Shaugh. No. 090501

EAB Log Out Date MAR 28 1986

Init. CKO

To: W. Michael McDavitt
Review 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 review of:

Reg./File No.: _____

Chemical: Alachlor

Type Product: Herbicide

Product name: Lasso

Company name: Monsanto

Submission Purposes: Revised Proposed Protocol for Monitoring Alachlor contamination of surface water.

ZBB Code: _____

Action Code 615 ??

Data In: 3/27/86

EAB #: none

Date Completed: 3/28/86

Days

1.0

Deferrals To:

___ Ecological Effects Branch

___ Residue Chemistry Branch

_X_ Toxicology Branch

Monitoring study requested by EAB: /X/

Monitoring study voluntarily conducted by registrant: /_/

(1)

Review of Protocol for
Monitoring Alachlor Contamination of Surface Waters

CHEMICAL:

Chemical name: 2-chloro-N-(methoxymethyl)-N-(2,6-diethylphenyl) acetamide
Common name: Alachlor
Trade name: Lasso

2. TEST MATERIAL:

Not applicable

3. STUDY/ACTION TYPE:

Review of protocol for monitoring alachlor contamination of surface waters.

4. STUDY IDENTIFICATION:

Title: Protocol for a Study to Determine Alachlor Concentrations in Drinking Water Derived from Surface Water Sources, 1986 Use Season
Author: Andrew J. Klein
Draft Protocol No: 86-35-R-2
Submitted by: Monsanto Agricultural Company with a letter from Lyle L. Gingerich to Mr. Robert J. Taylor, dated March 25, 1986 with the attached protocol.
Issue Date: March 24, 1986
Accession No: None

5. REVIEWED BY:

Linda L. Kutney, Chemist Linda L Kutney Date 3/28/86
Environmental Processes and Guidelines Section/EAB/HED

6. APPROVED BY:

Carolyn K. Offutt, Chief Carolyn K Offutt Date 3/28/86
Environmental Processes and Guidelines Section/EAB/HED

7. CONCLUSIONS:

The proposed protocol is acceptable with the caveats detailed below.

8. RECOMMENDATIONS:

The detailed comments on and caveats to the protocol should be given to Monsanto. The company should be requested to promptly modify the protocol to address these comments and caveats, and to submit a signed, original of the revised protocol to the Agency as soon as possible.

9. Background

The Registration Standard on Alachlor issued in November 1984 required Monsanto to conduct monitoring of surface and ground water for alachlor contamination. Monsanto began surface water monitoring in 1985 without having an approved protocol. A detailed protocol was submitted in May 1985 after sampling was under way. This review is of the proposed protocol submitted on March 25, 1986, for sampling projected to begin on April 1, 1986.

10. Discussion

(a) Objectives

The following objectives are listed on page 2 of the protocol and on page 1 of the analytical protocol #86-35-R-2A included with the March 25, 1986, letter:

(A) To determine the concentrations of alachlor in finished drinking water derived from surface water sources in areas where Lasso is used.

(B) To determine an annualized mean concentration of alachlor in drinking water derived from surface water sources in areas where Lasso is used.

(C) To determine seasonal fluctuations of alachlor concentrations in surface water.

(D) To identify soil type/usage combinations, if any, where annualized mean concentrations of alachlor in drinking water are of toxicological concern. For each soil-usage combination from which direct sampling is to occur, accuracy of the mean AMC will be no greater than 0.2 ppb. The accuracy of combinations not directly sampled will naturally depend upon the validity of any extrapolation process but should be similar to those of sampled cells.

(E) To provide data for calibration/validation of surface runoff models for pesticides. Runoff models may include, but may not be limited to hydrologic, geologic, meteorologic, soil, and other characteristics which may lead to concentrations of alachlor in drinking water which are of toxicological concern.

