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CHEMICALS
RESEARCH

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Manufacturing Chemists Association

TECHNICAL MEETING ON THERMAL DECOMPOSITION PRODUCTS
OF
POLYVINYL CHLORIDE FILMS

MCA Conference Room

Washington, D. C.

March 1, 1974

RECORD OF MEETING

PRESENT:

W. V. Andresen	American Cyanamid Company
J. D. Baker	Union Carbide Corporation
Frank Barbuscio	American Cyanamid Company
W. E. Barr	The Goodyear Tire & Rubber Company
Paul Beebe, Jr.	The Goodyear Tire & Rubber Company
R. Burkhart	Reynolds Metals Company
R. E. Byrne	Clopay Corporation
J. J. Connor	Polyvinyl Films, Inc.
Tom Connor	Polyvinyl Films, Inc.
A. S. Cummin	Borden, Inc.
A. S. D'Amato	Borden, Inc.
R. S. Detrick	Koppers Company, Inc.
K. W. Easley	Monsanto Industrial Chemicals Company
G. E. Field	Filmco
T. M. Finnegan	Filmco
R. W. Frank	Ferro Corporation
F. C. Gregory	Ethyl Corporation
L. Gross	Tenneco Chemicals, Inc.
R. W. Gutheil	Borden, Inc.
D. E. Harrington	The Goodyear Tire & Rubber Company
Richard Henderson	Olin Corporation
L. E. Ice	Diamond Shamrock Corporation
G. W. Ingle	Monsanto Company
E. J. Jacob	Filmco
D. G. James	Borden Chemical Division of Borden, Inc.
W. W. Kocher	Borden, Inc.
Bruno Krueger	Borden Chemical Division of Borden, Inc.
Max Miller	Ethyl Corporation
R. C. Parsons	Reynolds Metals Company

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PRESENT (cont.):

P. M. Peltz	Diamond Shamrock Corporation
W. E. Rinehart	Ethyl Corporation
E. E. Sandmeyer	Gulf Oil Corporation
J. P. Stallings	Chemetron Corporation
M. F. Tarker, Jr.	FMC Corporation
H. J. Trochimowicz	E. I. du Pont de Nemours & Company
Delbert Volchko	Filmco
J. A. Yourtee	FMC Corporation
B. M. Barackman	MCA
A. C. Clark	MCA
K. D. Johnson	MCA
H. L. Slatin	MCA
F. G. Stephenson	MCA

Mr. A. C. Clark convened the meeting at 10:00 AM. After he had briefly summarized the background for this meeting, and after those present had identified themselves and their companies, Mr. R. W. Gutheil, of Borden, Inc., was appointed chairman pro tem.

Mr. Gutheil recounted the increasing attention to the problem of alleged respiratory tract irritation in food packagers with exposure to the fumes generated in the hot-wire cutting and heat sealing of polyvinyl chloride films. He stressed the concern of industry that incomplete and inaccurate information was receiving wide dissemination and generating undue concern among both employees working with this material and the general public. He indicated particular concern that the public and the unions were confusing the problem, if any, of PVC film emissions and that of the risks of angiosarcoma experienced by workers in the PVC polymerization industry.

An informal poll of the companies represented at this meeting revealed that there was widespread interest in setting up an industry funded effort to generate valid data on the nature and extent of the problem, and of routes to its

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solution. Although commitments of support by a number of the companies were conditioned upon the ability of the group to develop acceptable plans and protocols for the project, it was evident that the great majority of those companies represented were interested in participation in a broad and meaningful investigation of the technical and communications problems faced by the manufacturers of film resins and their formulators and fabricators.

It was moved to define the mission and scope of the proposed project as follows:

- (1) a study of the decomposition products from polyvinyl chloride film resin formulations under heating short of ignition or combustion, and
- (2) a study of the health effects, if any, of such products as influenced by the various temperature, humidity, or other environmental factors attendant upon the processing and uses of the film resin formulations.

