6/25/87

Shaughnessy No.: 128850

Date Out of EAB: JUN 8 1987

To: Richard Mountfort
Product Manager 23
Registration Division (TS-767)

From: Therese M. Dougherty, Chief
Review Section #1
Exposure Assessment Branch
Hazard Evaluation Division (TS-769)

Attached, please find the EAB review of...

Reg./File # : 8340-EUP-10

Chemical Name: HOE-39866

Type Product : Herbicide

Product Name : IGNITE

Company Name : Hoechst-Roussel

Purpose : Review of Field Crop Rotation Protocols.

Date Received: 5/06/87

Action Code(s): 711

Date Completed: 6/8/87

EAB #(s) : 70606

Days: 1.0

Deferrals to: ____ Ecological Effects Branch

____ Residue Chemistry Branch

____ Toxicology Branch

Monitoring study requested by EAB: ☐

Monitering study voluntarily conducted by registrant: ☐

1.a CHEMICAL: HOE-39866. Ignite™

1.b Physical Properties: Not included in this submission, see earlier reviews.

2. TEST MATERIAL: N/A

3. STUDY/ACTION TYPE: Review Two Field Crop Rotation Protocols.

4. STUDY IDENTIFICATION: See 3, above.

5. REVIEWED BY:

Akiva D. Abramovitch, Ph.D.
Chemist
Environmental Chemistry Review Section 1/EAB/HED/OPP

Date: JUN 8 1987

6. APPROVED BY:

Therese M. Dougherty, Chief
Environmental Chemistry Review Section 1/EAB/HED/OPP

Date: JUN 8 1987

7. CONCLUSIONS:

EAB cannot accept field crop rotation studies as substitutes for an acceptable confined crop rotation study. The field studies should be conducted after the completion of a confined crop rotation study which identifies the major residues in the edible and the forage portions.

EAB strongly recommends wheat and barley over sorghum (in Maryland) as a small grain crop. The current EAB consensus is that sorghum and corn are not acceptable substitutes for small grains since they are much larger plants, require more moisture and therefore affect differently the movement of pesticides (see EAB memorandum of April 24, 1987 from Holst to NACA). EAB would consider sorghum if detailed studies indicate comparable accumulation to those in wheat and barley.

One site is in Maryland (sandy loam soil) and leaf lettuce, radishes and sorghum will be planted 90 days after treatment with 1.8 lb a.i./acre (maximum label application rate of 1.5 lb a.i./acre). The 90 days crop rotation is for a double crop of soybeans and wheat and sorghum are claimed to be the typical rotating crops. EAB concurs with the above conditions except with planting sorghum.

The second site is in Illinois where a field dissipation study was previously conducted and is typical of a soybean growing site. The application rate will be 1.8 lb a.i./acre preemergence to soybeans and winter wheat will be planted 90 days after application. The leafy and root crops to be planted after 90 days were not specified.

The two submitted protocols are very similar in calling for 120% of the average monthly irrigation of the last 10 years suplimented by irrigation on the first three days of the subsequent month.

EAB concurs with taking 10 soil cores and combining it for analysis for each 3 replicates (to what depth?). Samples will be frozen until analysis is conducted and sample stability evaluated. The analytical method was referenced but should be submitted for evaluation.

EAB concurs with superimposing a field dissipation study at the crop rotation site and under identical conditions as stated in part 1 of the letter from Dorr to Mountfort (see attachment).

The protocols can be considered generally acceptable but detailed experimental conditions are needed for complete evaluation.

8. RECOMMENDATIONS:

For the EUP, an acceptable confined crop rotation study is needed using wheat or barley for small grain and leafy and root crop. For registration, field crop rotation data are needed. For the evaluation of the protocols see recommendations in 7, above.

