UNION CARBIDE CORPORATION
CORPORATE PRODUCT SAFETY
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August 4, 1980

Dr. John Stafford
Imperial Chemicals Industries, Ltd.
Plastics Division
P. O. Box No. 6 Bessemer Road
Welwyn Garden City
Hertfordshire AL71HD
England

Subject: Brain Tumors
Union Carbide Corporation
Texas City, Texas

Dear John,

Knowing your great interest in the subject I am sending you the following items:

1. Clipping from The Washington Post dated July 24, 1980 on "Cancer Outbreak Found at Two Texas Plants".

2. Alexander, Victor, M.D. - "Brain Cancer in Petrochemical Workers - A Case Series Report Draft VI" Occupational Safety and Health Administration, U. S. Dept. of Labor, Washington, D. C., May 1980.

   This draft report and UCC comments are for your information only. Table 5 showing recognized and suspect carcinogens at the plant is misleading. Acrylonitrile, dioxane, hydrazine and vinylidene chloride are over-emphasized and should not be viewed as universal factors at the plant.

3. Lasagna, L., "Statistics: A New Co-Carcinogen", The Sciences, May/June 1980.

   This has no bearing on the subject, but it might be interesting.

4. Chemical Regulation Reported dated July 18, 1980 "Citizen Petition Seeks Regulation, Cites Carcinogenicity of Plasticizer"

We appear to have a developing furore on di 2 ethyl hexylphthalate and other vinyl plasticizers. If you have any news or data in the European area, please let us know.

Very truly yours,

R. N. Wheeler, Jr.
Assistant Director
Product Safety

RNWJr./rhw

Enclosures

cc: Dr. T. R. Torkleson

chemclips

Date:
JUL 24 1980

Compiled by Jane Rasmussen • 202/328-4229
Chemical Manufacturers Association, 1825 Connecticut Ave., N.W., Washington, D.C. 20009

THE WASHINGTON POST Thursday, July 24, 1980

Cancer Outbreak Found at 2 Texas Plants

By Victor Cohn and Joanne Omang
Washington Post Staff Writers

A serious outbreak of brain cancer has been discovered in two Texas petrochemical plants, and federal officials fear they may find a high incidence of brain cancer elsewhere in the huge industry that makes chemicals from oil.

In a probe that started in early 1979, 25 brain-tumor cases — 24 of them fatal so far—have been discovered among recent and past workers at a Dow Chemical plant in Freeport, Tex. Eighteen other fatal cases turned up at a Union Carbide plant in Texas City, Tex.

Both plants are in the Houston-Galveston area, which is thickly dotted with plants that make or process petrochemicals. But so far, federal investigators have not been able to pinpoint a guilty chemical—or, more likely, a group of chemicals or a process—though there are several under suspicion.

The brain-cancer incidence among workers in the plants in the last 24 years is twice the normal level in the general population, Dr. Richard Waxweiler of the National Institute of Occupational Safety and Health (NIOSH) said yesterday.

All of the victims are men. Few women work in the plants.

Investigators from the two federal agencies involved—the Labor Department's Occupational Safety and Health Administration (OSHA) and the Department of Health and Human Services' NIOSH—have not yet been able to look in detail at other plants, though they have started some investigations.

They have reports, they said, of possible concentrations of similar brain cancers in plants at Beaumont and Port Arthur, Tex.; Charleston, W. Va.; Louisville, and San Francisco, as well as one in Canada.

"There's no reason to suspect all petrochemical plants," Waxweiler said. But Dr. Victor Alexander of OSHA said there may be "five or six others" at least, and J. William Lloyd, OSHA epidemiologist, said, "There may be any number of chemical plants involved."

Spokesmen for Dow and Union Carbide noted that the results so far are inconclusive. "We see no common thread that would suggest [that] exposure to any particular material or location in the plant" is involved, said James Hansen for Dow. "There is nothing so far to connect the workplace to the brain cancer."

Damon Ingle, manager of Union Carbide's Texas City plant, agreed that the cancer incidence may be higher than the national average but has not yet been proved higher than incidence in the area. "If it is, we're just as anxious as anybody to get to the bottom of it," he said.

When the study began in 1978, researchers suspected that the cause of the cancers might be vinyl chloride, which is associated with the glioblastoma multiforms type of cancer that is the predominant one being found. But some of the victims had no exposure to vinyl chloride, the NIOSH researchers said.

Tony Mazzocchi of the Oil, Chemical and Atomic Workers Union said preliminary reports from other studies found higher-than-normal rates of brain and stomach cancers among petrochemical workers along the Texas Gulf Coast, and as a result the union and the National Cancer Institute are studying the entire industry. Eventually 60,000 workers will be checked, he said.

"There is a cancer epidemic among American workers and certainly among the workers we represent," Mazzocchi said.

Petrochemicals involve more than 30,000 workers in Texas alone and bring in about $3 billion annually, according to state figures. The Houston Chamber of Commerce reported last year that six of every 10 pounds or gallons of U.S. petrochemical production come from the Texas Gulf Coast. Dow's Freeport plant, which covers 4,500 acres and employs 7,000 persons, is the biggest one there.

OSHA and NIOSH officials are planning a joint conference on the problem, possibly in October, involving government, industry and the scientific and medical worlds. The situation "is something we didn't know about before," said Dr. Irving Selikoff of Mount Sinai Medical Center in New York.

He is editor of the American Journal of Industrial Medicine, which will soon publish the first scientific report on the outbreak, written by a group headed by Dr. Alexander of OSHA.

"We just don't know how widespread this problem is," said Sheldon Samuels, AFL-CIO director of occupational health and safety. There has been no industrywide study of it, just as "there is no systematic epidemiology yet of the American work force," he said.

But he said the fact that Dr. Eula Bingham, OSHA director, "put together OSHA's first medical and scientific team" meant OSHA had a skilled team to go to the Union Carbide plant early last year and begin to study the brain tumors.

Alexander headed that first investigation, which was triggered by a complaint in late 1978 from a brain cancer victim at Union Carbide.

