

US EPA ARCHIVE DOCUMENT

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

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™.

Handwritten notes on the left margin: "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."



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. In 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<sub>50</sub> 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.
- 4

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.

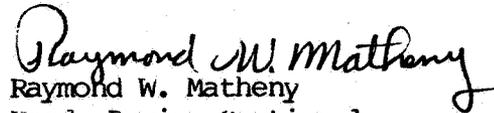
The company has indicated that, in the absence of a conditional registration, further testing would not be conducted. Available data shows that this product presents both a primary and secondary hazard to mammalian and avian species. The completed field study raises concerns about population impacts.

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

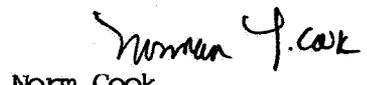
Date: 5/4/84

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

Date: 5/4/84

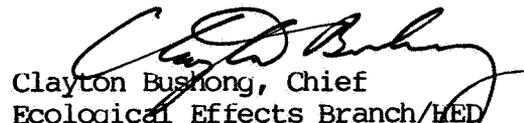
  
Ed Fite  
Wildlife Biologist  
EEB/HED

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: