9-26-84

112701
SHAUGHNESSY NO.

26
REVIEW NO.

EE BRANCH REVIEW

DATE: IN 6-18-84 OUT 9/26/84

FILE OR REG. NO. 10182-LI

PETITION OR EXP. PERMIT NO.

DATE OF SUBMISSION 5-22-84

DATE RECEIVED BY HED 6-15-84

RD REQUESTED COMPLETION DATE 10-3-84

EEB ESTIMATED COMPLETION DATE 9-26-84

RD ACTION CODE/TYPE OR REVIEW 121/NEW CHEMICAL

TYPE PRODUCTS(S): I, D, H, F, N, R, S RODENTICIDE

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. W. MILLER (16)

PRODUCT NAME(S) VOLID

COMPANY NAME ICI AMERICAS INC.

SUBMISSION PURPOSE SUBMISSION OF MEETING NOTES FOR COMMENT

SHAUGHNESSY NO.	CHEMICAL, & FORMULATION	%
112701	BRODIFACOUM	10ppm

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

TO: William Miller
Product Manager Team 16
(Attn: Daniel Peacock)

THRU: Raymond Matheny
Head, Review Section 1

THRU: Clayton Bushong
Chief, Ecological Effects Branch

SUBJECT: Review of minutes of the April 27th meeting with ICI Americas Inc. concerning the registerability of brodifacoum for use in apple orchards to control Microtus spp.

EEB has reviewed the minutes of the 27th April 1984, meeting with ICI Americas Inc., submitted by Mr. James W. Wagner, Manager, EPA Registration. ICI's interpretation of what transpired at this meeting differs from that of the EPA staff.

The primary objective of the meeting centered on ICI's desire to achieve conditional registration of brodifacoum for outdoor use. The initial outdoor use pattern would be apple orchards. This was for nationwide use. The question was and is: can a 10 ppm brodifacoum product be registered (fully or conditionally) for outdoor use in apple orchards?

The toxicological data that EEB has reviewed indicates 10 ppm brodifcacoum pellets used in orchards has killed seed-eating birds and nontarget mammals through direct ingestion. The ingestion of brodifacoum by the target species has been implicated in the death of a high number of raptors in limited areas of application. Based on the toxicological mode of action, time to death and measured residues in the target species,it is not inconceivable that nontarget carnivorous and scavenging mammals could be impacted. EEB has taken brodifacoum through the tiers (I-IV) of data requests. As these data have been generated, submitted and evaluated, the theorical significant population impact to non-target organisms appears to be a reality. Thus, EEB's hazard assessments, based on submitted data, would not be conducive to any form of registration for field uses of a product containing brodifacoum.

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Specific Points:

"Objectives of the meeting" (From ICI letter):

"1. To allow EPA to air any of their concerns which remained following their appraisal of our most recent document and to respond to them." (ICI)

Numerous points were quickly covered under the initial discussion and were later expounded upon in detail as the meeting progressed. These original comments and current clarifying comments are presented in the text below, and the review of 4 May 1984 (attached). Since, ICI interjected comments in their minutes which were not openly discussed in the meeting, EEB is opting to follow their lead.

"2. In light of 1, to reach a clear view on the long term registerability of brodifacom as a 10 ppm bait for outdoor use." (ICI)

This objective is very important as scrutiny indicates a conditional registration for a 10 ppm brodifacoum product for apple orchard use will inevitably be followed by applications for additional field uses. Thus, increasing exposure creates increased non-target avian and mammalian risks.

"3. To demonstrate to EPA that ICI being a responsible company have evaluated the potential hazards of this use of the product to the fullest extent possible given the constraints of limited use under EUP's and the current 'state of the art.'" (ICI)

In responding to the registration application of this product EEB has indicated that brodifacoum is a very highly toxic compound to all vertebrates. Additionally, brodifacoum remains in the tissue of animals for extended periods (200 + days) and mortality may be delayed. The tier one LC_{50} avian studies are an example. The initial tests were of eight days duration. Mortality was still occurring on day eight. EEB requested that the study be conducted again with the end point being no mortalities for 72 hours. The second set of tests were conducted for 40 days. The LC_{50} for mallard ducks at eight days was 778 ppm. The more definitive 40-day mallard study indicated an LC_{50} of 2.7 ppm. The LC_{50} for bobwhite quail at eight days was 201 ppm. The more definitive 40-day bobwhite study indicated an LC_{50} of 0.8 ppm. Thus, the more definitive studies for mallards and bobwhite show that the product is 288X and 251X more toxic than originally perceived. We state that these studies are "more" definitive because the criteria for the results are based on death. Savarie and LaVoie (1979) conducted a secondary toxicity study with American kestrels. Besides the usual criteria of death they measured prothrombin times. The

preliminary results indicated that kestrels consuming voles for 2 days and 6 days had increased prothrombin times (vs. controls) at 100 days post-treatment of 300 and 600 seconds, respectively. These results created further concerns because the basal diet contained a Vitamin K complex. The label indicates Vitamin K_1 is antidotal. At 98 and 96 days, respectively, on the basal diet containing a Vitamin K complex, the effects of brodifacoum were still being observed. Further, this study brought the question: how long will brodifacoum be retained in an organism? In the same data package, a study by Bratt and Hundson(?) addressed the biological stability of this product in rats. The following are excerpts of their findings:

"1. Absorption of brodifacoum may be a saturable process with fecal excretion increasing rapidly thereafter."

"2. Most (74.6%) of the dose was retained in the tissues of the animals 10 days after dosing, (0.25 mg/kg; 6.6 mg:/kg) principally in the liver (22.8%) and pancreas (2.3%), but also in kidney (0.8%), heart (0.1%) and spleen (0.2%). The remainder of the dose (approximately 50%) was present in the carcass and skin. Analysis showed that 31.3% and 19.6% of the dose present in the carcass and liver, respectively, was unchanged brodifacoum together with two other more polar components which were not identified. The biological half-life for the radioactive species in tissue was estimated to be 150-200 days."

"3. Brodifacoum has a moderate to high systemic toxicity to animals." This study has been deferred to other Branches in HED for validation EEB accepts the reported results without validation for purposes of discussion only. The study is not conclusive (statement #1) on the saturability of brodifacoum. Brodifacoum residues could be higher than the study indicates. The biological half-life of 150-200 day (approximately 5 to 7 months) indicates an application made in the dormant season could be carried by the target species into the reproductive season of nontarget avian raptors and mammalian carnivores. This could have a direct affect on adult non-target population who would be consuming the non-target species and accummulating brodifacoum from the residues of the sublethally dosed target species. Additionally, the adults will be feeding their young, who on a mg/kg basis would be more susceptible to intoxication, thus lowering or eliminating the recruitment levels per nest. This in turn affects the overall population dynamics."

