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EAB Log Out Date MAR 20 1986

Init. CM

To: W. Michael McDavitt
Review Manager
Registration Division (TS-767)

From: Carolyn K. Offutt *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: Proposed Protocol for Monitoring Alachlor
contamination of surface water.

ZBB Code: _____

Action Code 615

Data In: 2/24/86

EAB §: none

Date Completed: 3/20/86

Days _____

10.0

Deferrals To:

☐ Ecological Effects Branch

☐ Residue Chemistry Branch

☒ Toxicology Branch

Monitoring study requested by EAB: ☒

Monitoring study voluntarily conducted by registrant: ☐

(1)

Review of Proposed Protocol for
Monitoring Alachlor Contamination of Surface Waters

1. 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 proposed protocol for monitoring alachlor
contamination of surface waters.

4. STUDY IDENTIFICATION:

Title: Protocol for a Study to Determine Alachlor Concen-
trations in Drinking Water Derived from Surface Water
Sources, 1986 Use Season
Author: Andrew K. Klein
Draft Protocol No: 86-35-R-2
Submitted by: Monsanto Agricultural Company with a letter
from Stephen Muench to Douglas Campt dated February 24,
1986, with attached protocol.
Issue Date: February 20, 1986
Accession No: None

5. REVIEWED BY:

Carolyn K. Offutt, Chief
Environmental Processes and Guidelines Section/EAB/HED

Carolyn K. Offutt Date 3/20/86

6. CONCLUSIONS:

The proposed protocol is unacceptable for the reasons
detailed below.

7. RECOMMENDATIONS:

The detailed comments on the protocol should be given to
the company. The company should be requested to promptly
modify the protocol to address the comments.

8. 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 February 24, 1986, for sampling projected to begin in March 1986.

9. Discussion

(a) Objectives

We agree with the following objectives listed on page 2 of the draft protocol included with the February 24, 1986, letter:

- (1) To determine the concentrations of alachlor in finished drinking water derived from surface water sources in areas where Lasso is used.
- (2) To determine an annualized mean concentration of alachlor in drinking water derived from surface water sources in areas where Lasso is used.
- (3) To determine seasonal fluctuations of alachlor concentrations in surface water.
- (4) To identify geographic regions, if any, where annualized mean concentrations of alachlor in drinking water are of toxicological concern.
- (5) To provide data for calibration/validation of surface runoff models for pesticides.

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.

(b) Sampling Facilities

The number of community water supplies to be sampled will be determined after further discussions. The Agency has not agreed that sixteen should be the number of community water systems sampled. The facilities should be in areas of "intensive" alachlor use; the company has not documented a method of determining "extensive" use.

(c) Starting Date

The study can obviously not begin on March 1, 1986.

(d) Proposed Completion Date

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.

(e) Scope and Methods

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. Currently the scoping of the target population is indicated, with some contradictions, in the Scope and Methods in the Draft Protocol, the Study Overview, and in Appendix I - Experimental Design, as well as in the Outline of the Proposed 1986 Surface Water Studies attached to the December 20, 1985, letter and in the January 31, 1986, letter.

Currently, we understand that the scope of the study and the target population of 450 CWS were derived in the following way:

(1) Alachlor sales records for 1985 were summed by the county in which the sale occurred. Alachlor sales records were assumed to correlate reasonably well with alachlor use; i.e., there are enough distribution points that alachlor sold in a county was assumed to be used in the same county. The term "alachlor use" has subsequently been used to mean "alachlor sales".

(2) For those counties with alachlor sales (approximately 1800 counties in an unspecified number of states, possibly 24), USGS hydrologic unit maps with county boundaries were then used to identify visually the number and identity of hydrologic units (at the cataloging unit level) falling within each county's boundaries. The total county use amount was simply divided by the number of hydrologic units and an equal amount of the use was applied to each hydrologic unit without regard to the proportion of the county area represented by each hydrologic unit. In a similar fashion, the county land area was simply divided by the number of hydrologic areas represented and that area attributed to the hydrologic unit without regard to the proportion of the county represented by each hydrologic unit.

(3) The use by hydrologic unit was determined by summing the county shares of use attributed to each hydrologic unit. The size of the hydrologic units was determined by summing the county area attributed to each hydrologic unit. The application rate (lb/acre) was determined by simply dividing hydrologic unit use by hydrologic unit area without regard to the percent of land in cropland.

(4) The approximately 1800 counties in a unspecified number of states were represented by 825 hydrologic units at the cataloging unit level. A list of 267 (or 272?) of the 825 hydrologic units was identified with an application rate of 30.1 lb/acre. These hydrologic units are located in 22 states and comprise the Use Region.

