Monsanto

DEPARTMENT OF MEDICINE & ENVIRONMENTAL HEALTH

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
Phone: (314) 694-1000

November 13, 1986

Denise Oleske, Ph.D.
Northwestern University Medical School
W.G. Krummrich Study
215 E. Chicago, Suite 801
Chicago, Illinois 60611

Dear Denise:

As promised, I am providing you with updated information concerning the criteria used for identifying the exposed and unexposed study populations for the Northwestern/Monsanto health study and the edits that were compiled for the work histories of the employees in the study. Some of this information was recently obtained to provide answers for questions that had been submitted by the National Institute for Occupational Safety and Health (NIOSH). As you know, the NIOSH Dioxin Registry includes all hourly employees who worked three or more days in the pentachlorophenol/SANTOBRITE and/or 2,4,5-T esters units at the Krummrich plant. Since this group of employees from the NIOSH Dioxin Registry represents a subset of the exposed study population for the Northwestern/Monsanto health study, any information that I provide to NIOSH is also useful for our study.

With respect to the criteria that was used to select the exposed study population, there are really no changes from what was reported in the study protocol, except for department 226. It appears that department 226, which manufactured a product referred to as "Monsanto salt", did not manufacture SANTOBRITE. Instead the department manufactured a sulfonic toluene derivative that was sold as a red dye for the manufacture of inks, paints, etc. However, this sulfonic toluene derivative was manufactured in Building BO, along with chlorophenols (department 237) and pentachlorophenol/SANTOBRITE (department 236) for an undetermined number of years. I have yet to confirm the start-up and shut-down dates for department 226, although it appears that the department may have started as early as 1925 and may have closed as late as 1955. I hope to confirm this information once I receive copies of the standard manufacturing process (SMP) reports that date back to the 1920's.

I have been able to obtain some additional information concerning the pentachlorophenol/SANTOBRITE, chlorophenol, and 2,4,5-T esters units that may be helpful. This information is as follows:

Dept	Periods: Bldg. BO	Periods: Bldg. BD	Periods:	Product
236	1938-1947	1947-1978		molten pentachlorophenol
236	1938-1947	1947-1963		flaked pentachlorophenol
B-821		1963-1963		prilled pentachlorophenol (exp.)
B-236 (226)		1963-1978		prilled pentachlorophenol
236		1972-1977		block (2000 lb) pentachlorophenol
236		1972-1978		block (1000 lb) pentachlorophenol
A-236 (225)	1938-1947	1947-1975		SANTOBRITE powder
A-236 (225)		1949-1975		SANTOBRITE pellets
A-236 (225)		1972-1975		SANTOBRITE 30% solution
A-236 (227)	1938-195_	1947-1975		SANTOBRITE briquetts
237	193_-19__		19__-1982	o-, p-, di-chlorophenols
268			1960-1970	2,4,5-trichlorophenoxyacetic acid esters

(During 1967, the department codes were changed to the numbers in parentheses due to a machine accounting installation.) Furthermore, the department codes listed above were used primarily by the accounting department, since the personnel department only used the department codes and jobtitles that were listed in the union/management contracts. Since the detailed work histories were based on employment records from the personnel department, all of the department codes listed above can be categorized as follows:

Dept	Period	Product
236	1938-1978	Pentachlorophenol
A-236	1938-196_	SANTOBRITE
236	196_-1975	SANTOBRITE
237	193_-1982	o-, p-, di-chlorophenols
268	1960-1970	2,4,5-T esters

As a result of abstracting detailed work histories from employment records in the personnel department, reviewing old documents from the plant, and discussing past history with a few retirees who worked at the plant, I can state that the above department codes are unique and can be used to identify the exposed study population. I am unsure exactly when the personnel department stopped using A-236, although it appears that this may have occurred sometime in the early 1960's. I am also not sure of the start-up date for department 237, but some sources suggest that it may have been as early as 1931. In addition, some of the sources suggest that the 2,4,5-T esters unit ceased production in 1970; however, I have seen a few employment records that would suggest that there were a few employees in this department as late as 1971.