The motion was discussed in detail, and a number of motions to amend were offered and rejected. It was the consensus that the scope and mission of the project should be kept focused on the physical chemistry and industrial hygiene problems associated with plasticized PVC films under conditions associated with their formulation, fabrication, and use in their intended applications, and that it should not be broadened at this time to allow inclusion of potential occupational health effects associated with the molding, extrusion, or use application of rigid sheets, pipe and tubing, and other fabricated items.

A motion to amend item (1) of the original motion, by striking the phrase after heating, and inserting in its place the corresponding phrase from item (2) "attendant upon processing and uses of film resin formulations" carried, and the motion so amended was approved by voice vote.

It was agreed to name a small group to develop detailed recommendations for those elements of the project necessary for consideration by potential supporters of a research project and subsequent presentation to the MCA Board with any request for their approval of MCA administration of the project. These would include:

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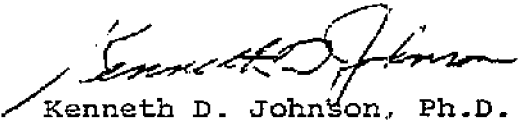
- (1) Mission and Scope
- (2) Recommended research projects, with protocols and budgets
- (3) Proposed bases for allocation of project costs among its sponsors.

The following companies volunteered to provide representatives to the group:

Borden, Inc.
Filmco (R. J. Reynolds)
Diamond Shamrock Corporation
Ethyl Corporation
Reynolds Metals Company
The Goodyear Tire & Rubber Company
Clipay Corporation
Monsanto Company (tentative)
Tenneco Chemicals, Inc. (tentative)

The first meeting of the group was scheduled for 10:00 AM, Wednesday, March 6, 1974. Subsequent to the adjournment of the meeting, Dr. K. D. Johnson, MCA staff representative, arranged for the meeting to be held at the DuPont Plaza Hotel, in the Gallery Room.

Respectfully submitted,


Kenneth D. Johnson, Ph.D.
Assistant Technical Director

KDJ:mb

Record Subject to Approval
March 28, 1974

March 18, 1974

VRD 0002001632

Associate Commissioner for Compliance Sam Fine discussed the upcoming April 1 public hearing on iron in flour and bread (See FOOD CHEMICAL NEWS, March 11, Page 46), indicating that there will be a pre-hearing conference, and that a possible date for that is March 25. Fine said FDA is "determined" that the hearing will not be a "circus," but will be "an orderly proceeding" sticking to the issue of safety.

Additional appearances have been filed for the iron-in-bread hearing (See FOOD CHEMICAL NEWS, March 11, Page 29) by Dr. William H. Crosby, of the Scripps Clinic and Research Foundation; Consumers Union's Dr. A. Karim Ahmed; Cooley's Anemia Blood and Research Foundation for Children's Edward D. Paradiso, Nunzio D. Cazzetta, Carmine Geonie, and Dr. Edward C. Zaino; and Order Sons of Italy in America's Dominic R. Massaro.

Crosby, a hematologist who has been one of the staunchest opponents of increasing iron levels in bread, is being represented by consumer advocate Anita Johnson, who requested that FDA move the public hearing from the Parklawn Building to FDA's Washington FOB 8 building.

Cooley's anemia is an iron binding disorder, which is also known as "Mediterranean anemia."

FDA MAY REVOKE PRIOR SANCTION FOR PVC FOOD PACKAGING

The Food and Drug Administration is considering a proposal to revoke the "prior sanction" for use of polyvinyl chloride in food packaging because of the possibility of migration of vinyl chloride monomer.

The new proposal to make PVC a "food additive" would replace the pending proposal which would formalize the "prior sanction" for general food packaging under §121.2009, but ban its use for packaging alcoholic beverages.

The agency had previously informed the Society for the Plastics Industry that more data is required on PVC and vinyl chloride monomer migration to food (See FOOD CHEMICAL NEWS, March 4, Page 25), but this was mainly in the context of alcoholic beverages. Industry had previously informed FDA that new processing of PVC would reduce migration of the monomer (See FOOD CHEMICAL NEWS, Oct. 22, Page 26; and Dec. 24, Page 22).

FDA's doubts about PVC packaging, especially for fatty foods, were conveyed to SPI representatives in a recent meeting in Washington.