Considering the above rationale, one might ask: "Why hasn't EEB required an avian reproduction study?" The previous reviewer, Mr. Larry Turner, determined that such a study could not be conducted because the residues immediately after application exceeded the LC_{50} and exposure would not occur during the breeding season. However, Mr. Turner did not have the benefit of all data now available. While direct exposure to the pelletized bait may not occur during the reproductive season following application, the potential for secondary exposure does appear probable. The breeding seasons for raptors is a stressful event to the adults. If they had been exposed sublethally to brodifacoum, during the dormant orchard treatment, the added stresses of breeding and rearing could produce lethal effects. Additionally, the use of sublethally exposed target and non-target organisms as a food base during breeding could be a source for additional biological loading of the raptor or mammalian predators. EEB is presuming that the product is not 100% efficacious to the target species population as Mr. Dale E. Kaukeinen of ICI has indicated. Since assumed direct mortality has been reported for non-target birds (juncos, pheasants, bobwhite quail and doves), it is not inconceiveable that sublethally dosed avian prey would be available during the reproductive season.

The Philadelphia and Washington, D.C. Zoos (Pest Control-1984, personal communication-1984, respectively) report avian mortality attributed to brodifacoum. Reportedly, insect eating and/or carnivorous birds consumed insects (mainly crickets) which had fed on or crawled over brodifacoum treated bait placed inside bait boxes to control rats and/or mice.

We anticipate that ICI will counter these reports in the following ways:

1. This was their 50 ppm product not the 10 ppm. EEB rebuttal will be that the toxicological mode of action of brodifacoum negates the amount of a.i. present. Brodifacoum is an acute anticoagulant; either a single or multiple dose can be fatal. Based on the biological half-life of brodifacoum, sublethal exposure can be continous over 100 or more days before lethality occurs. Thus, multiple dosing with brodifacoum could and apparently does procedure lethal effects.

2. There is no evidence the insectivorous birds were exposed secondarily to the toxicant (via insect ingestion) and the deaths were primary poisoning.

To date, however, EEB does not have data to conclusively prove insects can be a source for secondary poisoning. Dr. Amand (1981) in the publication, "Talon Alert," made the observation that pavement ants and roaches were seen foraging

in the birdproof bait boxes. Several days after Talon was placed, insectivorous birds died of hemorrhaging. This article further states that Talon is not known to be insecticidal and the fate of Talon inside the insect is not known. Thus, Dr. Amand's supposition was that insects could be linked to secondary poisoning. In April 1984, EEB received a call from Dr. Peratino of the National Zoo, Washington, D.C. He was concerned with mortality of insectivorous/carnivorous birds at the Zoo and its Front Royal, VA. facility. In this case crickets were presumed the secondary source for the toxicant. Residues of Talon were found in the birds by ICI. (Note: ICI has not provided these adverse data.) In addition, ensuing conversations with personnel from the Front Royal facility indicated they observed earthworms apparently feeding on a spill of the Talon pellets.

If invertebrates would consume a grain base bait such as Talon and Volid which can be even remotely implicated in an indoor secondary hazard, then why would invertebrates in field uses not provide for an equivalent exposure potential? If insectivorous birds were to consume brodifacoum-ladened invertebrates, then they could be sublethally or lethally intoxicated. If these birds are available to mammals or other avian species then what negates a tertiary poisoning event?

ICI was questioned about the Philadelphia Zoo incident. They attributed the poisoning to primary exposure through the insects carrying the crumbled pieces out of the bait box. We ask if insects were collected for residue analysis. Their response elicited a request for data to determine if the insects could consume and thereby become sources for intoxication of vertebrates. To date, ICI has not provided nor indicated they have generated these data in the elapsing two plus years.

Regressing to the original statement that "...ICI being a responsible company have evaluated the potential hazards..." we question further their sincerity to evaluate the hazards. In the course of reviewing EEB fish and wildlife data, for this product this interesting fact came to light: the basal diets of the treatment groups contained a Vitamin K complex. ICI labels state that Vitamin K_1 is antidotal. Thus, the question of whether the maintenance levels of Vitamin K complex in the basal diet could exert an effect on the outcome of the test arose. If the Vitamin K complex exerted a positive effect then the toxicity values which were highly to very highly toxic would, in reality, be inaccurate. The true LC_{50} values could be considerably lower. Since the antidotal statement is based on a Toxicology Branch/HED data requirement, I conferred with Mr. Salvatore F. Biscardi, the reviewer for toxicology. His July 7, 1984 conclusions reflected that the data submitted for the claim that Vitamin K_1 is antidotal were invalid. The study did not support the antidotal statement. Mr. Biscardi further indicated

EEB's concern over Vitamin K in the basal diet could not be confirmed with the data ICI had used to substantiated the antidotal qualities of Vitamin K_1. In EEB's review and during the subsquent meeting, we asked ICI if the maintenance levels of Vitamin K complex in the basal diets affects the true toxicity of this product. ICI replied that animals in the wild receive Vitamin K through the consumption of food items. We inquired about the amount of Vitamin K these wild animals receive by asking: "Are animals in the 'wild' receiving daily maintenance levels of Vitamin K?" ICI conceded that this could not be answered without additional testing. It was suggested that such testing be conducted prior to field use application. In July 1983, EEB reviewed a study by Bell et al. (Date?) submitted by ICI. This study was concerned with using 50 ppm brodifacoum bait for control of rabbits in New Zealand. While brodifacoum appeared efficacious for rabbit control, incidental nontarget mortality of sheep, cats and several unidentified bird species occurred. The authors, either concerned about the incidental mortality or as a side issue, conducted an antidote test with dogs. Quoting from the report, "Daily treatment with 2 mg/kg of Vitamin K^1 for at least 5 days after intoxication prevented any dog deaths until obvious signs of anticoagulant poisons appeared. However, since these studies it has been found that several such treatments may be needed because hemorrhaging can reoccur after a successful initial treatement." While EEB has not validated this study, we assume the quote will stand. Vitamin K in the basal diet of a test would appear to mask the true toxicity of brodifacoum. Thus, predatory and scavenging avian and mammalian species whose source of Vitamin K is the animal tissue they consume could be more susceptible to brodifacoum than vegetarian species.

The next part of the statement refers to "the constraints of limited use under EUP's." EEB to date has not recommended reducing acreage or pounds of brodifacoum product used. EEB has questioned brodifacoum application rates in a few instances, but has given ICI considerable leeway in their conduct of EUP's. EEB suggested ICI conduct their proposed population monitoring study under an EUP. ICI replied that it would cover too large an area and we probably would not approve it. We indicated this would be a more plausible approach than a conditional registration. ICI stated that the their upper management would not financially support additional testing of this magnitude.