With all of this information, what is the bottom line concerning our exposed study population? Since the personnel department never used the more detailed department codes that were used by the accounting office, we can feel comfortable that we have identified all of the hourly employees who may have worked three or more days in any of the exposed departments. The only exception may be employees who worked only in department 226; however, my preliminary analysis suggests that there were only 78 employees in the exposed study population who worked in department 226 and that each one also worked in at least one of the exposed departments sometime during his/her employment with the Monsanto Company. If this is the case, then the only problem that we must consider is the possibility of exposure to pentachlorophenol fumes or SANTOBRITE dust by the employee while he/she was working in department 226, since this department was in Building BO (a two-story, one-room, wooden structure) along with department 237 and later 236 for a yet confirmed number of years.

With respect to the criteria that was used to identify the unexposed study population, there have been a couple of modifications to what was reported in the study protocol. To be eligible, an employee had to meet the following criteria:

- never employed in an exposed department
- did not appear on the chloracne registry
- never employed in department 218 (muriatic acid), 224 (chlorinated benzenes), 233 (chlorinated benzenes), 239 (SANTOPHEN 1), 246 (arochlors or PCB's), or 262 (2,4-dichlorophenoxyacetic acid)
- never employed in the quality control laboratory (department 313 prior to 1951, 508 from 1951 through 1961, and 861 since 1962)
- never employed in maintenance (departments 333, 811, 899 or jobclass = 89XXXX)

When the unexposed study population was originally identified, it was done by using the above criteria, with the exception of departments 333, 811, and 899. Unfortunately, there were a few coding errors with respect to the jobclass codes for the maintenance jobs, which were not discovered until after the medical data had been collected for the study. The coding errors have been corrected, and hindsight has shown us that the inclusion of department 333, 811, and 899 to designate maintenance workers may have been a better indicator.

STLCOPCB4043021

Another small problem that has been discovered is the result of editing the detailed work histories. By correcting all errors (bid dates versus move dates, incorrect department and jobclass codes, etc.) in the work histories, approximately 100 employees in the unexposed study population were ultimately misclassified. Two earlier audits of the work histories (one by Northwestern University and the other by Monsanto) indicated a 3 to 5% overall error rate, but we decided to re-edit all of the work histories because of a concern over using bid dates instead of move dates as the "start date" for the work histories. Since bid dates had been used in some cases, there was the possibility of an employee being listed as working in a specific department although he/she had never been awarded the job in the department through the plant's bidding process. Although the decision to reduce the errors in the work history resulted in misclassifying a few employees in the unexposed study population, the re-editing was done with no knowledge of whether or not the employee participated in the study.

Other information that was shared with NIOSH that you will need to consider is the lack of job descriptions for the employees who worked in the pentachlorophenol/SANTOBRITE and 2,4,5-T esters units. Specific job descriptions are available for both departments beginning with the 1960's, but there is no written information prior to this decade. There is a general description of some of the jobs (operator, helper, repairman, foreman) in the union/management contracts, but the job descriptions are not specific for any department. Nevertheless, the work histories and the union/management contracts contain numerous jobtitles for many of the departments, including the pentachlorophenol/SANTOBRITE department.

According to a few retirees that were interviewed, it was discovered that frequent process changes that were initiated by the Plant Technical Services department required prior discussions with the local union before implementation, after which a revised list of jobtitles was published. Generally, a pay raise was involved and sometimes, but not always, a jobtitle change was made that attempted to differentiate the "new" job from the "old" one. Thus, a specific job with minimum changes in responsibilities might have had more than one job title. Actually, there were probably no more than 6-8 specific job titles that were in effect at any given time for the pentachlorophenol/ SANTOBRITE department, but over a 50-year period the changes that occurred resulted in 40+ different jobtitles.

Finally, I want you to know that I have been reviewing the edit runs that you submitted last month and the errors that you detected were minor. In other words, the changes that we have made to the work histories will not affect the status of the employees in either the exposed or unexposed study population. Most of the corrections have been made to our computer file, although we plan to check our work one more time before we send you a new

STLCOPCB4043022

copy of the work histories. I thought it would be easier to provide you with a new copy instead of asking you to make a number of miscellaneous changes to your copy of the work histories. In addition, I will add the work histories for the employees who were in the "chloracne registry", which should be completed in a couple of weeks. Furthermore, I promised to provide Dan with demographic information concerning the maintenance workers in the exposed study population, those who were mistakenly included in the unexposed study population, and those who were in neither group.

If I can be of further assistance, please do not hesitate to call.

Sincerely,

Terry L. Leet

Terry L. Leet
Epidemiologist

cc: W.R. Gaffey - F1WK
J.H. Spraul, MD - F4WB
Daniel Hryhorczuk, MD - Northwestern University