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REVIEW NO.

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

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. W. Miller (16)

PRODUCT NAME(S) Brodifacoum

COMPANY NAME

SUBMISSION PURPOSE Submission of "adverse effects" data for review

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

EEB REVIEW

Brodifacoum

100 Submission Purpose

The registrant, ICI Americas, Inc., submitted three field studies as adverse effects data for review.

101 Data Review

The following are the conclusions from the field study DER's:

1. TITLE: Brodifacoum: Hazard to Non-target Animals from "Pulsed" Baiting with "Klerat" Pelleted Bait Around Farm Buildings.

LABORATORY: Jealotts Hill Research Station

STUDY NO: RJ0369B

DATE OF STUDY: October 11, 1984

STUDY SPONSOR: ICI Americas, Inc.

CONCLUSIONS:

The use of "Klerat" pelleted bait caused primary poisoning of non-target birds. If bait was covered better, fewer non-target mortalities occurred. Only two secondary consumers (two magpies) were found dead. The study is supplemental in that it provides useful information but does not fulfill the requirements for a full field study measuring population effects.

It was submitted as adverse effects data and was not intended to fulfill any particular data requirement.

2. TITLE: Brodifacoum: Hazard to Non-target Animals from "Pulsed" Baiting with Wax Block Bait Around Farm Buildings.

LABORATORY: Jealotts Hill Research Station

STUDY NO: RJ0375B

DATE OF STUDY: October 11, 1984

STUDY SPONSOR: ICI Americas, Inc.

CONCLUSIONS:

Wax block formulations were of low palatability to birds and relatively few incidents of primary poisonings were observed. However, primary mortality, caused by brodifacoum, was observed at 5 of 10 treatment sites.

This study does not fulfill a requirement for a full field study. It does provide useful supplemental information. It was submitted as "adverse effects" data.

3. TITLE: Brodifacoum: Hazard to Non-target Animals from the Use of "Klerat" Bait on Farms in the UK for Control of the Common Rat Rattus novegicus.

LABORATORY: Jealotts Hill Research Station

STUDY NO: RJ0305B

DATE OF STUDY: October 7, 1983

STUDY SPONSOR: ICI Americas, Inc.

CONCLUSION:

This study is scientifically sound and provides information useful in preparing hazard assessment for the use of brodifacoum rodenticide.

This study shows that the use of Klerat bait (containing 50 ppm ai) will cause primary and secondary mortality to non-target terrestrial organisms. Non-target organisms that experienced primary mortality included small birds, a rabbit, and a gray squirrel. Non-target species that experienced secondary toxicity included cats, a fox, tawny owls, buzzard, and corvidae.

This study does not fulfill any data requirments. It does not serve as a full field study measuring population effects to terrestrial organisms because there is no way of knowing what portion of the entire population these observed deaths are. It was submitted as "adverse effects" data.

103 Conclusion

These studies support EEB's contention that the use of Brodificaoum bait to control rodents results in primary and secondary hazards to non-target birds and mammals.

Daniel Rieder 12/17/85
Daniel Rieder, Wildlife Biologist
Ecological Effects Branch
Hazard Evaluation Division (TS-769)

Norman Cook 12.17.85
Norman Cook, Section Head
Ecological Effects Branch
Hazard Evaluation Division (TS-769)

M. M. Slimak 12/18/85
Michael Slimak, Chief
Ecological Effects Branch
Hazard Evaluation Division (TS-769)

DATA EVALUATION RECORD

1. Chemical: Brodifacoum/112701

2. Test Material: Wax blocks, 20 g, 50% ai formed by pressing treated grain into blocks with wax

3. Study Type: Field study with carcass search

4. Study ID:

Title: Brodifacoum: Hazard to Nontarget Animals from "Pulsed" Baiting with Wax Block Bait Around Farm Buildings

Laboratory: Jealotts Hill Research Station

Study No.: RJ0375B

Date of Study: October 11, 1984

Study Sponsor: ICI Americas, Inc.

Study Location: 255989

5. Reviewed by: Daniel Rieder
Wildlife Biologist
EEB/HED

Signature: Daniel Rieder

Date: 12/10/85

6. Approved by: Norman Cook
Head-Section 2
EEB/HED

Signature: Norman Cook

Date: 12.17.85

7. Conclusions:

Wax block formulations were of low palatability to birds and very few incidents of primary poisoning were observed. However, primary mortality, caused by brodifacoum, was observed at 5 of 10 treatment sites.

