VII. RESEARCH NEEDS

Research is needed in the following areas to provide a better scientific basis for the recommended occupational health standard.

(a) Epidemiologic Study

A limited examination of the health records of employees at the Dow Chemical Company did not reveal any adverse health effects associated with exposure to ethylene dibromide [71]. In the absence of any published data, it is not possible to critically evaluate the basis of this conclusion or to estimate the significance of any effects which may have been induced by ethylene dibromide. A retrospective cohort study of a working population exposed primarilv to ethylene dibromide for a long duration should provide valuable information. Such a study should also address the effects of alcohol consumption, smoking habits, and obesity on the assessment of occupational hazards and risks. A study of a large population, such as gasoline station operators, chronically exposed to very low but measurable concentrations of ethylene dibromide should be given consideration.

A group of manufacturers and users has informed NIOSH that they are currently planning to conduct an epidemiologic study of employees with a history of exposure to ethylene dibromide.

(b) Carcinogenic Study

One carcinogenic study [56] has been found. However, because the route of exposure was by gastric intubation and the dosages were quite large, they do not provide a substantive basis for estimating the risk for human populations exposed to low concentrations of ethylene dibromide throughout their working lifetime. Properly designed and performed studies should be conducted on at least two mammalian species by inhalation and dermal absorption over a range of doses to further determine the risk of neoplastic induction by ethylene dibromide at concentrations and dosages approaching the recommended environmental limit. In addition, studies should be conducted to determine the cocarcinogenic or promotion potential of ethylene dibromide with substances with which it is commonly used, such as with ethylene dichloride, tetraethyl lead, and tetramethyl lead, or with carbon tetrachloride, ethylene dichloride, and carbon disulfide.

(c) Mutagenic Effect

This effect must be systematically investigated in greater detail with respect to dose, time, and route of exposure in both lower organisms and mammals. Animal tests using a variety of doses, schedules, and routes of administration should be performed to further elucidate the mutagenic potential of ethylene dibromide. Specific locus tests, heritable translocations, and multigeneration studies should be considered. Animals should also be tested to determine whether ethylene dibromide has any cytogenic effects. Experiments designed to either establish or refute the general applicability of the linear dose-response relationship for mutation induction found in Tradescantia [66] should be conducted in mammalian and submammalian species for both point mutations and chromosomal aberrations.

(d) Teratogenic and Related Reproductive Effects

Terata have occurred in the offspring of mammals as a result of exposure to ethylene dibromide vapor [69], and definite impairment of the reproductive system has occurred in mammals and avians as a result of ingesting ethylene dibromide [41,42,44,45]. Definitive experiments are needed with exposure concentrations approaching the recommended environmental limit to determine the effects of these small concentrations of airborne ethylene dibromide on the reproductive processes in a variety of mammalian species, such as dogs or monkeys. Additional studies are needed to determine whether sufficient quantities of ethylene dibromide can be absorbed through the skin to produce abnormal reproductive effects.

(e) Kidney and Liver Function Studies

The impairment of kidney and liver functions as a result of ethylene dibromide exposure has occurred in animals and in humans. As yet, there is no evidence that functional damage occurs in workers exposed to ethylene dibromide. Since a portion of a working population exposed primarily to ethylene dibromide can easily be identified, kidney and liver function tests should be given periodically to see whether any changes are occurring as a result of occupational exposure to ethylene dibromide.

(f) Skin Sensitization

Ethylene dibromide has been implicated in one study [24] on humans as being a skin sensitizer. However, the data presented in this study are far from complete or unequivocal. Additional information on the degree and character of skin sensitization of humans is highly desirable.

(g) Biologic Monitoring

Studies should be conducted to determine the feasibility of using body fluids, such as blood or urine, as the basis of a method for biologic monitoring of workers that are occupationally exposed to ethylene dibromide.

