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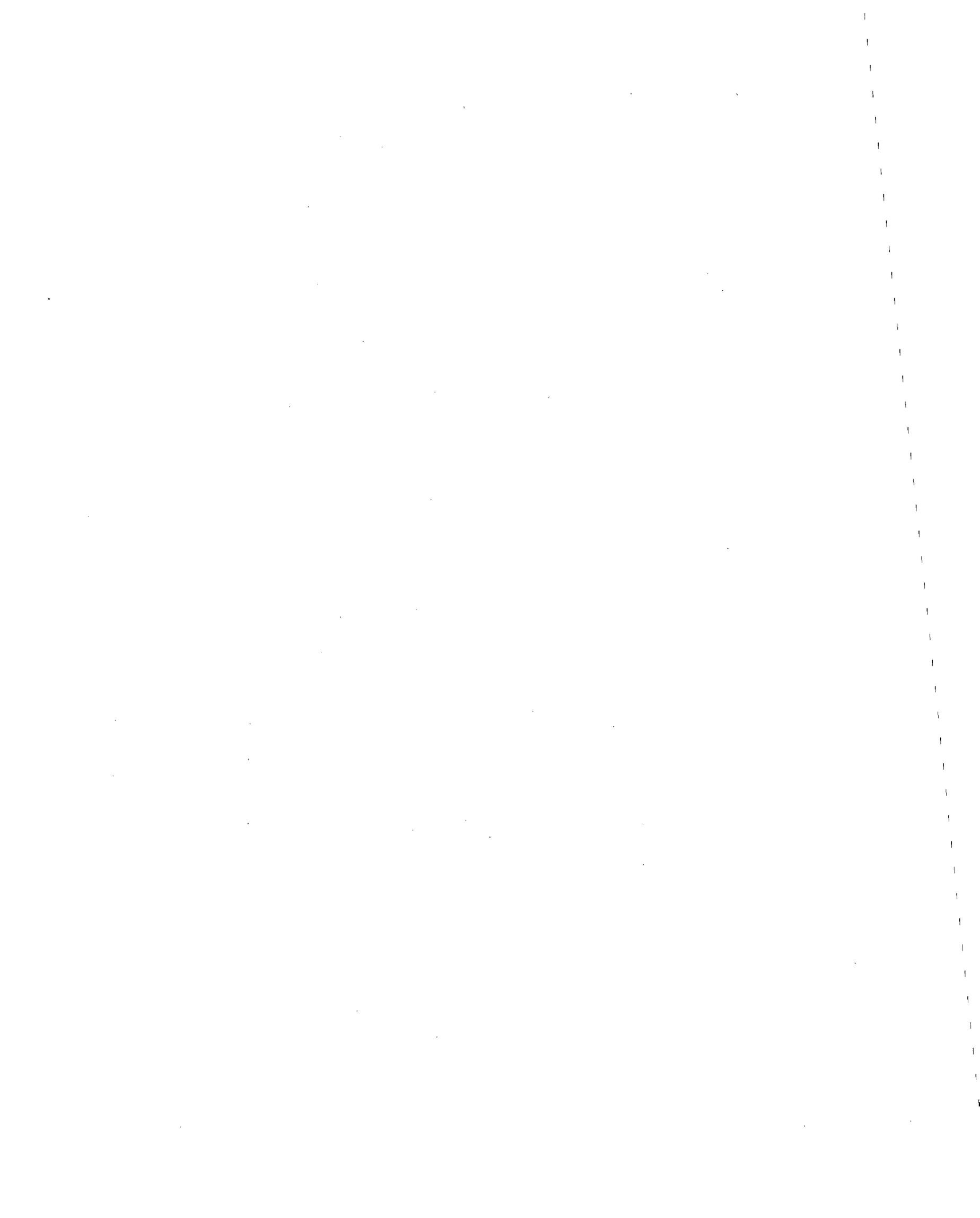
Statement of
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16. Abstract (Limit: 200 words) This statement reviewed the role of NIOSH in investigating ethylene-dichloride (107062) (EDC) and 2,4-diaminoanisole (615054) (DA). Occupational exposure to the chemical intermediate EDC was minimal. In 1976 a criteria documents suggested the standard for exposure to EDC be set at 5 parts per million (ppm) based on reports of adverse effects on the nervous system and livers of workers exposed to 10 to 15ppm EDC. Higher exposure levels were apparently related to cardiac and respiratory system effects. Nursing mothers were advised not to work with EDC as it could be carried in their milk. Subsequent to this time reports were made of excessive tumors occurring in laboratory mice and rats fed EDC for 78 weeks. If these reports are proved accurate, further recommendations will be made concerning exposures to EDC. In January of 1978 NIOSH issues a Current Intelligence Bulletin recommending that DA and its salts be handled as though they were human carcinogens. Two epidemiologic studies have been reported where excessive cancer has been diagnosed among cosmetologists. One study suggested excessive genital cancer and the other suggested excessive cancer in several organ systems. Other reports indicated mutagenic potential in bacterial systems and in the fruit fly. NIOSH recommended that skin exposure be limited and that engineering and work practice controls be made more stringent.			
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Mr. Chairman and Members of the Subcommittee:

I am Edward J. Baier, Deputy Director of the National Institute for Occupational Safety and Health (NIOSH). Accompanying me today is Dr. Norbert Page, Chief of the NIOSH Priorities and Research Analysis Branch. We are pleased to appear before you today to discuss the role of NIOSH in investigating certain chemical causes of cancer. You asked us to discuss two specific chemicals: ethylene dichloride, an intermediate in the production of other chemicals, including vinyl chloride, and 2,4-diamino-anisole, which is used in certain hair and fur dye formulations.

Under the Occupational Safety and Health Act, NIOSH is responsible for conducting occupational safety and health research, recommending standards to the Occupational Safety and Health Administration (OSHA), and providing technical assistance in evaluating employee exposures. NIOSH and OSHA share manpower development and training responsibilities.

In developing criteria for recommended standards, we attempt to evaluate all available data relevant to establishing an occupational standard and place particular importance on data indicating animal or human carcinogenicity and other chronic health effects. When we receive new information on the carcinogenicity of a chemical substance or physical agent, we may issue a Current Intelligence Bulletin, providing background information on the chemical, including its known toxicity to man and animals, known producers and users, estimated extent of occupational exposure and precautions which can be taken to reduce the hazard. These bulletins are now distributed to over 5,000 members of the occupational safety and health community, government agencies, management, labor, public

interest groups, and others. As a result of the evaluation of new data, we decide what further action may be necessary. This may include developing new or revised criteria documents for transmittal to OSHA and conducting additional epidemiologic or laboratory research to better characterize the hazard.

ETHYLENE DICHLORIDE

In 1972, the Institute developed a priority list of chemical and physical agents based on the number of workers exposed and the known toxicity of the agents. Relatively high on that list were a number of chlorinated hydrocarbon solvents including ethylene dichloride.

Approximately 10 billion pounds of ethylene dichloride are consumed each year in the United States by a variety of industries. Most of it is used as an intermediate in the production of other chemicals, including vinyl chloride, 1,1,1-trichloroethane, trichloroethylene, perchloroethylene, vinylidene chloride, and ethylene-amines. Occupational exposure in those processes is minimal. A total of 2 million workers may receive some exposure to ethylene dichloride, with perhaps 200,000 receiving a substantial exposure primarily during its use as a solvent in textile cleaning and metal degreasing, in certain adhesives, and as a component in fumigants. Low level exposure of gas station attendants can also occur from its use as a gasoline additive.

In March of 1976, NIOSH transmitted a criteria document to the Department of Labor recommending a 10-fold reduction in the existing Federal standard for ethylene dichloride from 50 to 5 parts per million

parts of air (ppm). This recommendation was based on reports of adverse effects on the nervous system and liver of workers exposed to 10-15 ppm ethylene dichloride. Exposure at higher levels was also reported to affect the cardiac and respiratory systems. We further advised nursing mothers not to work with ethylene dichloride since the chemical has been found in the milk of exposed mothers. In addition to an environmental limit, NIOSH made recommendations for medical examinations, labeling and posting requirements, personal protective equipment and clothing, informing employees of hazards, work practices, and monitoring and recordkeeping procedures.

When the criteria document was transmitted to OSHA in March 1976 there were no reports that ethylene dichloride caused cancer in animals or man. We did note that information on this subject was inadequate and that the National Cancer Institute (NCI) was conducting bioassay tests on the chemical. In December of 1977 NCI reported preliminary results from those tests indicating that male and female rats and mice fed ethylene dichloride for seventy-eight weeks had significant excesses of site-specific malignant and non-malignant tumors.

NIOSH is currently analyzing these preliminary results and is awaiting NCI's final report. The Institute is also preparing a Current Intelligence Bulletin which will advise the occupational health community as to the potential significance of those preliminary NCI data. If the final results of the NCI study on ethylene dichloride establish it to be carcinogenic, the Institute will transmit revised recommendations to the Occupational Safety and Health Administration. Additional recommendations will also be

made for appropriate medical monitoring, respiratory protection, engineering controls, and work practices.

2,4-Diaminoanisole

This past Fall NIOSH learned that a preliminary analysis of National Cancer Institute data indicated that laboratory rats and mice fed 2,4-diaminoanisole sulfate experienced a significant excess of site-specific malignant tumors as compared with controls. On January 13, NIOSH issued a Current Intelligence Bulletin recommending that 2,4-diaminoanisole (also known as 4-methoxy-m-phenylenediamine) and its salts be handled in the workplace as if they were human carcinogens.

