INDUSTRYWIDE STUDIES REPORT OF WALK-THROUGH SURVEY OF TAMBRANDS INC.

Formerly Tampax, Incorporated
Rutland, Vermont

PROJECT NUMBER: P:84:12

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16. Abstract (Limit: 200 words)

A walkthrough survey of Tambrands, Incorporated (SIC-2647), Rutland, Vermont, was conducted in December, 1983. The purpose of the survey was to determine the feasibility of including the facility in a NIOSH mortality and industrial hygiene study of ethylene-oxide (75218) exposure. Personnel records were reviewed. The facility used ethylene-oxide to sterilize tampons, its only product, from 1958 to 1976. Use of ethylene-oxide was terminated in 1976. No industrial hygiene monitoring of ethylene-oxide was ever conducted. The personnel record keeping system was adequate for identifying workers exposed to ethylene-oxide back to 1974. It was estimated that 111 workers who have been employed at the facility were potentially exposed to ethylene-oxide and that the facility could contribute about 1300 person years to the NIOSH study. The authors conclude that Tambrands Incorporated should be included in the study as it meets the eligibility requirements. The requirements are: the facility must contribute at least 400 person years of exposure; it must have adequate personnel records for identifying workers exposed to ethylene-oxide; and it must not have any serious confounding exposure to known leukemogens.

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PURPOSE:	To evaluate the industrial hygiene records, production processes, and personnel records to determine the suitability of including this facility in the mortality/industrial hygiene study of EtO.
EMPLOYER REPRESENTATIVES CONTACTED:	John L. Phillips, Vice President of Manufacturing Stanley Rhodes, Assistant Plant Manager Frank Donohue, Director Central Laboratories (413) 283-3431
EMPLOYEE REPRESENTATIVE CONTACTED:	No union.
STANDARD INDUSTRIAL CLASSIFICATION OF PLANT:	2647 - Sanitary Paper Products

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Tables

Abstract

On December 14 and 15, 1983, a site visit to Tambrands Inc. (formerly Tampax, Incorporated), Rutland, Vermont, was conducted to gather data and determine the feasibility of including this facility in the NIOSH mortality/industrial hygiene study of EtO.

During the visit, personnel records were evaluated and a walk-through survey of the plant was conducted in order to observe how the production processes related to past EtO sterilization. EtO is no longer used at Tambrands and no industrial hygiene monitoring has ever been conducted.

Results of the epidemiologic evaluation of records indicated that this facility meets all of the eligibility requirements as defined by the epidemiological portion of the protocol, and could therefore be included in the study. These requirements are: 1) the plant must contribute at least 400 person-years, 2) the plant must have adequate personnel records or other records that can be used for identifying past and present workers exposed to EtO, and 3) the plant must not have any serious confounding exposure to a known leukemogen.

Introduction

Under the Occupational Safety and Health Act of 1970 (set forth by the 91st Congress, S.9123, Public Law 91-596), the National Institute for Occupational Safety and Health (NIOSH) was given the authority and responsibility for conducting and reporting on field research studies in industry. Section 20(a)7 states that NIOSH shall conduct and publish industrywide studies of the effects of chronic low level exposure to industrial materials, processes, and stresses on the potential for illness, disease, or loss of functional capacity in the aging adult.

Ethylene oxide (EtO) is a major industrial chemical and is one of the 25 chemicals of highest production volume in the United States.[1] The major portion of EtO is used in the production of ethylene glycol (antifreeze) and as a chemical intermediate for polyester films, fibers, and bottles. A small fraction of EtO, less than 0.24%, has been used by the health care and medical supply industries over the past 35-40 years to sterilize heat-sensitive medical supplies.[1] However, it is in this industry that most of the employee exposures occur. This was shown in a 1977 survey conducted by researchers from NIOSH in which it was estimated that 75,000 health care workers were employed in EtO sterilization operations.[2] In addition, another 25,000 employees might be incidently exposed due to inadequate engineering controls.[3]

