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TYPE PRODUCT(S) Insecticide, Nematicide

DATA ACCESSION NO(S)

PRODUCT MANAGER, NO. J. Ellenberger (50)

PRODUCT NAME(S) Mocap EC

COMPANY NAME Rhone Poulenc Co.

SUBMISSION PURPOSE Submission of Rationale and Protocol For Testing Mocap EC in Potatoes Rather than pineapples (TFS Level 1)

SHAUGHNESSEY NO.	CHEMICAL	% A.I.

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM June 9, 1989

SUBJECT: Review of Avian Field Study Protocol for Mocap Use on Potatoes

FROM: James W. Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division H7507C

TO: Jay Ellenberger
Insecticide/Rodenticide Branch
Registration Division H7505C

The registrant, Rhone Poulenc, has requested that EEB consider two things:

1. They want to change the crop site of the avian field study for Mocap from Pineapples to Potatoes; and

2. They have submitted a protocol for review (mocap in potatoes).

Changing Sites

The field study was requested for pineapples because of the high use rate (40 lbs ai/acre), since this would represent the highest hazard situation. The registrant has proposed to change the pineapple labeled used for pineapples by reducing the use rate (i.e. dropping the 40 lbs ai/acre use on the Mocap 10G label) and limiting the 12 lbs ai/acre on the Mocap EC label to application only by drip irrigation either underground or under plastic. Thus they are proposing to perform the study with potatoes, where Mocap is also used at 12 lbs ai/acre.

EEB Response: Provided the label for the pineapple use specifically states that application is only through drip irrigation that is either under plastic or underground, and provided that the 40 lbs ai/acre use of the 10G is dropped, EEB

concurs with not conducting the study on pineapples. However, the registrant should fully justify selecting potatoes rather than other use sites as corn. It is insufficient to base the crop selection on use rate alone, although this is an important concern. One major concern is that if hazard is indicated for potatoes, how would that apply to corn and other crops which have lower use rates. Note that in the Registration Standard for Ethoprop, it was concluded that use rates as low as 2 lbs ai/acre would be acutely hazardous to birds.

Protocol

The EEB has completed reviewing the protocol to perform the avian field study on potatoes. Based on that review, we believe it is unlikely that the study, as designed, will be sufficient to negate the presumed hazard to birds. See the attached Field Study Protocol Review.

041101
Shaughnessey No

FIELD STUDY PROTOCOL REVIEW

1. Pesticide Name: Mocap, Ethoprop

2. Study Type: Avian Acute Field Study (Level I)

3. Pesticide Use: Nematicide-insecticide on potatoes

4. Study Purpose: The purpose of the study is to rebut the hazard EEB presumes exists when Mocap EC is used. Originally, the study was required for the turf use because it represented a high risk to birds. Then the registrant voluntarily cancelled the hazardous turf use. Then EEB required the same study on pineapples, as it represented the next highest hazard to birds, primarily because of the high use rate (i.e. 40 lbs ai/acre, broadcast). The registrant has since eliminated that use rate and has limited all treatment of pineapple to drip irrigation application. All irrigation lines will be covered by plastic or at least 4 inches of soil to reduce exposure to birds. Therefore, the registrant proposes to conduct the study with potatoes at 12 lbs ai/acre to rebut presumed hazard presented by EEB.

The protocol indicates that the objective is to determine if Mocap EC is likely to cause acute mortality among avian species.

5. Site Description:

Specific sites were not presented. However, the protocol did define the desired characteristics on which site selection will be based. The sites will be chosen from the eastern U.S. potato growing states (Virginia, Deleware and New Jersey were listed as examples). Criteria were listed:

A. A geographic area having a history of potato production;

B. Fields having sufficient areas of avian habitat and relatively high populations of a variety of avian species;

C. Negligible potential for presence of endangered or threatened species; and

D. Cooperative landowners.

6. Exposure Regime:

One broadcast application of Mocap EC will be made approximately one week before planting at a rate of 2 gal/acre (12

4

lbs ai/acre). The spray will be incorporated to 2 to 4 inches immediately after application.

The protocol does not preclude use of other pesticides. Rather if used, they will be selected to minimize hazards to avian species.

7. Study Methods:

Experimental Design and Data Analysis

The protocol indicates that the study will follow the recommendations for a screening study described in the EPA Guidance Document for Conducting Terrestrial Field Studies by Fite, et al., (1988) (GD).

Eight replicate potato fields will be selected for treatment, with an additional 4 fields selected as controls. The control fields will be monitored for comparative information on avian mortality and avian use of agricultural fields. The number of fields was based on recommendations in the GD.

Avian censusing will be done using "point counts" as described by Ramsey and Scott, 1979. A minimum of 4 sampling points will be located along the field perimeter of each test replicate. Each point will be marked with a permanent stake.

Carcass searches will be conducted on 3.5 acres at each field. The protocol indicates that, since the fields are "bare," the effective search width may be more than 6 meters. Transects on field perimeters will be larger than those on field interiors or adjacent habitats. Separate searches will be made of adjacent habitat. Search efficiency and carcass removal trials will be done simultaneously with each daily carcass search for the first four days after each application. This will be done by placing marked carcasses each day within search transects.

Residue monitoring will be done at 4 of the 8 test plots. Materials sampled include soil, water, plant parts, and invertebrates. All avian carcasses collected will be analyzed, providing carcass conditions permit.

Weather data will be obtained from the nearest NOAA weather station.

8. Protocol Evaluation:

Objectives:

The stated objective to determine if Mocap EC is likely to cause acute mortality is not appropriate since it does not clearly state what "hypothesis" is to be tested.

