

MANUFACTURING CHEMISTS ASSOCIATION

1825 CONNECTICUT AVENUE, N.W. WASHINGTON, D.C. 20009 (202) 483-6126

A K

MAY

May 2, 1974

To: MANAGEMENT CONTACTS OF COMPANIES SUPPORTING THE
VINYL CHLORIDE RESEARCH PROGRAM
TECHNICAL TASK GROUP ON VINYL CHLORIDE RESEARCH

Subject: NIOSH Request for Proposal for Study of
Vinyl Chloride Exposures

Gentlemen:

Enclosed herewith are the Statement of Work and Scope of Work sections of a request for proposal (No. CDC-99-OSH-128(4)) issued by NIOSH last March 28, and just now called to my attention. This material is being distributed for your information, so that you may be prepared to handle contractor visits should they select one or more of your plants for study.

Sincerely,



Kenneth D. Johnson, Ph.D.

Secretary -

Technical Task Group on Vinyl
Chloride Research

KDJ:mb

Attachment

cc : Mr. A. W. Barnes
D. P. Duffield, M.D.
Dr. Tiziano Garlanda

ASI 000017865

5/2/74

STATEMENT OF WORKA. Background and Purpose

Information recently has been made available to the National Institute for Occupational Safety and Health (NIOSH) that indicates a serious health problem potentially exists in workers involved with the polymerization of vinyl chloride to polyvinyl chloride and polyvinyl chloride copolymers. Preliminary mortality information concerning one vinyl chloride polymerization plant has revealed there is a definite excess of deaths due to angiosarcoma of the liver in workers that have been involved with this processing.

It has been reported by Imperial Chemical Industries of Great Britain that angiosarcomas of the liver develop in animals exposed to vinyl chloride. Since vinyl chloride is definitely present in the environs of the plant mentioned above, vinyl chloride has been postulated to be an etiologic agent in the above mentioned excess employee deaths.

Since there is a large work force involved with vinyl chloride polymerization processing, NIOSH immediately initiated an extensive epidemiological investigation (including environmental surveys) into vinyl chloride polymerization operations and workers thereof. Vinyl chloride exposures, of course, also can occur in the production of the monomer and may occur in the processing of the polyvinyl chloride and its copolymers and during the commercial and industrial use of these polymers. Because these polymers have widespread use and there is potential for quite a large number of persons to be exposed to vinyl chloride, in addition to those people working in polymerization operations, there is a need to document the extent of vinyl chloride exposures in operations other than polymerization processing.

The purpose of this contract is to document past and present worker exposures to vinyl chloride during (1) the monomer production and the (2) processing of polyvinyl chloride and polyvinyl chloride copolymers. In addition to documenting worker exposures to vinyl chloride, information on work practices, environmental control procedures, industrial hygiene practices and worker exposures to other known liver toxins also will be documented. These data will be utilized to ascertain the extent of worker exposures to vinyl chloride and possibly other liver toxins so that the possible health effects impact in the industry can be determined and appropriate priorities for corrective measures, if needed, can be set. If vinyl chloride exposures are considered to be significant in these areas, then a very critical look at possible general exposures will be made.

ASI 000017866

Enclosure 1

B. Scope of Work

1. The Contractor shall furnish the necessary personnel, material, services, facilities, and otherwise do all things necessary for or incident to the performance of work set forth herein. Specifically, the Contractor shall perform the following:

Task I. Vinyl Chloride Monomer Production

There are 15 plants in the United States that produce vinyl chloride monomer according to NIOSH information (Attachment A). From these 15 plants, and any other plants that the contractor identifies, three plants shall be selected for on-site environmental/industrial hygiene surveys. Within 90 days of the initiation of the contract, the contractor shall present to the project officer (s) the list of vinyl chloride monomer plants and polymer processing plants that have been chosen for the environmental/industrial hygiene surveys. This presentation shall include the basis for the selection. The actual surveys shall not commence until this information has been reviewed and approved by the project officer (s). Maximum review time shall be five working days. The criteria for selection shall include, but not be limited to: (1) information gained from preliminary site visits; (2) information gained from literature searches; (3) information gained from personal contacts; (4) the representativeness of the plants to industrywide operations; (5) the plants having the greatest potential for work exposure to vinyl chloride; (6) the plants having the greatest gradient of worker exposures to vinyl chloride; (7) the availability of historical inplant air measurements of vinyl chloride; and (8) the plants having the longest history of vinyl chloride monomer production.