EtO is a colorless gas at standard temperature and pressure or a liquid at higher pressures. EtO is miscible with water, ethanol, ether, and most common organic solvents. In addition, it is highly explosive when in concentrations of 3 to 100% (EtO) in air. The biological warning properties are essentially useless since the (ether-like) odor threshold among individuals ranges from 300 to 1,500 parts per million (ppm) and adverse health effects may be elicited at levels much less than this.[1,4]

Due to the toxicity and possible carcinogenicity of EtO (see section on Toxicity), NIOSH researchers initiated an investigation in 1982 to assess the feasibility of conducting a cohort mortality study and industrial hygiene evaluation of workers exposed to EtO. Based on the data gathered during the feasibility study, it was concluded that the cohort of workers exposed to EtO in industrial sterilization processes was the most adequate group to support a cohort mortality study.[5] In order to develop a final protocol for this study, a pilot study of six facilities was initiated to further develop the methods used for data collection and exposure classification.

The purpose of this walk-through survey was to determine the suitability of including Tambrands (formerly Tampax) in an industrywide mortality and industrial hygiene study of workers potentially exposed to EtO in industrial sterilization processes. Specifically this walk-through evaluated the following:

1. The documentation of production processes which have a potential for worker exposure to EtO.

2. The documentation of changes in these processes, e.g., engineering controls, which may have altered potential worker exposure to EtO.

3. The determination of historic and current jobs and/or departments within these processes in which workers have a potential exposure to EtO.

4. The existence of historic as well as current production data which includes total amount of EtO used per given time, type of product sterilized, and form of EtO used.

5. The availability, quality, and completeness of any existing industrial hygiene records and/or programs documenting historic as well as current potential worker exposure to EtO.

6. The ability of these records to identify workers with peak exposures to EtO; and, the number and concentration levels of these peaks.

7. The identification of any additional exposures in the work environment which would confound the interpretation of the mortality or industrial hygiene results.

The data gathered in this walk-through will be used to develop, to the extent possible, estimates of exposure to EtO by department and/or job category, level and duration of continuous and peak exposures, and calendar year within this plant. If possible (during the future mortality/industrial hygiene study) these exposure estimates will be compiled into an exposure matrix which will be used to determine the existence of a dose response relationship with any positive association observed in the mortality study.

Description of Plant

Tambrands established its present site at Rutland, Vermont, in 1955. The product line at Rutland consisted entirely of tampons, the manufacture of which began in 1938. In addition, waste paper was recycled and sold for use as pulp for paper.

The production area is located on the second floor; the sterilizing area and finished goods/raw material storage areas are located on the first floor.

Description of Workforce

The Tambrands plant employs 270 workers. During the years EtO was used (1958 to 1976), a maximum of 6 employees (2 per shift) with 1 back-up per shift worked as sterilizer operators (later called decatorization operators). These employees also conducted the maintenance work on the sterilizers and were the only employees, other than their supervisors, who were permitted entrance to the sterilizer room. Others who worked on the first floor were 8 shipping clerks and 6-8 watchmen.

Currently, employees in the general production area work two shifts (7:00 a.m. to 3:30 p.m. and 3:30 to 12:00 a.m.) five days a week. The number of shifts has varied; in 1958 there was only 1 shift; in 1960, 2 shifts; in 1975 and 1976, 3 shifts. There is a 6% employee turnover rate.

At the present time, the workforce is mainly Caucassian and 74% female. However, all sterilizer operators were male. The gender ratio has remained about the same since 1958. The greatest percentage (47%) of the employees fall within the 31 to 50 year age range; 38% are above 50 years of age. There is no union at Tambrands.

