

were engaged in operations outside the actual resin production. The productivity of these workers has probably increased since 1969 in view of some significant technological changes such as the introduction of the bulk polymerization process, but, on balance, the total number of workers has probably increased beyond 5,000, although less than 10,000. Some of the job classifications of workers involved in resin production with potential exposure to VC are shown in Table 4. No evaluation of the total industry exposure to vinyl chloride can be made at present, because no estimates of the personnel distribution in these categories are available for the entire industry, and because exposure varies according to job category.

The information available does tend to indicate that exposure to VC is greater in resin producing plants than in those synthesizing the monomer. The areas of greatest exposure in a PVC plant are judged to be the following:

- Unloading of incoming vinyl chloride;
- Reactor cleaning;
- Entry of vinyl chloride containing vessels for maintenance and repair work;
- Entry of PVC storage silos;
- Shipping or packaging of PVC; and
- Leaks of vinyl chloride in the process area.

Levels of VC exposure in these plants have been decreasing rapidly since January, 1974. For the entire industry, the average TWA is probably well below 25 ppm. Exposures differ

Table 4

Job Categories of WorkersProduction of PVC Resins

Bagging and shipping operator	Monomer recovery operator
Catalyst makeup man	Monomer supervisor
Dryer operator	Polymer supervisor
General laborer, custodial	Reactor cleaner
Laboratory technician	Reactor operator
Maintenance personnel	Slurry blender
Monomer maintenance personnel	Utilities operator
Monomer operator	Warehouse personnel

for each job category, but, from the available data, it appears that reactor cleaners are likely to suffer the greatest exposure. Operators of the polymerization process equipment, those involved in unloading or transferring the monomer, and maintenance personnel, respectively, have successively lower exposures to VC. Other personnel are likely to be exposed to considerably lower levels.

Reactor cleaning poses a special hazard. During the reaction process, the polymer, with entrapped monomer, builds up on the surface of the reactor, so that periodic cleaning is usually required. In the past, most of this cleaning was performed by hand using a scraper and chisel. Air analyses have shown that VC concentrations in the reactor prior to ventilation reach 3,000 ppm. After ventilation has been completed and the worker begins the scraping, concentrations between 50 and 100 ppm may easily be released. Air analyses have shown concentrations of 600 to 1,000 ppm of VC close to the hand. Since these studies were completed, industry has moved to greater use of water-jet or organic-solvent cleaning.

Industry has also instituted monitoring procedures of reactor interiors prior to worker entry.

Another exposure problem concerning reactor cleaning has been that the air left in the reactor disperses into workroom air, thus producing a major source of vinyl chloride exposure. Substantial efforts are currently underway to recover all unreacted monomer prior to opening the vessel, but the low levels

involved pose a significant technological difficulty.

3. Compounding of PVC Resins with Additives^{1,12,15,17}

In most applications, PVC is used with one or more additives to order to process and convert the compound into its final products. The additives used depend on the initial form of the resin, the type of processing to be used, and the desired application. Resins are classified either as general purpose (made by any of the techniques described in the previous section) or as dispersion (made primarily by emulsion polymerization). After the addition of a plasticizer, the general purpose resins can be further categorized into plasticized resins and unplasticized (i.e. rigid) resins. The dispersion resins, or latexes, may be plasticized for ultimate use as plastisols or organosols, or they may be chlorinated for processing similar to that performed on the general purpose resins.

To these basic resins, additives are compounded according to particular requirements. These additives are usually categorized as follows:

- o Plasticizers, to increase resin flexibility, softness, and elongation, and in some cases, to extend the basic resin;
- o Heat stabilizers, to prevent discoloration during the processing of resin compounds;
- o Fillers, to reduce costs, but sometimes to produce opacity, specific electrical properties, resistance \

to ultraviolet light, resistance to blocking, improved dryblending characteristics, and other properties;

- o Pigments and dyes, to color PVC resin compounds;
- o Processing aids, to facilitate the achievement of certain processing objectives, such as increased processing rates, lower processing temperatures, improved fusion, and reduced surface gloss;
- o Impact modifiers to protect rigid resins against brittle fracture;
- o Lubricants, to reduce friction of melts with the surfaces of processing machinery and molds;
- o Light stabilizers, to prevent PVC degradation from continuous exposure to sunlight;
- o Fungicides, to inhibit the vulnerability of compounded PVC to attack by microorganisms;
- o Flame retardants, to preserve the nonflammability of PVC compromised by the use of flammable plasticizers;
- o Antistatic agents, to improve electrical conductivity;
- o Antioxidants, to provide protection in high-temperature applications; and
- o Foaming agents, to influence cell structure for resins expanded into foams.

The compounding of these additives with PVC resins may occur in a plant producing the basic resin, in a plant designed for the purpose of compounding alone, or in a plant which also processes the compounded resins. Trade publications identify

approximately 200 companies supplying chlorinated, plasticized, and rigid PVC or copolymer resins.

The mechanism of the compounding stage ensures that the additives are fully dispersed in the PVC resins to yield a homogeneous material suitable for further processing. The resultant compounds may be in powder or granular form. The latter form is obtained by heating the compound into granules or pellets. These are then used as feedstock for subsequent extrusion and molding processes. The powder form can be fed directly into fabrication equipment where the PVC resin need be heated only once, thus requiring fewer additives.

(1) Process Descriptions

A wide variety of compounding equipment is currently available, most of which uses the resin and the various additives in dry form. Sometimes, the resin is premixed with several additives before it is used in further processing with other additives. The order in which specific compounding equipment is used depends on the specifications the PVC must meet.

Two-Roll Mill - The material in the form of a powder blend is fed into a mill consisting of two rolls separated by a small gap. The mill kneads the material for about 10 minutes at a temperature of 150-160°C and strips it off as a continuous band. This strip of material is then granulated into small cubes suitable for use in an extruder.

Banbury Mixer - The mixer consists of a jacketed mixing chamber fitted with blades rotating in opposite directions. It mixes batches of the material under pressure and heat to produce a fused and kneaded mixture. The mixture then is discharged in a doughlike mass which is converted into sheet form for granulation. A two-roll mill is utilized for this purpose. The use of Banbury mixers can lead to significant variations between batches. This inconsistency is tempered in some cases by the use of automatic weighing and feeding systems for the injection of the various mixing materials.

Continuous Mixers - This type of mixing is designed to enhance the consistency between batches by providing a continuous feed operation; however, this process requires great care to ensure the homogeneity of the resultant mixture. The machines used are basically single or twin-screw extruders, modified to optimize the handling of the material. The compound may be heated, fed directly to calenders, extruded through a die plate for granulation, or extruded through a die with a die-face cutter for granulation.

Multiscrew Compounders - A twin-screw extruder, specially adapted for the purpose, is also suitable for PVC compounding. The primary advantage this equipment offers, as opposed to the extruders described above, is that its screw sections and kneading discs can be changed to meet the specific requirements of the material being compounded.

High-Speed Mixers - Equipment featuring injection molding and extrusion has also been modified to accept PVC powder blends. To ensure satisfactory processing, such blends are combined in a high-speed mixer by friction-generated heat. When this type of equipment is used, the production of the proper blends must be performed with great care.

Wet Granulation - In this process, the PVC is taken directly from the polymeriser while still in an aqueous dispersion. The additives are introduced into the granulating vessel along with a plasticizer that had previously been mixed with some of the stabilizer and lubricants. The compounded resin particles are then rapidly plasticized, producing a substance in the form of granules which are easily separated from the suspension. This process is limited to polymer manufacture, since it is not economically feasible to redisperse the polymer once it has been dried out.

Mixing of Plastisols - PVC pastes can be produced using paddle-type mixers that can be operated under a vacuum, such as the vertical paddle mixer, the vertical planetary mixer, or the horizontal Z-blade mixer. The PVC resin is introduced into the mixer along with sufficient plasticizer to form a paste. Other ingredients are then incorporated slowly and at low temperatures until a smooth homogeneous paste is obtained.

APPENDIX A

EMERGENCY TEMPORARY STANDARD ON VINYL CHLORIDE

BOR 004740

ferent standard on exposure to asbestos dust which would otherwise be applicable by virtue of any of those sections.

(b) *Vinyl chloride.* Section 1910.93q shall apply to the exposure of every employee to vinyl chloride in every employment and place of employment covered by § 1910.12, § 1910.13, § 1910.14, § 1910.15, or § 1910.16, in lieu of any different standard on exposure to vinyl chloride which would otherwise be applicable by virtue of any of those sections.

Effective date. These amendments shall become effective on April 5, 1974.

(Secs. 4, 6, and 8, 24 Stat. 1592, 1596, 1599 (29 U.S.C. 663, 656, 657); Secretary of Labor's Order No. 12-71, 36 FR 8754.)

Signed at Washington, DC., this 2d day of April 1974.

JOHN STENDER,
Assistant Secretary of Labor.

[FR Doc. 74-7890 Filed 4-4-74; 8:45 am]

Title 29—Labor

CHAPTER XVII—OCCUPATIONAL SAFETY
AND HEALTH ADMINISTRATION, DE-
PARTMENT OF LABORPART 1910—OCCUPATIONAL SAFETY
AND HEALTH STANDARDSEmergency Temporary Standard for
Exposure to Vinyl Chloride

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 tissues, 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 present standard sets a ceiling value of 500 parts per million (ppm) (29 CFR 1910.93).

On January 22, 1974, the Occupational Safety and Health Administration 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 form of liver cancer may have been occupationally related. As a result of this notification, and after consultation with 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 both VC and polyvinyl chloride was announced on January 30, 1974 (39 FR 3874), and held on February 15, 1974.

2. *Carcinogenicity of VC.* Information produced at the hearing demonstrated that exposure of laboratory animals (mostly Sprague-Dawley rats) to VC by inhalation at and below the 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 so far reported are that tumors have been observed in groups of animals exposed to VC at concentrations as low as 250 ppm. No tumors have been observed in the group of animals exposed to VC at a concentration of 50 ppm. It also appears so far that the total number of tumors, as well as the numbers of angiosarcomas of the liver, decrease as the concentrations of VC are reduced to 250 ppm. Finally, another experiment by Professor Maltoni is 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 22:354-361 (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 Company and Goodyear Company are also reported in a post-hearing comment from NIOSH dated March 11, 1974, to have had exposure to vinyl chloride and to have died from angiosarcoma of the liver. Finally, autopsies of four deceased employees revealed that liver angiosarcoma tumors were histologically indistinguishable from the angiosarcoma tumors observed in Professor Maltoni's experimental animals. It is concluded therefore, that vinyl chloride is carcinogenic for humans.

We therefore conclude that the present standard for VC should be lowered from a ceiling of 500 ppm to a ceiling of 50 ppm for the following reasons:

(a) In light of the evidence referred to above including the Maltoni experiments demonstrating that VC is carcinogenic in animals at 250 ppm, we conclude that VC must be considered carcinogenic in man at the same level;

(b) Although Professor Maltoni did not induce tumors in his experimental animals at an exposure concentration of 50 ppm, these data do not support the concept that occupational exposure of employees to concentrations of 50 ppm throughout their working lifetime would be without detrimental health effects;

(c) The question whether safe levels of exposure to carcinogens exist for humans and, if so, what such levels would be, is the subject of continuing scientific deliberation. In the case of VC, Professor Maltoni did not observe tumors in his animals at exposure concentrations of 50 ppm. In addition, Torkelson, Oyen, and Rowe found that exposure to concentrations of 50 ppm of VC failed to induce tumors in rats, hamsters, rabbits, and dogs. Accordingly, there is insufficient evidence at this time to conclude that VC at concentrations of 50 ppm or below poses a grave danger to humans.

(d) The emergency temporary standard adopted represents a substantial reduction in the permissible level of exposure and, in our practical judgment, is the lowest level that can be complied with immediately; and

(e) This standard will be in effect for a period of no longer than six months, during which time the whole question of possible safe exposure of humans to VC will be reconsidered more fully and in the light of more information, including experiments which are under way at this time (TR 47, 49, 71-74).

3. *Petitions for an emergency tempo-*

rary standard. In a telegram to the Assistant Secretary of Labor, received on or about March 14, 1974, the President of the United Rubber Workers International Union urged the establishment of an emergency temporary standard for VC. During the hearing of February 15, 1974, the Industrial Union Department, AFL-CIO, and the United Rubber Workers International Union made a joint petition for an emergency temporary standard for VC (TR 141-148), which was also joined by the Oil, Chemical and Atomic Workers International Union (TR 37). At the same hearing, several participants urged, on the other hand, a regular rulemaking proceeding as the most suitable for the orderly development of relevant information (TR 112, 180).

The petitions for an emergency temporary standard specified in detail the contents of the standard requested. In substance, the request is to issue a comprehensive fully-developed standard based on the recommendations of the Standards Advisory Committee on Carcinogens submitted to the Assistant Secretary of Labor on or about August 27, 1973. The recommendations are far-ranging, and cover special categories of operations, signs and labels, medical surveillance, reporting, etc., including a permit system for the use of a carcinogen.

We agree that an emergency temporary standard is necessary; we cannot say on the basis of the information developed so far that a comprehensive standard, such as the one requested, is either necessary or even desirable. It has been decided to promulgate a standard containing only those essential provisions which are deemed necessary to provide protection to employees from grave danger until a regular rulemaking proceeding in accordance with sections 6 (b) and (c) of the Act can be concluded. The reasons for a decision to establish a ceiling value of 50 ppm have already been stated. A decision on other possible, appropriate provisions is best made after consideration of all relevant data and views that interested persons may submit during the proceeding soon to be initiated.

With respect to arguments in opposition to issuance of an emergency temporary standard, the concern and efforts of several companies participating at the hearing for the protection of their employees are recognized. It may also be that some employers in some plants have fully complied with the interim controls recommended by NIOSH on January 30, 1974. There is, however, reason to believe that employees are currently being exposed to VC at concentrations well above 50 ppm. This was asserted several times at the hearing, and not seriously questioned. Moreover, a report, dated March 1974, of a survey by the staff of the Office of Standards Development, OSHA, of several facilities manufacturing VC and polyvinyl chloride revealed concentrations for some job classifications as high as 229 ppm. Therefore, a regulation is considered necessary to provide, immediately, adequate protection to workers ex-

posed to VC. Also, the eight-hour, time-weighted average standard suggested by several participants at the hearing (see, for instance, TR 178), has been rejected. The March 1974 report of the survey revealed that several kinds of work or operations are of short duration. Loading or unloading of a tank car may require approximately 15 minutes. The cleaning of a reactor may require approximately half an hour. An eight-hour, time-weighted average standard would permit exposure to VC at concentrations of 400 ppm for one hour. Such upward excursions, several times the 50 ppm level, cannot be permitted to occur.

4. *The standard.* The standard set out below contains only the requirements deemed necessary to provide protection before the conclusion of the rulemaking proceeding to be commenced shortly.

Because exposure to VC is hazardous, and because such exposure can occur in the processes of synthesizing or polymerizing of VC or in the handling of VC polymers or copolymers which contain absorbed VC, this standard applies to all such processes and to the handling, reacting, manufacturing, processing, releasing, repackaging, or storage of any of these materials. The monitoring requirements serve two purposes, to trigger into operation a compliance program and to check the effectiveness of the program. Also, engineering controls are favored for compliance, and respirators are intended to provide protection until such controls can be installed or in cases where such controls are not feasible.

Accordingly, by reason of the foregoing and on the basis of the record of the hearing of February 15, 1974, with exhibits, the written submissions received before the hearing pursuant to the notice of the hearing, the post-hearing written submissions by the participants at the hearing, the March 1974 report of a fact-finding survey recommendations received from NIOSH, and the other data referred to herein, it is found (1) that VC at concentrations in excess of 50 ppm is physically harmful and carcinogenic; (2) that exposure to VC at concentrations in excess of a concentration of 50 ppm poses a grave danger to employees; (3) that employees are presently exposed to VC at concentrations in excess of 50 ppm; and (4) that the emergency temporary standard set out below is necessary to provide immediate protection to employees from such danger.

Pursuant to section 6(c) of the Occupational Safety and Health Act of 1970, a proceeding will commence shortly in accordance with section 6(b) of the Act, in which the emergency temporary standard will serve as a proposed rule, together with other subsidiary rules. As soon as possible a draft environmental impact statement will be filed with the President's Council on Environmental Quality, and copies will be provided to other appropriate Federal agencies for their comments.

Pursuant to sections 6(c) and 8(c) (3) of the Williams-Steiger Occupational Safety and Health Act of 1970 (84 Stat. 1596, 1599; (29 U.S.C. 655, 657)), and

Secretary of Labor's Order No. 12-71 (36 FR 8754), 29 CFR Part 1910 is amended by adding thereto a new § 1910.93q to read as set forth below. In addition, pursuant to section 4(b) (2) of the Act (84 Stat. 1592; (29 U.S.C. 653)), the standard in the new § 1910.93q is determined to be more effective than the corresponding standards now in Subpart B of Part 1910, in Parts 1915, 1916, 1917, 1918, and 1926 of title 29, Code of Federal Regulations, and in Part 50-204 of Title 41 of the Code of Federal Regulations. Therefore, these corresponding standards are superseded by the new standard in § 1910.93q.

1. In 29 CFR Part 1910, § 1910.93 is amended by deleting from Table G-1 the line: " * * * C Vinyl chloride * * * 500 * * * 1300".

2. Part 1910 of Title 29 of the Code of Federal Regulations is amended by adding thereto a new § 1910.93q to read as follows:

§ 1910.93q. Vinyl chloride.

(a) *Scope and application.* (1) This section applies to any area or operation in which vinyl chloride (chloroethene), Chemical Abstracts Service Registry Number 75015, is manufactured, reacted, handled, processed, released, repacked, or stored.

(2) This section does not apply to the handling, storage, or other use of vinyl chloride polymers and copolymers in the form of fabricated products.

(b) *Permissible exposure.* The occupational environment shall be controlled so that no employee is exposed to vinyl chloride at a concentration in excess of 50 parts per million (ppm) (127.0 mg/cum).

(c) *Monitoring.* (1) *Initial monitoring.* As soon as possible but not later than April 22, 1974, every employer of an employee working in an area or operation in which vinyl chloride is manufactured, reacted, handled, processed, released, repacked, or stored shall begin monitoring the ambient air of the area to determine whether it contains vinyl chloride in concentrations in excess of 50 ppm.

(2) *Frequency.* Monitoring of a sufficient number of employees so that a representative sample of exposures to vinyl chloride may be determined shall be accomplished not less frequently than weekly until all results for three consecutive weeks are at or below 50 ppm. Thereafter, monitoring shall be conducted not less frequently than monthly so long as the concentrations of vinyl chloride do not exceed 50 ppm. If a monitoring sample reveals vinyl chloride in concentrations in excess of 50 ppm, weekly monitoring shall be resumed until all results for three consecutive weeks are at or below 50 ppm.

(3) *Method of monitoring.* Personnel monitoring shall be accomplished by collecting samples by suitable devices worn by the employee. The samples shall be analyzed by gas chromatography or by any other method which is of equivalent sensitivity. The analytical procedure shall be sensitive to 5 ppm of vinyl chloride in air with an accuracy of ± 20 percent for a ten minute air sample.

(4) *Employee observation of monitoring.* Employees working in an area or operation whose ambient air is monitored, or their representatives, shall be given a reasonable opportunity to observe the personnel monitoring required by this section.

(5) *Recordkeeping.* The results of all monitoring shall be recorded in writing. The records shall be retained for at least 5 years and shall be made available for inspection and copying by representatives of the Assistant Secretary of Labor for Occupational Safety and Health and the Director of the National Institute for Occupational Safety and Health (NIOSH).

(6) *Employee access.* Each employee and former employee shall have access to such records of the results of monitoring required by this section as will indicate his own exposure to airborne concentrations of vinyl chloride.

(7) *Employee notification.* Each employer shall promptly notify any employee who has been or is being exposed to vinyl chloride in concentrations in excess of 50 ppm, and shall inform him of the corrective action being taken.

(d) *Compliance.* (1) Whenever any monitoring sample reveals vinyl chloride at a concentration in excess of 50 ppm, or whenever any accident, such as rupture of equipment or spillage, indicates the likelihood of a greater than usual release of vinyl chloride into the ambient air, all employees exposed to such concentrations shall be withdrawn to a safe area and shall not be permitted to re-enter the work area unless they wear either Type C continuous flow or pressure demand air supplied respirators or self-contained breathing apparatus.

(2) Work which may reasonably be expected to release vinyl chloride in concentrations in excess of 50 ppm, such as repair, maintenance or cleaning of reactors or other equipment containing vinyl chloride, shall be accomplished only by employees wearing Type C continuous flow or pressure demand air supplied respirators or self-contained breathing apparatus.

(3) In any case covered by paragraphs (d) (1) or (d) (2) of this section, in addition to providing the required respirators, the employer shall examine and analyze the source of the excessive concentrations of vinyl chloride in order to determine feasible engineering or operational controls appropriate to reduce the airborne concentrations to the permissible level. Such controls shall be implemented as quickly as possible.

(4) Periodic tests shall be conducted for equipment leaks and for emissions of vinyl chloride which may result from work practices.

3. In 29 CFR Part 1910, § 1910.19 is revised to read as follows:

§ 1910.19 Special provisions for air contaminants.

(a) *Asbestos dust.* Section 1910.93a shall apply to the exposure of every employee to asbestos dust in every employment and place of employment covered by § 1910.12, § 1910.13, § 1910.14, § 1910.15, or § 1910.16, in lieu of any dif-

APPENDIX B
PROPOSED STANDARD ON VINYL CHLORIDE

BOR 004744

PROPOSED RULES

DEPARTMENT OF LABOR
Occupational Safety and Health
Administration

[29 CFR Part 1910]

[Docket OSH-86]

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 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 18, 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 Istituto 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; 5,000; 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, C/en 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 12342) as 29 CFR 1910.93q. This standard reduced 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 18, 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, repackaged, 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. Provision would also be

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

C. Control methods. Where detectable levels of VC are monitored, two 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.

D. Medical surveillance. 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 to OSHA by NIOSH as reasonably appropriate to detect liver dysfunction which may be indicative of, or predisposing to, the development of liver angiosarcomas.

E. 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 (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;

(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:

§ 1910.93q Vinyl Chloride.

(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, repackaged, stored, or used, including areas and operations involving polyvinyl chloride where 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 assigned by the employer; and any employee who enters such an area as a designated representative of employees to exercise an opportunity to observe monitoring and measuring of 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 resin" means any resin or other reaction products removed in the cleaning of equipment, such as vessels and piping.

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

(4) *Regulated areas.* (1) A regulated area shall be established where (i) vinyl chloride is manufactured, reacted, released, repackaged, stored, or used; or (ii) polyvinyl chloride capable of releasing detectable levels of vinyl chloride is manufactured, reacted, released, repackaged, 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 made and maintained. The rosters, or summaries thereof, shall be kept for at least 20 years.

(e) *Monitoring.* (1) Every regulated area shall be monitored for detectable levels of vinyl chloride.

(2) The monitoring shall assure that any exposure may be determined for each authorized employee with a confidence level of 95 percent.

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

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

of protective clothing, equipment, facilities, or procedures is required, such clothing, equipment, facilities, and procedures shall be provided to all persons entitled to exercise the opportunity, at no cost to any of them.

(H) Persons exercising the opportunity shall be instructed regarding:

(A) The toxicity and fire hazard of vinyl chloride; and

(B) The protective steps and measures necessary for their protection.

(III) Observers shall be permitted, without interference to the persons performing the monitoring and measuring, to:

(A) Observe all steps and procedures related to the collecting, processing, and evaluation of particular monitoring and measurement samples;

(B) Record quantities and results obtained;

(C) Observe the condition of monitoring and measuring equipment;

(D) Receive a demonstration of the calibration and function tests of the monitoring and measuring equipment performed on site; and

(E) Examine instructions and documents related to the procedures and equipment for monitoring and measuring.

(4) Accurate and complete records of all required monitoring shall be made and maintained for not less than 20 years. Such a record shall (i) state the date of such monitoring and the levels determined; and (ii) identify the instruments and methods used.

(f) **Engineering controls and workpractice methods.** (1) Where detectable levels of vinyl chloride are measured, immediate protection shall be provided against exposure to vinyl chloride by the use of engineering controls, workpractice methods, and respirators as follows:

(i) Feasible engineering controls and workpractice methods shall immediately be used to reduce airborne concentrations of vinyl chloride below the detectable level;

(ii) Wherever feasible engineering controls and workpractice methods which can be instituted immediately are not sufficient to reduce concentrations of vinyl chloride below the detectable level, they shall nonetheless be used to reduce the concentrations to the lowest practicable level, and shall be supplemented by means of respirators in accordance with paragraph (g) of this section;

(iii) Wherever no feasible engineering control or workpractice method can be instituted immediately, immediate respiratory protection shall be provided in accordance with paragraph (g) of this section; and

(iv) In any case covered by paragraph (f) (i) (ii) or (iii) of this section, the employer shall also undertake as soon as practicable a program to reduce airborne concentrations of vinyl chloride below the detectable level, or to the greatest extent feasible, solely by means of engineering controls and workpractice methods and as soon as feasible.

(2) There shall be tests made for process or equipment leaks and for emission of vinyl chloride which may result from workpractices. The frequency of these tests shall be such as to insure the integrity of equipment and adherence to proper workpractices.

(g) **Respiratory protection.** (1) A respiratory protection program in accordance with § 1910.134 shall be established and implemented where respirators are required to be used by this section.

(2) Respirators shall be used only in cases of emergency and where required by any other provision of this section. Respirators may not be used in lieu of feasible engineering controls or workpractice methods.

(3) Respirators or combinations of respirators for protection against vinyl chloride shall be selected from among the following:

(i) A positive pressure full facepiece self-contained breathing apparatus;

(ii) A pressure-demand full facepiece self-contained breathing apparatus operating in the pressure-demand mode;

(iii) A combination type "C" pressure-demand full facepiece respirator operating in the pressure-demand mode and a pressure-demand self-contained breathing apparatus operating in the pressure-demand mode; or

(iv) A combination type "C" continuous flow respirator and a pressure-demand self-contained breathing apparatus operating in the pressure-demand mode.