The surveys at the selected three plants shall consist of documenting past and present worker exposures to vinyl chloride and past and present work practices, environmental control procedures and industrial hygiene practices that involve the reduction of worker exposures to vinyl chloride. At a minimum, the following specific information shall be obtained and/or constructed: (1) a general description of the vinyl chloride monomer processing operation; (2) 8-hour daily time-weighted average exposures (TWAs) of vinyl chloride for each different job-type/job-operation in the monomer processing area, including a specific job description for each of the job-types; (3) general area (stationary) samples of vinyl chloride in areas of suspected high concentrations; (4) raw material and product lists and quantities thereof that relate to the past and present vinyl chloride levels; (5) ventilation design and ventilation measurements, including documentation of dates of ventilation changes and the extent of changes and how they relate to past and present vinyl chloride levels; (6) documentation of past and present environmental control procedures and work practices that have been instituted to lower vinyl chloride levels and how they relate to past and present vinyl chloride levels; (7) photographs, sketches, etc. to document existing conditions; and (8) documentation of past and present industrial hygiene practices, including utilization of protective clothing (i.e. type, frequency of change, laundering practices, etc.), protective devices (i.e., respirator-usage, frequency type, etc.) housekeeping practices, shower requirements, eating, smoking and drinking practices in production areas, etc.

Task II. Processing of Polyvinyl Chloride and Polyvinyl Chloride Copolymers

Environmental/industrial hygiene surveys shall be conducted in production areas where polyvinyl chloride and polyvinyl chloride copolymers* are processed including, but not limited to, the following operations: (1) compounding; (2) extrusion; (3) molding; (4) calendering; (5) thermoforming; (6) binding; (7) foams; (8) fibers; and (9) plastisol processing. The surveys shall be conducted so that each processing operation is sampled at three different plants (locations). The criteria for the selection of these three plants shall include, but not be limited to: (1) information gained from preliminary site visits; (2) information gained from literature searches; (3) information gained from personal contacts; (4) representativeness of the operations to industrywide processing; (5) operations having greatest potential for worker exposures to vinyl chloride; (6) operations having the greatest gradient of worker exposures to vinyl chloride; (7) availability of historical inplant air measurements of vinyl chloride; and (8) the operations having the longest history of polymer processing. The information that shall be obtained and/or constructed shall be the same as the eight items listed above for the vinyl chloride monomer production operations. In addition, to these eight items past and present TWA worker exposures to other known liver toxins (if present) including, but not limited to, mercury, 2,2-dichlorovinyl dimethyl phosphate, ozone, dioxane, beryllium, lead, dimethylnitrosamine, arsenic, (amyl, methyl, ethyl, butyl, propyl and vinyl) acetate, copper, trichloroethylene, carbontetrachloride, arsine and tetrahydrofuran shall be measured and/or constructed.

Task III. Sample Collection and Data Analyses

All vinyl chloride sampling and analytical techniques shall be specified in the contract proposal. If sampling is required for other known liver toxins, the sampling and analytical procedures must be approved by the project officer(s) prior to use by the contractor.

The contractor should be cognizant of the fact that vinyl chloride is considered a potential human liver carcinogen and all employees and agents of the contractor should be provided with appropriate protective equipment. These equipment needs will be discussed with the project officer(s) prior to the field surveys.

The sample collection shall be conducted in such a manner as to provide statistically valid data that are representative of present worker exposures (categorized by different job-types) to vinyl chloride and other liver toxins, if found. Past worker exposures (by job-type) shall be constructed based on the information that is collected on the changes in processing, ventilation, environmental control, work practices and industrial hygiene practices that have occurred over the years and on historical

* Polyvinyl chloride-acetate, polyvinyl chloride-propylene and polyvinyl chloride vinylidene chloride

air sampling data (preferably personal sampling data) collected in the plant, if deemed reliable and accurate. All assumptions that are made in arriving at the constructed concentrations shall be presented. All of the above information on processing changes, ventilation changes, etc. shall be presented as part of the report on the surveys.

