In July 1975, a private physician submitted a blood sample to the Center for Disease Control (CDC) to be analyzed for kepone, a chlorinated hydrocarbon pesticide. The sample had been obtained from a kepone production worker who suffered from weight loss, nystagmus, and tremors. CDC notified the State epidemiologist that high levels of kepone were present in blood sample, and he initiated an epidemiologic investigation which revealed other employees suffering with similar symptoms. It was evident to the State official after visiting the plant that the employees had been exposed to kepone at extremely high concentrations through inhalation, ingestion, and skin absorption. He recommended that the plant be closed, and company management complied.

Of the 113 current and former employees of this kepone-manufacturing plant examined, more than half exhibited clinical symptoms of kepone poisoning. Medical histories of tremors (called “kepone shakes” by employees), visual disturbances, loss of weight, nervousness, insomnia, pain in the chest and abdomen and, in some cases, infertility and loss of libido were reported. The employees also complained of vertigo and lack of muscular coordination. The intervals between exposure and onset of the signs and symptoms varied between patients but appeared to be dose-related.

NIOSH responded to a request for technical assistance from the Regional Director of the Occupational Safety and Health Administration (OSHA) by sending an industrial hygienist from the regional office to assist in the investigation of the working conditions in the plant. Information on kepone was collected from several sources including one of the principal distributors of the material. No data were available regarding the effect of kepone on man or the mechanism of metabolism and excretion. NIOSH has concluded that kepone produced physical injury to workers exposed to it but has not determined what the dose-response relationship is because of the lack of environmental exposure information. NIOSH has identified fewer than 50 establishments processing or formulating pesticides using kepone and has estimated that 500 workers are potentially exposed to kepone. (NIOSH is unaware of any plant in the US which is currently manufacturing kepone; the only known plant manufacturing it was closed in July 1975.)

NIOSH has recently received a report on a carcinogenesis bioassay of technical grade kepone which was conducted by the National Cancer Institute using Osborne-Mendel rats and B6C3F1 mice. Kepone was administered in the diet at two tolerated dosages. In addition to the clinical signs of toxicity, which were seen in both species, a significant increase ($P<.05$) of hepatocellular carcinoma in rats given large dosages of kepone and in mice at both dosages was found. Rats and mice also had extensive hyperplasia of the liver.

In view of these findings, NIOSH must assume that kepone is a potential human carcinogen. Since we are unable to establish a safe exposure level, NIOSH recommends that the workplace environmental level for kepone be limited to 1 $\mu$g/cu m as a time-weighted average concentration for up to a 10-hour workday, 40-hour workweek, as an emergency standard.

January 27, 1976
I. RECOMMENDATIONS FOR A KEPONE STANDARD

The National Institute for Occupational Safety and Health (NIOSH) recommends that worker exposure to kepone in the workplace be controlled by adherence to the following sections. The standard is designed to protect the health and safety of workers for up to a 10-hour workday, 40-hour workweek over a working lifetime. Compliance with all sections of the standard should prevent the overt adverse effects currently reported from exposure to kepone in the workplace and materially reduce the risk of cancer from occupational exposure to kepone. The standard is measurable by techniques that are valid, reproducible, and available. Sufficient technology exists to permit compliance with the recommended standard. The standard will be subject to review and revision as necessary. “Occupational exposure to kepone” is defined as exposure to airborne kepone at concentrations greater than one-half of the workplace environmental limit for kepone. Exposure to kepone at concentrations less than one-half of the workplace environmental limit will not require adherence to the following sections, except for 3, 4(a), 5, 6(b,c,e,f), and 7.

(A) Anxiety, insomnia, personality or memory disturbances
(B) Visual disturbances
(C) Tremors
(D) Incoordination, ataxia
(E) Weight loss
(F) Chest pain or abdominal pain
(G) Arthralgia
(H) Decreased libido or unexplained infertility

(3) Complete physical examination with particular attention to any neurologic findings such as tremor, opsoclonia (jumpy, irregular eye movements in all directions), short-memory difficulty, exaggerated startle reflex, and signs of muscular incoordination, and to atrophy of testicles, splenomegaly, hepatomegaly, and jaundice.

(4) An evaluation of the worker’s ability to use negative or positive pressure respirators shall be made.

(b) For workers with occupational exposure to kepone, preplacement and periodic medical examinations shall include liver function studies, as considered necessary by the responsible physician.

(c) Medical examinations shall be made available to all workers with signs or symptoms of skin irritation likely to have been the result of exposure to kepone.

(d) If clinical evidence of adverse effects due to kepone is developed from these medical examinations, the worker shall be kept under a physician’s care until the worker has completely recovered or maximal improvement has occurred.

(e) Initial examinations for presently employed workers shall be offered within 6 months of the promulgation of a standard incorporating these recommendations.

