

PROPOSED RULES

have been occupationally related. As a result of this notification and after consultation with the National Institute for Occupational Safety and Health (NIOSH), and a joint inspection of the plant by OSHA, NIOSH, and the Kentucky Department of Labor, a fact-finding hearing on possible hazards involved with the manufacture and use of VC was announced on January 30, 1974 (39 FR 3874) and held on February 15, 1974.

2. *Carcinogenicity of VC.* Information produced at this hearing demonstrated that exposure of laboratory animals (mostly Sprague-Dawley rats) to VC by inhalation at and below the then current OSHA standard of 500 ppm induced tumors, including angiosarcomas of the liver. Professor Cesare Maltoni, of the Instituto di Oncologia, Bologna, Italy, reported on a series of experiments on the effect of exposure of rats, mice, and hamsters to VC at concentrations of 10,000; 6,000; 2,500; 500; 250; and 50 ppm for varying periods of time (TR-43-63). Some of the experiments have been concluded, and others are still ongoing. The experimental results reported were that tumors have been observed in groups of animals exposed to VC at concentrations as low as 250 ppm. No tumors were observed in the group of animals exposed to VC at a concentration of 50 ppm. It also appears that the total number of tumors, as well as the numbers of angiosarcomas of the liver, decreased as the concentrations of VC were reduced to 250 ppm. Another experiment by Professor Maltoni was reported underway involving the exposure of 300 animals to VC at concentrations of 50 ppm, in order to assess in a more definitive way whether that level of exposure produces tumors in animals. Data reported by Torkelson, Oyen and Rowe (American Industrial Hygiene Association J 22: 254-361 (1961)) indicate that exposure to VC at concentrations of 50 ppm failed to induce tumors in rats, hamsters, rabbits, and dogs.

The employees of the B. F. Goodrich Chemical Company who died from angiosarcoma of the liver had an average exposure of approximately 19 years to vinyl chloride, at unknown concentrations, and variable exposures to other volatile chemicals. (TR 93). Some employees of Union Carbide, Firestone Tire and Rubber, and Goodyear were also reported in post-hearing comments to have had exposure to vinyl chloride and to have died from angiosarcoma of the liver. Finally, autopsies of four deceased employees revealed their liver angiosarcoma tumors were histologically indistinguishable from the angiosarcoma tumors observed in Professor Maltoni's experimental animals.

3. *The Emergency Temporary Standard.* On the basis of all information available at that time, and the fact that employees were being exposed at levels around the experimentally observed effect level of 250 ppm, an Emergency Temporary Standard (ETS) was promulgated on April 5, 1974 (39 FR 14944) as 20 CFR 1910.103, which would reduce

the level from a ceiling of 500 ppm to 50 ppm ceiling. It was expressly recognized that this standard limiting exposures to a 50 ppm level was intended to be a tentative, interim standard, to be in effect no longer than six months, during which time the whole question of possible safe exposure to VC would be reconsidered more fully and in the light of more information, especially results of experiments which were known to be underway at that time.

4. *Additional information.* On April 15, 1974, information and data were presented to representatives of OSHA, NIOSH and the EPA by the Industrial Bio-Test Laboratories, Northbrook, Illinois, concerning results of animal exposure studies with VC, sponsored by the Manufacturing Chemists Association (MCA). Although only preliminary in nature, these results revealed that 2 out of 200 mice exposed to VC concentrations of 50 ppm for 7 hours a day, five days a week, for approximately 7 months, developed angiosarcomas of the liver.

The Industrial Bio-Test Lab data indicate that exposure to VC at 50 ppm may well constitute a serious health hazard to employees. Also, the question of a safe level of exposure for humans cannot be determined at this time, and may continue as a matter for scientific deliberation for many years. We therefore conclude that it is now necessary to propose to change the 50 ppm level established in the ETS to as low a level as can be detected using methodologies outlined in this proposal.

(5) *The proposed permanent standard.* The requirements for a complete standard under section 6(b) of the Occupational Safety and Health Act of 1970 are much more comprehensive than the provisions of the ETS promulgated on April 5. The following proposals are responsive to the additional information on the carcinogenicity of VC, and the requirements of the Act.

