NIOSH

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Testimony to DOL

Statement of

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Before the
Department of Labor
Occupational Safety and Health Administration
Public Hearing on Occupational Standard for Benzene

July 25-26, 1977

I am Edward J. Baier, Deputy Director of the National Institute for Occupational Safety and Health (NIOSH), administered by the Center for Disease Control within the Department of Health, Education, and Welfare. With me today are: Dr. Herman F. Kraybill, Division of Cancer Cause and Prevention, National Cancer Institute; Dr. Douglas L. Smith, Division of Criteria Documentation and Standards Development; Dr. Peter F. Infante, Mr. Robert A. Rinsky, and Mr. Ronald J. Young, Division of Surveillance, Hazard Evaluations, and Field Studies; Dr. Trent R. Lewis, Division of Biomedical and Behavioral Science; Dr. Judd C. Posner and Mr. William F. Todd, Division of Physical Sciences and Engineering; and Mr. Robert H. Schutz, Testing and Certification Branch. We welcome this opportunity to appear here today to discuss the effects of occupational exposure to benzene upon human health, including the results of recent studies conducted by NIOSH.

Benzene has been recognized as a bone marrow poison since the turn of the century. In the past 50 years, numerous cases of benzene-related leukemia have been reported throughout the world. This accumulation of reports lead to a declaration in 1971 by the Senate commission of the Deutsche Forschungsgemeinschaft for the Examination of Hazardous Industrial Materials which labeled benzene as a human carcinogen. A comprehensive scientific review validating this classification was published in 1971 [1].

In a 1973 review of industrial carcinogens, the director of medical research for a large United States oil company stated that, "the accumulation in the literature of cases of leukemia following benzene exposures leads to the inevitable conclusion that benzene is a leukemogenic agent" [2]. Also, in 1974, NIOSH addressed the occupational health hazards of benzene, especially its injurious effects on the hematopoietic system. At that time, NIOSH concluded that a cause-and-effect relationship between benzene and aplastic anemia seemed firmly established [3]. However, it was not considered conclusive that the alterations in marrow function observed from benzene exposure actually induced malignant changes; nevertheless, reports suggested a strong possibility that benzene could induce leukemia. In that same year, the International Agency for Research on Cancer (IARC), of the World Health Organization concluded that there was a suggestive relationship between benzene and leukemia [4].

In a 1975 review of chronic benzene toxicity, it was concluded that benzene exposure may lead to one of several types of leukemia, particularly myeloblastic leukemia [5]. In June of 1976, the Committee on Toxicology of the National Research Council [6] concluded that "benzene may be associated with leukemia; therefore, benzene must be considered a suspect leukemogen."

By mid-1976, results of additional epidemiologic investigations were reported [7-11]. When these observations were combined with those of previous epidemiologic studies [12,13] and with numerous case reports of benzene-related leukemia including a report indicating that 150 cases of leukemia attributed to benzene had been identified in Italy [14], NIOSH concluded that benzene is leukemogenic in man [15].

An epidemiologic report in the literature which failed to demonstrate an association between benzene and leukemia was the study by Thorpe [16]. However, the study is considered to be inadequate to address the question because of apparently relaxed case-finding techniques.

As a result of this evidence, NIOSH has recommended that benzene be considered carcinogenic in man for regulatory purposes [15]. In 1977, a critical review and evaluation of benzene toxicity sponsored by the American Petroleum Institute [17] reflected a similar conclusion of a causal relationship between benzene and leukemia. In reviewing benzene and leukemia, Goldstein concluded [17] that, "occupational exposure to benzene appears causally related to acute myelogenous leukemia and its acute variants." Kraybill [18] considers that the current study on Pliofilm workers, "seems to have tipped the balance insofar as implication of benzene exposure in causality of cancer (leukemia) and related blood dyscrasias." In view of the NIOSH conclusion that benzene is leukemogenic in man, and since it is not possible at this time to establish an exposure level at which benzene may be regarded to be without danger, we recommend that exposure to benzene be kept as low as possible. The use of benzene as a solvent or diluent in open operations should be prohibited. Furthermore, product substitution should be a paramount consideration whenever benzene is identified or its presence suspected. If there are concurrent indications of alterations in the blood or in the hematopoietic system, benzene should be replaced with less harmful substitutes wherever feasible. We recommend that occupational exposure be controlled so that no worker will be exposed to benzene in excess of a ceiling concentration of 1 part per million parts of air (ppm) (3.2 milligrams per cubic meter of air). Current sampling technology dictates that samples be collected by charcoal tube at 1 liter per minute for one hour. This one-hour sampling time is one-half that which was proposed by NIOSH in its update recommendations of 1976 [15]. Issues pertaining to sampling and analysis will be amplified later in this testimony.

