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OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

DEC 12

MEMORANDUM

SUBJECT: Review of Alachlor Ground Water Survey Design

FROM: Mary Frankenberry, Statistician *MF*  
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THRU: Amy Rispin, Chief *Amy S. Rispin*  
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TO: Michael R. Barrett, Acting Head  
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Environmental Fate & Effects Division (H7507C)

In response to your request for a review of the study design and initial results from the Alachlor Ground Water Survey, the following are my comments and a summary of the major points from our November 30th meeting that I think bear repetition in our request for additional data from the registrant.

Background

Monsanto's "National Alachlor Well Water Survey" was begun in 1985 and is expected to be completed by spring of 1990. Sample collection was completed this year and took place over the period of June, 1988 through April, 1989. The purpose of the survey was to estimate the prevalence of private drinking water wells in rural areas across the country which contain detectable levels of the pesticide alachlor and four other chemicals of concern. The estimates will be made for five different areas of interest, which the company refers to as "domains" of interest, and which were agreed upon with the Agency in advance as the basic minimum areas of study:

Domain 1) All wells (private, rural, drinking water) in "the Alachlor Use Area," that is, counties where alachlor is sold/used;

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- Domain 2) All wells (defined above) in counties with the highest ground water vulnerability scores, as measured by DRASTIC;
- Domain 3) All wells in the "most cropped and vulnerable" areas of counties with highest alachlor sales;
- Domain 4) All wells in counties with highest ground water vulnerability and highest alachlor sales;
- Domain 5) all wells in peanut producing counties.

Estimates for the other four chemicals, atrazine, metolachlor, cyanazine and simazine are indexed to this alachlor use area only, and will not be applicable to the country as a whole.

A multi-stage sampling approach was used. The company expected that of the approximately 1,759 counties in the alachlor use area, approximately 90 counties would be selected with probability proportional to size (number of households with wells) in the first stage of sampling. From these 90 counties, clusters of households containing private rural drinking water wells were selected in the second stage of sampling. Of the roughly 1,600-1,700 private rural wells selected for water sampling at the third stage, the company expected participation for about 1,400-1,500 of the selected wells.

These comments are based on a review of the original proposal submitted to the registrant by its survey contractor, a paper on the survey design presented at a 1988 conference on ground water ("Agricultural Impacts on Ground Water--a Conference," March 21-23, 1988, Des Moines, Iowa), several quarterly reports consisting mostly of preliminary laboratory data, and some general briefing slides on the survey presented to the Ground Water Technology Section in October of this year.

#### Major Issues

As we discussed in our meeting, I think the "bottom line" to keep in mind in evaluating results from this survey will be that, as David Wells pointed out, sampling took place in many instances during the period of the 1988 summer drought when very little movement of chemicals into the ground water was expected. Some sampling was reportedly done at later times after freezing temperatures had been in effect. If this is the case for only a modest number of samples, the prevailing hydrologic conditions could bias results of even the best statistical design without proper weighting. For this reason the analysis that the registrant plans of chemical level by water level will be very important, to the extent that it can be done using accurate data. In addition, the registrant should perform an analysis of the chemical levels for counties over time to see if levels show general rising or falling patterns that may correspond to area climatic conditions at the time of sample collection. I think we will also want to

know the relative percentages of samples that fall into the "low," "medium," and "high" water level categories and the distribution of the samples with respect to any climatologic information that was collected.

A second major point that will govern interpretation of the results is obviously the quality of the analytical method for the chemicals. I assume that the methods and quality assurance protocols have been discussed with EPA in advance, and that for a chemical as widely used as alachlor the methodology is fairly well developed. It appears that the company has a number of slides presenting QA information that they should include in the final report. Since the limit of detection for alachlor is very close to the level for the health advisory limit, the accuracy and precision criteria for the analytical method are very important. As we discussed earlier, Elizabeth Leovey's involvement in reviewing the final results would be extremely helpful in this regard.

With regard to the accuracy and precision of survey estimates that can be achieved with the design proposed, sample sizes were calculated for a given precision level that the registrant would accept for the survey when the true prevalence of wells with detectable levels is at or greater than a prespecified amount. For example, the company has accepted the variance constraint that the relative standard error (RSE) will not exceed  $\pm 50\%$  when the true proportion of wells with detectable levels is at least 1.0%. In general, a relative standard error of  $\pm 50\%$  is rather high, although not unprecedented. This precision could be even less good (i.e., a higher RSE) if the true proportion of wells with detectable levels is lower than the 1.0% specified by the company and better if the true proportion is higher than 1.0%, as is expected in the later domains. Preliminary data indicate that the true proportion of "detectables" is lower than 1.0% for Domain 1, the alachlor use area. The report should discuss the actual sample sizes obtained and the precision that was achieved for the estimates for each domain. It could be rather poor for any new "domains of interest" that either the company or EPA would like to examine, particularly if they are small in size or have a relatively low proportion of wells with detectable levels.