This study does not fulfill a requirement for a full field study. It does provide useful supplemental information. It was submitted as "adverse effects" data.

8. Recommendations:

This study is supplemental because of design, not because of missing data or an unscientific approach.

9. Background:

ICI submitted this study along with two others, RJ0369B and RJ0305B, as "adverse effects" data.

10. Discussion of Individual Studies:

N/A

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11. Materials and Methods:

This report presents the results of a survey on the effects on nontarget animals from using brodifacoum to control rats. Two types of wax blocks were used, both types weighed about 20 g and contained 50 ppm brodifacoum, nominally. Both were dyed dark blue.

Ten farmers were supplied bait for use on 16 sites. Ten sites were sites where ICI staff conducted surveillance and searches. The remaining six sites were used to supply additional dead rats for residue analysis.

Treatment:

"Pulsed baiting" means placing one to two blocks (20 g) at 5 to 10 m intervals every 7 days until infestation is controlled. Users were instructed to conceal bait and to not place it in wooded areas. Application took place starting November 11, 1983, and continued through the winter.

Surveillance of the 10 farm sites include the following ecologically related focuses:

a. Assessment of baiting quality to include where bait was placed, frequency of baiting, numbers of blocks at each bait point, and concealment of bait.

b. Weathering of bait blocks. A photographic record was made of the level of crumbling of wax blocks of known age either protected or unprotected.

c. Frequency of feeding on blocks by nontarget animals was determined by searching for footprints and blue-colored droppings near bait blocks.

d. Counts of nontarget animals around farm buildings were made once each week at each site. Surveys were conducted along a consistent route at the same time on each survey day. Presence or absence of fox scent and scat was recorded.

e. On each visit, usually twice weekly, routine searches for nontarget and rat carcasses were made.

f. Nontarget carcasses were examined for general nutritional health and for internal and external hemorrhaging. Both nontarget and some rat carcasses were saved for residue analysis.

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12. Reported Results:

The tables in the attached document present all the reported results. The following table shows the treated sites, amount of bait used, surveillance effort, and results of carcass searches by ICI staff.

Farm	Type Area	Amt. Bait Used (kg)	Surv. (hrs)	Nontarget Mortality
A	bldg.1/, hedgerow wood	17	29	1 jay 1 magpie 2 carrion crows 1 rabbit
B	bldg.	52	20.5	1 cat
C	bldgs., rough ground	32	27	1 magpie 1 stoat
D	bldg., hedgerow	18	24	-0-
E	bldgs.	15	18.5	-0-
F	bldgs.	15	11	-0-
G	bldgs., haystack in woods	10	20	1 gray squirrel 1 robin
H	bldgs.	7	16	-0-
I	bldgs.	5	8	-0-
J	bldgs.	5	16	1 chaffinch

1/ Around buildings

Baiting quality was poor as far as covering or concealing bait, but it was good as far as being close to buildings (< 100 m). The amount of bait generally was per instruction.

Bait (protected in cages from vertebrates) did not persist longer than 20 weeks. Blocks available to rodents disappeared as the rodents ate the grain; all that remained were piles of wax.

Nontarget feeding on bait appeared minimal based on tracking and blue-colored feces. See table 3, attached study.

The only animal population showing an unexplainable decline during treatment was four kestrels which disappeared midway through the trial. No kestrel carcasses were found.

The primary route of effect was apparently secondary exposure based on the types of animals found dead and the minimal feeding directly on the bait by primary consumers.

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Residues in nontarget animal livers ranged from 0.44 ppm to 2.4 ppm for those birds and mammals considered to have died from anticoagulant effects.

A total of 142 rats were found dead above ground at the 16 sites. A portion of dead rats had obviously been scavenged by animals other than rats. Based on unearthed rat's nests, some rats died underground also. There were also 21 more rats trapped for residue analysis.

Residues in dead rats ranged from 0.03 ppm to 6.7 ppm. Residues in trapped rats ranged from below the detection level to 2 ppm. See tables 1 to 12 in the attached report.

13. Author's Conclusion:

Wax block formulations were of low palatability to nontarget animals and, compared to pelleted baits, safer to birds even when left uncovered.

