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SUMMARY OF TESTIMONY BY
UNIROYAL, INC.
IN OBJECTION TO THE PROPOSED
PERMANENT STANDARD 1910.93q
RELATING TO VINYL CHLORIDE EXPOSURE

DOCKET OSH-36

June 21, 1974

# SUMMARY OF TESTIMONY BY UNIROYAL, INC. IN OBJECTION TO THE PROPOSED PERMANENT STANDARD 1910.93q RELATING TO VINYL CHLORIDE EXPOSURE

I am Martin J. Kleinfeld, Commercial Planning Director of the Chemical Division of Uniroyal, Inc. I am a chemist and for nine years, from 1948 through 1956, I was involved in research and development and manufacturing of vinyl chloride and polyvinyl chloride resins. In subsequent years I have been successively Marketing Manager and Research and Development Manager for Uniroyal's PVC resin operations.

My associates are Dr. Walter Harris, Corporate Toxicologist; Mr. Benton Leach, Factory Manager of our Painesville, Ohio polyvinyl chloride manufacturing facility and ~~Mr. Richard Weiler~~ Reuben of Arthur, Dry & Kalish, our legal firm.

Uniroyal has been in the business of manufacturing vinyl chloride monomer and polyvinyl chloride resins for 27 years. We are one of the world's major manufacturers of vinyl products such as coated fabrics (under the trade name of Naugahyde) and have been for 33 years.

While we were the third producer of polyvinyl chloride in the U.S. we have not expanded as rapidly as some and currently account for only about 3 percent of the total U.S. production. It is noteworthy, however, that with only 3 percent of the total production and about 300 people directly involved in the manufacture of these resins we affect about 25,000 employees in customers' fabricating operations dependent at least in part upon our resins. A simplified extrapolation of this ratio for the industry would suggest that as many as 800,000 employees could be adversely affected by a major cut-off of the polyvinyl chloride supply; and this does not, of course, account for the hundreds of thousands of

(CONTINUED)

workers whose jobs would be affected by a stoppage in the flow of fabricated products which are dependent upon polyvinyl chloride and not amenable to near future substitution of other materials, many of which are also in short supply as a result of the energy shortage.

As mentioned, our plant at Painesville, Ohio has been in continuous commercial operation for 27 years. During the first 14 years of operation we also produced vinyl chloride monomer at the same site. During these 27 years we have produced over 1.5 billion lbs. of PVC and have employed about 800 people in this plant during this period. 150 of these have worked in close proximity to the VCM/PVC operation for over 16 years; 56 of these for over 25 years. The medical data we have accumulated to date have disclosed no incidence of angiosarcoma and the incidence of abnormal liver function test results appears to be no greater than in the general population.

We are submitting to the OSHA at this time our written detailed discussion of our objections to the Proposed Standard; 19 are enumerated in our submittal. In the interests of conserving time I will highlight now only those points which we believe are of greatest importance relative to safety considerations and the economic impact of the Proposed Standard.



A. <u>Objections to Specific Portions of Proposed Standard</u>

1) Our major objection is to the "no detectable level" restriction. This has been detailed in our EXHIBITS A-1, A-2, A-3, A-7, A-9 and A-17 following.

2) We do not see the need for special protective clothing as we are unaware of any evidence that has proven a medical risk due to skin absorption of vinyl chloride gas. (See EXHIBIT A-6)

3) We believe the respiratory section should be written with more flexibility to allow the use of a greater variety of respirators based upon their proven ability to cope with the situation at hand. (See EXHIBIT A-11)

(CONTINUED)

4) "Emergency" situation by definition should be confined to release of large quantities of vinyl chloride. (See EXHIBIT A-4)

5) The mandatory requirement for removal of personnel from potential vinyl chloride contact areas if upon medical rescreening one or more abnormal liver function tests persist, leaves the examining physician no room for judgement. Furthermore, removal of an employee to an area with "no detectable level" of vinyl chloride, which in our opinion, is unlikely to be found consistently in the vicinity of a vinyl chloride or polyvinyl chloride plant, would appear to leave no alternative but transfer or dismissal. (See EXHIBIT A-16)

## Summary of Objections to Specific Sections of Proposed Standard 1910.93q

**Section:** (a) Scope and application (1) and (2)

**Objection:** Application to all areas where "detectable" levels are released. Inclusion of polyvinyl chloride containing "detectable" amounts of vinyl chloride.

**Grounds and/or Suggested Changes:**

Occupational health evidence does not warrant imposition of this Standard on all workplaces where a "detectable" level of vinyl chloride may be present. A "non-dectable" restriction is technologically infeasible in vinyl chloride monomer and polyvinyl chloride production plants. Some permitted level which has not been proven unsafe must be allowed in workplaces to avoid shut down of a major industry with the resultant severe effects upon both labor, i.e. loss of jobs, and our national economy.

There is no proven risk or any reasonable expectation of any medical risk from trace amounts of residual vinyl chloride in polyvinyl chloride in processing plants, i.e. fabricators. Further assurances of freedom from risk can be implemented by restricting the amount of free monomer in the polymer. Inclusion of the many thousands of processing workplaces under the total restrictions and demands of this Standard is we feel illogical as to need and unduly repressive as to cost and utilization of manpower. Ample precedent regarding exclusion of products containing trace amounts - e.g., 0.1% - of potentially hazardous materials may be found in Part 1910.93c-p, the recently promulgated standards on 14 alleged carcinogens.

We recommend that (a) (1) be rewritten so that it applies only to vinyl chloride and polyvinyl chloride production operations. For these operations, the provisions of the Standard would apply in all areas where exposures to concentrations of vinyl chloride in the workplace air exceed a specified "permissible level". Our definition of permitted level may be found under (b) (6) (EXHIBIT A-3).

We also recommend that (2) (2) be changed to clearly exempt both polyvinyl chloride processing workplaces as well as those workplaces involved in the handling or use of fabricated products from the scope and application of this Standard.

## Summary of objections to Specific Sections of Proposed Standard 1910.93q

**Section:** (b) (Definitions) (4) (5)

**Objection:** The word "detectable".

**Grounds and/or Suggested Changes:**

For reasons previously stated, we consider a no detectable level is an untenable concept. We suggest that "contaminated" be redefined to mean "capable of releasing any amount of vinyl chloride which would exceed the allowable permissible level".

"Decontamination" should be redefined to mean reduction of vinyl chloride concentrations to less than permissible levels.

Summary of Objections to Specific
Sections of Proposed Standard 1910.93q

Section: (b) (Definitions) (6)

Objection: The words "detectable level" and specific definition.

Grounds and/or Suggested Changes:

For reasons previously stated, a no detectable level is considered an untenable concept. We propose to substitute the term "permissible level" for "detectable level". However, establishment of a single, fixed, numerical, permissible level to be met immediately and to cover all operations within the PVC industry creates a difficult problem for a variety of reasons. Certain monomer plants - because of the nature of the process, age, size, location and other factors - could be expected to operate more easily at a lower level than PVC production units. Individual PVC plants also vary due to some of the same factors as above but also due to process variations, finishing operations, design and other reasons. We do not, however, see any justification for setting different permissible levels for different plants. It would be illogical to imply different levels of toxicity for different plants. Once properly established, one level should be applied to all.

Taking all factors into consideration, we feel that within a reasonable period of time the industry could and should achieve compliance with a "permissible level" defined as a maximum airborne concentration of vinyl chloride not to exceed a ceiling of 40 ppm or a TWA (8 hour) concentration of 25 ppm.

Our long range goal could involve reduction of any exposures to values considerably less than our proposed definition of a "permissible level". However, before any major commitments are made to reduce exposures to levels approaching zero we feel that further evidence is required to show that there is more than a minimal health risk to workers exposed to levels covered by our proposed definition.

Summary of Objections to Specific
Sections of Proposed Standard 1910.93q

Section: (b) (Definitions) (8)

Objection: Definition of "Emergency".

Grounds and/or Suggested Changes:

This definition is overly restrictive as it does not quantify what is meant by "release of vinyl chloride". Standard operating procedures would be used in all cases where a higher than "permissible level" exposures might take place.

Emergency - and the action to be taken - should be confined to such instances where release of vinyl chloride was of such magnitude that it would produce acute symptoms among exposed workers.

## Summary of Objections to Specific Sections of Proposed Standard 1910.93q

**Section:** (b) (Definitions) (10)

**Objection:** "Semifinished product"

**Grounds and/or Suggested Changes:**

Definition needs expansion to include "diced or pelletized stock" made from polyvinyl chloride.

Summary of Objections to Specific
Sections of Proposed Standard 1910.93q

Section: (b) (Definitions) (13)

Objection: Definition of "protective clothing".

Grounds and/or Suggested Changes:

As stated the definition has no practical meaning. The gaseous nature of vinyl chloride in the ambient air would require completely impervious clothing for absolute protection. Any requirements involving use of impervious clothing should be restricted to extraordinary exposure conditions such as emergencies involving large spills or massive release of vinyl chloride.

## Summary of Objections to Specific Sections of Proposed Standard 1910.93q

**Section:** (d) Regulated areas (1) (ii)

**Objection:** Definition of regulated area involving polyvinyl chloride operations.

**Grounds and/or Suggested Changes:**

Reasons have previously been stated regarding the need to change "detectable level" to "permissible level".

Regarding application to polyvinyl chloride, the regulated areas should be restricted to those operations or activities where vinyl chloride levels in the air may exceed the established permissible level.

## Summary of Objections to Specific Sections of Proposed Standard 1910.93q

Section: (d) (Regulated areas) (3)

Objection: Maintenance of "daily roster".

Grounds and/or Suggested Changes:

This requirement is neither practical or useful. It is at least a duplication of effort. Current time and work records provide information on each employee regarding his activities and regulated areas.