Likewise, for the power calculations presented, the survey group has calculated the probability of detecting the chemical for different sample sizes when the true proportion of "detects" is various prespecified amounts. This probability is very good (usually over 90%) if the true proportion of positives is at least 0.5%, but it drops very quickly as the true proportion or sample size decreases. Small differences in the actual sample sizes obtained probably will not greatly affect this power, although proportions less than 0.5% will be difficult to estimate, particularly for newly specified domains of small sample size. The report should include a discussion of power both in light of the actual sample sizes obtained, as well as for other hypothetical cases. That is, a discussion of the limits of precision and power

that can be achieved for different cases should accompany and elaborate Figures 6 and 7 of the proposal, including tables of calculations for various sample sizes and proportions.

The final major consideration in evaluating results of this survey involves statements that will be made concerning the other four chemicals sampled. The graphics and discussion in the report cannot overemphasize the fact that statistics presented on the other four chemicals are various estimates of their occurrence for THE ALACHLOR USE AREA only. Although there is probably a good deal of overlap or correlation in sales/usage for the five chemicals, the report should address this issue with any data available.

#### Other Major Information Needs

Several issues that require clarification or additional information fall into the two areas of: 1) the hydrologic (and agricultural) information used to stratify the sample and later to perform the statistical analysis; and 2) the actual mechanics of sample selection.

For sample stratification, how complete was the information base used to determine cropping at the subcounty level? Are the listing units mentioned on page 16 of the proposal the actual categories used for the stratification of the second stage of the sample? How were the "temporal strata" defined and how do they compare with data examined for the statistical analysis on the actual hydrologic and climatic variables in effect at the time of each sample collection? Are adjustments necessary to account for more meaningful temporal/climatic periods?

For the hydrologic stratification, what measures were used to apply a DRASTIC score below the county level, that is, for the enumeration districts and block groups? How were "relative vulnerabilities" across counties and listing units compared? What exact measures were used to determine "historic water levels" for the different areas and how complete were they? Information on the numbers of "observation wells" used and the numbers of areas where USGS records were obtained should be provided. What records were these? How complete was the information used to perform the hydrogeological analyses discussed in section 6 of the proposal? Were any actual water level readings taken to verify the estimates derived from asking occupants about the water level or from looking for records on the water level at the time of the well's drilling? How were the answers to questions on household water use combined to produce pumping estimates? The report should include an extremely detailed discussion of all measures included in the "Groundwater Quality Interpretation" (section 6 of the proposal), since it will direct all of the statistical analyses.

With regard to the mechanics of sample selection, I believe I now have a clearer vision of the process used, but it wouldn't hurt to ask the company for an illustration of the process of cluster selection followed by cluster identification as described in the proposal. In effect, it is a convenient method of assigning

households to clusters practically as they are selected. The report could benefit from a better description than is presented in the proposal, however.

Additionally, it appears that the households are selected systematically from within the household clusters they define. I would be interested in seeing the Field Listing Manual, or else a clear description of the method of ordering the lists for selection purposes. This ordering method is referred to, but not described in the proposal.

#### Additional Issues

A number of other more minor issues that might require some clarification or additional information are the following:

- o I assume that this registrant is the only manufacturer of a major alachlor containing agricultural product. Is this the case? What is the relative sales volume of their other product containing alachlor as a secondary ingredient and what percentage of that formulation does alachlor constitute?
- o The proposal states that all working wells normally used for drinking water on the same property or owned, leased, or managed by the same household will be listed for sampling. It is not clear how wells on different properties owned by the same household members are treated in the sampling clusters. In addition, how will the company process information on the numbers of wells on a given property that are not used for drinking water, since they are listing only working wells? (Farm wells are not listed either.) If a sizeable number of wells had been closed because of a problem such as contamination, this could bias the results. Contamination in one well on a given property might not be seen in the other wells on that particular property.
- o The original proposal estimated the target population of Domain 1, "eligible wells in the alachlor use area," to be approximately nine million. Recent notes from the company now estimate the number at six million. I would be interested in the elements that account for the difference.
- o Probably due to the length of the project, three different documents list the target area for the survey as the 1985, 1986, or 1988 sales area. The company should verify in the written report that the 1988 data were used and that they are representative of past usage/sales patterns.

I hope that these comments will help in our evaluation of the final report. Please call me on 557-9307 if you need clarification of anything.

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cc: Anne Barton  
Henry Jacoby  
David Wells ✓