(h) **Protective clothing.** (1) Employees entering regulated areas shall be provided full-body protective clothing, footwear or shoe covers, and gloves, at no cost to them, and required to wear it while in the regulated area.

(2) Where polyvinyl chloride powder containing detectable levels of vinyl chloride is handled, employees shall also be:

(i) Provided and required to wear head coverings;

(ii) Required to remove all protective clothing at each exit from the regulated area; and

(iii) Required to shower after the last exit of the day.

(3) Clean protective clothing shall be provided whenever contaminated or soiled, but not less frequently than weekly. Contaminated clothing shall be decontaminated before reuse by removal for laundering or disposal.

(i) **Hygiene facilities and practices.** (1) Where employees are required by this section to wear protective clothing and equipment, change rooms shall be provided in accordance with § 1910.141(d) (3).

(2) Where employees are required by this section to shower, shower facilities shall be provided in accordance with § 1910.141(d) (3).

(3) Storage or consumption of food or beverages, storage or use of smoking or non-food chewing products, and the storage or application of cosmetics are prohibited in regulated areas.

(j) **Emergency situations.** (1) A written operational plan for emergency situations shall be developed for each regulated area.

(2) In the event of an emergency, appropriate portions of the plan shall be put into operation.

(i) Hazardous conditions created by the emergency shall be eliminated and the affected area shall be decontaminated prior to the resumption of normal operations.

(ii) Special medical surveillance by a physician shall be instituted within 24-hours for employees present in the affected area at the time of the emergency.

(iii) Where an employee has a known contact with liquid vinyl chloride such employee shall be required to shower as soon as possible, unless contraindicated by physical injuries.

(iv) An incident report on the emergency shall be reported as required in paragraph (e) (2) of this section.

(3) Each authorized employee shall be trained in a program relating to the hazards of vinyl chloride and the precautions for safe use.

(i) The program shall include:

(A) The nature of the fire hazard, and the necessary protective steps;

(B) The nature of the toxic hazard, including local and systemic effects, acute and chronic effects including specifically the carcinogenic hazard;

(C) The specific nature of operations which could result in exposure to vinyl chloride, and necessary protective steps;

(D) The purpose for and application of the medical surveillance program;

(E) The purpose for and application of decontamination practices;

(F) The purpose for and significance of emergency practices and procedures;

(G) The employee's specific role under normal operating or emergency conditions;

(H) Specific information to aid the employer in recognition and evaluation of conditions and situations which may result in the release of vinyl chloride;

(I) The purpose for and application of specific first aid procedures and practices;

(J) A review of this standard at the employee's first training and indoctrination program and annually thereafter.

(4) All materials relating to the program shall be provided upon request to authorized representatives of the Assistant Secretary and the Director.

(k) **Signs and labels.** (1) Entrances to regulated areas shall be posted with signs bearing the legend:

CANCER-SUSPECT AGENT AREA
AUTHORIZED PERSONNEL ONLY

(2) Areas containing operations covered in paragraph (k) (1) (4) of this section shall be posted with signs bearing the legend:

CANCER-SUSPECT AGENT IN THIS AREA
FULL RESPIRATORY PROTECTION REQUIRED
AUTHORIZED PERSONNEL ONLY

(3) Containers of waste, or other materials contaminated with vinyl chloride shall be labeled:

**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.* (i) 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 (c) (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 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.

PROPOSED RULES

(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 by registered mail to the Director, and each employee 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(b), 6(c), and 8(c), 94 Stat. 1666, 1696, 1899 (39 U.S.C. 485, 487); Secretary of Labor's Order No. 12-71 (38 FR 5784))

Signed at Washington, D.C. this 6th day of May, 1974.

JOHN STENSON,
Assistant Secretary of Labor.

[FR Doc. 74-10748 Filed 5-6-74; 8:46 am]

APPENDIX C
COMMENTS ON DRAFT
ENVIRONMENTAL IMPACT STATEMENT

Appendix C

List of government agencies, private industries, and other groups who have commented on the Draft Environmental Impact Statement on Vinyl Chloride:

1. New England Plastics Corp.
2. John W. Whittlesey
3. Department of Health, Education, and Welfare
4. B.F. Goodrich Chemical Co.
5. Dow Chemical U.S.A.
6. Cities Service Co.
7. Keller and Heckman
8. Shell Chemical Co.
9. Union Carbide Corp.
10. Department of the Army
11. Fabri-Kal Corp.
12. Department of the Treasury
13. Atomic Energy Commission
14. Harvey Hubbell Inc.
15. Americhem Inc.
16. Department of Commerce
17. Goodyear Tire and Rubber Co.
18. Air Products and Chemicals Inc.
19. Industrial Union Dpt., AFL-CIO
20. Council on Environmental Quality

READY TO SERVE



NEW ENGLAND PLASTICS CORPORATION

310 SALEM STREET

WOBBURN, MASSACHUSETTS 01801

AREA CODE 617. 933-6004

July 12, 1974

Mr. David R. Bell
Department of Labor, OSHA
Office of Standards Development
Room 500
1726 M Street, N.W.
Washington, D.C. 20210

Dear Mr. Bell:

Herewith are my comments on the Draft Environmental Impact Statement for the Proposed Vinyl Chloride Regulation.

BACKGROUND

The product listing is inadequate. It should mention; phonograph records, packaging films, house siding, 1 billion lbs. of plastifols, agricultural products, calendered sheet and upholstery.

DESCRIPTION OF ACTION

No data is available that demonstrates the latency period for VCM exposure. It is presumptive. It must be established by human clinical data.

PROBABLE IMPACT

Adoption of any VCM level that exceeds present engineering capability will cause a major decrease in productivity and a significant increase in costs.

The existence of substitutes is nil, the properties of PVC are unique. It is the only thermoplastic that is naturally flame resistant. It lends itself to numerous methods of fabrication. It replaces many natural materials that are expensive, in short supply and aren't as durable.

ALTERNATIVES

The basis for a ban on VCM or the establishment of very low levels of exposure are not based on any human data. It is all conjecture.

PLANTS

310 SALEM STREET
WOBBURN, MASSACHUSETTS 01801
(617) 933-6004

INDUSTRIAL PARK, 126 DUCHAINE BOULEVARD
NEW BEDFORD, MASSACHUSETTS 01745
(617) 528-3111

BOR 004752

CHRONIC TOXICITY - pp 16, 17 & 18

If VCM is a carcinogen everyone who contracted acroosteolysis should develop angiosarcoma of the liver. If they haven't, your argument is lost. (next level enclosed 200 pp)

No evidence or data or testimony exists that establishes that the experimental animals metabolize VCM the same way as human beings, nor that liver functions are identical. No data was introduced as to the liver functions of the rats used in the clinical evaluations.

WORKER EXPOSURE

Concentration level is conjecture and not quantitative.

Most or all of the VCM found in resin is released in storage, very little is released in compounding unless resin is fresh, which is not common.

4 FABRICATION pp45 & 46

Estimated number of fabricators 4,000 - 20,000. Who estimated this number? What value is a range as broad as a factor of five (5).

PLASTISOL PROCESSING pp 47, 48

You don't understand PVC compounds. The plastisol is completely fused, not just the resin, but the entire mixture of resins, plasticizers, stabilizers, etc. all remain in the final product in much the same concentration as existed for the wet mix. The same is true of flexibles and rigids.

WORKER EXPOSURE pp 49, 50

You state the worker exposure for fabricators is unknown. How can you propose a standard for something you don't know? Your own writing should be sufficient cause for deleting fabricators from the proposed standard.

VI PROBABLE IMPACT OF THE PROPOSED STANDARD pg 60, etc.

The first justification begs the argument. There is no known hazard at levels of 50 ppm or even 200 ppm.

The second sentence is presumptive. No data exists to support that adoption of a level standard will result in lower concentrations in ambient air.

2nd PARAGRAPH

You do not know if petrochemicals are an irreplaceable resource.

What merit is there, in a human sense, in not fulling a need? This argument would certainly resolve the world-wide food shortage, i.e. eliminating the shortage by limiting consumption of a product.

PG 62

Who established scientifically that there is a latency of 20 years? Pure conjecture. You don't know and you must know to do this correctly.

PG 62 LAST PARAGRAPH

What is the estimate by engineers of the cost of modifying not only VCM plants, but PVC plants? You offer no data only opinion of non-experts, i.e. industrial hygienists, etc.

PG 64 LINES 3 & 4

You certainly are ignoring the present inflation to say increased costs can be sustained.

SUBSTITUTES PG 64

The materials such as wood, metal and rubber not only don't duplicate the properties and cost of PVC but are far more scarce.

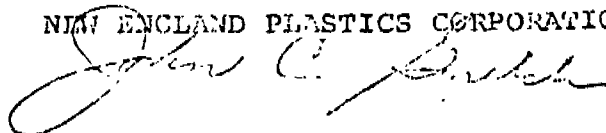
You do not know if the raw materials for manufacturing VCM are non-renewable. They were produced by the earth and there is no evidence that the bio-geological process has ceased.

SUMMARY

Your Impact Study suffers from a gross lack of facts and conjecture represented to be facts upon which its arguments are based. It must be redone by persons who are scientific and conversant in field.

Very truly yours,

NEW ENGLAND PLASTICS CORPORATION



John C. Gmelch
Marketing Manager

JCC:gh

BOR 004754

✓
JOHN W. WHITTLESEY
COUNSELLOR AT LAW
270 PARK AVENUE
NEW YORK, N. Y. 10017
581-6787

REGISTERED MAIL
SPECIAL DELIVERY

July 15, 1974

Mr. David R. Bell
Office of Standards Development
Room 500
1726 M. Street, N.W.
Washington, D.C. 20210

Re: Draft Environmental Impact Statement on
Proposed Regulation - Vinyl Chloride

Dear Mr. Bell:

In accordance with Secretary Stender's letter of June 17, 1974 and the invitation therein to submit comments on the Draft Environmental Impact Statement on Proposed Regulation - Vinyl Chloride, I am making the following response, as Counsel to Union Carbide Corporation.

It seems perfectly clear that the entire draft Environmental Impact Statement should either be rejected or that its conclusions which are wholly without substantial support, should be thoroughly reviewed and revised. No document of this nature, on a subject so important as the production and manufacture of vinyl chloride monomer; resins; and of fabricated products containing such resins, should be accepted or utilized on the basis of what this statement purports to contain.

There is here no need to review the lengthy and extensive hearings that have just been held as Docket OSH-36 before Judge Gordon Myant. It was plain from personally hearing the evidence presented by NIOSH and OSHA, together with the various unions that appeared, that no evidence of any kind or description whatsoever was presented that would warrant adoption of OSHA's wholly preposterous proposal to limit employee exposure to vinyl chloride monomer to "no detectable level." All the evidence presented, in fact, contravenes the need of such a drastic standard. The OSHA proposal is especially unrealistic in the light of the massive contrary evidence presented by various industry spokesmen (including Union Carbide) that:

1. Not even continuous exposure to vinyl chloride monomer in high concentrations over a period of time will necessarily result in any deleterious effects in humans. No evidence of any such effects at levels below 200 parts per million exposure were shown.

2. The animal data on vinyl chloride monomer exposure which is the only possible basis cited for imposing any exposure limits, is not only self-contradictory, inconclusive and non-probative in itself, but also cannot be and has not been related or translated into human experience. The testimony on the human experience, as for example, that of Dr. Dernehl, shows that little if any harm has in fact come from employee exposure to vinyl chloride monomer, even over extended periods at high concentrations; see also the Dow Chemical Company testimony that no ill effects on humans at less than 200 parts per million exposure levels were ascertainable from their extensive studies.

Indeed, the only allegations in the entire EI statement tending to endorse the proposed OSHA standard as appropriate do not state it is presently necessary to curtail exposure to no detectable levels. They merely say (p. 3, for example) that "vinyl chloride concentrations of 50 parts per million may yet pose a hazard." Such statements are clearly the antitheses of factual support for the proposed permanent OSHA standard, and are unquestionably admissions that the standard has in fact no evidentiary backing whatever. It has destroyed any vestige of justification for issuance of an OSHA proposal which takes account of a mere speculation and not a reality or a present danger.

The fact is, that the only basis cited for setting the proposed vinyl chloride monomer exposure level below 50 parts per million is the extrapolation of a supposition and not the hard proof required in law to buttress adopting any permanent standard.

3. The claim on page 5 of the statement that the "standard for the most part will likely cause a slight decrease in productivity and small increase in costs for the products made from vinyl chloride" is wholly without justification of any sort whatever. A review of the entire EI Statement to ascertain the basis for it is not only unrewarding but shows clearly that it is based on speculation and not solid fact. It is moreover, clearly reliant even for such a slender thread on non-management sources who have neither had nor sought access to the facts. The resort to respirators is universally accepted, for example, as raising labor costs of production by up to 50%, hardly a minor figure. Also, the only authority for the

(2) Worker Exposure

In regard to worker exposure during PVC compounding, the PVC resin and the compounds involved in the processing at this stage contain residual amounts of vinyl chloride in concentrations which may be as high as 3,000 ppm. If the basic resin is stored for some time in bags or drums, it will release an amount of the monomer inside the container which could enter the ambient air upon opening the container.

Mixing operations during compounding may allow an additional release of the monomer entrapped in the polymer. Levels in the workroom air are generally below 1 ppm, although evidence presented at the OSHA public hearing of June 25, 1974, shows that excursions above this level are not infrequent. These studies do not conclusively establish one way or the other whether workers engaged in compounding are exposed to concentrations in excess of 1 ppm. Sufficient information is not yet available to enable a categorization of plants into those where concentrations above 1 ppm are likely and those where they are not likely. The highest exposures in this phase probably occur in storage areas, places where containers are opened, and near processing equipment where the PVC is heated.

The numbers and types of workers exposed to vinyl chloride during these compounding operations are not known. Trade publications list about 200 firms, but give no estimate of their sizes.

4. Fabrication of End Products from PVC Compounds^{1,12,15}

The usefulness of polyvinyl chloride arises from its adaptability to many processing techniques used in the production of intermediate and final goods. These processes have been designed to accommodate a wide variety of plastic compounds, including PVC because of its ease in processing and its flexibility in allowing for the manufacture of a wide variety of products. In these processes, PVC resins compounded with the necessary additives are converted into products which need no further chemical handling. The products at this stage may be final goods (such as pipes), components of other equipment (such as wires), or materials for other industries (such as films and sheets for packaging). As a result, products made at this stage may or may not be subjected to further processing, but if so, they will no longer be designated as PVC. The number of firms engaged in this processing stage is not precisely known, but has been estimated to be between 4,000 and 20,000. Such firms range in size from those with few employees and simple equipment to large plants involving many employees and considerable capital.

(1) Process Descriptions

The processing of PVC compounds at this stage involves the shaping of the compound into its desired form. This is accomplished by subjecting it to intense levels of heat and considerable pressure. Several types of equipment are used according to the final product desired. The major processes

used to convert PVC into fabricated products are described below.

Extrusion - Both plasticized and rigid PVC formulations (as powder blends or granules) can be extruded (i.e. forced through a die) into a variety of shapes. Determination of the necessary temperatures and other process characteristics, such as rate at which the extrusion is to be carried out, can only be ascertained by careful experimentation. Extrusion is used primarily to produce wire and cable insulation, rigid pipe and tubing, blown film, and unplasticized PVC sheet.

Injection Molding - Generally, low-molecular-weight PVC resins in the form of granular or powder blends are used in screw type injection molding machines. The rotation of the screw produces a homogeneous melt which is then injected into a mold at high pressure.

Blow Molding - This process is generally limited to the production of bottles, and primarily uses powder blends with some interspersed granular compounds. Most of the equipment used in this process produces a parison (i.e. a partially formed mass of material still in plastic form) by continuous extrusion or by the use of a reciprocating-screw system. This parison is then blown into the proper mold.

Compression Molding - This technique is used primarily for processing rigid PVC compounds into phonographic records. Usually, a copolymer of vinyl chloride and vinyl acetate is

used to produce a low-viscosity melt. This melt is mixed and fused, passed to a two-roll mill from which it is stripped, and then molded by compression in a record press at high pressure. The initial compound can also be in pellet form from which a premeasured molten extrudate is pressed in a mold. This technique is also the only method used to manufacture thick, high-quality, rigid sheet.

Calendering - This technique is used extensively for the production of flexible and rigid PVC film and sheeting. It is usually found in conjunction with the mixing of additives rather than as a separate stage in the processing of PVC. Pellets or powder are fed directly to the hot rolls of the calender. The resulting molten material is carried through finishing rolls to produce rigid sheets or material laminated to a substrate.

Plastisol Processing (Coating) - In this process a paste (or plastisol) made from PVC resin compounded with various additives is coated on various substrates such as fabrics, sheet steel, and paper. Several types of equipment may be used to perform the coating. The paste is generally fed into a device which applies the material to the substrate, either once or several times to achieve the desired thickness. The material is then passed through a heating oven to produce complete fusion of the compounded PVC paste material.

Plastisol Processing (Molding Methods) - For molding purposes, several methods may be employed to shape a PVC paste into its desired shape. A measured amount of paste may be charged into a mold. The mold is then rotated to cause the paste to gravitate to the walls where it is fused to form a uniform thickness. The paste may also be poured into a mold where it is fused. Low-pressure injection molding is also used to produce PVC shoe soles.

Foams - Flexible or rigid PVC foams can be produced by subjecting PVC plastisol to mechanical or chemical blowing. In this process, the plastisol is mixed with an inert gas or air which is then fed through spray nozzles under carefully controlled conditions to produce a slowly expanding foam. The plastisol is whisked and the resulting froth is stabilized. One of these mixtures is then subjected to heat, while being calendered, extruded or molded, so that it is fused into the desired form.

(2) Worker Exposure

Exposure to vinyl chloride in the fabricating stage arises from the escape of residual monomer entrapped in the polyvinyl chloride. The monomer escapes at its fastest rate when the compound is heated. In general, the rate and the amount released depend on the residual amount, the extent to which the PVC has been diluted by additives, the type of equipment used for processing, and the temperature at which the PVC is processed. Worker exposure depends on the rate and the amount

released, as well as the extent to which the processing area is ventilated. These factors have yet to be definitively delineated for each type of processing, so that it is not possible at this time to state which processes might result in excess exposures.

Information presented at the OSHA public hearing of June 25, 1974, indicated that the concentrations of vinyl chloride in fabricating plants fall generally below 1 ppm with a small number skirting this level. An even smaller number of readings showed concentrations in excess of 1 ppm, ranging as high as 40 or 50 ppm on occasion. However, the information available as yet shows no clear-cut pattern which could permit a full characterization of exposure levels according to process type. In general the numbers and types of workers exposed to vinyl chloride in its fabricating stages cannot be estimated until a scientific sample of the industry is performed.

NOTES

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9. Statement of V. K. Rowe, Dow Chemical Company, at OSHA hearing on February 16, 1974, Appendix II.
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V. DESCRIPTION OF ACTION

In response to the health hazards of vinyl chloride that have recently become known, the Occupational Safety and Health Administration (OSHA) published a proposed standard in the May 10, 1974, Federal Register (Appendix B).

Public hearings were held beginning June 25, 1974, to obtain information from industry, labor, and other interested parties regarding the provisions of the proposed standard. Information presented at the hearing and in post hearing comments, as well as recently available research data, feasibility studies and this Environmental Impact Statement are being considered in the development of the final standard.

Applicability of Proposed Standard

The proposal would apply to any company manufacturing or using vinyl chloride or polyvinyl chloride (when the latter releases detectable amounts of vinyl chloride). Detectable levels were defined as those measurable by a method capable of detecting 1 ppm with an accuracy of $\pm$ 50 percent.

Raw polyvinyl chloride resin and the many compounds made from this resin for molding, calendaring, extrusion, or other similar processes were considered to have the potential for releasing detectable levels of vinyl chloride. If the PVC compounded resin contains a large proportion of unreacted monomer, its handling and heating will release some part of that monomer.

Operations handling fabricated products made from polyvinyl chloride, entirely or in parts, were specifically excluded from the standard. The reason was that the release of monomer from such products had not yet been demonstrated. The proposed standard specified that fabricated products would include such items as film, sheet, block, bar, and extrusion stock.

Level of Exposure

The proposed standard for employee exposure to vinyl chloride was set at the no detectable level, to be determined by a sampling and analytical method capable of detecting vinyl chloride at concentrations of 1 ppm with the accuracy of 1 ppm $\pm$ 50 percent. The method of 1 ppm sensitivity was recommended to OSHA by NIOSH on the basis of its review of the problem. The proposal also attempted to minimize the number of workers at risk by regulating areas where vinyl chloride is manufactured, reacted, stored, handled, released, repackaged, or used. Polyvinyl chloride operations containing detectable levels of vinyl chloride were also regulated. The proposal permitted only authorized employees to enter such areas; authorized workers were defined by the proposal as those employees whose duties require them to be in the regulated areas, and those employees who enter such an area as designated worker representatives to exercise their right to observe the monitoring and measuring of vinyl chloride.

Monitoring

A monitoring program was to be required by the proposal to determine if there were detectable levels of vinyl chloride in the workplace and to measure employee exposures on an individual basis. The standard permitted a maximum amount of flexibility for the employer in devising a suitable monitoring system. This was done on account of the diversity of the processing methods involving the monomer, the polymer resin, and the compounded resin. The employer was, however, to be required to monitor in such a way that detectable levels could be perceived and that exposure to an employee could be determined with a confidence level of 95 percent. These programs were to involve the use of point monitoring devices, portable air samplers, or personal samplers worn by employees.

In addition, Section 8(c)(3) of the Occupational Safety and Health Act requires that employees or their designated representatives be provided an opportunity to observe monitoring.

Engineering and Work Practices

If detectable levels of vinyl chloride were present under normal operating conditions, the employer was to be required to immediately institute engineering controls, work practice methods, and respirators in accordance with the proposal. Engineering controls and work practices were considered preferable to other methods of compliance, since they focus on eliminating contamination of the air in the workplace rather than on simply providing a temporary solution.

The proposal also required that tests be conducted for process or equipment leaks to ensure the integrity of the equipment and the propriety of work practices. In the event that these control measures were insufficient to control airborne concentrations of vinyl chloride, immediate use of protective respiratory devices was to be required.

Respiratory Protection

In the event that respiratory protection would be required under normal or emergency situations, the employer would be required to select equipment from among the following types:

- ° Positive pressure full facepiece self-contained breathing apparatus;
- ° Pressure-demand full facepiece self-contained apparatus operating in the pressure-demand mode;
- ° Combination type "C" pressure-demand full facepiece respirator operating in the pressure-demand mode and a pressure-demand self-contained breathing apparatus operating in the pressure-demand mode; or
- ° Combination type "C" continuous flow respirator and a pressure-demand self-contained breathing apparatus operating in the pressure-demand mode.

Protection against vinyl chloride was not considered reliable from cartridge type respirators due to the short break-through time for vinyl chloride at high concentrations. As a result, NIOSH

recommends the use of continuous flow and pressure-demand types of respirators. Respirators were not to be used instead of feasible engineering controls or work practice methods.

Protection in Special Situations

(1) Maintenance and Decontamination

The proposed standard recognized that VC and PVC operations are frequently conducted in batch processing equipment requiring frequent cleaning to ensure the purity of the process. The proposed standard required special precautions for cleaning operations designed to maintain or decontaminate equipment. Some types of equipment, such as reactors in the polymerization process, were believed to allow significant buildups of vinyl chloride. The proposed standard required adequate venting of such vessels to remove escaping vapor from occupied areas before worker entry. In addition, employers were to provide workers with whole-body, air supplied suits impervious to vinyl chloride. Workers were also to be required to shower after removing such equipment. The proposal emphasized the immediate clean up of spills, periodic inspections, and the prompt repair of equipment and leaks. Provisions also addressed the proper handling, storage, and disposal of materials to prevent airborne contamination and accidental skin contact.

(2) Transportation Loading and Unloading

The loading and unloading of vinyl chloride presents a special problem for the escape of vapors at detectable levels.

The proposed standard required that each transfer line and vapor-equalizing line be equipped with vent connections and have an inert gas purging system. Vent and purge effluent would be returned to a process stream or flared in a safe location. The proposal required that procedures for the transfer of vinyl chloride be developed and implemented.

(2) Emergency Situations

Operations involving the monomer have the potential for creating emergency situations in which significant leaks or spills occur. The proposal, therefore, required that a written operational plan for emergency situations be developed for each regulated area. Each employee was also to be trained to understand the hazards of vinyl chloride and the precautions for its safe use. In the event of an emergency, the decontamination of the affected area would be required before the resumption of normal operations. Special medical surveillance was also to be instituted within 24 hours for employees with known contact with VC. These employees were to be required to shower as soon as possible.

Medical Surveillance

Vinyl chloride in sufficient concentrations is known to cause changes in liver function. Liver dysfunction increases risk to health, possibly preceding the development of liver angiosarcomas. NIOSH has recommended the medical regulations

included in the proposal as reasonably appropriate to detect liver dysfunction. If specified biochemical determinations of liver function tests were abnormal, further screening was required. The employee would also be required to be withdrawn from areas where contact with vinyl chloride was possible.

Miscellaneous Requirements

(1) Waste Materials

The proposed standard required that waste materials be appropriately disposed of or decontaminated.

(2) Protective Clothing

The proposed standard required that each employee entering a regulated area be provided with full-body protective clothing, footwear or shoe covers, and gloves at no cost to them. The protective clothing required by the proposal would not only minimize skin contact with vinyl chloride vapor but would also protect the employee from splashes in the event of a spill or rupture of equipment containing liquid VC. Employees were to be required to remove all protective clothing upon leaving the regulated area.

(3) Hygiene Facilities and Practices

Shower facilities and change rooms were to be required under certain circumstances. Storage or consumption of food and beverages were to be prohibited in regulated areas.

