

Monsanto

FROM (NAME-LOCATION-PHONE)

L. W. Wassell - G4WF - 4-7002

DATE: July 3, 1991

cc: W. J. Boyle 1740
K. S. Cahill G4WD
J. J. Collins A2SL
G. F. Fort G4WT
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SUBJECT: PDCB STUDY AT WGK

REFERENCE:

TO: T. L. Blank 1740
P. R. Conner, M. D. A3NB
J. E. Downes G4WR
B. R. Friedlander, M.D. A3NA
T. L. Leet A2SL
M. W. McCombs G4WT
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Here is a revised draft of the announcement reporting preliminary results of the PDCB study and a Q&A for use in responding to some likely questions. These materials incorporate all your input; please let me know if they accurately reflect the situation.

A few specific questions:

Mr. Leet: Would it be possible, and appropriate, to compare the study group with the national population to expand the answer to Question 4?

Also, the discussion of exposure-response correlation in the answer to Question 7 may appear to conflict with the discussion of leukemia in the answer to Question 4. Can you suggest more precise language to clarify? The answer to Question 6 might be reviewed in this context as well.

Messrs. Blank and Leet: Are you comfortable with being identified as a contact for additional information? With data of this type, it seems like a designated expert is needed to respond to employees' specific questions.

Dr. Friedlander: Are you the appropriate person to sign this announcement? And, do you agree to do so?

(Anyone): Is there a more understandable way to identify the study group than "Department 224?" Or, is that, in fact, the most common name used by the people who work there?

Also, is a standard bulletin board announcement the appropriate format for the results? I am not aware of any other standard format for this kind of information.

Action Requested: Please review the attached materials and respond no later than July 12, so that we can report back to the employees involved with no further delay.

Thank you.



Loren W. Wassell

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STLCPCB4034234

In 1987, the Monsanto Department of Medical and Health Sciences began a health study of employees at the W. G. Krummrich Plant who were exposed to paradichlorobenzene (PDCB). The study has examined the causes of death for all production workers who worked in Department 224 between 1946 and 1975. The study includes approximately 650 employees who have been successfully traced and whose death has been verified by death certificate.

Preliminary study results show the employees exposed to PDCB had 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 cancer, accidents, and diseases of the circulatory, respiratory, digestive and urinary systems are either the same or fewer than expected for a study of this size.

There were five deaths from leukemia in the study group. This is more than expected, but the increase is not statistically significant. Leukemia does not appear to be related to PDCB exposure because it was not related to exposure levels and because four different types of leukemia were involved.

Based on early results from this study, Monsanto employees exposed to PDCB do not appear to have an increased risk of dying from any specific diseases. However, the Department of Medical and Health Sciences plans to expand the study. This will provide

additional information on effects of PDCB exposure, including the incidence of leukemia.

The expanded study will include approximately 1,000 workers exposed to PDCB between 1941 and 1989. This period encompasses the years of highest PDCB exposure for Monsanto employees, especially those who worked in the building where PDCB blocks were manufactured. The expanded study will also include a more detailed assessment for PDCB and other workplace exposures to evaluate exposure-response relationships. It is estimated that the expanded study will be completed in August, 1992.

For additional information, please contact Tom Blank, Superintendent, Safety and Industrial Hygiene, W. G. Krummrich Plant, or Terry Leet, Senior Epidemiologist, Monsanto Department of Medical and Health Sciences.

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

Questions & Answers

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 by stomach tube. Monsanto and several regulatory agencies do not believe these findings in animals are relevant to humans, because humans do not contact PDCB by stomach tube. Humans contact PDCB through inhalation or skin contact, and these exposures do not produce tumors in animals. 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. 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.

3. 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.

4. 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.

5. Have any other studies shown adverse health effects for 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 excesses in disease for the Krummrich employees who worked in Department 224 between 1946 and 1975.

This study did identify five cases of leukemia compared to 2.1 in the target population. This is not significant because leukemia did not vary with exposure levels and because four different types of leukemia were involved.

6. 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 and where PDCB exposures were highest.

The expanded study will provide additional information on the effects of PDCB exposure, including the incidence of leukemia. It is scheduled to be completed in August, 1992.

Another study, currently in progress, is examining health effects of 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 many authorities to be a cause of leukemia in humans.

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

One way of determining of 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 PDCB jobs by exposure levels from lowest to highest to look for exposure-response relationships.

8. 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.

9. Why will the expanded study take one to two years 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. Each task can take as long as a year to complete.

10. 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. As 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.