Description of Process

The basic materials used in the production of tampons are cotton and rayon (absorbent) and paper. The absorbent is kept in a humidified area. The entire line of tampons was sterilized with EtO between 1958 and 1976. The sterilizing process was terminated for the following reasons: discovery of potential health problems due to EtO exposure; concern over possible Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), and Environmental Protection Agency (EPA) involvement; and knowledge that there was no need to sterilize the product.

During the time EtO was used as a sterilant, the production process proceeded as follows. Initially, the product was loaded onto pallets which were pushed into the sterilizers. After the sterilizers were loaded, a 0.5 inch (in) of mercury (Hg) vacuum was pulled. Next a 50:50 mixture of carbon dioxide to EtO was added to the sterilizer at ambient temperature and pressure. The load was sterilized for up to 16 hours. At the end of the cycle another 0.5 in of Hg vacuum was pulled and held for 40 minutes. The sterilizer was then brought to ambient pressure and the product in the sterilizer was aerated with sterile air for another 40 minutes to reduce EtO in the chamber. The chamber was then opened and the product was pulled from the sterilizing chamber by a rope which was attached to rollered pallets. The finished product was stored on the first floor from 6 days to 6 months prior to shipment.

Description of Past Exposures and Controls Used

Tambrands' use of EtO was initially experimental, from 1952 to 1958 only 100 pounds (lbs) of EtO were used in 1952; 500 lbs/year were used between 1953-1958. It's use as a sterilant began in 1958 with the installation of two 925 cubic foot (ft^3) sterilizers. Two additional sterilizers (975 ft^3) were added in 1960 and 1971. Between one to two cycles per day per unit were run. The amount of EtO gas used to sterilize product increased from 9,426 lbs in 1958 to a maximum of 260,123 lbs in 1973. After 1973, the amount of EtO gas used decreased yearly to 102,820 lbs in 1976. The decrease in poundage was due to better methods of gas usage. At times, EtO gas was reused. Periodically, spore strips were inserted into the load to be sterilized to check the effectiveness of sterilization. Other chemicals used within the plant included lubricants, cleaners, and glues which included: Dextrin powder (glue), caustic soda, isopropyl alcohol, Devcon

hardner, chlorothene (a cleaning solvent used between 1972 and 1978; replaced by isopropyl alcohol), malathion spray, room lacquer thinner and undercoat primer, muriatic acid, hydrogen peroxide, and Decahydrate.

Since the 50:50 CO_2:EtO mixture could become explosive if exposed to a large influx of air, explosion proof motors, tools, and lighting were used. Two 3600 cubic feet per minute (cfm) fans were installed in each of the three sterilizing rooms for general ventilation purposes. The room ventilation was also a single pass (no recirculation) system with the exhaust vented outside. One fan in each room was run 24 hours per day, every day; the balance of the fans were run whenever the sterilizer rooms were in use. However, the make-up air for the sterilizer room passed from the finished goods storage room into the sterilizer rooms; therefore, the sterilizer operators were probably exposed to the EtO which was off-gasing from the stored product.

During chamber unloading, however, the sterilizer operators were provided with an overhead clean air wash. After the sterilized product was unloaded, it was transferred to the storage area where any remaining EtO was allowed to dissapate. The product was warehoused from one week to six months; the average storage time was 2 to 3 months prior to shipment. An infra-red spectrophotometric analysis of the air above the final product (conducted on September 17, 1975) showed an EtO residual of 1 part per million (ppm).

Each sterilizer had an enclosed drain as well as an exhaust, which was vented 1 foot above the roof. The fresh air intake was located on the opposite side of the building from the exhaust with the prevailing winds usually blowing from the air intake towards the exhaust. However, louvers for room ventilation were located on the same side of the building as the sterilizer exhaust. Therefore, depending on wind direction, some EtO sterilizer exhaust could have reentered the building through the louvers.

Periodically, the EtO sterilization process was shut down in order to check the lines for polymerization. The EtO cylinder lines were also back flushed with nitrogen before disconnecting to prevent leakage of EtO.