ASI 000017869

MANUFACTURING CHEMISTS ASSOCIATION

1825 CONNECTICUT AVENUE, N.W. WASHINGTON, D.C. 20009 (202) 483-6126 W A R

MAY

May 1, 1974

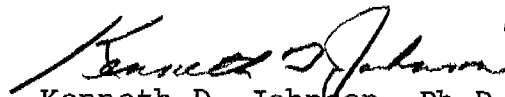
To: TECHNICAL TASK GROUP ON VINYL CHLORIDE RESEARCH

Subject: Federal Register Notice re Suspension
of Registration of Pesticide Sprays
Containing Vinyl Chloride Propellant

Gentlemen:

Enclosed herewith is the subject notice from
the Federal Register for Friday, April 26, 1974.

Sincerely,



Kenneth D. Johnson, Ph.D.

Secretary

Technical Task Group on
Vinyl Chloride Research

KDJ:mb

Attachment

cc : Mr. A. W. Barnes
D. P. Duffield, M.D.
Dr. Tiziano Garlanda

ASI 000017870

VINYL CHLORIDE

Emergency Suspension Order Concerning Registrations for Certain Products and Intent to Cancel Registrations

Notice is hereby given of the emergency suspension of, and notice of intent to cancel the registrations, under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended ("FIFRA"; 7 U.S.C. 135 et seq., 7 U.S.C. 136 et seq.), of all pesticide spray products containing vinyl chloride, whether as an active or inert ingredient, for uses in the home, food handling establishments, hospitals or in enclosed areas. Concurrent with this notice of suspension and notice of intent to cancel, the Environmental Protection Agency, is requesting that all existent stock of such products be recalled by the manufacturers.

FINDINGS OF FACT

1. In January 1974, it was reported that four workers who had had intimate occupational contact with vinyl chloride had died from angiosarcoma of the liver.

2. Angiosarcoma of the liver is an extremely rare form of cancer. Data from the Third National Cancer Survey, conducted by the National Cancer Institute over the three-year period, 1969 to 1971, indicates that the number of cases of angiosarcoma of the liver expected in any one year could range from 11 to 53 for the total United States population.

3. On February 15, 1974, an Italian scientist, Professor Cesare Maltoni of the Bologna Institute of Oncology, reported on an experiment in which rats exposed to vinyl chloride gas for four hours per day, five days per week, for 127 weeks developed angiosarcoma of the liver. These cancers were found at an increasing frequency at several dosages, beginning at 250 ppm and above, but not at 50 ppm, the lowest dosage tested.

4. Since the first occupational reports this year, several more cases of angiosarcoma of the liver have been confirmed, bringing the total number of these cancers among occupationally exposed workers in the United States to twelve. Two additional deaths from angiosarcoma have been reported among occupationally exposed workers outside of the United States. The evidence relating vinyl chlo-

ride exposure and these deaths is circumstantial, but strongly suggestive of a causal relationship, especially when combined with animal data.

5. In 1973, the Manufacturing Chemists Association contracted with Industrial Bio-Test Laboratories, Inc. of Northbrook, Illinois, to conduct laboratory studies exposing mice and hamsters as well as rats to vinyl chloride gas. While this experiment is not yet completed, there have been a high number of deaths among the test animals, controls as well as exposed. In the course of examining these animals to determine the cause of death, a significant number of the dead mice in the exposed group showed tumors of various sorts. Two cases of angiosarcoma of the liver were observed in mice exposed to 50 ppm vinyl chloride in the air, four cases of the rare cancer in mice exposed to 200 ppm, and in seventeen of those exposed to 2,500 ppm. No angiosarcomas have been found in the rats or hamsters that have died during the course of the experiment. The significance of these figures is still not fully understood because data on the deaths in the control group of mice has not yet been fully analyzed. Nevertheless, the observation of a dosage-related pattern of occurrence of this rare form of cancer, coupled with the previous results in Italy, provides strong evidence that exposure to vinyl chloride can cause liver cancer.

6. Seventeen manufacturers have registered pesticidal aerosols in which vinyl chloride was one of the inert ingredients, and thus unlisted on the label. These manufacturers plus their distributors account for 41 different brand name products. Vinyl chloride is used as a propellant component in such aerosols.

7. Although all of these manufacturers state that they have stopped using vinyl chloride as a propellant, some as early as May 1973, there are at least an estimated 19,000 cans of such products in commercial channels.

8. Last Friday, I learned of preliminary testing and calculations done by EPA involving the use of an aerosol containing vinyl chloride showing that a 30 second release of the aerosol could result in a concentration as high as 400 ppm in the air. In a separate test, preliminary results showed that after as long as four days, only about 1% of the vinyl chloride gas would dissipate under conditions where the exposure area was not ventilated and little, if any, light was present. Calculations based on this information, assuming three changes of air per hour in an enclosed area, and experiments by EPA scientists measuring vinyl chloride levels following spraying in the home would indicate that a detectable concentration of vinyl chloride could still persist for several hours after spraying.

