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Read 6-3-80

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In re:	
The Dow Chemical Company, et al.	FIFRA Docket Nos. 415, et al.

TRANSMITTAL OF THE DIRECT TESTIMONY AND EXHIBITS OF DR. RAINER FRENTZEL-BEYME AND NOTICE OF TRANSMITTAL TO THE REPOSITORY OF A REFERENCE

Respondent hereby transmits advance copies of the direct testimony and exhibits of Dr. Rainer Frentzel-Beyme and notifies the parties that the document listed as a reference in Dr. Frentzel-Beyme's direct testimony has been transmitted to the repository. Dr. Frentzel-Beyme is scheduled to testify on June 17, 1980.

Respectfully submitted,

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June 3, 1980

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing TRANSMITTAL OF THE DIRECT TESTIMONY AND EXHIBITS OF DR. RAINER FRENTZEL-BEYME AND NOTICE OF TRANSMITTAL TO THE REPOSITORY OF A REFERENCE were hand delivered or mailed first class postage prepaid on June 3, 1980 to the following persons:

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In re: THE DOW CHEMICAL COMPANY, et al.	FIFRA Docket Nos. 415, et al.

DIRECT TESTIMONY OF DR. RAINER FRENTZEL-BEYME */

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*/ EPA Exhibit No. 535

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In re:	
The Dow Chemical Company, et al.	FIFRA Docket Nos. 415, et al.

DIRECT TESTIMONY OF DR. RAINER FRENTZEL-BEYME*/

My name is Rainer Frentzel-Beyme. I received my medical degree from Martin Luther University, Halle/Saale, German Democratic Republic, in 1963 and have subsequently specialized in tropical diseases and chronic diseases epidemiology. I received post-graduate training in epidemiology at the Johns Hopkins School of Hygiene and Public Health, where I graduated as Master of Health Science in 1972. My curriculum vitae is attached.

I am presently working as a Cancer Epidemiologist at the German Cancer Research Center, Department of Documentation, Information and Statistics, Heidelberg. In addition to my full-time commitment at the Cancer Research Center, I have a part-time consultantship at the BASF chemical manufacturing facility in Ludwigshafen, near Heidelberg. My task at BASF is to provide advice and assistance in planning and conducting epidemiological studies designed to identify chemical hazards in the occupational environment.

My testimony concerns an epidemiological investigation of mortality in a group of workers accidentally exposed to TCDD

*/ EPA Exhibit No. 535

(and other chemicals) during and after an uncontrolled reaction at a BASF chemical manufacturing plant. This investigation found an increased incidence of cancer, particularly stomach cancer, in the cohort of TCDD-exposed workers (study cohort). The available data indicates that the increased incidence of cancer may be related to exposure to TCDD (Exhibits 536 through 538).

BACKGROUND

On November 17, 1953, an explosion in a reaction autoclave used for the manufacture of 2,4,5-trichlorophenol contaminated the autoclave room and adjoining areas of the BASF plant at Ludwigshafen with a chemical sublimate containing TCDD. Many workers who entered the contaminated areas following the incident developed chloracne and a variety of other health disorders (Goldmann 1973, Exhibits 539a, 539b).

Immediately following the incident, the proper structure, characteristics, and toxicity of the substance responsible for the health effects in exposed workers were unknown. Nevertheless, BASF implemented an extensive cleanup and industrial hygiene program, including measures intended to remove or neutralize chemicals released during the explosion. Unfortunately, this elaborate cleaning program was subsequently found to be ineffective, and the entire building was demolished according to a detailed plan (Frentzel-Beyme 1979, Exhibit 537).

During a five year period following the incident, investigators conducted a series of clinical observations of exposed workers and animal experiments using chemical residues

collected after the incident. In 1957, 2,3,7,8-tetrachloro-dibenzodioxin (TCDD) was identified as the agent most likely to have caused the health effects in exposed workers. However, only in 1958, after the death of a worker following inadvertent exposure to residual dioxin during repair work on one of the autoclaves, was the full extent of the toxicity of TCDD appreciated. As a result, an intensive clinical follow-up of a group of exposed workers was undertaken. A number of dermatological symptoms such as chloracne were observed, as well as evidence of neurological damage and damage to internal organs (Goldmann 1973, Exhibits 539a, 539b).

Following a similar accident in Seveso, Italy in 1976 which resulted in reports of human illness due to TCDD exposure, a further clinical follow-up of workers exposed to TCDD at the BASF facility in 1953 was conducted (Thiess and Goldmann 1976, Exhibits 540a, 540b). The resulting report, which indicated continued adverse health effects in exposed workers, stimulated interest by epidemiologists in the health status of the cohort of TCDD-exposed workers, especially the incidence of cancer in the cohort 25 years after exposure. For this reason, an epidemiological cohort study was planned and carried out in 1977, and the results were reported as a preliminary communication at the 5th Medichem Congress in San Francisco, September 1977 (Thiess and Frentzel-Beyme 1977, Exhibits 536a, 536b). The remainder of my testimony concerns the methods utilized and information developed in this study.