We believe that recent reviews on the health effects of benzene [4,5,6,17] along with evaluations pertaining to occupational health presented by NIOSH [3,15] and OSHA [19] have been sufficiently complete so that repetition at this point is unnecessary. Also, the subject of gasoline as a fuel will not be addressed in this testimony, because OSHA intends to hold a public hearing as a separate proposal at a future date. We will address issues in this testimony which we believe to be important for consideration by OSHA for the permanent standard on benzene.

Within the past few months, NIOSH has reported findings [20] from an ongoing study to determine mortality patterns among workers occupationally exposed to benzene during the manufacture of a natural rubber cast film, commercially marketed under the trade name of Pliofilm. Current findings indicate a 5-fold excessive risk of total leukemia and a 10-fold excess of myelogenous and monocytic leukemias combined. This excessive risk was demonstrated under conditions leading to an underestimate of the true leukemia risk. Those conditions are the treatment in the analyses of approximately 25% of the workers whose vital status was not known as being alive until the last day of the study period. The procedure overestimates the person-years of observation which leads to an overestimate of expected deaths and thus reduces the ratio of observed to expected deaths. Since some of the past epidemiologic studies are subject to criticism because of worker exposure to a variety of solvents in the rubber product manufacturing industry, the ongoing study by Infante et al. [20] is considered especially pertinent because, except for the natural rubber base employed, benzene represents the only solvent used in the process.

It has been stated [19] that the report of leukemia among workers exposed to benzene in the manufacture of Pliofilm provided conclusive evidence that benzene is a leukemia-causing agent. Although these current findings indicate a highly significant benzene-leukemia association, it is emphasized that the conclusion that benzene is a leukemogen has been based on findings from numerous clinical reports and epidemiologic studies which have been cited by NIOSH. Thus, the report by Infante et al. [20] is confirmatory of a large body of evidence accumulated over the past 80 years.

With regard to estimates of atmospheric benzene concentrations during the manufacture of Pliofilm, data from both Ohio locations are available. From these data, it would not be possible to determine a dose-response relationship or to determine at what benzene levels the cases of leukemia were induced. The environmental concentrations are presented rather as the best available data and span the period of 1946 to 1976. A detailed discussion of these data is presented in Appendix A.

Reports indicate the company was knowledgeable about benzene toxicity and that environmental monitoring, medical surveillance, engineering controls, and respiratory protection were part of the precautionary measures employed by this company [21,22]. Our analysis of the environmental data leads us to the conclusion that, for the most part, employees' 8-hour time weighted average exposures were fairly consistent with the recommended standard in effect at the time. In some areas of the process, excessive benzene concentrations were present; however, through periodic air monitoring, management was aware of these locations and reportedly required respiratory protection.

We believe that some provision is needed in the permanent stand to better specify when certain procedures are necessary. For example, the presently proposed standard specifies that monitoring shall be performed, and training programs shall be provided, for employees in workplaces wherever benzene is present. Also, a program of medical surveillance is to be made available for all employees who are, or will be, exposed to benzene. Segments of the general population encounter benzene in drinking water, in the diet, and in the urban atmosphere in sufficient quantities which may approach those received from workplace exposures in the range of 0.1 to 0.5 ppm. Terms such as "exposed" and "benzene presence," therefore, need to have better meanings if used. A possible solution might be to define "exposure to benzene" as exposure at or above a specific concentration, possibly 0.5 ppm. This would aid in clarifying at what point programs such as monitoring, training, and medical surveillance are to be instituted, and at what point air monitoring and medical surveillance are not required.

