













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.