EEB questions ICI's position that they have considered the potential hazards of outdoor use of brodifacoum with "the current 'state of the art.'" Dietary exposure to an avian species using basal diet with and without a Vitamin K complex does not require a totally new "state-of-the-art" procedure.

Exposure to invertebrates which consume grain base products in order to determine if they are a source of secondary exposure

is a straightforward test. While not under EEB testing requirements, EEB wonders what advancements in the state-of-the-art are required to determine an antidote for brodifacoum. This new procedure could significantly affect, possibly invalidate, previous fish and wildlife data. What constraints in the current 'state-of-the-art' are there to negate proving that brodifacoum is not going to adversely affect nontarget populations of avian and possibly mammalian organisms? Based on the comments at the meeting and the ICI minutes of that meeting to which this document is addressed [their points], upper management does not desire to give additional funding to a product whose [additional] data have continued to be negative towards its registerability.

EEB's sole purpose is to develop a hazard assessment, addressing the potential impact this pesticide presents to nontarget organisms. We presented the above findings to make a more comprehensive understanding of EEB's position. It is hoped that the above sound rationale will sufficiently counter the applicant's #3 statement which, in essence, is totally misleading.

4. Following 3, to suggest to EPA that the only realistic way forward is for them to grant ICI a conditional registration, i.e., a registration contingent upon a monitoring of the non-target effects of the compound during extensive use over a protracted period of time.

EEB is willing to discuss a proposed longterm monitoring of a population of screech owls in specific states. Baseline data for the resident populations will have to be developed. The Van Camp and Henny (1975) study on the screech owl was artificial in that the owls which were monitored were residents utilizing man made nest boxes. The proposed study would entail monitoring of natural populations without artificially induced man-made structures (e.g., nest boxes niches) which would bias the data. It took Van Camp and Henny thirty years to arrive at the conclusions on the populations of screech owls in their study.

EEB has reservations about a three year monitoring study and questions whether definitive data would result. The establishment of control areas must be such that non-target species within are not exposed in any way to the product. A thorough in-depth knowledge of animal populations within control areas is essential at the on set and throughout the study. There are questions regarding whether Van Camp and Henny data are accurate in regards to fluctuations after 30 years of monitoring. Further, there is enough literature available to indicate causal effects of population fluctuations in other geographical areas. ICI representatives indicate the monitoring study would last three years. We submit this is insufficient. This limited duration would not allow determination of pesticidal

effects over natural population fluctuations unless the monitored population disappeared. We question how a control area is going to be set up. If one area of a state is going to be the control, what assurance does ICI have that the conditionally registered product for that state is not going to be used in the control plot? If a control plot is going to be established in an adjacent state to a treatment state how is ICI going to prove that the population of the control state is fluctuating with the treatment states? With the present proposed states for which conditional registration is sought (Delaware, New Jersey, Maryland, New York, North Carolina, Ohio, Pennsylvania, Virginia and West Virginia) what geographically located and climatically similar states are available to serve as a control plot? (Points stressed in this summary page 3 of minutes of meeting as presented by ICI)

> "1. The limited area over which the product will be used (0.45% of all cultivated land in the USA)." ICI

The opening comments indicated ICI was seeking a "clear view on the long term registerability of brodifacoum as a 10 ppm bait for outdoor use." When we arrived at discussion of this point their initial objective was a conditional registration for apple orchards. Now ICI "being a responsible company" has shown their true intent is to register other uses. [redacted] . EEB realizes that apple orchards are a small part of the total agricultural area in the U.S. However, pastures, rangeland and non-agricultural areas constitute more geographical area than all cultivated land. We bring this up because there have been EUP's issued for ground squirrel and pocket gopher control. There have been reports of testing on prairie dogs. When we have attempted to follow-up on these reports we can get neither a confirmation nor a denial of their existence. Thus, EEB perceives ICI as ascertaining that a small agricultural acreage conditionally registered will allow them to broaden use patterns while awaiting the results of the initial conditional registration data request. Due to the Registration Guidelines procedures they could have nationwide multiple area use patterns under conditional registration before the results of a multi-year orchard study was available.

Delete 11/8/84 RSIII

> "2. The limited amount of active ingredient which will be used even at the year of maximum sales." ICI

EEB will accept the amount of active ingredient which will be used in the year of maximum sales will be small [redacted] #a.i.). However, as with other statements made by ICI this one lacks relativity to the formulated product. One pound of active ingredient formulates 100,000 pounds of formulated, ready-to-use product. This amount dispersed at the maximum

coverage of acreage equates to 20,000 acres being treated. Thus, the use of a limited amount of active ingredient does not negate high exposure potential. Further, the registrant has stated the pellet breaks down in a relatively short period of time in moist conditions. I was on-site of the Harmony Hollow secondary hazard study in the fall of 1981. Before my arrival, the orchard had been treated with brodifacoum pellets. Upon arrival at the site and a casual walk through the treated area, I easily located pellets. I will concede that the orchard was treated at a higher than recommended rate. However, I was informed by the field personnel that a 2 to 3 inch snow and one to two inches of rainfall had occurred prior to my arrival. The pellets after broadcast application are persistent even with the presence of moisture. Therefore, ICI has produced a pellet with a very small amount of active ingredient (0.001%) that appears to be stable for an indeterminant number of months under moist conditions. (Please note: EEB has requested from ICI actual field persistence data on their pelleted formulation. ICI still refuses to quantify their statement: "most of the pellets will disappear within a short period of time.")

"3. We have a produced specific information for this market which has reduced both primary and secondary hazard." (ICI)

ICI representatives repeat their claim that the reduction from 50 ppm to 10 ppm reduces primary hazard. EEB repeatedly has requested the comparative data that proves this point. To date ICI has not been able to substantiate this claim. On the other hand they have submitted one study by Bell et. al. (Date?) that appears to partially refute this claim. They found that the higher the initial dose given to sheep the greater the amount excreted. Further, the representatives and management appear oblivous to what their biologists have reported brodifacoum can be consumed by the target organism over several days or longer. Efficacy studies have indicated generally those animals collected toward the end of a trial will have the similar residues to those collected earlier. Thus, with lower doses to the target animal over time, the longer the residue level in the animal remains, and the greater the potential for secondary hazards. Further, the long biological half-life of brodifacoum allows nontarget prey species, birds (e.g., juncos, pheasants, quail) to repeatedly feed on the product, accumulating a lethal dose over a long time. Thus, unless a pre- and post-population survey was conducted on a bird (i.e., pheasants), it would be totally inconclusive to state that reducing the amount of toxicant reduces hazards. Being as arbitrary as ICI has been producing these minutes, we draw the following comparison: With the 10 ppm product a field test was conducted to determine secondary hazard to raptors. One screech owl was found dead, and juncos, seed eaters, and rabbits were reported as nontarget deaths. The application rate was determined to be around 45.9 kg/ha of

the 10 ppm product. ICI contracted another field study to determine the secondary hazards to raptors associated with their 10 ppm formulation. Not only did they find dead juncos and rabbits but also found seven raptors attributed to a 10 to 20 pound application rate. Where has this specific formulation reduced the primary and secondary hazard? That is to say, instead of perpetuating this "off-the-cuff" statement, submit the comparative data and support documents substantiating this claim.