A slight modification in the sampling and analytical method recommended by NIOSH in the criteria document [3] is indicated in order to be applicable to the 1 ppm ceiling limit we recommend. The modification involves collection of the sample on a standard charcoal adsorption tube at a sampling rate of 1 liter per minute and a sampling time of 1 hour. Desorption and analysis remain unchanged. Desorption of the sample is accomplished with 0.5 milliliter of carbon disulfide and benzene is determined by gas chromatography using a flame ionization detector and a 5 microliter aliquot.

For a 1 hour sample containing 1 ppm benzene (3.2 micrograms/liter), the amount collected would be 192 micrograms. The data which support the ability to detect benzene at this level come from two sources. First, the NIOSH Standards Completion Program Backup Data Report for Benzene [23] indicated 4-5% coefficient of variation and 95-98% desorption efficiency for benzene at the 80-90 microgram level. Second, results from collaborative testing [24] demonstrated that samples of benzene adsorbed on charcoal at levels of 181 and 208 micrograms could be analyzed with a bias (difference between the true value and the expected value) of 3.7% and 5.1%, respectively; coefficients of variation were 8.5 and 6.0, respectively. For samples involving both sampling and analysis at levels of 187 and 197 micrograms of benzene, the bias was 9.0% and 3.6%, respectively; the coefficients of variation were 5.6 and 16.2, respectively.

Details of the recommended method along with suggested information to identify and quantitate benzene in hydrocarbon mixtures are presented in Appendix B.

We wish to reiterate NIOSH's basic recommendation that employee exposure should be reduced to the lowest possible level by the use of engineering controls. Respirators may be used to protect employees engaged in maintenance operations, while engineering controls are being installed, or to temporarily supplement such controls until they are shown to be adequate. NIOSH does not recommend continual respirator use as the primary method for controlling any employee's exposure. Respirators must be regarded as temporary solutions to problems or as devices available for emergency respiratory protection, not as a permanent answer to control employee exposure. A list of the recommended respirator requirements for the permanent benzene standard is submitted for the record [25]. It is important to note that NIOSH has not included chemical-cartridge respirators or gas masks, except where the latter may be used for escape only. These are excluded because of the poor warning properties of benzene at low concentrations. However, if OSHA believes there is sufficient reason to permit use of chemical-cartridge respirators and gas masks for benzene, NIOSH recommends that such devices be required to have end-of-service-life indicators and be approved specifically for benzene. A Guide to Industrial Respiratory Protection is included as Appendix C.

Based on the assumption that employee exposures to liquid mixtures containing 1% or less benzene by volume will be generally less than 1 part per million, the OSHA final standard proposes to exclude liquid mixtures which contain no more than 0.1% benzene (1% benzene during the first year after the effective date of the standard). However, there are some indications that benzene-in-air levels from such mixtures would exceed 1 part per million and might be as high as 60 parts per million under conditions of confined space, poor ventilation, or elevated temperature. A report dated July 5, 1977 [26], described leukemia-induced deaths of two Medical Center employees who had worked in the Center's powerhouse which uses a heavy fuel oil for heating purposes. Laboratory analysis of the fuel oil indicated about 0.1% benzene by weight which may vary among batches and reportedly could amount to as much as 0.5% by weight. The fuel is taken from outside storage tanks, heated to 140°F, pumped through filters, and further heated to 210°F before being sprayed into the firebox. Both deceased employees had worked in the powerhouse for over 20 years. The first employee died in 1972 at age 66 of acute myelogenous leukemia. The second employee died in 1975 at age 55 from complications of thrombocytopenia resulting from subacute myelogenous leukemia. In 1973, leukemia was suspected in the second employee and the possibility of bone marrow injury was recognized from a substance such as benzene with the possibility of exposure to hydrocarbons. Traces of benzene reportedly had been found in the employee's blood during examination in 1973. Air samples taken at the powerhouse with benzene detector tubes in January, 1977, during an industrial hygiene survey, indicated that general workroom air levels were less than 1 ppm, which was stated to be due to the ventilation produced by the boiler's air intake fans. Air samples from inside the storage tanks and at the fuel filters inside the powerhouse showed concentrations exceeding 60 ppm, the maximum reading possible with the detector tubes used. The filters were cleaned weekly by the employees, the process taking about 20 minutes per filter, by filling a metal bucket with warm fuel oil and cleaning the filter by hand in the bucket. At the time, no gloves or other protective equipment were used and the employees frequently got fuel on their hands, arms, and clothing. It is recognized that substances other than benzene are present in the fuel oil which may interfere with the benzene detector tube determination; however, the interferences are generally noted by different colors or color intensities from that produced by benzene so that a fairly reliable qualitative estimate of the benzene concentration can still be obtained. Nevertheless, quantitative sampling and analyses using charcoal tubes are needed. NIOSH is proceeding with followup of these preliminary findings; however, it is considered noteworthy at this time that these observations may be associated with liquid mixtures containing approximately 0.1% benzene.