Secondary poisoning increases as treatment extends away from buildings.

14. Reviewer's Discussion:

a. Test Procedure:

The procedure was adequate for the purposes of the study. It provides little on quantitative population effects.

b. Statistics:

None

c. Results:

Based on the number of carcasses found, the use of block baits is less of a hazard to primary consumers. However, several scavenging birds and some predatory mammals were found dead. This and the disappearance of the kestrels suggests that secondary hazard still exists. Furthermore, it is apparent that secondary hazard is less when baiting is close to buildings.

This study tends to support EEB's contention that the use of brodifacoum may adversely affect nontarget bird and animal populations.

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d. Adequacy of Study:

The study provides useful supplemental information. It does not (nor was it intended to) fulfill requirements for a full avian/mammal field study measuring population effects.

15. Completion of One-liners:

N/A

16. CBI Appendix:

The document attached is considered to be CBI.

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PAGES 11 THROUGH 18A ARE NOT INCLUDED. THOSE PAGES CONSIST OF REGISTRATION DATA.

DATA EVALUATION RECORD

1. Chemical: Brodifacoum/112701

2. Test Material: Klerat pelleted bait containing 50 ppm

3. Study Type: Field use with carcass search

4. Study ID:

   Title: Brodifacoum: Hazard to Nontarget Animals from "Pulsed" Baiting with "Klerat" Pelleted Bait Around Farm Buildings

   Laboratory: Jealotts Hill Research Station

   Study No.: RJ0369B

   Date of Study: October 11, 1984

   Study Sponsor: ICI Americas, Inc.

   Study Location: Acc# 255989

5. Reviewed by: Daniel Rieder
   Wildlife Biologist
   EEB/HED
   Signature: Daniel Rieder
   Date: 12/10/85

6. Approved by: Norman Cook
   Head-Section 2
   EEB/HED
   Signature: Norman Cook
   Date: 12.17.85

7. Conclusions:

   The use of "Klerat" pelleted bait caused primary poisoning of nontarget birds. If bait was covered better, fewer nontarget mortalities. Only two secondary consumers (two magpies) were found dead. The study is supplemental in that it provides useful information but does not fulfill the requirements for a full field study measuring population effects.

8. Recommendations:

   This study cannot be upgraded.

9. Background:

This study was submitted along with two others, RJ0305B and RJ0375B.

10. Individual Studies:

N/A

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11. Materials and Methods:

This study presents the results of a survey of effects to nontarget animals from using brodifacoum around buildings.

Thirteen farmers were supplied bait for use on a total of 16 sites. "Klerat" bait pellets weigh about 0.2 g and contain 50 ppm; they are dyed red.

Application:

- Rats: Use 20 to 50 g (1 to 2 oz) per baiting point. Place bait at 5 to 10 m intervals.

- Mice: Use 5 to 15 g (1/4 to 1/2 oz) per baiting point. Place at 2 to 5 m intervals.

Instructions:

- Only place bait in and close to infested buildings.

- Do not place in woods or fields.

- Place bait in boxes or other suitable containers.

- Inspect bait points weekly, replenish until bait consumption ceases.

- Replace contaminated or spoiled bait.

In addition to the specific label instructions (above), ICI staff members verbally instructed the users on how to conduct "pulsed" baiting. In principle, "pulsed" baiting is the placing of bait in small quantities at many points, so that rodents are less likely to greatly overconsume the toxicant and more rodents can feed at once.

ICI staff conducted surveillance at all 16 sites. Visits were made once or twice weekly during and shortly after baiting.

Observations:

a. Frequency of Feeding on Bait by Nontarget Animals

Bait points were observed through binoculars from a discrete distance. Areas around bait points were searched for "pink" feces which would show animals had been eating the red-dyed bait.

b. Counts of Nontarget Animals

During visits, birds were counted on a consistent route around farm buildings at the same time each day. Presence of fox was determined by the distribution of fresh feces. Tawny owls were monitored by using tape recordings of a tawny owl territorial "hoot." Owl monitoring went on for 3 months after baiting started.

c. Search for Nontarget Corpses

During visits, treated areas were searched for carcasses. Searching included likely roosting sites in buildings or nearby bushes. Woods were searched for tawny owls if any failed to respond to the tape recording. Nontarget corpses were saved for postmortem and residue analysis if they were in suitable condition.

d. Postmortem Examination and Residue Analysis

Postmortem inspection included observing general health and searching for internal and external hemorrhaging. Livers were stored for residue analysis.

e. Counts of Dead Rats Above Ground

Rats found dead above ground were counted and some stored for residue analysis.

