

EXHIBIT 91

July 5, 2000

to: Farm Family Exposure Task Force

from: John Acquavella & John Cowell

re: Site visit to Minnesota field site

John Cowell and I visited the Minnesota field site on Friday, June 30 and Saturday, July 1. There were no applications scheduled at that time, so we focused our attention on evaluating the field and lab procedures and the data collected to date. At the time of our visit, 21 farms had been completed, 5 were in progress, and 5 were scheduled to begin on July 6. The counts by chemical were:

	Completed	in progress	pending
glyphosate	16	3	3
2,4-D	2	2	2
chlorpyrifos			
glyphosate & 2,4-D	3		

Obviously, we should have been in the field checking adherence to the study protocol before so many farms were done.

ABC Labs partnered with the Minnesota Valley Testing Labs so as to use existing local personnel and facilities to conduct the study. We were impressed with the facilities and with the staff assigned to the project, but we found several problems that need to be fixed. We've summarised the deficiencies in a table (see below) and provide an annotated version of the site visit checklist that Carol and Curt developed.

The major issues are as follows:

Issue	contributing factors	implications
study team were not preparing concurrent field spikes	we didn't supply the LOQ promptly for 2,4-D and chlorpyrifos	don't have concurrent spike of known concentration to show that handling from the field and transit from the field didn't influence urinary values.
Protocol had incorrect volume (50 ml vs. 100 ml) for field spikes	TF missed it in protocol review	1. could give a higher LOQ for field spikes; 2. identifies field

		spikes to lab analysts
up to date protocol amendments not on site	insufficient communication within study team	1. clear GLP violation 2. possibility for errors by field personnel
urines were not being reviewed for completeness	insufficient understanding of the protocol by field team; insufficient oversight by senior study team members	many urines, especially for children, looked incomplete - some of which could have been prevented with immediate follow-up and coaching
insufficient review of questionnaire content	large number of incoming urine samples precluded keeping up with paperwork	missing entries; many will be more difficult to correct as time passes
less contact than anticipated between study team and farm families	busy schedules of farm families; remoteness of some farms	lots of uncertainty about urines; no coaching; missed urines probably not documented & too late to correct
children not getting daily incentives as agreed at February 2000 TF meeting	difficulties in making contacts with participating subjects	unknown, but assume resulting in less complete urine collection
study data base kept on stand alone computer with floppy disk backup; no secure backup	lack of interaction of study team	potential to temporarily lose valuable data

FARM FAMILY EXPOSURE STUDY SITE VISIT CHECK LIST
Annotated during visit to Minnesota field site 6/30-7/1

I. General Items

- Approved protocol with amendments on site

[The protocol was available, but not the amendments. The Minnesota field team did not remember receiving amendments.]

- SOPs for field events on site

[Yes.]

- Field notebook to document field events on site

[Some, but many were with the agronomist who was doing the field evaluations.]

II. Test System

- Does the treated field met the protocol requirements

[Yes, but some barely met our criteria. It seems that several farmers tailored their applications to qualify for the study and make maximum use of the incentives. The study team encouraged this to get a high participation rate.]

- Does the field notebook or other documentation adequately describe treated area

[The ones we saw were okay.]

- Is there a history of pesticide and fertiliser use for the treated area

[History of pesticides used during the study and in the preceding 7 days was okay. In one instance, a farmer had used a product that contained chlorpyrifos within 7 days of the study and the farmer and the investigators were unaware of this. As a result, we lost the chance to have a chlorpyrifos farm in the study.]

- Environmental parameters documented

[This was okay in the reports that were available to us.]

III. Test Substance

- Receipt of test pesticide formulation documented

[The test substance was documented, but we were unable to ascertain whether they were taking lot numbers and retaining samples of the test substance.]

- Use of test pesticide documented including date of use and amount used

[Yes.]

- Application equipment acceptable by protocol

[Yes.]

- Descriptions of mixing/loading and application procedures used by farmer documented

[Yes, but these could have been more complete. We didn't see all the field notes, so perhaps they contain more detail.]

- Field personnel observing farmer but not interfering in application process

[We didn't observe a field application.]

- Participant consent forms signed and available

[Yes, but we saw one form that wasn't signed by the spouse. The husband had signed it and, subsequently it seems, the spouse printed her name near the date line.]

IV. Field Sampling

- Sampling procedures consistent with protocol

[Yes, but amendments missing for compositing samples.]

[The following 5 items were found to be acceptable.]

- Sampling equipment meets protocol requirements
- Sampling equipment and sample storage is separated from test substance including field fortification solutions
- Gloves worn during sample handling
- Samples stored according to protocol
- Sample history recorded and available
- Sample logs acceptable

[Yes, with some correctable errors and exceptions.]

V. Field Fortifications

- Field fortification conducted according to protocol

[No, these weren't being done at all!]

- Field fortification process conducted in correct order of control to high dose

[No, these weren't being done at all.]

- Proper measuring equipment, containers, and labelling used

[Yes.]

- Field fortification equipment and sample storage is separated from test substance

[Yes.]

- Gloves worn during sampling

[Yes.]

- Technician techniques proper for accurate measurements

[Yes, though we suggested a change of gloves after each individual's composite was prepared to eliminate the chance of contamination between family members.]

- Fortification sample storage conducted according to protocol

[No field fortifications had been done.]

- Sample logs acceptable

[Mostly, but some of the info was attributed to the incorrect day. This can be corrected during data cleanup. There were also many instances where editing will be necessary to meet GLP requirements.]