# Summary of Objections to Specific Sections of Proposed Standard 1910.93q

**Section:** (e) Monitoring (1) (2)

**Objection:** Clarity of definitions.

**Grounds and/or Suggested Changes:**

For reasons previously stated, "detectable levels" should be changed to "permissible levels".

The phrase "confidence level of 95 percent" presumes that adequate monitoring techniques can be developed by someone prior to the effective date of adoption of the Proposed Standard since they are not spelled out in the Standard. There is also some confusion regarding appropriate monitoring methods as related to personal monitoring versus area monitoring or a combination of both techniques.

Summary of Objections to Specific
Sectionf of Proposed Standard 1910.93q

Section: (f) Engineering controls and work practice methods

Objection: Application and need.

Grounds and/or Suggested Changes:

This entire section addresses itself to the need for immediate use of engineering controls and methods to reduce airborne concentrations of vinyl chloride to zero. Reasons have been previously stated indicating the infeasibility of the zero exposure concept.

We recommend that this section be rewritten to recognize that appropriate controls and practices be implemented to reduce exposures to below the maximum permissible level, and that a time schedule of several years will be required to select, purchase and install the necessary equipment.

## Summary of Objections to Specific Sections of Proposed Standard 1910.93q

**Section:** (g) Respiratory protection

**Objection:** Definition of allowable respiratory protection devices.

**Grounds and/or Suggested Changes:**

Allowable devices all have "self-contained breathing apparatus" as a common denominator. There is no provision for independent use of continuous flow or pressure demand types as described in the Emergency Temporary Standard. There is no allowance for cannister respirators. Full facepiece equipment is mandatory.

There should be more flexibility allowed in the choice of respiratory equipment. The use of what is specified can be impractical, cumbersome and hazardous in various typical production activities.

Half face masks offer protection without the hazard of restricting visibility. Cannister masks - although shown to have fast breakthrough times at high concentrations of vinyl chloride - may be adequate to give protection at the low levels of exposure which may be expected to be experienced most of the time.

This section of the Standard should be general enough to accommodate alternate suitable devices that may now be available - or could come on the market in the near future - to provide the protection needed without creating other personal hazards in the workplace.

## Summary of Objections to Specific Sections of Proposed Standard 1910.93q

Section: (h) Protective clothing

Objection: Definition of proper clothing and removal requirements. Application to polyvinyl chloride. "Contaminated" clothing.

Grounds and/or Suggested Changes:

The definition "full-body" implies some type of impervious suit. A demand of this type should apply only to extraordinary exposure situations. Type of clothing required should fit the particular job assignment - e.g., an employee engaged in manual cleaning of a reactor vessel would require more protection than a supervisor or process control operator.

Except under very special circumstances there should be no need to remove work clothing except at the end of the work day.

No special clothing requirements should be associated with the handling of polyvinyl chloride powder unless such powder is capable of releasing vinyl chloride which exceeds the allowable permissible level in the air.

It is difficult to understand why laundering or disposal of "contaminated" clothing is recommended when it is recognized that the volatile nature of vinyl chloride precludes the possibility of any significant residual life.

# Summary of Objections to Specific Sections of Proposed Standard 1910.93q

Section: (j) Emergency situations

Objection: Definition. Shower requirement.

Grounds and/or Suggested Changes:

"Emergency" is defined (Webster) as:
"an unforeseen combination of circumstances or the resulting state that calls for immediate action." In any well run operation involving vinyl chloride there already exists a written operational plan for emergency situations.

Small-scale excursions of air concentrations above a permissible level should not be defined as an "emergency situation". A massive release of vinyl chloride would constitute an emergency.

This definition should be clarified.

Further, (2) (iii), the requirement to shower after any skin contact with liquid vinyl chloride is not technically sound due to the rapid volatility effect.

## Summary of Objections to Specific Sections of Proposed Standard 1910.93q

**Section:** (k) Signs and labels

**Objection:** Wording of signs and labels.

**Grounds and/or Suggested Changes:**

Use of the word "Cancer" on signs and labels creates emotional and irrational fears and morale problems which are not warranted. The use of the word "Hazardous" plus action-oriented instructions in place of "Cancer-Suspect" would accomplish the desired purpose of this section.

The requirement to wear "full impervious air-supplied equipment" is unwarranted and unnecessary. The use of such cumbersome equipment would create a safety hazard to the employee. Adequate protection for special situations can be insured through the use of proper respiratory equipment. In all instances where vinyl chloride levels are within the permissible range there should not be any special requirements regarding signs and labels.

No special label requirements should apply to polyvinyl chloride unless a hazardous situation can be reasonably anticipated based on residual vinyl chloride content. Under no circumstances should any polyvinyl chloride product containing under 0.1% vinyl chloride fall under this special labelling requirement.

## Summary of Objections to Specific Sections of Proposed Standard 1910.93q

Section: (1) Maintenance and decontamination

Objection: Definition of terms: "contaminated" and "decontaminated". Requirement involving "whole-body air-supplied impervious suit".

Grounds and/or Suggested Changes:

"Contamination" must be expressed in terms of exceeding a permissible level. "Decontamination" must relate to reducing a level to within the permissible range. How to achieve decontamination is unclear.

The "whole-body" suit is objected to for reasons previously stated. It must be emphasized that this Proposed Standard is for the purpose of reducing an alleged carcinogenic medical risk. We are unaware of any indictment of vinyl chloride involving such a risk by skin absorption of airborne vinyl chloride.

A practical consideration involving "vessel entry" should take into account that many reactors have small manholes which would make it impossible for a person to enter if clothed in the full "whole-body air-supplied" suit.

# Summary of Objections to Specific Sections of Proposed Standard 1910.93q

**Section:** (o) Medical surveillance (8)

**Objection:** Mandatory removal of personnel from job.

**Grounds and/or Suggested Changes:**

The mandatory requirement for removal of personnel from potential vinyl chloride contact areas if upon medical rescreening one or more abnormal liver function tests persist, leaves the examining physician no room for judgement. Furthermore, removal of an employee to an area with "no detectable level" of vinyl chloride, which in our opinion is unlikely to be found consistently in the vicinity of a vinyl chloride or polyvinyl chloride plant, would appear to leave no alternative but transfer or dismissal.

We recommend that removal of personnel from a work area be the discretionary responsibility of the examining physician who will be in the best position to take into account all of the employee's symptoms and other medical background which can affect such a decision.

## Summary of Objections to Specific Sections of Proposed Standard 1910.93q

Section: (n) Polymer handling operations

Objection: "Detectable level" terminology.

Grounds and/or Suggested Changes:

For reasons previously stated, a "permissible" level should replace a no detectable level.

Processing of polymer should be outside the scope of this Proposed Standard. Limiting of residual vinyl chloride - e.g., to 0.1% - in polyvinyl chloride would add further assurance of insignificant risk to processing workplaces.

# Summary of Objections to Specific Sections of Proposed Standard 1910.93q

Section: (q) Reports

Objection: Definition of "incidents".

Grounds and/or Suggested Changes:

An "incident" must be better quantified to avoid overly burdensome and voluminous report requirements covering each incident involving the release of a small amount of vinyl chloride greater than some allowable permissible amount

Incident reporting should be confined to those cases wherein a massive or extraordinary amount of vinyl chloride is released into the workplace environment.

B. Technological Nonfeasibility

Regulations involving protection of workers and their health must recognize the fact that absolute safety in any work situation is impossible. From a technical point of view steps can be taken to reduce risk to a minimum.

At our PVC production facility it is not feasible to reduce airborne concentrations of vinyl chloride to zero. The attached report from our consulting engineers, Bowshot, Cooper and O'Donnell supports this contention. (See EXHIBIT B)

It is feasible to reduce exposure to vinyl chloride to a low level but not to a non-detectable level. At our plant we have initiated engineering changes and improved work practices to minimize worker exposure to vinyl chloride. A major change being planned involves automatic vessel cleaning which requires an investment, in our relatively small operation, of over $1 million. Improved ventilation in general will also improve the working atmosphere.

EXHIBIT B
p. 1 of 2

19571 Roseland Ave.
Cleveland, Ohio 44117
Phone 692-0460

# Bowshot, Cooper & O'Donnell

ENGINEERS

M. L. COOPER 16570
J. F. O'DONNELL 16732
R. K. FIELD 24378
R. E. SCHAEFFER 23065

June 14, 1974

Uniroyal, Inc.
P.O. Box 460
Painesville, Ohio 44077

Attention: Mr. W. M. Iliff
Plant Engineer

Subject: To reduce the concentration of Vinyl Chloride Monomer in the working areas of your Painesville Plant to a level of one part per million (1PPM)

URL 00025

Dear Sir:

Our study has indicated that from an engineering standpoint, reducing the concentration to this level is impractical to the point of being impossible. In reaching this conclusion we gave careful consideration to the following factors.

1. The "state of the art" at the present time does not permit the measurement of 1PPM of VCM in your area. All of the methods used for detecting VCM to some extent either respond to other hydrocarbons or are reduced in sensitivity by their presence. The use of alcohols and acetates etc. around and in the Uniroyal Plant plus marsh gas and automobile contaminants serve to produce a variable "background" that would make calibration of any continuously monitoring instrument almost impossible to a level of one part in a million of VCM only.

   During our investigation of this problem we have examined most of the instruments used to measure the quantity of VCM present.

   All these instruments have had a poor history for serviceability. It is unlikely that immediate improvements will be made to increase their reliability beyond what is now being experienced.

19571 Roseland Ave.
Cleveland, Ohio 44117
Phone 692-0460

# Bowshot, Cooper & O'Donnell

ENGINEERS

H. L. COOPER 16570
J. F. O'DONNELL 16732
R. K. FIELD 24378
R. E. SCHAEFFER 23065



2. Due to the batch process of making PVC, some VCM must be lost during cleaning and recharging of the vessels.

3. The polymerization or conversion of the monomer is less than 100% so that even with current stripping technology some of the monomer is included in the final product. Some monomer will be discharged from resin drying systems as well as in the finished product.