A. *Level of exposure.* The proposed standard for employee exposure is set at no detectable level, as determined by a sampling and analytical method capable of detecting vinyl chloride at concentrations of 1 ppm with an accuracy of 1 ppm±50 percent. Although more sensitive methods may be available now or in the future, the methodological sensitivity proposed appears to be the most feasible and generally available. A method of 1 ppm sensitivity has been recommended to OSHA by NIOSH. To minimize the number of persons at risk, a requirement would be established for regulating areas where vinyl chloride is manufactured, reacted, stored, handled, released, packaged, or used, including operations with polyvinyl chloride containing detectable levels of vinyl chloride. Access to the areas would be limited to authorized employees.

B. *Monitoring.* A program of monitoring would be required to establish whether there are detectable levels in regulated areas and to permit determination of employee exposures on an individual basis. Monitoring would also be

DEPARTMENT OF LABOR

Occupational Safety and Health
Administration

[29 CFR Part 1910]

[Docket OSH-36]

VINYL CHLORIDE

Proposed Standard

1. *Background.* Vinyl chloride (chloroethene) Chemical Abstracts Service Registry No. 75015, is a synthetic chemical made by oxychlorination of ethylene or by hydrochlorination of acetylene. It is the parent compound of a series of thermoplastic resin polymers and copolymers which are widely used for containers, wrapping film, electrical insulation, pipe, conduit, and a variety of other products. Vinyl chloride has been made commercially in this country since 1939 and present production is in excess of seven billion pounds per year.

Vinyl chloride (VC) is a gas at ambient temperature and pressure and is a chlorinated hydrocarbon which has moderate liver toxicity. The previous standard set a ceiling value of 500 parts per million (ppm) (29 CFR 1910.93, Table G-1).

On January 22, 1974, the Occupational Safety and Health Administration (OSHA) was informed by the National Institute for Occupational Safety and Health (NIOSH) that the B. F. Goodrich Chemical Company reported that deaths of several of its employees from a rare liver cancer (angiosarcoma) may

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made for an opportunity to observe monitoring by employees or their designated representatives, as required by section 8(c)(3) of the Act.

Control methods to maintain detectable levels of VC are monitored; the programs would be triggered; an engineering and work practice program to reduce levels below detectability; and while this is on-going, a respiratory protection program for employees in the regulated area.

Engineering controls and work practices are favored methods of compliance because they tend to avoid contamination of the ambient air in the workplace. Accordingly, it is proposed to require the institution of engineering controls and of work practice methods as soon as feasible, and to require the use of respirators pending the institution of such controls, to supplement such controls where they are insufficient to reduce concentrations of vinyl chloride below the detectable level, in specified work situations, and in cases of emergency. The proposal for continuous flow and pressure demand types of respirators is based on the recommendations of NIOSH, which has observed leakage through chemical cartridge respirators at high concentrations of VC.

A requirement would also be established for the provision and use of protective clothing for employees in the regulated areas. The protective clothing would minimize skin contact with VC vapor, and would provide some measure of protection from splash of liquid in the event of a spill or rupture of equipment. Food, beverages, and like products would be prohibited in the regulated area.

Written operational and emergency plans would be required, along with employee training in routine and emergency duties. Specific requirements would be established for emergency actions and for routine maintenance and decontamination operations, including vessel entry, which are known to present particular hazards.

The purposes of operational and emergency plans and training are to apprise employees of the hazards to which they may be exposed, of the precautions they must take to avoid such hazards, and to rehearse employees in the procedures they must follow in emergencies.

Medical surveillance and comprehensive requirements for employee medical examinations are proposed, including necessary tests. Some additional guidance is included for the convenience of physicians. The proposed requirements have been recommended by OSHA to NIOSH as reasonably appropriate to detect liver dysfunction which may be indicative of or predispose to the development of liver and biliary diseases.