Tambrands has no records of EtO sterilizer leaks; however, according to management, there were small EtO cylinder leaks and EtO was smelled on an infrequent basis (approximately 3 times in 15 years). A water hose was placed over the EtO cylinder while tightening the valve as a preventive measure. A limited number of EtO cylinders were stored in a small room in the building next to the sterilizers. The EtO storage room was sealed off by a fire door and an exhaust fan was installed for ventilation (no recirculation).

The back walls of the sterilizer room and EtO weigh room, which contained the exhaust fans, were made to blow out in case of an explosion. In addition, the top of each chamber was constructed with an 8 inch rupture disc; these and other parts were eventually put on a timed replacement schedule. This was done to reduce the possibility of leaks.

Description of Industrial Hygiene, Safety, and Medical Programs

Industrial Hygiene

No industrial hygiene sampling was ever conducted at Tambrands.

Safety

The sterilizer operators were provided gloves, aprons, safety face shields, and head covers since 1958. Scott air pacs, were also available, but only for emergencies; they were never used. The Vice-President of Medical Affairs was also head of safety operations.

Medical Program

Tambrands employed a vice president of Medical Affairs. Unannounced visits to Tambrands were made by the Vermont Occupational Safety and Health Administration (VOSHA) on a routine basis. In addition, the Rutland facility was inspected by the FDA; however, the FDA inspections were only conducted after the sterilizing process was terminated.

Description of Personnel Record Keeping System

A. Description

All active and former hourly employees have a personnel file folder on file at the plant site. Personnel file folders for salaried employees are maintained at the plant in Palmer, Massachusetts. The company officials indicated that only 10 salaried workers had ever worked in the areas of the plant that had potential EtO exposures, and that they could easily identify these workers.

The personnel files do contain the basic information required for conducting the epidemiologic study such as name, social security number, date of birth, and sex. These records also contain necessary job history information including job titles, and dates of job transfers. Each time a person changes position a form is added to the file, which contains the new job title and the effective date for the change.

There are 270 active personnel records on file. For former employees there are 13 file drawers which contain approximately 180 records in each box; resulting in a total of approximately 2340 records. Finally, there is a file containing 56 records of individuals that are alive and have retired with at least 10 years of service at age 55 or older.

B. Identification of Exposed Workers

The exposed job categories can be identified by the job titles listed in the personnel files. Since the product was allowed to degas in a nonenclosed area on the first floor, it seems reasonable to assume that all workers on this floor were potentially exposed to EtO. A specific job title for the sterilizer operators was not used until January of 1974. This job title was Decatorization Operator. Prior to 1974, sterilizer operators were included in the job category of Building Maintenance. This is a broad category that includes many other job functions all of which were on the first floor, and thus, had potential exposure to EtO. It may be possible to identify which of the workers in Building Maintenance had worked as sterilizer operators by interviewing

personnel at the facility. Other job categories that had potential EtO exposures that would be included in the study are: material handler, watchman, laboratory technician, and slitter operator.

C. Sampling of the Personnel Files

1. Inactive Files

A list of 10 former employees who had worked in the area where EtO was used (first floor) was obtained from plant management. Personnel files were then checked in order to test whether these files were complete, and whether the occupational histories in these files could be used to identify these workers as exposed. All 10 subjects were located in the files, and all of them had job histories which indicated that they had worked in a job with potential exposure to EtO.

In order to estimate the frequency and number of exposed subjects in the personnel files, 200 inactive files were sampled. The year of birth, sex, dates of employment, and job titles of workers potentially exposed to EtO were also recorded. Out of the 200 records reviewed 8 (4%) workers were identified who were potentially exposed to EtO. Extrapolating from the total number of inactive records on file (2396), it was estimated that there are 96 potentially exposed workers in the inactive personnel files.

