ROUTING SLIP

DATE: _____

TO J. E. Bowler

FOR:

Legal

- ☐ APPROVAL ☐ RETURN
- ☐ COMMENTS ☐ RETAIN
- ☒ INFORMATION
- ☐ ACTION
- ☐ SEE ME
- ☐ SIGNATURE

L. Powers

REMARKS:

RECEIVED

APR 23 1974

LEGAL DEPT.

FORWARD TO:

FROM:

[redacted]

[redacted]

File
ICD
Baton Rouge
OSHA

G. P. R.

APR 23 1974

JOSEPH E. KELLER
JEROME H. HECKMAN
CHARLES M. MEEHAN
WILLIAM H. BORGHESANI, 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
202 296-2700
CABLE ADDRESS "KELMAN"

April 15, 1974

TO: All Members of:

SPI Food, Drug and Cosmetic
Packaging Materials Committee;
General Polyvinyl Chloride Interest
Mailing List;
Ad Hoc Liquor Bottle Committee;
Plastic Pipe Institute
(Executive Board);
Plastic Bottle Institute
(Voting Representatives);
SPI Executive Committee;
SPI Public Affairs Committee

RE: Polyvinyl Chloride Prior-Sanctioned
Status, Proposed Rulemaking

Gentlemen:

To put it mildly, the past week has seen a continuing and somewhat intensifying concern over the entire vinyl chloride monomer and polyvinyl chloride resins problem. Again, it is difficult to encapsulate everything that is taking place but we shall try to continue to post you in as telegraphic a style as possible with a weekly letter. In this instance, we are actually sending two letters for reasons hereinafter explained. As far as indicated action is concerned, we ask that you pay particular attention to the separate letter being sent herewith. The reason for the separate letter is so that copies could be sent to the Food and Drug Administration thereby enabling us to comply with a request that we circulate all known contacts in an attempt to see that FDA gets information it believes needed as promptly as possible.

Taking the FDA situation first, although it may not really be the most critical in some respects, we are now seeing what amounts to something of a developing panic in bureaucratic circles. We can imagine how much pressure the Food and Drug Administration Staff is experiencing because we spent the better part of last week taking your PVC telephone calls ourselves. In addition, we know from our sources at FDA that it is receiving a multitude of calls from all sorts of industry representatives advising it about the ubiquitousness of the use of PVC, and the fact that any unduly restrictive action could create chaos. Just for example, we were told that one trade association chief executive advised the agency that if its regulatory efforts were not carefully considered, the entire country could begin suffering a protein shortage due to the shortage of appropriate alternative materials for the packaging of meat and other food products.

What all of this expression of concern has led to is an increase (perhaps not really necessary since the situation has been recognized as critical for some time) in FDA's feeling that it needs more information and should proceed as responsibly as possible. Nevertheless, the pressure from so-called consumer interests is intense.

In any event, the week's events led to our receiving something of a startling telephone call late Friday afternoon requesting that a select group of technical personnel from companies representing some sort of cross-section of interests in the use of PVC be called together for a meeting on Friday, April 19. A number of telephone conversations took place immediately thereafter. The fact is that we advised the FDA Staff we were anxious to cooperate but certainly could not select a group of no more than 40 persons for a meeting intended to develop broad-based technical data about the resins; food, drug and cosmetic packaging; and devices areas. Indeed, I informed our contacts on the Staff that were such a meeting called, we would need to have considerable additional notice, would be required by our

obligations to inform all of you, and that this would probably lead to FDA's being literally swamped with requests to attend any session held.

The net result was that Dr. Schaffner of the Office of Technology who is playing a leading role in overseeing the PVC question from the food, drug, cosmetic and device point of view has at least temporarily withdrawn from the meeting idea in favor of our sending out the enclosed letter. This is why you will note that copies of the letter have been directed to Dr. Schaffner, and Messrs. Ronk and McCowin who continue to have the assignment of trying to resolve the Food and Drug Administration situation.

Finally, I might point out that Mr. Ronk advises that FDA is still hopeful of publishing a Proposed Regulation in the Federal Register "in the next two or three weeks." The only other bit of information relating to FDA activity which might interest you is included in the attached reproduction of an HEW News Release dated April 3, but received here in the middle of last week.

Turning to the other PVC "fronts," as of now we consider the Occupational Safety and Health Administration (OSHA) problem the most critical. As you know from last week's letter, the temporary OSHA standards allow for a 50 ppm upper limit in the vinyl monomer and polyvinyl chloride production environments. There is now reason to believe that the ultimate limits will more closely follow the recommendations of the National Institute for Occupational Safety and Health (NIOSH) which call for a virtually zero tolerance. Some of you may not have seen the NIOSH recommendations so a copy of the March 11, 1974 version is enclosed.