Ironically, that victim's cancer had spread from another part of his body. So he is not officially considered one of the victims.

But it's important for workers to speak up, Waxweiler said. "If we hadn't heard from that worker," he said, "we wouldn't have known about Union Carbide. We wouldn't have known about Dow or any of it."

Working with Texas doctors and health officials and with Union Carbide—a company that has been "highly and unusually cooperative," Alexander said—Alexander found 18 tumors among 9,000 people who had worked at the Texas City plant since 1956, when the first victim died.

He then investigated "a second plant"—which he would not name—and found five brain tumor deaths. But two of these people had also worked at Union Carbide.

Statisticians at the famed M.D. Anderson Hospital and Tumor Institute in Houston then combed their computerized Texas death records for lists of brain cancer victims and their work records.

This led the investigators to the Dow plant, the site of 25 tumors among more than 30,000 workers since the early 1960s. Studies now are focusing on company records to determine where the men worked and what

(more)

Petrochemicals

chemicals they were exposed to in the vast complex, which makes 200 different products, including antifreeze, chlorine, latex, ethylene, vinyl chloride and other industrial chemical building blocks.

Workers at Union Carbide's plant had jobs "all over the place," Waxweiler said. One of the few common denominators was that 13 of the 18 victims had worked there more than 15 years.

The Texas plant studies, and the studies of workers' backgrounds, are still not complete, federals investigators said.

But "we strongly suspect" said Alexander, that the cause of the tumors may be not a single chemical but "a chemical process"—exposure to all or some of the many steps that lead to a single chemical product. Or, he said, it may be more than one process involving the 300 or so chemicals commonly found in a modern petrochemical factory.

European Chemical Firms Expect Profits To Fall Sharply in 1980 Due to Recession

7/24 By Jonathan Spivak And John M. Geddes

Staff Reporters of The Wall Street Journal

The rapid retrenchment in the West European chemical market will cut deeply into profits of major European producers this year.

The sales decline that started abruptly in March has already spurred price cutting by Continental European companies and plant curtailments in the United Kingdom, where chemical concerns are even more severely hit.

"With Europe's dropoff in industrial production in 1980, chemicals will almost certainly drop," declares Chris Burbridge, an investment analyst at Phillips & Drew, a London stockbroker.

Besides the drag of a general business slowdown, European chemical concerns are being hurt by substantial stockpiling last year in advance of expected price increases, inroads into the market by aggressive selling of lower-cost American imports, and the sales-inhibiting impact of strong currencies, such as the British pound.

Hurting, too, are rising prices for natural gas and oil. The cost of such raw materials for Western European chemical concerns rose 10% in the first quarter of this year and 40% in the past 12 months.

The producers, moreover, are facing increasing competition from Eastern European chemical plants, many of which were brought into production in recent years with the aid of Western capital.

Most European chemical concerns, however, are broadly diversified, and some areas of their business, such as agricultural chemicals, drugs and inorganic chemicals, are holding up. "The chemical crunch won't be so overwhelming as in 1974-75," reasons one industry specialist, referring to the squeeze five years ago following the quadrupling of oil prices by members of the Organization of Petroleum Exporting Countries.

Industry leaders expect the next 12 months to be the most difficult, with a pickup beginning in the second half of 1981 and further recovery in 1982. "The current recession, which is only now beginning in Europe, will last until mid-1981," predicts Jean Gandois, president of Rhone-Poulenc S.A., the French chemical concern.

In the U.K., the chemical-industry slide began in March, and results in April and May have been "disastrous," says one industry specialist. The British companies have been affected by plummeting industrial production, which is expected to be down 4% for the year, in contrast to a 1% to 2% increase in Continental Europe; the strong pound which prices British products out of some export markets, and higher prices for some raw materials than those paid by West German and French companies.

Imperial Chemical Industries Ltd., the biggest U.K. chemical company, is likely to end the year with pretax profit of less than the equivalent of $1.19 billion, down more than 10% from last year, industry analysts forecast. ICI, itself an oil producer, will benefit from new North Sea Oil production, but the gains won't be enough to offset chemical-earnings declines. During the 1975 recession, ICI pretax profits fell 30%.

Other U.K. chemical concerns are also running into serious difficulties. Pretax profit could be down as much as 20% at Laporte Industries Ltd. and 5% to 10% at BOC International Ltd., industry specialists say.

"One thing is sure, 1980 will certainly be a worse year for the chemical industry than 1979," says Karl Wamsler, chairman of the German Chemical Industry Association. Chemical production in Germany began to lag in April and weakened further in May and June, he notes.

All the big three German chemical companies—Hoechst AG, Bayer AG and BASF AG—have been affected by the downturn, but are hesitant to forecast the effect on results.

Matthias Seefelder, chairman of BASF, says that the chemical industry's "economic prospects will be increasingly influenced by world-wide political insecurity, which will handicap world trade, and by recessionary tendencies in the U.S."

While sales for the German chemical concerns rose 20% in the first quarter, the rate of increase dropped to 12% for the first half and will further decline to 9% for the full year, Deutsche Bank AG predicts. And the bank notes that most of the full-year increase will be due to higher prices.

In Switzerland, a spokesman for F. Hoffmann-La Roche & Co. says: "Inflation is the main problem, as prices can't be raised enough to compensate for wage increases

NY Times 7/24

Louisiana Waters Searched For Toxic-Chemical Drums

SHELL BEACH, La., July 23 (AP) — The Coast Guard searched a Mississippi River waterway near here today for more than 150 drums of hazardous chemicals whose potential danger led to the closing of an outlet to the Gulf of Mexico.

The drums went into the water last night from the cargo ship Testbank after she collided with the Sea Daniel, a Panamanian ore carrier, the Coast Guard said. No injuries were reported in the collision about 25 miles southeast of New Orleans.

Missing from the Testbank were 63 drums of hydrobromic acid and a cargo ship container holding 99 drums of penta chlorophenol. The hydrobromic acid forms a poisonous gas when it is combined with water, but the gas dissipates quickly in open air, the Coast Guard said.