(f) Pertinent medical records shall be available to the designated medical representatives of the Secretary of Health, Education, and Welfare, of the Secretary of Labor, of the employee or former employee, and of the employer.

(g) Medical records shall be maintained for all employees with occupational exposure to kepone and for maintenance personnel with periodic exposure. All pertinent medical records with supporting documents shall be retained at least 30 years after the individual’s employment is terminated.

Section 2 — Medical

Employers shall make medical surveillance available to all workers occupationally exposed to kepone, including personnel periodically exposed during routine maintenance or emergency operations. Periodic examinations shall be made available at least on an annual basis.

(a) Preplacement and periodic medical examinations shall include:

(1) A comprehensive or interim work history.

(2) A comprehensive medical history to include, but not be limited to, information on conditions which may preclude further exposure to kepone, specifically:

Section 3 — Labelling (Posting)

(a) All shipping and storage containers of kepone shall bear the following label in addition to, or in combination with, labels required by other statutes, regulations, or ordinances.
KEPONE
DANGER! EXTREME HEALTH HAZARD
MAY CAUSE CANCER
MAY CAUSE IRRITATION OR RASH
INHALATION MAY CAUSE PERMANENT NERVE DAMAGE

Keep container closed.
Avoid contact with skin and eyes.
Avoid breathing dust or solution spray.
In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician. Flush skin with water. Wash clothing before reuse. Use fresh clothing daily. Take showers after work, using plenty of soap. Change to clean street clothing before leaving place of employment.

(b) In areas where there is occupational exposure to kepone, the following warning sign shall be posted in readily visible locations, particularly at the entrances to the area.

DANGER! EXTREME HEALTH HAZARD
CANCER-SUSPECT AGENT
NERVE-DESTROYING AGENT
USED IN THIS AREA
UNAUTHORIZED PERSONS KEEP OUT

This sign shall be printed both in English and in the predominant language of non-English-speaking workers, if any, unless employers use other equally effective means to ensure that these workers know the hazards associated with kepone and the locations of areas in which there is occupational exposure to kepone. Employers shall ensure that illiterate workers also know these hazards and the locations of these areas.

Section 4 — Personal Protective Equipment and Protective Clothing

(a) Protective Clothing

(1) Coveralls or other full-body protective clothing shall be worn in areas where there is occupational exposure to kepone. Protective clothing shall be changed at least daily at the end of the shift and more frequently if it should become grossly contaminated.

(2) Impervious gloves, aprons, and footwear shall be worn at operations where solutions of kepone may contact the skin. Protective gloves shall be worn at operations where dry kepone or materials containing kepone are handled and may contact the skin.

(3) Eye protective devices shall be provided by the employer and used by the employees where contact of kepone with eyes is likely. Selection, use, and maintenance of eye protective equipment shall be in accordance with the provisions of the American National Standard Practice for Occupational and Educational Eye and Face Protection, ANSI Z87.1-1968. Unless eye protection is afforded by a respirator hood or face-piece, protective goggles or a face shield shall be worn at operations where there is danger of contact of the eyes with dry or wet materials containing kepone because of spills, splashes, or excessive dust or mists in the air.

(4) The employer shall ensure that all personal protective devices are inspected regularly and maintained in clean and satisfactory working condition.

(5) Work clothing may not be taken home by employees. The employer shall provide for maintenance and laundering of protective clothing.

(6) The employer shall ensure that precautions necessary to protect laundry personnel are taken while soilied protective clothing is being laundered.

(7) The employer shall ensure that kepone is not discharged into municipal waste treatment systems or the community air.

(b) Respiratory Protection from Kepone

Engineering controls shall be used wherever feasible to maintain airborne kepone concentrations at or below that recommended in Section 1 above. Compliance with the environmental exposure limit by the use of respirators is allowed only when airborne kepone concentrations are in excess of the workplace environmental limit because required engineering controls are being installed or tested, when nonroutine maintenance or repair is being accomplished, or during emergencies. When a respirator is thus permitted, it shall be selected and used in accordance with the following requirements:

(1) For the purpose of determining if it is necessary for workers to wear respirators, the employer shall measure the airborne concentration of kepone in the workplace initially and thereafter whenever process, worksite, climate, or control changes occur which are likely to increase the airborne concentration of kepone.

(2) The employer shall ensure that no worker is exposed to kepone above the workplace environmental limit because of improper respirator selection, fit, use, or maintenance.


(4) The employer shall provide respirators in accordance with Table I-1 and shall ensure that the employee uses the respirator provided.

(5) Respirators described in Table I-1 shall be those approved under the provisions of 29 CFR 1910.134 and 30 CFR 11.

(6) The employer shall ensure that respirators are adequately cleaned, and that employees are instructed on the use of respirators assigned to them, their location in the workplace, and on how to test for leakage.