THE STUDY

BASF, using information previously collected during the clinical observations, compiled a list of the names of the total cohort of workers exposed during and after the accident, including all those involved in cleaning operations. The list included 75 persons. The health status and location of each of these 75 individuals was successfully determined as of the closing date of the study, which was June 1, 1977.

Seventeen members of the cohort were deceased as of the closing date. The cause of death for each of these individuals was ascertained from documents such as death certificates and hospital charts. This information was evaluated by the same personnel based on the same criteria used to establish population mortality data for the general population. Of the 17 deaths in the study cohort, 6 deaths were due to malignant neoplasms, including 3 deaths from stomach cancer.

The observed deaths in the study cohort were compared to (1) deaths observed in an internal comparison group, and (2) deaths expected based on reference population mortality statistics. The internal comparison (control) group was utilized in order to eliminate possible mortality differentials (such as healthy worker effect)*/ and erroneous associations due to mixed

*/ The "healthy worker effect" refers to a common tendency toward lower mortality among workers than in the general population. This effect results from the fact that cohorts of workers are normally composed of persons at least healthy enough to be employed, while the general population includes the chronically ill and disabled.

exposures to other toxic substances as a result of working in a chemical plant. It was felt that this type of comparison was necessary in order to interpret the data on mortality in the cohort properly.

The internal comparison group was selected at random from a total of almost 10,000 employees in the same factory. The internal comparison group was made comparable to the study cohort by matching non-exposed employees with members of the study cohort according to age and date of entry to the factory. Comparison of mortality in the study group and the control group revealed a higher total mortality and a higher incidence of cancer in the study cohort. Of 75 subjects in each group, 17 had died in the study cohort, whereas only 11 deaths had occured in the comparison group. There were 6 cancer deaths in the study cohort as compared to 4 cancer deaths in the comparison group. Moreover, there were 3 deaths from stomach cancer in the study cohort but not one in the comparison group.

Mortality in the study cohort was also compared to expected figures derived from reference mortality data for the general populations of Ludwigshafen,*/ Rheinhessen-Palatinate (a region including Ludwigshafen), and the Federal Republic of Germany. These calculations also revealed increased cancer mortality in the study cohort relative to these reference populations. In particular, the data indicated a statistically significant excess incidence of stomach cancer in the study cohort. See

*/ Due to a computational error and possible inaccuracies in a portion of the original Ludwigshafen reference date, the expected mortality figures for Ludwigshafen in the 1977 report were inaccurate. Revised expected mortality figures for Ludwigshafen are included in Exhibit 538.

Table 1. For example, 3 deaths from stomach cancer were observed in the study cohort as compared to .494 deaths expected in a cohort of this size on the basis of reference mortality statistics for Rheinhessen-Palatinate (p=.014). The occurrence of lung cancer was also above expectation, although this excess was not statistically significant. */

Cancer deaths in the study cohort occurred in the period from 1965-1974, 12-21 years after the initial exposure to TCDD. The effects of exposure to a chemical carcinogen are generally not clinically apparent until years after the initial exposure. Consequently, excess mortality among exposed workers would not be expected during the period immediately following exposure, and use of an analysis which begins at the time of initial exposure could underestimate an actual increased risk. Therefore, additional risk calculations for cancer in the study cohort were performed after allowing for minimum induction or latency periods of 10 years and 20 years (Frentzel-Beyme 1979, Exhibit 537). Utilizing this approach, observed cancer mortality in the study cohort, particularly for stomach cancer, was far above expected cancer mortality based on the Rheinhessen-Palatinate reference data. See Table 1. With a 10 year minimum latency period, three stomach cancer deaths were observed versus 0.4 expected (p = .008). Two of these stomach cancer deaths were observed

*/ Recent follow-up has identified another death from lung cancer and an additional lung cancer patient (still alive) in the study cohort (Exhibit 538), whereas the expected figures for lung cancer have not substantially changed.

TABLE 1. Stomach cancer mortality in the BASF study cohort

	Period of observation		
	1953-1977 (no induction period)	1963-1977 (10 year induction period)	1973-1977 (20 year induction period)
observed deaths	3	3	2
expected deaths*/	.49	.4	.1
risk ratio (obs)/(exp)	6.0	7.5	20.0
p**/	.014	.008	.005

*/ Expected deaths are derived from reference mortality data for Rheinhessen-Palatinate, the region in which the BASF facility is located, for the years 1972-1975.

**/ Calculated by the one-tailed Poisson test of statistical significance.

20 or more years after initial exposure, versus 0.1 expected ($p = .005$).*/

The excess incidence of stomach cancer in the study cohort is unusual and so far unexplained. The observed excess mortality, although statistically significant and consistent with the latency periods for other human carcinogens, is based on only three deaths. In studies with small absolute numbers of deaths, one or more errors in identification of the cause of death could substantially influence the results. Nevertheless, the data do suggest a relationship between stomach cancer mortality and prior exposure to TCDD. In a recent review of 12 separate prior epidemiological studies of cohorts of workers in the chemical industry (see, e.g., publications 13, 24, 25, 28, 29, 30, 31 in my curriculum vitae), the observed stomach cancer mortality not only was never particularly different from expected stomach cancer mortality, but was, on the contrary, always below expectation. Moreover, the excess stomach cancer mortality observed in the BASF study cohort is consistent with the observation of an approximately six-fold excess risk for stomach cancer in a Swedish study of individuals occupationally exposed to phenoxyacetic acid herbicides and their dioxin contaminants (Axelson et al. 1980, Reference 1).

