Shaugh. No. 090501

EAB Log Out Date: MAR 20 1987

To: Bob Taylor
Product Manager
Registration Division (TS-767)

From: Carolyn K. Offutt
Chief, Environmental Processes and Guidelines Section
Exposure Assessment Branch, HED (TS-769)

Attached, please find the environmental fate review of:

Reg./File No.: 190263

Chemical: Alachlor

Type Product: Herbicide

Product Name: Lasso

Company Name: Monsanto

Submission Purposes: Review of amendments to well water protocol

Action Code: 495 EAB #(s): 70274

Date In: 2/24/87 TAIS Code: 102

Date Completed: 2/26/87 Total Reviewing Time: 1

Monitoring study requested: x

Monitoring study voluntarily: ___

Deferrals To:

_____ Ecological Effects Branch

_____ Residue Chemistry Branch

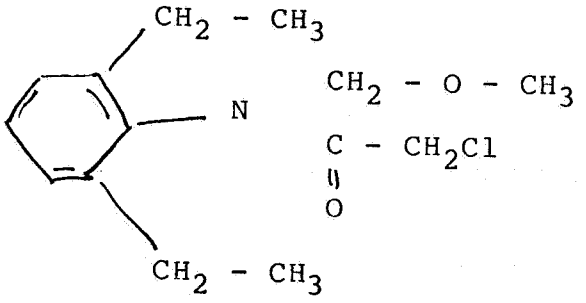
_____ Toxicology Branch

(1)

REVIEW OF AMENDMENTS TO GROUND WATER PROTOCOL

1. CHEMICAL:

Chemical name: 2-Chloro-2'6'diethyl-N-(methoxymethyl)-acetanilide
Common name: Alachlor
Trade name: Lasso
Structure:



2. TEST MATERIAL:

Not applicable

3. STUDY/ACTION TYPE:

Review of amended ground water protocol. The original protocol was submitted July 25, 1986.

4. STUDY IDENTIFICATION:

Title: February 3, 1987, letter on amendments to well water protocol, covering January 14, 1987, memorandum from Ray Whitmore, Research Triangle Institute to Larry Holder
Author: Monsanto Agricultural Products Company
700 Chesterfield Village Parkway
St. Louis, MO 63198
Submitted by: Stephen R. Muench
Registration Manager
Identifying No: 090501
Issue Date: 2/3/87
Record No: 190263

5. REVIEWED BY:

Matthew N. Lorber, Acting Team Leader
Ground Water Team/EPGS/EAB/HED
Date 3/30/87

6. APPROVED BY:

Carolyn K. Offutt, Chief
Environmental Processes and Guidelines Section/EAB/HED
Date 3/20/87

7. CONCLUSIONS:

Monsanto's 2/3/87 response to Stuart Cohen's 11/5/86 comments (attached) regarding the 7/25/86 protocol for a national monitoring survey for alachlor in wells is adequate with two exception. In the proposed schedule, Monsanto would retain the final report from RTI for 4 months prior to delivery to the EPA. This is longer than necessary and also reduces the amount of time that EPA can scrutinize the results prior to the 1990 growing season. Secondly, RTI did not adequately address Stuart's questions concerning temporal stratification (see Discussion Section).

8. RECOMMENDATIONS:

Accept the protocol and require that Monsanto begin the survey immediately. Also require an amendment to the schedule such that delivery of the final report from Monsanto to the Agency happen 32 months after EPA approval rather than 34 as suggested. As well, require that Monsanto submit RTI's final report as well as any of their own interpretation and analysis. Finally, RTI did not adequately respond to Stuart Cohen's question concerning temporal variability (see Discussion Section). They should do so, although this should not delay initiation of the survey.

9. BACKGROUND:

Stuart Cohen's 11/5/86 review of the protocol received by the Agency on 7/25/86 is attached. In this review, Stuart approves of the protocol and suggests that work begin immediately, and that his questions be answered as the survey is progressing. His review, dated 11/5/86, was still 3 months beyond the starting date of 8/15/86 proposed by Monsanto in the 7/25/86 protocol. Stuart's memorandum was addressed to the Special Review manager of alachlor, David Giamporcaro. The Branch Chief of the Special Review Branch, Janet Auerbach, responded to Monsanto on 12/15/86 outlining the Agency's position on Monsanto's protocol. A copy of her letter is attached to this review. This letter basically reiterates what Stuart said in his review. However, it does <u>not</u> say that the survey should begin, as Stuart's memorandum suggested. Rather, it implies that Monsanto respond to Stuart's concerns before beginning the survey. For this reason, the survey has not yet begun. In Monsanto's response to Janet's letter, they suggest an EPA approval date of Mar. 1. This is an appropriate date, and EPA approval should be relayed to Monsanto immediately.