Washington Post 7/24

U.S. Accuses Chemical Maker

CHICAGO—The federal government wants to hold Monsanto Corp. liable for contaminating Lake Michigan by selling a toxic chemical to a lakeside maker of boat motors.

Civil charges against Monsanto were added to a 1978 lawsuit against Outboard Marine Corp. of Waukegan, Ill. The government says Monsanto continued selling polychlorinated biphenyl to OMC even when it knew the motor firm was discharging the pollutant into the water.

OMC has filed its own complaint against Monsanto.

7/24

Wall Street Journa

GOVERNMENT REGULATIONS r banks to tell customers more than they to know. Northwestern National Ba Minneapolis sent customers a 4,500 booklet entitled "New Electronic Transfer Disclosure Notice." To test re ship, 100 of the booklets contained an paragraph promising $10 for the askin one has yet requested the money.

JUL 24 1980

chemclips

Compiled by Jane Rasmussen
Chemical Manufacturers Association

UCC
049376

New York Office
22nd Floor

UNION CARBIDE

5-20-80

FROM THE DESK OF
R. Van Mynen
551-6131

RE: TEXAS CITY EPIDEMIOLOGY STUDY

J. V. WHITTLESEY-46

JOHN,

THE ATTACHED IS FYI. NO NEW CAUSE/EFFECT RELATIONSHIPS HAVE BEEN IDENTIFIED. DR. VIC HERMAN OF OSHA IS THE AUTHOR. THIS DRAFT WAS SENT TO UCC HEALTH PROFESSIONALS FOR COMMENT AND, IN ADDITION, THEY WERE ASKED IF THEY WOULD LIKE TO BE INCLUDED AS CO-AUTHORS. THIS WAS DECLINED. THE PAPER WILL MOST PROBABLY BE PUBLISHED IN A MEDICAL/HEALTH JOURNAL. IT HAS NOT BEEN ACCEPTED FOR PUBLICATION AT THIS TIME.

Ron Van Mynen

Brain Cancer in Petrochemical Workers - A Case Series Report

Nineteen primary brain cancer deaths have been found among workers at one United States petrochemical plant. We believe this is the largest single series of presumably occupationally-related brain cancers reported in the medical literature.

In November, 1978, the Occupational Safety and Health Administration (OSHA), the Federal occupational health enforcement agency of the U.S. Department of Labor, received an employee complaint that work-related chemical exposures might have caused brain tumors in fellow workers as well as his own recently diagnosed brain cancer.

OSHA's Office in Houston, Texas began an investigation of brain cancer mortality at the employee's worksite, a moderate-sized petrochemical production facility in Texas City, located in Galveston County south of Houston. Workers, family members and surviving relatives, union officials, local physicians and hospital staff, Texas state health officials and company personnel were interviewed. Four primary brain tumor deaths were discovered among former employees in this way. It is ironic that the worker who filed the original complaint with OSHA was found to have a metastatic carcinoma to the brain, and is not counted among the cases. The plant physician subsequently reviewed death information maintained by the medical department, primarily covering workers who died while employed and who by virtue of 15 years of company service were eligible for death benefits. Ten deaths from primary brain cancer were identified. These ten

included the four previously found. OSHA then requested technical assistance from the National Institute for Occupational Safety and Health (NIOSH), its companion research agency in the U.S. Department of Health, Education, and Welfare.

In February, 1979 OSHA, NIOSH, and the company established a collaborative study plan to investigate the apparent excess of brain cancers. An historical prospective cohort mortality study was begun to determine the Standardized Mortality Ratio (SMR) for brain cancer, and whether there exists any other unusual mortality pattern. Also included within the cohort study is a case-control study of all primary brain cancer cases to establish whether a particular job or chemical exposure at the plant is associated with an excess risk of brain cancer. A reference neuropathology laboratory has agreed to examine autopsy and surgical pathology specimens to provide histologic confirmation of the cause of death. Each of these studies is well underway, and results are expected within a few months.

An experimental case-finding technique was added to the study design to provide an early estimate of the extent of the problem. A computer-assisted search was conducted of Texas Bureau of Vital Statistics data maintained by the M.D. Anderson Tumor Institute Department of Epidemiology. Since company records showed that 99% of plant employees reside in Galveston, Harris and Brazoria counties, a list of all primary brain cancer deaths among males more than twenty years of age from 1950 through 1977 was obtained for these three counties. This list of 732 primary brain

cancer deaths was matched against company personnel files. Four additional confirmed cases resulted. Further investigation of company records revealed two more cases. Three other employees became ill during the preliminary period of the study. All cases were deceased as of March, 1980. The current total of 19 cases is the subject of this case series report.

Work history data for the 19 cases are provided in Table 1. The average age at death for the cases was 52; the youngest died at age 30, and there were four deaths after age 60. Over half the deaths occurred between ages 50 and 59. The age distribution observed in this series does not differ significantly from that reported in other series.[1,2,3]

Total length of employment at the plant ranged from 1 month to slightly more than 35 years, with a median value of 20 years. Two cases had short exposure periods of 38 and 29 days respectively. Median length of employment excluding these two cases was 22 years. The interval from first employment to death, which provides an estimate of latency, varied from as few as 3 1/2 years to nearly 36 years, with a median of 24 years. The median values for exposure and latency period in this series are typical of those found for other tumor types in occupational cancer investigations and are consistent with a hypothesis of occupational etiology resulting from chemical exposures.

No particular trend or clustering by hire date among the cases has been identified as compared to the general plant population. One case was

hired in late 1940 as part of a small plant start-up crew. Three more were hired in 1941 during the first year of plant operation, and the others at fairly regular intervals until the last group of four started work during 1953. The first death occurred in 1956, followed by five others during the 1960's. Twelve of the deaths occurred after 1970, three of them during the past year. No established pattern is evident from the observed years of death, but there is no evidence that the rate of appearance of cases is declining.