VI. Shipping Procedures

- Samples packaged and shipped according to protocol

[We assume so. However, we observed one shipment where the containers were sideways in the box and urine leaked over all the containers.]

- Control and treated samples are packed separately

[Yes for nearby farms. Uncertain for remote locations in northern Minnesota.]

- Sample ID accurate and complete on packaging

[Yes.]

- Chain of Custody forms complete and accurate

[Yes.]

- Shipping information documented to date

[Yes, but nothing has been shipped to ABC yet since the protocol requires that field spikes must accompany samples.]

VII. Questionnaires

- Applicator enrolment completed

[The questionnaires were fairly complete. But it was obvious that they weren't reviewed critically as they were received. Thus, there were noticeable errors that, in some instances, may be more difficult to correct as time goes on.]

- Applicator follow-up completed if applicable

[Same as for the previous item.]

- Spouse follow-up completed if applicable

[Same as for the previous item.]

- Were the interactions with the family conducive to asking questions, understanding the incentives of the study and its purposes.

[The consent visits resulted in a high participation. Some of that was because the study team encouraged the potential participants to take advantage of the incentives. We doubt the importance of collecting complete urines got through to the participants. There was very little contact with the participants once they agreed to participate. Clearly, no coaching was being done to maximise the number of complete urines.]

- How was the family insuring that the child collected complete urine samples?

[This aspect of the protocol was largely being ignored.]

- Was the plot diagram accurate

[Yes.]

July 7, 2000

to: Farm Family Exposure Task Force

from: John Acquavella & John Cowell

re: Site visit to South Carolina field site

John Cowell and I visited the South Carolina field site on Thursday July 6 and Friday, July 7. The first day was spent reviewing records and procedures. The second day was spent observing an application. This report is necessarily brief because I squeezed this visit in just before a vacation and didn't have time for a detailed report.

The South Carolina field team is comprised of qualified persons with appropriate backgrounds and they are working carefully on the study. However, we discovered a number of problems that need to be addressed. We are uncertain at this time whether these problems will detract significantly from the study.

As of COB July 7, the number of farms completed, in progress, or pending were:

	Completed	in progress	pending
glyphosate	8	2	3
2,4-D	2		2
chlorpyrifos	1		1
glyphosate & 2,4-D			1

We noticed the following problems in reviewing records:

1. urines were being composited daily instead of on a 24 hour cycle in relation to the start of pesticide application.
2. Protocol amendments had not yet been forwarded to the study team from Exponent.
3. Many of the urines were very spotty and we found one day's urine that was obviously doctored. As at the Minnesota field site, the field team is not reviewing the urines carefully and there is little, if any, coaching of the farm families - though the South Carolina team has much more contact with the farm families than we found in Minnesota.
4. There were some obvious errors or missing entries in the questionnaires. This field team is not really reviewing the questionnaires. They are expecting the U. Minn team to do that. However, there will be a month or two lag before the records are sent to Minnesota and that may be too late to correct the entries.

5. There were lots of date errors in the notebooks on the compositing sheets - all by one technician.

6. Exponent has not yet executed a contract with HERAC, causing concern about the schedule of payments to HERAC.

7. The South Carolina team felt that not enough effort was being expended to locate eligible farms in South Carolina. As a result, they felt that they could not utilise resources most efficiently.

The application we observed involved Roundup Ultra sprayed over approximately 22 acres of Roundup Ready soybeans. The application rate was one quart per acre. The application equipment was a tractor with a closed cab and a boom sprayer. We learned in discussions with the farmer that he has a commercial application business and that he had been applying Roundup Ultra for the last two weeks over some 2000 acres.

The farmer did not use any protective equipment. He wore shorts and did not use gloves. That seemed to be his standard practice. It took about an hour to complete spraying. During the spraying, one of the nozzles malfunctioned. Both times, the farmer stopped the tractor in the middle of the field and got out to fix the nozzle. There was obvious exposure to his bare legs and his bare hands. The farmer washed his hands, but not his legs, after he finished the application.

The applicator and his family hadn't filled out the enrolment questionnaire in advance of the application. He said he would complete it later that day or at least in advance of when his urine was picked up the next day. We saw a similar protocol deviation in another record that we reviewed.

We looked at the pre-application day urines from the family with Rich and Millie while in the field. It was obvious that the child (a 15 year old boy) had only provided a partial sample. Millie mentioned this to him in front of us and I think embarrassed him. It struck me that none of the field personnel had really been trained about how to coach participants and that this a major deficiency in preparation for the study.

Summarising what we saw in Minnesota and South Carolina, there are some clear problems that need to be fixed at each site. We won't know until we review the data systematically whether the problems will detract appreciably from the study. Two things are clear, however: the field teams are not checking the questionnaires or coaching the participants to give complete urines. We attribute this to the lack of interaction between the epidemiologists and the field teams - the epidemiologists on the study team had not visited either field site. A contributing factor is our delayed oversight of this project.

Things seem to be winding down in Minnesota and to a lesser

extent in South Carolina. The field teams will probably complete approximately half of the farms for the study. This is due to the late start in both states, whereby we missed most of the chlorpyrifos season and much of the spring 2,4-D season. This gives us a chance to take stock and work to improve things for the fall application season and the year 2001 spring application season. We'll be scheduling a conference call in the near future to discuss our site visits in detail and to decide what, if anything, needs to be done.