9. Exposure to vinyl chloride has been associated with a significant number of cases of a rare liver cancer in experimental rats and mice, and in humans. Although vinyl chloride is apparently no

longer being used as a propellant in pesticides, some stocks remain on the market. The use of these pesticides in an enclosed space, even in short bursts (e.g., 30 seconds), could result in exposure levels similar to those which have produced angiosarcomas in test animals. The health implications for humans at these levels for short exposure periods are undetermined, but it is prudent to assume that any exposure at these levels will have increased the risk of cancer should the strongly suspected causal relationship between vinyl chloride and cancer be finally confirmed.

10. The benefits of the use of vinyl chloride as a propellant are very small because several suitable substitutes exist which, in fact, are frequently used. Although the number of pesticide products containing vinyl chloride presently in commercial channels or in use is not thought to be substantial, the risk of continuing such use in the face of acceptable substitutes is unjustified.

11. Attached to this order are the names of the pesticide products containing vinyl chloride which are known by this Agency to be registered for uses in the home, food handling establishments, hospitals or in enclosed areas. There may be others.

CONCLUSIONS

Section 6(c) of FIFRA provides for the suspension of a registration of a pesticide if the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation proceedings under section 6. Section 6(c) also provides for issuance of an emergency order of suspension by the Administrator in the event he finds that an emergency exists that does not permit the holding of an expedited hearing on the question of suspension before issuing an order. The statute also provides a general definition of the term "imminent hazard" in section 2(1) which states that "imminent hazard" means a situation which exists when the continued use of a pesticide during the time required for cancellation would be likely to result in unreasonable adverse effects on the environment. A determination of unreasonable adverse effects on the environment must consider the degree of risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide (Section 2(bb)).

The evidence available at this time indicates the presence of a clear risk to human health from continued exposure to vinyl chloride. Indeed, this chemical presents a most unusual case because the rare form of cancer found in occupational workers can be readily demonstrated in test animals. Thus we are faced with a substantial risk to human health upon continued exposure to vinyl chloride. The existence of this risk would require a compelling demonstration of benefits to justify the continued use of

the product pending the outcome of either cancellation proceedings or any hearing pursuant to section 6(c) (2) of FIFRA.

Present information indicates that most, if not all manufacturers of pesticides containing vinyl chlorides as a propellant, are willing to utilize substitute substances for this purpose. The Environmental Protection Agency has already received several applications for amended registrations to eliminate vinyl chloride as an ingredient. It is my understanding that similar amendment applications will be forthcoming from other manufacturers. Thus, there is no indication that elimination of use of these products pending completion of suspension and cancellation proceedings will have any effects upon availability of the associated aerosol pesticides. Indeed, in the course of investigating use of these products prior to this order, instances were discovered of previous voluntary discontinuance of the use of vinyl chloride as a propellant (without amended registrations having been submitted or issued).

Although voluntary discontinuance of the use of the substance is a commendable development, significant quantities of pesticide products containing vinyl chloride have previously been distributed and are now in retail outlets or in actual use. In addition, although the Environmental Protection Agency desires, whenever possible, to secure voluntary compliance rather than proceeding by order, the time required to insure that such compliance has actually taken place would necessarily delay achieving the most rapid possible nationwide cessation of the sale of products containing vinyl chloride, and the recall of existing stocks. Therefore, I have concluded that in view of the substantial risk from continued use of vinyl chloride, and the absence of any significant benefit from its continued use pending completion of cancellation proceedings pursuant to section 6, an imminent hazard does exist under the terms of section 6(c) of FIFRA and an emergency does exist which does not permit delay of suspension pending a possible hearing pursuant to section 6(c) (2) prior to issuance of an order of suspension. Indeed, I find that as a result of the above findings of fact, particularly the recent results of Agency testing, that immediate action is required.