During the course of this week meetings of vinyl monomer and PVC producers are scheduled so there will probably be more to report in this area in due course. Meanwhile, there is some concern that OSHA will be moving more promptly than had originally been anticipated with respect to final and much more stringent regulations. We would

prefer not to speculate unduly in this regard so we hope you will await further word from us on the subject without calling for our "guesstimates" as to what might happen.

In the realm of "in case you didn't see the items" and "for your information" reports, we are enclosing (1) a Washington Post article dated April 10 entitled "'Killer Chemicals' In Hair Spray?" and (2) a copy of a letter and extract of proceedings in Parliament graciously and alertly supplied to me by our associate counsel in the United Kingdom. These enclosures will probably be of some interest.

The Post article does not really contain anything new but will demonstrate the kind of publicity which is bound to give rise to increasing pressures.

The report from Mr. Gamon will simply indicate to you that the British, as might be anticipated, are being a good bit more calm about the problem than are some officials here and elsewhere in the world. You might even find the excerpt from the Parliamentary report helpful in providing some reassurance to your contacts.

It should again be recalled that, as of now, PVC remains prior sanctioned for all uses in this country and is likely to remain so during the time it takes for the Food and Drug Administration to issue its expected proposal, receive comments and data thereon, perhaps even hold a legislative-type hearing (another suggestion that came up when the idea of a "select group" meeting was thrust upon us suddenly last Friday evening), and finalized Rule-making is adopted.

We will continue to be in touch as matters proceed and will also do our best to be responsive to your inquiries in the meantime. We do want to urge that as many of you as can possibly do so respond to the call for help set forth in our separate letter, and that if you do send

data directly to FDA, you supply us with copies of anything submitted to the extent that this is feasible.

Cordially yours,

Jerome H. Stockman

Enclosures

JOSEPH E. KELLER
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TO: All Members of:

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(Executive Board);
Plastic Bottle Division
(Voting Representatives);
SPI Executive Committee;
SPI Public Affairs Committee

RE: Prior Sanctioned PVC Status;
Proposed Rulemaking; Additional
Analytical Information Request

Gentlemen:

On Friday, April 12, 1974 we delivered to the Food and Drug Administration on behalf of The Society of the Plastics Industry, Inc. additional analytical information supplied to us by M & T Chemicals, Inc.; the data was designed to aid FDA in its quest for suitable methodology to specify in its anticipated rulemaking proposal on PVC.

During the course of discussions about the data, the Food and Drug Administration indicated its urgent need for additional information regarding a number of related aspects of the polyvinyl chloride packaging materials matter. While the FDA staff members did not "demand" this information, it was repeatedly urged that the information be provided promptly so that the Agency will not find it necessary to use its powers to "demand" on a company-by-company basis. This letter, therefore,

should be considered a most urgent request for action by all interested or involved parties.

The basic FDA position, as we understand it, is that it needs the requested information in order to soundly evaluate the extent of the public health problem. With facts at hand, FDA can react responsively suiting its response to the actual need. Without facts, its response will have to be extremely broad and probably severely stringent to encompass any possible or conceivable hazard.

SPI has provided gas chromatographic analytical methods which were believed to be suitable for regulatory purposes and is now providing supplemental amendments to improve one of the methods in line with FDA requirements. However, the Food and Drug Administration has received indications that other analytical procedures differing in the nature of the column packing detector, or even based on different analytical principles are being used to determine vinyl monomer either as residues in polyvinyl chloride resins and plastic materials, or as a migrant into foods and food simulating solvents. The first FDA request is that all those doing analytical work involving vinyl chloride monomer submit the procedures being used to the Food and Drug Administration as a part of the write-up of any such procedures; chromatograms and calibration curves should be included so that FDA personnel can independently assess the utility of the analytical method. The written procedures should include all necessary manipulative details that have been developed to minimize or eliminate loss of vinyl chloride monomer from the calibration standards of the samples being analyzed; and a full description of the instrumentation including all necessary instrument operating parameters such as column packings, temperatures, gas flows, sample sizes, and instrument settings to the extent that these influence the signal intensity. Further, the chromatograms should be adequately labeled to indicate the point of sample injection, a time scale, the sample identification, the sample size, and instrument settings that may affect the signal height.

A second type of data requested by the Food and Drug Administration concerns the residual monomer level in typical PVC materials; this concerns not only food contact

materials including potable water pipe, but also drug and cosmetic materials. In particular, the Food and Drug Administration wants to know what the residual monomer levels are in the rigid and/or flexible packaging materials in the form in which they contact food or fluids that enter the body. For example, this means the residual monomer content of flexible film used as a food wrap, of fused plastisol used as gaskets or cap liners for closures, of vinyl can enamels after application and baking, of PVC pipe (both new and old), and of bottles. In addition, one might say especially, the Food and Drug Administration urgently needs residual monomer data in PVC tubing used in milk handling as in milking machines, and in PVC compounds (tubing and sheet material) used in medical applications such as blood bags, IV sets and any other medical application (drug or device) where there is any reasonable possibility that residual monomer (if any) from the PVC item might enter the human body by any route. These data should be submitted along with the methodology employed, complete with calibration and validation data, and properly labeled chromatograms.