A point-by-point summary of Stuart's concerns and Monsanto's response is as follows:

1) Information dissemination:
Stuart requested that Monsanto immediately send the list of sample counties once they are selected, as well as the "Dear Respondant" letter which will be sent by Monsanto to households which are candidates for well sampling. Monsanto agreed to forward both to EPA as soon as they are finalized. Stuart also required that Monsanto take the lead in informing appropriate state and county agencies on the survey prior to third stage. Monsanto agreed to do this, cautioning however that coordinating with appropriate agencies on the exact dates of interviewing and sampling is infeasible. This is also agreeable to the Agency.

2) Temporal Stratification:
Stuart requested clarification on the plan to temporally stratify sample collection based on aquifer recharge and discharge conditions. Monsanto did not adequately address Stuart's concerns (Stuart's questions on stratification were adequately described by Janet Auerbach's letter). Stuart noted that RTI proposed 6 first stage strata: a 3 * 2 matrix of high, medium, and low vulnerability, and high and low alachlor use. The temporal stratification called for sampling 3 sets of counties, with each set representing either high, medium, or low water levels (where "high water level" represents a recharge condition and "low water level" represents a "discharge" condition). Stuart then asked whether this implied that the 6 first stage strata is now increased to 18 first stage strata: 3 (vulnerability) * 2 (use) * 3 (temporal). Monsanto did not answer this question (see attached), but rather only clarified the meaning of temporal stratification. Without this clarification, it is possible that counties could be placed in the temporal sets in a purposeful manner rather than a statistically random manner. As an extreme example, counties with high vulnerability and high alachlor use could be placed in the "low" temporal category, meaning that they would be sampled during long dry periods and low water levels in the well. This would be unacceptable. Ideally, high vulnerability and use counties should appear in all three temporal strata, with perhaps a statistically valid bias towards sampling in the "high" (recharge) conditions, when residues are moving, possibly toward the wellhead. In any case, a clarification of the relationship between the temporal stratification and the other 6 first stage strata is required from Monsanto. This clarification should not hold up the survey.

3) Population of Inferential Interest:
There was a typographical error on p. 57 of the protocol, acknowledged by Monsanto.

4) Actual Sales or Use Data:
Monsanto proposes to use 1986 sales data for the first stage stratification, and every effort will be made to stratify the second stage based on use or sales on a sub-county level. This is acceptable.

5) Respondent Reliability:
RTI suggests that information gained from the National Pesticide Survey on respondent reliability be used for Monsanto's survey, and that a separate study need not be initiated. This is acceptable. Other suggestions by Monsanto on collection of well depth information and well-owner alachlor use information are also acceptable.

6) Hydrographic Information:
Monsanto's comments on their plans to obtain information on aquifers which are tapped by sampled wells are acceptable.

7) Third Stage Sample Collection:
RTI's justification of their plan to sample randomly rather than systematically within clusters is appropriate. They state that, based on experience from the National Pesticide Survey, the optimal approach (perhaps based on cost implications) would be one or two randomly selected wells per cluster with additional sample clusters to compensate for nonresponse. The precision gained from systematically sampling within clusters is minimal when only two wells are sampled per cluster. RTI states that if final sampling plans call for more than two wells sampled in a given cluster, than the households will be geographically ordered and a systematic sample of wells will be selected. This is acceptable.

Lorber

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

NOV 5 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of the July 25, 1986 Monsanto/RTI Ground-Water Monitoring Protocol

FROM: Stuart Z. Cohen, Ph.D.
Ground-Water Team Leader
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

TO: David Giamporcaro
Alachlor Project Manager
Special Review Branch
Registration Division (TS-767C)

This protocol has been reviewed by George DeBuchananne, Bert Litt, Matt Lorber, and me. It is a sound protocol which should achieve the study objectives. It is also the most sophisticated, expensive single monitoring study ever undertaken by a registrant, and I look forward to reviewing the results.

None of my comments below should be viewed as holding up implementation of the survey. Rather, they are mostly questions or suggestions. In the interest of time, I suggest that you direct Monsanto to proceed with the first stage of design (county selection), and concurrently phone their responses to me and followup the phone call with a letter summarizing the key points of our conversation.

The one concern which must be addressed is informing local governments. This should be handled as follows:

1. Once the counties are selected, the list should be sent to me. I will inform the appropriate EPA regional offices, and request that they inform the appropriate State agencies. When Monsanto sends me the list of

6

counties, they should enclose a copy of their "Dear Respondent" letter described on p. 48 of their proposal. I will also send this to our regional offices.

