

Monsanto

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DATE: August 6, 1991

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SUBJECT: PDCB STUDY AT WGK

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Here is the final draft of the announcement reporting preliminary results of the PDCB study and a Q&A for internal use in responding to some likely questions. These materials reflect a few additional clarifications suggested by our legal community, as well as all prior input.

The Krummrich Plant plans to issue this announcement during the week of August 12; the exact day will depend on meeting schedules.

Since this study covers the years 1946-1975, many of the employees included in the study group have since retired from Monsanto and will not be aware of the in-plant announcement. Kevin Cahill, Terry Leet and Greg Penny will meet August 7 to discuss arrangements to mail this announcement (with a brief, suitable cover letter) to retirees who were in the study group. We will also consider how we might reach former employees who are not currently on the pension rolls.



Loren W. Wassell

DSW 134270

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In 1987, the Monsanto Department of Medical and Health Sciences began a study of employees at the W. G. Krummrich Plant who were exposed to paradichlorobenzene (PDCB) to determine if any adverse health effects resulted from that exposure.

Based on the preliminary results from this study, Monsanto employees exposed to PDCB do not show any exposure-related health effects. However, the Department of Medical and Health Sciences plans to continue the study by expanding the number of workers. This will provide additional information on effects of PDCB exposure.

So far, the study examined the causes of death for production workers who worked in Department 224 between 1946 and 1975. This examination included approximately 650 present and former employees who have been successfully traced.

Preliminary study results show the employees exposed to PDCB have a lower death rate than the general population. There were 211 deaths among the employees. Using the population of St. Clair County, Illinois, for reference, there would have been 247 deaths expected. The number of deaths from all forms of cancer, accidents, and diseases of the circulatory, respiratory, digestive and urinary systems are either the same or fewer than expected for a group of this size.

There were five deaths in the study group from leukemia, which is one form of cancer. While this is somewhat more than expected, the leukemia does not appear to be related to PDCB exposure because (1) several different types of leukemia were involved, (2) the leukemia rate does not increase with higher PDCB exposures, and (3) the increase is not statistically significant.

The expanded study will include approximately 1,000 present and former employees exposed to PDCB at the Krummrich Plant between 1941 and 1989, including the 1946-75 group reviewed earlier. The 1941-89 period encompasses the years of highest PDCB exposure for Monsanto employees, including those who worked in the building where PDCB blocks were manufactured.

The expanded study will also include a more detailed exposure assessment for PDCB and other workplace chemicals to evaluate exposure-response relationships. It will provide additional information on whether PDCB exposure has any effect on the health of workers.

It is estimated that the expanded study will be completed in August, 1992. The results will be shared with employees and submitted to a peer-reviewed scientific journal.

For additional information, please contact Patrick R. Conner, M. D., Monsanto Department of Medical and Health Sciences, or Florence Levy, Supervisor, W. G. Krummrich Plant Medical Department.

Barry R. Friedlander, M.D.
Director, Medical and Health Sciences

James J. Collins, Ph. D.
Epidemiology Director

St. Louis
August 12, 1991

Questions & Answers
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1. Why conduct a health study of Monsanto employees exposed to PDCB?

PDCB has produced tumors in mice and male rats in studies where the animals were given high doses of the material. Monsanto and several regulatory agencies do not believe these findings in animals are relevant to humans. Nevertheless, the company feels a responsibility to investigate the matter more definitively, especially since Monsanto's data ~~is~~ more extensive and complete than anyone else is likely to have.

2. Why aren't the PDCB animal studies relevant to humans?
Aren't animal studies often used to identify health risks?

Animal studies are frequently used to identify health risks. However, for the PDCB animal studies, the types of tumors found, the way they were formed, and the means of exposure are all different from human experience.

3. How were the employees exposed to PDCB identified for the study?

Payroll records were used to identify Monsanto employees who held production jobs in Department 224 between 1946 and 1975. The same kind of records will be used to expand the study to the periods 1941-1946 and 1975-1989.

4. How were the deceased workers in the study identified?

All PDCB-exposed workers in the study were traced by using various government records and credit bureaus. Once a worker was reported to have died, a copy of the worker's death certificate was ordered from the vital statistics agency in the state where the death occurred. Information from these sources is often used by epidemiologists to determine the status of workers in health studies.

5. Why was St. Clair County, Illinois, used as the reference population?

St. Clair County, Illinois, was used as the reference population for the study because it represents the area where most Krummrich employees have resided during the past 40 years. By using St. Clair County, instead of the national population, the comparison is less likely to be biased by regional differences in mortality.

6. Have there been any other studies of workers exposed to PDCB?

This is the first health study of workers exposed to PDCB. The preliminary results of this study do not indicate any statistically significant exposure-related health effects for the Krummrich employees who worked in Department 224 between 1946 and 1975.

This study did identify five cases of leukemia in the group of employees studied, compared to an expected rate of 2.1. This difference is not believed to be related to PDCB because several different types of leukemia were involved and there was no relationship between different exposure levels and leukemia.

7. Why expand the study of workers exposed to PDCB?

When this study was initiated in 1987, the records needed to identify all employees at the Krummrich plant were not available. Since then, the Department of Medical and Health Sciences has obtained additional government records for the period 1941 to 1989. This will allow the epidemiologists to expand the study and include additional workers who were exposed to PDCB before 1946 and after 1975. The extended period, from 1941 to 1989, covers the entire period that the old building was used to process PDCB blocks where PDCB exposures were highest.

The expanded study will provide additional information on whether there is any relationship between PDCB exposure and disease, including leukemia. It is scheduled to be completed in August, 1992.

Another study, currently in progress, is examining whether any health effects have resulted from benzene exposure at the Krummrich Plant. The results of this study may indicate whether the leukemia deaths observed in the PDCB study are related to benzene exposure, since benzene is considered by some authorities to be a cause of one form of leukemia (acute myelocytic leukemia) in humans.

8. Why does expanded study include a more detailed exposure assessment for PDCB?

One way of determining if PDCB exposure increases the risk of disease is to look for an exposure-response relationship. In other words, the risk of disease might increase with increasing exposure to PDCB if long-term exposure to PDCB is harmful. A more detailed exposure assessment will allow the study team to group jobs by PDCB exposure levels from lowest to highest to look for any exposure-response relationships.

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9. Who is on the study team?

Epidemiologists, toxicologists, physicians and industrial hygienists from Monsanto's corporate Environmental Safety and Health Department and the Krummrich Plant.

10. Why will the expanded study take another year to complete?

Before the data can be analyzed, the epidemiologist working with industrial hygienists must first identify all employees who have been exposed to PDCB and then determine if they are still living. The first task requires the epidemiologist to abstract work history information from employee records. The second task requires feedback from outside, government agencies. Either task can take as long as a year to complete.

11. How will the study results be communicated?

Once the study is completed, the results will be reviewed by other scientists and will be shared with employees and retirees who have been exposed to PDCB, plant management, and union officials. Where required by government regulations, a copy of the results will be sent to the Environmental Protection Agency and National Institute for Occupational Safety and Health. The results also will be submitted to a peer-reviewed scientific journal.

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