

MX 1167

MONSANTO BIOHAZARDS COMMITTEE

Minutes of a Meeting

October 4, 1979

Those present were Drs. George Roush and William McCarville, Monsanto; Dr. Marvin Kuschner, School of Medicine, State University of New York at Stonybrook; Dr. Robert Neal, Vanderbilt University School of Medicine; and Dr. Robert E. Olson, St. Louis University School of Medicine.

The meeting was called to order at 9:00 A.M. The first item on the agenda was a report by Dr. Ward on the present status of the analysis of dioxins from samples taken from spills or residues at the Krummrich plant. By combination of gas chromatography and mass spectrometry, the Monsanto facility at Dayton, Ohio has been able to obtain reasonable results on mixed tetrachlorodibenzodioxins (TCDD) derived from 2,4-dichlorophenol which was the main product in the spill. The present resolving power of GLC in that facility does not distinguish between the various isomers of TCDD, the 2,3,7,8-tetrachlorodibenzodioxin being the most toxic. The recovery of total isomers seemed reasonable in the range of 100-600 parts per billion (ppb). It was urged that capillary GLC be established and interfaced with the mass spectrometer in order to more properly distinguish the isomers. Dr. B. Ward presented this data.

Miss Judy Zak, of the Monsanto Company, and Dr. Suskind, Director of the Institution of Environmental Health, University of Cincinnati, have submitted a paper to the Journal of Occupational Medicine titled "The Mortality Experience of Workers exposed to Tetrachlorodibenzodioxins in a Trichlorophenol manufacturing Accident" at Monsanto's Nitro West Virginia plant. One hundred twenty-one workers who developed chloracne resulting from this accident on March 8, 1949, were selected for study. The relative risk for all cause of death was shown to be 0.69 with 32 deaths observed and 46.4 expected. With the categories of malignant neoplasms and circulatory disease the relative risks were 1 and 0.68. Although the cohort is small and the number of deaths also small, it appeared there was no apparent excess in total mortality or in deaths from malignant neoplasms or diseases of the circulatory system in this group of workers followed for nearly 30 years.

Dr. McCarville then presented some American Industrial Health Council comments on a report of the Inter-agency Regulatory Liason Group (IRLG) on risk assessment entitled "Scientific Basis for Identification of Potential Carcinogen and Estimation of Risks." The American Industrial Health Council stressed the point that scientific and social considerations should be distinguished in developing regulatory procedures. The Committee felt that it is intrinsically difficult to ask a regulatory agency not to engage in any scientific considerations in determining what substances seem likely to be carcinogenic, and then to collect and review data.

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Two other items were presented. A report by Paul Deisler, vice president of Health and Safety Environment of the Shell Oil Company, suggesting a mathematical model for cancer risk assesment and reduction, was considered a useful model for further study.

Finally, Dr. McCarville presented the "Report to the President by the Toxic Substance Strategy Committee" dated August 1979, (Speth Report) which is presently in the Federal Register for comment by October 15th. This document was considered by all members of the Committee to contain many inaccuracies. The paper is not balanced and does not stress evolution of criteria for investigating suspected human carcinogens and quantitating risk-benefit. It is inflammatory in the sense that it exaggerates the morbidity and mortality arising from industrial exposures and adheres to a very rigid Delaney-based standard for determining the human carcinogenicity of chemicals.

Dr. B.W. Karrh, Medical Director of the DuPont Company, submitted his final report "Epidermological Study of Workers Exposed to Acrylonitrile" to EPA and it was made available to Monsanto. A 98% follow-up of a cohort of 475 former employees exposed to acrylonitrile was made. It was discovered that 89 deaths at Camden, South Carolina had occurred in this group between 1957-1976, of which 25 were cancer deaths. These persons succumbed from a variety of tumors: 8 lung, 3 colon, 3 prostate, 2 bladder and 1 each of thyroid, nasopharynx, penis, esophagus, brain, leukemia, lymphosarcoma, Hodgkins, and malignant melanoma. The different distribution of these causes of death were not significant from that expected. A slight excess of cancer deaths was found when only compared with the DuPont controls but not the U.S. death rate or even that of surrounding counties in South Carolina. On the basis of this study, the question was asked the committee, "What should Monsanto tell their employees?" It was concluded they should tell them that acrylonitrile causes cancer in animals, that the environment in the Monsanto acrylonitrile manufacturing plants is at the very low level of 2 p.p.m. in conformity with the standards of OSHA, and that there is no conclusive evidence that this compound at this level causes cancer in humans.

Dr. Roush reported the present status of the hypersensitivity pneumonitis problems at the Pensacola plant. He has engaged the services of Dr. Jordan Fink, from the Medical College of Wisconsin in Milwaukee, to 1) carry out a clinical laboratory study involving the evaluation of pulmonary function in employees with circulatory antibodies to air-conditioner residue antigens, 2) to discover whether an immunologic challenge to provoke a change in pulmonary function can be developed and 3) to monitor any changes in antibody levels.

Dr. Roush also reported that the Environmental Health Laboratory (EHL) is going to be expanded to include additional space to expand research opportunities which will be in agreement with company goals in the testing of chemicals. The committee was asked

to provide suggestions for areas for research and new technologies which might be developed. It was agreed that the short-term tests should be extended to include cultured human cells to determine how this system correlates with other short-term tests and with responses in animals. Studies of metabolic differences between human and other cells that might provide a clue to the interspecies variation in carcinogenicity was urged. Finally it was recommended that studies of neurotoxicity of chemicals be expanded.