The plant has a current workforce of slightly more than 2,200, including nearly 1,500 hourly and production employees. The average age is 44, and approximately 1,050 current employees have 25 or more years of company service. Since the plant began operation in 1941, there have been a total of 8,850 employees. These include 6,802 white males, 884 black males, 1,083 white females, and 81 black females through December, 1979. The distribution by county of residence for current workers is provided in Table 2. The plant also engages a temporary independent contractor workforce of 100-250 daily, mostly for construction jobs. Unfortunately, no employment records are available for this group.

Demographic and cause of death data from the death certificates are provided in Table 3. All cases occurred among male employees, 18 whites and 1 black. The mortality rate for primary brain cancer in Texas among black males is about one-half that for white males.(4) However, very little can be said regarding the racial distribution of cases, since it appears

that increased numbers of black employees have been employed at the plant only in recent years.

All but one of the cases were native-born Americans; the lone exception was Norwegian. The great majority of the cases were born in Texas, two were from Louisiana, and one each was from Massachusetts, New Mexico, and Oklahoma. None of the U.S. states of origin have a particularly high risk for brain cancer, compared to the U.S. national average. There is presently no information available about the age of the cases when they moved to Texas, or where else they may have lived.

Sixteen of the cases were Galveston County residents at the time of death; the other three were from Harris County. The possibility of an environmental etiology related to Galveston County was considered. County-wide data from the National Cancer Institute on the brain cancer mortality rates for Harris, Galveston, and Brazoria Counties from 1950-1969 are in the mid-range for Texas and U.S. national values as shown in Table 4. A survey made by the Texas State Department of Health for 1977 showed that the Galveston County brain cancer crude mortality rate was 3.6/100,000. There is no evidence from these data that local environmental factors outside the plant are responsible for the apparent excess of brain cancer.

To obtain an initial estimate of the brain cancer risk, brain cancer deaths among adult white males in Galveston County were analyzed using the list described previously. A total of 54 primary brain cancer deaths occurred in the county from 1962 through 1977. To establish a rough

comparison, information from the Health Services Administration on county population characteristics was used.(5) In 1970 Galveston County was 68% white, and 62% of the population were between the ages of 14 and 64. A 1970 county population estimate was 170,000 of whom 49% were males.(6) Thus, the white male population of employment age at risk during 1962-1977 was somewhat less than 38,000; the plant white male population was about 1,800 or about 5% of the county total. Yet during this period, 11 of 54 brain tumor deaths among county residents occurred in plant employees, nearly 20% of the total. This suggests an approximate plant-wide risk of about four-fold.

The underlying causes of death as recorded on the death certificates are listed in Table 2. Nine cases of glioblastoma multiforme were recorded directly on the certificate. Further investigation of hospital and physicians' records provided evidence that there were six additional cases of glioblastoma multiforme among the total of 19. According to these records one case also was reported to be a metastatic lesion to the cerebellum. Preliminary medical evidence thus suggests that 81% (15/19) of the tumors were glioblastomas. Because this type of tumor usually accounts for 40-55% of deaths in reported brain cancer series, this would indicate an excess of glioblastoma multiforme among these cases.(1,2,3,7,8) The difficulty of precise neuropathological diagnosis for brain cancer is recognized, and the pathology review is expected to better define this observation.

The plant is a diversified petrochemical manufacturing facility with a large number of major product lines, including ethylene, butadiene, naphtha,

ethylene dichloride, diethyl sulfate, glycols, aldehydes, acetates, alcohols, amines, organic acids, and plastics and resins (polyethylene, vinyl chloride-vinyl acetate copolymers, phenol-formaldehyde resin). Review of the plant's chemical inventory reveals the presence of at least 11 recognized or suspect carcinogens in significant quantities as raw materials, reaction by-products, or manufactured compounds. These are shown in Table 5. Careful preliminary examination of the work histories of affected employees does not yet establish any common job title, department code, or chemical exposure. Eight of the men were chemical operators in production departments but they were spread throughout the plant, and worked on different chemical processes. Six others were maintenance workers who may have had the opportunity for plant-wide exposures over the years. Two worked in the chemical shipping department as weighmasters with likely multiple exposures. Five worked in various construction trades. Work histories on the cases are limited to employment by the company with two exceptions. Case 1 was a salaried employee at a nearby petrochemical plant from 1948-1964, and Case 6 worked as a pipefitter from 1952-1974 in the same plant. No information about other potential chemical exposures is presently available. The detailed examination of work histories in the case-control study offers the best opportunity to establish a connection between a particular chemical exposure or type of work and an excess risk of brain cancer.

A detailed literature search for compounds inducing brain cancer has identified 26 different chemicals from experimental animal studies as shown in Table 6. Review of available epidemiological studies provided in Table 7

offers several intriguing clues, but little solid documentation for occupationally-related brain tumors, except in the case of vinyl chloride.[9,10] Recent mortality studies of oil refinery workers in Canada [11] and petrochemical workers in Texas [12] suggest the possibility of an excess brain cancer risk among these groups, although as yet no specific causative agent has been identified.

A comparison of experimental studies, epidemiological data, and the plant chemical inventory shows that vinyl chloride, acrylonitrile, and diethyl sulfate are possible suspect agents for inducing brain cancer in these workers. On the basis of prior knowledge from human and animal studies, and its presence in the work environment under poorly controlled circumstances in the past, vinyl chloride must be the first compound considered. However, to date, examination of the work histories of the 19 cases does not support a significant positive association with vinyl chloride exposure, and other agents must be carefully evaluated.

The information available indicates that this number of brain tumors is excessive in a population of this size, and that the tumors are likely to be occupationally-related. There is no good evidence to implicate non-plant, general environmental factors. A very careful and thorough investigation of this situation must be made, since a previously unsuspected chemical exposure may be responsible for this striking appearance of brain cancers in a single petrochemical plant.