Finally, we wish to comment briefly on the subjects of signs and labels, informing employees, engineering controls, and "representative" exposure measurements. Because benzene is extremely flammable, NIOSH continues to recommend that the potential danger for fire be displayed on signs with equal prominence with the toxicologic hazards. Concerted effort should be made to keep benzene away from heat, sparks, and open flames. The flammability of benzene should be emphasized in all aspects of employee education. NIOSH believes that employee information and training should concentrate not only on initial, but continuing education. The subject of continuing education has not been adequately addressed in the proposed permanent standard. We recommend that provisions be made for monitoring and recording of appropriate engineering control data to assure that engineering controls are effective and working properly. Measurements should be made at the time of initial installation, after process changes, and at regularly scheduled time intervals. It is especially important that a preventive maintenance schedule be established and that ventilation measurements be taken and recorded on a regular basis because of changing requirements necessitated by factors such as changing environmental conditions, equipment wear, and system loading. We recommend that these measurements be taken at least every 6 months. Many factors need to be considered in order for airborne measurements to be representative of workplace exposure conditions. For example, different strategies must be used when making time-weighted average versus ceiling determinations. We believe that exposure levels of all potentially exposed employees should be determined over a given time period: we suggest at least annually. Proper evaluation of employee exposures necessitates taking valid quantitative exposure measurements, interpreting these measurements in the light of experience, and exercising professional judgment. A comprehensive approach entitled, "Occupational Exposure Sampling Strategy Manual" which applies to occupational exposures to airborne concentrations of chemical substances as dust, fumes, mists, gases, and vapors will be available from NIOSH within the next 60 days.

Before closing, I would like to list the backup material which is submitted for the record:

1. Communication of the Working Group "Establishment of MAK-Werte" of the Senate Commission for the Examination of Hazardous Industrial Materials. Considerations Bearing on the Question of Safe Concentrations of Benzene in the Work Environment (MAK-Wert), Prepared in cooperation with Dr. Gertrud Buttner. Bonn-Bad Godesberg, Deutsche Forschungsgemeinschaft, 1974, 63 pp.
2. Eckhardt RE: Recent Developments in Industrial Carcinogens. J. Occup. Med. 15:904-907, 1973.
3. Criteria for a Recommended Standard...Occupational Exposure to Benzene: National Institute for Occupational Health, US Department of HEW, HEW pub (NIOSH) 74-137, 1974.
4. Benzene: In IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Man.. International Agency for Research on Cancer, Lyon, 203-221, 1974.
5. Snyder R, Kocsis JJ: Current Concepts of Chronic Benzene Toxicity: CRC Crit Rev Toxicol 3:265-88, 1975.
6. Committee on Toxicology, Assembly of Life Sciences, National Research Council: A review of health effects of benzene. National Academy of Services, Washington, DC, June 1976.
7. McMichael AJ, Spirtas R, Kupper LL: An Epidemiologic Study of Mortality Within a Cohort of Rubber Workers, 1964-72. J Occup Med 16:458-64, 1974.

8. McMichael AJ, Spirtas R, Kupper LL, Gamble JF: Solvent Exposure and Leukemia Among Rubber Workers--An epidemiologic study. J. Occup Med 17:234-39, 1975.

9. Andjelkovic D, Taulbee J, Symons M: Mortality Experience of a Cohort of Rubber Workers, 1964-1973. J. Occup Med 18:387-94, 1976.