Dr. Roger Falk, of the Battelle Institute, has been appointed Director of the EHL. He has been on site for three weeks and appears to be a competent and congenial man.

Finally, Dr. George Levinskas asked for comments on the recent statement in the Federal Register regarding the Toxic Substance Control Act which requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice to EPA at least 90 days before manufacture or import. The question is "What should be submitted?" The only requirement appears to be that one submit what is available with respect to physical state, chemical properties and health or ecologic effects of the agent. Dr. Levinskas asked "What is the minimum battery of tests to be applied to such new chemicals?" It was the opinion of the Committee that it was hard to give advice without finite examples. It was suggested that Dr. Levinskas provide us with a list of ten chemicals that might be prioritized in terms of potency, type of danger, degree of danger, type of exposure and amount of exposure to workers in the plant and possible long-term consequences.

After some discussion of the Toxicology budget for 1980, the meeting was adjourned at 3:30 P.M.

The next meeting of the Biohazards Committee will take place on November 12, 1979.

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BIOHAZARDS COMMITTEE MEETING

October 4, 1979

1. DIOXINS - ANALYSIS

KRUMMRICH STUDY - SUSKIND

NITRO

B. WARD

G. ROUSH

G. ROUSH

podly attached
2. OSHA - CHICAGO MEETING FOR PRESS

W. MCCARVILLE

3. AIHC - COMMENTS OF IRLG

W. MCCARVILLE

SPETH REPORT

SHELL APPROACH

upper 4
inclusion
4. DUPONT ACRYLONITRILE STUDY

STATEMENT TO EMPLOYEES

W. GAFFEY

Answer to workers.

W. Schletter M.D.

G. ROUSH

5. PENSACOLA STUDY *Today's Funk is Pers*

6. EHL EXPANSION

G. ROUSH

T.B. S. Wiseman
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PMN, TIER TESTING, AND CHEMICAL TREES

G. LEVINSKAS

EHL Div

Rog. Falk

to J.P.H.O.
Toxicologists
Patella

susit. ant
pneumonia

Gordon Penjacob News, Journal Oct 3 1979.

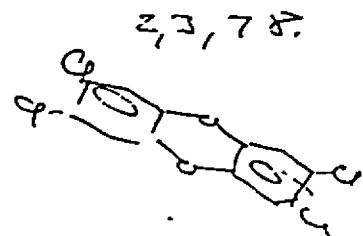
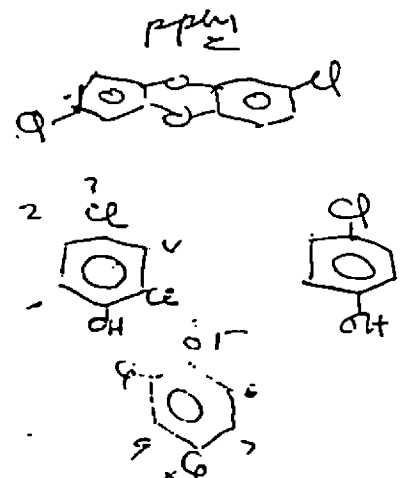
Tests Show Many Employees Exposed to Baffling Lung Disease.

Antibiotic Interference Pneumonia, LP *Alien*

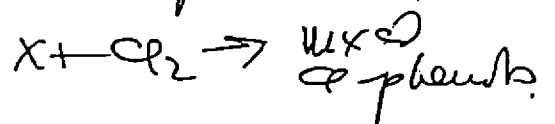
W. Metz
Testy
Human cells
Issue Culture

Humrich Hart Murphy
 0 0 2 1 9 7 5

Spills All Tetra PPB - 45/mel.
 (Monsanto-Dagira) NEMA/STC.
 2,4 DCP 479 2600 2378
 2,4 DCP 541 2600 443/185
 2,4 DCP 657 2700
 +104 ppb.
 2/5 # 3 206 (474) 6100 12/185
 1/3 # 3 120 (589) 450
 Buseck



236, 245, 246 products
 & copolymer



2378 (1 & 2) hydrolysis - two
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245T. supplies
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OSHA 18 DC Citation 3

Si. Ad. Panel
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 notes)

FIFRA OSTP.
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 fungicides
 rodenticides
 Act

IRLG
~~IRG~~
 mushrooms
 Agency
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 evaluation

BASIS FOR STAFF TOXICOLOGY BUDGET

$\$ \times 10^6$

privatize

OPERATING COMPANY ¹	CARRYOVER ONGOING STUDIES	NEW STUDIES	IDENTIFIED AS INCREMENTAL
MAP <i>Am</i>	804	2020	-
MCI <i>Chem Int.</i>	629	942	-
MIC <i>Drugs Chem</i>			
PLASTICIZERS	370	246	242
D&P	250	312	-
RUBBER	890	170	2915
SCD	504	65	450
TOTAL	3447	3755	3607

\$/Share

*\$17.00
.30*

30 x 10⁶ outstanding

INTC AND MP&R HAVE NOT INDICATED SPECIFIC NEEDS. GENERALLY, THEY DO RELATIVELY SMALL AMOUNTS OF TESTING.

*July 7 x 10⁹
35% R/D*

THRESHOLD

ONGOING STUDIES + 1/2 NEW STUDIES : (5,500)

INCREMENT ²

1/2 NEW STUDIES + 1/3 INCREMENTAL (3,000)

INCREMENT ³

1/5 INCREMENTAL (750)

*200,000,000
2,000,000
[Shares]*

PRELIMINARY PROJECTIONS (10,800)

ANTICIPATED BUDGETING (9,250)

*10 x 10⁶
total*