12. Reported Results:

The tables in the attached document (enclosure 2) present all the reported results. The following table shows the amount of bait used, surveillance effort, number of "Klerat" colored bird feces counted, and nontarget deaths caused by or suspected due to brodifacoum.

Farm	Amt. Bait (kg)	Surv. (hrs)	No. Feces	Nontarget Mortality
A	40	16	350	14 small birds
B	30	14	110	2 small birds 1 magpie 2 chickens
C	30	14	220	17 small birds 1 magpie 2 pheasants 2 rabbits
D	25	14	180	4 small birds 1 gray squirrel
E	25	10	180	5 small birds
F	20	9	110	1 small bird
G	12.5	6	53	2 small birds
H	10	7	10	1 rabbit
I	10	13	200	4 small birds
J	10	6	4	-0-
K	10	5	0	-0-
L	10	4	12	-0-
M	5	2	3	-0-
N	5	2	7	-0-
O	5	3	0	-0-
P	5	2	0	-0-

As far as nontarget populations around treated areas, some declines in numbers of sedentary species, e.g., robin and dunnock, around farm buildings were apparent. Fourteen tawny owl territories were identified. Out of these 14, 12 were still occupied by the end of the study. However, two of those occupied territories were apparently occupied by different owls than at the beginning of the study. See pages 46 and 47 of the attached study.

Residues in livers or livers and flesh from nontarget carcasses ranged from < 0.05 ppm (detection level) to 23 parts per million (ppm). See table 6, page 18 of attached study.

A total of 240 rats were found dead above ground at the 16 treatment sites. See table 7, page 19 of attached study. Residues in whole bodies of dead rats ranged from 0.02 ppm to 4.4 ppm. See table 8, page 20 of the attached study.

13. Study Author's Conclusion:

"Klerat" pelleted bait was palatable to birds. Feeding on bait by birds, and deaths were associated, in general, with poor covering of bait during cold dry weather.

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"The risks to secondary poisoning depends largely on the frequency of poisoned rodents in the diet. In this trial, very little secondary poisoning was observed following baiting around farm buildings and indicates a lower potential for secondary poisoning from this use. As baiting extends away from buildings the rodents contaminated may be more likely to be eaten by predators or scavengers and the potential for secondary poisoning may also increase" (page 29 of attached study report).

14. Reviewer's Discussion:

a. Procedure:

The procedure was adequate for the purposes of the study. That is, the study was intended to show if hazard existed to individual nontarget birds and mammals. It provides little on quantitative population effects.

b. Statistics:

None

c. Discussion of Results:

I agree that there was apparently less secondary toxicity in this study than in RJ0305B. This may have been due to several factors:

i. pulsed baiting;
ii. reduced use per site compared to RJ0305B; and
iii. use in close proximity to buildings.

However, in spite of reduced secondary mortality, there was substantial mortality from birds eating the bait directly. This, even when the bait was apparently covered well.

The disappearance of the tawny owls may very well have been losses due to secondary poisoning.

The results of observing nontarget populations suggests some declines, but without control or baseline data it is difficult to draw any conclusions. In any case, the study does not show safety nor disprove EEB's contention that the use of brodifacoum may adversely affect bird and mammal populations.

The study states that wet bait is unpalatable to rats and birds. It also indicates that bait became damp quickly when kicked out of rat burrows in wet weather.

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This seems somewhat inconsistent with the reference (summary, page i of attached study) to the cold dry winter weather being responsible for nontarget animals eating the bait. No weather data were provided.

d. Adequacy of Study:

The study is supplemental in that it provides useful information. It does not (nor was it intended to) fulfill requirements for a full avian/mammal field study measuring population effects.

15. Completion of One-liners:

N/A

16. CBI Appendix:

The document appended is considered CBI.

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PAGES 26 THROUGH 35A ARE NOT INCLUDED. THOSE PAGES CONSIST OF REGISTRATION DATA.