The third area on which the Food and Drug Administration needs specific information pertains to monomer migration. Here it is requesting information on monomer migration from the various classes of fabricated products discussed in the preceding paragraph into appropriate foods, food simulating solvents, or medical fluids. Of particular interest to the Food and Drug Administration is specific information regarding the migration of vinyl chloride monomer into milk and into medical or body fluids which may have contacted PVC fabricated products. In supplying this information, the reports should include a description of the analytical procedures used, calibration and validation data, and typical chromatograms obtained during calibration and during analysis itself.

You will all recognize that summaries of some of the type of information requested have already been submitted to the Food and Drug Administration. What it seeks now is specific information from each manufacturer concerning its products so that some type of overall assessment can be made of whether there now exists a public health problem with respect to monomer migration to foods, drugs, or cosmetics and whether any of these areas would require special

regulatory attention either immediately or in the future. The Food and Drug Administration also recognizes that in some cases complete information is not available but it would rather have fragmentary preliminary information now and obtain complete details and data later than wait for polished reports at some time in the future.

It may be of interest to you to know that we are distributing this letter as broadly as possible at the specific request of the Food and Drug Administration. Before making this request to us, the Food and Drug Administration had originally planned to convene a meeting on short notice to which it planned to invite fifteen or twenty of the "leading" companies in various aspects of the industry including some resin producers, compounders, manufacturers of bottles, film and sheeting, tubing; and users of such products such as food packages and several drug firms. The Food and Drug Administration requested our assistance in compiling such a list and we informed it that we were utterly unable to make a judgement since so many companies are vitally interested in the matter. Rather than call such a meeting, therefore, the Food and Drug Administration decided to try to obtain the information it needed by means of this letter and by directly contacting other companies who might be involved, and yet not be on our extensive circulating list.

Those of you who wish to respond to the foregoing request for information should send your reports either to us for forwarding to the Food and Drug Administration or directly to:

Mr. Gerad L. McCowin
Division of Food and
Color Additives
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Cordially yours,

Jerome H. Stecklum

cc: Dr. R. Schaffner
Director, Office of
Food Technology, FDA

Mr. R. Ronk
Director, Division of Food
and Color Additives, FDA

Mr. G. McCowin
Assistant to Director
Division of Food and
Color Additives, FDA

Dr. C. Jelinek
Director, Division of
Chemical Technology, FDA

HEW NEWS

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

74-23
FOR IMMEDIATE RELEASE
April 3, 1974

(Food and Drug Administration)
BERRETH--(301)--443-3285
(Home)--(301)--869-1795

The Food and Drug Administration today initiated action to insure that vinyl chloride is not used in any aerosolized food, drug or cosmetic product.

Vinyl chloride is a gaseous substance used to produce a type of plastic called polyvinyl chloride (PVC). It has also been used as the propellant in aerosol products. The substance has been associated with ten cases of a rare liver cancer among U.S. industrial workers exposed to the chemical over extended periods of time.

Use of vinyl chloride in aerosol products regulated by FDA has been minimal. FDA is unaware of any past or present use of the substance in aerosolized food products. Such use would require prior FDA approval, and no such approvals have been given.

FDA is also unaware of any present use in aerosolized cosmetic or drug products. The Agency has, however, learned of two cosmetic manufacturers and one drug manufacturer who used vinyl chloride as a propellant before June of 1973. Although little is likely to remain on the market, FDA is requesting the manufacturers to recall the products as a precautionary measure. (Specific details on any products being recalled will be provided as they are developed and published on FDA's Weekly List of Recalls.)

MORE

FDA will use the Drug Listing Act of 1972 to require manufacturers of drugs to provide information on any aerosolized drug products which contain vinyl chloride. The Agency has also written to all known cosmetic manufacturers requesting them to identify products which contain the substance. Recalls will be requested if necessary.

The use of PVC as a food packaging material has been under active FDA investigation since May of 1973, when the Agency learned that VC monomer was leaching from plastic liquor bottles into the liquor. FDA immediately proposed to ban PVC packaging of alcohol-containing food or beverages and, concurrently, the Bureau of Alcohol, Tobacco and Firearms ended the experimental use of such bottles for packaging liquor.

FDA is currently reviewing data and comments which have been submitted in response to the May proposal. The Agency is also looking at other foods packaged in PVC containers to determine if a similar leaching problem exists.