(4) Signs and Labels

The proposal specified the signs and labels required at entrances, in regulated areas, on containers of waste materials contaminated with vinyl chloride, on containers of polyvinyl chloride containing detectable levels of vinyl chloride, and on containers of vinyl chloride.

(5) Reports and Records

The proposed standard required that monitoring and medical records be maintained for 20 years. In addition, reports identifying companies which have regulated areas, as well as other information, were to be provided to OSHA. Provisions regarding employee access to monitoring records were also included.

VI. PROBABLE IMPACT OF THE FINAL STANDARD*

Since January 1974, when the human carcinogenicity of vinyl chloride first became evident, significant measures were taken throughout the vinyl chloride and polyvinyl chloride industries to protect workers (as well as consumers of final products) by reducing the amounts of vinyl chloride to which they might be exposed.^{1,7} The initial industry-wide efforts were relatively easy to institute as compared to the goals which are set by the proposed standard. The cost of continued reduction in exposure would be increasingly significant in industry and would ultimately be passed to the consumer.

1. Reduction in Worker Risk

Achieving a safe and healthful workplace in an effective and equitable manner has been OSHA's goal in the development of a standard for vinyl chloride. The available data suggest that to reduce worker risk, one must reduce to the maximum extent feasible worker exposure to vinyl chloride.

The animal studies and epidemiologic information (discussed more fully in chapter III) strongly suggest a cause/effect relationship between exposure to vinyl chloride and certain types of liver cancer, including angiosarcoma. The data also

*Note: References in this section have been selected as representative of testimony presented at the OSHA hearing of June 25, 1974. The cited references are in general not unique.

suggest that lower exposure levels are correlated to lower risk of occupational disease from vinyl chloride. However, the epidemiologic evidence is too inconclusive to estimate dose-response relationships with precision. Because the comparability between human and experimental animal physiology is not completely understood, the animal data provide only approximations of human susceptibility. Although the possibility of a threshold level of tumor induction may exist, the available scientific evidence does not establish a threshold level for vinyl chloride. In addition, the metabolism of vinyl chloride in the human body has not been conclusively delineated, and no proximate or ultimate carcinogenic metabolites have been demonstrated.

Although knowledge of the quantitative relationship between vinyl chloride exposure and induction of human liver angiosarcoma is lacking, the experience of workers exposed to vinyl chloride and of animal studies provides cogent reasons for regulating workplace exposure. One of the primary impacts of the proposed standard will be to reduce, insofar as practicable, the risk of employees developing occupational disease from exposure to vinyl chloride.

2. Expected Impact on Industry

The vinyl chloride industry in the United States has become a vital component of the national economy since VC was first produced in 1930.² Applications of PVC tend to proliferate as rapidly as available supplies permit, even though there are few

market innovations. PVC has replaced many other materials because of its superior qualities. The history of PVC is replete with examples where, once it has penetrated a particular market, it has assumed a position of dominance.³

Prior to the current concern for reducing health hazards associated with exposure to VC, the industry was already somewhat unstable as VC production depends on the availability of petrochemical feedstocks which have been in short supply. The appearance of the OSHA standard may upset the existing uneasy balance; however, prediction of the exact nature of the impact on this complicated industry is fraught with uncertainties.

(1) Cost of Compliance

The most direct impact of the OSHA standard on industry will be the capital costs for implementing engineering controls and for purchasing monitoring, respiratory, and miscellaneous equipment. Monomer, compounding, and fabricating plants are likely to be less affected than polymer plants. According to industry estimates, the engineering changes required in polymer plants could well cost as much as the original capital expenditures for the plants.^{4,5} Firestone estimates⁵ a cost of \$55 million to attempt to achieve a "no-detectable" level at two PVC plants. Altogether, approximately 37 plants would be required to make major investments.

The main sources of exposure in monomer plants are operations involving tank car loading, in-plant sampling, and laboratory

analysis. Additional emissions may come from process venting and from fugitive sources such as pumps, flanges, and valves. Costs for equipment to control exposures associated with tank-car loading and process venting will be substantial. Capital costs for the other items will be much less, since the emissions from these sources can be reduced primarily by work-practice methodology. Costs for replacing pumps, flanges, and valves to provide more leakproof equipment may be necessary. Engineering changes to reduce emissions from these sources will be also substantial, and the capability of achieving 1 ppm may not be technologically and economically feasible for all plants.

Compared to engineering costs, expenditures for monitoring instrumentation, respiratory protective devices, and other equipment will be relatively low.⁸ In general, the capital expenditures and time required to reduce VC concentrations to acceptable levels may be substantial.

Capital costs for compliance with the proposal in compounding and fabrication plants are not expected to be particularly high, but they still may be significant for some smaller companies.⁴ In these plants, the greatest expenditures are expected to be for ventilation and monitoring equipment. Most companies already have installed ventilation equipment to control dust problems.^{9,10} The cost of monitoring equipment may be several thousand dollars, but should be within the financial capability of large companies. For small companies, such purchases may be sufficiently prohibitive to upset their competitive position. However, such

likely be rapidly replaced by an increased demand elsewhere. There seems little likelihood of any total movement away from PVC unless it appears that U.S. industry cannot control the exposure hazards.

(3) Imports and Exports⁵

Vinyl chloride and polyvinyl chloride currently constitute relatively minor products in international trade. The demands for PVC resins are so great that each producing country is hard pressed to meet its own needs and is able to export very little. This situation will probably remain static for the foreseeable future, although an increase in prices caused by the OSHA regulation could alter this stability. If domestic prices increase substantially, PVC users may be able to obtain resins from manufacturers in countries where regulation is less strict. This is not likely to occur in the short run because of internal demands in all countries. In the long run, U.S. companies might find it profitable to build plants abroad. In any event, the extent to which the OSHA standard may impair the trade situation cannot be assessed at present, but some increased imports are expected.

(3) Miscellaneous Impacts

The OSHA standard may necessitate increased energy consumption in polymerization plants.⁵ Increases in energy demand will

not be as great in monomer, compounding, and fabricating plants, although some rises may occur.

An adverse environmental effect of the standard may be a temporary increase in the amount of vinyl chloride entering the atmosphere as plants seek to eliminate VC from the workplace. Since vinyl chloride will readily disperse in the atmosphere, the increased background level of VC in the ambient air resulting from the standard will probably not be significant. The Environmental Protection Agency is examining the significance of levels presently found around various types of plants and will determine the necessity of imposing regulations to deal with VC emissions.

1. Statement of Ralph L. Harding, Jr., Society of the Plastics Industry, at OSHA hearing of June 25, 1974 (Exhibit 20-B).
2. Statement of Vincent P. Ficcaglia, Arthur D. Little, Inc. at OSHA hearing of June 25, 1974 (Exhibit 20-F).
3. D. P. Keane, R. B. Stobaugh, and P. L. Townsend, "Vinyl Chloride: How, Where, Who-Future," Hydrocarbon Processing, February 1973, pp. 99-110.
4. Statement of Anton Vittone, B. F. Goodrich Chemical Company, at OSHA hearing of June 25, 1974 (Exhibit 20-D).
5. "Statement of Position of Firestone Plastics Company" presented as Exhibit 48-C at OSHA hearing of June 25, 1974.
6. Statement of John L. Nelson, B. F. Goodrich Chemical Company, at OSHA hearing of June 25, 1974 (Exhibit 27-A).
7. Statement of K. H. Oelfke, Dow Chemical Company, at OSHA hearing of June 25, 1974 (Exhibit 24).
8. Statement of Rodney P. Becker, Diamond Shamrock Chemical Company, at OSHA hearing of June 25, 1974 (Exhibit 20-R).
9. Statement of Louis J. Molinusi, Gillot-Analytical Service Corp., at OSHA hearing of June 25, 1974 (Exhibit 20-O).
10. Statement of Michael J. George, Canvas Products Association International, at OSHA hearing of June 25, 1974 (Exhibit 16).
11. Comment of Dow Chemical Company on Draft Environmental Impact Statement reproduced in Appendix C.

VII. ALTERNATIVES

The proposed OSHA standard is based on an evaluation of many factors, most of which are not readily quantifiable. In its development, many alternatives, both in general approach and in specific provisions, were evaluated. Although the limited amount of available time has precluded a definitive analysis of all the relevant factors, each section of the standard was based on a careful weighing of the available evidence. This chapter describes the major alternatives that were considered during the development of the proposed standard.

1. ALTERNATIVES CONCERNING THE SCOPE AND APPLICATION OF PROPOSED STANDARD

Polyvinyl chloride (containing entrapped vinyl chloride) eventually finds its way to companies which constitute over 10 percent of the national economy. Because of its widespread industrial use, the breadth of the standard's applicability has always been an important consideration. Polyvinyl chloride, even in products used by the general consuming public, apparently is always capable of releasing vinyl chloride. Thus, one alternative to the proposal would regulate all industries where VC or PVC might find application. This alternative is not supported by the data; the release of VC by most finished PVC products has not been documented. Once PVC has been heated to the point where it fuses, the amounts of vinyl chloride that can be released generally seem to be substantially reduced. It appears that finished or semi-finished PVC products are not capable

of releasing measurable amounts of vinyl chloride as long as they are not further subjected to temperatures such as those used in processing.

The position has also been proposed that compounding and fabricating plants handling PVC need not be covered by the OSHA regulation, but should be regulated by a separate standard. Indeed, it appears that no detectable or low levels of vinyl chloride will be observed in most compounding and fabricating plants.

Although there appears to be little or no VC in the breathing zones of most workers in the majority of these plants, measurable and perhaps significant amounts of vinyl chloride can build up inside heating and mixing vessels and in storage areas.

A significant amount of PVC used by fabricating companies is in pellet form. Since PVC pellets have already been subjected to processing temperatures, it is conceivable that most of the vinyl chloride that may have been entrapped in the PVC would have been released on this basis. The position has been advanced that

PVC pellets do not constitute a significant source of vinyl chloride and that fabricators using pellets do not need to be regulated. However, these pellets are subjected at other points in their processing to high temperatures, and it is not clear that further releases of VC do not occur.

Another alternative that has been raised is to distinguish between monomer and polymer plants. Since these operations pose significantly different sets of hazards which may need to be regulated accordingly, it has been proposed that the OSHA standard reflect such differences.

It is possible that the monitoring provisions may affect many companies where VC hazards will not be found. It seems necessary to identify those companies where potentially hazardous exposures may occur. On the other hand, the exclusion of firms using finished or semi-finished fabricated products is not likely to exclude establishments with measurable levels of VC.

2. ALTERNATIVES CONCERNING LEVELS OF EXPOSURE

At any level of exposure except zero (which in effect would ban vinyl chloride manufacture), there may be a risk that a worker will contract liver angiosarcoma. However, a complete ban, causing a total shutdown of vinyl chloride or PVC plants, would severely disrupt the economy and worsen the employment situation. In all likelihood, a shutdown of VC and PVC plants would reverberate throughout the economy by effecting work stoppages in important sectors of the economy.

At the OSHA public hearing of June 25, 1974, many polymer producers stated that a requirement to reach a level of "no-detectable" VC upon the effective date of the standard would require them to shutdown. The producers claimed that the requisite technology to achieve a "no-detectable" level simply is not available; therefore, employees would be required to wear respirators at all times. The companies indicated that plants would close rather than attempt to meet this requirement. In any event, where engineering changes are needed, some time would be required.

Another alternative is to establish the permissible permanent level of exposure at or below 50 ppm. Risk estimates based on animal studies suggest the prudence of attaining TWA levels of exposure as low as feasible in all plants.

3. STAGING OF COMPLIANCE

Considerations of practicality must enter into the decision as to when companies will be required to comply with the particular provisions of the standard. As indicated at the hearing, many monomer and polymer producers already have initiated most of the actions needed to meet monitoring requirements. A problem arises with respect to the compounders and fabricators. If the alternative of immediate compliance with the monitoring procedures were adopted, industrial sources point out that the large number of companies involved would induce a severe shortage in supplies of monitoring equipment and of industrial hygiene consultants.

In evidence presented at the OSHA hearing of June 25, 1974, industrial sources claimed that a standard requiring immediate compliance to the proposed "no-detectable" level is not technically feasible in view of the massive engineering alterations that may be required.

If companies are required to meet the exposure level goal stipulated in the proposed standard, the companies have alleged that the practical effect would be to require employees to wear respiratory equipment at all times. A substantial amount of testimony was presented at the public hearing describing the difficulties of reliance on personal protective equipment. Some respiratory equipment is bulky and

cumbersome. Wearing certain types of this equipment continuously may strain workers, perhaps lessening their alertness. Some workers could suffer a claustrophobic effect and would be unable to use some equipment at all, even for short time periods. In addition, monomer plant layouts require workers to climb narrow ladders and traverse narrow catwalks in the normal performance of their duties, thus creating a potential safety hazard.

VIII. RELATIONSHIP TO OTHER FEDERAL ACTIONS

Production workers constitute the part of the population most obviously exposed to the hazards of vinyl chloride. However, in view of the fact that polyvinyl chloride products contain residual amounts of vinyl chloride which may be released, the general population may also be exposed, though as yet to an undetermined extent. Since vinyl chloride and polyvinyl chloride products find many uses throughout society, several Federal agencies in addition to OSHA have become concerned about possible population exposures to vinyl chloride. These agencies focused initially on the exposure that arose from the aerosol use of vinyl chloride; subsequently, efforts have been initiated to determine the extent to which vinyl chloride exposure occurs in other uses and the precise extent to which such exposures constitute a problem.

1. REGULATORY ACTIVITY

Historically, the only consumer use of vinyl chloride in monomer form has been as an aerosol propellant for hair sprays, pesticides, and other aerosol products. Tests conducted by the Environmental Protection Agency (EPA) and reported in the Federal Register on April 26, 1974, revealed that a VC aerosol released for 30 seconds sometimes produced concentrations as high as 400 ppm in the air of a closed room. By that time, manufacturers of aerosol hair sprays and pesticides indicated that they had voluntarily ended, in 1973, the use of vinyl chloride as a propellant. Nonetheless, some products containing vinyl chloride

probably still remained on the market even after this date. As a result, on April 26, 1974, EPA announced an emergency suspension of all pesticide spray products for indoor use containing vinyl chloride and also gave notice of its intent to cancel the registration of these products. At the same time, EPA requested that all existing stock of such products be recalled by the manufacturers.

On April 22, 1974, the Food and Drug Administration (FDA) published two proposed rules: one which would regulate the use of vinyl chloride as an ingredient of aerosol drug products such as in the form of a propellant; and another which would regulate the use of vinyl chloride as an ingredient (propellant included) of cosmetic aerosol products. Since evidence indicated that some supplies of hair sprays containing vinyl chloride were still on the market, FDA requested that all manufacturers initiate recalls for such hair sprays as well as for other drug and cosmetic aerosol products containing VC. On May 9, 1974, the Consumer Product Safety Commission commenced an information gathering process to determine the specific aerosol products which now use or have used vinyl chloride. It may ban the use of VC in aerosols for such products as spray paints, household cleaners, and de-greasing agents.

Significant programs are currently underway to determine other areas where vinyl chloride or polyvinyl chloride formulations should be regulated. The Department of Transportation (DOT) currently regulates the shipping (46 CFR 145.24-100) and

transportation (49 CFR 172.5) of vinyl chloride as a flammable compressed gas. The containers that may be used are specified by these regulations. At present, DOT is considering whether any changes in its regulations are warranted by the fact that the chemical has been identified as a carcinogen. The major issue is whether a single exposure to the chemical can cause cancer. At present, DOT is considering changes in labeling requirements, but not necessarily in packaging regulations.

The Environmental Protection Agency is currently collecting and assessing data on: (1) the ambient emission and effluent levels of vinyl chloride in air and water from VC and PVC manufacturing plants; (2) the environmental impact of all disposal methods for vinyl chloride and polyvinyl chloride wastes; (3) the overall ecological effects of vinyl chloride. EPA has also collected data in a preliminary monitoring program covering seven industrial complexes containing 10 PVC and 2 VC plants. Similarly, it is receiving data concerning emissions and control from the VC/PVC industry under Section 114 of the Clean Air Act. The results of these studies will determine the need for EPA regulations.

At present, certain polyvinyl chloride formulations are sanctioned for use in food packaging, and hence are exempt from classification as food additives subject to pre-marketing clearance by the Food and Drug Administration. Early in 1973, FDA received reports that vinyl chloride was migrating to the interior surface of polyvinyl chloride bottles then being test marketed for alcoholic beverages. Use of polyvinyl chloride bottles for this

purpose ceased after the Commissioner of FDA issued a proposal which concluded that polyvinyl chloride bottles may cause the adulteration of alcoholic beverages.

There have been further reports of migration when polyvinyl chloride is used as an ingredient of containers for non-alcoholic products. Therefore, FDA has requested information on the extent of polyvinyl chloride usage by type of container and type of product, on the vinyl chloride content of polyvinyl chloride used to manufacture such containers, and on the level of and rate at which vinyl chloride can be extracted from such containers under certain test conditions.

FDA may establish maximum levels for the amount of the vinyl chloride that can be extracted from such polyvinyl chloride packaging. FDA has also requested that manufacturers submit information on every drug product containing vinyl chloride as an ingredient or packaged in polyvinyl chloride containers. FDA currently does not know whether vinyl chloride is being used in the manufacture of drug products.

2. RESEARCH STUDIES

Despite the fact that vinyl chloride and polyvinyl chloride have been present in large quantities in the U. S. for many years, little is known about their health effects. As a result, many studies have been initiated during the past several months, and others are being proposed.

The Center for Disease Control (CDC) is conducting a national search for all deaths from angiosarcoma of the liver which have been reported since 1965. For each case identified, the health history of the individual will be reviewed and analyzed to determine whether or not there had been any exposure to vinyl chloride or polyvinyl chloride. CDC is also conducting studies to determine deaths from other causes that may be related to exposure to vinyl chloride. In these studies, pathological information will be obtained from hospitals. A survey among meat wrappers in Houston, Texas presently underway will determine whether vinyl chloride released from polyvinyl chloride packaging materials may be the cause of "meat wrappers asthma."

The National Institute for Occupational Safety and Health (NIOSH), an agency of CDC, is conducting several studies on various aspects of the vinyl chloride question. The most significant effort is a comprehensive epidemiologic survey of workers from 11 polymerization and fabricating plants. Employee medical records are being subjected to intense screening to determine the scope and magnitude of vinyl chloride effects. All hospital data obtained in this study is being sent to CDC for its angiosarcoma search. NIOSH is also planning studies to determine if cosmeticians exposed to vinyl chloride from aerosol hair sprays have contracted any cases of liver angiosarcoma. NIOSH is examining the types of monitoring equipment that would be feasible for use in the workroom environment. The primary problem in this respect is developing monitoring equipment of greater sensitivity than was necessary in

the past when the principal concern was the explosive potential of vinyl chloride.

The Environmental Protection Agency will conduct epidemiologic studies of the neighborhoods surrounding selected VC and PVC production plants. In addition, studies are being made of the effects of vinyl chloride on developing rat fetuses, the effects of other stresses (such as ethanol and vinylidene chloride), and the importance of nutritional factors in vinyl chloride toxicity.

The National Cancer Institute is conducting some cell culture studies to discover the carcinogenic mechanism of vinyl chloride. The Fish and Wildlife Service of the Department of Interior is concerned about the ecological effects of polyvinyl chloride piping, since the residues from such piping seem to give rise to liver problems in fish being raised in hatcheries. No clear statement as to the ultimate cause has been proposed, although a possible source of the problem may be the plasticizers used with the polymers.

The National Bureau of Standards (NBS) is performing some preliminary investigations into the development of permeation tubes which could serve as more accurate calibration sources for vinyl chloride monitoring equipment. NBS is also examining the mechanism by which residual vinyl chloride escapes from the polymer.

BOR 004791

IX. COMMENTS

Those comments which have been submitted in direct response to the draft environmental impact statement on vinyl chloride are included as Appendix C to this report. In addition, the testimony of witnesses at the OSHA public hearing on June 25, 1974, was permitted to stand as comments on the draft statement. Accordingly, the discussion of the comments presented in this chapter will attempt to treat the complete record of the public hearing. Although some of the comments presented at the public hearing are reflected in those included in Appendix C, this appendix does not show the full range of the testimony presented at the public hearing. Since the testimony at the public hearing was not specifically directed at the impact statement, but more directly addressed the substance of the standard, no attempt is made to reproduce it here.

The testimony presented at the hearing and the comments on the draft environmental impact statement fall into three main categories: critiques of sections of the draft environmental impact statement; background information on the nature of the health effects of vinyl chloride, the sources of occupational exposure, and the methods of dealing with the hazard; and critiques of the provisions in the proposed standard (Appendix B). The first category is relatively small, since few participants at the hearing commented directly on the statement and few responses have been received during the period provided for public comment.

1. Comments on Draft Environmental Impact Statement

The comments shown in Appendix C primarily address the same issues as those discussed in the other two sections of this chapter. In addition, they also address specific statements made in the draft of this report. These latter comments fall into two categories: (1) those dealing with statements of fact; and (2) those dealing with the general tone and interpretation of data made in the draft impact statement. Suggested changes arising with respect to statements of fact have been accepted and are incorporated in the relevant portions of this final statement.

The second category of comments was concerned primarily with the discussion of the impact and the alternatives included in the draft. Since these same issues were dealt with by witnesses appearing at the public hearing, particularly in their predictions of the impact of the proposed standard, the relevant chapters (VI and VII) have been revised to reflect these comments.

2. NATURE OF BACKGROUND INFORMATION PROVIDED

A large number of witnesses at the public hearing presented evidence directly bearing on the health hazards associated with vinyl chloride. Generally, this testimony falls into the following areas:

- o Carcinogenicity of vinyl chloride in animals
 - Results of animal experiments
 - Interpretation of experiment results

Problems of extrapolation of results from animals to humans

- Mechanism of vinyl chloride carcinogenesis
- Unknown areas that await further study
- o Carcinogenicity of vinyl chloride in humans
 - Results of clinical studies
 - Results of epidemiologic studies
 - Problems in diagnosing angiosarcoma of the liver
 - Interpretation of results of studies in terms of a "safe" level of exposure for humans

This testimony has been evaluated and incorporated into Chapter III of this report insofar as was possible in the time available.

The second major area of information provided at the hearing was the results of monitoring studies designed to identify the current levels of exposure in several types of plants and operations. Witnesses provided the following types of information:

(1) the major sources of vinyl chloride in the workplace, identifying the types of equipment which constitute the major problems; (2) exposure levels observed in the plant and related to worker job categories; and (3) the relationship between residual monomer levels and the existence of an exposure hazard in compounding and fabricating plants. This information was provided for monomer, polymer, compounding, and fabricating operations.

Much of this information has been provided in post-hearing comments which have been included in the hearing record. At this

time, the patterns that can be discerned from the data are relatively general in nature. To the extent possible, this information has been incorporated into Chapter IV.

The third major type of information provided at the hearing bears on methods for dealing with exposures in the various plants and operations. The primary areas of discussion dealt with: (1) methods of monitoring to detect the presence of vinyl chloride; (2) the ability of respiratory equipment to reduce exposure; and (3) engineering changes and work practice methods that could reduce exposures in each of the types of plants and operations.

3. COMMENTS ON PROVISIONS OF THE PROPOSED STANDARD

Testimony presented at the public hearing and comments received on the draft environmental impact statement dealt with the ability of the affected companies to comply with its provisions. The comments fall into two categories: (1) those discussing the feasibility and effect of the proposed standard taken as a whole; and (2) those dealing with specific provisions of the proposed standard.

In the first category of comments, witnesses described the structure of the PVC industry, demonstrating the interdependence of its various parts and the relationship to other parts of the economy. Witnesses demonstrated the effect of the proposed standard if certain of its requirements were imposed on industry. Industry witnesses were concerned with the technological feasibility of complying with the standard as proposed, specifically, the feasibility of installing engineering controls to achieve a "no detectable level". These issues are discussed in Chapter VI and VII.

The second category of comments on the proposed standard concerned specific language that was used. In most cases, the comments reflected the difficulties of interpreting certain provisions. In particular, these comments addressed the following parts of the proposed standard: (1) definitions of the terms "authorized employees," "contaminated," decontamination," "detectable level," emergency, "exposure," "fabricated product," and "waste resin;" (2) the accessibility of records to employees; (3) the nature of engineering controls for different types of

operations; (4) the necessity of certain requirements for hygiene facilities and practices and for protective equipment; (5) interpretation of the confidence level requirement for monitoring; (6) the necessity of specifying the medical surveillance requirements in detail; (7) the language to be used on signs and labels; (8) the correctness of the specifications for respiratory equipment; and (9) the length of time for record retention. A consideration of these comments have been incorporated into the discussion of the provisions of the proposed standard.

companies may be able to satisfy their monitoring requirements by contracting for the services of industrial hygiene consultants rather than by purchasing equipment themselves, thus avoiding the capital cost of monitoring equipment.

The capital costs in polymer plants are likely to be substantial. Plants in this industry are so diverse that some may lose their competitive position, especially smaller firms with older equipment whose operations are already marginal. Previously, the heavy demands for PVC had ensured the continuance of such companies, but compliance with the proposed standard may prove to be an excessive strain. Several employers may find it necessary to close operations, concentrating the industry into fewer companies and causing disruptions of several markets.² It is also possible that demand for PVC would in the long term induce some companies to enter the market with larger and safer plants.

Substantial increases in energy requirements and in number of personnel may significantly increase direct operating costs. According to an industry spokesman, decreased efficiency of the equipment and lowered worker productivity may also have a significant impact on operating costs.⁵ In all likelihood, a substantial price increase may be necessary to insure the viability of the industry. Since demand for PVC is strong and users have become dependent on this material, price increase will likely be accepted.

In situations in which several suppliers produce the same PVC product, the competitive position of individual companies may be seriously affected. However, the diversity of PVC types and characteristics may limit this type of impact to a small fraction of the companies involved. The standard may slightly improve the utilization of vinyl chlorid feedstocks, since less would escape during processing and more would be reacted during polymerization.