EMERGENCY SUSPENSION ORDER AND NOTICE OF INTENT TO CANCEL

In accordance with the attached findings and conclusions, it is hereby ordered that the registrations for all pesticide products containing vinyl chloride, whether as an active or inert ingredient, be suspended immediately for all uses in the home, food handling establishments, hospitals, or in enclosed areas. I also serve notice of my intent to cancel such registration within 30 days from the receipt of this notice by the registrant, or publication of this order in

the FEDERAL REGISTER (April 26, 1974), which ever occurs later, unless the registrant makes the necessary corrections to its registration. These pesticide products containing vinyl chloride may not be legally shipped in interstate commerce.

Dated: April 24, 1974.

RUSSELL E. TRAIN,
Administrator.

INDOOR AEROSOL PESTICIDES AFFECTED BY TODAY'S SUSPENSION

Product	Company
Bruhin Bug Bomb----	Bruhin & Co.
Paracide with Sovin--	Carson Chemicals, Inc.
Demert Raw Roach, Ant and Wasp Killer.	Demert & Daugherty.
Cobra International Roach, Ant and Wasp Killer.	Cobra International [D].
Rexall Ant and Roach Killer.	Rexall Drug Co. [D].
Walgreen Ant & Roach Killer.	Walgreen Laboratories, Inc. [D].
Flea Killer for Dogs and Cats.	Chase Products Co.
Barcolene Spray Disinfectant.	The Barcolene Co.
Coop Dairy Insecticide for Milk Houses and Animals.	Farmland Industries, Inc.
Excellide 16-oz. Aerosol Bomb.	The Hugo Co.
Navy Brand Thrifty 50	Navy Brand Mfg. Co. [D].
Mothrid Moth Proofer	Hysan Corp.
Mothrid Moth Proofer Cedar Scented or Activated Moth Proof Spray Cedarized.	Liberty Products Co. [D].
Nokout 25 Aerosol Insecticide.	Hysan Corp.
Strike--Wasp and Hornet.	Albert Woods Wholesale [D].
Nokout 35 Insecticide-Spritz Metered Air Sanitizer.	Hysan Corp.
Anchor Flea, Lice and Tick Bomb.	Philips-Roxane, Inc.
F-L-T Bomb-----	Elo-Ceutic Laboratories [D].
WAYNE, Flea, Lice and Tick.	Allied Mills, Inc. [D].
Rodgers' Insecticide and Repellent.	Jay Rodgers Co.
Total Release Insect Fogger.	Spray-Chem Corp.
Crown "Total" Complete Release Insect Fogger.	Crown Chemicals, Inc. [D]
Roberts' "Total" Complete Release Insect Fogger.	Roberts Laboratories [D]
Chaperone Flea & Tick Killer.	Sudbury Laboratory
Pyrethrin Insecticide Pressurized Dairy Insecticide.	Woodbury Chemical Co.
COOP Pyrethrin Insecticide Pressurized Dairy Insecticide.	Farmland Industries, Inc. [D]
Mid-Am Brand Pyrethrin Insecticide Pressurized Dairy Insecticide.	Mid-American Dairyman, Inc. [D]

[D]—Distributor of Product Listed Above
[FR Doc.74-9719 Filed 4-25-74;8:45 am]



MANUFACTURING CHEMISTS ASSOCIATION

1825 CONNECTICUT AVENUE, N.W. WASHINGTON, D.C. 20009 (202) 483-6126

ALBERT C. CLARK
VICE PRESIDENT
TECHNICAL DIRECTOR

W. A. K.

To the Occupational Health (Medical) Contacts
of MCA Member Firms

APR 22 1974

Dear Sirs:

One of our member companies has expressed interest in a study of the carcinogenic potential of vinylidene chloride. It has been recommended that MCA call a meeting of representatives of those manufacturers and users having an interest in a collective approach to a technical information-gathering program which may involve funded research.

A meeting to explore the breadth of such interest is scheduled for Wednesday, May 15, in MCA's Conference Room, beginning at 10:00 AM. If your company might wish to actively participate in and support such a joint program, you are invited to arrange for representation at the meeting. Limiting the attendance to no more than two persons from each company would be appreciated.

Please let me know by telephone or TELEX (89-617) if your company plans to be represented, advising the name of your representative(s).

Sincerely,

cc: Plastics Committee Members
Vinyl Chloride Research Contacts
and

Contacts suggested by proposer:

Dr. B. W. Duck, BP Chemicals

Dr. H. J. Kiefer, Glidden-Durkee Division of SCM Corporation

Mr. Henry Weigl, Standard Brands, Inc.

Mr. James White, White Chemical Corporation

ACC:tp
April 18, 1974

ASI 000017873