(h) Long-term Animal Exposure Studies

Long-term exposure of several animal species at a variety of concentrations of ethylene dibromide vapor approaching the recommended environmental limit is needed. These studies should simulate occupational exposure conditions of 8-10 hours/day, 4-5 days/week, for at least 18-24 months and the animals maintained until the end of their natural life. These studies should be properly designed and performed to allow for assessment of general body parameters, biochemical/physiologic parameters, and gross or microscopic examinations of involved organs including at least the liver, lungs, spleen, kidneys, CNS, and circulatory system.

In addition, repeated long-term experiments should be performed to determine the effects of ethylene dibromide absorption through the skin. Similar schedules and experimental designs as those for inhalation studies should be followed.

The National Cancer Institute has informed NIOSH that a long-term experiment to study the possible carcinogenic effects from the inhalation of ethylene dibromide is presently being conducted.

(i) Metabolism and Distribution

The pathways of metabolic transformation, distribution, and elimination of ethylene dibromide as a function of the dose rate and route of administration in mammals have not been adequately investigated. It is critical to determine the fraction of the dose that is converted into harmless metabolites and the dependence of the magnitude of this fraction on the dose rate. Both in vivo and in vitro studies should be conducted to determine the pathways. It is also essential to determine the concentration at which partial impairment of the detoxification mechanisms begin to occur.

(j) Excretion in Biologic Fluids

Several studies [9,10] have indicated that ethylene dibromide, or its metabolites, is widely circulated throughout the body and remains widely distributed in the body tissues for a considerable time. These studies also indicated that ethylene dibromide, or its metabolites, is excreted in the urine and eliminated in the feces. No studies have been conducted to determine whether ethylene dibromide is excreted intact in the milk of lactating mammals. It is imperative to determine whether ethylene dibromide is excreted in the milk of mammals and, if so, at what concentrations and for how long.

(k) Electroencephalographic (EEG) Studies

The reports of possible CNS effects in animals [23,31,33] and the broad chemical reactivity of ethylene dibromide toward all classes of cellular nucleophiles suggest a careful study of CNS function by noninvasive techniques in human populations exposed to ethylene dibromide. A thorough study of EEG patterns may provide useful information.

(l) Personal Protective Equipment

Materials impervious to ethylene dibromide should be identified for use in protective clothing, boots, gloves, and air-supplied hoods. Materials chemically resistant to ethylene dibromide should be identified for use in waste containers, drainage channels, diverting dikes, and floors.

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IX. APPENDIX I

METHOD FOR SAMPLING ETHYLENE DIBROMIDE IN AIR

The following sampling method is adapted from Method No. S104 of the Physical and Chemical Analysis Branch of NIOSH [78, and S Tucker, written communication, March 1977].

Atmospheric Sampling

Collect breathing zone or personal samples representative of the individual employee's exposure. At the time of sample collection, record a description of sampling location, equipment used, time and rate of sampling, total sample volume, temperature, atmospheric pressure, relative humidity, and any other pertinent information. Collect enough samples to permit calculation of an exposure for every operation or location in which there is exposure to ethylene dibromide.

(a) Equipment

The sampling train consists of a charcoal tube and a vacuum pump.

(1) Charcoal tubes: Glass tubes, with both ends flame-sealed, 7-cm long, with a 6-mm OD and a 4-mm ID, containing two sections of 20/40 mesh activated charcoal separated by a 2-mm portion of polyurethane foam. The activated charcoal is prepared from coconut shells and is fired at 600 C prior to packing. The primary section contains 100 mg of charcoal, the backup section, 50 mg. A 3-mm portion of polyurethane foam is placed between the outlet end of the tube and the backup section. A plug of silylated glass wool is placed in front of the primary section.

The pressure drop across the tube when in use must be less than 1 inch of mercury at a flowrate of 1 liter/minute. Tubes with the above specifications are commercially available.

(2) Pump: A battery-operated pump, complete with clip for attachment to the employee's belt, capable of operation at 200 ml/minute or less with a controlled accuracy of ± 5%.