Our previous review of the Alachlor protocol (Carolyn Offutt, March 20, 1986) stated that "objective 4 should be expanded to include identifying hydrologic, geologic, meteorologic, soil, and other characteristics which may lead to concentrations of alachlor in drinking water of toxicological concern." We continue to request that this information be added to objective D, instead of being added to objective E, so that objective D reflects the intent to subsequently analyze the monitoring data to determine other factors which may lead to alachlor contamination of drinking water.

In addition, objective 4 should be revised to state that "the accuracy of the mean AMC will be within 0.2 ppb" (or whatever numerical value is appropriate) instead of "the accuracy of the mean AMC will be no greater than 0.2 ppb."

The company should include in its protocol the level of confidence that soil type/usage combinations and the monitoring results sampled apply to areas in the United States not sampled.

We agree with the objectives, provided objective D is clarified as outlined in the previous paragraphs.

(b) Sampling Facilities

The community water supplies to be sampled should be in areas of intensive alachlor use. The protocol should state that the 28 CWS to be sampled will be evenly distributed between four alachor use/soil type groups. The criteria for inclusion in these four groups should be given explicitly in the protocol, namely:

Group 1	High Alachlor Use/High Soil Type
Group 2	Low Alachlor Use/High Soil Type
Group 3	High Alachlor Use/Low Soil Type
Group 4	Low Alachlor Use/Low Soil Type

In addition to this, Monsanto may wish to refer to Section 12 of the Alachlor Protocols, Scope and Methods.

(c) Starting Date

The new April 1, 1986, starting date is acceptable to the Agency.

(d) Proposed Completion Date

In our previous review (Carolyn Offutt, March 20, 1986), we stated that "the proposed completion date for the analyses of March 1987 probably could be earlier because sampling may not continue throughout the year and could be completed in late fall. Therefore the final report could be completed earlier."

The proposed completion date for the analyses is still March 1987. The company should also specify whether an interim report and interim analytical data will be given to the Agency, what that report will contain, and when that information will be submitted.

(e) Scope and Methods/Experimental Design

The March 20, 1986, review of the Alachlor protocol said that there must be an explicit and detailed explanation in

one place in the protocol on how the target population of 450 community water supplies (CWS) was selected. The revised section (e) is acceptable, noting the following limitations:

1. The county use data was converted to hydrologic unit without regard to the proportion of the hydrologic unit represented by each county.

2. The use by hydrologic unit was determined without regard to the percent of land in cropland.

3. The total number of counties for which use information was obtained should be specified in Appendix I -- Experimental Design.

4. The total number of CWS in the 272 hydrologic units should be specified in Appendix I.

5. The average soil type was determined without regard to the proportion of the soil association within the hydrologic unit.

6. The linkage between hydrologic units when a CWS is located on a major river should be specified. The list of CWS should specify whether more than one hydrologic unit was used to derive use and soil type and, if so, which hydrologic units were used.

7. In order to assess the validity and representativeness of the target population for interpreting the monitoring data, the company must submit the bases for the design of the study. This includes the alachlor use data by which the areas were designated and correlations between use/county, use/hydrologic unit, county/hydrologic unit, hydrologic unit/county, hydrologic unit-to-unit linkage, CWS/county/state/ hydrologic unit, hydrologic unit/CWS/county/state, soil type/hydrologic unit, and all CWS/county/state. The most convenient forms of the data would be in tabular form, in computer-readable form, and in map form.

8. The monitoring study will detect parent alachlor, but will not quantify any alachlor metabolites.

The company should submit data on the 28 participating CWS sites when selected, along with FRDS numbers and maps giving site locations.

(f) Appendix I - Experimental Design

See comments listed under (e).

(g) Appendix II - Determination of Sample Size for 1986 General Monitoring Survey

Detailed comments will be provided later.

(h) Appendix III - Draft Sampling Standard Operating Procedure and List of Monsanto Residue Section Standard Operating Procedures and Guideline Document

The sampling SOP is acceptable.