The FDA actions announced today will formally be issued in the FEDERAL REGISTER next week.

####

RECOMMENDED OCCUPATIONAL HEALTH STANDARD

FOR

THE MANUFACTURE OF SYNTHETIC POLYMER FROM

VINYL CHLORIDE

MARCH 11, 1974

U. S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Center for Disease Control
National Institute for Occupational Safety and Health

1. SCOPE AND APPLICATION

This standard regulates the manufacture of synthetic polymer from vinyl chloride (chloroethene, Chemical Abstracts Registry No. 75014), in order to protect the health and safety of workers.

Vinyl chloride also known as vinyl chloride monomer (VCM), chloroethylene and chloroethene, is a colorless sweet smelling gas at ordinary temperature and pressure and has a boiling and melting point at one atmosphere of -13.8°C, and -153.71°C, respectively. Its chemical formula is CH_2CHCl and it has a molecular weight of 62.50. Although noncorrosive at normal atmospheric temperatures, in contact with water and at elevated temperatures it accelerates the corrosion of iron and steel. Of considerable concern is the fact that vinyl chloride is easily ignited and has a lower and upper explosive limit of 3.6% and 26.4%, respectively.

2. DEFINITIONS

For the purpose of this standard:

a. "Assistant Secretary" means the Assistant Secretary for Occupational Safety and Health, U.S. Department of Labor or any person directed by him.

b. "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.

c. "Authorized employee" means an employee whose duties require him to be in the regulated area and who has been specifically assigned by the employer.

d. "Detectable levels" means the determination that airborne concentrations of vinyl chloride are in excess of the limit of sensitivity of the sampling and analytical method recommended by the Director.

e. "Clean change room" means a room where employees put on clean clothing; clean change room shall be contiguous to and have an entry from a shower room, when the shower room facilities are otherwise required in this standard.

f. "Closed container" is any container which is used to prevent the physical contact of employees with material containing vinyl chloride monomer.

g. "Closed system" means an operation involving vinyl chloride where containment prevents the release of vinyl chloride into regulated areas, nonregulated areas, or the external environment.

h. "Contaminated" refers to detectable levels of vinyl chloride monomer.

i. "Decontamination" means the inactivation of vinyl chloride to less than detectable levels or its safe disposal.

j. "Disposal" means the safe removal of vinyl chloride from the work environment.

k. "Emergency" means an unforeseen circumstance or set of circumstances, such as a ruptured transfer line, resulting in the release of vinyl chloride sufficient to produce acute symptoms among workers exposed or having contact with the vinyl chloride.

l. "External environment" means any environment external to regulated and nonregulated areas.

m. "Regulated area" means an area where entry to and exit from a vinyl chloride workplace is restricted and controlled.

n. "Nonregulated area" means any area under the control of the employer where entry and exit is neither restricted nor controlled.

o. "Protective clothing" means clothing designed to protect an employee against contact with or exposure to vinyl chloride.

p. "Waste resin" means any resin or other vinyl chloride reaction product which has been removed from vessels during clean-up operations, or which has been collected as a result of in-plant housekeeping operations.

3. REQUIREMENTS FOR REGULATED AREAS

A regulated area shall be established where synthetic resins containing vinyl chloride are manufactured. These regulated areas shall include but are not limited to vinyl chloride loading or unloading operations, storage, and transfer facilities; synthetic resin polymerization processes and operations; and resin handling, compounding, packaging and storage areas. Access shall be restricted to authorized employees only. All such regulated areas shall be controlled in accordance with the following requirements.

a. Routine Operations

(i) Initial concentration of vinyl chloride in all regulated areas shall be determined by performing air measurements at strategic sampling points under normal operating conditions. These initial sampling points must be selected by a professional industrial hygienist and will serve as monitoring locations for future environmental measurements.

The sampling pattern shall be adequate to represent the environment of the controlled area.

(ii) Where detectable levels of vinyl chloride are measured, a Control Plan to reduce such levels shall be developed and implemented. The Plan shall consist not only of establishing goals for reducing vinyl chloride levels by designing and introducing engineering and process controls, but shall also identify plans for developing additional (healthful) work practices. Target dates shall be established for all goals and the Plan must be updated at least on an annual basis. Copies of the Control Plan shall be posted in all regulated areas and be provided to all authorized employees.

(iii) There shall be periodic tests for process or equipment leaks and for emission of vinyl chloride which may result from work practices. The frequency of these tests shall be such as to insure the integrity of equipment, adherence to proper work practices, and to determine achievement of the goals of the Control Plan. Tests shall be performed at each sampling point at least daily or more frequently if concentrations of vinyl chloride are in excess of those established in the Plan. When such levels are exceeded, additional samples to identify sources of contamination shall be taken. Results of all such tests shall be made available to authorized employees in such a manner as to evaluate achievement of goals contained in the Control Plan.