Records and reports. Records of monitoring, medical examinations, and entry to regulated areas are proposed with provision for access by appropriate OSHA and NIOSH officials. Specific provisions for employee access to monitoring records are included, as well as the requirement to furnish a copy of a medical

record to an employee's physician on the employee's request. Establishments conducting VC operations would be required to identify themselves to OSHA, and to report incidents of accidents resulting in the release of vinyl chloride.

Accordingly, pursuant to sections 6(b), 6(c), and 8(c) of the Occupational Safety and Health Act of 1970 (84 Stat. 1593, 1596, 1599; 29 U.S.C. 655, 657; Secretary of Labor's Order No. 12-71 (36 FR 8754), and 29 CFR Part 1911, it is hereby proposed to amend 29 CFR Part 1910 by revising § 1910.93q as set forth below.

Written data, views, and arguments concerning the proposals may be mailed to the Docket Officer, Docket OSH-36, Room 230, 1726 M Street, N.W., Occupational Safety and Health Administration, Washington, D.C. 20210, postmarked not later than June 10, 1974.

Pursuant to 29 CFR 1911.11(b) and (c), interested persons may file objections to the proposals, requesting an informal hearing with respect thereto, in accordance with the following conditions:

(1) The objections must include the name and address of the objector, stated in writing.

(2) The objections must be postmarked on or before June 10, 1974.

(3) The objections must specify the provisions of the proposed rule to which objection is taken, and must state the grounds therefor.

(4) Each objection must be separately stated and numbered, and

(5) The objections must be accompanied by a summary of the evidence proposed to be adduced at the requested hearing.

As revised, § 1910.93q would read as follows:

(a) Scope and application. (1) This section applies to any area or operation in which vinyl chloride (chloroethene), Chemical Abstracts Service Registry No. 75015, is manufactured, reacted, released, unpackaged, stored, or used, including areas and operations involving polyvinyl chloride wherever detectable levels of vinyl chloride are released.

(2) This section does not apply to the handling or use of fabricated products made entirely or in part of polyvinyl chloride.

(b) Definitions. (1) Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or his designee.

(2) Authorized employee means an employee whose duties require him to be in the regulated area and who has been specifically designated by the employer, and any employee who enters such area as a designated representative of employees to exercise an opportunity to observe monitoring and measuring for vinyl chloride.

(3) Closed container means any container which prevents the release of vinyl chloride to the environment.

(4) Contaminated means capable of releasing a detectable level of vinyl chloride.

(5) "Decontamination" means reduction of vinyl chloride concentrations to less than detectable levels.

(6) "Detectable level" means an airborne concentration of vinyl chloride measurable by a sampling and analytical method capable of measuring concentrations of 1 ppm with an accuracy of 1 ppm ± 50 percent.

(7) "Director" means the Director, National Institute for Occupational Safety and Health, or any person directed by him or the Secretary of Health, Education, and Welfare to act for the Director.

(8) "Emergency" means an unforeseen circumstance or set of circumstances, resulting in the release of vinyl chloride into areas occupied by employees.

(9) "Exposure" means actual contact with vinyl chloride when unprotected by required personal protective equipment and clothing.

(10) "Fabricated product" means a finished product or part of such product made of polyvinyl chloride, entirely or in part, including semifinished products such as film, sheet, block, bar, or extrusion stock.

(11) "OSHA Area Director" means the Director for the Occupational Safety and Health Administration Area Office having jurisdiction over the geographic area in which the establishment is located.

(12) "Polyvinyl chloride" means polyvinyl chloride homopolymer or copolymer before such is converted to a fabricated product.

(13) "Protective clothing" means clothing protective against vinyl chloride.

(14) "Vinyl chloride" means vinyl chloride monomer.

(15) "Waste" means any material or other reaction products remaining in the cleaning of equipment, and residues and sludge.

(c) References. College of American Pathologists, 230 N. Michigan Ave., Chicago, Illinois 60601.

(4) Regulated areas. (1) A regulated area shall be established where (A) vinyl chloride is manufactured, reacted, released, unpackaged, stored, or used, or (B) polyvinyl chloride, capable of releasing detectable levels of vinyl chloride, is manufactured, reacted, released, unpackaged, stored, or used.