(2) Substitutes¹²

At present, there is no known material or materials which could substitute adequately for all the wide range of PVC uses. Historically, identification of a chemical as a carcinogen has resulted in an increased search for substitutes and a gradual decrease in its use. However, few previously identified chemical carcinogens have had a volume of production close to that of vinyl chloride. While there are substitutes for almost every use of polyvinyl chloride, such materials have been long abandoned for various reasons, such as scarcity, cost, and their inferiority to PVC. Furthermore, most PVC users indicated that they are now too dependent on this substance to permit a very rapid switch to other materials.

There is no evidence yet of a lessened demand for PVC (implying a concomitant shift to substitutes). The search for adequate substitutes may be heightened as the price of PVC resin increases, but any slackening of demand in one area would

Fabri-Kal

Corporation 3303 East Cork St. / Kalamazoo, Mich. 49001 / 616-492-497



July 19, 1974

Mr. David R. Bell
Office of Standards Development
Room 500
1726 M Street, N. W.
Washington, D. C. 20210

Re: Draft Environmental Impact Statement on Proposed Regulation
Vinyl Chloride

Dear Mr. Bell:

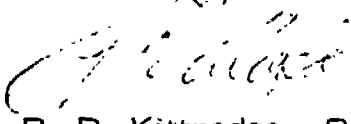
To be sure our commentary thereon is in all appropriate hands, we are attaching a copy of our submission related to Docket OSH-36, OSHA hearing.

We feel this is the most relevant data we can present specifically noting that the actual data of real operating PVC procedures and the pertinence, or lack of it, for the converting end of the industry are features which dictate against the proposed regulation.

We would appreciate your making this statement part of the record.

Very truly yours,

FABRI-KAL CORPORATION


R. P. Kittredge - President

RPK:d
Attachment

Since 1950 Producers of The Finest in Plastic Products



BOR 004800

Fabri-Kal

Corporation 3303 East Cork St. / Kalamazoo, Mich. 49001 / 616 382-4923



June 28, 1974

POSITION STATEMENT

Re: Vinyl Chloride Proposed Standard (Docket OSH-36) (29CFR Part 1910)

A. Background:

Fabri-Kal Corporation was founded in 1950 in Kalamazoo, Michigan, primarily to engage in the forming of sheet plastics into packages and industrial components. It has grown from that time and an investment of \$35,000 to become one of the leading plastics package manufacturers in the country with assets of approximately \$9,000,000. Sales are \$18,000,000 a year and we employ about 450 people at plants in Kalamazoo; Hazleton, Pennsylvania; Somerville, New Jersey; El Segundo, California and Cincinnati, Ohio.

The company entered into the PVC bottle producing business with the purchase of the Tennepak Division of Tenneco in 1969 and the subsequent acquisition of Famco in 1973. Two of our plants (Somerville and El Segundo) with a combined employment of 118 are devoted exclusively to the manufacture of PVC bottles. Furthermore, they represent approximately \$3,000,000.00, or a third of our assets. Our company supplies between 5% and 10% of all the PVC bottles supplied in the country and our leading customers, to whom we supply more than 25% of their requirements, number 48. In some 10 cases we are the 100% source.

B. Exposure Status:

We have had our plants thoroughly reviewed by an established outside testing concern. The results of these tests taken within the past few weeks indicate that there are no operations or locations within our facilities that could meet the proposed zero ppm standard. We are, however, well within the 50 ppm current level and see no problem in retaining compliance to a 25 ppm level.

BOR 004801

Impact of Proposed Standard:

Of basic importance, it is our understanding that there is no possibility that any PVC manufacturer could produce under the zero tolerance levels indicated, hence our total supply situation would be eliminated; we would be out of the bottle business.

In spite of our diligent efforts over the past months to acquire materials replacements for PVC and/or variations of bottle business, this is not a viable situation since petrochemical supplies are in such short supply already that moving tonnage to the "EX" PVC bottle field is something that just can't be done. Logical choices of acrylic based materials, high density polyethylene and polypropylene are simply not available. Accordingly, the dismissal of our 118 employees would have to be immediate. The fallout to our customers in the absence of a minimum of 40,000,000 bottles per year could be even more traumatic since the replacement supply situation in glass, cans or paper bottles is likewise severely hampered by supply already.

Of most significance to our company, it would have to be presumed that our banks would call their loans; we could not dispose of the unneeded bottle making equipment to a voided market and our whole company would be in jeopardy.

D. Alternatives:

It has been described above regarding alternate materials, the most obvious solution; under the present supply circumstances they are no solution at all.

Conversion of equipment to another use is likewise impossible; there are no other uses for plastic blow molding equipment.

In short, we see no alternatives, nor have we had any explained.

E. Summary Conclusion:

Beyond the immediate fallout if the proposed standard is adopted of payroll terminations (118); factory closings (2), and customer disorientation, we view the potential of this matter as nothing less than catastrophic for Fabri-Kal. We are privately held, we are not a division of any major corporation of any kind. We enjoy a record of growth and performance which is perhaps better than typical for the American free enterprise system.

We feel that it is not proper from the scientific information and circumstances OSHA has utilized that we should be administrated out of business. It is our firm opinion that the proposed standards are founded on incomplete information and significantly jeopardize a major segment of the American economy. Proper steps can be taken to have VC exposure at safe and acceptable levels. They should be. A zero tolerance level is not required for safety or acceptability. The standard should be adjusted to the suggested plan of the Society of the Plastics Industry.

Fabri-Kal Corporation
Kalamazoo, Michigan

June 28, 1974

BOR 004802



OFFICE OF THE SECRETARY OF THE TREASURY
WASHINGTON, D.C. 20220

JUL 24 1974

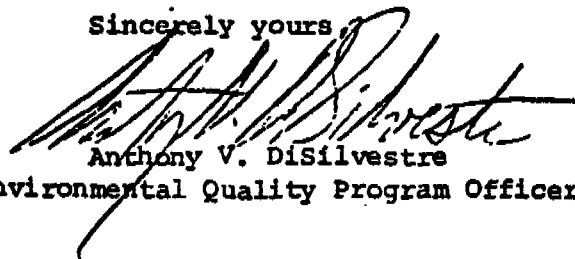
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July 22, 1974

Dear Mr. Bell:

This is in response to Mr. Stender's letter of June 17 transmitting a copy of the OSHA draft environmental impact statement on the Proposed Regulation - Vinyl Chloride for comment. This Department has no comments on the Statement.

Sincerely yours,


Anthony V. DiSilvestre
Environmental Quality Program Officer

Mr. David R. Bell
Office of Standards Development
Department of Labor
Room 500
1726 M Street, N.W.
Washington, D. C. 20210

BOR 004803



UNITED STATES
ATOMIC ENERGY COMMISSION
WASHINGTON, D.C. 20545

JUL 22 1974

Mr. David R. Bell
Office of Standards Development
Room 500
1726 M Street, N.W.
Washington, D. C. 20210

Dear Mr. Bell:

This is in response to Mr. John H. Stender's letter of June 17, 1974, inviting the U. S. Atomic Energy Commission to review and comment on the U. S. Department of Labor, Occupational Safety and Health Administration (OSHA), Draft Environmental Impact Statement entitled "Proposed Regulation - Vinyl Chloride," on the proposed action by OSHA to limit exposure of workers to vinyl chloride.

We have reviewed the Statement and have determined that vinyl chloride is not being used in large quantities at any of the sites under the control of the AEC General Manager.

However, at one of our sites, there is use of a liquid containing plasticized polyvinyl chloride, but air samplings taken in the vicinity of the operation have indicated vinyl chloride does not pose a significant hazard in this operation.

The Statement in general is quite informative and does serve as useful background to the proposed regulation, but additional information is needed.

The animal data of Dr. Maltoni and Industrial Bio-Test provide the only quantitative dose-response data upon which to justify the concern regarding the 50 ppm exposure; however, there is inadequate detail presented as to the experimental design or the nature of the results. It would appear that sufficiently more detail of the experimental data should be presented to justify this or any other such concern that has such far reaching effects. Similarly, the discussion on alternatives (page 73) "to allow zero exposure" is superficial and also warrants considerably more discussion.

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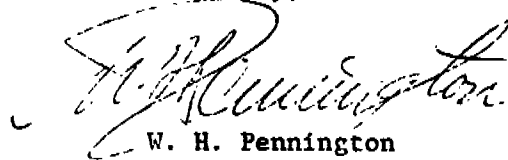
The proposed work by the Environmental Protection Agency (EPA) should include the assessment of the interaction of vinyl chloride exposure with other chemicals, such as HCl, Cl₂, and Hg salts, used in the manufacture of the monomer. This could also be expanded to include the many types of additives used during the manufacture of the polymer. In the discussion of the prospective work, the last two words of the phrase "the mutagenesis and teratogenesis of angiosarcomas" (line 12) appear to be a typographical error, and the meaning of "paralytic degradation of plastic" (line 13) is unclear. It is suggested that the impact of exposure upon lung, kidney, and brain malignancies may also warrant attention.

Overall, we feel that more systematic and well-defined experimental needs and plans would be better met following a coordinated policy decision between the appropriate agencies, if vinyl chloride exposure standards are to be consistent with the potential released per annum. In this regard, we feel that a commitment to sponsor research and development on low-level vinyl chloride monitoring equipment, personal dosimeters, as well as continuous recording types, is needed.

There are several aspects of concern with respect to the proposed regulation. The proposed standard, "no detectable level" is somewhat ambiguous since it is based on an analytical method which is sensitive to 1 ppm $\pm$ 50% accuracy, but the detection method (sampling or analytical) is not specified nor described. There already appear to be even more sensitive methods available; it is not clear that industry can achieve the 1 ppm sensitivity level routinely. We suggest that the monitoring system for measuring the ambient levels of vinyl chloride involve the use of a continuous recorder with an alarm signal to detect out of range excursion. Finally, the precautionary measure of not employing females of child-bearing age or pregnant women should be noted.

We appreciate the opportunity to comment on this Statement.

Sincerely,



W. H. Pennington
Assessments and Coordination
Officer
Division of Biomedical and
Environmental Research

cc: Council on Environmental Quality (5)



DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
WASHINGTON, D.C. 20314

10

REPLY TO
ATTENTION OF

DASG-HCH-O

18 JUL 1974

Mr. David R. Bell
Office of Standards Development
Room 500
1726 M Street, NW
Washington, DC 20210

Dear Mr. Bell:

The Draft Environmental Impact Statement, Proposed Regulation - Vinyl Chloride has been reviewed and the following comments are provided.

a. The proposed standard limits employee exposure to no detectable level of vinyl chloride monomer when measured by an instrument capable of detecting $1 \text{ ppm} \pm 50 \text{ per cent}$. Neither sampling nor analytical methods with this sensitivity and accuracy is addressed in the proposed standard or draft impact statement. Appendix C to the impact statement does refer to gas chromatography as being a common method for analysis, but a concentration of 2 ppm was given as the lower confidence limit. This is unacceptable. Recommend that preferred sampling and analytical methods be specified with the stipulation that other methods may be used if the accuracy and sensitivity meet the proposed standard requirements.

b. Protective clothing, defined as "clothing protective against vinyl chloride," is required in regulated areas by the proposed standard to prevent dermal exposure to the chemical (Appendix B). However, Appendix C states that "vinyl chloride vapor or gas is not considered to be absorbed through the skin in sufficient amounts." Recommend defining the need for protective clothing in light of above contradictions and, if required, specifying the type of clothing for particulate, liquid and gas exposures.

c. The proposed standard requires that "waste materials be appropriately disposed of or decontaminated." Recommend specifying appropriate methods with the stipulation that equivalent quality alternative methods be permitted.

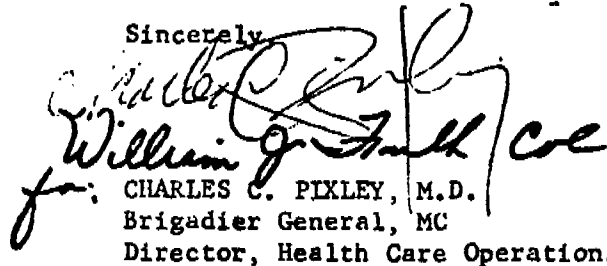
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DASG-HCH-O
Mr. David R. Bell

18 JUL 1974

d. Medical surveillance requires numerous biochemical liver function tests including Gamma Glutamyl Transpeptidase (GGTP). This test, reported to be a sensitive indicator of obstructive liver disease, is relatively new, not in common usage, and the sensitivity and specificity are ill-defined. Recommend that this test not be included in standard until sufficient routine experience is obtained to establish quality control and confidence in the results.

Sincerely,


for: CHARLES C. PIXLEY, M.D.
Brigadier General, MC
Director, Health Care Operations

1 Incl
Memo US Dept. of Labor
(wd incl)

18 JUL 1974

DASG-HCH-O

Mr. David R. Bell
Office of Standards Development
Room 500
1726 M Street, NW
Washington, DC 20210

Dear Mr. Bell:

The Draft Environmental Impact Statement, Proposed Regulation - Vinyl Chloride has been reviewed and the following comments are provided.

a. The proposed standard limits employee exposure to no detectable level of vinyl chloride monomer when measured by an instrument capable of detecting $1 \text{ ppm} \pm 50$ per cent. Neither sampling nor analytical methods with this sensitivity and accuracy is addressed in the proposed standard or draft impact statement. Appendix C to the impact statement does refer to gas chromatography as being a common method for analysis, but a concentration of 2 ppm was given as the lower confidence limit. This is unacceptable. Recommend that preferred sampling and analytical methods be specified with the stipulation that other methods may be used if the accuracy and sensitivity meet the proposed standard requirements.

b. Protective clothing, defined as "clothing protective against vinyl chloride," is required in regulated areas by the proposed standard to prevent dermal exposure to the chemical (Appendix B). However, Appendix C states that "vinyl chloride vapor or gas is not considered to be absorbed through the skin in sufficient amounts." Recommend defining the need for protective clothing in light of above contradictions and, if required, specifying the type of clothing for particulate, liquid and gas exposures.

c. The proposed standard requires that "waste materials be appropriately disposed of or decontaminated." Recommend specifying appropriate methods with the stipulation that equivalent quality alternative methods be permitted.

BOR 004808

DASO-1041-0

Mr. David R. Bell

18 JUL 1974

d. Medical surveillance requires numerous biochemical liver function tests including Gamma Glutamyl transpeptidase (GGT). This test, reported to be a sensitive indicator of obstructive liver disease, is relatively new, not in current usage, and the sensitivity and specificity are ill-defined. Recommend that this test not be included in standard until sufficient routine experience is obtained to establish quality control and confidence in the result.

Sincerely,

1 Incl
Hq US Dept. of Labor
(1 Incl)

CHARLES E. FERRY, M.D.
Brigadier General, MC
Director, Health Care Operations

Mr. David R. Bell

-3-

July 15, 1974

claim (p. 4, 61) that "700,000 workers are exposed to vinyl chloride monomer" is an estimate from the AFL-CIO, which plainly does not take into account that all but a fraction of that number are engaged in operations which could not possibly result in any exposure at all. This is a blind stab masquerading as fact.

The critical facts are, as the hearing testimony clearly showed without meaningful rebuttal, that there is no way for the industry, with existing technology, to meet the standard proposed by OSHA. The fact that many companies, including Union Carbide, are able to meet an employee exposure level for vinyl chloride monomer lower than 50 parts per million does not mean that they can achieve levels below 25-30 parts per million and achieve a no detectable level. The companies are the only ones that have the facts on this phase of the problem, and are the only ones in any position to make this sort of assessment. They conclude, unanimously, as all have emphatically stated, achieving a no detectable level is simply not possible at the present time, even though they are all willing to make the attempt. Statements that the OSHA proposal can be met arise wholly out of ignorance or a self-serving desire to justify a position otherwise unsupportable. The allegation in the EI Statement (p. 5) of "minimal economic impact," resulting from the standard proposed indeed, is wholly at variance with the statement admitting, in the very next sentence, that "some firms may incur substantial capital costs in meeting the requirements of the standard." The allegations on page 62-63 is so completely erroneous as to "readily available" technology that it is difficult to see how they could have been made with any degree of confidence in their accuracy on the basis of a 5-plant walkaround alone.

How substantial the compliance costs will be may be judged from a survey of just one of the many Union Carbide polyvinyl chloride product lines that will have to be changed if the standard goes into effect as proposed. It will have cost the Corporation some \$430,000 just to meet the requirements of the temporary emergency standard. To attempt even to meet the level of exposure in the proposed permanent standard will require, it is estimated, an expenditure of some \$12-14,000,000, without any assurance that the necessary results will be attainable in fact. The prospect of this amount of expenditure for what may easily turn out to be a futility has

BOR 004810

Mr. David R. Bell

-4-

July 15, 1974

led many companies to say they may well have to shut down rather than face it. And the above figure was an estimate for only a portion of this Corporation's production of polyvinyl chloride resin.

The most disturbing feature of this whole procedure is the type of thinking that it exhibits. This may be described as a willingness to plunge ahead with issuance of a proposal, regardless of the economic and social consequences, solely on the basis of fear-inspired assumptions that lack solid proof and whose major thrust is to place their targets on the defensive. American jurisprudence has been founded on the principle that one who asserts a proposition has the burden of supporting it with proof. This wholly salutary principle has been cast aside in this standard-making procedure. The proposed OSHA standard is promulgated as the answer to a possible, ("potential" in the language of the Statement), not a proven, or an actual hazard. Those affected are asked once the unsupported assertion is made, to undertake a massive effort to prove that a hazard does not exist in order to avoid costly, burdensome, dangerous and wholly unnecessary regulation. The proof of the negative of a proposition, of course, is a legal impossibility in most cases, including this one, particularly where nothing of evidentiary support is offered for the positive of the proposition.

This is a principle that the courts well recognize, and it is why they do not require indulgence in such absurdities, which they have repeatedly cited as untenable at law see Dry Color Mfrs. Ass'n. v. Labor Department (CCA 3, 1973), 486 Fed. 2d 98. Certainly, OSHA should recognize the force of such judicial logic is valid after its previous experiences in the courts, and should proceed to set standards based, as the statute requires on substantial evidence on the record as a whole.

Yet, despite its past record, OSHA has apparently headed down the same road as before, of making non-factual and conclusionary assertions which almost seem to invite court action. This vinyl chloride monomer environmental impact statement is no exception; its conclusions have already been rendered nugatory by the hearing record.

BOR 004811

What OSHA should have concluded; what the hearing record shows; and what OSHA could validly have previously ascertained for itself had it (or NIOSH) been willing to listen; is that the environmental impact of the proposed regulation of vinyl chloride monomer stemming from the severe economic impact of the regulation would be substantial; but, on the other hand, (as EPA has already concluded) the environmental impact of current vinyl chloride monomer permissible limits was negligible, indeed, not even discernable; and that no environmental considerations whatsoever would dictate any vinyl chloride monomer regulation, even at the level of the current OSHA emergency standard. The actual economic disaster the permanent standard proposal portends is hardly justified by the minimal number of individuals that could potentially (not actually) benefit.

The evidence OSHA possesses merely shows that a statistically insignificant number of employees, exposed continuously for prolonged periods of time to high vinyl chloride monomer concentration, could possibly get angiosarcoma; even that result is not a proven certainty. The evidence showed nothing else, nor will a review of the OSHA and NIOSH presentations at the hearing show any warrant for any such stringent regulations as is proposed. If there is truly a hazard, even from unregulated vinyl chloride monomer exposures, it at best is slight; limited to a workplace producing or making vinyl chloride monomer and, indeed, to a very few areas in any such workplace, without any impact on the environment outside; and a hazard in the workplace only at continuous exposure levels far beyond those OSHA limits either in effect at any time or proposed. OSHA's findings should also include a statement that there will be a severe environmental impact resulting from the economic consequences of adopting the proposed standard, wholly unwarranted by the hazard sought to be met, and which ought not to be imposed either on employers; on the employees affected by job loss; or on the consumers who use vinyl chloride monomer-related products in many harmless forms.

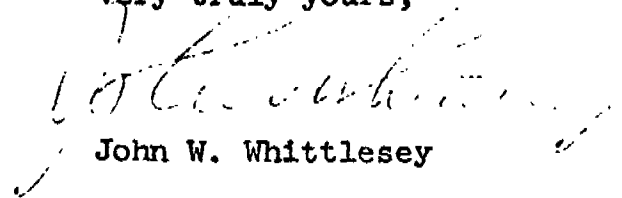
Mr. David R. Bell

-6-

July 15, 1974

I urge that such a conclusion is far more warranted even under OSHA's own factual assertions that the ones reached in fact, and that OSHA should substitute such conclusions for those in the statements. If not, the only alternative would appear to be a complete rejection of the statement, and its issuance in revised form, as above recommended.

Very truly yours,



John W. Whittlesey

JWW:me

BOR 004813

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

TO : David R. Bell
Office of Standards Development, OSHA

DATE: July 16, 1974

3

FROM : Director, Office of Research and
Standards Development

SUBJECT: Draft Environmental Impact Statement - Vinyl Chloride

As requested in Mr. Stender's memorandum of June 17, the following comments concerning the Draft Environmental Impact Statement on Vinyl Chloride are offered. There are a compilation of a number of reviews made by NIOSH professional staff and serves as the official NIOSH response to the draft statement.

Page 1

Delete the term research arm of OSHA and replace with Center for Disease Control, U.S. Department of Health, Education, and Welfare.

Page 3

You may wish to modify the final paragraph of the Background section to note that both foreign and U.S. animal studies have induced tumors at 50 ppm.

The last sentence concerning protective respiratory devices should identify such items as interim measures until engineering controls can be implemented.

Page 4

The statement that health effects resulting from Vinyl Chloride probably have a long latency period is somewhat misleading. The effects do have a long latency period, notably 20 years (average) for the development of angiosarcoma of the liver.

It is stated that the proposed standards "deals with the disposition of waste materials." A review of the standard does not disclose any meaningful coverage of this subject. This should be deleted or clarified at a minimum.

BOR 004814

Page 2 - Mr. David Bell

Page 22

The last sentence discussing migration of VC to the surface of PVC does not make sense. In that the VC can, under certain conditions, migrate to the surface of the PVC resin and subsequently be released, does this not constitute a potential worker exposure? It would seem that the intent of the standard should be to control VC in the workplace no matter what the source of exposure.

Page 57

It is stated that the proposed standard requires adequate venting of reactor vessels before worker entry. This is also stated in the preamble to the standard but cannot be found in the standard itself. Aside from that point, it should be made clear that ventilation is also necessary during cleaning/repair operations.

Pages 63-65

Starting on p. 63, we question the extent to which OSHA has demonstrated that "technology appears to be readily available" for engineering controls. We certainly don't have the data to support such a strong statement. Control techniques, including ventilation may not be too difficult for VC production which is intended to be a closed process in the open. Ventilation of process vessels for maintenance should also be straightforward, although we don't have sufficient data to establish the effectiveness of air cleaning devices in removal of VC from exhaust air.

In producing PVC, particularly with respect to the compounding operations including mixing, and in the fabrication of end products from PVC including calendaring very specific control systems would be needed to achieve the no detectable level.

In general, the broad statement on p. 63 appears too unsubstantiated and should be at least modified to more accurately reflect the state-of-the-art. Unfortunately, the state-of-the-art for engineering control techniques for vinyl chloride has not in our opinion really been established and this is a sizable gap in the proposed standard.


Vernon E. Rose

BOR 004815

MEMORANDUM

B. F. Goodrich Chemical Company

A DIVISION OF THE B. F. GOODRICH CORPORATION

5100 BAK TREE BOULEVARD - CLEVELAND, OHIO 44131 - PHONE 216-521-5000

ANTON VILIONE
DIVISION PRESIDENT

July 16, 1974

Mr. David R. Bell
Office of Standards Development
Room 500
1726 M Street N. W.
Washington, D. C. 20510

Dear Mr. Bell:

Pursuant to the Memorandum dated June 17, 1974 from John H. Stander, Assistant Secretary of Labor, we have the following comments regarding the Draft Environmental Impact Statement (DEIS) on Proposed Regulation - Vinyl Chloride.

DEIS is a commendable effort by a number of people to educate themselves quickly to a very complex problem through readily available publications and a walk through survey of seven plants located in the Southern part of the United States.

The conclusions drawn from such an effort by both the survey group in Appendix C and the authors of the DEIS applied to the 15 summer plants (mostly Southern and open locations) and the 36 polymer plants (mostly Northern and closed locations) seem to be unsupported.

We note a number of inaccuracies in reporting published information, but, since we understand the DEIS will be revised taking into consideration all information presented at the recent hearing, we will comment on only a few errors.

It appears that the DEIS is based on certain assumptions which are not supported by fact, namely:

1. That the proposed permanent standard is a non-detectable level of exposure to VCM, since exposure to a ceiling level of 2 ppm.
2. That it is technically feasible by engineering changes to operate VCM and PVC plants under a 1 ppm ceiling standard and that, while such engineering changes are being made, it is feasible to operate with workers in self-contained air supplied masks and whole-body air supplied suits.

BOR 004816

The possibility of engineering or re-engineering to meet the proposed standard is discussed on page 62. There is no data offered to support technological feasibility, except to say that "costs could be very substantial". Also, there is recognition that the use of "required personal protective equipment may reduce the productivity of a worker through reduced mobility", but again, no comment as to the discomfort and health and safety hazards to the individual through such use.

OSHA Industrial Hygienists conducted an on-site survey in March, 1974 (Appendix C) of five vinyl chloride manufacturing facilities and two PVC plants in the Baton Rouge-New Orleans area. From this survey, the following conclusions were drawn:

- "2. The PVC manufacturers have a more serious problem of VCM exposure than the VCM producers because most of the polymerization process equipment is in enclosed areas and ventilation is inadequate.
- "3. Leaks from the process equipment, vessel entry, VCM tank car loading, unloading, and process sampling, PVC reactor cleaning, compounding and packaging areas are major potential sources of VCM exposure found during this survey.
- "4. Engineering technology for control of VCM exposure is available and has been implemented by industry.
- "5. The observed practices relative to equipment maintenance, monitoring, medical examinations and surveillance and training are considered to be inadequate to control the employee's exposure to VCM."