4. VCM must be stored, transported, and pumped at a pressure greater than atmospheric. The most assiduous maintenace program will not prevent some leaks.

5. Vinyl Chloride Monomer is a volatile explosive gas at normal ambient conditions and relatively low concentrations. The only safe method to eliminate the explosive danger after it has been exposed to air is dilution by ventilation.

6. The amount of ventilation required to approach 1PPM would result in air speeds through the buildings that would cause excessive noise, unsafe working conditions, and unacceptable structural changes to the walls for explosion release. The heat required to temper this volume of air would be an impractical waste of energy.

7. It is our opinion that the most practical way to significantly reduce VCM levels in a PVC resin plant is through the application of known engineering principles in the design of an entirely new facility. To bring a plant built within the last ten years to such a standard appears to be impractical.



Very truly yours,

BOWSHOT, COOPER & O'DONNELL
ENGINEERS

James F. O'Donnell
Partner & Chief Engineer

Howard L. Cooper
Partner

C. PVC Processing and Fabrication

We do not believe that the proposed Standard should be written to cover PVC processing workplaces. There is no evidence of medical hazard in these operations. Although it is possible to detect some VCM in the processing workplaces it is unusual to find any substantial concentrations. Proper workplace ventilation and emphasis on reducing residual VCM levels in PVC should insure the absence of risk.

Data on monitoring of processing workplaces within Uniroyal may be found in EXHIBIT C.

F-237 REV. 3-67

Mishawaka Rubber & Analytical

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JUN 17 1974

EXHIBIT C
p. 1 of 8

UNIROYAL
U.S. RUBBER

UNIROYAL, Inc.

Mishawaka
(Location)

May 31, 1974

COM. DEV.

W. D. Harris
Oxford

Attached you will find the initial results of our vinyl chloride sampling and analysis. The complete test method and chromatagraphic results are included.

We will continue the program as we set it up during your recent visit.

L. J. Grecco Jr.

L. J. Grecco
Manager, Technical Services

cc: Factory Manager - Mishawaka

INTERCOMPANY CORRESPONDENCE

URL 00028

U.S.RUBBER

UNIROYAL, Inc.

Mishawaka
(Location)

May 31, 1974

W. D. Harris
Oxford

Subject: The Determination of Vinyl Chloride Monomer in Air

A method has been developed by the Mishawaka Analytical Laboratory for the determination of VCM in air. Current tests are being done throughout the plant to determine VCM levels. This report will give the analytical method and the valves obtained to date:

1. Apparatus

   1. Hewlett - Packard 7620 Gas Chromatograph with flame ionization detector and recorder.
   2. Two stainless steel chromatographic columns:
      a. 10' X 1/8" 10% Silicone SE-30 on diatoport S.
      b. 20' X 1/8" 10% FFAP on Chromosorb WAN DMCS.
   3. 100 microliter gas tight syringe (Hamilton Co.).
   4. Air sampling pump. Willson Products Division, ESB Incorporated.
   5. Flowator tube. Laboratory Equipment Corp.
   6. Charcoal tubes 5" X 8 mm packed with Darco 12 X 20 charcoal, washed and dried.
   7. 5 ml pipet.
   8. 10 ml glass stoppered volumetric flask.
   9. 10 microliter syringe (Hamilton Co.).
   10. Lecture bottle - pure VC or gas (Matheson).
   11. $CS_2$ - Spectro grade (Fisher).

## II. Procedure for Sampling

The sampling tubes were prepared in the laboratory as follows:

Darko 12 X 20 mesh charcoal was placed on a 30 mesh screen and washed thoroughly with tap water to remove impurities and fines. The charcoal was dried in an oven at 370°F for two hours. The glass tube 5" X 8 mm O.D. was crimped slightly toward one end and packed with one inch and two inches of charcoal respectively, separated by a fiberglass plug and fiber glass plugs on each end. The tube ends were covered with polyethylene caplugs. Each tube was calibrated individually with the Willson pump and flowator tube. The air volume sampled was 10 liters in every test.

## III. Description

The 2 inch sample section of the charcoal tube was desorbed with 5 ml of $CS_2$. The blank section was disorbed with one mil $CS_2$. Spectral grade $CS_2$ was used in each case.

## IV. Injection

The solvent flush injection technique was used to inject 5 microliters of sample into the G.C. The chromatographic parameters were as follows:

| | |
|---|---|
| Range | $10^2$ |
| Attenuation | 16 |
| Injection Port | 200° C |
| Detector | 210° C |
| Oven | 100° C isothermal |
| Hydrogen Flow | Tank pressure 10 psi |
| Air Flow | Tank pressure 33 psi |
| Nitrogen Flow | Tank pressure 70 psi flow 50 ml/min. |

Double injections of the sample was made on each column. Only one injection was made on the plank to show that it was VCM free. If VCM was found in the blank, its total was added to the sample total.

## V. Preparation of a Standard

A standard was prepared from the lecture bottle by removal of gas from an attached rubber tube which was purged of all air. This gas was injected directly onto a charcoal tube while drawing air with the sampling pump. The charcoal was desorbed with $CS_2$. A description factor is not necessary as both the sample to standard are desorbed by the same method.

V. Preparation of a Standard (Cont'd.)

Example: 100 microliters of VCM absorbed on charcoal and then desorbed with 5 ml $CS_2$. Injected volume is 5 microliters.

$$\frac{5 \text{ microliters}}{5 \text{ ml}} \times 100 = 0i/ul \text{ VCM injected}$$

This standard is called 100 ppm and relates to 1 ml of air at 100 ppm concentration. The sample peak heights are related to this standard by direct ratio.

Analytical Dept. 492

G. A. Shaw D. K. Moore

EXHIBIT C
p. 5 of 8

URL 00032

MISHAWAKA PLANT

VINYL CHLORIDE SAMPLING

DATA TABLE

| SAMPLE DESIGNATION | DATE TAKEN | LOCATION | VINYL RESIN IN USE | P.P.M. V.C.M. |
|---|---|---|---|---|
| #18 | 5/23/74 | CF-6 Banbury | VR-22 & 24 | 0.0 |
| 19 | 5/23/74 | KoKneader - Exit | VR-23 | 0.0 |
| 20 | 5/23/74 | KoKneader - Blender | VR-23 | 38.0 |
| 21 | 5/23/74 | CF-8 Banbury | VR-22 & 24 | 1.4 |
| 22 | 5/23/74 | CF-8 Calander | VR-22 | 2.2 |
| 23 | 5/23/74 | CF-6 Calander | VR-22 | 1.5 |
| 24 | 5/24/74 | Hopper Car | VR-22 | 0.5 |
| 25 | 5/24/74 | Under Silo (Inside) | VR-22 | 12.5 |
| 26 | 5/24/74 | KoKneader - Mix Area | VR-22 | 0.2 |
| 27 | 5/24/74 | Ensolite Banbury #2 | VR-23 | 0.0 |
| 28 | 5/24/74 | Seald Bin Bldg. 120 | VR-24 | 1.3 |
| 29 | 5/24/74 | Ensolite Banbury #4 | VR-23 | 0.0 |
| 30 | 5/24/74 | KoKneader - Mix Area | VR-24 | 0.0 |
| 31 | 5/28/74 | CF-6 Banbury | VR-22 & 24 | 2.3 |
| 32 | 5/28/74 | CF-8 Banbury | VR-22 | 1.4 |
| 33 | 5/28/74 | KoKneader - Blender | VR-23 | 23.3 |
| 34 | 5/28/74 | CF-8 Calander | VR-22 | 1.5 |
| 35 | 5/30/74 | Hopper Car | VR-22 | 2.6 |
| 36 | 5/28/74 | CF-6 Calander | VR-22 | 0.3 |
| 37 | 5/30/74 | Under Silo (Inside) | VR-22 | 25.8 |
| 38 | 5/30/74 | Bag Storage Bldg. 120 | VR-24 | 13.0 |

Notes:

1. Sampling - 0.5 liters/minute for 20 minutes using a Willson-Caselim Pump with Mishawaka fabricated 5 inch charcoal tubes.
2. CF - Designated Coated Fabrics
3. All samples were taken with pump and sample tubes attached to operator in breathing zone area except samples #25 and 37, which were static samples.

P-332 REV. 2-67

EXHIBIT C
p. 6 or 8

ORIGINAL

RECEIVED
JUN 13 1974
MEDICAL DEPARTMENT

UNIROYAL, Inc.

Mishawaka
(Location)
June 11, 1974

JUN 17 1974 COM. DEV.

Dr. W. D. Harris
Oxford

Attached you will find results of our vinyl chloride sampling and analyses for the:

1. Chicago Plant (initial)

2. Mishawaka Plant (supplemental)

The test procedure is outlined in Mr. L. J. Grecco's May 31, 1974 report to you.

D K Moore

D. K. Moore
Manager, Analytical Services

cc: J. R. Sellers

URL 00033

INTERCOMPANY CORRESPONDENCE

MISHAWAKA PLANT

VINYL CHLORIDE SAMPLING

DATA TABLE

| Sample Designation | Date Taken | Location | Vinyl Resin In Use | P.P.M. V.C.M. |
|---|---|---|---|---|
| #43 | 6/7/74 | KoKneader - Mix Area | VR-23 | 2.40 |
| #44 | 6/7/74 | Seald Bin Bldg. 120 | VR-24 | 4.00 |
| #45 | 6/7/74 | CF-6 Banbury | VR-22 | 4.50 |
| #46 | 6/7/74 | CF-6 Calander | VR-22 | 1.00 |
| #47 | 6/10/74 | Hobart Mixer | VR-24 | 0.80 |
| #48 | 6/11/74 | CF-8 Banbury | VR-24 | 3.00 |
| #49 | 6/11/74 | CF-8 Calander | VR-24 | 0.60 |

NOTES:

1. Sampling - 0.5 liters/minute for 20 minutes using a Willson-Casella Pump with Mishawaka fabricated 5 inch charcoal tubes.
2. All samples attached to operator in breathing zone area.
3. A third week sampling of the major manufacturing areas (except #47).
4. This data table is a supplement to the 5/31/74 report to Dr. W. D. Harris from L. J. Grecco (G. A. Shaw & D. K. Moore).