2. Active Files

One hundred twenty-three records were sampled from the active personnel record files. Out of 123 records sampled, 7 (5.7%) workers were identified as having had a potential exposure to EtO. Extrapolating from the total number of active records on file (270) it is estimated that these files contain approximately 15 potentially exposed workers. Combined with the estimated number of former employees, it is believed that there is a total of approximately 111 workers potentially exposed to EtO that have ever worked at this facility.

3. Summary

In Table 1, a summary is presented of the characteristics of the workers identified as having been potentially exposed to EtO. All of the workers were men. The average year of birth was 1936 for current employees, and 1944 for former employees. The average duration of employment was 3.5 years for current employees, and 20.1 years for former employees. The average year of first year of employment was 1963 for active employees and 1966 for former employees. Assuming follow-up from the time of first employment until 1983, the expected number of person-years (p.yrs) contributed to the mortality study would be 1362 (17 years X 96 workers) for former employees and 300 (20 years X 15 workers) for current workers. Thus, the total number of person-years that this plant population would contribute to the study is 1662.

TABLE 1

Characteristics of Exposed Workers
in Terms of Year of Birth, Sex, Duration of Employment,
and First and Last Year Worked[a]
Tambrands Inc.
Rutland, Vermont

EMPLOYMENT STATUS	SEX	YEAR OF BIRTH	FIRST YEAR EMPLOYED	LAST YEAR EMPLOYED	DURATION OF EMPLOYMENT (YEARS)[b]
Inactive	M	1946	1967	1969	2
Inactive	M	1948	1966	1970	4
Inactive	M	1939	1964	1970	6
Inactive	M	1941	1964	1964	0.3
Inactive	M	--	1967	1972	5
Active	M	1930	1953		30
Active	M	1934	1968		15
Active	M	1942	1964		19
Active	M	1935	1962		21
Active	M	1949	1976		7
Active	M	1939	1960		23
Active	M	1922	1957		26

a. Based upon a sample of 200 inactive and 123 active personnel records.
b. Estimated by subtracting the first year worked from the last year worked.

Toxicity

Evidence from animal studies suggests that EtO may have carcinogenic properties.[6,7] A group of EtO manufacturers sponsored a study at the Bushy Run Research Center in which male and female Fischer 344 rats were exposed to EtO at airborne concentrations of 10, 33, or 100 parts per million (ppm) for 6 hours per day, 5 days per week for two years.[6] Two other groups of animals served as controls. Initially, there were 120 animals of each sex, in each exposure group. The researchers observed a statistically significant increase in the incidence of mononuclear cell leukemia among the female rats, and peritoneal mesothelioma among the male rats exposed to EtO. The increase in leukemia incidence was found to increase linearly as a function of EtO exposure. An elevation in mortality from brain cancers (glial type) was also observed in the rats exposed to EtO.

NIOSH researchers have recently reported on the results from an animal experiment which corroborated the findings of the Bushy Run Study.[7] Male Fischer 344 rats were exposed to EtO for 7 hours/day, 5 days/week for 2 years at airborne concentrations of 0, 50, or 100 ppm. There were 80 rats in each exposure group. Increases in the incidence of mononuclear leukemia, peritoneal mesothelioma, and cerebral gliomas were observed among the EtO exposed rats, relative to nonexposed controls.

Only a few epidemiologic studies have examined the potential human carcinogenicity of EtO.[8-10] Hogstedt, et al, conducted a retrospective cohort mortality study of a group of workers in a Swedish chemical factory that had previously been included in a hematologic investigation.[8] This facility produced EtO via the chlorohydrin process in which, in addition to EtO, there was potential exposure to ethylene, ethylene chlorohydrin, ethylene dichloride, and small amounts of bis(2-chloro-ethyl) ether. Among 89 "full-time" exposed workers, a statistically significant (p less than .01) excess of leukemia mortality was observed (2 observed versus 0.14 expected). In addition, a statistically significant (p less than .01) excess of stomach cancer was observed (3 observed versus 0.4 expected). Because of the mixed exposures, these findings could not be attributed to EtO; however, ethylene oxide and ethylene dichloride were the prime suspects.