(iv) Until exposures to vinyl chloride are reduced below detectable levels, employees entering any regulated area shall be provided with and required to wear and use a full-face, supplied air respirator, of the continuous flow or pressure demand type in accordance with §1910.134.

(v) In operations involving loading or unloading vinyl chloride monomer from tank cars, trucks, barges, or other conveyance equipment, each transfer line and each vapor-equalizing line shall be equipped with vent connections permitting, at the completion of the transfer, pressure to be vented and the hose purged with an inert gas in such a manner to preclude any employee exposure. Specific and detailed transfer procedures shall be developed and provided to involved employees in written form.

(vi) Employees shall be provided with and required to wear, clean, full-body protective clothing (smocks, coveralls, or long-sleeved shirt and pants), and gloves prior to entering the regulated area.

(vii) Prior to each exit from a regulated area, employees shall be required to remove and leave protective clothing and equipment at the point of exit and at the last exit of the day, to place used clothing and

equipment in impervious containers at the point of exit for purposes of decontamination or disposal. The contents of such impervious containers shall be identified as required under paragraph c(2)(i) of this standard.

b. Reactor and Vessel Entry

(i) A reactor and vessel entry procedure shall be developed and provided to involved employees in written form. Employees shall be familiarized with the procedure and shall be trained and rehearsed in the techniques provided for in the procedure. Emphasis shall not only be placed on concern for potential exposure to vinyl chloride but shall also include appropriate precautions for entry into confined spaces.

(ii) Techniques shall be developed and applied to minimize to the maximal practicable extent employee exposure to vinyl chloride when opening any closed vessel. Examples of effective methods are the application of heat or suction to the vessel prior to opening, or use of sufficient exhaust ventilation around the vessel. Where operations such as cleaning or maintenance conducted inside an open vessel could result in the liberation of vinyl chloride, suitable procedures such as exhaust ventilation shall be developed and implemented to insure that vinyl chloride is not released into the general work environment.

(iii) Exhaust air shall not be discharged to regulated areas, nonregulated areas, or the external environment unless decontaminated.

(iv) All piping to and from the vessel shall be blanked or otherwise isolated prior to entry.

(v) Employees entering the reactor or vessel shall be provided with and required to wear and use a full-face, supplied air respirator, of the continuous flow or pressure demand type in accordance with §1910.134.

(vi) Employees entering the reactor or vessel where levels of vinyl chloride are monitored and are found to not exceed ambient levels external to the vessel shall be provided with and required to wear clean, full body protective clothing (coveralls or long-sleeved shirt and pants), gloves, footwear or foot coverings, and head covering. Where vessel levels are in excess of ambient levels, employees shall instead be provided with and required to wear impervious clothing to prevent skin contact of vinyl chloride or other materials containing vinyl chloride.

(vii) After each exit from the reactor or vessel, employees shall be required to remove and leave protective clothing and equipment at a designated point in the regulated area, and at the end of each work shift to place used clothing and equipment in impervious but vented containers for the purpose of decontamination or disposal. The contents of such impervious containers shall be identified as required under paragraph e(2)(i) of this standard.

(viii) Employees engaged in reactor cleaning or other operations involving vessel entry shall shower at the end of the work shift.

c. Maintenance and Decontamination Activities

(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. Because vinyl chloride is a gas at normal temperatures, waste materials, equipment, and other sources of the monomer in closed containers, shall 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.

(ii) Waste resins or other materials contaminated with vinyl chloride shall be placed in closed containers identified as required under paragraphs e(2)(i) or (ii) of this standard.

(iii) Appropriate procedures shall be developed and implemented for the decontamination and/or dispoal of all such waste material.

(iv) In clean-up of leaks or spills, maintenance or repair operations on contaminated systems or equipment, or any operation involving work where direct contact with vinyl chloride monomer could result, each authorized employee involved in such operations shall be provided with and required to wear clean, impervious garments, including gloves, boots and continuous air supplied hoods in accordance with §1910.134, be decontaminated before removing the protective garments and hood; and be required to shower upon removing the protective garments and hood.

d. General Regulated Area Requirements

1. Employee identification.

A daily roster of employees entering regulated areas shall be

established and maintained. The rosters or a summary of the roster shall be retained for a minimum period of 20 years by the employer or successors thereto. The rosters and/or summaries shall be provided upon request to authorized representatives of the Assistant Secretary and the Director. In the event that the employer ceases business without a successor, rosters shall be forwarded by registered mail to the Director.

2. Emergencies.

In an emergency, immediate measures including but not limited to the requirements of subdivisions (i), (ii), (iii), (iv), and (v) of this subparagraph shall be implemented.