9. BACKGROUND:

A. Introduction: See EAB review of July 30, 1986.

B. Directions for Use: See label in the EAB July 30, 1986 review.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES: N/A

11. COMPLETION OF ONE LINER: N/A

12. CBI APPENDIX: None.

~~4/13/87~~ 5/6/87

REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information — Does Not Contain National Security Information (E.O. 12065)

5/6/87
36149 Hoe

1. CHEMICAL NAME (New Chemical)
Monoammonium 2 Amino-4-(hydroxymethylphosphinyl) butanoate (HOE-39866)

2. IDENTIFYING NUMBER	3. ACTION CODE	4. ACCESSION NUMBER	TO BE COMPLETED BY PM
8340-EUP-10	711	Request for Protocol Review of Field Crop Rotation Studies.	5. RECORD NUMBER 195.323
			6. REFERENCE NUMBER 2
			7. DATE RECEIVED (EPA) 4/10/87
			8. STATUTORY DUE DATE
			9. PRODUCT MANAGER (PM) Mountfort/Ikeda
			10. PM TEAM NUMBER 23

14. CHECK IF APPLICABLE

- ☐ Public Health/Quarantine
- ☐ Minor Use
- ☐ Substitute Chemical
- ☐ Part of IPM
- ☒ Seasonal Concern
- ☒ Review Requires Less Than 4 Hours.?

TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS 5-6-87

12. PRIORITY NUMBER 36

13. PROJECTED RETURN DATE 5-21-87

15. INSTRUCTIONS TO REVIEWER

A. HED
- ☐ Total Assessment - 3(c)(5)
- ☐ Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977.

B. SPRD (Send Copy of Form to SPRD PM)
- ☐ Chemical Undergoing Active RPAR Review
- ☐ Chemical Undergoing Active Registration Standards Review

C. ☐ BFSD
D. ☐ TSS/RD
E. ☒ Other

F. INSTRUCTIONS

Request expedited protocol review of field crop rotation studies to be conducted in Illinois & Maryland. (Guidelines reference 165-2) American Hoechst is requesting EAB review within 30 days (Please refer to attached letter dated 4/10/87. Also attached letter dated 4/30/87.

16. RELATED ACTIONS
4G3156 Refer to Therese M. Dougherty's review dated July 30, 1986.

17. 3(c)(1)(D)
- ☐ Use Any or All Available Information
- ☐ Use Only Attached Data
- ☐ Use Only the Attached Data for Formulation and Any or All Available Information on the Technical or Manufacturing Chemical.

18. REVIEWS SENT TO
- ☐ TB
- ☐ EEB
- ☐ EF
- ☐ PL
- ☐ RCB
- ☒ EFB
- ☐ CH
- ☐ BFSD

19.	To	TYPE OF REVIEW	NUMBER OF ACTIONS: Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED		TOXICOLOGY								
HED		ECOLOGICAL EFFECTS								
HED		RESIDUE CHEMISTRY								
HED	X	ENVIRONMENTAL FATE EAB			1					
RD/TSS		CHEMISTRY								
RD/TSS		EFFICACY								
RD/TSS		PRECAUTIONARY LABELING								
BFSD		ECONOMIC ANALYSIS								

20.	21.	22.	23.	24.
☐ Label Submitted with Application Attached	☐ Confidential Statement of Formula	☐ Representative Labels Showing Accepted Uses Attached	Date Returned to RD (to be completed by HED)	Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review. 4

EPA Form 8570-13 (Rev. 11-81) PREVIOUS EDITIONS ARE OBSOLETE.

American Hoechst Corporation
Route 202-206 North • Somerville, New Jersey 08876
Telex 833-449 • Cable Hoechstus, Somerville, N.J.
Telephone (201) 231-2000

Direct dial number: (201) 231-2028

April 10, 1987

VIA PERSONAL DELIVERY

Mr. Richard Mountfort
Product Manager (23)
Fungicide-Herbicide Branch
Registration Division (TS 767C)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Dear Mr. Mountfort:

Subject: Ignite™ Non-Selective Herbicide (HOE-39866)
EPA EUP No. 8340-EUP-10
Request for Protocol Review of Field Crop Rotation Studies

We are preparing to conduct two field crop rotation studies with Ignite Herbicide this season in Illinois and Maryland. The protocols for these studies are designed to fulfill the data requirements for field accumulation studies on rotational crops (guidelines reference 165-2), however, there have been on going refinements in these guidelines which present somewhat of a moving target to us. We would therefore like to request protocol review and approval from the Exposure Assessment Branch (EAB) before we start these studies.