DATA EVALUATION RECORD

1. Chemical: Brodifacoum/112701

2. Test Material: Klerat pelleted bait containing 50 ppm

3. Study Type: Field use with carcass searches

4. Study ID:

   Title: Brodifacoum: Hazard to Nontarget Animals from the Use of "Klerat" Bait on Farms in the UK for Control of the Common Rat Rattus novegicus.

   Laboratory: Jealotts Hill Research Station

   Study No.: RJ0305B

   Date of Study: October 7, 1983

   Study Sponsor: ICI Americas, Inc.

   Study Location: Acc# 255989

5. Reviewed by: Daniel Rieder
   Wildlife Biologist
   EEB/HED
   Signature: Daniel Rieder
   Date: 12/10/85

6. Approved by: Norman Cook
   Head-Section 2
   EEB/HED
   Signature: Norman Cook
   Date: 12-17-85

7. Conclusion:

   This study is scientifically sound and provides information useful in preparing hazard assessments for the use of brodifacoum rodenticide.

   This study shows that the use of Klerat bait (containing 50 ppm ai) will cause primary and secondary mortality to nontarget terrestrial organisms. Nontarget organisms that experienced primary mortality included small birds, a rabbit, and a gray squirrel. Nontarget species that experienced secondary toxicity included cats, a fox, tawny owls, buzzards, and corvidae.

This study does not fulfill any data requirement. It does not serve as a full field study measuring population effects to terrestrial organisms because there is no way of knowing what portion of the entire population these observed deaths are. It was submitted as "adverse effects" data.

8. Recommendations:

This study is supplemental because of its design, not because data are lacking.

9. Background:

The registrant, ICI Americas, submitted this study as "adverse effects" data. It was accompanied by two other studies, RJ0375B and RJ0369B.

10. Discussion of Individual Tests:

N/A

11. Materials and Methods:

This report presents the results of a survey of effects on nontarget animals. Twenty-eight farmers were provided free "Klerat" bait, instructions, and a questionnaire which included a section on reporting deaths of nontarget animals. The ICI staff conducted surveillance on 11 farms.

Surveillance on the 11 farms was conducted during November and December 1981 and on some sites into January 1982. Baiting on Farm H, the 630 ha field, began in September, 5 weeks before any observations were made.

The baiting instructions included:

Use In and Around Buildings

Maintain bait points until rodent activity ceases. Replace old bait periodically.

Rats: place 20 to 50 g heaps at 5 to 10 m intervals.

Mice: place 5 to 15 g heaps at 2 to 5 m intervals.

Field Use:

Place 10 to 20 g heaps outside burrows and where rodents feed or run. A rate of 1 to 3 kg/ha will generally be suitable. Bait not only crop to be protected but also surrounding area. Start treatment at first sign of infestation and repeat at weekly intervals.

A cautionary note was added: "Access of nontarget animals and birds should be prevented and the bait should as far as possible be protected from moisture."

Surveillance by ICI personnel was conducted on 11 farms. With the exception of farm H (630 ha field) the entire baited area was surveyed on each visit. On each survey, three factors related to nontarget effects were recorded:

a. Assessment of quality of baiting:

1) degree to which bait was covered,

2) quantity of bait,

3) frequency of baiting,

4) bait removal.

b. How frequently nontarget animals fed on bait. Bait points observed through binoculars from a discrete distance. Presence of pink bird droppings, the same color as the Klerat, was evidence of regular feeding.

c. Location of nontarget corpses: On each visit, routine searches for bodies were made. Visits started shortly after baiting and were continued regularly about twice each week for 4 weeks. Searches around farm buildings included likely roosting sites for birds, in farm buildings or bushes, etc., near-by. If peripheral areas were baited, these areas were checked also. In farms H and J (both fields) fencelines and hedgerows were searched and in the case of farm H a small woods was included. On farm H (630 ha field) no searching was conducted until 5 weeks after start of baiting. Nontarget carcasses were collected, individually numbered, and stored at -20 °C for postmortem examination.

Postmortem examinations included inspection for physical trauma and hemorrhage and inspection of fat deposits as an indication of nutritional health. Livers were preserved for residue analysis.

12. Reported Results:

The tables in the attached document present all the reported results. The following shows the treated areas, amount of bait used, surveillance effort, and results of carcass searches by ICI personnel.