(5) By directly contacting each of the 22 states, a list was obtained of an unspecified number of community water supplies (CWS) which derive drinking water in all or part from surface water in those 267 hydrologic units. The Scope and Methods of the Protocol indicates that information from both state agencies and the Federal Reporting Data System was used to obtain the list, while the Experimental Design indicates that the data came directly from the states. The list was restricted to those CWS which both obtain water from surface water and treat their own water to eliminate water purchased from another system. Were the states requested to provide information on all CWS in the state, all CWS using surface water, or only CWS in particular counties or hydrologic units. It is not clear that all states responded. A list of state contacts for all states is necessary. Those CWS which obtain water from the Great Lakes were excluded because in 1985 no detectable concentrations were found in those waters. Those CWS which obtain water from either the Mississippi, Missouri, or the Ohio Rivers were also excluded because the 1985 data showed only small, broad peaks of alachlor. The final list of 450 community water supplies comprises the Target Population.

(6) An average classification of hydrologic soil group was made for each hydrologic unit was made by visual inspection of state soil association maps from the Soil Conservation Service. Based upon information found in the Study Overview but not in Appendix I - Experimental Design, the soil associations within a hydrologic unit were identified without regard to the proportion of the association within the hydrologic unit. Then each soil type in those associations were listed by hydrologic soil group (A, B, C, or D) and assigned numerical values (1, 2, 3, or 4). A simple average was calculated. A better method would have been to have assigned an average soil group to the soil associations and then to have weighted the soil associations by the proportion of the hydrologic unit in each soil association.

(7) The CWS were stratified (possibly by visual inspection) on the basis of the watershed upstream of the CWS. If the drainage area at the CWS was 50% of the hydrologic unit area, the CWS was classified as "large". If the drainage area at the CWS was 50% of the hydrologic unit area, the CWS was classified as "small". This clearly is a relative measurement, because 50% of a large hydrologic unit could, in fact, be much greater than all of the drainage of a small hydrologic

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unit. Again, this stratification was without regard to amount of land in cropland. The purpose of stratification by watershed size is not clear, and such stratification does not seem to be useful in the study design.

(8) A "vulnerability factor" was derived for each hydrologic unit based upon application rate and soil type. The mathematical basis for the vulnerability factor equation is not clearly shown; it is stated that the equation was derived from the 1985 monitoring data which the Agency has not yet seen, except in preliminary, summary form. In fact, the equation first provided in a December 20, 1985, letter is different from the equation in the February 20, 1986, protocol, without any explanation. The usefulness of the vulnerability factor in stratifying the hydrologic units is not justified.

In order to assess the validity and representativeness of the target population, 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, CWS/source/county/state/hydrologic unit, hydrologic unit/CWS/source/county/state, soil type/hydrologic unit, vulnerability factor/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.

Although the Appendix I - Experimental Design of the Protocol indicates that several of the listing of information are available at Monsanto's Washington Office, when the listings were first requested, several days passed before the information was made available and, then, only accompanied by a company representative; the information was not allowed to remain in the hands of the Agency. Several times we have attempted to review the data with the company representative present; this constraint has made our review efforts very difficult.

Because the Exposure Assessment Branch has not had the freedom to adequately review the basis for the protocol, the monitoring data may not be given much weight in making the risk assessment for alachlor contamination of surface water used for drinking. This difficulty could be resolved, even at this late date, if the Agency could obtain the alachlor use data and other information in usable form. For the purposes of continuing with the protocol development, the target population of 450 CWS will be accepted, pending further review of the basis for selection. The target population will become unacceptable if the basis for selection is not validated.

(f) Experimental Design

The protocol does not distinguish between the Scope and Methods and the Experimental Design; a number of the scope aspects are included in Appendix I - Experimental Design, but not enough. A separate appendix on Scope and Methods would solve that problem.

(1) Final Site Selection

The 2x2 stratification using vulnerability factor and size of drainage basin is unacceptable. A 3x3 matrix would provide better characterization of the extremes and avoid an entry shifting from high to low category merely by changing the dividing point. The sample size of 16 sites is unacceptable based upon discussions with Agency statisticians. The use rate should not be imbedded in a vulnerability factor, but used as one stratification factor. Soil type could be used as the other stratification factor. Any sites selected for sampling which decline to participate must be reported, as a high turndown rate can have statistical implications.

(2) Sampling Procedures

The Standard Operating Procedure for sampling does not specify the length of time during which samples will be collected. The Agency believes that year round sampling will not be necessary; sampling for 1986 from April to October should be sufficient, if concentrations are below detectable levels on either end. Finished water alone will not be acceptable, if the CWS uses both surface and ground waters and mixes the waters for finished water. Further written comments will be provided on this section.

(3) Quality Control Procedures

Further written comments will be provided on this section.

(g) Analytical Procedures

The analytical procedures need a separate heading. Further written comments will be provided on this section.

(h) Records and Data Retention

Further written comments will be provided on this section.