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Table 1. WORK HISTORY DATA FOR 19 PRIMARY BRAIN CANCER CASES IN A TEXAS PETROCHEMICAL PLANT

Case	Date of Hire	Date of Death	Age at Death	Length of Employment (years-months)	Job Title	Department
-1	12/16/40	05/15/64	51	3-6	Operator	Production
-2	05/18/41	02/19/66	56	24-8	Operator	Production
-3	07/29/41	05/18/76	66	31-8	Foreman	Maintenance
-4	11/30/41	12/13/65	55	20-4	Operator	Production
-5	07/09/44	10/28/79	59	35-0	Boilermaker	Structural Shop
-6	09/18/44	05/21/74	55	0-1	Operator	Production
-7	09/19/46	03/07/79	55	32-3	Laborer/Oiler	Maintenance
-8	09/26/46	03/22/73	63	26-6	Operator	Production
-9	01/12/48	01/26/71	53	1-2	Painter	Maintenance
-10	09/21/48	07/02/75	49	2-1	Pipefitter	Maintenance
-11	03/02/49	06/05/71	61	22-3	Operator	Production
-12	01/25/50	01/13/68	66	16-7	Equip. Operator	Maintenance
-13	10/19/50	05/14/74	59	17-1	Operator	Energy Systems
-14	10/23/50	02/18/80	57	28-10	Operator	Production
-15	09/19/51	01/08/74	52	22-3	Machinist	Machine Shop
-16	04/27/53	10/03/56	33	0-1	Machinist	Maintenance
-17	03/17/53	04/05/62	30	8-7	Weighmaster	Shipping
-18	08/21/53	05/05/71	44	17-3	Operator	Production
-19	10/30/53	12/21/78	49	24-8	Weighmaster	Shipping

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Table 2. CURRENT PLANT WORKFORCE BY COUNTY OF RESIDENCE

County of Residence	Type of Employee Hourly	Salaried	Total	Percent
Galveston	1,389	609	1,998	90.0
Harris	44	110	154	6.9
Brazoria	41	15	56	2.5
Other	7	4	11	0.5
Total	1,481	738	2,219	100.0

Source: Data provided by company

Table 3. DEATH CERTIFICATE DATA FOR 19 PRIMARY BRAIN CANCER CASES IN A TEXAS PETROCHEMICAL PLANT

Case	Race/ Sex	Residence	Place of Birth	Cause of Death: Death Certificate	Cause of Death: Medical Records
1	WM	Galveston	Texas	Carcinoma of Brain	Glioblastoma (MR)*
2	WM	Galveston	Missouri	Malignant Brain Tumor	Meningioma (A)
3	WM	Harris	Texas	Brain Tumor	Glioblastoma (A)
4	WM	Galveston	Texas	Brain Tumor-Meningioma	Meningioma (MR)
5	WM	Galveston	Louisiana	Glioblastoma	Glioblastoma (SP)
6	WM	Galveston	Texas	Brain Tumor-Glial IV	No Records Available
7	BM	Galveston	Texas	Glioblastoma	Glioblastoma (MR)
8	WM	Galveston	Texas	Glioblastoma	Glioblastoma (SP)
9	WM	Galveston	Massachusetts	Cerebellar Tumor	Metastatic Cerebellar Tumor (SP)
10	WM	Harris	Texas	Astrocytoma	Astrocytoma-Grade I (SP)
11	WM	Galveston	Texas	Malignant Glioma	Glioblastoma (MR)
12	WM	Galveston	New Mexico	Glioblastoma	Glioblastoma (A)
13	WM	Galveston	Norway	Glioblastoma	Glioblastoma (SP)
14+	WM	Galveston	Texas	Glioma-Grade III	Astrocytoma-Grade IV (MR)
15	WM	Galveston	Texas	Glioblastoma	Glioblastoma (A)
16	WM	Harris	Texas	Glioblastoma	No Records Available
17	WM	Galveston	Louisiana	Brain Tumor	Glioblastoma (A)
18	WM	Galveston	Texas	Malignant Glioma	Glioblastoma (SP)
19	WM	Galveston	Texas	Brain Tumor	Glioblastoma (A)

+Data from company records, death certificate not available
*Source: MR-Medical Records; A-Autopsy; SP-Surgical Pathology

Table 4. BRAIN AND OTHER CNS CANCER MORTALITY, 1950-1969: AVERAGE ANNUAL AGE ADJUSTED RATES PER 100,000

Location	White Male	White Female	Black Male	Black Female
United States	4.4	2.9	2.3	1.5
Texas	4.3	2.9	1.9	1.5
Galveston County	4.5	2.9	2.5	2.1
Harris County	4.5	3.6	2.0	1.9
Brazoria County	3.1	3.9	1.2*	1.5

*Based on one case

The range of U.S. rates for males for counties with >10 deaths from 1950-1969 were 3.1-5.4 (white) and 1.3-3.9 (black). The range of Texas rates for white males for counties with >deaths from 1950-1969 was 2.3-10.8.

Source: U.S. Cancer Mortality by County, 1950-1969, National Cancer Institute, DHEW Pub. No. (NIH) 74-615, Bethesda, Maryland, 1974

Table 5. RECOGNIZED AND SUSPECT CARCINOGENS IN A TEXAS PETROCHEMICAL PLANT

Acrylonitrile	Isopropyl Oils
Benzene	Trichloroethane
Diethyl sulfate	Trichloroethylene
Dioxane	Vinyl chloride
Ethylene dichloride	Vinylidene chloride
Hydrazine	

Table 6. EXPERIMENTAL BRAIN CARCINOGENS

2- Acetylaminofluorene (13)
Acrylonitrile (14)
1-Aryl-3,3-Dialkyltriazenes (15)
Azoethane* (16)
Azoxyethane* (16)
Azoxymethane (15)
Butylnitrosourea (17)
Cycasin (18)
1,2-Diethylhydrazine (15)
Diethylnitrosamine* (15)
Diethyl Sulfate* (19)
Dimethylbenzanthracene* (20)
Dimethyl Sulfate* (19)
Elaiomycin (21)
Ethyl methanesulphonate (22)
Ethylnitrosobiuret* (16)
Ethylnitrosourea* (23)
1-Methyl-2-Benzyl-Hydrazine* (15)
Methyl methanesulphonate (24)
Methylnitrosourea* (25)
Methylnitrosourethane (intraplacental)
Procarbazine* (23)
Propane Sultone (27)
Propylene Imine (27)
Pyrrolizidine Alkaloids (28)
Vinyl Chloride (29)