CHICAGO PLANT

VINYL CHLORIDE SAMPLING

DATA TABLE

| Sample Designation | Date Taken | Location | Vinyl Resin In Use | P.P.M. V.C.M. |
|---|---|---|---|---|
| #39 | 6/4/74 | Static-Storage | VR-24 | 5.96 |
| #40 | 6/4/74 | Banbury - On Operator | VR-23 & VR-24 | 0.35 |
| #41 | 6/4/74 | Static - Storage | VR-23 | 1.64 |
| #42 | 6/4/74 | Sheeter Mill - On Operator | VR-23 & VR-24 | 0.35 |

NOTES: 1. Sampling and testing - performed by G. A. Shaw (Mishawaka) per Mishawaka sampling & testing techniques.

2. This is a first sampling and testing of this plant.

Although we reject the concept of "zero exposure" to vinyl chloride, we recognize - and accept - our responsibility to protect the health of our workers. We believe that low level exposure to vinyl chloride represents a minimal risk situation. We recommend that a finite "permitted level" be substituted in the Permanent Standard in place of the "no detectable" requirement.

In our PVC manufacturing operation we feel that we can reduce airborne levels of vinyl chloride to under 50 ppm as a ceiling limitation. For practical purposes we strongly endorse the concept of a TWA value. In our opinion the TWA number could ultimately be set at 25 ppm and the ceiling at 40 ppm if it is felt that sufficient evidence exists to warrant reduction from 50 ppm called for in the Temporary Standard.

It should be recognized that due to individual plant design and operation, compliance dates should be on a plant to plant basis. We urge that OSHA personnel - with outside engineering consultants if necessary - establish a proper and achievable timetable for regulatory compliance at each plant location.

Regarding the future, we do not believe that permissible vinyl chloride exposure levels should be set lower and lower unless there is more adequate medical justification. Proper epidemiological studies should be immediately initiated to evaluate the degree of risk at low levels of vinyl chloride exposure.

D. Economic Impact

Another major objection to the concept of "no detectable" restrictions on vinyl chloride involves the economic impact which would result from the closing of production plants due to the technological infeasibility of meeting such a Standard.

The Department of Labor recognizes the validity of economic impact arguments in the prologue to carcinogen regulations issued as Part 1910's c-p (FR, Vol. 39, No. 20 - January 29, 1974). They state ... "the intent of the standards is to reduce exposure of workers to any of the listed substances to the maximum extent practicable, consistent with continued use". The prologue also exempts or excludes certain operations or levels of alleged carcinogens on the basis that without such exclusions or exemptions the Standards ... "would have the effect of closing down large segments of industry, such as steelmaking, wood preserving, roofing, aluminum reduction, and possibly even power plants".

The polyvinyl chloride (PVC) industry is the single most important segment of the entire U.S. plastics industry. Annual output of base resin is close to 5 billion pounds per year. A recent survey by Peter Sherwood Associates (Chemical Marketing Reporter - 5-27-74) projects growth to 8.5 billion pounds in 1980.

It should be recognized that the growth of PVC to this tremendous usage stemmed from the unique properties of this resin. Uses and fabricating techniques have for the most part been developed to handle PVC and are not easily adapted, or adapted at all, to other materials. One does not simply substitute rubber or another plastic without substantial changes in skills, equipment and capital costs.

A rough breakdown of application areas follows. (Chemical Marketing Reporter - 5-20-74)

| | PVC Use Areas |
|---|---|
| Pipe and Fitting | 27% |
| Flooring | 10 |
| Construction | 6 |
| Wire and Cable | 9 |
| Furniture | 6 |
| Transportation | 5 |
| Film and Sheet | 4 |
| Textile, Paper and Adhesives | 5 |
| Sound Records | 3 |
| Export | 5 |
| Miscellaneous | 20 |

The total worth of the PVC industry in terms of jobs and dollars is difficult to measure exactly but it is known to be responsible for hundreds of thousands of jobs and many billions of dollars. Other presentations at this hearing will give additional data on the magnitude and importance of the PVC industry.

To grasp the proliferation of impact starting with our Chemical Division PVC production facility, we have made a rough economic analysis based on predicted effects on Uniroyal as well as our customers. It has been noted that although we are a small producer of PVC (about 3% of the U.S. total) the impact of a shut down of our PVC plant would create severe economic effects.

At our Painesville, Ohio PVC production plant we employ about 300 people with an annual payroll of about $4 million. The resin we produce is used by other Uniroyal divisions and outside customers giving employment to over 25,000 people and an annual payroll of over $200 million.

Communities that would suffer from the loss of PVC - related jobs within the Uniroyal corporation are: Painesville, Ohio; Port Clinton, Ohio; Stoughton, Wisconsin; Philadelphia, Pennsylvania; Mishawaka, Indiana; Chicago, Illinois; Farmville, Virginia, and Washington, Indiana.

Industries that would be severely affected by curtailment of our PVC production operations include: coated fabrics, flooring, footwear, medical, automotive, shoes, hose, insulation, wire and cable.

In EXHIBIT D we have illustrated some detailed effects that would results within the Uniroyal organization.

FOR20233

EXHIBIT D
p. 1 of 4

JUN 13 1974 COM. DEV.

**UNIROYAL, Inc.**

OXFORD D-2-2
(Location)

June 12, 1974

R. J. Dowling
NAUGATUCK CHEMICAL

SUBJECT: PROPOSED VCM OSHA REGULATION #1910.939

The Plastic Products Division would be forced to shut down our Coated Fabrics and certain Royalite ABS-Thermoplastic Sheet operations if the proposed Government standard of "zero" or "no detectable level" of vinyl chloride exposure is made permanent.

This would result in an immediate loss in Divisional sales of **over $100 million/yr.** At a minimum, 1,812 salary and wage jobs would be eliminated with an annual value of wages and salaries in excess of $18,580,000. (This value is exclusive of Fringe Benefits)

The number of employees effected with monthly wage and salary loss by plant is listed below:

| PLANT | WAGE EMPLOYEES | MONTHLY WAGE LOSS | SALARIED EMPLOYEES | MONTHLY SALARY LOSS | SALESMEN |
|---|---|---|---|---|---|
| Chicago, Ill. | 150 | $155,204 | 30 | $ 35,268 | 4 |
| Stoughton, Wisc. | 240 | 198,663 | 42 | 42,116 | |
| Port Clinton, Ohio | 250 | 192,436 | 65 | 62,906 | |
| Masland-Phila.,Pa. | 350 | 230,046 | 90 | 91,702 | 12 |
| Mishawaka, Ind. | 360 | 305,712 | 147 | 139,240 | 73 |

The economic impact on the local communities of Mishawaka, Port Clinton, and Stoughton would be extremely severe since these plants are either the largest or next largest employer in their respective area.

In addition, approximately 122 Coated Fabrics Distributors averaging 10 employees each would be effected as 26% of their business is derived from the sale of vinyl coated fabrics.

Richard Morgan

j

cc: W. J. Mulvey

INTERCOMPANY CORRESPONDENCE

URL 00040

JUN 7 1974 COM. DEV.



**UNIROYAL, Inc.**
Consumer Products
Oxford R-1-31
(Location)

June 6, 1974

TO: R. J. Dowling
Naugatuck Chemical Division

FROM: F. C. Cesare

SUBJECT: Proposed VCM OSHA Regulation #1910.93q
Re: Consumer Products Co.

The Consumer Products Co. would include the Farmville, VA and Washington, Indiana plants.

In Farmville the economic impact would be as follows if we could no longer operate under the non-detectable OSHA requirements, loss in Net Sales in excess of $6 million.

Salary and wage jobs eliminated 216.

Value of wages and salary in dollars $1,600,000.

The loss of $2,600,000 in materials cost and overhead which includes purchases from local vendors and the community such as taxes, utilities, etc.

At the Washington Indiana plant the loss in net sales would be over $4 million and the elimination of 100 salary and wage positions.

The value of salary and wages is $870,000 and the materials and overhead dollars which would be lost to the community is estimated at $366,000.

Since the Washington Indiana plant manufactures other products it is conceivable that a balanced plant could not exist profitably and that under these conditions the losses could be greater. In the event of total plant shut down the loss in net sales would amount to $12,000,000, the salary and wages lost would be approximately $3,585,000. The materials and overhead dollars lost to the local community and vendors would be $1,335,000. The total number of positions eliminated assuming complete plant close down would be 416.

There are no substitutes for plastisol or slush cast footwear in Farmville, VA or for the clothing operation in Washington, Indiana.

F. C. Cesare

FCC/dh

cc: D. Thomson
P. G. Brown
E. C. VanBuskirk
D. Dudrow

UNIROYAL

UNIROYAL, INC.
Route 2, Box 32
Farmville, Virginia 23901

June 7, 1974



Mr. John Stender
Assistant Secretary of Labor
U. S. Department of Labor
Washington, D. C. 20210

Dear Mr. Stender:

We have been following with some interest the information developing on the Poly Vinyl Chloride problem and have read the proposed rules for emission standards as contained in OSHA Regulation 1910.93Q.

Our plant currently employs some 220 people with an annual payroll in the area of $1,600,000. In addition we are billed from the community for services some $600,000 annually.

The material cost for manufacturing our products approximates $1,600,000.

We are certainly receptive to practical regulations for the protection of personnel both in industry and at the consumer level and encourage such action.

Any regulations set up must be manageable and realistic in order for us to protect the livelihood and health of everyone involved. Any impractical regulations resulting in cutbacks or shutdowns would certainly introduce undue hardship on people employed in our plant and have an adverse effect on the local community.