*/ Apparent excesses of lung cancer and cancer of the colon were also found: for lung cancer, after 10 years, 2 observed cases versus 0.82 expected and, after 20 years, 1 observed case versus 0.21 expected; for colon cancer, after 10 years, 1 observed case versus 0.18 expected and, after 20 years, 1 observed case versus .048 expected.

Epidemiologic studies can only indicate possible risks and are unable to actually prove a causal relationship, in part because of the possibility of unidentified confounding factors. For example, there is a possibility that some members of this study cohort were exposed to other unknown occupational hazards before or after the incident. However, the use of an internal comparison group composed of matched controls from the same factory was designed to eliminate, to the extent possible, other occupational exposure as an important confounding factor.

Due to the small size of the study cohort and the small absolute number of stomach cancer deaths, the results of this study do not permit definitive conclusions concerning the apparent carcinogenic effect of dioxin exposure. Thus, it would be desirable to identify and study other and larger groups of persons unintentionally exposed to dioxin in order to facilitate further analysis of the meaning of these results. Nevertheless, the observed incidence of malignant neoplasms, especially stomach cancer, in the BASF study cohort was consistently greater than expected values and cannot be readily dismissed as a mere chance event.

Due to the continued interest in the longterm effects of human dioxin exposure, my colleagues and I have continued to study mortality in the BASF study cohort. Some additional data developed since the 1977 report are included in Exhibit 538. In addition, a new report, including follow-up of the study

cohort for an additional 2 years and a new internal control group matched and selected by computer, is in preparation. As soon as the results are available, this update of our study will be published in the English language. It has, however, already become obvious to my colleagues and me that the findings of the preliminary study conducted in 1977 will not change substantially.

Rainer Frentzel-Beyme (tdb)

Rainer Frentzel-Beyme, M.D., M.H.S.

EXHIBIT LIST

Exhibit No.

536a Thiess, A.M. and R. Frentzel-Beyme, 1977. Mortality of persons exposed to dioxin after an accident which occurred in the BASF on 13th November 1953. Paper presented at MEDICHEM Congress V in San Francisco, September 5-9, 1977

536b Table: Cancer deaths of the BASF Dioxin study, by site and morphology of malignancy (1977).

537 Frentzel-Beyme, R., 1979. Revised draft of BASF dioxin study.

538 Tables: Additional data from follow-up of BASF dioxin study.

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539b EPA translation of Goldmann 1973.

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CERTIFICATE OF SERVICE

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CURRICULUM VITAE

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Education:

1957-1963 Medical Studies at the Martin-Luther-University, Halle/Saale

Sept.1963 Graduation (State examination)

Sept.1964 "cum laude" promotion: Doctor Medicinae
Thesis: Alkaline leucocytie phosphatase behaviour in viral and bacterial diseases

1965 Postgraduate training in tropical diseases (leprosy, ophthalmology) at the Institut Marchoux and the Institut de l'Ophthalmologie Tropical d'Afrique (IOTA) at Bamako, Mali

1967 Postgraduate training and Diploma in Tropical Medicine and Parasitology Bernhard-Nocht-Institute for Tropical and Naval Medicine, Hamburg, Federal Republic of Germany

1971-1972 Postgraduate training in epidemiology at the Johns Hopkins School of Hygiene and Public Health, Dept. of Epidemiology
Advisor: Dr. David Thomas
Graduation: Master of Health Science (epidemiology).

1975 Workshop: Occupational Cancer and Cancer Registries

1976 Workshop Cancer Epidemiology (Advisor Dr. P. Cole, Boston) both at the International Center for Research on Cancer Lyon, France

Languages: German, English, French, Russian, Swedish , Spanish

Publications: see attached list .

Work experience: 1964-1966: Extensive medical practice in the Republic of Mali, participation in Public Health Programs and viral as well as parasitologic diseases studies (Savannah area of West Africa).

1968-1971: Epidemiologic field work investigating the prevalence and economic impact of the filarial disease onchocerciasis (river blindness) in the Republic of Liberia (forest area of West Africa). National survey including socio-economic and parasitological/immunological studies (see list of publications). Data processing of examination findings from 11.000 study subjects.

1972-1978: Epidemiology of chronic diseases. Practical work in the field of occupational hazards in the chemical industry (cohort studies). Cancer documentation (world cancer mortality analyses on bone sarcoma, soft tissue sarcoma), regional analyses of cancer mortality in Germany - (Cancer Atlas of the Federal Republik of Germany). Bone tumour registry for the Federal Republic of Germany (population-based registry).
Case-control studies into the aetiologic factors of juvenile bone tumours, bladder cancer, testis tumours, cancer in vegetarians.
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