(7) Where an emergency may develop which could result in employee injury from kepone, the employer shall provide an escape device as listed in Table I-1.
TABLE 1-1
RESPIRATOR SELECTION GUIDE FOR PROTECTION AGAINST KEPONE

Self-contained breathing apparatus with positive pressure in full facepiece
Combination supplied-air respirator, pressure-demand type, with auxiliary self-contained air supply

Section 5 — Informing Employees of Hazards from Kepone

At the beginning of employment or assignment for work in a kepone area, employees with occupational exposure to kepone shall be informed of the hazards, relevant signs and symptoms of overexposure, appropriate emergency procedures, and proper conditions and precautions for the safe use of kepone.

Instruction shall include, as a minimum, all information in Appendix III which is applicable to the specific kepone product or material to which there is exposure. This information shall be posted in the work area and kept on file, readily accessible to the worker at all places of employment where kepone is involved in unit processes and operations.

A continuing educational program shall be instituted to ensure that all workers have current knowledge of job hazards, proper maintenance procedures, and cleanup methods, and that they know how to use respiratory protective equipment and protective clothing correctly.

Information as specified in Appendix III shall be recorded on the Material Safety Data Sheet or a similar form approved by the Occupational Safety and Health Administration, US Department of Labor.

NOTICE

Appendices I, II, and III will be supplied when they become available.

Section 6 — Work Practices

(a) Control of Airborne Contamination

Emission of airborne particulates (dust, mist, spray, etc.) of kepone shall be controlled at the sources of dispersion by means of effective and properly maintained methods such as fully enclosed operations and local exhaust ventilation. Other methods may be used if they are shown to effectively control airborne concentrations of kepone within the limit of the recommended standard.

Air discharged from facilities in which kepone is manufactured, processed, stored, or used may not contain kepone at concentrations greater than 5% of the workplace environmental limit in Section 1 or at concentrations greater than those permitted by other ordinances, statutes, and regulations.

(b) Control of Contact with Skin and Eyes

(1) Employees working in areas where contact of skin or eyes with kepone, dry or wet, is possible shall wear full-body protective clothing, including neck and head coverings, and gloves, in accord with Section 4(a).

(2) Clean protective clothing shall be put on before each work shift.

(3) If, during the shift, the clothing becomes wetted with a solution, slurry, or paste of a kepone material, or grossly contaminated with a dry form of such material, it shall be removed promptly and placed in a special container for garments for decontamination or disposal. The employee shall wash the contaminated skin area thoroughly with soap and a copious amount of water. A complete shower is preferred after anything but limited, minor contact. Then, clean protective clothing shall be put on before resuming work. When working directly with kepone, with unsealed containers of kepone, or with kepone in other than fully enclosed operations, protective devices and clothing shall be removed and the arms, hands, and face thoroughly washed after working with kepone, and at 30-minute intervals when working with kepone for extended periods of time.

(4) Small areas of skin (principally the hands) contaminated by contact with kepone shall be washed immediately and thoroughly with an abundance of water. Water shall be easily accessible in the work areas through low-pressure, free-running hose lines or showers.

(5) If kepone comes into contact with the eyes, they should be flushed with a large volume of low-pressure flowing water for at least 15 minutes. Medical attention shall be obtained without delay, but not at the expense of thoroughly flushing the eyes.

(c) Procedures for emergencies, including firefighting, shall be established to meet foreseeable events. Necessary emergency equipment, including appropriate respiratory protective devices, shall be kept in readily accessible locations. Only self-contained breathing apparatus with positive pressure in the facepiece shall be used in firefighting. Appropriate respirators shall be available for use during evacuation.

(d) Special supervision and care shall be exercised to ensure that the exposures of repair and maintenance personnel to kepone are within the limit prescribed by this standard.

(e) Prompt cleaning of spills of kepone:

(1) No dry sweeping shall be performed. Wet methods or dry vacuuming shall be used as appropriate.

(2) Wet spills and flushing of wet or dry spills shall be channeled for appropriate treatment or collection for disposal. They may not be channeled directly into the municipal sanitary sewer system.

(f) General requirements:

(1) Good housekeeping practices shall be observed to prevent or minimize contamination of areas and equipment and to prevent build-up of such contamination.

(2) Good personal hygiene practices shall be encouraged.
(3) Equipment shall be kept in good repair and free of leaks.

(4) Containers of dry kepone shall be kept covered as is practical.

Section 7 — Sanitation

(a) Washing Facilities

Emergency showers and eye-flushing fountains with adequate pressure of cool water shall be provided and be quickly accessible in areas where contact of skin or eyes with kepone may occur. This equipment shall be frequently inspected and maintained in good working condition.

Showers and washbasins shall be provided in the employees’ locker areas. Employers shall ensure that employees exposed to kepone during their work shift shall wash before eating or smoking periods taken during the work shift.