Morgan, et al, conducted a retrospective cohort mortality study of workers involved in the production of EtO at a Texaco Facility.[9] A total of 850 workers were included in the study, of which 767 were potentially exposed to EtO. No EtO was detected in most samples taken in the production area, and all measurements in this area were below 10 ppm. No cases of leukemia were observed in this study; however, the authors estimated that the lowest relative risk that they had a high probability of detecting (80% power) was 10.5.

Hogstedt also reported on three cases of leukemia that occurred in a small group of workers at a Swedish company.[10] The company used a mixture of 50% EtO and 50% methyl formate to sterilize hospital equipment. The 8-hour TWA exposure for EtO at this facility was estimated at 20 ppm. According to national statistics, only 0.2 deaths due to leukemia were expected in this

cohort. One of the cases was exposed to benzene, a known leukemogen, and it was speculated that the combined exposure of EtO and methyl formate might produce a special risk.

EtO is also a potent alkylating agent capable of causing irreversible changes or mutations in cellular proteins and DNA in animals.[11,12] EtO is also a positive mutagen in several in vitro systems such as Salmonella typhimurium, viruses, and Tradescantia poludosa.[3]

Chromosomal aberrations related to EtO exposure have been observed in a number of animal studies and epidemiologic investigations.[7,12-19] Yager and Benz observed a dose related increase in sister chromatid exchanges (SCEs) among New Zealand white rabbits that were exposed via inhalation to 50 to 250 ppm of EtO.[13] NIOSH (Lynch, et al) recently reported preliminary findings in which cynomolgus monkeys were exposed to 0, 50, or 100 ppm of EtO for 7 hours per day, 5 days per week.[7] After 24 months of exposure, statistically significant increases were observed in the frequency of chromosomal aberrations (including quadriradial chromosomes) and SCEs in the peripheral lymphocytes of the 50 and 100 ppm exposed groups versus the controls.

Garry, et al, examined the occurrence of SCE in the peripheral lymphocytes of 12 EtO exposed workers and 12 nonexposed controls in a hospital sterilization facility.[14] The exposed group showed statistically significant elevations in the number of SCEs compared to the controls. Particularly high SCE frequencies were observed among 4 workers that had reported either neurologic or respiratory symptoms. The maximum peak exposure level of EtO measured at this facility was 36 ppm.

Cytogenetic abnormalities have also been observed in several studies of workers exposed to EtO. Ehrenberg, in a study of workers at a factory manufacturing and using EtO, observed a high frequency of chromosomal aberrations in 8 workers who were accidentally exposed to high concentrations of EtO. One case of leukemia was also observed among the 37 workers studied.[15]

American Hospital Supply initiated a cytogenetic survey of workers that were exposed to EtO in the sterilization of medical devices in 1972.[16,17] Seventy-five exposed workers at 9 facilities were studied, as well as 37 nonexposed workers who served as controls. Compared to controls, exposed workers were found to have statistically significant increased frequencies of SCEs and chromosomal aberrations.

In response to the findings from the American Hospital Supply study, Johnson and Johnson initiated a cytogenetic study of workers that were also exposed to EtO in the sterilization of medical products.[18,19] Approximately 50 workers not exposed to EtO were compared to 50 exposed workers at three facilities with 8-hour Time-Weighted Average (TWA) exposures to EtO of less than 1 ppm, 1-10 ppm, and 25-200 ppm, respectively. Statistically significant elevations in SCE frequency were observed in the latter two

facilities, and these changes have persisted after one year. The frequency of SCEs appeared to increase in a dose response manner. Chromosomal aberrations were also elevated in the high exposure groups; however, these findings were not statistically significant.