Approximately three out of four current oxidation or "permanent" hair dye formulations contain 2,4-diaminoanisole or its sulfate salt, accounting for about \$200 million in annual retail sales. Although NIOSH is unaware of any current domestic production of 2,4-diaminoanisole, approximately 25,000 pounds a year are imported. NIOSH estimates that about 400,000 workers have potential occupational exposure, primarily hairdressers and cosmetologists. A relatively small number of fur dyers are also exposed to the chemical.

NIOSH has conducted two epidemiologic studies that suggest excess cancer among cosmetologists. One study indicates an excess of genital cancer among hairdressers and cosmetologists. The other, which has not yet been completed, suggests excess cancer of a number of organ systems among this occupational group. It should be recognized that hairdressers and cosmetologists are also exposed to a wide variety of other chemicals and that the epidemiologic studies do not clearly demonstrate a casual

connection between hair dyes and cancer. Nevertheless, we believe that the studies give additional cause for concern.

NIOSH has also been informed that unpublished data recently acquired by the Food and Drug Administration (FDA) indicate that 2,4-diaminoanisole penetrates the skin and enters the system of both man and the rhesus monkey. There are other reports indicating that 2,4-diaminoanisole is mutagenic in bacterial systems and in the fruit fly (*Drosophila*). These reports are of interest because correlations have been suggested between mutagenicity in bacterial systems and carcinogenic potential in higher systems.

As an interim and prudent measure, pending further evaluation of the carcinogenicity of 2,4-diaminoanisole, NIOSH recommends that occupational exposure to 2,4-diaminoanisole and its salts be minimized by engineering and workpractice controls. In particular, skin exposure should be avoided. Although substitution is a possible control measure, NIOSH recommends that caution be exercised in selecting substitutes for dye formulations and other products containing 2,4-diaminoanisole. Alternatives should be fully evaluated for possible human health effects. This is particularly important in view of the many questions that have been raised recently regarding the safety of numerous components of hair dye formulations.

These two examples illustrate some of the kinds and sources of data that contribute to our evaluation of carcinogenicity. As shown in the accompanying table, we receive information on carcinogenicity from a variety of sources including the National Cancer Institute bioassay program, the published scientific literature, industry studies, and

NIOSH-sponsored studies. Such hazards may be identified by epidemiologic studies of people who have been exposed to suspect chemical agents as well as by animal experiments. After reviewing all available information, including biological effects and exposure conditions, NIOSH determines the need for recommended occupational standards and specific preventive measures, as well as for further research to better assess the potential hazards.

Mr. Chairman, this concludes my prepared testimony. Dr. Page and I will be happy to answer any questions you or Members of your Subcommittee may have.

OCCUPATIONAL CARCINOGENS*

<u>Substance</u>	<u>Source of Data</u>			
	<u>Published scientific literature</u>	<u>Industry conducted/ sponsored studies (unpublished)</u>	<u>NCI bioassay data</u>	<u>NIOSH data</u>
Acrylonitrile		X		
Alpha-Naphthylamine	X			
Asbestos	X			X
Benzene	X			X
Benzidine	X			
Beryllium	X			X
Beta-Naphthylamine	X			
Beta-Propiolactone	X			
Bis-Chloromethyl Ether	X			
Carbon Tetrachloride	X		X	
Chloroform	X		X	
Chromium (VI)	X	X		
-certain compounds-				
Coal Tar Products	X			
-coal tar, coal tar pitch creosote-				
Coke Oven Emissions	X			X
Dioxane	X	X		
Ethyleneimine	X			
Epone			X	X
Ethyl Chloromethyl Ether	X			
4-Nitrosodimethylamine	X			
Nickel, Inorganic	X	X		
Polychlorinated Biphenyls (PCB's)	X	X	X	
Vinyl Chloride		X		X
2-Acetylaminofluorene	X			
2,3-Dichlorobenzidine (and its salts)	X			

*NIOSH Recommendations

OCCUPATIONAL CARCINOGENS*

<u>Substance</u>	<u>Source of Data</u>			
	<u>Published scientific literature</u>	<u>Industry conducted/ sponsored studies (unpublished)</u>	<u>NCI bioassay data</u>	<u>NIOSH data</u>
4-Aminodiphenyl	X			
4-Dimethylaminoazobenzene	X			
4-Nitrobiphenyl	X			
4,4'-Methylene bis (2-chloroaniline)	X			

Chloroprene +	X			
Dibromochloro propane			X	
Ethylene Dibromide +	X		X	
Isopropyl Alcohol +	X			
-possible cancer threat in the manufacturing process-				
Tetrachloroethylene +			X	

*NIOSH Recommendations

+Stated as having potential for cancer