10. McMichael AJ, Spirtas R, Gamble JF, Tousey PM: Mortality Among Rubber Workers--Relationship to specific jobs. J Occup Med 18:178-85, 1976.

11. Monson RR, Nakano KK: Mortality Among Rubber Workers. I. White Male Union Employees in Akron, Ohio. Am J Epidemiol 103:284-96,1976.

12. Ishimaru T, Okada H, Tomtyasu T, Tsuchimoto T, Hoshino T, Ichimaru M: Occupational Factors in the Epidemiology of Leukemia in Hiroshima and Nagasaki. Am J Epidemiol 93:157-65, 1971.

13. Aksoy M, Erdem S, Din Col G: Leukemia in Shoe-Workers Exposed Chronically to Benzene. Blood, 44:837-841, 1974.

14. Vigliani, EC: Leukemia Associated with Benzene Exposure. Ann New York Acad Sci 271:143-151, 1976.

15. Update Criteria and Recommendations for a Revised Benzene Standard, NIOSH, August, 1976.

16. Thorpe, JJ: Epidemiologic Survey of Leukemia in Persons Potentially Exposed to Benzene. J Occup Med 16:375-382, 1974.

17. Laskin S, Goldstein BD (eds): A Critical Evaluation of Benzene Toxicity. J Toxicol Environ Health (In press). Prepublication copy from N. K. Weaver, American Petroleum Institute, June 27, 1977.

18. Kraybill HF: Experimental and Epidemiological Evaluation of Carcinogenic Risk from Exposure to Benzene. Testimony for OSHA Public Hearings on Benzene, July 25-26, 1977.

19. Occupational Exposure to Benzene: Emergency Temporary Standards; Hearing. Federal Register 42:27452-27464, May 27, 1977.

20. Infante PF, Rinsky RA, Wagoner JK, Young RJ: Leukemia Among Workers Exposed to Benzene. Lancet. In Press

21. Wilson RH: Benzene Poisoning in Industry. J Lab Clin Med 27:1517-1521, 1942.

22. Seferian S: Correspondence to I. Hall, Goodyear Tire and Rubber Company, February 13, 1956.

23. Backup Data Report for Benzene. Standards Completion Program No. 5311. National Institute for Occupational Safety and Health, U.S. Department of HEW, P. 1-5, 1976.

24. Reckner RL, Sachdev J: Collaborative Testing of Activated Charcoal Sampling Tubes for Seven Organic Solvents. National Institute for Occupational Safety and Health, U.S. Department of HEW; Contract No. HSM 99-72-98, HEW pub (NIOSH) 75-184, 1975.

25. Respirator Selection Guide for Benzene Applicable Under Proposed Standard of 1.0 ppm. National Institute for Occupational Safety and Health, Department of HEW, 1977.

26. Memorandum to Secretary of Defense concerning possible benzene hazard in fuel oil. U.S. General Accounting Office, Human Resources Division, HRD-77-118, July 5, 1977.

We are now ready for any questions.

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16. Abstract (Limit: 200 words)

The effects of occupational exposure to benzene (71432) on human health were discussed. After a brief mention of earlier findings, most of this testimony revolved around an ongoing mortality pattern study of workers exposed to benzene during the manufacture of a natural rubber cast film with the trade name Pliofilm. The cohort demonstrated a five fold excessive risk of total leukemia and a ten-fold excess of myelogenous and monocytic leukemias combined. Except for the natural rubber base employed, benzene was the only solvent used in this process. Employees' 8 hour time weighted average exposures were fairly consistent with the recommended standard in effect at that time. In areas where excessive concentrations of benzene occurred, respiratory protection was required. A modification was recommended in the sampling and analytical method recommended by NIOSH in the criteria document. The sample should be collected on a standard charcoal adsorption tube at a sampling rate of 1 liter per minute and a sampling time of 1 hour, and desorbed with 0.5 milliliters of carbon-disulfide; benzene should be determined by gas chromatography using a flame ionization detector and a 5 microliter aliquot. According to this testimony, employees should be educated as to the potential dangers from benzene exposure, continuing education programs should be in place, and monitoring and recording of engineering control data should be emphasized to assure that engineering controls are effective and working properly.

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