> "4. Toxicity measurements from laboratory tests have to be taken in context of the real in use exposure. In practice, primary hazard is restricted to a limited range of birds and mammals." (ICI)

These statements are almost complete. Mr Wagner's presentation of these statements would have been more complete if he had finished them with the following statement.

That is to say, any bird or mammal that will consume a grain based pellet within a treated area can be exposed.

Again, ICI has made a statement without the benefit of data to support their conclusions. If in practice, primary hazard is restricted to a limited range of birds and mammals where are the field data to support these conclusions?

> "5. Laboratory studies have indicated a potential for hazard in predatory birds which subsist largely on the target species. However, laboratory studies are of limited value and there was a need for a field study. The protocols for the field study (Hegdal, radiotelemetry) were developed with EPA who even visited the site during the course of the work. EPA had full opportunity to comment on this study and, from previous experience with radiotelemetry (1080, strychnine, etc.), were aware of the objectives and potential limitations of such an exercise." (ICI)

ICI realizes laboratory studies are of limited value. While most of the concerns have been directed towards avian species, ICI has failed to supply the data on mammals that were requested in 1978. If, as ICI suggests, the laboratory studies for primary and secondary hazards to canids, fields, and mustelides are of little value, perhaps the company would prefer skipping over tier II and III testing and provide an adequate field study for these groups of animals.

The protocols for the field study were initiated with a meeting. A very general discussion ensued with conclusions being that a protocol would be developed and submitted to the Agency for review with adequate lead time(120 days). On August 10, 1981, EEB received the protocol. On October 30, 1981, EEB completed an unofficial expedited review of the

protocol. We were informed that Mr. Paul Hegdal (USFWS) had been working on site since August 1981. The signed off review left the Branch November 2, 1981. It went through the HED and RD tracking systems. The actual date received by the product manager team is unknown. Transmittal to ICI of the approved EUP was not determined. Broadcasting of the Volid pellets, according to Hegdal's report, began on November 9, 1981. When was there time to comment between the initiation of the study which commenced before we reviewed the final protocol? ICI, in an effort to get the product registered, failed to accept our recommendations on how to proceed with developing the protocol, for this field study. We suggested they develop a protocol, ascertain the personnel necessary to conduct the test, send the protocol to us for review, and have all parties meet to discuss any differences and/or procedures surrounding the test. This would have alleviated the subsequent problem expressed by Mr. Wagner, that the study was in progress and changes could not be incorporated.

There were no official EPA visits to the site as Mr. Wagner indicates. Two individuals from EEB did unofficially visit with Mr. Paul Hegdal. Mr. Ed Fite visited Mr. Hegdal since they had worked together prior to Mr. Fite's employment with EPA. It is quite apparent to us that Mr. Wagner has reached another conclusion which was unsubstantiated. With the study in progress, it is doubtful that even unofficial visits by a friend would persuade Mr. Hegdal to deviate from an ICI approved study design.

In conclusion, EPA (EEB/HED) was not given full opportunity to comment on this study. We were not given the opportunity to discuss the protocol with the researcher. He, in turn, was not given the opportunity to ask us questions, the answers which would have affected his study design. Therefore, EEB reviews another study conceived by ICI, under Mr. James Wagner's direction, which did not avail ICI of the opportunity of an in-depth discussion of this field study by EEB biologists in order that it could be conducted to answer specific secondary hazard questions.

The numbered issues (1-3) on page 4 have been addressed in various parts of the document. Issue #2 is somewhat buried in this document. I was curious why the application rate of 15 pounds per acre was chosen. The more material applied, the greater the possibility of nontarget organisms locating and consuming the pellet. ICI personnel had indicated that 100 voles per acre would be an average population level. Approximately 50 pellets are required to reach a vole LD_{100}. ICI has indicated that their pellet has high efficacy (see statement #3). Based on their data on the number of pellets per pound and a 15 pound per acre application rate, there are 190,800 pellets available to this average population of 100

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voles. Each of these 100 voles would have to locate and consume 1734 pellets to clean up the application. This would appear unrealistic. What appears as a more conceivable alternative is that pellets are available for voles immigrating into the treated area. Thus, voles that are immigrating into the area provide a continuous source of secondary exposure until all pellets are consumed or are weathered away. The question of how long pellets survive in a form that allows the toxicant to be transmitted to a target organism is apparent.

> "Following this series of questions, Clayton Bushong asked about the hazard of brodifacoum relative to other available rodenticides. He accepted Paul Hegdal's view that, like other materials used, brodificoum did show some degree of hazard; but in terms of primary hazard, this was probably acceptable." (ICI)

Mr. Hegdal was brought into the meeting to address questions relative to his raptor study. I question whether Mr. Hegdal is aware of the biological half-life of this compound. Does Mr. Hegdal, or ICI for that matter, have baseline data to support these statements? Before ICI begins to rely on this statement, they should consider that it was an opinion expressed by a biologist who may not have data to support his conclusions. If ICI wishes to pursue Mr. Hegdal's opinion, then we suggest that they provide comparative data for all other rodenticide formulations versus the brodifacoum 10 ppm formulations. ICI should recognize they cannot provide or, to date have not provided the necessary information to prove that the 10 ppm formulation provides less primary and secondary hazard then the 50 ppm.

Page 5 Residues

> "1. Several criteria were used in the telemetry study to establish the cause of death. As it happened, removal of the residues data would not alter the conclusions of that study." (ICI)

The study, as created by ICI, left only one outcome or conclusion plausible. The way the study was designed and conducted only allowed for addressing whether there was a hazard to individual screech owls. Mortality occurred in individual screech owls that were associated with brodifacoum treated orchards and their deaths have been attributed to the toxicant. EEB and ICI therefore agree that brodifacoum can cause screech owl mortality. The screech owls that Mr. Hegdal killed for residue analysis would have at best produced more mortality attributed to the toxicant. The fact that Mr. Hegdal harvested these owls would indicate ICI had not provided him with a complete overview of the toxicological data. In light of the Savorie and LaVoie (1974) study of kestrels, we would have recommended prothrombin time

determination on these birds. This could have allowed a determination of their survival and/or recovery through the harsher winter months. Another factor to consider was the actual time of exposure of the owls which could not be determined.