*Transplacental carcinogenesis

Table 7. EPIDEMIOLOGICAL STUDIES:
CLUES TO HUMAN BRAIN CANCER ETIOLOGY

Aluminum Workers (30)

Anti-Convulsant Use (31,32,33)

Farm/Rural Residents (3)

Geographic Clustering
Kentucky (34,35), Rhone Valley (36)

Halomethanes in Drinking Water (37)

Lead Smelter Workers (38)

Machinists (39)

Oil Refinery Workers (11)

Petrochemical Workers (12)

Rubber Workers (40,41,42)

Toxoplasmosis (43)

Vinyl Chloride Workers (9,10,44,45)

UNION CARBIDE CORPORATION

270 PARK AVENUE, NEW YORK, N.Y. 10017

OCCUPATIONAL SAFETY & ENVIRONMENTAL AFFAIRS DEPARTMENT

CORPORATE EPIDEMIOLOGY

Victor Alexander,M.D.,
Chief Medical Advisor, OSHA,
Room N3656
U.S.Department of Labor,
Occupational Safety & Health Administration,
Washington,D.C. 20210

21st May 1980

Dear Doctor Alexander,

Re: "Brain Cancer in Petrochemical Workers - A Case Series Report"
DRAFT VI

Speaking on behalf of my Corporation and those staff expressly involved in this investigation, in collaboration with your Administration and NIOSH, I wish to express our appreciation for this opportunity to review the above cited draft paper, prior to your submitting it for publication. We do have a few comments and suggestions to make, which we hope may be helpful in enhancing the accuracy and clarity of the paper. I shall handle them on a line by line basis:

Page 1 - first sentence. We feel it is not strictly true that nineteen primary brain cancer deaths have been found, but rather eighteen, one having turned out to be a metastatic cerebellar tumor (Case No.9) as you comment in the text, and in Table 3. We appreciate that this case was classified as "cerebellar tumor" on the Death Certificate, and in some aspects this paper describes a Death Certificate Study. Would it not be better to give the number as eighteen and add, in parentheses (nineteen as originally certified)?

Page 1 - third and second lines from bottom: we suggest: "...primarily covering workers who died while employed and also those who by virtue of 15 years...."

Page 3 - lines 12 and 13 - we suggest:"Two cases had short periods of employment, 38 and 29 days respectively."

Page 3 - lines 17 through 20 - we feel that this is a weak argument, almost a non-sequitur: long latency periods between onset or death and postulated causal exposures are equally consistent with non-occupational cancer, surely.

Page 4 - line 5 - In fact thirteen of the deaths have occurred since 1970 (the last one recorded to date in February of this year).

Page 5 - Second complete paragraph - We feel that the conclusion in the final sentence of this paragraph may be unwarranted at this time. Brain cancer mortality rates for the relevant three counties have been reviewed only through 1969 and 13 of our 18 deaths have occurred since 1970. It is our impression from talking with Dr. Patricia Buffler of the University of Texas Health Science Center at Houston that in the past decade brain cancer mortality rates for that general region may well have climbed steeply, either with or relative to national rates.

Pages 5 & 6 - Paragraph commencing on Page 5 and ending on Page 6 - We all have real problems with this method of estimation. The statement that the plant white male population at risk, which contributed 11 of 54 brain tumor deaths for the county, during 1962-1977, was 1800 or 5% of the county total, appears to refer to a static plant population. However, many more than 1,800 would have "passed through" the plant and have been at risk of dying over that 16 year period. It is true that there would have been some in-migration and out-migration to and from the county over such a period too, but such dynamic population effect would be proportionately much less in a population the size of a county, than in the population of a single industrial plant. We do not have any argument with the resulting estimate of an apparent four-fold relative risk for the plant population, which is consistent with our crude PMR estimate based on the total deaths recorded at the plant since 1941, but rather with the valididty of the method by which it was reached.

Page 6 - last two lines and first 3 lines of Page 7 - this list of major product lines is an historically comprehensive one which does not reflect the situation at any point in time: we suggest: "...a large number of major product lines, which over the years have included ethylene, butadiene,etc....."

Page 7 - lines 15 - 17 - Cases 1 and 6 refer, we believe, to workers whose employment we shared with Monsanto. In view of the fact that you have informed us that Monsanto in Texas City has also shown an excess of brain cancer cases above expectation, and that Case 6 worked with us for only 38 days in 1944, then for 22 years for Monsanto, we feel that it is rather biased NOT to discuss this aspect of Case 6, who probably "belongs" in the other plant's cohort, just as you have awarded Case 1 to Union Carbide!

Page 7 - lines 17-18 - "No information about other potential chemical exposures is presently available". Dr. Glenn points out that previous work histories record on our pre-employment medical forms on many of our cases were provided to OSHA NIOSH.

Page 8 - line 8 - and Table 5 - We feel that undue and misleading prominence has been given to acrylonitrile. This known human carcinogen has never been on our plant site, even as an on-stream intermediate. That it appeared on our exhaustive inventory at all is purely by virtue of the fact that it has been transhipped at our Ocean Terminal which is some miles from the Plant Site. Only a very small number of Texas City employees would have had any potential at all for exposure to this compound, and that extremely remote.

A general comment: as this is a preliminary paper, explaining the need for the joint agency and corporate study of the problem, we find the failure to mention the apparently parallel problem at two other petrochemical plants in the general area rather prejudicial.

We hope that these comments and suggestions have been helpful and that it will be possible for you to implement most of them with minimal modification of your paper.

Once again we thank you for this timely opportunity for us to review and comment upon the paper. Dr. Glenn and I also wish to thank you for the courtesy of the offer of co-authorship of the paper, an offer which however we wish to respectfully decline.

All of us at Union Carbide look forward to ongoing cooperation with your Administration and NIOSH in trying to shed more light on this heretofore quite baffling problem through the timely completion of the agreed studies.