(2) Access to regulated areas shall be limited to authorized employees.

(3) A daily roster of employees entering regulated areas shall be maintained. The roster shall summarize the number of employees entering the area, shall be kept for at least 30 days, and shall be available to OSHA.

(4) Monitoring. (1) Regulated areas shall be monitored for vinyl chloride.

(2) The monitoring shall be made at intervals of not more than 15 minutes for each authorized employee with a confidence level of 95 percent.

(3) Employees shall be afforded an opportunity to observe monitoring and measuring required by this paragraph.

(4) Where exercise of an opportunity requires entry to an area where the use

**VINYL CHLORIDE CONTAMINATED MATERIAL
CANCER-SUSPECT AGENT
DISPOSE OF OR DECONTAMINATE USING
AUTHORIZED PROCEDURES**

(4) Containers of polyvinyl chloride containing detectable levels of vinyl chloride shall be labeled:

**POLYVINYL CHLORIDE
CONTAINS VINYL CHLORIDE
VINYL CHLORIDE IS A
CANCER-SUSPECT AGENT
ABSORBED BY BREATHING AND
THROUGH SKIN**

(5) Containers of vinyl chloride shall be labeled:

**VINYL CHLORIDE
DANGER
EXTREMELY FLAMMABLE GAS
UNDER PRESSURE
MAY POLYMERIZE WITH
EXPLOSIVE FORCE
POISON
CANCER SUSPECT AGENT AND
ANESTHETIC
ABSORBED BY BREATHING
AND THROUGH SKIN**

(6) No statement shall appear on or near any required sign, label or instruction, which contradicts or detracts from the effect of any required warning, information or instruction.

(1) *Maintenance and decontamination.* (1) Emphasis shall be placed upon immediate clean up of spills, periodic inspection, prompt repair of equipment and leaks, and proper handling, storage and disposal or decontamination of materials to prevent airborne contamination and accidental skin contact with vinyl chloride. Waste materials, equipment, and other sources of vinyl chloride in closed containers, may not be placed in areas of excessive temperature or sunlight since build-up of internal pressure may result in rupture of the container, fire or explosion.

(2) Waste resins or other materials contaminated with vinyl chloride shall be placed in closed containers pending disposal or decontamination.

(3) Appropriate procedures shall be developed and implemented for the decontamination or disposal of all such waste material.

(4) In maintenance or repair operations on contaminated—systems or equipment, including vessel entry, employees engaged in such operations shall be (i) provided with and required to wear and use a whole-body air-supplied suit impervious to vinyl chloride, and a respirator in accordance with paragraph (g) of this section; and (ii) required to shower after removing protective equipment.

(5) Protective clothing and equipment shall be clean and dry for each use.

(6) When vessels or piping systems are opened local exhaust ventilation shall be provided to remove the escaping vapor from all occupied areas.

(7) (i) Vessels to be entered shall first be ventilated and monitored so that the concentration of vinyl chloride is reduced to a level within the protection factor capability of the protective equipment.

(ii) When vessels are to be entered, all piping to such vessel shall be:

(A) Opened, blanked and tagged; or
(B) Where welded piping is in use, not less than 2 valves in series, which isolate the vessel from any other connection to such line, must be closed and secured.

(iii) No employee shall enter a vessel, except when another employee properly trained and equipped for entry is present and is observing the employee in the vessel. The observer shall have means for signalling for help in the event the employee experiences problems. Under such conditions, the observer shall signal for help, and shall not enter to assist the employee until another person is present to observe.

(m) *Transportation loading and unloading.* (1) Facilities for the loading and unloading of vinyl chloride to and from containers shall have each transfer line and vapor-equalizing line equipped with vent connections, and shall have an inert gas purging system. Vent and purge effluent shall be returned to a process stream or flared in a safe location.

(2) Procedures shall be developed and implemented for the transfer of vinyl chloride. Written copies of such procedures shall be provided employees engaged in such operations, and such employees shall be fully trained and rehearsed in all procedures.

(3) Employees engaged in transfer operations shall be provided with and required to wear respirators in accordance with paragraph (g) of this section.