Any efforts by your department to help insure practical regulatory procedures while also insuring proper health safeguards would be appreciated.

A. C. Young
Factory Manager
Uniroyal, Incorporated
Farmville, Virginia

ACY:sw

# Uniroyal Vinyl Chloride and Polyvinyl Chloride Experience

We started making both VCM and PVC in Painesville, Ohio in 1947. In 1961 we discontinued VCM production and started purchasing our VCM requirements from Monochem (a joint company formed by Uniroyal and Borden). At all times - up to the present - the acetylene process has been used for VCM production.

Our PVC operations involve the manufacture of both suspension and dispersion resins. We also manufacture a PVC-nitrile rubber blend at our Painesville facility.

Our total work force is about 300 people, 56 of whom have been employed continuously for over 25 years. No cases of either acroosteolysis or angiosarcoma have been found among any of our workers (See EXHIBIT E, p. 1).

NIOSH published data (EXHIBIT E, p. 9) shows 13 cases of deaths from angiosarcoma in the U.S. confirmed as related to vinyl chloride. These cases were confined to only 4 individual plants out of 36 producing locations. Further, it should be made clear that there hasn't been any significant increase in annual rate of angiosarcoma fatalities as shown by available yearly summary data:

| Year | Angiosarcoma Deaths |
|---|---|
| 1961 | 1 |
| 1962 | 0 |
| 1963 | 0 |
| 1964 | 1 |
| 1965 | 0 |
| 1966 | 0 |
| 1967 | 0 |
| 1968 | 3 |
| 1969 | 1 |
| 1970 | 1 |
| 1971 | 1 |
| 1972 | 0 |
| 1973 | 2 |

UNIROYAL, Inc.

OXFORD
(Location)

June 14, 1974

TO: W. D. Harris

FROM: J. D. Forbes, M.D.

SUBJECT: MEDICAL RESULTS FROM PAINESVILLE

Ever since the description of acroosteolysis, we have been conducting an examination program for those in poly cleaning. We can report that we have had no cases of acroosteolysis. We are continuing on with our annual examinations for all active poly cleaners with the evaluation consisting of a special AOL history, physical examination and hand x-rays. Since the plant has an annual or biannual (depending upon age of the employee) examination program, all individuals who have worked in poly cleaning in the past are covered in our medical surveillance.

In regard to the recent revelations about angiosarcoma, we have found no cases in Painesville to date. We have followed the NIOSH medical surveillance recommendations of screening the entire plant with a brief medical history, limited physical examination, and five biochemical tests of liver function. (These are total bilirubin, alkaline phosphatase, SGOT, SGPT, and GGTP.) To date, 410 people have had initial biochemical tests complete with the result that 46 (11.2%) showed abnormalities in one or more of these five tests. Rescreening results have returned on less than half of these 46 with the result that all of them continue to show a persistance of one or more abnormalities. Thus it would appear with our testing still under way that those who will deserve an extended and individualized medical evaluation might be in the vicinity of the same 11.2%.

At Monochem, our vinyl chloride monomer plant where our exposures have been significantly less, 44 people have had initial biochemical screening with the result that 7 individuals (15.9%) showed one or more abnormalities. Rescreening is presently in progress.

JDF/mab

J D Forbes MD

INTERCOMPANY CORRESPONDENCE

WOA testimony 1/7/74



The concept of "detectable levels" is unrealistic and meaningless. Hardware is now available to detect a few parts per billion of VC and this can undoubtedly be extended. If this wording persists those who favor the zero concept will insist that the most sensitive tests be used resulting in unnecessary expense and waste of scarce technical manpower. Furthermore, there is nothing in the toxicology data to support the need for such low levels.

## TOXICOLOGICAL DATA

We are indebted to Prof. Cesare Maltoni for his excellent animal studies which throw careful light on the toxicity of vinyl chloride. The earlier work of Viola showed that while animals can live in tremendous concentrations of vinyl chloride for long periods with no apparent effect, under these conditions it caused cancer. Maltoni extended and greatly refined these studies.



His data are presented in English translation in Tables II and III which follow. The complete tables from which these data were taken are from a paper by Cesare Maltoni and Guiseppe Lefemine, Estratto dal fasc, .3, Serie VIII, Vol. LVI, Marzo 1974 and are given untranslated in the pages which follow our tables.

Experiment BT1 involved exposure of animals at the various concentrations for 52 weeks and observation until death. At the time the paper was presented this was 130 weeks and a few animals were still alive. Experiment BT3 is identical except that the animals were exposed for only 17 weeks and at the time of writing observation had continued for a total of 59 weeks. To get a comparison he shows records for BT1 at 59 weeks.

TABLE II

Experimental BT1: Experimental Results at 130 Weeks



| Group and Treatment | Animals (Rats) Sprague-Dawley | Animals With Tumors | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | Carcinoma of the Zymbal Gland | Nephro blastomas | Angiosarcoma | | Other Types and/or locations | Total |
| | Total | Living | | | Liver | Other Locations | | |
| I Vinyl Acetate 2500 ppm | 96 | - | - | - | - | - | - | - |
| II VC 10,000 ppm | 69 | - | 16 | 4 | 7 | - | 6 | 25 |
| III VC 6,000 " | 72 | - | 7 | 4 | 13 | 2 | 1 | 24 |
| IV VC 2,500 " | 74 | - | 2 | 6 | 14 | 3 | 1 | 24 |
| V VC 500 " | 67 | - | 3 | 4 | 7 | 2 | 1 | 16 |
| VI VC 250 " | 67 | 1 | -- | 6 | 4 | 2 | 2 | 12 |
| VII VC 50 " | 64 | 3 | - | - | - | - | - | - |
| VIII Control | 68 | 1 | - | - | - | - | - | - |
| TAL | 577 | 5 | 28 | 24 | 45 | 9 | 11 | 101 |

TABLE III

Experimental BT3: Experimental Results at 59 Weeks

| Group and Treatment | Animals (Rats) Sprague-Dawley | Animals With Tumors | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | Carcinoma of the Zymbal Gland | Nephro blastomas | Angiosarcoma | | Other Types and/or locations | Total |
| | Total | Living | | | Liver | Other Locations | | |
| I VC 10,000 ppm | 60 | 36 | 3 | - | - | - | - | 3 |
| II VC 6,000 ppm | 60 | 48 | 1 | - | - | - | - | 1 |
| III VC 2,500 ppm | 60 | 54 | - | - | - | - | - | - |
| IV VC 500 ppm | 60 | 56 | - | - | - | - | - | - |
| V VC 250 ppm | 60 | 44 | -- | - | - | - | - | - |
| VI VC 50 ppm | 60 | 50 | - | - | - | - | - | - |
| VII Control | 190 | 183 | - | - | - | - | - | - |
| TOTAL | 550 | 471 | 4 | - | - | - | - | 4 |

Nelle Tabelle II-VI vengono esposti i dati preliminari relativi agli esperimenti BT 1, BT 3, BT 6, BT 5, BT 4. Per quanto concerne gli altri esperimenti dobbiamo attendere ancora per avere risultati.

Da quanto presentato nelle Tabelle e dallo studio istologico emergono i seguenti punti:

1) il CV è oncogeno nelle condizioni sperimentali da noi saggiate: esso provoca carcinomi delle ghiandole di Zymbal (fig. 1), nefroblastomi (fig. 2) e angiosarcomi epatici (figg. 3, 4) e di altri tessuti ed organi (figg. 5, 6) nel ratto, e adenomi-adenocarcinomi polmonari, carcinomi mammarii e angiosarcomi epatici nel topo;

TABELLA II

*Esperimento* BT 1: *Risultati sperimentali a 130 settimane*

| Gruppi e trattamenti | Animali (ratti Sprague-Dawley) | | Animali con tumori | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Totale | Sopravvissuti | Carcinomi delle ghiandole di Zymbal (A) | Nefroblastomi (B) | Angiosarcomi: Fegato (C) | Angiosarcomi: Altre localizzazioni | Altri tipi e/o localizzazioni | Totale (O) |
| | N. | | N. | N. | N. | N. | N. | N. |
| I) AV 2.500 ppm | 96 | — | — | — | — | — | — | — |
| II) CV 10.000 ppm | 69 | — | 16 | 4 | 7 | — | 6 (H) | 25 |
| III) CV 6.000 ppm | 72 | — | 7 | 4 | 13 | 2 (D) | 1 (I) | 24 |
| IV) CV 2.500 ppm | 74 | — | 2 | 6 | 14 | 3 (E) | 1 (L) | 24 |
| V) CV 500 ppm | 67 | — | 3 | 4 | 7 | 2 (F) | 1 (M) | 16 |
| VI) CV 250 ppm | 67 | 1 | — | 6 | 4 | 2 (G) | 2 (N) | 12 |
| VII) CV 50 ppm | 64 | 3 | — | — | — | — | — | — |
| VIII) Nessun trattamento | 68 | 1 | — | — | — | — | — | — |
| Totale | 577 | 5 | 28 | 24 | 45 | 9 | 11 | 101 |

A) Metastasi al polmone. B) Metastasi al fegato e/o al polmone e alla milza. C) Metastasi al polmone. D) 1 angiosarcoma in angioma fibrosante sottocutaneo; 1 angiosarcoma ossificante auricolare. E) 2 angiosarcomi *intraddominali* (1 vicino alla milza, 1 vicino all'ovaio); 1 angiosarcoma ossificante laterocervicale. F) 1 angiosarcoma polmonare; 1 angiosarcoma dell'utero. G) 1 angiosarcoma intraddominale (vicino alla milza); 1 angiosarcoma ossificante intratoracico. H) 2 adenomi delle ghiandole di Zymbal; 1 neurilemmoma del padiglione auricolare; 2 carcinomi mammarii; 1 cistoadenocarcinoma dell'ovaio. I) 1 carcinoma sebaceo della cute. L) 1 adenoma delle ghiandole di Zymbal. M) 1 epatoma a minima deviazione. N) 1 adenoma delle ghiandole di Zymbal; 1 carcinoma delle ghiandole salivari. O) Diversi animali con due o più tumori.