Yours sincerely,

Michael Utidjian

H.M.D.Utidjian,M.D.,
Associate Corporate Medical Director for Epidemiolo

c.c. to Dr. Susan G. Austin, Corporate Epidemiologist
Dr. Thomas A. Lincoln, Corporate Medical Director
Dr. Dave Glenn, Divisional Medical Director, Texas/Gulf Coast
Mr. Damon Engle, Plant Manager, Texas City
Mr. Jackson B. Browning, Corporate Director of Health,Safety & Environmental Affairs

blind copy to John Whittlesey,Esq., Law Dept., for info. ✓

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Continued from page 29

exceed 18 percent. But what is *not* said is that the data also permit one to assert that AS usage could easily be associated with a 16 percent *reduction* in risk. These are the confidence limits of the *best* estimate, which is that there is neither more nor less risk.

The report justifies its use of many, many statistical comparisons by asserting that all of the spotted associations in subgroups were specified as possible prior to the study. It also adds, to the credit of the authors, that "the positive associations seen herein [may] represent merely chance variations in subgroups of a study which, overall, fails to demonstrate an association between AS use and bladder cancer." I suspect that many neutral observers will opt for the latter possibility. For instance, of the 42 P values given for AS associated risks (and there is no way to tell how many others were computed but not described) only 11 are statistically significant with one-tailed tests, and five of these fall by the wayside if one prefers two-tailed tests. Place your bets, friends.

In fairness to the report, it must be said that these (and some other) sources of error and bias are at least mentioned. But the press release and the media coverage ignore these caveats, and thus represent journalism that is at best sloppy and at worst dishonest.

The statisticians involved have thus become allies of those waging a holy war against AS. Saccharin and cyclamates seem to be such weak carcinogens that it requires a horde of statistician-epidemiologists, plus $1.5 million of public monies, to keep the carcinogenic pot boiling. Meanwhile, the Canadians have recanted, muttered "mea culpa" (not very loudly), and exonerated cyclamates because "there is not a shred of evidence" of the carcinogenicity which once seemed to demand regulatory action.

Miguel Cervantes, let thy shade rest in peace. Don Quixote is alive and well. □

BNA

Current Report

Polychlorinated Biphenyls

ARKANSAS, TEXAS TEST BURNS SUCCESSFUL; INCINERATOR APPROVAL WEIGHED BY REGION

Approval of two incineration facilities to burn polychlorinated biphenyls commercially appears imminent.

Environmental Protection Agency officials in Region VI, Dallas, are performing final evaluations of the results of test burns conducted last fall at PCB incineration facilities in Deer Park, Tex., and Eldorado, Ark.

Agency officials at EPA headquarters in Washington, D.C., already have reviewed the data from the test burns and said regional officials have the authority to approve or disapprove the facilities' permit requests as they see fit, agency officials told Chemical Regulation Reporter July 17.

Approval of either incinerator by the region would make it the first site approved for commercial destruction of PCBs.

The effective date of several clauses of PCB rules promulgated under the Toxic Substances Control Act and PCB regulations recently proposed by the Department of Agriculture and the Food and Drug Administration hinges on approval of commercial incineration facilities for PCBs.

Roger Meecham, a spokesman for EPA Region VI, said, however, officials there were not ready to announce a decision on the incinerators.

The Deer Park facility is operated by Rollins Environmental Services, while the Eldorado incinerator is operated by Engineering Systems Company (ENSCO).

According to agency hazardous waste officials in Dallas, the agency is under pressure from the two facilities and from industries storing PCBs to approve the incinerators. Community groups, however, have protested the incineration plan and were assured by the agency that every precaution would be taken in evaluating the test burn results.

"We still see a few anomalies we want to review," an EPA regional official said, adding that the agency was being supercautious because of the controversial nature of the decision.

Even if the incinerators were approved, the approval would be "tentative" until the public in the affected areas had a chance to comment and until the agency addressed "each comment very carefully," the official added.

He would not estimate when the agency may announce its decision.

EPA officials in Washington, however, said they believed the decision was imminent.

99 Percent Efficiency

According to agency headquarters officials, both test burns achieved well in excess of 99 percent efficiency and emitted no PCBs into the ambient air.

Gas chromatograph studies of the emissions showed that both incinerators were well within the PCB rule limit of 99 percent destruction efficiency for commercial incineration facilities, the officials noted.

Regional officials in April had asked for more data on the ENSCO test burn (Current Report, April 25, p. 92). The consultant on the project had supplied only summaries rather than the chromatograph strips themselves, regional officials said.

Evaluation data on the Deer Park burn, however, included the strips so there was no need to ask for further raw data on the Rollins test burn, they added.

Because community concern about the safety of the incinerators is high, regional officials have promised to announce their tentative decision on the incinerator, to schedule at least a 30-day comment period, and to hold public hearings before granting final operating approval.

Should the region decide to approve the incinerators, the hearing and comment process would require at least 60 days, the regional officials said (October 26, 1979, p. 1292; January 11, p. 1588).

Phthalates

CITIZEN'S PETITION SEEKS REGULATION, CITES CARCINOGENICITY OF PLASTICIZER

A former Environmental Protection Agency employee July 10 petitioned the agency to take regulatory action against a widely used plasticizer, saying the agency knows the substance causes cancer and poses a risk to humans.

The petition, filed by William Myers, Arlington, Va., said di-ethylhexyl-phthalate (DEHP) should be declared a hazardous stubstance under Section 4(f) of the Toxic Substances Control Act.

A chemical may be designated as a 4(f) substance if it is a carcinogen, mutagen, or teratogen which poses "significant risk of serious or widespread harm."

After such a designation, the agency must move to regulate the 4(f) chemical within 180 days using provisions of Section 5, 6, or 7 of TSCA. On the other hand, if the agency decides the risk is not unreasonable, it must publish that finding in the Federal Register.

Myers filed the petition under Section 21 of TSCA which allows citizens to demand that the agency take regulatory actions, including actions against specific substances. The Act requires the agency either to grant or deny the petition within 90 days.

Test Results Accepted

According to Myers' petition, the agency received and concurred with the results of a study done by the National Cancer Institute, which found di-ethylhexyl-phthalate to be a potential carcinogen.