In contradiction to these conclusions, the DEIS (page 63) states: "Since the technology appears to be readily available, it can be assumed that substantial development costs will not be incurred."

Even the meager data quoted on the two of seven plants visited (both obviously VCM manufacturing facilities) disclosed only one ceiling value below 1 ppm. Plant A data reported was on a Time Weighted Average basis (not recognized in the proposed standard), and all showed detectable exposure levels.

This data certainly cannot be used to support the feasibility of the proposed permanent standard. In addition, this data shows significant exposure above the present emergency standard (several readings in excess of 150 ppm).

The DEIS (page 63) mentions several possible areas of improvement which would lead to lower exposure levels. While we recognize that these suggestions may, while they are not now being effectively implemented, reduce exposure, we have of no way to reduce exposure to 1 ppm or non-detectable level. Moreover, we know of no other PVC or VC plant which is operating or can operate within the proposed permanent standard.

In summary, there are no data in Appendix C that could logically lead to the conclusion that a ceiling of 1 ppm is feasible in work areas of existing facilities even with engineering modifications.

Therefore, we find that there is absolutely no substantial basis, either in the DEIS or in fact, for the statement on page 63:

"No evidence to date indicates that promulgation of the proposed standard will stop vinyl chloride production and use, although production in some plants could be curtailed if re-engineering is required."

To the contrary - the evidence reinforces the industry position that it cannot now, nor in the foreseeable future, comply with a work area ceiling level of 1 ppm VCM in either its VCM or PVC manufacturing facilities.

Cartridge respirators are summarily dismissed (page 56) without provision for future improvement or recognition of their effectiveness under appropriate operating conditions. There is no recognition of the personal problems involved in wearing "full face respirators", nor "whole-body air supplied suits impervious to vinyl chloride".

The statement supports the inclusion (page 58) of a specific protocol for testing, medical diagnosis and treatment for a newly identified disease for which there is no known predictive testing.

There are a number of technical inaccuracies. For example:

1. Production of vinyl chloride Table 1 page 26

Shell's testimony at the February 15, 1974 hearings is referenced as a source of their vinyl chloride monomer capacity. The reported figures of 1,200 and 1,000 millions of pounds (per year?) are actually stated in the testimony as 1200 and 1000 tons per day, respectively, for their two plants. This may explain why, on page 28, the authors were puzzled by the apparent discrepancy in the number of workers reported by PPG and Shell required -- "per million tons" -- (of what time?).

2. Production of vinyl chloride polymer and copolymer resins amongst others, page 31

"The output of bulk processing plants is said to be more than twice that of good suspension plants of comparable size". Typically, such statements are repeatedly made without specific reference in the statement. We do not believe this statement to be accurate.

On page 60, the DEIS states that "vinyl chloride, a petrochemical, is produced from irreplaceable natural resources, and reduced demand on these resources could be of merit".

Are OSHA and other Governmental agencies cognizant that over 50% of vinyl chloride (and PVC) is derived from salt, of which the world has a superabundance. Likewise, ten percent of the chlorine produced in the United States is used to make PVC and a reduction of caustic production would have a significant environmental impact.

In summary, in our judgment, the proposed permanent standard is not technically feasible and the DEIS provides no evidence to the contrary.

Yours very truly,

B.F. GOODRICH CHEMICAL COMPANY
a Division of The B.F. Goodrich Company



Anton Vittone
Division President

AV/jb



DOW CHEMICAL U.S.A.

July 16, 1974

POST OFFICE BOX 1706
MIDLAND, MICHIGAN 48640

Mr. David R. Bell
Office of Standards Development
Room 500
1726 M Street, N.W.
Washington, D. C. 20010

DRAFT ENVIRONMENTAL IMPACT STATEMENT ON PROPOSED REGULATION
OF VINYL CHLORIDE

Dear Mr. Bell:

OSHA is certainly faced with a most complex and difficult area of decision making in establishing a new occupational health standard for vinyl chloride. Preparation of an adequate environmental impact statement is thus a compounded difficulty. Even so, the draft environmental impact statement is a gross over-simplification of a most complex area of technology and decision making. Extensive data were submitted at the June and July public hearing on the Proposed Standard for Vinyl Chloride. We sincerely suggest that the final environmental impact statement represent a more balanced perspective of the new data presented in these hearings.

We have several suggestions relating to the gaps in data and in quantification of judgments in assessing risk and technical feasibility. We also feel that the consideration of alternative standards needs more reasoned judgment of benefit/risk considerations, weighing of technical feasibility, and articulation of the risk for each alternative.

A. Gaps in Data and Quantification of Judgment

Hazards of Vinyl Chloride and PVC - The data cited to illustrate the hazard of vinyl chloride are the results of animal experiments and the known cases of angiosarcoma of the liver which have been associated with only certain plants producing vinyl chloride and PVC. Most other reports of adverse effects have been associated with operations where exposures are acknowledged to have been very high - in the thousands ppm range. The data from the Tabershaw-Cooper epidemiological study of the total industry, although available in early May, 1974 are not cited.

AN OPERATING UNIT OF THE DOW CHEMICAL COMPANY



BOR 004820

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We also note that considerable data have been presented in the June/July public hearing indicating that a number of plants have been operating in a manner that has resulted in no known cases of angiosarcoma of the liver. We believe that a careful judgmental weighing of the epidemiological data must be made in establishing a standard. We base our conclusion on the hearing record which indicates that test animals, particularly mice, are more susceptible to diseases caused by vinyl chloride exposure than are humans. It may be worthy of note that in Professor Maltoni's studies the rats that developed angiosarcoma of the liver and elsewhere (at 50 ppm) were 135 weeks on the experiment - or about 148 weeks old. This equates to a human well over 100 years old. Data on metabolism of vinyl chloride in the rat is also relevant to the decision making because it suggests a reasonable explanation for a dose-response relationship.

Occupational Exposure to Vinyl Chloride - The EIS indicates that at present "a reliable model designed to predict the expected number of cases" of angiosarcoma cannot be formulated. With this statement, the assessment of health hazards is dismissed in the EIS. The statement implies that judgments of hazard will have to be made. We concur. It therefore seems that the EIS should reflect at least semi-quantitative estimates of risk at various exposure levels.

We suggest that the final EIS reflect more accurately the trend in exposure levels that has occurred during the last twenty years. Semi-quantitative data on the trend of decreased exposure have been presented in the public hearing. To us, this trend seems highly relevant to the assessment of the degree of hazard faced by workers today compared to the hazards of approximately 20 years ago.

The Proposed No-Detectable Level of Exposure - The EIS attempts, by strong inference, to imply that assignment of the level of exposure in the proposed standard is not a judgmental decision. The level of exposure selected in the proposed standard, 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 ± 50 percent, is cited as the recommendation of NIOSH. Presumably, this recommendation was based on a judgmental assessment of the feasibility of analytical methodology. Further, to decide that the limit of analytical method feasibility will provide a reasonably safe workplace is another judgmental decision. We strongly believe, as

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will be cited in part B of this communication, that there are better criteria of judgment for permissible exposure levels.

The proposed standard "is intended to assure, so far as possible, a safe and healthful work environment." It seems to us that judgments should be made of the possible benefits and risks of the other alternatives, like zero exposure, the ETS, and some intermediate level(s) of environmental concentration. These will be difficult judgments, but certainly experience of plants at estimated environmental concentrations over 20 to 30 years of operating experience are now available to OSHA.

Probable Impact of the Proposed Standard - The impact of the adverse consequences of the proposed standard seems to be grossly over-simplified. Recent news reports indicate that compliance with the ETS is already decreasing productivity in the PVC industry; rated capacities have been decreased by as much as 7 to 25% (Chem. Mktg. Reporter, July 1, 1974). The statements in the EIS relating to "small increase in costs" and "ability to absorb such costs" is in stark contrast to the preponderance of testimony presented in the public hearing.

Substitution of other materials, wood, metal, or rubber, for polyvinyl chloride seems to be projected with undue optimism. Replacement of a five billion pound product simply cannot occur over night. Potential substitutes for relatively simple applications are already in short supply and it is questionable whether cited substitutes would meet product engineering property specifications - testing for performance frequently takes 1, 2, or more years. If substitute materials are to be considered as part of the decision making, it seems only reasonable that their technical feasibility be documented. Also, the availability of fabricating equipment and the time to develop and produce it are among the practical problems associated with any switch in basic materials.

The assertion is made that some substitute materials would be less consumptive of irreplaceable natural resources. This should be viewed in the context that U.S. PVC production consumes hydrocarbons equivalent to only about 0.4% of U.S. gasoline consumption. Further, whereas potential plastic substitutes for PVC are essentially hydrocarbon in origin, more than half of PVC derives from common salt.

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The impact of decreased commercial availability of caustic (sodium hydroxide) has not been considered in the EIS. Approximately twenty percent of U.S. chlorine production is utilized in manufacture of vinyl chloride. Caustic is a co-product in chlorine production. Shut-down of PVC manufacture would result in loss of 20% of the U.S. caustic supply. Caustic is already in tight supply. Any decrease in caustic production will decrease pulp and paper and aluminum production and seriously threaten production levels of a larger number of essentials, such as soaps and detergents, petroleum refining, waste and water treatment, and food processing.

Technical Feasibility - The courts have recently held that occupational health standards must meet certain tests of technical feasibility. The EIS contains several references to the technical feasibility of various engineering controls and other production techniques. These appear to be qualitative appraisals and often suppositions, with no cited basis for evaluation of their validity. In contrast, the June/July public hearing record is filled with numerous references to lack of technical feasibility to meet the proposed standard. We feel that the discrepancies between the EIS statements and the public hearing statements must be resolved in the decision making.

We note that EPA has recently developed a definition of "available technology" as follows:

1. Technology which has been demonstrated and is currently known to be feasible.
2. Technology for which there will be a production capacity to produce the estimated number of parts required in reasonable time to allow for distribution and installation prior to the effective date of the regulation.
3. Technology that is compatible with all safety regulations and takes into account operational considerations, including maintenance, and other pollution control equipment. (Federal Register, 39, No. 129, page 24580, July 3, 1974).

BOR 004823

Although this definition was developed in conjunction with proposed establishment of noise emission standards for railroad equipment, it's reasonableness and simplicity appear applicable to the present decision making. It seems to embrace the concept of technical feasibility. We urge that the EIS reflect objective evaluation of various proposals against the criteria enumerated above.

- B. The Weighing of Alternative Standards - We strongly urge adopting of a more reasoned judgment of benefit/risk considerations, the weighing of technical feasibility, and the articulation of risk in evaluating the various alternative standards that might be promulgated by OSHA.

The alternative of "allowing zero exposure" which literally permits no exposure, is presented rather superficially. In reality, this is not a practical alternative. It is essentially the same as a ban.

Dow supports reduction of the ETS to levels which can be reasonably attained within the limits of technical feasibility. However, to state that the ETS is inadequate because of the animal data, without giving an assessment of how this equates to 20 to 35 years of industrial experience, seems an over-simplification.

The alternative of relying on personal protective equipment is dismissed on the basis of not meeting the test of acceptability under OSHA. We believe the record should show that such an alternative would have highly undesirable features and hazards as cited in the testimony at the public hearing. This seems most important since many believe that the proposed standard would, in reality, necessitate the continual wearing of respirators and other protective equipment by a large percentage of the vinyl chloride workers. These comments do not imply that appropriate protective equipment should not be used for certain jobs of short duration or emergency situations.

We strongly maintain that the alternative of setting a limit between one and 50 ppm vinyl chloride has been dismissed capriciously. This alternative was summarily dismissed on the basis that "the selection of a permissible level between 1 and 50 ppm would be judgmental." As indicated earlier, the proposed standard is based on a judgmental decision - that the feasible limit of detection equates to a reasonably safe workplace level. To select one alternative on a judgmental basis and to reject another alternative strictly on the basis that it would be judgmental is incongruous.

Mr. Bell

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Dow, and others, presented factual data at the June/July public hearing showing that operations on the leading edge of technology generally maintain 8-hour time weighted average environmental concentrations of approximately 10 ppm with short-term concentrations in excess of this value. Epidemiological data are also now available (hearing record) to evaluate the health effects of such operations. We urge that any environmental impact statement should reflect decision making based upon carefully weighted judgments of technical feasibility, risk to workers, and the societal benefits of vinyl chloride.

Sincerely,



Fred Hoerger, Ph.D.
Operations Manager
Health and Environmental Research

cc: Council on Environmental Quality (5)
Dr. V. K. Rowe, Dow
D. A. Rausch, Dow

pl

BOR 004825

6

CITIES SERVICE COMPANY

BOX 300

TULSA, OKLAHOMA 74102

July 16, 1974

Mr. David R. Bell
Office of Standards Development, Room 500
Occupational Safety and Health Administration
U. S. Department of Labor
1726 M Street, N. W.
Washington, D. C. 20210

Dear Mr. Bell:

Cities Service Company is a large diversified company primarily engaged in petroleum, petrochemicals, gas, copper, industrial chemicals and plastics. One of the facets of Cities Service is Chester Cable Operations, a relatively small fabricating facility that uses polyvinyl chloride in insulating wire and cable. Cities Service does not produce vinyl chloride or polyvinyl chloride. Testimony has been presented by Cities Service at the hearing convened on June 25 to receive comments on the prepared vinyl chloride standard.

We perceive a tone of retrospective condemnation in the draft statement, for example, on Page 2: "Vinyl chloride has been used in this country for over 30 years with little concern for health problems ...". A more accurate description would have been that vinyl chloride exposure was controlled according to the hazard potential described by the information available at the time. This is true of other substances as well, whether they are very hazardous radioactive isotopes or innocuous peanut hulls.

It appears that the views and arguments presented at the hearing on the proposed vinyl chloride standard be considered in developing the final environmental impact statement. It is patently clear the draft statement grossly underestimates the effect the proposed "no detectable level" would have. This underestimation is partly due to the misinterpretation that "no

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Mr. David R. Bell

Page Two

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detectable level" means 1 ppm. The proposed standard only specifies the accuracy of the measuring technique at the 1 ppm level. There is no sensitivity or lower detectable limit specified. Neither is a specific sampling and analytical technique required, allowing considerable variation in sensitivity. Our own sample collection and analytical technique was given in testimony at the hearing. This method measures accurately within the $\pm 50\%$ limits at 1 ppm but can detect vinyl chloride below 0.1 ppm, and the detection limit can probably be extended another order of magnitude. Without specifying the lower detectable limit or sensitivity required or the precise details of one selected sample collection and analytical technique, the "no detectable level" is that detected by the best method available in the technical world. Unless otherwise stated, the regulated must assume the regulator could have the best possible method at his disposal. Techniques used by a large research laboratory are not necessarily feasible for a small PVC fabricating plant. If the proposed standard intended to set an exposure limit of 1 ppm, 8-hour time weighted average, that could have been simply stated.

In estimating the probable impact of the proposed vinyl chloride standard, the draft statement refers to low levels of exposure in many operations under normal operating conditions and favoring engineering controls, for example, Pages 55 and 62. The proposed standard is not a recommendation of guidelines for good practice -- it is a recommendation of law. The proposed standard clearly requires, not favors, engineering and work practice controls. The requirement is categorical and not limited to normal operations.

Definitive results are currently not available to accurately describe the carcinogenic mechanism in man, define a precise no-effect level in man or animals, or identify an animal species that responds similarly to man. In spite of this, the draft statement draws on the Bio-Test Laboratory results using mice exposed to 50 ppm as more significant than the lack of angiosarcoma in rats and hamsters exposed under the same conditions.

All data available must be considered in developing a vinyl chloride standard and estimating the possible environmental impact. We strongly recommend a thorough objective evaluation of all data, views and arguments available, including the testimony provided at the hearing convened on June 25 and reconvened July 8. From testimony to date it is clear the vinyl chloride and PVC industry could not continue to operate under a "no detectable level"

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Mr. David R. Bell
Page Three
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standard. This environmental impact is significantly greater than, "additional capital and other operating costs".

We have reviewed the Draft Environmental Impact Statement on the Proposed Vinyl Chloride Regulation. It is difficult to make specific comments on each of the sections and paragraphs of the draft statement. This is due to misinterpretation of the specific language of the proposed standard used in forming conclusions presented in the draft environmental impact statement. The imbroglio created does not encourage constructive recommendations.

Sincerely,

CITIES SERVICE COMPANY



Everett L. Smith
Manager, Safety & Training

ELS:jb
JWS:sw

BOR 004828

JOSEPH R. KELLER
JEROME E. HECKMAN
CHARLES M. MERRMAN
WILLIAM R. DORCHESANI, JR.
ROBERT R. TIERNAN
WAYNE V. BLACK
DAVID L. HILL
MARTIN W. BERCOVICI
EDWIN B. SPIEVACK
PETER M. NEMKOV
JOSEPH E. HADLEY
CAROLE C. HARRIS
WILLIAM W. PUGH

LAW OFFICES
KELLER AND HECKMAN
1150 17TH STREET, N. W.
SUITE 1000
WASHINGTON, D. C. 20036

TELEPHONE
202 908-2100
CABLE ADDRESS "KELMAN"

July 17, 1974

Mr. David R. Bell
Office of Standards Development
Occupational Safety and
Health Administration
U.S. Department of Labor
Room 500
1726 M Street, N.W.
Washington, D. C. 20210

Re: Draft Environmental Impact
Statement on Proposed Action
to Limit Exposure of Workers
to Vinyl Chloride

Dear Mr. Bell:

Responsive to Assistant Secretary John H. Stender's June 17, 1974 "Memorandum for Recipients of the Draft Environmental Impact Statement on Proposed Regulation--Vinyl Chloride", the following Comments are hereby submitted to the Office of Standards Development of the Occupational Safety and Health Administration (OSHA) on behalf of our client, The Society of the Plastics Industry, Inc. (SPI) and its Vinyl Chloride and Polyvinyl Chloride Resin Producers Committee. 1/

1/ The Society of the Plastics Industry, Inc. (SPI) is a Corporation organized under the Not-For-Profit Corporation Law of the State of New York. It is composed of approximately 1400 member companies and individuals who supply raw materials; process or manufacture plastics or plastics products, engineer or construct molds or similar accessory equipment for the plastics industry; and engage in the manufacture of machinery used to make plastics products or materials of all types. SPI is the major national trade association of the plastics industry, its membership being responsible for an estimated 75% of the total dollar volume of sales of plastics in this country. A more complete (cont'd)

It should be noted at the outset that the following Comments are being submitted for your consideration with full recognition of the fact that Dr. Daniel P. Boyd, Director of the Office of Standards Development, clearly stated on the record at the recent OSHA Hearings on the proposed permanent standard for occupational exposure to vinyl chloride that, to the extent any interested party testified regarding the proposed permanent standard, such testimony will be considered as that party's comments on the Draft Environmental Impact Statement referenced above. ^{2/} In light of Dr. Boyd's statement, in the following paragraphs we have simply summarized the basic SPI positions on the proposed standard and are requesting that the views expressed be considered along with the entire record as a statement of SPI's Comments on the Draft Environmental Impact Statement.

I. STATEMENT OF POSITION

1. The positions of the Society and the members of its Vinyl Chloride and Polyvinyl Chloride Resin Producers Committee on the technological feasibility and economic impact issues relative to the proposed standard were presented in depth at the recently concluded OSHA Hearings, and, in our view, stand generally uncontroverted by factual evidence. We respectfully submit that a "no detectable" level of vinyl chloride in the workplace is (a) infeasible, (b) unwarranted, and (c) therefore, beyond the intent and scope of the Occupational Safety and Health Act and the case law developed to date.

2. More specifically, SPI and many other parties participating in the referenced Hearing repeatedly provided hard data showing that the proposed "no detectable" level of vinyl chloride is technologically infeasible to

1/ (cont'd) discussion of the interest of the Society in this entire matter is set forth in the Occupational Safety and Health Administration Hearings, In the Matter Of: PROPOSED PERMANENT STANDARD FOR OCCUPATIONAL EXPOSURE TO VINYL CHLORIDE, Transcript at 330 et seq., June 26, 1974. (Hereinafter cited as: Transcript at _____, (date) .).

2/ Transcript at 1110, 1111, July 8, 1974.

achieve because the vinyl chloride monomer and polyvinyl chloride producers, in the present state of the art, cannot completely eliminate vinyl chloride exposure in their manufacturing operations. This most vital element of the Society's position was not countered by even a scintilla of evidence showing that a "no detectable" exposure limitation is technologically feasible. Furthermore, no evidence was adduced at the Hearings that would controvert the Society's position that the imposition of an infeasible exposure level would result in a shut-down of the vinyl chloride and polyvinyl chloride industries.

3. It is also SPI's position with respect to the proposed standard that the medical and scientific evidence alleged as the basis for proposing the complete insulation of the work force from minimal vinyl chloride exposure is not sufficient to warrant the conclusion that more reasonable exposure limitations would cause an undue hazard to employees. The Society's view is that the toxicity of vinyl chloride does justify limiting exposure levels but that the industry's alternative proposals to a "non-detectable" level give reasonable assurance that any hazard will be reasonably delimited and that employees will be protected from exposure to dangerous levels of vinyl chloride in the breathing zone.

4. Furthermore, medical experts testifying on behalf of the Society and others urged that the human experience data assembled is entitled, on toxicological grounds, to far greater weight than the inconclusive animal test data presented. Additionally, the human experience data justifies those exposure limitations which the industry considers feasible now and in the future. Considering all the testimony given at the Hearings, it is submitted that the tenor of the composite medical opinion was that the human experience data indicates that human toxicity problems associated with vinyl chloride stem from a time period when occupational exposure to vinyl chloride was at a considerably higher level than currently exists under the Emergency Temporary Standard.

II. COMMENTS ON THE DRAFT ENVIRONMENTAL IMPACT STATEMENT

5. OSHA's Draft Environmental Impact Statement is premised on the finalization of the current proposal without

change, the conclusion that the proposed standard is technologically feasible, and a presumption that the animal toxicology data mitigates against human exposure at levels above "non-detectable". SPI takes exception to these general propositions and urges that they be revised in the final Environmental Impact Statement insofar as evidence adduced during the Hearing and otherwise contained in the record illustrates that these premises are invalid.

6. With regard to the outline of the proposed standard at Pages 53-60 in the Draft Environmental Impact Statement, the Society's specific comments on the details of the proposed standard are a matter of record and can be found in the transcript of the Hearing. 3/

7. The Society, herein addressing the Draft Environmental Impact Statement rather than the proposed standard, takes strong exception, as enumerated below, to the sections in the Draft Environmental Impact Statement dealing with: "VI. Probable Impact of the Proposed Standard" at Pages 60-65 and "VIII. Alternatives" at Pages 73-75.

8. The Probable Impact section begins with the conclusion that adoption of the proposed standard will result in a workplace free of vinyl chloride exposure and result in less vinyl chloride escaping into the ambient air. It is stated also that compliance costs will threaten marginal firms, raise the price for PVC, and encourage the substitution of other materials but that high reliance on PVC will reduce demand elasticity despite these price changes. The Draft likewise postulates that other costs associated with compliance are deemed capable of internalization.

9. While understanding that the Draft Environmental Impact Statement was prepared prior to the conduct of the above-referenced Hearings and that the evidence adduced at those Hearings consolidated considerable background and expertise upon which OSHA's ultimate decision will be reached, the Society is compelled to note that, in its view, the Draft Statement itself offers no documentation

3/ Transcript at 300-685, June 26-27, 1974 (and elsewhere throughout the record).

or supporting evidence for the conclusions reached. In fact, it is respectfully submitted that the evidence gathered through the hearing process just completed indicates that it is technologically infeasible to achieve the proposed "no detectable" level of exposure in the workplace, that this technological infeasibility is not primarily economically related, and that substitutes for PVC are not in adequate supply. 4/

10. At Page 62 in the Draft Statement it is indicated that the proposed standard favors engineering and work practice methods that would reduce the exposure level and, at Page 64 and elsewhere, it is indicated that these engineering and work practice methods should include improved ventilation, air filtration, and housekeeping. Testimony at the Hearing indicates that engineering and work practice methods could reduce but not eliminate exposure to vinyl chloride in the workplace. It is submitted that the record is replete with information on these points and that such should be reviewed in great detail prior to the finalization of this Statement so that the environmental analysis will be based on a more accurate assessment of the state of the technology.

11. On the same page the Draft addresses supply problems, specifically with regard to personal protective equipment, that should be expected to occur with the implementation of a regulation such as is now proposed. Supply shortages, and lead-time for ordering and installing various types of equipment to reduce vinyl chloride concentrations in the workplace were addressed at length throughout the course of the Hearings. SPI submits that, since indications were that order placement and installation lead-time are currently running in excess of 20 months, this factor must be addressed in more detail in the final Statement.

12. Again on Page 62, the Draft states that preliminary assessments of the cost of compliance indicate that the expenditures to achieve such compliance will not be prohibitive. Without addressing the economics involved in detail here, reference should again be made to the statements in the record concerning ability to comply

4/ Transcript at 350 et seq., June 26, 1974 and at 455 et seq., June 26, 1974.

with the proposed standard; the testimony simply does not support the conclusion that economic consequences may not be prohibitive. Moreover, review of the Draft does not indicate that the preliminary assessment of cost of compliance is supported by the data in Appendix C. This Appendix indicates, at Page 6, that control technology is available, and in some cases installed, for limiting vinyl chloride exposure. However, we have found nothing in Appendix C to indicate that technology which would eliminate exposure to vinyl chloride is either available or installed.

13. We hasten to emphasize this point because, on Page 63 of the Draft, it is stated that since the technology appears to be readily available and existing practices already result in low exposure levels, some hazardous function operations, housecleaning and maintenance improvements required notwithstanding, the conclusion is that substantial development costs for vinyl chloride control technology will not be incurred. Continuing on the same page, there is a statement that no evidence exists to date indicating that the promulgation of the proposed standard will stop vinyl chloride production and use. Again, Appendix C does not support this conclusion and the evidence now in the hearing record as a minimum tends to controvert it almost completely. As a conclusion, its only support seems to stem from the statement on Page 64 indicating that PVC-reliant customers can be expected to sustain the industry despite the increased costs of polyvinyl chloride end products.