2. It is Monsanto's responsiblity to contact the county health department, or the appropriate drinking water agency, before they begin the third stage interviews.

My technical comments and questions follow:

- It was not clear from the discussion on pp. 22 to 24 and later pages exactly how the temporal stratification will be done. For each of the six first stage strata, will they also classify the counties according to the two or three types of water table conditions? If so, that exercise is commendable and should be challenging, especially if a requirement is imposed that some sample counties be chosen from each of the 6x2 or 6x3 possibilities. I further understand that local observation data will be used in the covariance analysis at the end of the study. Please clarify these points for me.

- On p. 3, the alachlor use area is defined as 1800 counties, and on p. 57 the population of inferential interest is defined as 1000 counties. I believe the two numbers should be the same and I believe that number should be 1800. Please clarify.

- I have not reviewed the questionnaire closely, but I request that Monsanto/RTI repeat some questions in slightly different ways within the questionnaire as an internal QC check on the respondent's reliability.

- Every effort should be made to use actual sales or use data in the second design stage.

- Regarding the hydrographic analysis which will be done on the sampled wells (p. 73), we urge caution. Neighboring wells completed in different decades and/or by different well drillers could be tapping different aquifers.

- On p. 81, I note that RTI intends to deliver monthly progress reports to Monsanto. Quarterly or semiannual reports from Monsanto to us is all that I would require.

- On the questionnaire, they ought to allow provision in the well variables section for steel and teflon casing.

- Finally, I would like to repeat Bert Litt's comment. 'It may be possible to reduce the sample variance by using systematic sampling at the third stage (p. 21). If there is an available logical basis for ordering wells within clusters, for example, arranging the wells so as to maximize the representativeness of the sample (given the size of the cluster for the area), the results should reduce the sampling variance compared to that from simply random selection.' I would like to add that it is not necessary to pursue this option if the cost implications are significant.

cc: M. Lorber
B. Litt
G. DeBuchananne

Carl G.

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

DEC 15 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Mr. Stephen R. Muench
Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167

Dear Mr. Muench:

The Agency has completed its review of the Monsanto well water protocol dated July 25, 1986. The protocol is sound and should achieve the study objectives. The Agency does require clarification of several points which are discussed below.

Once you have completed the first stage of design (county selection), forward the list of counties to the Agency. Include a copy of the letter which will be provided to household interviewers, which is described on page 48 of the protocol. EPA will inform the appropriate regional offices and request that they in turn inform the appropriate State agencies. It is Monsanto's responsibility to contact the county health department, or the appropriate drinking water agency, before beginning the third stage interviews. In addition, every effort must be made to use actual sales or use data in the second design stage.

Temporal Stratification

Some clarification is needed of this discussion on pp. 22 to 24 and later pages. Indicate whether, for each of the six first stage strata, counties will also be classified according to the 2 or 3 types of water table conditions. Please also verify that local observation data will be used in the covariance analysis at the end of the study.

Population of Inferential Interest

There is a discrepancy in the number of counties which you define as the population of inferential interest. Please refer to pages 3 and 57 of the protocol, and clarify.

9

Questionnaire Development

Monsanto and Research Triangle Institute (RTI) should repeat some questions in slightly different ways in the questionnaire as an internal quality control check on the respondent's reliability. In addition, there should be provision in the well variables section for steel and teflon casing.

Hydrogeological Analyses

In conducting the hydrographic analysis of the sample wells, you must attempt to identify the aquifers. Neighboring wells completed in different decades and/or by different well drillers could be tapping different aquifers.

Sample Selection

On pages 21-22 of the protocol, you discuss the selection of drinking water wells at the third stage of the study. It may be possible to reduce the sample variance by using systematic sampling at the third stage. If there is an available logical basis for ordering wells within clusters, for example, arranging the wells so as to maximize the representativeness of the sample (given the size of the cluster for the area), the results should reduce the sampling variance compared to that from simply random selction. This procedure need not be followed if the costs are significant, but you should indicate whether the procedure was considered, and why it was rejected.

Progress Reports

RTI plans to deliver monthly progress reports to you. The Agency will require only quarterly progress reports. These should be forwarded to the attention of the Ground Water Team in the Exposure Assessment Branch.

If you have any questions regarding this letter, please contact Mr. Matt Lorber at (703)557-3935.

Sincerely yours,

Janet Auerbach

Janet Auerbach, Chief
Special Review Branch

10