The reason the study is being conducted is because EEB has made a presumption of hazard. It is the objective of the study to show that this presumed hazard does not occur, i.e. to negate the hazard. If that is the objective of this study, it should be stated in the "study objective," and the entire protocol designed around that hypothesis.

Crop selection:

The registrant has proposed to test the use of ethoprop on potatoes because it represents the next highest use rate. However, the EEB requires that the registrant give further consideration to what crop(s) is(are) selected for testing and provide a rationale including more than use rate as the justification.

Field selection:

The eastern potato growing states may well represent higher avian exposure than western or midwestern potato growing areas, however, the protocol does not address this issue. The rationale for region selection must be included.

The second criteria for site selection indicates that fields must have a sufficient area of avian habitat and a relatively high population of a variety of avian species. However, the protocol does not qualify this description by explaining what minimum standards will be accepted for a site to be acceptable. This is critical in determining whether the treated fields are big enough to result in realistic exposure and to provide the area needed to be searched to detect avian mortality should it occur.

Application

Application is acceptable, however, the registrant should be cautioned against using other pesticides. Since this is a measure of effects of Mocap, EEB will attribute all mortality and impacts to Mocap, regardless of what other pesticides are used.

Experimental Design

The protocol indicates, initially, that the design follows the GD, thus using 8[1] fields. However, it then digresses from the document by indicating that a specific proportion of a population, representing mortality observed during a Level I field study (referring to the 20% suggested in the GD) implies greater precision than field techniques can supply. This reason is then used, implicitly, to justify selecting an arbitrary area (3.5 acres) to be searched for carcasses rather than calculating the area necessary using the N=DREAP[2] formula. From review of past field studies, EEB has found that 3.5 acres is rarely enough area to ensure a high probability of detecting mortality to a small portion of an avian population (e.g. around 20%). While EEB appreciates the fact that many times field techniques lack precision, for example, to exactly determine population density or to indicate that <u>exactly</u> 20% mortality occurred. It is not a reason to reduce the effort to detect mortality to below what even crude estimates dictate. When precision is a problem, the shift must be to err on the side of safety and search a greater area (in this case), rather than less area. If more acreage is searched than would be dictated using the N=DREAP formula, the registrant may be in a position to explain that the number of dead birds found actually represents less than a certain proportion of the population. If less than this minimum area is searched, and no mortality is observed, EEB would be forced to conclude that the study was insufficient to detect mortality and therefore does not fulfill the requirement.

The protocol indicates that a listing of avian casualties will be used in conjunction with residue analysis results to determine if effects occurred in the field. It further indicates that results from avian censuses will be used to aid in interpretation of casualty data. The protocol does not indicate exactly how these various pieces of information will be used to indicate whether effects have occurred.

The registrant may, according to the GD, develop their own "experimental design." However, when they digress from the GD, they must thoroughly explain and justify the alternate design and the statistics that will be used. All assertions must be justified; including number of study plots, avian census techniques

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[1] According to the GD, 8 sites may be used if the fields can be shown to represent maximum hazard to birds. If this is not shown, 14 fields must be tested.

[2] Where N=Number of carcasses found
D=Density of animals per acre
R=Proportion of carcasses remaining
E=Search efficiency
A=Acres searched
P=Proportion of population killed

7

and use of census data, amount of area involved in carcass searching, number of residue sampling stations, and types of environmental material sampled. The protocol must also state how the data will be used to test a hypothesis, and how that hypothesis relates to negating EEB's presumed hazard.

Methods:

Avian Censusing: Several assumptions/assertions were made, that were not justified. The basis for such things as the number of census points, the length of time at each point and the location of each point, should be provided.

Carcass Searching: Why was 3.5 acres selected?

The "effective" search width, 6 meters, is wider than would be recommended, even with a plowed field. It is unlikely that adjacent habitat with "high wildlife value" can be searched effectively with a search width of even close to 6 meters. In the past, EEB has suggested a transect width of 12 feet for relatively bare soil. Habitat with high wildlife value should be searched with transect widths of much less than 12 feet. Transect search width must be justified.

The EEB agrees with the method of determining search efficiency and carcass removal. However, it is recommended that the specific numbers of carcasses not be specified in the protocol, so the number will be unknown to the biologists conducting the carcass searches. The method of determining number of carcasses used must be justified.

The registrant must justify strategy for handling and interpreting the number and condition of incapacitated birds found during the study.

Residue Monitoring: Since the residue monitoring will be used in conjunction with carcass search results and avian census data to determine if effects occurred, there should be further explanation of why the residue monitoring portion was designed the way it was. The hypothesis to be tested, and statistics to support a test of that hypothesis, should be the basis for all study design, including the residue monitoring effort.

Weather Data: Weather data should be gathered from each test plot. The potential variation between the NOAA station and the test plot could be significant, especially with regards to rainfall.

Reported Information:

Recognizing that this protocol is not acceptable, the following is provided if the registrant chooses to describe

specific fields in the protocol and also to emphasize the importance of site description. In addition to the detailed description of each test field, the following must also be provided.

A. Original maps (preferably USGS topography maps), not photocopies, of each test site. Maps must clearly show topography, treated area, sampling/census points, carcass search areas and all adjacent habitat. Carcass search areas and residue monitoring sampling locations must also be identified.

B. A regional "to scale" map showing the treated fields in proximity to each other.

C. A thorough description of adjacent habitat including taxonomy and density, with photographs.

D. Original (not photocopies) of photographs taken of each test plot showing the appearance <u>at</u> the time of the study. Maps must indicate what the photographs show.

9. Suggested Modifications:

Provide a hypothesis to be tested, then design a study based on the statistics necessary to test that hypothesis.

10. Conclusions: Based on what was provided in this protocol, the EEB believes it is unlikely that this study could negate the presumed hazard.