"2. The pharmacokinetic properties of brodifacoum mean that the residue in animals taken by itself can never be used in a diagnostic sense." (ICI)

ICI is not presenting the full basis for this statement. The basis for this statement is Mr. Hegdal's harvest of some screech owls associated with treatment areas. The residues were equitable to those owls found dead from brodifacaoum. There is no way of determining when these owls were exposed to brodifacoum. All that can be determined is that the owls were exposed after bait placement, and had similar residues to those owls found dead.

"3. Since the original submission, the 'state of the art' has improved and much lower limits of determination can now be achieved." (ICI)

First, ICI tells us in #2 above that residues cannot be used in a diagnostic sense. Then they tell us the 'state of the art' for residues has been improved. So now we are able to receive more accurate residue data. However, ICI does not want us to use it as a diagnostic mean of determining mortality when the study is cut short and additional animals are harvested.

"4. The average time to death of screech owls was 20-24 days in the study. The majority of birds surviving this period are likely to survive in the long term." (ICI)

This is another statement without a data base. The average time of exposure before death of the screech owls appears to be 20-24 days. However, the time from exposure to death is indeterminant. The second sentence was not supported by data. As this report indicates, ICI has failed to provide basic data on the persistence of the pellet. As long as the pellets are present, then primary lethal or sublethal toxicity to the target organism could occur. Primary intoxication allows for a source of secondary intoxication. Thus, rodent or avian immigrants into the orchard could provide a continual or long term secondary exposure potential. If sheep are considered surrogates to the vole, a sublethally dosed vole could be carrying residues for over 200 days. This is further complicated by the observation of kestrels which exhibited intoxication from brodifacoum for over 100 days. Additional exposure, stress, or time could have conceivably allowed the terminal intoxication of the harvested owls.

Telemetry page 5 and 6 ICI's minutes

I feel this section is acceptable. I suggest ICI re-read the sections that allude to what EEB would consider extensive. They should consider the pre- and post-surveys.

Conditional Registration (page 6 ICI minutes)

The following is a reiteration of EEB's previous points:

1. EEB indicated that the way to proceed at this time is an EUP.

2. ICI asked if we would consider a conditional registration. EEB indicated that they are required to consider any type of submission.

3. ICI is proposing a 3-year monitoring study as the condition for registration. EEB contends that this is probably inadequate. There own market analysis [redacted] Therefore, a study over the first 3 years of sales would not maximize exposure.

4. ICI was wanting to go to market with this product during the 1984. We indicate we would not have our review including the OES biological opinion finished in time.

5. We indicated that there were additional data gaps to mammals that had been requested and have not been filled.

6. "ICI agreed to submit a proposal for monitoring as quickly as possible for EPA consideration and also to submit a revised Volid label for OES review that:

   "1. Restricted use of Volid to certified applicators.
   2. Restricted use in apple orchards only,
   3. Restricted use to limited number of states, and
   4. Restricted applications to 15 pounds of bait per acre per season." (ICI)

The label was received by EEB in May 1984. While 3 out of 4 of their proposals are incorporated in the label, the restriction of allowing application only in apple orchards was expanded (from the label) "to help prevent invasion, application to noncrop border areas such as ditchbanks, hedgerows and fence lines may also be made." Our meeting discussed broadcast baiting. The label indicates spot baiting under trees. After application the bait is covered with a weather impermeable substance to improve efficacy. The problem arises in that coverings provide for extended life of the pellet. This, in turn,

provides for increased secondary exposure due to increased time primary exposure occurs.

"ICI stressed the importance of a registration decision by August 1984 in order to treat orchards during the 1984 use season."

EEB stresses the need for ICI to supply the necessary data and additional information with sufficient lead time to complete our review. For instance, it will take 90 to 120 days to receive an OES biological opinion. If we had had the new label by the 1st of May 1984 we might have received a biological opinion by the first of August 1984. ICI, "being a responsible company," did not submit their label until the end of May. EEB received the label May 30, 1984. We completed and transmitted the request for consultation on June 7, 1984. At the time of this writing, August 27, 1984, we have not received the monitoring proposal that we indicated would have to be submitted by late May or very early June. EEB finds the fact that this protocol has not been submitted reassuring in light of the reported responsibility that ICI has towards this product.

In conclusion, the following data have been previously requested and have not been fulfilled:

1. Acute dietary LC_{50} to canids, felids, and mustelids.
2. Secondary dietary toxicity test to canids, felids, and mustelids.
3. Persistence data on the pellets under field use conditions (hand and broadcast).
4. Persistence of the active ingredient under field use conditions.
5. Data demonstrating that insects are not a source for secondary exposure to insectivorous vertebrates.

Additional data requests, in light of past and present data, meetings, etc:

1. Avian reproduction study.
   Due to the long biological half-life of this compound applications made in the dormant season are expected to still be affecting avian species during the breeding season. Second, without data to support the conclusion that the pellets are not available during the reproductive season, EEB is assuming that the pellets will still be available. This study should be run with a dose level equivalent to expected field residues (10 ppm) and a 5X factor (50 ppm).

2. Description of the new analytical techniques for the residue analysis should be sent to Residue Chemistry Brand/HED for validation with a copy of their review

transmitted to EEB for use in evaluating our data.

3. Under special test section of the guidelines, EEB can request testing of a nonstandard nature. EEB is considering the necessity of a mammalian reproduction study. This study requirement is based, in part, on the long biological half-life in mammals.

4. In addition to the standard avian reproduction study in #1 of this section, EEB is considering a request for a raptor (probably owl) secondary exposure reproduction study. The necessity of this study will be determined after review of the proposed monitoring study.

5. If, as in the past, each higher tier study indicates increasing hazard, additional special tests, may be required to answer specific questions. EEB, therefore, informs ICI that additional field use patterns may necessitate additional testing. Also, the results of the above could necessitate additional data requests.

6. ICI has not submitted documentation,(data) that Vitamin K complex level in the basal diets are equivalent or less than those occurring under natural conditions. Thus, EEB has to assume that the toxicity data do not reflect a true LC_{50}, LD_{50} or toxicity level.

7. If ICI desires to pursue conditional registration, with a monitoring study as part of the conditions, EEB suggests that they review Van Camp and Henny (1975) to determine an adequate duration of time for a pre and post survey. EEB requests them to submit the protocol in advance of the conditional request. EEB requests a meeting after submission of the protocol and before the due date of the review. This will allow all parties to discuss the idiosyncrasies of the study. The proposed study areas should be delimineated. All personnel anticipated to be involved should be present (biologist, analytical chemists, management, etc.).

EEB recommends that ICI submit all protocols for the tests in both sections prior to implementation.