(b) Calibration

The accurate calibration of a sampling pump is essential for the correct interpretation of the volume sampled. The frequency of calibration is dependent on the use, care, and handling to which the pump is subjected. Pumps should also be recalibrated if they have been misused or if they have just been repaired or received from a manufacturer. If the pump receives hard usage, more frequent calibration may be necessary. Maintenance and calibration should be performed on a regular schedule and records of these should be kept.

Ordinarily, pumps should be calibrated in the laboratory both before they are used in the field and after they have been used to collect a large number of field samples. The accuracy of calibration is dependent on the type of instrument used as a reference. The choice of calibration instrument will depend largely on where the calibration is to be performed. For laboratory testing, a soapbubble meter is recommended, although other standard calibrating instruments can be used. The actual setups will be similar for all instruments.

Instructions for calibration with the soapbubble meter follow. If another calibration device is selected, equivalent procedures should be used. The calibration setup for personal sampling pumps with a charcoal tube is shown in Figure XII-1. Since the flowrate given by a pump is dependent on the pressure drop across the sampling device, in this case a charcoal tube, the pump must be calibrated while operating with a representative charcoal tube in line.

(1) Check the voltage of the pump battery with a voltmeter to ensure adequate voltage for calibration. Charge the battery if necessary.

(2) Break the tips of a charcoal tube to produce openings of at least 2 mm in diameter.

(3) Assemble the sampling train as shown in Figure XII-1.

(4) Turn on the pump and moisten the inside of the soapbubble meter by immersing the buret in the soap solution. Draw bubbles up the inside until they are able to travel the entire buret length without bursting.

(5) Adjust the pump flowmeter to provide the desired flowrate.

(6) Check the water manometer to ensure that the pressure drop across the sampling train does not exceed 2.5 inches of water at 200 ml/minute.

(7) Start a soapbubble up the buret and measure with a stopwatch the time it takes the bubble to move from one calibration mark to another.

(8) Repeat the procedure in (7) above at least three times, average the results, and calculate the flowrate by dividing the volume between the preselected marks by the time required for the soapbubble to traverse the distance. If, for the pump being calibrated, the volume of

air sampled is calculated as the product of the number of strokes times a stroke factor (given in units of volume/stroke), the stroke factor is the quotient of the volume between the two preselected marks divided by the number of strokes.

(9) Data for the calibration include the volume measured, elapsed time or number of strokes of the pump, pressure drop, air temperature, atmospheric pressure, serial number of the pump, date, and name of the person performing the calibration.

(c) Sampling Procedure

(1) Break both ends of the charcoal tube to provide openings of at least 2 mm, which is half the ID of the tube. A smaller opening causes a limiting orifice effect which reduces the flow through the tube. The smaller section of charcoal in the tube is used as a backup section and therefore is placed nearest the sampling pump. Use tubing to connect the back of the tube to the pump, but tubing must never be put in front of the charcoal tube. The tube is supported in a vertical position in the employee's breathing zone.

(2) Sample a maximum of 25 liters of air at a flowrate of 200 ml/minute. For the determination of ceiling concentrations, the sampling time is 15 minutes.

(3) Measure and record the temperature and pressure of the atmosphere being sampled.

(4) Treat at least one charcoal tube in the same manner as the sample tubes (break, seal, and ship), except draw no air through it. This tube serves as a blank.

(5) Immediately after samples are collected, cap the charcoal tubes with plastic caps. Do not use rubber caps. To minimize breakage during transport, pack capped tubes tightly in a shipping container.

(6) Along with collected samples, send reference samples of the suspected compounds in a glass container capped with a teflon-lined cap. Do not transport these bulk liquid samples in the same container with the collected charcoal tubes.

(7) Low levels of 1,2-dibromoethane cannot be stored on charcoal at ambient temperatures for long periods of time. Therefore, if the analysis cannot be performed within 16-24 hours after sampling has been completed, the samples must be stored at -25 C or below. Refrigerated samples may be stored for two weeks.

(8) For shipment to the laboratory, the samples are packed firmly in an insulated container cooled with dry ice.

(9) If appropriate, a sample of the bulk material in a glass container with a teflon-lined cap is prepared and shipped to the laboratory in a separate container.