## TABELLA III

*Esperimento* BT3: *Risultati sperimentali a 59 settimane* (1)

| GRUPPI E TRATTAMENTI | ANIMALI (RATTI SPRAGUE-DAWLEY) | | ANIMALI CON TUMORI | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | Angiosarcomi | | Altri tipi e/o localizzazioni | Totale (2) |
| | Totale | Sopravvissuti | Carcinomi delle ghiandole di Zymbal | Nefroblastomi | Fegato | Altre localizzazioni | | |
| | | | N. | N. | N. | N. | N. | N. |
| I) CV 10.000 ppm | 60 | 36 | 3 (11) | — (2) | — (2) | — | — (4) | 3 (15) |
| II) CV 6.000 ppm | 60 | 48 | 1 (3) | — (2) | — (3) | — (1) | — | 1 (9) |
| III) CV 2.500 ppm | 60 | 54 | — (2) | — (1) | — (1) | — | — (1) | — (5) |
| IV) CV 500 ppm | 60 | 56 | — (1) | — | — (1) | — | — | — (2) |
| V) CV 250 ppm | 60 | 44 | — | — | — (1) | — | — | — (1) |
| VI) CV 50 ppm | 60 | 50 | — | — | — | — | — | — |
| VII) Nessun trattamento . . . . | 190 | 183 | — | — | — | — | — | — |
| TOTALE . . . | 550 | 471 | 4 (17) | — (5) | — (8) | — (1) | — (5) | 4 (32) |

(1) Tra parentesi viene indicato il numero di tumori riscontrati nell'esperimento BT1, dopo 59 settimane. (2) Alcuni animali con due tumori.

## TABELLA IV

*Esperimento* BT6: *Risultati sperimentali a 34 settimane*

| GRUPPI E TRATTAMENTI | ANIMALI (RATTI SPRAGUE-DAWLEY) | | ANIMALI CON TUMORI | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | Angiosarcomi | | Altri tipi e/o localizzazioni | Totale |
| | Totale | Sopravvissuti | Carcinomi delle ghiandole di Zymbal | Nefroblastomi | Fegato | Altre localizzazioni | | |
| | | | N. | N. | N. | N. | N. | N. |
| I) CV 30.000 ppm | 60 | 60 | 2 | — | — | — | — | — |

Total tumors are summarized for both BT1 and BT3 in simplified form.

(1) It is obvious that the critical concentration range in experiment BT1 is between 250 and 50 ppm. Studies are underway at 100, 150 and 200 ppm.

(2) Both time of exposure and concentration are important factors.

Table 3 from the Tabershaw-Cooper report shows number of workers entering the work force where VC was handled either in monomer or polymer plants. Note the rapid growth of the industry in the 50's and 60's.

Most of the angiosarcoma have been found in workers who were vessel cleaners. There is general agreement in Europe and the U.S. that exposure in the early years of the industry in the vessel cleaning operations probably exceeded 1,000 ppm. We know that some men were overcome by VC indicating concentrations over 10,000 ppm. In the late 50's and early 60's most manufacturers tightened the operation somewhat to reduce losses for economic reasons and also to try to conform to the 500 ppm TLV. However, explosion meters were used as monitors so the available data is not precise. The identification of acroosteolysis in this country in the late 60's and of angiosarcoma in January 1974 has resulted in an order of magnitude reduction in exposure so that most plants are now well below a TWA of 50 ppm except for vessel cleaning where it is necessary for the present to wear supplied air respirators.



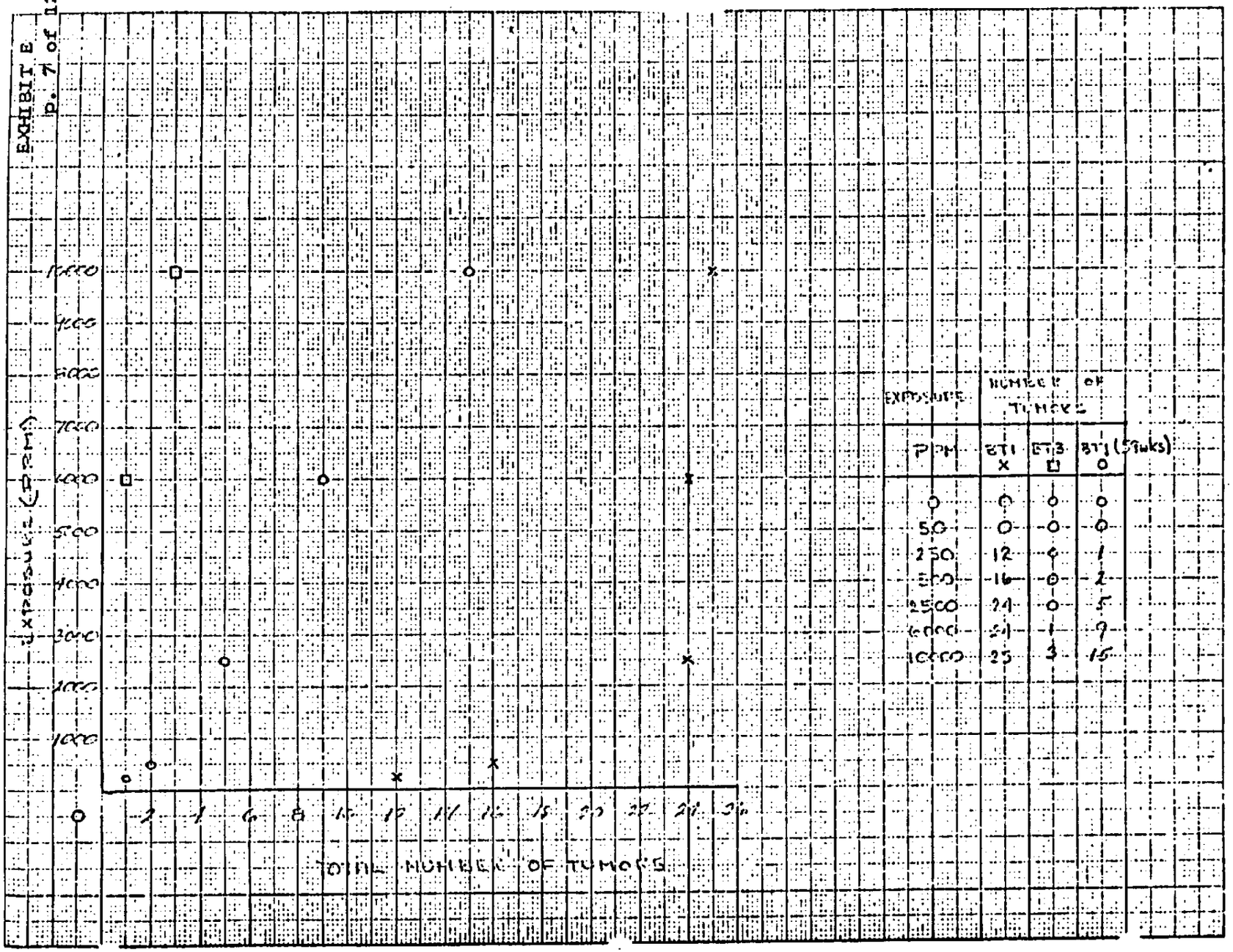
Keeping the above in mind, it is interesting to dissect the data compiled by NIOSH.

| Year of First Exposure | | NIOSH No. | Years In PVC | Years From First Exposure to Death | |
|---|---|---|---|---|---|
| 1944 | U.S. | 05 | 18 | 20 | |
| | U.S. | 07 | 18 | 24 | Ave 25 |
| | U.S. | 13 | 30 | 30 (alive) | |

12-18C
5788

URL 00051

EXHIBIT E
p. 7 of 12




| EXPOSURE PPM | NUMBER OF TUMORS BT1 X | BT3 □ | BT1 (Stalks) O |
|---|---|---|---|
| 0 | 0 | 0 | 0 |
| 50 | 0 | 0 | 0 |
| 250 | 12 | 4 | 1 |
| 500 | 16 | 0 | 2 |
| 2500 | 24 | 0 | 5 |
| 6000 | 24 | 1 | 9 |
| 10000 | 25 | 3 | 15 |

Table 3

Distribution of Months in Exposed Employment by Year
in Which Exposure Began, for 7128 Vinyl Chloride Workers with Completed Follow-up

| Year Exp. Started | Total | Months of Exposure | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | <60 | 60-119 | 120-179 | 180-239 | 240-299 | 300-359 | 360-419 | Unknown |
| 1930-39 | 35 | 2 | 4 | 1 | 4 | 6 | 13 | 5 | |
| 1940-49 | 1048 | 135 | 93 | 119 | 151 | 277 | 237 | 34 | 2 |
| 1950-59 | 1962 | 389 | 257 | 383 | 631 | 282 | | | 20 |
| 1960-69 | 3368 | 1714 | 1442 | 195 | | | | | 17 |
| 1970-71 | 715 | 715 | | | | | | | |
| Total | 7128 | 2955 | 1796 | 698 | 786 | 565 | 250 | 39 | 39 |

April 15, 1974

| Year of First Exposure | | NIOSH No. | Years In PVC | Years From First Exposure to Death | |
|---|---|---|---|---|---|
| 1945 | U.S. | 03 | 28 | 28 | |
| | U.S. | 09 | 17 | 29 | Ave 28 |
| | Sweden | 02 | 23 | 27 | |
| 1946 | U.S. | 08 | 15 | 15 | |
| | U.S. | 11 | 23 | 23 | Ave 22 |
| | Gr.Br. | 01 | 20 | 27 | |
| | | | | Average to here | 25 |
| 1948 | U.S. | 01 | 16 | 25 | |
| 1949 | U.S. | 12 | 15 | 20 | |
| 1950 | Norway | 01 | 21 | 22 | |
| 1951 | U.S. | 10 | 17 | 17 | |
| | Sweden | 01 | 19 | 19 | |
| 1952 | U.S. | 04 | 15 | 15 | |
| 1955 | U.S. | 02 | 13 | 16 | |
| 1957 | W.Ger. | 01 | 14 | 14 | |
| | | 02 | 11 | 11 | |
| 1962 | U.S. | 06 | 12 | 12 (alive) | |
| | Total | 19 | Ave 18.2 | 21.3 | |

Two points appear likely.

