either turnover will not occur because no owls died, or turnover will occur because owls did die. Even several years of marking and recapturing will not allow distinction of emigrants (young or adult) from young produced within the treatment area or simply adults in the treatment area not yet captured.

Even <u>if</u> a study successfully shows a population of screech owls to be resilient and to not show decline in three years, that does not eliminate concern. If a population of screech owls is using up its supposed natural resiliency to withstand losses to rodenticide poisoning, it is more

susceptible to natural perturbations such as lowered food supply, disease or climatic changes. While these natural perturbations may occur and be only moderately detrimental to a healthy owl population, they may substantially reduce a population that is on the borderline health-wise due to rodenticide effects.

Rationale for (c): EPA is concerned for many bird and mammal populations, including primary consumers, predators and scavengers. This includes but is not limited to owls, hawks, vultures, crows, blue jays, fox, weasels, skunks, and raccoons. Even if screech owls prove to be resilient, that says nothing for the host of other exposed species.

As for the residue collection effort, that would only show what previous studies have shown. It would be useful information, but could not show that screech owl populations would not be adversely affected by the use of Volid rodenticide.

9. Suggested Modifications: There are a few modifications that could be made, such as performing mark and recapture as part of the baseline effort to obtain a index of population at both the control site and treatment site.

But none of the modifications could remedy the underlying problems (b and c) mentioned in "8. Protocol Evaluation."

10. Conclusions: Protocol: Rejected

This study can do no more than show what previous studies have already shown. It could not show that brodifacoum can be used safely as a rodenticide in apple orchards.

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