While EEB has referenced some of the data that ICI has submitted, this document does not address all the adverse data. ICI biologists are well aware that this chemical has an extensive data base. The data EEB has reviewed indicates brodifacoum is very highly toxic acutely and chronically in primary and secondary exposure. The biological half-life of this compound appears to be around 200 days indicating it is biologically persistent. Being bioligically persistent indicates exposure over a long period of time to sublethal dose will culminate in death. This could have affected

Mr. Hegdal's study design. If ICI had supplied the study design before Mr. Hegdal was on-site working on the study plots, EEB could have presented additional factors to be considered in the design. Mr. Wagner was well aware of EEB's interest in a meeting to discuss study design prior to implementation. EEB, therefore, finds Mr. Wagner's minutes of the meetings of April 27th, 1984, erroneous in regard to the field study and other sections delineated above.

Russel T. Farringer, III
Wildlife Biologist
EEB/HED

Attachments: Minutes of Meetings by ICI dated May 22, 1984.
Minutes of Meetings by EEB dated May 5, 1984.
Label for Volid™ Rodenticide Pellets Revised 5/14/84.
References.

References

Bell, J., J.M. Williams, M.E.R. Godfrey. (Date?) Brodifacoum in Rabbit Control. New Zealand Study, Acc. #250077.

Bratt, H. and Pamela Hundson (?). Brodifacoum: Absorption, excretion and tissue retention in the rat. ICI, Ltd., Alderly Park, Macclesfield, Cheshire, UK. CTL Study No. UR0110, Report No. - CTL/P/462, Acc. # 245704.

Pest Control (1981) Talon Alert. Vol. 49:54

P.C. (1984) National Zoo. Suspected poisoning of avian species by brodifacoum.

Savarie, Peter, J. and G. Kieth LaVoie (1979). Secondary Toxicity Hazards of the Anticoagulant Brodifacoum of the to American Kestrels (Falco sparverius). Cooperative agreement between ICI and Denver Wildlife Research Center (FWS) Acc. #245704.

Van Camp L.F. and C.J. Henny (1975). The Screech Owl: Its Life History and Population Ecology in Northern Ohio. North American Fauna No. 71, U.S. Department of the Interior, Fish and Wildlife Service.

ICI Americas Inc.

Agricultural
Chemicals
Division

HAND DELIVERED

May 22, 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
For Control of Microtus
in Apple Orchards
EPA File Symbol 10182-LI

My thanks to you and Dan Peacock for arranging the meeting with HED on April 27. This meeting was very helpful to ICI in assessing the registerability of brodifacoum for this use pattern.

I am enclosing three copies of our minutes of this meeting for your review and file. We would be grateful if you would provide HED with a copy for their review also. Please let me know if you have any problems with the minutes as recorded.

Thank you again for your assistance in this matter.

Sincerely,

James M Wagner

James M. Wagner
Manager, EPA Registration

JMW/bmw

Enclosures

Wilmington, Delaware 19897 Phone (302) 575-3000

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Farringer

MINUTES OF MEETING BETWEEN
EPA and ICI Americas
on the Pending Registration of
VOLID® RODENTICIDE

April 27, 1984

Persons in Attendance:

EPA Representatives

William H. Miller (RD)
Daniel B. Peacock (RD)
Clayton Bushong (HED/EEB)
Stephen D. Palmateer (RD)
Russell Farringer (HED/EEB)
Edward Fite (HED/EEB)
Richard A. Loranger (HED/RCB)
Raymond Matheny (HED/EEB)
William M. Butler (HED/TB) part-time

ICI Americas Inc. Representatives

Dale E. Kaukeinen
Robert E. Hawk
James M. Wagner
Godfrey Teal
C. J. Richards

Also Attending

Paul L. Hegdal - U.S. Fish & Wildlife Service, Denver, CO
Bruce Colvin - Bowling Green State University, Bowling Green, OH

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BACKGROUND

VOLID Rodenticide is a grain base pelleted bait for controlling Microtus (meadow voles) in apple orchards. VOLID contains 10 ppm of the anticoagulant active ingredient brodifacoum.

ICI submitted the original application requesting EPA registration of VOLID in September 1981. Additional supporting data was filed with the EPA in April 1983. By letter of October 27, 1983, EPA rejected the application due to hazard to non-target species.

EPA agreed to meet with ICI on April 27 to further discuss the basis for the rejection letter. In preparation for the meeting, ICI filed additional comments with the Agency on April 3.

OBJECTIVES OF THE MEETING

1. To allow EPA to air any of their concerns which remained following their appraisal of our most recent document and to respond to them.

2. In light of 1, to reach a clear view on the long term registerability of brodifacoum as a 10 ppm bait for outdoor use.

3. To demonstrate to EPA that ICI being a responsible company have evaluated the potential hazards of this use of the product to the fullest extent possible given the constraints of limited use under EUP's and the current 'state of the art'.

4. Following 3, to suggest to EPA that the only realistic way forward is for them to grant ICI a conditional registration, i.e., a registration contingent upon a monitoring of the non-target effects of the compound during extensive use over a protracted period of time.

MEETING

ICI (JW) opened the meeting with a summary of the development of 'VOLID' in the USA and brought everyone up to date with the reasons for the meeting.

Points stressed in this summary included:

1. The limited area over which the product will be used (0.45% of all cultivated land in the USA).

2. The limited amount of active ingredient which will be used even at the year of maximum sales.

3. We have produced a specific formulation for this market which has reduced both primary and secondary hazard.

4. Toxicity measurements from laboratory tests have to be taken in context of the real in use exposure. In practice, primary hazard is restricted to a limited range of birds and mammals.

5. Laboratory studies have indicated a potential for hazard in predatory birds which subsist largely on the target species. However, laboratory studies are of limited value and there was a need for a field study. The protocols for the field study (Hegdal, radiotelemetry) were developed with EPA who even visited the site during the course of the work. EPA had full opportunity to comment on this study and, from previous experience with radiotelemetry (1080, strychnine etc.), were aware of the objectives and potential limitations of such an exercise.

   It was stated that a prime objective of the ICI team was to reach a clear view of the registerability of brodifacoum in this outlet.

The floor was then given over to EPA to respond on areas which were still of concern to them following perusal of ICI's response to their review of the original submission.

Primary Hazard

A number of issues were raised by EPA, including:

1. Can ICI substantiate its claim that the 10 ppm pellet is safer in respect of primary hazard than the 50 ppm product. (Answer - Trials with 50 ppm pellets were terminated and EPA informed when a number of pheasant deaths were recorded. Subsequent trials with the 'VOLID' (10 ppm) pellet have not caused similar problems. Use of 'TALON' (50 ppm) pellets obviously resulted in 'overkill' of voles.)

2. EPA - "Assuming 110 voles per acre and that 50 pellets are required to kill a vole, the indicated rate is 5,500 pellets per acre but the proposed use rate is equivalent to 190,800 pellets per acre." (Answer - 100% efficacy is unobtainable; voles are not evenly distributed; individual voles can consume much more than a lethal dose.)