(1) The cause of death for some of the people who died from exposures in the early years has not been found. The records for those who died in the 50's are probably not readily found.

NIOSH 4/27/77

## CONFIRMED CASES OF LIVER ANGIOSARCOMA AMONG PVC WORKERS

| COUNTRY | CASE # | BIRTH DATE | 1st PVC WORK | DX ANGIO-SARCOMA | AGE AT DX | YRS 1st PVC TO DX | TOT YRS PVC | DATE OF DEATH |
|---|---|---|---|---|---|---|---|---|
| United States | 01 | 00-00-22 | 12-09-48 | 03-00-71 | 49 | 22 | 16 | 03-03-73 |
| United States | 02 | 00-00-34 | 11-15-55 | 05-00-70 | 36 | 14 | 13 | 09-28-71 |
| United States | 03 | 00-00-15 | 11-28-45 | 12-00-73 | 58 | 28 | 28 | 12-10-73 |
| United States | 04 | 00-00-24 | 07-06-52 | 08-00-67 | 43 | 15 | 15 | 01-07-68 |
| United States | 05 | 00-00-12 | 06-19-44 | 04-00-64 | 52 | 20 | 18 | 04-09-64 |
| United States | 06 | 00-00-29 | 01-17-62 | 02-00-74 | 45 | 12 | 12 | ALIVE |
| United States | 07 | 05-03-22 | 08-00-44 | 00-00-68 | 45 | 24 | 18 | 03-23-68 |
| United States | 08 | 05-06-20 | 10-07-46 | 08-00-61 | 41 | 15 | 15 | 08-29-61 |
| United States | 09 | 00-00-31 | 05-28-45 | 03-01-74 | 43 | 29 | 17 | ALIVE |
| United States | 10 | 08-16-13 | 06-00-51 | 05-00-68 | 55 | 17 | 17 | 05-10-68 |
| United States | 11 | 05-27-09 | 10-14-46 | 03-00-70 | 61 | 23 | 23 | 03-16-70 |
| United States | 12 | 11-17-18 | 09-13-49 | 05-00-69 | 50 | 20 | 15 | 05-02-69 |
| United States | 13 | 12-01-21 | 08-19-44 | 05-00-74 | 53 | 30 | 30 | ALIVE |
| W. Germany | 01 | 07-26-31 | 10-14-57 | 00-00-71 | 40 | 14 | 14 | 12-14-71 |
| W. Germany | 02 | 06-04-30 | 10-01-57 | 00-00-69 | 39 | 11 | 11 | 01-25-69 |
| Great Britain | 01 | 00-00-01 | 00-00-46 | 12-00-72 | 71 | 26 | 20 | 12-00-72 |
| Norway | 01 | 12-23-15 | 03-00-50 | 12-20-71 | 56 | 22 | 21 | 01-04-72 |
| Sweden | 01 | 00-00-27 | 00-00-51 | 00-00-70 | 43 | 19 | 18 | 00-00-70 |
| Sweden | 02 | 00-00-11 | 00-00-45 | 00-00-72 | 61 | 27 | 23 | 00-00-72 |

Note: '00' indicates unknown date

Note: In Column titled YRS 1ST PVC TO DX the Mean = 20, the Median = 20 and the Modes = 14, 15, 20, 22.

Note: In Column titled TOT YRS PVC the Mean = 18, the Median = 17 and the Modes = 15 and 18.

(2) Additional cases of angiosarcoma are likely to be found for several years from the people exposed in the early fifties no mater what steps are taken today. This is almost certain to be interpreted by the untrained as indicating that controls are not tight enough.

The paragraphs which follow are intended to show that the steps already taken should eliminate the problem of cancer due to VC once the already exposed population is removed from consideration.

Looking back at the compilation of cases by year of first exposure note that the longest period of exposure is 30 years and this worker is still alive. At the other extreme we find a West German worker who died after only 11 years exposure. Assuming 1000 ppm TWA exposure all fall between 11,000 and 30,000 ppm years. (From the various reports reaching this country it is likely that exposure in the German plant was particularly high). If we apply a liberal safety factor of 10 (remembering that we are using human data so there is no need for the 100 fold safety factor relied on by FDA to convert animal safe levels to general human exposure), we arrive at a figure of about 1000 ppm years. Thus a worker could work for 25 years at 40 ppm, 40 years at 25 ppm, 100 years at 10 ppm, etc.



Our sampling confirms what others are finding that monomer plants generally operate with no more than a very few ppm exposures. Fabricating, plants for the most part operate at 0-5 ppm with a few "hot spots" in storage areas where the breathing zone level can reach as high as 25-50 ppm but typically no one works steadily in these locations. Thus monitoring in these plants can be greatly restricted, limiting it to those areas shown by preliminary study to have the highest levels. PVC plants should be monitored periodically in all areas which are frequently

above TWA of some level such as 25 ppm. Sequential samplers should monitor carefully chosen spots as an ongoing check with alarms set when excursions indicate a leak.

W. D. Harris, Ph. D

WDH/mab

6/17/74

I think that the testimony and comments presented at this hearing should have made it clear to all of us who are concerned with the health of people and of the economy that the precipitate action proposed in the Permanent Standard would not be in anyone's best interest.

I believe Dr. Hammond, Vice President of the American Cancer Society, made a very rational statement when he said, as quoted in the news media, "There's no such thing as zero risk; I want to get the risk down as low as feasible, so low that I wouldn't hesitate myself to take that employment. But I don't want to make it so low that I couldn't earn a living...."

We would like to go on record in favor of a practical and reasonable set of controls. We feel in good conscience that a ~~time~~ ceiling weighted average of 50 ppm of vinyl chloride in both vinyl chloride monomer plants and polyvinyl chloride plants would be proper protection, supported by the data now available.

We believe that there should be no restriction on polyvinyl chloride processing and fabricating plants so long as the residual vinyl chloride content of the resins used is not over 0.1%.

(CONTINUED)

Since more and more people have become directly involved in vinyl chloride operations over the past 30 years, if this chemical was a truly potent human carcinogen there should be an indication of such a fact by a steady increase in angiosarcoma fatalities. As yet, these have not materialized.

It is recognized that more vinyl chloride related deaths could come in the future but we believe it is scientifically reasonable that these occurrences will also relate to earlier extensive exposures to high levels. The relatively recent overall industry reductions in exposure coupled with future mandatory reductions should eventually reduce the hazard to a minimal risk situation.

We do not believe that the available human medical evidence warrants reduction of worker exposure to "non-detectable levels". Experiments with animals may suggest levels of potential hazard but these levels are not exactly translatable to man. In fact, as prior testimony has strongly indicated, the methods used for projecting animal data and correlating with expectations of similar occurrences in humans are far from precise. Identified angiosarcoma cases in man to date appear to be directly related to high level, long term exposures.

A review and update of medical and toxicological considerations by our Corporate Medical Director, Dr. J. D. Forbes and by our Corporate Toxicologist, Dr. W. D. Harris, may be found in EXHIBIT E, pp 2-12.

STATEMENT FOR RMA ON VINYL CHLORIDE
WALTER D. HARRIS

Modified
Not given in exactly
this form.

It is most interesting to me to take part in this hearing. One of the great problems of the past was that we were unable to bring together all that was known about a large social-economic-scientific problem and to get balanced action. We have been a nation which sometimes lets the pendulum swing from one extreme to the other. Recent examples are DDT, cyclamates and spray adhesives.

As has been pointed out by others, the PVC industry has grown rapidly during the past 35 years. It started at a time when the field of toxicology was not sufficiently advanced to predict long term effects of chemicals on man. No one suspected a chronic hazard from VC. In the light of present knowledge, it is most regrettable that men were exposed to what we now know were much too high concentrations. In spite of strong criticism of industry, I am mildly hopeful that the various segments of our economy are working in what I like to call dynamic tension. If kept within reasonable bounds, this tension can lead to a stronger economy. If the tension becomes too great, it can be destructive. We have here industry pooling resources and information. Universities, hospitals, research groups, labor and government are each making their contribution. Together we have moved at a rate undreamed of even a few years ago.



However, there is a danger that we may try to move too fast. Yes, we can live without PVC, the car or the airplane. A few would survive even in the cave. I submit that it is not necessary to destroy an industry because it can't meet an October 5, 1974 deadline which seeks to guarantee absolute safety.

No prudent manufacturer knowing that VC is capable of causing cancer will long take the risk of exposing men to concentrations likely to cause harm. Let us not overlook our competitive system. Resin manufacturers will be forced to lower VC concentration by competition. A new criterion has entered the market place and I believe you will see the energies of the large companies turned to solving these problems. Whoever best invests talent and money to build or rebuild plants able to turn out acceptable products with a low level of VC at a profit will stay in business. It is a sad fact that the small manufacturer will likely fall by the wayside.

We have a tendency to over-react in this country. It is all or nothing. If we were to drive PVC off the market what will take its place? Do we know all we should about it? Let us not jump from the frying pan into the fire. Let us approach this problem even handedly. We have already reduced the highest exposures probably 20 fold. This may already have reduced the problem to a non-hazardous level. Let us challenge industry to compete in finding even better solutions and marshall the best efforts of the industry. Lets

keep alive the dynamic genius which has made America great and not try to operate by force alone. OSHA will never have enough inspectors to enforce an unrealistic standard. There is presently in this country too much disrespect for law. Setting unenforceable standards only increases this disrespect. We believe that an 8 hour time weighted average of 25 ppm is achievable in the near future. During the next two years much new data will be available. We urge OSHA to keep the regulation as simple as you can but build in provision for collection of meaningful data for periodic review. If it is necessary to move lower, some will build new plants to meet the new situation. We challenge OSHA to move creatively, not destructively.