Applicable Standards and Recommended Levels

Prior to June 22, 1984, the Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) for EtO was 50 ppm as a TWA concentration for an 8-hour workshift, and the Immediately Dangerous to Life and Health (IDLH) level was 800 ppm.[20] However, OSHA established a new PEL of 1 ppm as an 8-hour TWA; this final standard will become effective on August 21, 1984.[21] In addition, an "action level" of 0.5 ppm as an 8-hour TWA was established (by OSHA) as the level above which employers must initiate periodic employee exposure monitoring and medical surveillance. The Environmental Protection Agency (EPA) supported the OSHA PEL of 1 ppm in the Federal Register (June 22, 1984).[22]

In 1977, NIOSH recommended a ceiling level of 75 ppm for 15 minutes.[3] This level, however, was set prior to the recognition of the carcinogenic potential of EtO. Based on recent findings, NIOSH recommends that EtO exposures not exceed 5 ppm for a maximum of 10 minutes per day and that exposures be controlled to less than 0.1 ppm determined as an 8-hour TWA (NIOSH Policy Statement, July 20, 1983). The American Conference of Governmental Industrial Hygienists (ACGIH) recommends a Threshold Limit Value (TLV) of 10 ppm for an 8-hour TWA based on data available prior to 1982.[23] However, in 1982, the ACGIH issued a notice of intended change in which it was proposed that the TWA concentration be lowered to 1 ppm. This recommendation will be reviewed in 1984.

Conclusions

Tambrands does not have any industrial hygiene data; in addition, the plant no longer sterilizes with EtO. Therefore, it would be extremely difficult to construct an exposure classification for job categories, unless another facility is found which uses the same process and has EtO sampling data. Otherwise, a more subjective exposure classification scheme would have to be developed.

There is an adequate personnel record keeping system for identifying workers exposed to EtO. However, prior to 1974, it will not be possible, based upon personnel records alone, to determine which workers were directly involved in operating the sterilizers and were thus probably highly exposed. Also, establishing an exposure matrix for this plant will be very difficult because there are no EtO monitoring data of any kind. In addition, the plant no longer uses EtO; therefore, it is not possible to conduct industrial hygiene sampling now. Based on the review of a sample personnel records, it is estimated that this plant would contribute about 1300 person-years to the study. In addition, the plant had no serious confounding exposure to a known leukemogen. Therefore, this facility meets all of the eligibility requirements as defined by the epidemiologic portion of the protocol, and therefore could be included in the study.

REFERENCES

1. NIOSH. Current Intelligence Bulletin 35 - Ethylene Oxide (EtO). DHHS (NIOSH) Publication No. 81-130, May 22, 1981.

2. National Occupational Hazard Survey, National Institute for Occupational Safety and Health, 1977.

3. Glazer, Z.R., Special occupational hazard review with control recommendations for the use of ethylene oxide as a sterilant in medical facilities. National Institute for Occupational Safety and Health, DHEW (NIOSH) Publication No. 77-200, 1977.

4. Chemical Economics Handbook, SRI International, Ethylene Oxide, January, 1980.

5. NIOSH. Draft Feasibility Study for a Cohort Mortality Study of Workers Exposed to Ethylene Oxide. Internal report from the Industrywide Studies Branch, June, 1983.

6. Snelling, W.M.; Weill, C.S.; and Maronport, R.R., Final report on ethylene oxide two-year inhalation study on rats. Project Report 44-20, Bushy Run Research Center, January 28, 1981. Submitted by Union Carbide Corporation to the U.S. Environmental Protection Agency under section 8(e) of the Toxic Substances Control Act, on behalf of co-sponsors of the study (February, 1981).

7. Lynch, D.W.; Lewis, T.R.; Moorman, W.J.; Sabharwal, P.S.; and Burg, J.R., Chronic inhalation toxicity of ethylene oxide and propylene oxide in rats and monkeys -- a preliminary report. Presented at the 21st Annual Society of Toxicology Meeting, Boston, Massachusetts, February 22-26, 1982.