(i) The potentially affected area shall be evacuated as soon as the existence of the emergency has been determined.

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

(iii) Special medical surveillance by a physician shall be instituted within 24-hours for employees present in the potentially affected area at the time of the emergency. A report of the medical surveillance and any treatment shall be included in the incident report, in accordance with paragraph (g)(3) of this standard.

(iv) 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.

(v) An incident report on the emergency shall be reported as provided in paragraph (g)(3) of this standard.

3. Hygiene facilities and practices.

(i) Storage or consumption of food, storage or use of containers of beverages, storage or application of cosmetics, smoking, storage of smoking materials, tobacco products or other products for chewing, or the chewing of such products, are prohibited in regulated areas.

(ii) Where employees wear protective clothing and equipment clean change rooms shall be provided, in accordance with §1910.141(e)(3).

(iii) Where employees are required by this standard to wash, washing facilities shall be provided in accordance with §1910.141(d)(1) and (2)(ii) through (vii).

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

4. Contamination control.

(i) Regulated areas, except for outdoor systems, shall be maintained under negative pressure with respect to nonregulated areas. Local exhaust ventilation may be used to satisfy this requirement. Clean tempered makeup air shall replace air removed. Exhaust air shall not be discharged to regulated areas, nonregulated areas, or the external environment unless decontaminated.

(ii) Any equipment, material, or other item taken into or removed from a regulated area shall be done so in a manner that does not cause contamination in nonregulated areas or the external environment.

(iii) Decontamination procedures shall be established and implemented to remove vinyl chloride from the surfaces of materials, equipment and the decontamination facility.

e. Signs, Information, and Training

1. Signs.

(i) Entrances to regulated areas shall be posted with signs bearing the legend.

CANCER-SUSPECT AGENT AREA

AUTHORIZED PERSONNEL ONLY

(ii) Entrances to regulated areas containing operations covered in paragraph 3(c) of this standard shall be posted with signs bearing the legend:

CANCER-SUSPECT AGENT IN THIS AREA. IMPERVIOUS SUIT INCLUDING GLOVES, BOOTS, AND AIR-SUPPLIED HOOD REQUIRED AT ALL TIMES. AUTHORIZED PERSONNEL ONLY.

2. Container contents identification.

(i) Containers of waste or other materials contaminated with vinyl chloride shall be labelled as follows.

VINYL CHLORIDE CONTAMINATED MATERIAL

CANCER SUSPECT AGENT

DISPOSE OF OR DECONTAMINATE USING

APPROVED PROCEDURES

(ii) Containers of synthetic polymers made from vinyl chloride shall be labelled as follows.

SYNTHETIC VINYL CHLORIDE POLYMER

VINYL CHLORIDE IS A CANCER SUSPECT AGENT

POLYMER CONTAINS __*% BY WEIGHT UNREACTED

VINYL CHLORIDE

*(To be analytically determined by manufacturer and appropriate value entered on labels.)

(iii) Containers of vinyl chloride shall be labelled as follows.

V I N Y L C H L O R I D E

DANGER! EXTREMELY FLAMMABLE LIQUID AND GAS UNDER PRESSURE

CANCER SUSPECT AGENT

HARMFUL IF INHALED

MAY POLYMERIZE VIOLENTLY UNDER FIRE CONDITIONS
OR LOSS OR REMOVAL OF INHIBITOR

Keep away from heat, sparks, and open flame.
Keep container closed.
Use with adequate ventilation.
Avoid breathing vapor.
Avoid contact with skin.
Keep cylinder out of sun and away from heat.
Container should be grounded when being emptied.
Never drop cylinder.

FIRST AID: If inhaled, remove to fresh air. If not breathing give artificial respiration, preferably mouth-to-mouth. If breathing is difficult, give oxygen. Call a physician.

In case of:

Fire - Use water spray, dry chemical, or CO_2.

Spill or Leak - For small spills, evacuate area and permit to evaporate. For large spills or leaks, evacuate area. Dike or flush to ground and let evaporate. Do not flush to sewer because of explosion hazard.

3. Training and indoctrination.

(i) Each employee, prior to being authorized to enter a regulated area, shall receive a training and indoctrination program including, but not necessarily limited to:

(a) The nature of the carcinogenic hazards of vinyl chloride monomer, including local and systemic toxicity;

(b) The specific nature of the operation involving vinyl chloride monomer which could result in exposure;

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

(d) The purpose for and application of decontamination practices and purposes;

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

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

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

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

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

(ii) Specific emergency procedures shall be prescribed, and posted, and employees shall be familiarized with their terms, and rehearsed in their application.

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

f. Environmental Monitoring and Recordkeeping

(i) Environmental concentrations of vinyl chloride shall be determined through the use of methods for sampling and analysis

recommended by the Director or by methods of at least equal sensitivity.