Three copies of each protocol are enclosed. We would appreciate your forwarding these to the appropriate EAB section for their review and, hopefully, concurrence that the studies as described will meet current test requirements. As the soybeans will be planted in mid-May and soil sampling will begin at the same time, **we would appreciate the EAB comments on the protocols within 30 days.** We are, of course, prepared to meet with you and EAB staff to discuss these studies if desired.

5

Thank you for your assistance in this matter.

Very truly yours,

Vic Dorr/iam

Victor A. Dorr
Manager Agricultural Products
Registration & Projects Coordination

VAD/iam

vadim220

Hoechst-Roussel Agri-Vet Company
Route 202-206 North • Somerville, New Jersey 08876
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Telephone (201) 231-2000

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April 30, 1987

Mr. Richard Mountfort
Product Manager (23)
Fungicide-Herbicide Branch
Registration Division (TS 767C)
US Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Dear Mr. Mountfort:

Subject: Ignite™ Non-Selective Herbicide (HOE-39866)
EPA EUP No. 8340-EUP-10
Amplification of Request for Protocol Review of Field Crop Rotation Studies

On April 10, 1987 I wrote to you to request an Exposure Assessment Branch (EAB) review of two protocols for field crop rotation studies with Ignite Herbicide. Shortly thereafter Mr. Ikeda called and suggested that we amplify our request and specify our specific areas of concern in the study protocols and/or any known deviations from the EPA Pesticide Assessment Guidelines. We agree that this approach should be more effective in securing the appropriate commentary from the EAB than merely asking for a generalized protocol review.

The specific areas of the previously submitted Illinois and Maryland field crop rotation study protocols that we wish the EAB to address are therefore as follows:

1. In a typical rotation crop study, soil residue data are required at frequent intervals throughout the rotation crop growing stage. Typically, soil data are required at planting, as well as at the 1/4 and 1/2 maturity samplings and at the final harvest of each of the rotated crops (root crop, leafy vegetable crop and cereal crop).

These protocols propose, instead of the intensive sampling, to superimpose a soil degradation study. Sampling begins at application but also includes sampling at rotation crop planting. Subsequent soil samples approximate interim and harvest intervals. We request concurrence with this approach.

2. A typical rotational crop study calls for rotation at three time periods - emergency replant (30 days); fall rotation (120 days) and annual rotation (365 days).

   These protocols propose only one rotation - 90 days. Ignite Non-Selective Herbicide will be used on double crop soybeans. As a result, a label providing for a 90 day rotation is of major importance. The annual rotation is not a problem with Ignite, based on confined rotational crop studies.

3. Irrigation will be provided to maintain 120% of the 10 year monthly average for the area in any one given month. Any additional rainfall (via irrigation) will be made up during the first three (3) days of the subsequent month.

4. Ten (10) soil cores will be taken for each 3 replicates. Does the EAB concur with this?

5. The cereal crops selected for the trials are winter wheat for the Illinois study and sorghum for the Maryland study. These crops are typical for double crop soybeans. EAB concurrence is requested.

We will appreciate your forwarding this information to the EAB with a request for a quick turnaround. These studies must now be started in just a few more weeks so a rapid response will be most appreciated. As previously stated, we can speak directly to EAB staff by phone or meet with them to discuss these protocols if this considered desirable.

Thank you for your assistance in this matter.

Very truly yours,

Victor A. Dorr

Victor A. Dorr
Manager Agricultural Products
Registration & Projects Coordination

VAD/iam

vadim252

8340-EUP-10

PROTOCOL

FIELD ACCUMULATION STUDY ON CROPS ROTATED AFTER SOYBEANS TREATED WITH IGNITE™ NON-SELECTIVE HERBICIDE

FIFRA Pesticide Assessment Guidelines (Subdivision N - Environmental Fate)

Field Accumulation Studies on Rotational Crops

165-2

HRAV Field Trial Number: ER-87-USA-13-MD-01

RIN 5218-93

EFGWB Reviews of Glufosinate (128850)

Page____ is not included in this copy.