(n) *Polymer handling operations.* (1) Containers of polyvinyl chloride releasing detectable levels of vinyl chloride shall be opened and transferred only under local exhaust ventilation which reduces the concentration of vinyl chloride below the detectable level.

(2) Hot operations, such as but not limited to milling, calendaring and extruding, which release detectable levels of vinyl chloride, shall be carried on only under local exhaust ventilation which reduces the concentration of vinyl chloride below the detectable level.

(o) *Medical surveillance.* Not later than _____ 1974, a program of medical surveillance shall be instituted, and shall provide each authorized employee with an opportunity for examinations in accordance with this paragraph. All medical examinations and procedures shall be performed by or under the supervision of a licensed Doctor of Medicine (MD) or Doctor of Osteopathy (DO). All medical examinations and tests shall be provided without cost to the employee.

(1) At the time of initial employment, or upon institution of screening, a physical examination shall be performed with specific attention to detecting enlargement of liver or spleen by abdominal palpation.

(2) At the time of initial employment or upon institution of screening, and annually thereafter, a medical history checklist shall be completed by the employee. This list shall include questions concerning:

(i) Alcohol intake;
(ii) Past history of hepatitis;
(iii) Past exposure to potential hepatotoxic agents, including drugs and chemicals;

(iv) Past history of blood transfusions; and

(v) Past history of hospitalizations.

(3) At the time of initial employment, or upon institution of screening, a serum specimen shall be obtained for screening with respect to the following biochemical determinations of liver function:

(i) Total bilirubin;
(ii) Alkaline phosphatase;
(iii) Serum glutamic oxalacetic transaminase (SGOT);

(iv) Serum glutamic pyruvic transaminase (SGPT); and

(v) Gamma glutamyl transpeptidase (GGTP).

(4) Additional tests that may optionally be considered for use in screening include:

(i) Lactic dehydrogenase;
(ii) Serum protein determinations;
(iii) Serum protein electrophoresis; and

(iv) Platelet count.

(5) Laboratory analyses for all biological specimens included in medical examinations shall be performed in laboratories accredited by the College of American Pathologists or licensed under 43 CFR Part 74.

(6) If the results of screening required in paragraph (o) (3) of this section are normal, screening shall be repeated:

(i) Every six months for employees who have been employed in vinyl chloride related operations for 10 years or more; and

(ii) Annually for all other employees entering regulated areas.

(7) If one or more liver function tests performed are abnormal, serum testing shall be repeated as soon as possible, preferably within two to four weeks. If no abnormalities are present upon re-screening, serum testing shall be repeated in three months.

(8) If abnormalities persist upon re-screening, the employee shall be withdrawn from areas where contact with vinyl chloride is possible, and an individualized medical workshop shall be instituted. Suggested as initial steps are a complete physical examination and various special procedures such as hepatitis B antigen determination and liver scanning. If liver function abnormalities are determined to be unrelated to liver disease, the employee may be permitted to return to vinyl chloride-related employment, subject to individual medical evaluation.

(9) A complete and accurate record of the results of medical examinations shall be made and maintained for the duration of employment plus five years, or for 20 years, whichever is longer.

(p) *Records.* (1) Records of monitoring and measuring, medical records, and regulated area entry rosters and summaries, shall be made available for examination and copying upon request to authorized representatives of the Assistant Secretary and the Director.

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(2) In the event that the employer ceases to do business and there is no successor to receive and retain his records for the prescribed period, these records shall be transmitted to the Director of the Department of Labor, who shall be individually notified in writing of this transfer.

(3) Employees and their designated representatives shall be provided access to examine and copy records of monitoring and measuring.

(4) Former employees shall be provided access to examine and copy records reflecting their own exposures.

(5) Upon written request of any employee, a copy of the medical record of such employee shall be furnished to a physician designated by the employee in such request.

(q) *Reports.* (1) Not later than _____ the following information shall be reported to the OSHA Area Director. Any change in such information shall be reported to the OSHA Area Director within 15 days of such change.