(ii) Employees or their representatives shall be provided with the opportunity to observe environmental monitoring activities and shall have access to the results.

(iii) Complete and accurate records of all environmental measurements shall be maintained for at least 20 years by the employer or successors thereto and shall be provided upon request to authorized representatives of the Assistant Secretary or the Director.

g. Reports

1. Operations.

Within 60 days the following information shall be reported in writing to the appropriate Occupational Safety and Health Administration (OSHA) Area Director. Any change in such information shall be similarily reported within 15 calendar days of such change.

(i) A brief description and in-plant location of the area(s) regulated and the address of each regulated area.

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

(iii) A copy of the Control Plan as developed under paragraph 3(a)(ii).

(2) Environmental Measurements.

On a semi-annual basis the results of measurements taken at strategic sampling points, presented in such a manner as to identify achievement of goals established in the Control Plan, shall be reported in writing to the appropriate OSHA Area Director.

(3) Incidents.

Incidents which result in the release of vinyl chloride monomer into any area where employees may be potentially exposed shall be reported in accordance with this subparagraph.

(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 appropriate OSHA Area Director.,

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

(a) A specification of the amount of material released, the amount of time involved, and an explanation of the procedure used in determining this figure;

(b) A description of the area involved, and the extent of known and possible employee exposure and area contamination;

(c) A report of 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.

h. Medical Surveillance

(To be provided by NIOSH as soon as possible.)

'Killer Chemicals' In Hair Spray?

H. William Rogers

Special to The Washington Post

LOUISVILLE, Ky.—An industrial killer, both proven and potential, is making headlines here this week and investigators believe the danger may have spread across the nation to such unlikely places as hair salons and family medicine chests.

Clairol, Inc. recalled about 100,000 cans of aerosol hair spray, those labeled Summer Blonde Aerosol Hair Spray and Miss Clairol Hair Spray at the request of the Food and Drug Administration which wants them destroyed.

The FDA request linked the hair sprays to the grimy, clangorous industrial plants here and elsewhere that manufacture what some workers call the "killer chemical," vinyl chloride.

Clairol spokesmen say vinyl chloride was used in the aerosol propellant of the two brands recalled for about four years but was discontinued last summer. Some of the 100,000 cans, however, contain it.

So far, at least 10 deaths have been linked to vinyl chloride. All have been workers who died of angiosarcoma — a rare form of liver cancer — after continued exposure to the chemical in plants that produce it for plastics, cosmetics, insecticides and other household products.

Clairol maintains the chance of anyone being harmed by using the hair spray under normal conditions is "extremely remote." But FDA apparently isn't so sure and is worred about other products as well.

Five of the dead workers were members of the vinyl cloride production unit at the B. F. Goodrich Co. plant here in Louisville's sprawling, fume-ridden industrial complex called Rubbertown.

Almost by coincidence, this porter was touring the fa-l plant area when the news of the Clairol recall came.

With hard hat and gas mask, accompanied by the general foreman of the production unit, the reporter found huge vats, scurrying workmen (possibly scurrying because the foreman was there with a stranger taking notes) and an earnest effort to beat the "killer chemical."

The vats, which are sunken into the floor below from the third-floor bewildering array of metal pipes, conduits and other industrial whatnot, are either "working" or being cleaned.

The general foreman, an incongruously dapper (even in his hard hat and gas mask) towering commander who knew his men by their first names, went to some lengths to describe the principal safety device.

That device is an elaborate monitoring system, using two sets of electronic equipment.

An electronically controlled graph, not unlike that of a lie-detector, registered the offensive parts of vinyl cloride in gas form in the air.

Conventional wisdom is that anything up to 50 parts per million is satisfactory.

On this day, the highest reading on the graph among the five working vats was 18. The rest were much lower.

The foreman, R.S. Kinnamon, insists that his instruments provide complete safety.

What happens if the graph goes higher?

Once again, conventional wisdom:

Leave—and leave quickly.

Kinnamon commented:

"We're a lot better off today.

He noted, as have other Goodrich officials, that the problem—or tragedy—is industry-wide, not confined to the Goodrich operations.

(For example, a chemical worker at the Goodyear Tire & Rubber Co. plant in Niagara Falls, N.Y., died in 1961 of the same kind of liver cancer that killed the five Goodrich employees here in Louisville. This was not known until 1974.)

But Goodrich seems to be taking the lead in funding research that, in the customary officialese by the recipients of the grant, "affords the opportunity to serve our

See RECALL, B3, Col. 7

THE WASHINGTON POST
April 10, 1974

Hair Spray Recalled

RECALL, From B1

community by bringing to bear our already-existing scientific expertise and research methods in regard to the apparent occupational health problem that has developed here . . ."

The tab, so far, to Goodrich: $300,000.