Farm	Type Area	Amt. Bait Used (kg)	Surv. (hrs)	Birds Feeding on Bait[1/]	Nontarget Deaths[2/]
A	bldgs[3/]	20	5	No	1 cat
B	bldgs	20	8	Yes	2 cats 1 sm. bird
C	bldgs	5	3	Yes	-0-
D	bldgs	50	13	No	1 fox
E	bldgs	20	5	No	-0-
F	bldgs	120	10	Yes	9 sm. birds 1 rabbit
G	bldgs	40	6	No	-0-
H	field (630 ha)	280	48	No	2 tawny owls 2 buzzards 17 corvids 3 sm. birds 1 gray squir.
I	bldgs	20	13	Yes	15 sm. birds 2 corvids
J	field (30 ha)	40	23	No	-0-
K	bldgs	50	18	No	-0-

1/ Evidence of regular feeding on bait by birds.

2/ Nontarget deaths caused by brodifacoum or where brodifacoum poisoning was suspected.

3/ Around buildings, sometimes extending 50 m down hedgerows, or in nearby haystacks or rubbish dumps.

At farm C the farmer reported three small birds, while the ICI staff did not find any carcasses. Also, on three farms where ICI did not visit, there were 1 cat, 7 chickens, and 10 small birds reported as nontarget mortalities.

Residues in livers of nontarget animals found dead ranged from 0.04 ppm (detection level) to 3.8 ppm in birds and < 0.04 ppm to 2.1 ppm in mammals. See table 11 in attached study.

The following shows the numbers of rats found dead above ground.

Farm	No.	Farm	No.
A	6	G	27
B	9	H	63
C	0	I	9
D	57	J	38
E	0	K	22
F	100		

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Residues in whole rat carcasses found dead above ground ranged from below the detection level of 0.02 ppm to 2.6 ppm, average = 0.52 ppm. See table 10 and figures 1 and 2 of attached report (enclosure 1).

13. Author's Conclusion:

The risk of secondary poisoning could be reduced by developing baiting techniques which avoid gross overdosing of rodents. Little primary poisoning of wildlife was detected when bait was well concealed.

14. Reviewer's Discussion:

This study shows that both primary and secondary exposure to "Klerat" will cause mortality to nontarget organisms, but because of its design, the study cannot provide any indication of population effects.

Tables 1, 2, and 3 of the attached report provide summaries of referenced primary and secondary acute toxicity studies. References 19, 20, and 32 have been validated by EEB. Reference 27 was received previously but was not categorized. Secondary toxicity tests are all supplemental because there were too few test animals per concentration and per test to develop statistically sound effect levels. However, the sum of the data clearly shows that, in the laboratory at least, a secondary toxicity hazard exists with the use of brodifacoum as a rodenticide.

Clearly, the field use (630 ha) resulted in the most nontarget mortalities.

2 tawny owls
2 buzzards
17 corvidae
3 small birds
1 gray squirrel

Note that visits to this site (farm H, 630 ha field) did not begin until 5 weeks after treatment began. Furthermore, according to the report, "(a) large portion of dead animals found in the field were not in a condition to allow a conclusive postmortem examination" (page 16 of attached report). Most of these unidentifiable corpses came from field H. It is likely, in the reviewer's opinion, that these carcasses could have been nontarget mortalities caused by brodifacoum. At farm H, the bait was placed deep in rat holes precluding direct feeding by nontarget birds.

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The number of dead rats found above ground is also significant. There is no way of knowing what percentage of the total mortality these "above-ground" deaths constitute, but it is obvious that a substantial number of brodifacoum-killed rats would be available for scavenging. A few dead rats were found disemboweled suggesting carrion feeding, possibly by corvids.

The report also noted that postmortem examination showed that major hemorrhage sites were similar within species and were associated with likely physical stress points considering their behavior in the wild. For example, pecking birds experienced hemorrhage between the roof of the cranium and the brain. In owls, hemorrhage occurred along the sternum keel.

No statistics were performed.

Adequacy of study:

Supplemental. This study provides useful supplemental information but does not fulfill requirements for a full terrestrial field study because it cannot address population effects. It cannot be upgraded.

15. Completion of One-liners:

N/A

16. CBI Appendix:

The attached study is considered CBI.

PAGES 43 THROUGH 53 ARE NOT INCLUDED. THOSE PAGES CONSIST OF REGISTRATION DATA.