(i) The address and location of each establishment which has one or more regulated areas; and

(ii) The number of employees in each regulated area during normal operations, including maintenance.

(2) Incidents which result in the release of vinyl chloride into any area where employees may be exposed shall be reported in accordance with this paragraph.

(i) A report of the occurrence of the incident and the facts obtainable at that time including a report on any medical treatment of affected employees shall be made within 24 hours to the OSHA Area Director.

(ii) A written report shall be filed with the OSHA Area Director within 15 calendar days thereafter and shall include:

(A) A specification of the amount of material released;

(B) A description of the area involved and the extent of known and potential employee exposure and area affected;

(C) A report on any medical treatment of affected employees and any medical surveillance program implemented; and

(D) An analysis of the circumstances of the incident, and measures taken or to be taken, with specific completion dates, to avoid further similar releases.

(3) Upon completion of any monitoring and measuring which discloses that any employee has actually been exposed to detectable levels of vinyl chloride, each such employee shall be individually notified in writing. The notice shall:

(i) Be delivered not later than 10 working days after completion of the monitoring and measuring;

(ii) State the actual exposure in terms of concentration and time; and

(iii) State the steps which have been taken, are being taken, and will be taken, with specific completion dates, to terminate the exposure and prevent a recurrence.

(Secs. 6-61, 6-61, and 6-61, 84 Stat. 1533, 1970, 1970 (29 U.S.C. 655, 657); Secretary of Labor's Order No. 12-71 (36 FR 8754))

Signed at Washington, D.C. this 6th

JOHN STANLEY,
Assistant Secretary of Labor.

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URL 20578

DEPARTMENT OF LABOR
Occupational Safety and Health
Administration

[29 CFR Part 1999]

STANDARD FOR OCCUPATIONAL
EXPOSURE TO VINYL CHLORIDE

Notice of Intent To Prepare an
Environmental Impact Statement

The National Environmental Policy Act of 1969 (42 U.S.C. section 102) requires each Federal agency to consider the environmental effects of proposed actions and to prepare environmental impact statements on major actions affecting the quality of the human environment. Accordingly, the Occupational Safety and Health Administration, U.S. Department of Labor, in conformance with its procedures for environmental impact statements (29 CFR Part 1999), announces its intention to prepare an environmental statement assessing the impact of a proposed standard for occupational exposure to vinyl chloride to be published in the FEDERAL REGISTER in the near future.

The Office of Standards Development, Occupational Safety and Health Administration, is currently collecting information and data on possible environmental impacts of the proposed standard, such as any adverse environmental effects which cannot be avoided should the standard be adopted; alternatives to such a standard; the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity; any irreversible commitments of resources which would be involved if the standard be implemented. Those issues of particular interest are:

- a. Any medical or toxicological evidence which indicates that exposure to vinyl chloride or its polymers produces adverse effects to living organisms, especially primates.
- b. Current and historical levels of occupational exposure.
- c. Combustible characteristics associated with vinyl chloride or its polymers, especially information correlating accident experience; damage to facilities, interruption of plant activities, and/or storage and shipment difficulties.
- d. Identification of the uses of vinyl chloride or its polymers, through finished products, and determination of the quantity of use.
- e. Any information suggesting substitutes for vinyl chloride or its polymers, to include estimates of the extent to which substitution is feasible.
- f. Any suggested actions which will control the health hazards associated with production, storage, or shipment of vinyl chloride or its polymers through finished products.
- g. Any other pertinent information.

Any person having information or data on this subject which is not readily available in the open literature is invited to submit it, with accompanying documentation, to the Director, Office of Standards Development, Occupational Safety

and Health Administration, 1725 M Street, N.W., Room 500, Washington, D.C. 20546. All information received will be available for public inspection at the Office of Standards Development.

When the draft environmental impact statement on vinyl chloride is completed, copies will be available to any member of the public who requests it. A 45-day period will be allowed for the public to submit their comments.

Signed at Washington, D.C., this 18th day of April 1974.

JOHN STENDER,
Assistant Secretary of Labor.
[FR Doc. 74-9300 Filed 4-23-74; 8:45 am]