The researchers at the University of Louisville, headed by Dr. Charles Kupchella, are careful about public announcements on the project.

For one thing, both company and other sources point out that vynil cloride has nothing to do with the production of Goodrich tires. VC, as the plant people call it, is the raw material, or base, for products ranging through tectiles and plastics and, if a layman's view may be permitted, just about everything else.

The description of "just about everything else" includes, of course, those hair sprays just now taken off the market.

Meanwhile, the research continues ("it is conceivable that this program would lead to expanded medical studies on angiosarcoma and other liver diseases, for which broader, additional support from various sources would be sought, as necessary").

Meanwhile, production of vynil choride continues in this country and in most other industrialized nations —notably West Germany and Japan.

Also meanwhile, just here in Louisville, two more men —both Goodrich workers— have been diagnosed as victims of the rare liver cancer.

SHERWOOD & [redacted].

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QUEEN ANNE'S CHAMBERS,
41, TOTHILL STREET,
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LONDON, SW1H 9LG.

8th April, 1974.

Dear Jerry,

It is sometime since I was in touch with you and I trust that life is treating you kindly. On looking at the official report of proceedings in Parliament the other day I noticed the report of a question and answer which I thought might conceivably be of interest to you. In case it is I enclose the relevant extract from Column 409 of the Written Answers to questions appended to the House of Commons Hansard for 4th April.

With best wishes,

Yours sincerely,

Hugh

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U.S.A.

Mr. Freud asked the Minister of Agriculture, Fisheries and Food if, in his negotiations with Great Britain's partners in the EEC, he will seek to ensure that a guaranteed price for beef becomes a feature of the common agricultural policy.

Mr. Peart: The United Kingdom will certainly aim to ensure that the common agricultural policy for beef includes features which ensure adequate returns to beef producers.

Food Additives and Contaminants

28. **Mrs. Joyce Butler** asked the Minister of Agriculture, Fisheries and Food what are the terms of reference of the food additives and contaminants review of the use of PVC (polyvinyl chloride) in food packaging; and what restriction is being put on such use while the results of the study are awaited.

Mr. Moyle: My Ministry's scientists put in hand a study of monomers in food and drink from PVC early in 1973 in the light of information from the United State of America. The results have been submitted to the Food Additives and Contaminants Committee which considers that at the tiny levels at which these monomers are present, and in view of the lack of evidence of a hazard to health through ingestion, there is no need to restrict the use of PVC. The matter is, however, being kept under review.

Glasshouse Producers

29. **Mr. Wiggin** asked the Minister of Agriculture, Fisheries and Food if he will make a further statement on his consideration of the present financial difficulties of glasshouse producers brought on by the increase in the price of fuel oil.

Mr. Moyle: I would refer the hon. Member to the reply given on 3rd April to my hon. Friend the Member for Harlow (Mr. Newens).

31. **Mr. Wells** asked the Minister of Agriculture, Fisheries and Food if he is aware of the financial difficulties of the British glasshouse industry; and if he will seek to obtain the findings of the recent inquiry into allegations of unfair trading by Dutch and German growers who are receiving fuel subsidies, and request permission to publish them.

Mr. Moyle: We are considering the effects of increased prices for fuel oils on the financial position of the British glasshouse industry but we have no knowledge of the specific inquiry to which the hon. Member refers.

Common Agricultural Policy

30. **Mr. Marten** asked the Minister of Agriculture, Fisheries and Food if he will make a statement on reform of the CAP.

Mr. Buchan: A number of changes in the methods of support have been agreed as part of the decisions on EEC farm prices reached by the Council of Ministers on 23rd March. The Council agreed that the review of the common agricultural policy should continue.

Barley and Pig Prices

32. **Sir P. Bryan** asked the Minister of Agriculture, Fisheries and Food if he will give figures for the average price of barley now being paid in other EEC countries and the price paid per live score to pig producers in those countries.

Mr. Buchan: The following is the information:

BARLEY AND PIG PRICES IN CERTAIN EEC COUNTRIES

Country	*Barley prices £ per long ton**	*Average pig prices £ per score deadweight†*
Denmark ...	n.a.	4·84
Germany	63·74	5·34
France	53·54	5·00
Netherlands ...	61·62	4·72

Note: All prices converted from national currencies at spot rates.

* Barley prices come from HGCA Weekly Bulletin and are prices delivered to selected market centres in week ending 20th March.

† Liveweight pig prices are not readily available. Prices shown are for grade II pigs in week ending 17th March.

Wheat

33. **Mr. Charles Morrison** asked the Minister of Agriculture, Fisheries and Food if he will take steps to encourage the production of bread wheat in the United Kingdom.

Mr. Buchan: British wheat now constitutes 54 per cent. of all flours compared with 28 per cent. in 1970-71. I