14. However, as pointed out above, industry members repeatedly pointed out during the course of the Hearings that the technology required to achieve a "no detectable" level of occupational exposure to vinyl chloride simply does not exist. Consequently, it is respectfully submitted that the final Statement should address the question of available technology in depth and in a more realistic light. Since compliance with the proposed standard would be absolutely predicated upon the existence of technical know-how, SPI submits that it is essential that the final Statement address and resolve these questions and the probable effects of such a standard on an industry unable to achieve compliance.

15. Turning now to the treatment of "Alternatives" at Pages 73 through 75, the options OSHA sees available

could be simply restated as (1) a ban on vinyl chloride production, (2) adoption of the current proposal, (3) retention of the Emergency Temporary Standard, (4) complete reliance on personal protective equipment and (5) an occupational exposure limitation somewhere between 1 and 50 parts per million (ppm).

16. The first alternative, a ban on polyvinyl chloride production, is not, it is submitted, a viable alternative because (1) such action would be contrary to the public interest as a matter of common sense, and (2) the Occupational Safety and Health Act does not contemplate elimination of any industry. It is, therefore, urgently submitted that, since legal authority for such an action is lacking, further consideration of a ban as an alternative is inappropriate.

17. Insofar as the second alternative deals with the instant proposal, the comments in the preceding paragraphs hereof on Probable Impact are wholly applicable and indicate the inaptness of this approach.

18. Alternative number 3, retention of the current 50 ppm exposure level specified by the Emergency Temporary Standard, is stated, on Page 73, to have been rejected as inadequate because animal tests "indicate that exposure to vinyl chloride at 50 ppm may well constitute a serious health hazard to employees." This statement implies that the conclusion is justified not only by animal toxicity studies but that such animal experience can be directly extrapolated to human experience.

19. It is respectfully suggested that this conclusion is no longer supported by the available evidence. During the referenced Hearings, considerable new evidence, interpretations and further reports on animal studies being conducted and their relationship to human experience were introduced into the record. It is the SPI position that in addition to the ongoing animal studies being conducted, some of which were referenced in the Draft Environmental Impact Statement, careful attention in the final Statement must be directed to the human experience data presented 5/ and the new toxicological research studies reported. 6/.

5/ See, e.g., Transcript at 500, et seq., June 26, 1974.

6/ See, e.g., Transcript at 955, et seq., June 28, 1974.

20. At Page 74, the last alternative offered in the draft Statement refers to the "judgemental" [sic] selection of an exposure level between 1 and 50 ppm. Such an alternative is stated to be viable only assuming that disease in man from vinyl chloride exposure is dose related and low levels are not hazardous to man.

21. Since this is precisely the essence of the medical and scientific evidence given in the Hearings, it is respectfully submitted that such evidence, entered into the record subsequent to the time when the Draft Environmental Impact Statement was prepared, should be thoroughly reviewed and given great weight prior to preparation of the final Statement. It is our view that the medical and scientific data specifically indicate a dose related response and that industry will do everything feasible to reduce the dose/exposure levels of vinyl chloride. This "Alternative," therefore, appears a feasible one, as does alternative three.

22. Finally, Appendix C, the Industrial Hygiene Survey Report on Vinyl Chloride and Polyvinyl Chloride Manufacturing Facilities, states, at Page 6, that vinyl chloride control technology is available and installed in some cases but that a reasonable time should be allowed for implementation of further engineering control methods such as local exhaust ventilation systems. It is important to note that this report does not and should not state or be interpreted to imply that the VCM exposure control technology currently available and implemented by the industry is capable of eliminating vinyl chloride exposure or making it possible for producers and manufacturers to reach a "no detectable" exposure level in the foreseeable future.

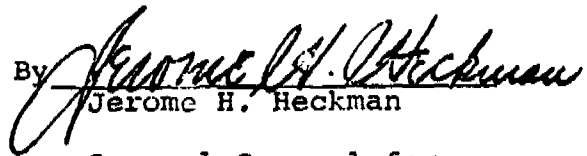
* * *

THESE PREMISES CONSIDERED, it is respectfully submitted that the Draft Environmental Impact Statement should be revised extensively so that the final Statement more completely and accurately addresses all of the issues as they have now been more fully developed. It is the

Society's view that unless the draft is so changed, the final Environmental Impact Statement may well lack the balance and objectivity required by the National Environmental Policy Act.

Respectfully submitted,

THE SOCIETY OF THE PLASTICS
INDUSTRY, INC.

By 
Jerome H. Heckman

General Counsel for
The Society of the Plastics
Industry, Inc.



SHELL CHEMICAL COMPANY

A DIVISION OF SHELL OIL COMPANY

ONE SHELL PLAZA

P.O. BOX 2463

HOUSTON, TEXAS 77001

July 17, 1974

U. S. Department of Labor
Occupational Safety and Health Administration
Office of Standards Development
Room 500
1726 M. Street, N.W.
Washington, DC 20210

Attention David R. Bell

Gentlemen:

Draft Environmental Impact-Statement June 12, 1974

Proposed Regulation - Vinyl Chloride 29 CFR Part 1910

This submission by Shell Chemical Company, a division of Shell Oil Company, P. O. Box 2463, Houston, Texas, 77001 responds to the notice in 39 FR 14522, April 24, 1974, of OSHA's intent to prepare an environmental impact statement and the subsequent issuance of a draft of such statement on June 12, 1974.

The Draft Environmental Impact Statement was introduced formally into the public record by Edward Klein, solicitor for OSHA, as evidence during the public hearings June 25, 1974 in the matter of the Vinyl Chloride Proposed Standard 29 CFR Part 1910 (see transcript page 7 lines 17-18).

Shell Chemical Company, commenting from the standpoint of a monomer producer only, disagrees with statements made in the Draft Environmental Impact Statement and questions its acceptability as a valid impact statement, as drafted for purposes of deliberating the necessity, feasibility or potential impact of the Vinyl Chloride Proposed Standard. As drafted;

- 1) It presents insufficient bases in fact or supposition to permit a reasonable estimate or judgement to be made of the technical feasibility or economic practicality of achieving the Vinyl Chloride Proposed Standard.

2) It is misleading with respect to:

- a) The justification for a "no detectable level" standard.
- b) The feasibility and costs to achieve such a standard.
- c) The possible consequences to the work force and to the economy if the proposed standard was imposed.

3) It fails to cite some pertinent toxicologic and epidemiologic evidence and is imprecise and misleading in citations of some of the evidence which is presented.

4) Statements of the vinyl chloride monomer capacity operated by our company (Table I) and of the personnel exposure per unit of capacity (pg. 28) are incorrect. These overstate the available domestic vinyl chloride monomer capacity (by 660 million pounds per year) and understate the work force directly employed.

5) There is an error in one of the exposure levels in Table II. No acknowledgment is made of the substantial information on sampling conditions and methods given OSHA during and subsequent to the visit to the Shell Chemical plant referred to in Appendix C.

6) The references to cost of compliance and the availability of technology and implications as to feasibility on pages 62, 63, and elsewhere in the report are not justified. It is apparent that these are attributable, at least in part, to a visit to our monomer plant at Norco, Louisiana the afternoon of March 13, 1974. At that visit, an OSHA industrial hygienist, an industrial hygienist trainee, and one OSHA fire protection specialist spent approximately 60 minutes touring the facility and another 90 minutes in discussions with our plant staff during the referenced "fact-finding survey." It would be extremely difficult even for engineering and design personnel highly qualified in the specifics of vinyl chloride manufacture to perform a preliminary investigation to relate exposure levels to equipment source, equipment capability, and to the operating conditions during such a brief visit.

These considerations do not permit acceptance of OSHA's contention that compliance with the proposed standard is technically feasible and carries little economic consequence based as it is on the short visit and discussion by the OSHA representatives cited above.

- 7) With respect to our operations, the report gives an incorrect impression that our housekeeping was poor and our maintenance inadequate or non-existent. Such misrepresentation invites an erroneous impression that more effort merely on housekeeping and maintenance will permit easy compliance with the vinyl chloride proposed standard. The last sentence on page 6 of Appendix C "Usually, a time period of six months may be sufficient to install VCM emission controls..." is not justified.
- 8) The report possibly could generate unwarranted uneasiness amongst the public and our workers as to our Company's attitude, progress and efforts to deal with the VCM problem. Contrary to the implications in Appendix C of the impact statement, our equipment is evacuated and purged before attempting maintenance, vessel entry is seldom necessary and requires a signed permit. We have an established medical surveillance program (see reference 3, bibliography pg. 51); our housekeeping and maintenance programs are thorough. We shut down operations when equipment malfunctions cannot be readily corrected during evening hours or in any case when continued operations would significantly increase worker exposure levels. Substantial maintenance is better investigated and planned in daylight hours when visibility is better.
- 9) The rigorous definition and imposition of a "no detectable limit" standard as proposed would require our discontinuance of vinyl chloride monomer manufacture. This would deprive industry of about 23% of the installed monomer capacity in the U.S.A. and cause a very serious upset to the PVC industry and to other major industries dependent on PVC. Loss to the U.S. economy could be serious as suggested by testimony at the recent public hearings and which OSHA could confirm by thorough economic impact studies. The Draft Environmental Impact Statement suggests there may be alternatives to PVC but does not identify viable substitutes. Shortages of some natural or synthetic products which might be suggested may already be severe and it would be expected that considerable retooling may be required to accommodate such substitutes as may be viable.

Attachment I to this letter is a copy of portions of the Draft marked to identify those portions which should be modified. We believe the need for revision in many of these cases will be readily apparent to OSHA in the light of our comments and of testimony at the recent public hearings dealing with evidence previously and newly available. Accordingly, we shall not comment on all of these cases. Attachment II offers comments on those numbered portions identified in Attachment I, which are most objectionable to us from the standpoint of need and feasibility as seen from the vantage point of a monomer producer.

We request that OSHA include this letter and its attachments as part of the record in opposition both to the Draft Environmental Impact Statement and to the Vinyl Chloride Proposed Standard 29 CFR Part 1910. We request that OSHA give serious consideration to the comments in this letter and its attachments as well as to the comments previously submitted by our letter of June 25, 1974 re 29 CFR Part 1910 before promulgating a permanent standard.

Very truly yours,

A handwritten signature in dark ink, appearing to read "R. J. Reynolds". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

R. J. Reynolds, Manager
Chemical Intermediates



UNION CARBIDE CORPORATION

CHEMICALS AND PLASTICS

P. O. BOX 8004, SOUTH CHARLESTON, W. VA. 25303

SOUTH CHARLESTON PLANT

July 17, 1974

Mr. David R. Bell
Office of Standards Development
Room 500
Occupational Safety and Health Administration
Department of Labor
1726 M Street N. W.
Washington, D. C. 20210

Draft Environmental Impact Statement-Vinyl Chloride

Dear Mr. Bell:

Attached are detailed comments on the Draft Environmental Impact Statement-Vinyl Chloride to be attached to a general statement sent you earlier by

Mr. J. W. Whittlesey
Union Carbide Corporation
270 Park Avenue
New York, N. Y.

I hope these additional comments will be of value in revising the Draft Statement.

Very truly yours,

R. N. Wheeler, Jr.

cc: /H
Attachment

cc: Mr. J. W. Whittlesly
Dr. A. B. Steele
Dr. N. L. Zutty
Mr. M. E. Eisenhower
Mr. J. L. Carvajal

BOR 004842

DRAFT ENVIRONMENTAL IMPACT STATEMENT

Proposed Regulation Vinyl Chloride

COMMENTS

Summary Page 2

The second paragraph implies that 13 people in the U. S. died recently of angiosarcoma. The initial death in this series occurred in 1961 and the last two occurred in 1974, a 14 year period.

Summary Page 3

The method of analysis as specified permits a variability in absolute vinyl chloride concentration of 0.3 ppm to 3 ppm. The proposed standard calls for no detectable by this method but the last paragraph states that the proposed standard is to assure that levels do not go above 1 ppm. In addition it states that the employer is required to initiate engineering and work practices "designed to bring the level below 1 ppm. This is all very confusing.

Summary Page 4

The last paragraph states that the proposed standard will reduce pollution of the environment external to the immediate work place.

This is a conclusion based on no data. All discussions in regard to control of the work place air have stressed ventilation i.e. remove the vinyl chloride from the work place and blow it into the external air.

Summary Page 5

"The proposal is not without adverse consequences. The standard for the most part will likely cause a slight decrease in productivity and a small increase in costs for products made from vinyl chloride."

Summary Page 5 (Cont'd)

This is a conclusion not based on the facts presented in the statement and is contrary to industry statements that the proposed standards will cause withdrawal from the business. The carcinogenic potential of vinyl chloride will not initiate a search for substitutes for polyvinyl chloride products are not hazardous to man; therefore, the only incentive to replace them will be economic. This does not fit with the statement that productivity will decrease slightly and there will be a small increase in costs of PVC resins.

Page 22 IV Occupational Exposure to Vinyl Chloride
Paragraph 2

This paragraph ignores the fact that after the vinyl chloride polymerization step the polymer is exposed to a vinyl chloride stripping or removal step. The final vinyl chloride monomer content of the resin is a function of resin particle size, particle porosity, and the efficiency of the monomer removal operation. The unconverted monomer contained in the resin is a factor in worker exposure only if ventilation at the first processing is poor or if the worker enters a closed vessel containing resin. OSHA is obviously concerned with the migration of VC to the surface of a PVC product since the proposed standard often refers to resin containing detectable quantities of vinyl chloride monomer.

Page 25 (1) Process Descriptions

"Until the late 1950's VC was generally produced from acetylene and hydrogen chloride."

Vinyl chloride was initially produced in the U.S. by caustic hydrolysis of ethylene dichloride. This process was followed by pyrolysis of ethylene dichloride to vinyl chloride and hydrogen chloride. Since hydrogen chloride was a pollution problem, the material was reacted with acetylene to yield vinyl chloride. The statement that vinyl chloride prior to the 1950's was generally produced from acetylene and hydrogen chloride is erroneous.

"Acetylene Route ... The product gases are then purified to vinyl chloride by water and alkaline scrubbing, drying and finally fractional distillation."

The product gases are fractionally condensed. The liquid condensate is then fractionally distilled to recover the pure vinyl chloride. The purified vinyl chloride is often caustic scrubbed after distillation.

Acetylene Route (Cont'd)

The oxychlorination process from ethylene to ethylene dichloride to vinyl chloride is replacing the "balanced" or acetylene route because of the high cost of acetylene, not because of greater efficiency.

Page 28 Process Descriptions

The differences noted between PPG and Shell in workers employed per million tons of vinyl chloride capacity is due to failure to secure the same information from both producers. Shell is giving information on all workers involved including maintenance and services whereas PPG has given information on only workers directly involved in production.

Page 33 Process Descriptions

"Four basic processes ... polymerization. The bulk process is a dry process requiring no water, suspending agents, or emulsifiers, the other three processes require water, solvents, or other liquids, but they are similar enough that they can be used in the same equipment."

This statement implies that any given suspension, dispersion or solution polymerization plant can operate on any other process. This implication is erroneous. Each process uses a specialized plant to produce products for a particular market.

Page 33 (1) Process Descriptions

In the United States approximately 78% of PVC resins are produced by suspension polymerization, 13% by emulsion polymerization (not solution as printed), 6% by bulk polymerization and 3% by solution polymerization.

Page 34 Suspension Polymerization

The PVC slurry is then blended in another vessel with other batches to reduce small variations, and dewatered by a continuous solid bowl centrifugal (Superdecanter is a trade name) to yield a polymer cake containing about 20% moisture.

Page 34 Emulsion Polym rization

"This process is very similar to the suspension process and is used to produce very fine particles. There are two primary differences: (1) Usually two emulsifying agents are soluble in water and one soluble in the monomer, are used to prevent coalescence of the polymer particles, and (2) The polymer is separated from the water by spray drying."

This is erroneous. The suspension polymerization process uses mechnaical mixing to suspend monomer particles in water and thereby produces large spherical particles. The emulsion process uses one or more surfactants and agitation to convert the monomer and water mixture to a stable emulsion containing very fine particles of monomer which polymerize to very fine particles of resin in a stable latex. The polymer is recovered by spray drying because there is no choice but to use this form of drying.

Page 35 Bulk Polymerication

"The output of bulk processing plants is said to be more than twice that of good suspension plants of comparable size."

A resin plant is normally sized by its output; thus this statement is in error. The author may have meant that output per fixed investment dollar is twice that of suspension plants.

Page 36 Solution Polymerization

The author of this section obviously took this information from an ancient patent. The process description is erroneous.

Page 53 V The Proposed Standard

Detailed comments on this Proposed Standard are as follows:

14



harvey hubbell incorporated

July 22, 1974

Mr. David R. Bell
Office of Standards Development
Room 500
1726 M Street, N. W.
Washington, D. C. 20210

Dear Mr. Bell:

I understand that the deadline for comments on the draft environmental impact statement for vinyl chloride has been extended, therefore, we request that our comments contained in this letter be considered before a final environmental impact statement is issued.

Harvey Hubbell, Incorporated is a Connecticut Corporation with operations producing electrical wiring devices, outdoor lighting products, electrical control equipment, specialty electric cable, communications equipment and commercial plastic molded products. Our concern with the vinyl chloride impact statement arises primarily from our use of PVC in our plastic molding operation and in our specialty electric cable operation.

We are unable to offer technical substantiation for our comments beyond the attached report prepared by the Liberty Mutual Insurance Company at our Kerite Company Subsidiary, the producer of specialty electric cable.

We believe, however, that the attached report substantially confirms much of the comment at the public hearings on the proposed OSHA standard in regard to the almost non-existent hazard associated with the handling and storage of PVC in the diced or pelletized form.

The draft environmental impact statement of June 12, 1974 could be modified on page 22, by rewriting the last sentence as follows:

"Since the proposed OSHA regulation is concerned only with the worker potentially exposed, the migration of VC to the surface of the diced or pelletized PVC compound or of a PVC product has not been considered."

Mr. David R. Bell--2--July 22, 1974

We believe that this addition will make clear that the VC monomer is probably not present in detectible levels in the materials used for conversion to the final product. We can see the possibility that residual monomer may be released during the conversion process. We are concerned in this case with regulations governing the unloading, storage and handling of the diced or pelletized compound.

Page 23, first sentence of the second paragraph does not, we believe, express what was intended by the writer of the statement. We believe that there has been some confusion about the fourth stage product and that the term "extrusion stock" is intended to include milled pellets or diced material. We believe this inclusion should be stated specifically, and that the fourth box from the top on figure 1, page 24, should also be reworded to specifically include the diced or pelletized form of PVC.

We are concerned with the last paragraph on page 49 headed "(2) Worker Exposure." The second sentence of this paragraph uses the term raw materials to describe the material used in the fabricating stage. We believe that the general interpretation of the term raw materials would apply to a product prior to compounding and converting it into the diced or pelletized in-process material, and we recommend study of this sentence for the purpose of clarification of the meaning intended.

Page 53, last paragraph, states that "fabricated products include such items as....." In this case we again recommend that the description be modified to include specific reference to the pelletized or diced in-process material.

Pages 63 and 64 seem to understate the problem of potential interruption of production of vinyl chloride and PVC. We believe that an argument can be supported with substantial logic to the effect that conversion to the proposed OSHA standard can cause substantial interruption in the supply of both the monomer and PVC, that prices of the products may increase substantially, and that the competitive position of the manufacturers of the end products could be seriously affected by such reduction in supply and increase in price levels.

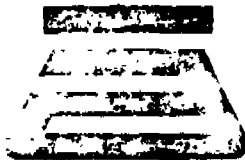
We must repeat, other than on the attached copy of an inspection report at our subsidiary's plant, we are unable to supply substantiating technical data, but we suggest that an examination of the record of the testimony at the OSHA hearings on the proposed regulation related to the environmental impact statement will produce testimony and, hopefully, test data which will support our position.

Sincerely,


William H. Gatenby
Vice President

WHG:arl

BOR 004848



americhem[®]

AMERICHEM, INC., 2038 MAIN STREET, CUYAHOGA FALLS, OHIO 44221 (216) 929-4213

July 24, 1974

Mr David R Bell
Office of Standards Development
Room 500
1726 M Street N.W.
Washington, D.C. 20210

Dear Mr Bell:

Enclosed is a copy of our comments relative to the proposed OSHA standard for vinyl chloride monomer exposure. We have chosen this method of comment rather than personal presentation.

Thank you for including it in the minutes of the proceedings.

Very truly yours,

AMERICHEM, INC.

John L Satterfield, m
John L Satterfield
New Products Manager

JLS/md
attachment

BOR 004849

COMMENTS ON THE DRAFT ENVIRONMENTAL IMPACT STATEMENT
PROPOSED STANDARD FOR OCCUPATIONAL EXPOSURE TO VINYL CHLORIDE

Americhem is a PVC processor engaged in the manufacture of color concentrate compounds which are used by other PVC processors. Our unique position as both user and supplier puts us into close contact with all aspects of the vinyl industry and because of the multiplier effect of the low usage levels of our product, we have access to a sizable portion of the market. In addition, our management has been associated with the development, manufacture, compounding and processing of PVC resin since shortly after World War II.

It is this background of long association with this industry that makes us feel compelled to offer our comments as to the probable effects that this proposed standard will have on us and on our customer. We have no expert opinion to offer as to the existence or nonexistence of carcinogenic hazard from vinyl chloride monomer and we do agree that if a hazard does exist then reasonable steps should be taken to either eliminate it or control it. Our concern is with the very real economic impact that will be felt if over reaction causes productive capacity to be shut down rather than comply with over restrictive controls.

PVC resin is presently in short supply. Presently this is due to the combination of petroleum shortage, increased demand and inadequate production capacity. During the recent Arab oil embargo PVC processors had great difficulty in purchasing adequate supplies of resin and, as a matter of fact, some companies were unable to buy any at all. It has been our experience that shortages have not been equally distributed over the industry but rather were quite spotty in their effect with some

July 24, 1974

users being hit quite hard while other more fortunate ones were hardly affected.

A number of reasons can be advanced for this result. Some processors through their purchasing policies had either limited their own sources of resin or had so negotiated the price that their suppliers felt encouraged to phase out their business when allocation time came. Some grades of resin had become so competitive or unprofitable that suppliers chose to discontinue them in favor of more profitable grades. Some customers were favored over others either because of geographic proximity or because of other relationships that had been developed over the years. Each situation was different but the point is, supply shortages affected different people differently and unequally.

The whole thrust of this discussion was to support the proposition that what may seem to an outside observer to be a minor disruption in supply may well have a devastating effect on some people and almost none on others. OSHA's own impact statement recognized that increased cost of compliance with the standard would threaten marginal producers. By OSHA's own figures there are seven plants out of thirty-six which produce less than 100 million pounds of PVC per year. If just one of these plants were forced to close, it is a good bet that some of their customers would not be able to replace this loss and would have to curtail their production.

It is also a reasonable assumption that any productivity decrease in the larger plants would not be distributed evenly. For one reason or another this decrease would be unevenly felt by their customers and in all probably would result in severe hardship to some processors, even to the point of closing them up.

We have had a number of experiences in which we have invested substantial time, money and effort into development programs which have fallen through when resin suppliers dried up. Jobs have been eliminated and product lines canceled not because they were non-productive or non-profitable, but because resin was not available.

Increased production costs may not be distributed equally either. Resin prices vary with grade and with volume. If product lines are dropped because of marginal profitability, some customers will be forced to use alternate grades of resin which may be considerably more costly than the proportional increased production cost. No doubt, competitive forces will correct this problem when production catches up with demand but until then some processors will bear a disproportionate share of the burden.

Another probable result of decreased domestic production will be an increase in the purchase of imported PVC resin. Aside from international balance of payment problems, importing PVC is less than desirable. Not only will any increased cost be disproportionately distributed to the industry but there is some real chance that residual monomer will

July 24, 1974

be higher in foreign material than in domestic. If so then use of such resin will increase our hazard to domestic workers rather than lessen it.

Responsible industry experts have proposed a step wise reduction in exposure which will have minimum impact on production. We urge serious consideration be given to the adoption of this proposal. It is our view that the certainty of serious economic effects outweigh the possible benefits of an over restrictive regulation. We ask that the regulation finally adopted be established in such a way as to minimize unequal burdens on our segment of the vinyl industry.

Respectfully submitted,

July 24, 1974

John L Satterfield



Rec'd 8/1/74
UNITED STATES DEPARTMENT OF COMMERCE
The Assistant Secretary for Science and Technology
Washington, D.C. 20230

16

August 1, 1974

Mr. David R. Bell
Office of Standards Development
1726 M Street, N. W., Room 500
Washington, D. C. 20210

Dear Mr. Bell:

The draft environmental impact statement for the proposed "Regulation Vinyl Chloride," which accompanied your letter of June 17, 1974, has been received by the Department of Commerce for review and comment.

The statement has been reviewed and the following comments are offered for your consideration.

General Comment

The draft statement furnishes a rather comprehensive and generally accurate description of the processes used in the vinyl chloride industry. The following weaknesses are evident.

- (1) Critical judgment has not been applied to some of the data reported, and invalid and unsupported generalizations are numerous.
- (2) The scope of the impact of the proposed regulation is limited and conspicuous by the lack of documentation.
- (3) A time plan offering an orderly transition has not been presented.

We suggest that the statement be revised to accommodate these points.



BOR 004854

Specific Comments

I. Summary

Introduction, page 1-3

The manner of presenting pertinent information on vinyl chloride implies precipitous action without adequate justification. To soften this effect the second paragraph on page 1 may be inserted at the end of the Introduction.

The discussion of health problem on page 2 relates only 4 deaths from liver angiosarcoma among workers with industrial exposure to vinyl chloride in this country. A total of 19 deaths are declared from angiosarcoma, 13 of which occurred in this country. The remaining six cases of angiosarcoma which are recorded presumably occurred outside the U. S., but the etiology of these cases is not clearly related to vinyl chloride.