Walter D. Harris, Ph.D.
Corporate Industrial Toxicologist

WDH/mab
6/27/74

I am Walter D. Harris, Industrial Toxicologist for UNIROYAL located at its main office in Middlebury, Connecticut. I have a B.A. degree in chemistry from the College of Wooster in Ohio and a Ph.D. in Organic Chemistry from the Ohio State University. In 1944 I joined the then U.S. Rubber Company at its Naugatuck Chemical headquarters where I was engaged in research in Agricultural Chemicals for 11 years. During this period I was author or co-author of 15 patents and several papers related to this field. For the next 9 years I handled patent liaison and toxicology problems for the division. In 1964 I joined the corporate staff where I remain as Industrial Toxicologist. In this position, I maintain liaison with Corporate and Divisional research, Plant Management, Corporate Safety and the Medical Departments with respect to overall safety of chemicals.

I am Chairman of the Health Sub-committee of the Rubber & Plastics Section, National Safety Council, a member of the RMA Occupational Safety and Health Committee and the AIHA Toxicology Committee. I have worked on various ad hoc committees in this field including MCA's vinyl chloride committee.

UNIROYAL, Inc.
Oxford Management & Research Center
Middlebury, Connecticut 06749

June 21, 1974

Mr. James Kallenborn
Office of Program Development, OSHA
U.S. Department of Labor
1726 M Street, N.W.
Washington, D.C.

RE: VINYL CHLORIDE

Dear Mr. Kallenborn:

At your meeting with ORC on June 18, you asked for informed opinions on eight questions related to vinyl chloride. In the following paragraphs are my considered opinions based on many years experience in research and development of Agricultural Chemicals as well as ten years as Corporate Industrial Toxicologist for UNIROYAL. In this last capacity, I have been in many plants. I am thoroughly familiar with the processes in every phase of the problem and have been heavily involved in the vinyl chloride problem. My comments follow in the order in which you listed them.



1. Engineering. Considerable freedom must be left with the engineering department in each plant. Processes differ. Some plants already have eliminated hand cleaning of vessels, the source of the greatest exposure. In our own plant, we are not this far along and estimate that it will be about two years before we can have a solvent cleaning operation in operation.

2. Personal protective equipment. Considering the great reduction in exposure I see very little need for personal protective equipment other than the usual safety shoes, hard hats, safety glasses, etc., customary in most chemical operations. We are dealing with a very dilute concentration of a gas in air. Nothing short of a completely sealed space suit will be really effective. There is no toxicological reason to specify such protection. In my mind, it would create a far greater risk than the VC exposure even in a PVC plant. It would be an unconscionable inconvenience, hazard and expense to inflict on the worker and management in any kind of fabricating operation where concentrations are very low generally. Again, we should let local union-management communities work out solutions to meet local needs.

3. Monitoring. Except for preliminary study in a few plants, this should not be necessary in the ordinary fabricating plant. It is too time consuming and not enough competent manpower is available to do enough monitoring to be reliable. A little data can be quite misleading. Most fabricating operations will result in well under 10 ppm and I see no data to suggest that this is a hazardous level. We should concentrate our effort where the problem is worst - the PVC plant and to a minor extent the worst places

in the monomer plants. In PVC, I believe there should be sequential samplers capable of measuring 10 ppm with reasonable accuracy. They should sample critical points where the highest exposure might occur and should include an alarm to warn when exposure climbs greatly above the norm for that point. Hand monitoring with a portable instant indicating instrument will enable plant personnel to detect the source and to take immediate corrective action. Personnel monitoring should also be largely limited as above to the PVC plant. Competition will force manufacturers to reduce monomer content as much as possible, thereby reducing exposure potential in fabricating plants.

Some sequential monitoring in monomer plants is probably desirable to pick up leaks for prompt maintenance. Portable instant reading instruments could be used as an alternative. It is not necessary in fabricating plants.

In general, wherever personal monitoring is done it should be based on a reasonable statistical design so as to get the maximum data with the minimum waste of manpower. We must keep in mind that there are few trained workers capable of doing the kind of analytical work required and there will be many equally pressing calls on their time.

4. Medical program. A good medical program is always desirable. However, the specialized NIOSH liver function type of test should be reserved for PVC plants, and to a lesser extent VC plants. In any case, they should be limited to personnel having over 10 ppm TWA exposure. These tests are not good predictors of angiosarcoma. Much freedom should be given the local health personnel who are trained professionals. They have to deal with the total man.

   This medical surveillance program above should be part of an international long range research effort as proposed by Prof. Maltoni.

5. Medical and monitoring records as discussed above should be kept until the man dies, then transferred to a central group as discussed in the last paragraph under item 4 above. There should be provision for periodic review of the health data until about the year 2000 when it will be possible to determine whether changes made now have been successful in eliminating significant incidence of tumors due to VC.

6. Covered workers - those with TWA exposure greater than about 20 ppm. This will eliminate most fabricating plants and customers of their products.

7. Regulated areas - Workplaces covered by item 6.

8. Exposure level. I strongly suggest a TWA of 50 ppm with review in one and two years when the various studies will be coming to completion. My study of the Maltoni data on rats, the Tabershaw-Cooper and Dow's studies convince me that there is no scientific basis to predict that this level will result in undue risk.

Please call on me if I can be of help. We will present more data in our written report submitted at the hearing next week.

Sincerely,

Walter D. Harris

Walter D. Harris, Ph. D.
Corporate Industrial Toxicologist

WDH/mab

bcc: Mr. Wayne Brooks, ORC
Dr. Daniel Boyd, U.S. Dept. of Labor
R. J.Dowling
B. R. Leach
J. D. Forbes, M.D.
D. E. Dudrow
R. E. Lowell
Frank Ryan, RMA

Vinyl chloride

UNIROYAL, Inc.
Oxford Management & Research Center
Middlebury, Connecticut 06749

May 2, 1974

RE: EMERGENCY TEMPORARY STANDARD FOR EXPOSURE TO VINYL CHLORIDE - RELATION TO PVC PROCESSING PLANTS

On April 5, 1974 an Emergency Temporary Standard for exposure to vinyl chloride was promulgated by the Occupational Safety and Health Administration, U.S. Department of Labor, a copy of which is attached. This standard was considered by OSHA to be necessary to provide immediate adequate protection for workers exposed to vinyl chloride, following receipt of information that vinyl chloride was carcinogenic to both test animals and humans. It is expected that a proposed permanent standard will be published in the Federal Register in the near future which, following a time period for comments, hearings, reconsideration and revision, will be promulgated as a permanent OSHA standard.

The essential features of the emergency temporary standard as applicable to PVC fabricating plants are as follows:

1. The standard applies to any areas or operations where vinyl chloride is manufactured, reacted, processed and handled up to that point where the polymer or copolymer is in the form of a fabricated product.

2. No employee shall be exposed to a vinyl chloride concentration in excess of 50 parts per million at any time.

3. Monitoring

   (a) Both area and personnel monitoring are to be started by April 22, 1974.

   (b) Area or operator monitoring shall be carried out where vinyl chloride is manufactured, reacted, processed, packaged or stored to determine whether concentrations exceed 50 ppm.

   (c) Personnel monitoring is to be accomplished using a suitable collection device worn by the employee, and the samples collected analyzed by gas chromatography or other means of equivalent sensitivity.

   (d) The frequency of personnel monitoring shall be such that employees exposure at all representative jobs are monitored not less frequently than weekly until results for each job for three

RE: EMERGENCY TEMPORARY STANDARD

consecutive weeks are below 50 ppm. Thereafter, monitoring shall be not less than monthly. If monthly monitoring reveals concentrations in excess of 50 ppm, weekly monitoring is resumed until results for three consecutive weeks are again below 50 ppm.

4. Monitoring results must be recorded in writing, with records kept for at least 5 years and available for inspection and copying by OSHA representatives.

5. Each employee shall have access to records indicating his exposure.

6. Each employee shall be informed when his exposure exceeds 50 ppm and of corrective measures being taken.

7. (a) Where monitoring indicates vinyl chloride concentrations are in excess of 50 ppm, or whenever there is the likelihood of greater than usual release of vinyl chloride into the ambient air, as for example equipment ruptures, or when the work may reasonably be expected to release vinyl chloride in excess of 50 ppm, employees are required to wear air-supplied respirators or self-contained breathing apparatus.

   (b) At the same time, employers are required to apply feasible engineering or administrative controls to reduce airborne concentrations of vinyl chloride.

We have not as yet developed a formal program of personnel monitoring for the UNIROYAL Plants involved in the manufacture of PVC products, because of the lack of a reliable analytical method for the determination of any vinyl chloride released in the manufacturing processes. Personnel monitoring involves the use of activated charcoal tubes for collecting the sample, with vinyl chloride being absorbed on the charcoal. A problem has been encountered in desorbing or releasing the vinyl chloride from the charcoal, the desorbing solution then being analyzed by gas chromatographic means. The Analytical Laboratory at the Naugatuck Chemical Plant has been working on this problem, and feel they will have a suitable method in a very short time.



As soon as the Naugatuck Analytical Laboratory is satisfied as to the reliability of the method, we will be in contact with the plants involved in fabrication of PVC products, to assist in setting up a monitoring program for meeting compliance with the emergency temporary standard.

D. E. Dudrow
Corporate Manager
Safety & Plant Protection

DED/maz
Attachment

cc: A. J. Fontana
R. E. Lowell
J. D. Forbes, M.D.
W. D. Harris, Ph. D
L. F. Dieringer
J. Foster - Mishawaka