3. EPA questioned the length of time taken for the pellets to decompose. (Answer - Due to the high efficacy of brodifacoum pellet, it is not necessary to produce the durable formulation needed for other rodenticides. Due to the high degree of palatability of 'VOLID' to the target species and the speed with which the pellets break down in precipitation, most of the pellets will disappear within a short period of time.)

The trial in which Russ Farringer had found intact 'VOLID' pellets 3 weeks after application had been treated with an excessively high rate of 45.9 kg/ha.

Following this series of questions, Clayton Bushong asked about the hazard of brodifacoum relative to other available rodenticides. He accepted Paul Hegdal's view that, like other materials used, brodifacoum did show some degree of hazard; but in terms of primary hazard, this was probably acceptable.

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Residues

In their review, EPA questioned the validity of the residue data (ABC Labs) supplied in the original petition and raised the question again during the meeting. EPA also concluded that the live owls containing residues were 'destined to die'.

The ICI team therefore responded as follows:

1. Several criteria were used in the telemetry study to establish the cause of death. As it happened, removal of the residues data would not alter the conclusions of that study.

2. The pharmacokinetic properties of brodifacoum mean that the residue in animals taken by itself can never be used in a diagnostic sense.

3. Since the original submission, the 'state of the art' has improved and much lower limits of determination can now be achieved.

4. The average time to death of screech owls was 20-24 days in the study. The majority of birds surviving this period are likely to survive in the long term.

Telemetry

EPA accepted the three tiered approach to hazard evaluation:

1. Is there a hazard to individuals?
2. What percent of the population is affected?
3. What are the long term effects on the population?

and that the telemetry study could, and was only intended to relate to 1. They said we had shown a significant hazard on an individual basis but needed more data to address 2. and 3.

EPA asked Paul Hegdal directly - "Is mortality too high to be acceptable." PH replied that the mortality seen in the telemetry study indicated the need to do further monitoring and in particular, a population study.

Both Paul Hegdal and Bruce Calvin made a plea that the study should be sufficiently extensive to examine population effects under conditions of typical use.

By mutual consent, the computer model was dropped from the discussion since it appeared to be creating enormous problems without providing the basis for a way forward.

Conditional Registration

ICI introduced the concept of a conditional registration whereby registration would be granted on the proviso that the effects on wildlife, and particularly screech owls, are monitored according to protocols agreed and developed with EPA.

In response to questioning, ICI stated that monitoring would be conducted for as long as necessary and it was envisaged that this would take at least 3 years. ICI also said that the product would be immediately withdrawn if the results of the monitoring showed the hazard to wildlife to be unacceptable.

It was agreed by EPA that a conditional registration was feasible but that this would be dependent upon acceptance by EPA of the monitoring proposals made by ICI and a satisfactory review by OES. The need for a special review prior to conditional registration would be assessed on the same ground.

EPA suggested the alternative of development via further EUP's, but the need for a study following extensive commercial use was stressed by ICI.

ICI agreed to submit a proposal for monitoring as quickly as possible for EPA consideration and also to submit a revised VOLID label for OES review that:

1. Restricted use of VOLID to certified applicators,
2. Restricted use in apple orchards only,
3. Restricted use to limited number of states, and
4. Restricted applications to 15 pounds of bait per acre per season.

ICI stressed the importance of a registration decision by August 1984 in order to treat orchards during the 1984 use season.

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112701
SHAUGHNESSEY NO.

23
REVIEW NO.

EE BRANCH REVIEW

Date: IN 4-11-84 OUT 5-4-84

FILE OR REG. NO. 10182-LI

PETITION OR EXP. PERMIT NO.

DATE OF SUBMISSION 4-5-84

DATE RECEIVED BY HED 4-10-84

RD REQUESTED COMPLETION DATE 6-20-84

EEB ESTIMATED COMPLETION DATE 6-16-84

RD ACTION CODE TYPE OF REVIEW 171-Old Chemical

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

DATA ACCESSION NO(S). 252894

PRODUCT MANAGER NO. W. Miller (16)

PRODUCT NAME(S) Brodifacoum (Volid)

COMPANY NAME ICI Americas Inc.

SUBMISSION PURPOSE Submission of data and rebuttal for meeting

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	
112701	Brodifacoum-Volid	10 ppm

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Minutes of Meeting with ICI Americas

Date: April 27, 1984, 9 am - 12 noon

Subject: Can Volid™ Rodenticide (EPA File Symbol 10182-LI) be conditionally registered with the data that has been generated to date?

Participants:

ICI Americas

Mr. James Wagner
Dr. Godfrey Teal
Dr. Christopher G.J. Richards
Mr. Dale Kaukeinen
Mr. Robert E. Hawk

USFWS/Denver Research Center

Mr. Paul Hegdal

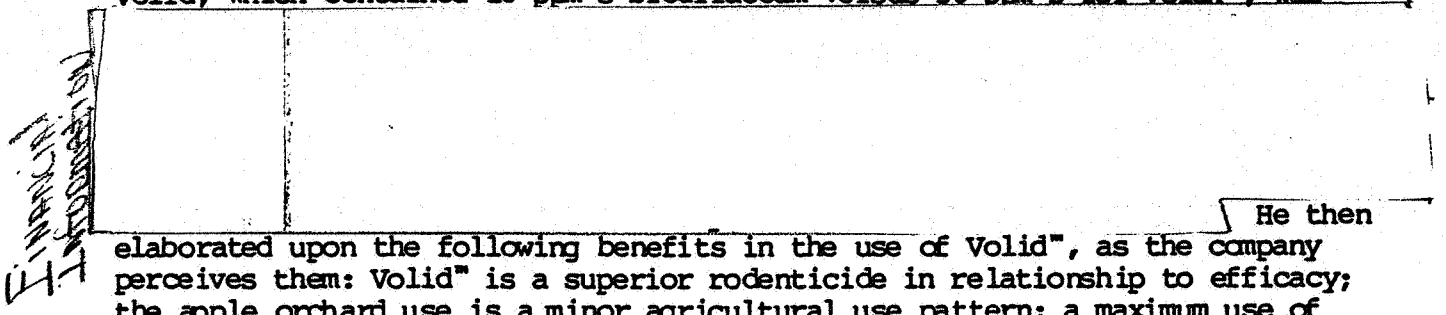
Bowling Green State University, Ohio

Mr. Bruce Colvin

EPA

Mr. William Miller	Product Manager, Team 16/RD
Mr. Daniel Peacock	Member of Team 16/RD
Mr. Rick Loranger	RCB/HED
Dr. William Butler	TB/HED
Mr. Steve Palmateer	IRB/RD
Mr. Clayton Bushong	EEB/HED
Mr. Raymond W. Matheny	EEB/HED
Mr. Edward Fite	EEB/HED
Mr. Russel T. Farringer	EEB/HED

Mr. Wagner lead off the meeting with a past submission record for Volid™ (Volak™). Volak™ was the original formulation for orchard use. ICI, after experiencing nontarget mortality through primary poisoning, decided to re-formulate the product. This re-formulated product was designated as Volid™. Volid, which contained 10 ppm's brodifacoum versus 50 ppm's for Volak™, was



He then elaborated upon the following benefits in the use of Volid™, as the company perceives them: Volid™ is a superior rodenticide in relationship to efficacy; the apple orchard use is a minor agricultural use pattern; a maximum use of 30 pounds of active ingredient per year would be required to formulate their entire market; the active ingredient of the pellet has been lowered from 50 to 10 ppm; they have reduced the pellets attractiveness to birds by changing size and color of the pellets; the product would be classified "restricted", thus only certified applicators would apply the product; they reduced the number of applications from two to one during the dormant apple season, and reduced the total amount of product applied from 20 pounds to 15 pounds.