(b) Food Facilities

Food storage and preparation as well as eating shall be prohibited in areas where kepone is handled, processed or stored.

Eating facilities provided for employees shall be located in areas in which the airborne concentrations of kepone are not greater than 5% of the workplace environmental limit in Section 1. Surfaces in these areas shall be kept free of kepone. Employers shall ensure that before employees enter premises reserved for eating, food storage, or food preparation, they remove protective clothing. Washing facilities should be accessible nearby.

(c) Employees may not smoke in areas where kepone is handled, processed, or stored.

(d) Clothing and Locker Room Facilities

Locker room facilities shall be provided in an area without occupational exposure to kepone for employees required to change clothing before and after work. The facilities shall provide for the storing of street clothing and clean work clothing separately from soiled work clothing. Showers and washbasins should be located in the locker area to encourage good personal hygiene.

Covered containers should be provided for work clothing discarded at the end of the shift or after a contamination incident. The clothing shall be held in these containers until removed for decontamination or disposal.

Section 8 — Monitoring and Recordkeeping

Requirements

Workers are not considered to have occupational exposure to kepone if, on the basis of a professional industrial hygiene survey, the airborne concentration of kepone in an area where kepone is handled, processed, or stored is sufficiently low that a sampling volume equal to or greater than 1.0 cu m is necessary in order to collect 0.5 μg of kepone. The minimum quantity of kepone which must be collected in order to determine with reliability the presence of kepone in a sample is 0.5 μg. In order to determine that kepone is only present in workplace air at concentrations equal to or less than 0.5 μg/cu m, it is necessary that each sample of airborne kepone that is analyzed for the purpose of making this determination be the residue from the filtration of at least 1.0 cu m of workplace air. All samples of airborne kepone shall be analyzed by the chemical analytical method in Appendix II. Records of these surveys, including the basis for concluding that there is no occupational exposure to kepone shall be maintained until a new survey is conducted.

In workplaces where kepone is handled or processed, surveys shall be repeated annually and when any process change indicates a need for reevaluation. Requirements set forth below apply to areas in which there is occupational exposure to kepone.

Employers shall maintain records of workplace environmental exposures to kepone based on the following sampling, analytical, and recording schedules:

(a) In all monitoring, samples representative of the exposure in the breathing zone of employees shall be collected by personal samplers.

(b) An adequate number of samples shall be taken in order to permit construction of TWA exposures for every operation or process. Except as otherwise determined by a professional industrial hygienist, the minimum number of representative TWA determinations for an operation or process shall be based on the number of workers exposed as provided in Table 1-2.

(c) The first determination of the worker’s exposures to airborne kepone shall be completed within 6 months after the promulgation of a standard incorporating these recommendations.

(d) A reevaluation of the exposures of workers to airborne kepone shall be made within 30 days after installation of a new process or process changes.

(e) Samples of airborne kepone shall be collected and analyzed at least every 2 months for those work areas with occupational exposure to kepone.

(f) A reevaluation of the worker’s exposures to airborne kepone shall be repeated at 1-week intervals when the airborne concentration has been found to exceed the recommended workplace environmental limit. In such cases, suitable controls shall be instituted and monitoring shall continue at 1-week intervals until 3 consecutive surveys indicate the adequacy of controls.

(g) Records of all sampling and analysis of airborne kepone and of medical examinations shall be maintained for at least 30 years after the individual’s employment is terminated. Records shall indicate the details of (1) type of personal protective devices, if any, in use at the time of sampling, and (2) methods of sampling and analysis used. Each employee shall be able to obtain information on his own exposure. If the employer who has or has had employees with occupational exposure to kepone ceases business without a successor, he shall forward their records by registered mail to the Director, National Institute for Occupational Safety and Health.
TABLE 1-2

SAMPLING SCHEDULE

<table>
<thead>
<tr>
<th>Number of Employees Exposed</th>
<th>Minimum Number of Employees Whose Individual Exposures Shall Be Determined</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-20</td>
<td>50% of the total number of exposed employees</td>
</tr>
<tr>
<td>21-100</td>
<td>10 plus 25% of the excess over 20 exposed employees</td>
</tr>
<tr>
<td>over 100</td>
<td>30 plus 5% of the excess over 100 exposed employees</td>
</tr>
</tbody>
</table>

(h) A regulated area shall be established and maintained where:
(1) Kepone is manufactured, reacted, mixed with other substances, repackaged, stored, handled, or used; and
(2) Airborne concentrations of kepone are in excess of the workplace environmental limit in Section 1.

(i) Access to the regulated areas designated by Section 8(h) shall be limited to authorized persons. A daily roster shall be made of persons authorized to enter; these rosters shall be maintained for 30 years.

(j) Employers shall ensure that before employees leave a regulated area they remove and leave protective clothing at the point of exit.