8. Hogstedt, C.; Rohlen, O.; Berndtsson, B.S.; Axelson, O.; and Ehrenberg, L., A cohort study of mortality and cancer incidence in ethylene oxide production workers. Br. J. Ind. Med., 39:276-280, 1979.

9. Morgan, R.W.; Claxton, K.W.; Divine, B.J.; Kaplan, S.D.; and Harris, V.B, Mortality Among Ethylene Oxide Exposed Workers. J. Occ. Med., 23:767-770, 1981.

10. Hogstedt, C.; Malmqvist, N.; and Wadman, B., Leukemia in workers exposed to ethylene oxide. JAMA, 241:1132-1133, 1979.

11. Calleman, C.J.; Ehrenberg, L.; Jansson, B.; Osterman-Golkar, S.; Segerback, K.; and Wachtmeister, C.A., Monitoring and risk assessment by means of alkyl groups in hemoglobin in persons occupationally exposed to ethylene oxide. J. Environ. Pathol. Toxicol., 2:427-442, 1978.

12. Ehrenberg, L.; Heische, K.D.; Osterman-Golkar, S; and Wennberg, I., Evaluation of genetic risks of alkylating agents: Tissue doses in the mouse from air contaminants with Ethylene Oxide. Mutat. Res., 24:83-103, 1974.

13. Yager, J.W., and Benz, R.D., Sister chromatid exchanges induced in rabbit lymphocytes by ethylene oxide after inhalation exposure. Environ. Mutagen., 4:121-134, 1982.

14. Garry, V.E.; Hozier, J.; Jacobs, D.; Wade, R.; and Gray, D., Ethylene Oxide: evidence of human chromosomal effects. Env. Mutag., 1:375-382, 1979.

15. Ehrenberg, L., and Hallstrom, T., Haematologic studies on persons occupationally exposed to ethylene oxide. In: International Atomic Energy Agency Report, SM 92/26, pp. 327-334, 1967.

16. Abrahams, R.H., Recent studies with workers exposed to ethylene oxide, in The Safe Use of Ethylene Oxide. J.F. Jorkasky, ed. Health Industry Manufacturers Association, Washington, D.C., HIMA Report No. 80-4: 211-220, 1980.

17. Abrahams, R.H., Chromosomal changes in workers exposed to ethylene oxide -- an update. Ethylene Oxide Worker Safety Issues. J.F. Jorkasky, ed., Washington, D.C., HIMA Report No. 82-2:27-38, 1982.

18. Herman, A.A., (Johnson and Johnson Corporate Submittal to OSHA). Pilot research chromosome study of workers at sites where ethylene oxide gas is utilized as a sterilant. Submitted to OSHA, March 30, 1982.

19. Jones, J.P., Chromosomal changes in employees exposed to ethylene oxide. Ethylene Oxide Worker Safety Issues. J.F. Jorkasky, ed., Washington, D.C., HIMA Report No. 82-2, 5-25, 1982.

20. Occupational Safety and Health Administration (OSHA), Safety and Health Standards 29 CFR 1910, General Industry Standards, OSHA 2206, Revised, June, 1981.

21. Federal Register, Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910, Occupational Exposure to Ethylene Oxide. 49(122):25734-25809, June 22, 1984.

22. Federal Register, Ethylene Oxide; Certain Pesticide Products Registered for the Sterilization of Equipment and Supplies in Hospitals and Health Care Facilities. 49(122):25675-25676, June 14, 1984.

23. Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment with Intended Changes for 1983-84, American Conference of Governmental Industrial Hygienists, 1983.

24. NIOSH Manual of Analytical Methods, Second Edition, Vol. 3, DHEW (NIOSH) Pub. No. 77-157-C, 1977.

25. Federal Register, Notice of Termination of Voluntary Testing and Certification Programs for Gas Detector Tube Units and Industrial Sound Level Meters. 48(191):44931-44032, 1983.