Dr. William Butler presented Toxicology Branch views on the technical and formulated products. He presented four preliminary data request, determined by his reviewer, to be necessary for the technical and formulated products Additionally, his reviewer had determined that the label for Talon® and possibly the other formulations should bear the signal word "Danger" due to the acute mammal toxicity level. His reviewer was uncertain as to the amount of active ingredient in each trade name product.

Mr. Wagner responded that ICI was not prepared to discuss these points and would wait for the Toxicology Branch review before commenting.

EEB began a discussion on ICI's opening comments. We began by challenging the statement that the change from the Volak™ formulation to the present Volid™ formulation "significantly reduced primary hazards to nontarget organisms". EEB questioned the registrant as to the base line data they had for Volak. They explained that they terminated their EUP with Volak early due to primary poisoning of nontargets. Then, through considerable discussion, we finally made the point that there was no comparative data on nontarget mortality between the two products to indicate that Volid was significantly less hazardous than Volak. Further, the registrant admits that "some" (non-quantifiable) nontarget mortality through primary poisoning would occur. If fact, under limited searches of orchards treated with Volid, primary poisoning was reported with birds and rabbits. Mr. Bushong asked Mr. Hegdal if other registered rodenticides had primary poisoning associated with their use? Mr. Hegdal replied "yes". Mr. Fite and myself tried to get a quantification or comparison of

primary toxicity to nontarget species for the various registered products and Volid from Mr. Hegdal. He replied that he did not have the necessary data for comparison. Further questioning indicated that he could not determine if Volid produced a negative population effect due to primary toxicity. From these points we went into a discussion of the field study. This study was originally designed to determine if a secondary poisoning hazard existed when Volid was applied in orchards. Throughout the discussion numerous points were made in regards to potential hazard. The field study indicates "high" individual mortality to screech owls through secondary hazard. This hazard exists at a time of year when adult owls are associated with the orchards. These adult owls appear to represent the core breeding population for the following year. This EUP application site of Volid does not represent the amount of treated area under operational control. In fact, the treated area under the EUP is probably considerably less than if the area was treated under operational control (e.g. registered product use). Again, Mr. Hegdal was asked if the data could be used for population predictions. He replied that the data did not lend itself to population affect and that a study over several years might be able to answer the population affect question. Due to the primary and secondary toxicity of brodifacoum, EEB proposes to request a population monitoring study. The registrant had perceived that further data would be necessary for the registration of this product and had proposed a population study with conditional registration. ICI did not submit nor did they have sufficient detailed information at the meeting to address the population monitoring requirement. There was a general discussion on size of study area, control plots, amount of acreage to be treated and other parameters. No conclusion was reached, however. EEB indicated that if this is the approach they wanted to pursue, we would review any protocols for such a monitoring study.

Additional comments of the meeting:

The following studies were previously required and are considered outstanding data gaps:

1) Acute dietary LC_{50} test to canids, felids and mustelids (protocol should be submitted before initiation).

2) Secondary dietary toxicity test to canids, felids, and mustelids.

Additional data requests in light of past and present data requests for brodifacoum:

1) Avian reproduction study.

2) Persistence data on pellets and technical under field use conditions.

3) Description of the new analytical technique which allows determination to 0.002 ppm.

Mr. Loranger (RCB) indicated to ICI that he was reviewing their analytical methodology in response to a request from EEB. He plans to forward his review to EEB and RD upon completion.

ICI is willing to throw out their computer model as a misconceived idea. EEB agreed that this was in the best interest to both parties as the model was overly simplistic and based on unsubstantiated assumptions.

Mr. Wagner said that within a week they would submit a revised label for conditional registration. He asked about the formal consultation with OES and was informed that, after receiving the request from us, OES has 90 days in which to reply with a biological opinion. ICI wants field use of this product later this year, if at all possible.

ICI stated that they would submit their minutes of the meeting as a summary of both parties synopsis of data Accession Number 252894.

At this point and time EEB feels that there are ~~fewer~~ four options regarding Volid for outdoor agricultural use patterns:

1) Cease seeking registration for brodifacoum products used in outdoor agricultural uses.

   - ICI is not ready to quit seeking a conditional registration.

2) Under an experimental use permit, conduct a monitoring study with an appropriate nontarget species to determine population effects.

   - ICI representatives at the meeting indicated that their upper management would not accept this proposal.

3) Apply for conditional registration with a monitoring study as a condition for full registration.

   - EEB agree to consider such a proposal. We stated that we would be required to consult with OES/FWS regarding this use. We emphasized that the monitoring study would have to be well designed and scientifically sound.

4) Refer Volid to Special Review

   - At this point and time special review appears to be a viable option. Our conclusion at this point is that this chemical exceeds criteria established by EPA for determining unreasonable adverse effects. The company (ICI) has not provided data which demonstrates that this product (brodifacoum) can be used without significantly impacting nontarget populations. Data submitted thus far, while scant, implies that it could adversely affect nontarget populations.

The company has indicated that, in the absence of a conditional registration, further testing would not be conducted. Available data shows that this product presents both a primary and secondary hazard to mammalian and avian species. The completed field study raises concerns about population impacts.

Finally, in the absence of further data, EEB cannot fully assess the severity of this products' potential impacts to nontarget populations.

RD stated that these minutes (Registrants and EEB's) would be sufficient to complete this review.

Russel T. Farringer, III
Wildlife Biologist
EEB/HED

Date. 5/4/84

Raymond W. Matheny
Head, Review Section 1
EEB/HED

Date: 5/4/84

Ed Fite
Wildlife Biologist
EEB/HED

Date: 5/4/84

Norm Cook
Head, Review Section 2
EEB/HED

5.4.84

Date:

Clayton Bushong, Chief
Ecological Effects Branch/HED

5/4/84

Date:

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