The last paragraph of the introduction which ends on page 3 explains why the Occupational Safety and Health Administration (OSHA) established a temporary standard for vinyl chloride at 50 ppm and implies that a permanent standard of no detectable level ($1 \text{ ppm} \pm 0.5 \text{ ppm}$) will adequately assure no material impairment of health or functional capacity of men exposed for the duration of their working lives. The available evidence indicates the need for a permanent standard, but use of available data to support the claims for the proposed permanent standard is not apparent.

page 5

The proposed range of alternates is expanded to include the possibility that results of additional testing may indicate a safe level. The second sentence asserts that hazards of vinyl chloride have been assessed. An interim evaluation has been made, but scientific data which support the parameters used in the assessment have not been presented. It is agreed that retaining 50 ppm as a standard level may be untenable. However, since a dose response has been reported, the degree of hazard will depend on the amount and duration of the exposure. The reasons for not using this information in selecting the proposed standard should be explained.

II. Background

Page 7, paragraph 1, reports that on January 22, 1974, B. F. Goodrich identified four deaths among their employees of angiosarcoma of the liver. It is our understanding that only three such deaths were identified at that time. The fourth was, as of that date, only identified as liver cancer of unspecified type.

III. Hazards of Vinyl Chloride and Polyvinyl Chloride

This section appears to be a historical account of the toxicology studies with vinyl chloride. In several instances alleged effects have not been precisely identified with the cited documents. Pertinent information has been cited which apparently was not used in the subsequent evaluation of hazards of exposure. Information used to support the establishment of safe vinyl chloride levels in air has not been clearly identified.

In the first paragraph of page 15 reversible changes in liver functions were mentioned. Available results of these tests apparently were not considered in selecting the 50 ppm interim standard or the standard of "no detectable amount." An explanation of this omission is necessary to justify requiring liver function studies of humans in the proposed monitoring studies.

On page 17 the impression is given that all the pathology reported is considered to constitute a syndrome of interrelated symptoms. The wide disparities in the comparative incidence and/or the association of these symptoms in affected employees in different studies reported in the literature do not appear to support that concept.

In the second paragraph, page 18, occurrence of angiosarcoma in employees of the B. F. Goodrich company is cited. However, no mention was made of the incidence of angiosarcomas reported among vinyl chloride workers by Union Carbide, Firestone Tire and Rubber or Goodyear cited in F. R. 39:92 May 10, 1974. The reason for this omission should be explained. No data were presented which permitted relating occurrence of tumors with the rate of exposure or the type of work performed. This omission seriously limits the range of amounts to be considered in selecting a safe level of exposure.

On page 19, the reference to Industrial BIO-TEST Laboratories studies fails to identify the experimental animals in which the experimental findings were observed as mice rather than rats which were used in earlier studies.

IV. Occupational Exposure to Vinyl Chloride

In the second sentence of the first paragraph on page 22 reference is made to the "mechanism of carcinogenesis" Relevance of the mechanism to an assessment of hazard has not been identified. How knowledge of the mechanism might influence the selection of a standard value is not clear.

The last sentence of the second paragraph on page 22 infers that the regulation is concerned only with potential hazard. In reality the hazard of exposure is the factor to be regulated, and the extent to which hazards may be regulated should be influenced by the gravity of the consequence. In this case the potential hazard is the tendency for vinyl chloride to be released. The hazard is the amount of vinyl chloride in the air breathed by workers.

Worker Exposure, page 27

The discussion of the numbers of employees involved in production of vinyl chloride is a typical example of the authors' failure to evaluate critically the data they report. The cited levels of employment cannot possibly be per million tons of stated capacity (which would give PPG somewhere between 0.3 and 0.6 employees to operate the Lake Charles plant), nor can it be per million pounds capacity (in which case the entire 1500 people reported for industry would be required to operate the plant).

In the last paragraph on page 28 reference is made to time-weighted-average of exposure of workers in different categories. However, no attempt is made to make these projections with available data or to confirm the validity of the projection by comparing occurrence of adverse effects of exposure with the exposures sustained by workers in the different categories.

In the last two sentences at the top of page 30 the statements are made "time-weighted-averages are generally well below 50 ppm" and without information on sampling time and analytical method "the data cannot be used to estimate the employees exposure to vinyl chloride." Reconciling the validity of both of these statements is difficult.

Worker Exposure, page 36

It is apparent that all available data have not been considered in assessing worker exposure to vinyl chloride. Although adequate air sampling information may be lacking, other references cited in the Acroosteolysis section on page 15 indicate results of several recent epidemiological studies which may be useful in comparing rates of occurrence of adverse effects of exposure with job categories of workers. No attempt has been made to relate the occurrence of angiosarcomas or other adverse effects among workers in different plants with job categories of workers. It is of interest to note that the Goodrich Chemical Company cited several cases of angiosarcoma among its workers but Dow Chemical Company did not. Some justification probably should be offered for failing to discuss this difference.

On line 14 of page 36 a range "between 4,000 and 20,000," is stated. It is not clear what these values represent; do they refer to the number of processing firms, or the number of employees?

V. The Proposed Standard, page 53

The term "detectable amounts" is misleading and difficult to enforce. To avoid confusion a finite value should be specified, i.e., 1 ppm as measured by a method with sensitivity of 1 ppm $\pm$ 50 percent. Industrial sources claims that adherence to no detectable levels would cause close down of the industry due to the lack of technology to completely eliminate exposure. As a short-term interim standard consideration could be given to the proposal set by the Society of Plastic Industry (SPI) of concentration of 40 ppm through October 1974, with scheduled reductions as set forth by SPI (Chemical and Eng. News July 22, 1974, pages 9-10). While the SPI recommended schedule may prove to be somewhat on the high side, the risks from such exposure levels over a

limited time period would appear to be nominal. There should be a re-examination of all relevant data within 12 months to determine whether firm factual information has been developed to establish a standard substantially lower than the SPI proposal.

VI. Probably Impact of the Proposed Standard, page 60-65

In the space of 4 pages the editors have attempted to present the substantive matter relating to the title of this document. The first paragraph on page 60 states: "the major impact of the proposed OSHA standard . . . is a working place free of vinyl chloride exposure." This assumes the attainability and the enforceability of the proposed standard and ignores the basic considerations that the proposed standard is an effective 1 ppm ceiling standard, and that its attainment would not constitute a workplace free of vinyl chloride exposure.

In the second paragraph the capital and operating costs of complying with the standard are discussed. The feasibility of compliance is implicitly assumed and no consideration is given to the possibility that efforts at compliance may engender unlimited capital and operating costs and still fail of achieving their goal. The statement is made that, as vinyl chloride is a product dependent upon nonrenewable natural resources, a reduced demand for vinyl chloride could be considered an environmental benefit. Without an expressed comparison of the stresses on the environment from the production of vinyl chloride as compared with those involved in production of substitute materials, such a statement is sheer speculation.

Termination of production of VCM and PVC resin, and replacement of PVC products with other material, is not a viable option. In many cases, there is no reasonable substitute material which can serve as a replacement material. In many cases, the required quantity of replacement material would not be available on short notice. Hence, the economic impact on downstream industries would be very significant if PVC resins were not available.

The concluding section of this statement "that a preliminary assessment of the cost of compliance indicates that expenditures required will not be prohibitive" is completely unsupported by

evidence in this document. The industrial hygiene on-site survey referenced in this identified techniques for reduction of vinyl chloride exposures but nowhere makes the judgment that these techniques would be adequate to achieve compliance with the "no detectable level" standard. The reduction in productivity associated with efforts to comply with this "no detectable level" standard has been estimated as high as 50% by union representatives. At the current OSHA hearings industry representatives have testified that, for all intents and purposes, productivity would decline to almost zero.

The Industrial Union Department of the AFL-CIO is reported to have estimated that 700,000 men and women are exposed to vinyl chloride monomer in monomer, polymer, secondary, and tertiary production. The authors also state: "because of turnover of employees, the population over time exposed to vinyl chloride will be significantly larger than any estimate of the working population exposed." The number cited by the union refers to people working in the identified industries and has no relationship to the number of employees exposed to vinyl chloride monomer. A great majority of these people work in secondary and tertiary operations with no known evidence of vinyl chloride monomer exposure. Exception must be taken to the presentation of this kind of unsupported generalization.

VII. The Relationship to Other Federal Actions, pages 66-72

Regulatory Activity, page 66

The reference to the EPA tests on vinyl chloride aerosols erroneously associates the 400 ppm vinyl chloride monomer in the air of a closed room with a reported persistence of vinyl chloride in a sealed space. The implication that only about 1% of vinyl chloride propellant would dissipate in 4 days from a room in which an aerosol product is used seems totally unwarranted. Vinyl chloride has been banned by FDA as a propellant in hair sprays and other cosmetics, and by EPA in insecticides.

Air pollution threat by VCM around plants may require closing down ventilation systems outlets. However, EPA has stated that VCM is not a threat now around plants as more than 95 percent of

samples taken showed levels of less than 1 ppm. Pollution of plant water effluents varied in the amounts of VCM depending with degree of waste water treatment. Highest level found was 20 ppm, but typical levels were 2-3 ppm. EPA has also stated that there is no evidence to indicate VCM is presented in detectable levels in drinking water.

In the first paragraph, on page 71 the discussion of EPA ongoing research programs, reference is erroneously made to "the mutagenesis and teratogenesis of angiosarcoma." Presumably the intent was to identify studies of possible mutagenesis and teratogenesis by vinyl chloride monomer. In the same paragraph "paralytic degradation of plastics" should read pyrolytic.

In the discussion of alleged liver problems in hatchery-raised fish, if in fact the ultimate cause is the plasticisers in flexible tubing, such tubing should be identified as such. PVC pipe, such as is used in domestic water supply systems, is prepared from unplasticized resins.

VIII. Alternatives, pages 73-75

It must be kept in mind that the proposed standard, to which the listed alternatives are compared, does not "eliminate vinyl chloride from the workplace air." The standard of "no detectable exposure," as written, constitutes a 1 ppm ceiling standard, not a "zero exposure."

The points made in the fourth alternative against dependence upon respiratory protection for workers are well taken, and OSHA should recognize that the promulgation of a workplace standard that cannot be met by engineering and work practices changes will inevitably result in the situation there portrayed.

The fifth alternative, the setting of a vinyl chloride standard at some point between 1 ppm and 50 ppm, is rejected on the ground "in the absence of scientific evidence to conclusively establish a safe level selection of a permissible level between 1 and 50 ppm would be judgmental." This certainly is true, but it is no less arguable that the selection of a "no detectable level based on a 1 ppm level sensitivity" is also judgmental and just as unsupported by scientific evidence as would be some number set at a higher level between 1 and 50 ppm.

The reported occurrence of angiosarcoma among employees with long histories of exposure to vinyl chloride offers convincing evidence of the need to establish an allowable rate of exposure to humans. However, there appears to be no attempt to relate this effect to the degree of exposure or the type of work assignment of each stricken individual. Lack of this information hinders assessing a cause and effect relationship needed to justify the selection of the 1 ppm level published in the Federal Register May 14, 1974.

The significance of the results of studies with experimental animals was not discussed. Two investigators reported the same levels of no-effect (50 ppm) from long-term feeding studies with several animal species. A graded response to dosage was reported by Maltoni (page 18) which indicates possible drug effect type of response and a reasonable possibility to establish a safe level of exposure. Rowe reported that low levels of vinyl chloride may pose little hazard, but high levels may overload metabolic pathways and cause subsequent carcinogenic metabolities.

Thank you for giving us an opportunity to provide these comments which we hope will be of assistance to you. We would appreciate receiving a copy of the final statement.

Sincerely,


Sidney R. Galler
Deputy Assistant Secretary
for Environmental Affairs

The Goodyear Tire & Rubber Company

Akron, Ohio 44316

August 2, 1974

Mr David R Bell
Office of Standards Development
Occupational Safety and
Health Administration
U S Department of Labor
Room 500
1726 M Street, N W
Washington, D C 20210

Re: Draft Environmental Impact Statement
on Proposed Action to Limit Exposure
of Workers to Vinyl Chloride

Dear Mr Bell:

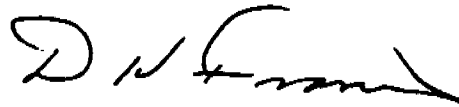
The Goodyear Tire & Rubber Company, in commenting on the Draft Environmental Impact Statement on Vinyl Chloride, is not interested in reciting the text of its submission or in restating a general industry position advanced during the informal hearings on the Proposed Standard for Occupational Exposure to Vinyl Chloride, held June 25, 1974 through July 11, 1974. It is Goodyear's intent, however, to take strong exception to the Department of Labor's position that the proposed level of exposure to vinyl chloride is currently technically achievable and that the economic impact of the proposed standard on industry will be minimal.

The Draft Statement, at pages 5 and 62, draws conclusions from Appendix C, an on-site survey of several vinyl chloride (VCM) and polyvinyl chloride (PVC) manufacturing facilities. One of those facilities surveyed was Goodyear's PVC bulk polymerization plant in Plaquemine, Louisiana. This facility is an outdoor plant where little improvement in VCM exposure can be accomplished by forced ventilation. The 8-hour TWA mean for all operators in its open reactor building with the latest in modern equipment and controls is 8 PPM with a range of 1.4 to 28 PPM over a 27-day period. While this is a low exposure level, it is nevertheless an exposure level above "no detectable level."

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contained in the last alternative offered in the Draft Statement at page 75. As the great weight of evidence indicates that disease from vinyl chloride exposure is dose-related and at low levels not hazardous to man, this is the only feasible solution suggested in the Draft Statement. In conclusion, Goodyear respectfully submits that the SPI recommendation of a graduated standard with an eventual limitation of 25 PPM ceiling with a TWA limit of 10 PPM is a realistic and achievable goal.

Sincerely,



Director of
Chemical Production

D H Francis
eg

REGISTERED AIRMAIL
RETURN RECEIPT REQUESTED

Labor Organizations

Mr. Arnold Mayer
Legislative Representative
Amalgamated
Meat Cutters and Butcher Workmen
2800 North Sheridan Road
Chicago, Illinois 60657

Mr. Peter Bommarito
President
United Rubber, Cork,
Linoleum and Plastic
Workers of America
87 South High Street
Akron, Ohio 44308

Mr. Angelo Cafalo
Special Assistant to the
International President
International Association of
Machinists and Aerospace
Workers
Machinists Building
1300 Connecticut Avenue, N.W.
Washington, D.C. 20036

Mr. Adolph E. Schwartz
Director
Safety and Health Department
United Steelworkers of America
Five Gateway Center
Pittsburgh, Pennsylvania 15222

Mr. Sheldon W. Samuels
Director
Industrial Union Department,
AFL-CIO
815 Sixteenth Street Street, N.W.
Washington, D.C. 20006

Mr. Anthony Mazzocchi
Director
Oil, Chemical and Atomic
Workers International Union
1126 16th Street, N.W.
Washington, D.C. 20036

Mr. Louis S. Beliczky
Director of Industrial
Hygiene
United Rubber, Cork,
Linoleum and Plastic
Workers of America
87 South High Street
Akron, Ohio 44308

Mr. Harvey R. Robinson
Attorney at Law
609 Third Avenue
Freedom, Pennsylvania 15042

Mr. William E. Nichols
Consultant
Organization Resources Counselors,
Inc.
1660 L Street, N.W., Suite 212
Washington, D.C. 20036

Mr. Onslow B. Hager
Environmental Advisor
Alco Standard Corporation
Valley Forge, Pennsylvania 19481

Mr. Michael J. George
Director
Canvas Products Associate
International
600 Endicott Building
St. Paul, Minnesota 55101

Ms. Donna J. Roberts
Attorney
The Dow Chemical Company
Bennett Building
2030 Dow Center
Midland, Michigan 48640

Mr. Martin J. Kleinfeld
Director
Uniroyal Chemical, Inc.
Elm Street
Naugatuck, Connecticut 06770

Mr. William W. Sadd
President and General Manager
Glass Container Manufacturing
Institute
1800 K Street, N.W.
Washington, D.C. 20006

Mr. David A. Weinstein
Attorney
Borden, Inc.
277 Park Avenue
New York, New York 10017

Mr. Paul I. Weiner
Associate Counsel
Certain-Teed Products
Corporation
Post Office Box 860
Valley Forge, Pennsylvania 19482

Miscellaneous

Dr. Everett Marcum
Chairman, Safety Studies
Department
West Virginia University
Room 280 Coliseum
Morgantown, West Virginia 26505

Dr. William Olson
2347 Paddock Lane
Reston, Virginia 22091

Mr. C. Nelson Coddling
Cooperate Environmental Control
Jim Walter Research Corporation
10301 Ninth Street North
St. Petersburg, Florida 33702

Mr. Charles E. Kupchella
Administrative and Scientific
Coordinator
University of Louisville
Health Sciences Center
Louisville, Kentucky 40201

Mr. John Messervey
Refinished Mouldings
Manufacturers Association
1201 Waukegan Road
Glenview, Illinois 60025

Mr. Edwin A. Olsen
Secretary and Treasurer
Compressed Gas Association, Inc.
500 Fifth Avenue
New York, New York 10036

Mr. Ulrich H. F. Wollmann
Representative of the Huls-Group
for the United States of America
750 Third Avenue
New York, New York 10017

Mr. H. Paul Friesema
Associate Professor
Northwestern University
Center for Urban Affairs
2040 Sheridan Rd.
Evanston, Illinois 60201

Mr. R. F. Kalmbach
Jomac, Inc.
863 Easton Road
Warrington, Pennsylvania 18976

Mr. William H. Gatenby
Vice President
Harvey Hubbell Incorporated
584 Derby Milford Road
Orange, Connecticut 06477

Mr. Barton J. Menitove
Collier, Shannon, Hill
and Edwards
1666 K Street, N.W.
Washington, D.C. 20006

Mr. Thomas F. Mitchell
Executive Representative
Georgia-Pacific Corporation
1735 I Street, N.W.
Washington, D.C. 20006

Mr. Robert F. Magill
Vice President
Industry Government Relations
General Motors Corporation
1660 L Street, N.W.
Washington, D.C. 20036

Mr. Jerome H. Heckman
Keller and Heckman
1150 17th Street, N.W.
Suite 1000
Washington, D.C. 20036

Mr. John C. Gmelch
New England Plastics
Corporation
310 Salem Street
Woburn, Massachusetts 01801

Mr. Robert I. Martin
President
RIMAR, Inc.
27 East Ferdinand Street
Manheim, Pennsylvania 17545

Mr. George E. Field
Vice President and
General Manager
1450 South Chillicothe Road
Aurora, Ohio 44202

Mr. John D. Farr
Technical Service and
Development Manager
Emergy Industries, Inc.
4900 Este Avenue
Cincinnati, Ohio 45232

Mr. Harold Jones
Scandura Company
Post Office Box 949
Charlotte, North Carolina 28201

Mr. Earl F. Webster
UNILOK
Belting Division
Georgia Duck and Cordage Mill
Scottdale, Georgia 30079

Mr. Thomas F. Humphries
Fenner America
400 East Main Street
Middletown, Connecticut 06457

Mr. Lyall Morrill, Jr.
Lyall Electric, Inc.
Post Office Box 107
Alvion, Indiana 46701

Mr. Boris Osheroff
Interim Principal Environmental
Offices for Health
Parklawn Building, Room 17A-43
5600 Fishers Lane
Rockville, Md. 20852

Mr. Radford and Wandrei
Attorney at Law
Post Office Box 223
Bedford, Virginia 23523

Mr. Gerald Kessler
Secretary-Treasurer
Kessler Products Company, Inc.
302 McClurg Road
Box 389
Youghstown, Ohio 44501

Mr. Gerard R. Quinn
Vice President
U-Brand Corporation
Clark Street
Ashland, Ohio 44805

Mr. John L. Satterfield
New Products Manager
Americhem, Inc.
2038 Main Street
Cuyahoga Falls, Ohio 44221

Mr. Chris Seibel
Junior Vice President
Posh Chemical, Inc.
17 Matinecock Avenue
Port Washington, New York 11050

Mr. Paul A. Korody, Jr.
Director of Governmental Affairs
The National Association Food
1725 Eye Street, N.W.
Washington, D.C. 20006

Mr. Morton F. Guerine
Executive Vice President/
General Manager
Geauga Plastics Company
900 South Wiley Street
Crestline, Ohio 44827

Mr. Harry J. Lambeth
Kothe, Eagleton, Barton
and Lambeth
632 Shoreham Building
806 Fifteenth Street, N.W.
Washington, D.C. 20005

Mr. H. M. Basow
Kreonite, Inc.
715 East 10th Street
Post Office Box 2099
Wichita, Kansas 67201

Mr. Stephen B. Bogese
President
Virginia Plastics Company
Post Office Box 165
Roanoke, Virginia 24002

Mr. John E. Sloat
Technical Director
L. Frank Markel & Sons, Inc.
Norristown, Pennsylvania 19404

Mr. Leonard H. Devenow
Director of Procurement
Sheller-Globe Corporation
Toledo, Ohio 43624

Mr. Jack C. White
President
Tridyn Industries, Inc.
Post Office Box 156
Colfax, North Carolina 27235

Mr. Frank D. Gaus
President
Superior Products Company, Inc.
833 47th Avenue
Oakland, California 94601

Mr. Richard Douglas, Jr.
President
PEP Industries, Inc.
6115 Robertson Avenue
Nashville, Tennessee 37209

Mr. W. D. Lovett
Development Engineer
Calgon Corporation
Post Office Box 1346
Pittsburgh, Pennsylvania 15230

Mr. M. Martin Maglio
Executive Vice President
PCI Industries, Inc.
Post Office Box 9845
Riviera Beach, Florida 33404

Mr. H. M. Zimmerman
Director of Manufacturing
A. Schulman, Inc.
3550 West Market Street
Akron, Ohio 44313

Mr. Addison Hawley
President
United States Concrete
Pipe Company and
Sedco Corporation
Post Office Box 6982
Cleveland, Ohio 44101

Mr. William F. Miller, Jr.
Johnson Plastic Corporation
Post Office Box 100
Munn and Stafford Road
Chagrin Falls, Ohio 44022

Mr. John Steven Harris
Chairman of the Board
American Plastics
Bainbridge, New York 13733

Mr. R. F. Williams, Sr.
Chairman
Genova, Inc.
300 Rising Street
Davison, Michigan 48423

Mr. Nelson E. Schmidt
39 South LaSalle
Suite 1500'
Chicago, Illinois 60603

Mr. Phillips
Covington and Burling
888 Sixteenth Street, N.W.
Washington, D.C. 20006

Mr. Robert Homel
Assistant General Counsel
Boise Cassett Corporation
One Jefferson Square
Boise, Idaho 83701

Mr. John E. Sloat
Apartment B-406
251 W. Dekalb Pike
King of Prussia, Pennsylvania 19406

Mr. Etcyl H. Blair
Director of Health and
Environmental Research
U.S. Area Research and Development
Dow Chemical U.S.A.
2020 Dow Center
Bennett Building
Midland, Michigan 48640

Mr. Joseph T. Flanagan
Technical Consultant
The Hartford Insurance Group
Loss Control Department - ESU
Hartford Plaza
Hartford, Connecticut 06115

Mr. W. M. Laughton
Standards Section
Engineering Assurance
Stone and Webster Engineering
Corporation
Post Office Box 2325
225 Franklin Street
Boston, Massachusetts 02107

Mr. R.J. O'Leary
General Manager
Plastic Film Department
Allied Chemical Corporation
Post Office Box 1057R
Morristown, New Jersey 07960

Mr. Eugene Ritchie
Ray Josephs
230 Park Avenue
New York, New York 10017

Shell Development Company
Library
Biological Sciences Research
Center
Post Office Box 4248
Modesto, California 95352

Mr. G. E. Westerlund
Facilities Engineering
The Okonite Company
Post Office Box 340
Ramsay, New Jersey 07446

Mr. Harlan Bentzinger
Chemical Products
King Philip Road
East Providence,
Rhode Island 02914

Mr. Thomas G. Riley
Goodyear Tire and Rubber Co.
Manager of Public Relations
812 National Press Building
Washington, D.C. 20004

Private Industry

Mr. H. B. Allick
Goodyear Tire and
Rubber Company
5408 Baker Avenue
Niagra Falls, New York 14302

Mr. Marshall Miller
Reavis, Pogue, Neal and Rose
1100 Connecticut Avenue, N.W.
Washington, D.C. 20036

Mr. Fred Sacks
Diamond Shamrock Technical Center
Post Office Box 191
Painesville, Ohio 44099

Mr. Jon Heider
Law Department
Air Products and Chemical, Inc.
Five Executive Mall
Wayne, Pennsylvania 19087

Mr. George Coling
APHA
1015 Eighteenth Street, N.W.
Washington, D.C. 20036

Mr. J. T. Moore, Jr.
President
Moore Chemical Corporation
Post Office Box 34184
San Francisco, California 94134

Mr. R. Craig Andrews
Counsel
Diamond Shamrock Chemical Corporation
1100 Superior Avenue
Cleveland, Ohio 44114

Mr. F. V. Prus
Vice President
The Goodyear Tire and Rubber
Company
Akron, Ohio 44316

Mr. William C. Becker
Assistant General Counsel
The B. F. Goodrich Company
500 South Main Street
Akron, Ohio 44318

Mr. L. H. Bingham
President
Gaspro, Inc.
Post Office Box 2454
Honolulu, Hawaii 96804

Mr. R. O. Kittredge
President
Fabri-Kal Corporation
3303 East Cork Street
Kalamazoo, Michigan 49001

Mr. B. W. Smith, Jr.
Vice President
Olin Corporation
120 Long Ridge Road
Stamford, Connecticut 06904

Mr. John W. Swanson
Cities Service Company
Post Office Box 300
Tulsa, Oklahoma 74102

Mr. David A. De Ghetto
Manager
Carlton
Three Commerce Park Square
23200 Chagrin Boulevard
Cleveland, Ohio 44122