Agency official noted that testimony before the Occupational Safety and Health Administration had indicated monomer migration to foods, especially fatty foods, and that FDA has found that regulatory agencies in other countries have found vinyl chloride in food.

FDA-ers say that the new-process PVC might take care of the problem, but that "trade secret" considerations have prevented the investigations that are needed. It is probable that firms will have to file Food Additive Petitions, in which they will have to demonstrate that vinyl chloride monomer migration meets a specific limit.

A way must be found to limit the amount of vinyl chloride monomer to less than the sensitivity of the most sensitive method available, FDA-ers say. Current methods are sensitive to 50 p.p.b. Officials indicate that PVC will have to meet both tests for residues and an end-test on the package itself.

There will also have to be toxicological work, FDA-ers say, in order to establish a no-effect level for vinyl chloride.

There are now a number of clearances for PVC as a "food additive" under the Subpart F indirect Food Additive Orders. These probably will be reviewed. FDA-ers say there is information that PVC used in can coatings under §121.2514 for resinous and polymeric coatings does not result in vinyl chloride getting into the food.

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FDA GIVES C-U ACCESS TO LEAD-IN-MILK DATA

The Food and Drug Administration and Consumers Union are continuing their faintly acrimonious correspondence about lead in canned evaporated milk, despite the fact that both parties are agreed that lead levels have successfully been reduced (See FOOD CHEMICAL NEWS, Feb. 4, Page 40).

The latest letter was from FDA Commissioner Schmidt in response to a letter from CU's George A. Pollak.

The agency said that CU is entitled under the Freedom of Information Act to the FDA test data and to a summary of results submitted by the Evaporated Milk Association. It is understood that CU has been unable to obtain EMA's results, since FDA lacks the Association's raw data.

Noting that CU's second survey showed lead levels within the agency's guideline, as did the FDA and EMA data, Schmidt noted that "industry is obligated to monitor its own production and report any lots exceeding the FDA guideline of 0.5 p.p.m.," and that "none has been reported nor have we found any lots exceeding the guideline."

Pollak had written that the tests relied upon by FDA had involved composite samples rather than single cans, and Schmidt said that "the investigators at the Albert Einstein College of Medicine did analyze 15 single cans of evaporated milk which they purchased in 1972 and 1973," finding the highest lead content 0.22 p.p.m. and the average 0.11 p.p.m.



To File Date 2/20/74

From 1m

per agreement with K. L. Schurter, he will copy JDBu, JJL, and JDBr on all SPI mailings. FK will continue to copy WRS.

MANUFACTURING CHEMISTS ASSOCIATION

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

March 1, 1974

**CHEMICALS
RESEARCH**

MAR 4 1974

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AUTHOR
TITLE
LOC.

TO: TECHNICAL TASK GROUP ON VINYL CHLORIDE RESEARCH

TO: TECHNICAL TASK GROUP ON VINYL CHLORIDE RESEARCH

**Subject: NIOSH Health Hazard Evaluation Report on
"Meat Wrappers' Asthma"**

Gentlemen:

Distributed herewith are copies of the subject report for one of the six retail establishments investigated by NIOSH. Each is substantially identical to the others, except for the identification of the establishment involved. As you will note, NIOSH emphasizes the plasticizer contribution to the aerosol as compared to that of polyvinyl chloride per se.

Sincerely,

Kenneth Johnson

Kenneth D. Johnson, Ph.D.
Secretary
Technical Task Group on Vinyl
Chloride Research

KDJ : mb

Attachment

cc : D. P. Duffield, M.D.
Mr. D. M. Elliott
Dr. Tiziano Garlanda

U. S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
CINCINNATI, OHIO 45202

HEALTH HAZARD EVALUATION DETERMINATION

REPORT 72-58

CITY FOODS
SEATTLE, WASHINGTON

SEPTEMBER 1973

I. TOXICITY DETERMINATION

In response to six requests for Health Hazard Evaluations from retail meat wrapping employees in and around Seattle, Washington, regarding exposure to the thermal decomposition products of polyvinyl chloride (PVC) meat packaging film, a limited study of retail meat wrappers was undertaken. Although the data presented in this report did not result from direct evaluation of the work environment at the City Foods, Seattle, Washington, the findings of this study are generally applicable to retail meat wrapping operations using PVC meat packaging films.