Pages 10 through 20 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

✓ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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

APR 24 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Dr. John F. McCarthy
Director of Scientific Affairs
National Agricultural Chemical Association
115 Fifteenth Street, N.W.
Washington, D.C. 200-5

Dear Dr. McCarthy:

In response to your letter of February 10, 1987, we have reviewed the items with respect to both content and effect on the overall policy with which we require, review, and use the results of the field dissipation and crop rotation studies. I will try to answer each of the questions giving rationales as may be available. It should be noted that the positions given here may change as new methodologies are developed and accepted and the intent of the studies change.

1. The purpose of performing any set of field studies is to determined how many factors affect the dissipation of the pesticide. Treating or irrigating only one site to force a worst case situation, does not follow the intent of the guidelines. We are trying to estimate what happens under a variety of conditions that would be normally found where labelled use directions are followed. If irrigation is normally used, several sites using irrigation should be studied. Irrigation may, however, be used to ensure average or even above-average soil moisture conditions.

2. Pan evaporation data from the site are not required. However, where that data is required, as in specific studies for modeling purposes, it must be collected from the vicinity of the study and under similar weather conditions of the study site. There is supposedly a model that can take dry bulb temperature, relative humidity, wind, and another readily available factor (possibly solar incidence?) and generate approximate pan evaporation information. These four weather conditions can be readily measured at the site.

3. Application rates for 1987 crop rotation studies need not be exaggerated above the maximum label rate. The desire for data using rates at 10 and 20 percent above the maximum primarily rests with gaining information on occasions when inter-row overlapping and end-row piling may occur. Also enhanced or exaggerated rates of application may result in the need for addtional testing or setting of a tolerance.

4. Soil samples cannot be taken only at rotational crop planting rather than at planting and harvest. We need to know whether the material dissipated in the soil as well as in the plant over the period that the plant is in the ground.

5. It will not be acceptable to only characterize soil to the maximum depth of sampling. The leaching study is of finite duration and we need to know what may have happened if the study had continued. We also know that the soil hydrology of the layers below the leaching front have a strong influence on the movement of chemical substances. Also note that we will be requiring characterization of soil and analysis for chemical constituents for up to two feet below the leaching front in order to identify any unsuspected and fast-moving chemicals.

6. The pooling of samples into one sample for analysis or characterization is unacceptable. With only one pooled sample, there is no possibility of noting any sampling errors, varability in pesticide concentration in the soil or soil water, application rate differences, variability in the chemistry or other characteristics of the soil, etc.

7. It will be unacceptable to record soil temperatures at only one depth (preferrably 2 to 4 inches). Degradation of pesticides, especially those influenced by biological means, varies with temperature. Soil temperature varies with depth, and the degree of variation changes with each soil type and region.

8. Knowledge of soil moisture-holding capacities is needed to interpret the soil metabolism studies. It is not needed just for model validation and, therefore, is still required.

9. Two three-inch residue-free zones below the last residue detected are insufficient indicators of non-leaching. We will be requiring soil sampling two feet below the last zone of detected residues in order to be certain that there are no fast-moving plumes of pesticide. (See item 5 above.)

10. Corn and sorghum are not acceptable substitutes in a crop rotation study for small grains at spring/summer planting time. Corn and sorghum are much larger plants and require more moisture than small grains and thereby have a different influence on the movement of pesticides from the surrounding rhizospere. The Agency may reconsider this issue if a detailed study has been done to show there is no difference relative to influence on the rhizospere and plant uptake.

An additional issue which we recently discussed is the use of xenon lights for photolysis studies. These lights generate considerable heat and have a wide spectrum including UV. In order to closely approximate sunlight, a cooling system and a UV filter are needed. These efforts may not be altogether successful. We would recommend that these types of studies be done in a greenhouse or other facility where natural sunlight is of sufficient duration and intensity to approximate the season of use.

I hope that this will answer some of your questions. I am sorry that there was such a long delay in getting these issues answered. If we may be of further assistance on these or other issues, do not hesitate to contact us.

Sincerely,

Robert W. Holst, Ph.D., Chief (Act.)
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)