Mr. Harold A. Wagner
Vice President
Harvel Plastics, Inc.
Post Office Box 757
Easton, Pennsylvania 18042

Mr. Saul Goldstein
President
Lyncor Plastics Corp.
Two Brookline Street
Lynn, Massachusetts 01902

Mr. Zvi R. Cohen
President
Prevue Products, Inc.
195 McGregor Street
Manchester
New Hampshire 03120

Mr. Willard Smith
Economic Analysis Division
Office of Planning and Evaluation
Environmental Protection Agency
Room 3009, Waterside Mall
401 M Street, S.W.
Washington, D.C. 20460

BOR 004872

Department of Labor

Daniel P. Boyd, Ph.D.
Director
Office of Standards Development
U.S. Department of Labor, OSHA
Room 610, 1726 M Street, N.W.
Washington, D.C. 20210

Mr. Edward Klein
Office of the Solicitor
U.S. Department of Labor
14th & Constitution Avenue, N.W.
Washington, D.C. 20210

Mr. Ray McClure
Office of Compliance Programming
U.S. Department of Labor, OSHA
Room 760, 1726 M Street, N.W.
Washington, D.C. 20210

Mr. Benjamin L. Mintz
Office of the Solicitor
U.S. Department of Labor
Room 5420, Main Labor
14th & Constitution Avenue, N.W.
Washington, D.C. 20210

Dr. John P. O'Neill
Office of Standards Development
U.S. Department of Labor, OSHA
Room 660, 1726 M Street, N.W.
Washington, D.C. 20210

Mr. John E. Plummer
Associate Assistant Secretary
for Administrative Programs
U.S. Department of Labor, OSHA
Room 1100, 1726 M Street, N.W.
Washington, D.C. 20210

Mr. Eugene Regad, Jr.
Office of Standards Development
U.S. Department of Labor, OSHA
Room 660, 1726 M Street, N.W.
Washington, D.C. 20210

Mr. Howard Schulte
Deputy Assistant Secretary
U.S. Department of Labor, OSHA
Room 2116, Main Labor
14th & Constitution Ave., N.W.
Washington, D.C. 20210

Mr. John H. Stender
Assistant Secretary for
Occupational Safety and
Health Administration
U.S. Department of Labor
Room 3115
14th & Constitution Ave., N.W.
Washington, D.C. 20210

Mr. Barry S. White
Associate Assistant Secretary
for Regional Programs
U.S. Department of Labor, OSHA
Room 820
1726 M Street, N.W.
Washington, D.C. 20210

Ms. M. Pospur
HEW North Building
300 Independence Avenue, S.W.
Room 371A
Washington, D.C. 20201

Marcus M. Kay, M.D.
Director, National Institute for
Occupational Safety and Health
Department of Health, Education,
and Welfare
12420 Parklawn Drive
DANAC Building
Rockville, Maryland 20852

Mr. Vernon Rose
Office of Research and
Standard Development
National Institute for
Occupational Safety and Health
12420 Parklawn Drive
DANAC Building
Rockville, Maryland 20852

Mr. Gene Proctor
Occupational Medicine and
Environmental Health
NASA, 600 Maryland Avenue, S.W.
Washington, D.C. 20546

Mr. William C. Salmon
Deputy Director
Office of Environmental Affairs
State Department
Washington, D.C. 20520

Mr. Stanley D. Allen
Chief, Management Analysis Division
Office of the Secretary
Department of Treasury
Washington, D.C. 20220

Mr. W. J. Burns
Director, Office of
Hazardous Materials
Department of Transportation
Washington, D.C. 20590

Mr. Martin Convisser
Director
Office of Environmental
Quality
Office of the Secretary
Department of Transportation
400 Seventh Street, S.W.
Washington, D.C. 20590

Deputy Secretary of the Treasury
Treasury Department
15th & Pennsylvania Ave., N.W.
Washington, D.C. 20220

Mr. Walter J. Barrows
Landscape Coordinator
Parks Department
501 Poli Street
Ventura, California 93001

Mr. Barry H. Lockton
Director of Public Works
107 North Ventura Street
Ojai, California 93023

Mr. J. L. Wootan
Environmental Program
Specialist II
Occupational Health
Planning Project
Oklahoma State Department
of Health
N.E. Tenth & Stonewall
Oklahoma City, Oklahoma 73105

Ms. Williams
Office of Environmental Affairs
Department of Commerce
Room 3425
Washington, D.C. 20350

Mr. S. A. Leone
DBER
Room E-201
U.S. Atomic Energy Commission
Washington, D.C. 20545

Governmental Agencies

Colonel Herbert E. Bell
Headquarters
USAF (Prev)
Washington, D.C. 20330

T. C. Byerly, Ph.D.
Coordinator
Environmental Activities
Department of Agriculture
Room 312-E
Washington, D.C. 20250

Colonel John E. Ward
Occupational Health Consultant
Office of the Surgeon General
Department of the Army
Forrestal Building, Room B207
Washington, D.C. 20314

Mrs. Griffiths
Joint Medical Library
Office of the Surgeon General
Forrestal Building, Room 6E040
Washington, D.C. 20314

Mr. M. B. Biles
U.S. Atomic Energy Commission
Washington, D.C. 20545

Mr. Robert J. Catlin
Division of Environmental Affairs
U.S. Atomic Energy Commission
Washington, D.C. 20545

Mr. W. H. Pennington
Division of Environmental Affairs
U.S. Atomic Energy Commission

Mr. Julius Ruben
Assistant General Manager
of Environment and Safety
U.S. Atomic Energy Commission
Room A303
Washington, D.C. 20545

Sidney R. Galler, Ph.D.
Deputy Assistant Secretary
Environmental Affairs
Department of Commerce
Washington, D.C. 20230

Dr. Warren Muir
Council on Environmental Quality
722 Jackson Place, N.W.
Washington, D.C. 20575

Mr. David Rosse
Materials Division-Chemicals
Department of Commerce
14th and E Street, N.W.
Washington, D.C. 20230

Mr. George L. Feazell
Director of Safety Policy
Department of Defense
The Pentagon
Washington, D.C. 20301

Sheldon Meyers, M.D.
Director of Federal
Activities
Environmental Protection Agency
Waterside Mall Building
Room 535, 4th & M Street, S.W.
Washington, D.C. 20460

Mr. Pope Laurence
Environmental Protection Agency
Waterside Mall Building
Room 535, 4th & M Street, S.W.
Washington, D.C. 20460

Mr. Paul Crowell
Acting Chief Environmental
Officer
Department of Health,
Education and Welfare
Room 3718N
300 Independence Avenue, S.W.
Washington, D.C. 20201

APPENDIX D

DISTRIBUTION LIST FOR FINAL
ENVIRONMENTAL IMPACT STATEMENT

Worker exposure to vinyl chloride can occur at VCM plants, PVC plants, and at plants which fabricate the PVC into plastics. The greatest number of workers exposed and the greatest economic impact of vinyl chloride regulation would occur if the plastic fabrication facilities were severely impacted. If, as we expect, your proposed standard will result in very low VCM residuals in the resins produced at PVC plants, they will probably cause no detectable exposure to workers in plastics fabrication plants and eliminate the need for any additional action by the plastics manufacturers. In this event, the economic impact of your regulations would be limited to the relatively few VCM and PVC manufacturers.

The Council is convinced that OSHA's proposed standard is both necessary and feasible. We encourage you to pursue it. We look forward to receiving your final impact statement and remain available for consultation at any time.

Sincerely,


Steven D. Jellinek
Staff Director

Dr. Daniel Boyd
Director, Office of Standards Development
Occupational Safety & Health Administration
Room 610, 1726 M Street, N.W.
Washington, D.C. 20210

We wrote the Manufacturing Chemists Association (MCA), sponsors of the T-C Associates study, for additional information, but only part of the data we requested was supplied. We were informed that the remainder will not be forthcoming. We are concerned that this industry has not seen fit to supply this important data. Thus, while the T-C Associates study shows excess cancers due to vinyl chloride it by design vastly underestimates the rate, and analyses to correct this deficiency will not be conducted.

Similarly, the Industrial Bio-Test data shows angiosarcomas in animal feeding studies at 50ppm VCM. This data is very preliminary since few animals had full pathological examinations and the study group was reduced by an unspecified number due to cannibalism. So, while the study tends to confirm carcinogenicity and the preliminary findings of Professor Maltoni, a complete analysis of the data when the experiment is run full-term is likely to show a very substantially higher rate of malignancies.

Based on our review of the draft EIS and other available information, we strongly believe that an occupational standard, such as that proposed, which affords workers no detectable level of exposure to vinyl chloride, is necessary. The vinyl chloride issue, however, is more than just an occupational health concern. It is also a consumer and environmental concern. In order to eliminate risks to consumers from vinyl chloride entrapped in polyvinyl chloride plastic products and in order to prevent environmental exposures from air and water pollution emissions from VCM, polyvinyl chloride (PVC), or plastics plants, it is clear that industrial process changes are required. The proposed standard would make such changes necessary and, we believe, would substantially improve environmental levels of vinyl chloride outside the plant.

EXECUTIVE OFFICE OF THE PRESIDENT
COUNCIL ON ENVIRONMENTAL QUALITY
722 JACKSON PLACE, N. W.
WASHINGTON, D. C. 20006

AUG 5 1974

Dear Dr. Boyd:

The Council has received and reviewed OSHA's Draft Environmental Impact Statement (EIS) on Proposed Regulation of Vinyl Chloride. We note with approval that the proposal upon which the EIS is based is fully articulated in the statement. We encourage this approach in the future and expect it to be followed in the case of each final impact statement.

Much additional information concerning the health risk from vinyl chloride exposure has become available since the draft EIS was filed. This includes industry supplied epidemiological data from Tabershaw-Cooper (T-C) Associates, preliminary animal feeding study data from Industrial Bio-Test, and the report of angiosarcomas potentially resulting from environmental exposures in plastic fabrication plants. This new data should be included in the final EIS. It will strengthen the already compelling case for the strong standard OSHA has proposed.

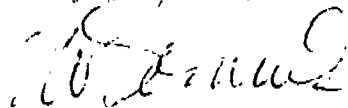
Although we encourage incorporation of the Tabershaw-Cooper Associates study and the Industrial Bio-Test data in the final EIS, we are concerned that some interpretations of these studies might understate their findings. The T-C study covers some 8,000 workers with a history of exposure to vinyl chloride. It reports elevated incidents of several types of cancer, but it provides only a grossly underestimated incident rate over the expected rate because a very large fraction of the workers studied were not exposed to VCM long enough ago to show cancers that will develop after the latency period characteristic of all chemical carcinogenesis.

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of worker exposure may be even more serious than previously believed.

Finally, the draft quotes us as saying that some 700,000 workers are seriously exposed in this country. Indirect data, a study of the industry in Japan, would indicate that our estimate is grossly in error and that the actual population at risk is in the order of 1.5 million.

Respectfully submitted,



Sheldon W. Samuels
Director
Health, Safety and Environment

Attachment

SWS:aek
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**INDUSTRIAL
UNION
DEPARTMENT
AFL - CIO**



19
815 Sixteenth Street, N.W., Washington, D.C. 20006
Area Code 202 393-5581

I. W. Ahel, *President*
Jacob Clayman, *Secretary-Treasurer*

August 5, 1974

Dr. Dan Boyd, Director
Office of Standards and Development
Occupational Safety and Health Administration
1726 M Street, N. W.
Washington, D. C.

Dear Dr. Boyd:

Enclosed is a detailed comment on the draft environmental impact statement for the proposed regulation of vinyl chloride.

A general comment on the statement is in order.

First, if economics must be considered, then micro-economic cost/benefit analyses are grossly inadequate. Second, the full range of effects to be considered include those which are not quantifiable and those which lie entirely out of the normal discourse of even macro-economics.

In addition, we wish to denote that our comment cannot take into account two new lines of evidence: teratogenic and genetic effects noted at the NIEHS meeting last week by Dr. Irving Selikoff and the additional case of angiosarcoma identified by the NIOSH epidemiological study of B. F. Goodrich's Louisville plant. Evidenced by death certificate data (an autopsy was performed at death), James W. E. Howard becomes the 16th vinyl chloride-related angiosarcoma case found in the United States and the 8th at the Louisville plant. Mr. Howard died on March 27, 1969 at the age of 42. He worked for B. F. Goodrich for four and one-half years in the early 1950's and spent only nine months on the polymerization operations there. This case is especially distressing because of the short period of exposure to vinyl chloride and, in concordance with the increasing numbers of cases being found worldwide among fabricators, suggests that the problems

VICE PRESIDENTS

Peter Bonaventura
M. J. Burke
Sol C. Chazan
Doris Doyle

Max Greenberg
M. J. Green
Paul Jennings
Gilbert Jewell

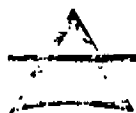
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S. Frank Rattery

A. Philip Randolph
W. Vernon Reed
Roland E. Roley
David Sorenson

Jacob Shoenkman
Edward F. South
Sol Stein
Elwood Towler

Joseph P. Tonelli
Shannon J. Wall
Glenn Watts
Clyde Webster

BOR 004881



Air Products and Chemicals
INC.

CHEMICALS GROUP

Five Executive Mall, Swedesford Road, Wayne, Pa. 19087

RICHARD FLEMING
GROUP VICE PRESIDENT-CHEMICALS

August 5, 1974

Telephone: (215) 687-6150
Telex: 846-445

Mr. David R. Bell
Occupational Safety and
Health Administration
Office of Standards Development
Room 500 1726 M. Street N.W.
Washington, D.C. 20210

HAND DELIVERED

Re: Draft Environmental Impact
Statement Proposed Regulation
Vinyl Chloride

Dear Mr. Bell:

Air Products and Chemicals, Inc. submits herewith
its comments on the Draft Environmental Impact Statement
("Draft") - Proposed Regulation Vinyl Chloride.

In addition to the comments contained herein, we
incorporate by reference the testimony of Richard Fleming,
John T. Barr and Dr. Paul Kotin, M.D. on behalf of Air
Products which is found at pp. 781-857 of the Official
Report of Proceedings (hereinafter cited as "Official Report")
before the Occupational Safety and Health Administration
("OSHA") of the U.S. Department of Labor in the matter of
Proposed Permanent Standard for Occupational Exposure to
Vinyl Chloride (Attached hereto as Exhibit A). This pro-
cedure is in accordance with the statement made by Dr. Daniel
P. Boyd, Director of the Office of Standards Development

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for OSHA (pp. 1110-11 of the Official Report). Also incorporated by this reference are our detailed comments on the proposed standard itself which have previously been submitted to OSHA and made part of the Official Report as Exhibit 23-B. (Attached hereto as Exhibit B.)

I. INTRODUCTION

The National Environmental Policy Act ("NEPA") requires that every major federal action, such as the promulgation of the proposed standard for vinyl chloride, be preceded by detailed statement on

- (i) the environmental impact of the proposed action,
- (ii) any adverse environmental effects which cannot be avoided should the proposal be implemented,
- (iii) Alternatives to the proposed action,
- (iv) the relationship between local short term uses of man's environment and the maintenance and enhancement of long-term productivity, and
- (v) any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.

Preliminarily we would like to note that the Draft goes far beyond the scope of its purpose as specified by NEPA. We note this point for two reasons: (1) our comments will

be restricted to responses relative to assertions made by OSHA which are pertinent to the purpose of the Draft as outlined above; and (2) we would hope that in the final Statement, OSHA will restrict its observations and remarks to those areas relevant to NEPA. In this manner we believe that those individuals directly involved in reducing employee exposure to vinyl chloride can avoid wasting the time and effort involved in refuting irrelevant, but erroneous, remarks such as those contained in the Draft.

Thus, while there are substantial errors, mis-statements and omissions in Sections I through IV of the Draft, we do not believe these Sections are at all pertinent, and should be deleted in their entirety. We will confine our comments to Sections V through VIII which are the Sections mandated by NEPA. With respect to Section V dealing with the Standard as proposed, we will merely reference our detailed comments which are attached as Exhibit B.

As a general comment applying to practically every Section of the Draft, it must be emphasized at the outset that much of what is contained in the Draft is in error because the underlying assumptions are erroneous. One erroneous assumption is that technology exists which will meet the no-detectable level of the proposed Standard. This is simply not the case. The underlying erroneous assumption is somewhat explained by the fact that OSHA did not make any technological

or feasibility studies prior to the time the Draft was prepared. This fact was pointed out by Dr. Boyd. (See pages 1110 and 1112 of the Official Report.)

We cannot help but comment that the issuance of this draft statement, based as it is on largely unfounded assumptions and expressing viewpoints far beyond any valid purpose of the document is indeed lamentable. It is to be hoped that in the future OSHA will take a much more responsible and factual approach before making documents of this kind public. Promulgating misinformation is hardly a function of OSHA.

II. Comments on Sections VI. Probable Impact of the Proposed Standard

1. The Draft states that one major impact of the proposed standard would be a workplace environment free of the "known hazards" of vinyl chloride exposure (p. 60). The uncontradicted testimony adduced at the hearings, however, was to the effect that it is technologically impossible to meet the "no detectable level" required by the proposed standard. Indeed, Dr. Marcus Key of NIOSH testified that it was not his impression that a non-detectable level of vinyl chloride could be achieved (p. 131 of the Official Report). The major impact of the standard would, therefore, be the complete shutdown of the VCM/PVC industry with its attendant economic and social disruptions.

Moreover, since the standard, in effect, sets a level of 1 part per million, one would assume that levels above that constitute "known hazards" of vinyl chloride. But the hazards to humans of exposure to vinyl chloride are "known" only in relation to high concentrations over long periods of time. (See the chart of the estimated levels of exposure of those PVC workers who have died of angiosarcoma which is attached hereto as Exhibit C.) It is not known that exposure to 50 ppm VCM constitutes a hazard to man. In fact, the most authoritative human toxicological study done to date demonstrates no adverse medical effects related to continuous long term exposure to concentrations of vinyl chloride up to 200 parts per million. (See pages 932 et. seq. of Dow testimony in the Official Report.) Therefore, it would be a true statement to assert that the temporary standard of 50 ppm would create a "workplace environment free of the known hazards of vinyl chloride exposure."

2. Even though it is technologically impossible to achieve the level of vinyl chloride concentration mandated by the proposed standard, it is possible to achieve average levels lower than the 50 ppm provided for in the Temporary Emergency Standard. Meeting these levels will also cause the impact of substantial additional capital and other operating costs which OSHA states (page 60) industry will incur in

attempting to meet the proposed standard. The degree of this impact will be governed in part by the reasonableness of the final standard and in part by the time frame during which compliance is mandated.

3. While it is true that vinyl chloride is a petrochemical produced from irreplaceable natural resources, diminished production of vinyl chloride and polyvinyl chloride would only increase the demand for ABS, polyethylene and other plastics similarly derived from petrochemicals. The proposed standard would not, therefore, reduce the total demand for such irreplaceable natural resources. Moreover, petrochemical production accounts for less than 5% of the use of petroleum in the United States; the remaining 95+% is burned as fuel, producing heat and carbon dioxide. Rather than discourage petrochemical production, the policy of the United States should be to encourage the shift in petrochemical usage from fuel to durable products such as polyvinyl chloride, while more plentiful resources such as coal should be used for fuel.

4. Implementation of the proposed standard would affect the working environment of the estimated 1,500 workers engaged in monomer production, 5,000 in PVC resin production, and others in processing and fabrication. The AFL-CIO estimate of 700,000 exposed workers is too high, however, since the

proposed standard does not purport to apply to tertiary production. A shutdown of the entire industry would, however, have an adverse economic and social impact on at least the 700,000 workers cited in the AFL-CIO estimate as well as tens of thousands more in jobs that depend on polyvinyl chloride products. A study by A. D. Little concluded that between 1.7 million and 2.2 million workers could lose their jobs if vinyl chloride and PVC production terminated immediately. (Page 456 in the Official Report.)

5. The Draft is too casual in its analysis of the decline in productivity that would result from implementation of the proposed standard. Work practice changes will have a significant adverse impact on worker productivity, and personal protective equipment (e.g. respirators) of the type proposed will result not only in decreased productivity, but more importantly will in themselves constitute a safety hazard due to decreased vision, mobility and oral communication and increased fatigue and psychological distress. (See pp. 88 and 307-16 of the Official Report.)

6. The statement at the bottom of page 62 of the Draft that "a preliminary assessment of the cost of compliance indicates that the expenditures required will not be prohibitive" is preposterous and totally refuted by the fact that OSHA has made no study whatever to support this statement. Moreover, the testimony of the companies affected, the only

knowledgeable people to comment on this, is quite to the contrary. See, e.g. the testimony of Tenneco Chemicals, Inc. at pp. 694-95 and the Firestone testimony at pp. 1698-99 of the Official Report.

The steps which industry has already taken to reduce VCM exposure are described at the top of page 63 of the Draft, but the last sentence of that paragraph stating that technology is readily available to meet the proposed level without substantial developmental costs is without foundation. As testified by Air Products at pp. 790-91 of the Official Report, "Everyone has obviously done the quickest, easiest, most effective things first." Existing technology and improved work practices have been utilized to bring the VCM level as low as possible; further reductions in the VCM level must await new technology and/or the installation of new equipment. As was stated throughout the OSHA hearings on the proposed standard, there is no known technology to achieve the standard. Since the technology is not available, development will require substantial expenditures of time and money without any degree of certainty as to the achievable levels. Indeed, as was pointed out in Tenneco's testimony, they estimate that they will spend approximately 10 million dollars (plus millions in additional operating costs) attempting to attain a TWA level of 10 ppm by 1976. (p. 694 in the Official Report.) Firestone estimated that between 50 and 55 million dollars would be required in attempting to reach a non-detectable level. (p. 1699 in the Official Report.)

7. Contrary to the last sentence on page 63 of the Draft, promulgation of the proposed standard will most certainly stop vinyl chloride production and polymerization in the United States. It is impossible to retrofit existing polymerization plants to meet the proposed standard, and APCI has estimated the cost of replacing its present capacity with a new PVC plant at approximately \$30 million. Since this estimate was determined in 1973, the same plant would cost considerably more because of inflation. We do not believe, however, that a new plant will meet the no detectable standard. To propose as on page 63, that improvements in housekeeping and maintenance schedules will permit meeting the standard shows a degree of naivete about the difficulty of the proposed standard that is incredible.

8. The only discussion of the adverse environmental impact of the proposed standard occurs in the middle of page 64 of the Draft. Not discussed, however, are other adverse effects. For example, there was testimony at pp. 202-03 of the Official Report concerning the use of PVC conveyor belting in the crucial industries of coal mining, grain handling and food processing. A shortage of PVC belting in the coal mining industry would have disastrous consequences for this nation's energy policy.

Among other adverse impacts resulting from the proposed standard which readily came to mind are the following. Any

reduction in PVC, for example, will reduce the demand for chlorine; since caustic soda is produced simultaneously with production of chlorine, caustic soda products will be reduced by about 20%. The adverse impact of lower caustic production will be evident in the paper, aluminum, pollution control fields and many others. In addition, as a non-flammable wire coating, PVC is virtually irreplaceable for a number of applications.

9. The Draft states on page 64 that one of the likely methods of approaching compliance with the proposed standard will be in the form of improved ventilation into the atmosphere for dilution and dispersal. It seems pertinent to comment that following control of vinyl chloride losses from the equipment wherever possible, the primary engineering control to reduce vinyl chloride monomer concentrations in the working atmosphere is the ventilation of vinyl chloride laden air to the atmosphere. No feasible method other than ventilation is now known. It must be stated, therefore, that controls on atmospheric ventilation by the EPA, or other governmental agencies will have an interlocking impact along with OSHA regulations on vinyl chloride monomer and polyvinyl chloride industry.

There was testimony at the hearing from Calgon Corp. concerning the adsorption of VCM on activated carbon. (The

word "filtration" is a misnomer since it is impossible to filter a gas from a gas.) Calgon had no practical or technical suggestions as to how the ambient air in a PVC or VCM plant could be moved in such a way as to pass through a bed of activated carbon. Even if Calgon's activated carbon technology could effectively remove VCM from an airstream, the evidence clearly shows that its use would be primarily directed to the reduction of emissions to the atmosphere, and not to solving the problem of in-plant worker exposure to VCM.

III. Comments on Section VII. Relationship to Other Federal Actions

Our comments here are limited to our previous statements to the effect that action by one agency, such as the EPA in limiting VCM emissions, would increase worker exposure to VCM. We cannot help but also comment, however, that the report on page 66 of the Draft concerning retention of all but 1% of vinyl chloride in a room for four days is sheer nonsense.

IV. Comments on Section VIII Alternatives

1. It is submitted that OSHA does not have the authority to ban the production of vinyl chloride. (See IUD, AFL-CIO v. Hodgson, April 15, 1974, U.S. Ct. of Appeals, D.C. Cir.) The first alternative is therefore not viable.

2. Since the practical effect of a zero exposure level is equivalent to a ban on vinyl chloride, it is submitted that the second alternative is likewise not viable. Given the inevitability of vinyl chloride leaks, the only conceivable method of complying with a zero exposure level would be by continuous use of respirators. As noted at pp. 88 and 307-16 of the Official Report, such continuous use of respirators would in itself constitute a safety hazard and prove impractical.

3. It is unwise to dismiss summarily the third alternative providing for retention of the 50 ppm level prescribed by the Temporary Emergency Standard. While it is true that mice have developed angiosarcomas at 50 ppm, the translation of this data cannot be directly related to human experience. Moreover, the testimony of Dow Chemical referenced above and the medical testimony of Air Products (pp. 805-12 of the Official Report); SPI (pp. 500-14 of the Official Report) Diamond Shamrock (pp. 1033-1040 of the Official Report) and others give great credibility to the position that 50 ppm will not create adverse medical effects.

4. While we agree that reliance on personal protective equipment cannot be the sole source of protection, setting a ceiling level requires that such equipment be permitted when the ceiling is exceeded. Since it is impossible to avoid occasional excursions above any given level, use of protective equipment on those occasions are the only means of protecting the employee.