That concurrence was reflected in the agency's action to block manufacture of six related phthalates submitted for premanufacture review, Myers said.

"That [NCI] study apparently satisfied . . . the agency as to its validity in showing di-ethylhexyl-phthalate to be a carcinogen," Myers wrote in his petition.

Shortly after receiving the NCI study on DEHP, Myers said, the agency initiated its first regulatory action under Section 5(e) of TSCA to require further testing of six related phthalates then undergoing premanufacture review (Current Report, April 25, p. 91).

The firm two weeks later dropped its manufacturing plans saying the ensuing publicity could jeopardize its confidentiality claim, the tests would cost about $4 million, and it did not know of the NCI study on the analogues (May 16, p. 155).

According to Myers' petition, the agency believed such plasticizers posed a risk or it "would not have moved against the production" of the new substances under Section 5(e).

Myers noted that about a billion pounds of DEHP is produced in the United States each year. The substance is

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used in a wide variety of consumer and commercial goods (See related story, p. 399.).

"This volume, and this exposure should be cause for some concern," Myers wrote. "However, knowing the Office of Pesticides and Toxic Substances as I do, I think their management could probably use a little help in acting."

Clarification Sought

Myers, who left the staff of EPA Assistant Administrator Steven Jellinek about three months ago, also asked the agency for an explanation of its position on "me too" chemicals.

The "me too" issue involves agency policy on handling chemicals already in production and use when a premanufacture notification review or new tests show that related substances or analogues pose a risk to humans or the environment.

Although the agency has no clear policy on handling such substances after they are on the market, it said in a May policy memorandum that substances known to be carcinogens before January 1979 would not be subject to action under Section 4(f) of TSCA.

An agency staff member told Chemical Regulation Reporter July 17 that a policy for handling "me too" chemicals is being drafted. He conceded that Myers' petition and his earlier one demanding that the agency declare benzene a 4(f) chemical (June 6, p. 227) were spurring the agency to act more quickly to develop a policy on "me too" chemicals.

Policy Questions Involved

According to the staff member, Myers' filing of the two petitions raises several policy issues and legal questions which must be resolved before responding to the petitions.

"We need to have a consistent approach rather than deal haphazardly" with each "me too" or 4(f) chemical, he said.

Among the issues involved is determining what Congress intended when it gave the agency 180 days to initiate regulatory action on a 4(f) chemical, he noted. It is clear that Congress, in passing TSCA, did not intend to make Section 4(f) a type of chemical Delaney Clause, he said.

The Delaney Clause of the Food, Drug, and Cosmetic Act requires the banning of any food additive which is shown to cause cancer in humans or laboratory animals. The clause does not allow the agency to gauge risk or exposure.

According to the staff member, EPA in responding to Myers' petitions must decide the criteria for declaring a chemical a 4(f) substance. The agency must decide what kind of information is needed and what kind of certainty it must have of "serious and widespread" harm before making a 4(f) declaration, he noted.

The agency also is faced with deciding the appropriate disposition for 4(f) substances, he said. Although the Act gives EPA authority to regulate a 4(f) substance under Section 5, 6, or 7 of TSCA, those sections give the agency many alternative means of regulation, he noted.

The agency also must develop a policy on handling chemicals when a "new unreasonable risk" is discovered, he said. This "whole question of what you do with 'me too' chemicals has been one of the most difficult questions we're facing as we review" premanufacture notifications, he added.

Current plans are for the agency to draft a comprehensive policy on the handling of "me too' chemicals and 4(f) substances within the 90 day time limit which began to run when the benzene petition was filed June 3.

The staff member explained, however, that because of the complexity of the issues involved, no reply is likely until close to the September deadline.

Pesticides

EPA MAKING PROGRESS, HOPES TO PUBLISH FOUR REGISTRATION STANDARDS, JOHNSON SAYS

The Environmental Protection Agency hopes to publish four pesticide registration standards this summer, according to the agency's deputy assistant administrator for pesticide programs, Edwin Johnson.

Speaking at a July 9 meeting of the State FIFRA Issues Research and Evaluation Group, Johnson said progress is being made on developing a final model standard, but the format may change following comments on a prototype standard issued in January (Current Report, January 18, p. 51).

The method by which EPA will determine use clusters for chemicals also will be published shortly, he said. The use cluster approach would not include all uses because of different application rates and dosages, Johnson said, but added the approach would cover existing uses and would put a product in the cluster which deals with its major uses.

According to Johnson, the agency will not concern itself with nitrosamines unless a product has more than one part per million, in which case a rebuttable presumption against registration review will be triggered.

As for classifying products by regulation, he said his office is looking at fumigants to see if they should be handled this way or through the RPAR process.

On the early call-in of data program, Johnson said EPA would accept test data not done according to agency protocols if they provide all necessary answers. The agency has a problem with data developed before the registration standard was worked up because EPA does not know where the data fit in, he said.

The Office of Pesticide Programs is trying to carry out a group tolerance program, Johnson said, but is having difficulty grouping by botanical families when types within the species may retain pesticide residues at different rates.

State Primacy

Terrell Hunt, of the agency's Pesticides and Toxic Substances Enforcement Division, July 10 gave SFIREG a status report on the major elements of the state primacy program.

Regulations setting up procedures for rescinding a state's primary enforcement responsibility for pesticide use violations are scheduled to be published by mid August, Hunt said. Final state grant regulations, which include primacy-related reporting requirements, will be promulgated in late August, he said.

Reporting regulations which apply the above requirements to states which received primacy without having a grant will be proposed in October or November, Hunt said.

A policy statement interpreting the major items in Sections 26 and 27 of the Federal Insecticide, Fungicide and Rodenticide Act will be proposed in September, Hunt said. Some of items to be covered in the statement, he said, will be procedures for referring allegations of misuse to states having primacy, criteria for granting and rescinding primacy, and emergency conditions to which EPA can immediately respond.

According to Hunt, the area of most controversy to be addressed by the policy statement will be the meaning of the term "commence appropriate enforcement action." This term refers to the 30-day period within which a state must act on a violation or have EPA assume enforcement responsibility.

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