It has been determined that air contaminants generated by the thermal cutting of polyvinyl chloride (PVC) packaging films in conjunction with the wrapping of meat are potentially toxic to some meat wrapping employees. This determination is based upon medical evidence compiled during a limited study of meat wrappers in the United States. This study involved a review of the pertinent scientific literature, consultation with researchers in this area of investigation, the collection of medical histories, clinical observations at the worksite, pulmonary function testing of meat wrappers, and consideration of wrapping procedures, equipment, and meat wrapping environmental conditions.

Evidence suggests that a sizeable percentage of meat wrappers suffer from mild symptoms to include eye, nose, and throat irritation. A portion of these affected meat wrappers who have an underlying predisposition to respiratory difficulties resulting from a variety of conditions (tobacco abuse, asthma, emphysema, and other serious respiratory diseases) experience more serious respiratory problems. These can include shortness of breath, difficulty in breathing, coughing, and general physical distress. This study has not established whether or not presently healthy meat wrappers may develop respiratory difficulties after prolonged exposures to contaminants from thermal decomposition of PVC packaging films.

Although substances in the meat wrapping environment other than those associated with PVC films may be responsible for the previously stated clinical manifestations, the available evidence strongly implies that the air contamination from thermal cutting of PVC packaging film is the causative agent. As yet, the patho-physiologic mechanism for this malady is not clearly understood.

VRD 0002007639

Based on present experience with this particular problem, it is recommended that the following practices be instituted:

1. Pre-employment physical examinations, including chest x-rays and pulmonary function tests be performed on all individuals entering the meat wrapping industry. (Individuals who are found to have severely compromised pulmonary function or who exhibit strong predisposition to pulmonary disorders should not enter the meat wrapping profession.)
2. Meat wrapping machinery should be clean and well maintained. Machines with controlled low temperature cut-off wires are to be preferred. (There is need for further study with regard to controlling contamination at its source via new cutting mechanisms or local exhaust ventilation, etc.)
3. Meat wrapping should be conducted in well ventilated surroundings.

II. DISTRIBUTION AND AVAILABILITY OF THE DETERMINATION REPORT

Copies of this Determination Report are available upon request from the Hazard Evaluation Services Branch, NIOSH, U.S. Post Office Building, Room 508, 5th and Walnut Streets, Cincinnati, Ohio 45202. Copies have been sent to:

- a) City Foods, Seattle, Washington
- b) Authorized representative of employees
- c) U. S. Department of Labor - Region X
- d) NIOSH - Region X
- e) Washington State Department of Labor and Industries

For the purposes of informing the 1-3 affected meat wrappers the employer will promptly "post" the Determination Report in a prominent places near where affected employees work for a period of 30 calendar days.

III. INTRODUCTION

Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 669 (a)(6), authorizes the Secretary of Health, Education, and Welfare, following written request by any employer or authorized representative of employees, to determine whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found.

The National Institute for Occupational Safety and Health (NIOSH) received such a request from an authorized representative of the meat wrapping employees at the City Foods, Seattle, Washington,

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as well as from five other stores in Seattle, Washington area regarding employee exposures to the potentially toxic substances emitted from thermal decomposition of polyvinyl (PVC) packaging films in use in the meat department. One to three meat wrapping employees are employed in each of these stores and are subsequently exposed to the substances in question.

IV. HEALTH HAZARD EVALUATION

A. Description of Process - Conditions of Use

Although several types of meat wrapping machines were observed during the course of this study, most machines incorporated the basic features of the "typical" hand wrapping machine shown in Figure 1.

Wrapping meat involves: (1) pulling out a desired length of film, (2) wrapping the film around a tray or cut of meat, (3) severing the film from the supply roll using the hot wire cut-off, (4) folding the film ends under the package, and (5) sealing the folded ends under the package by touching the package to the heated pad.

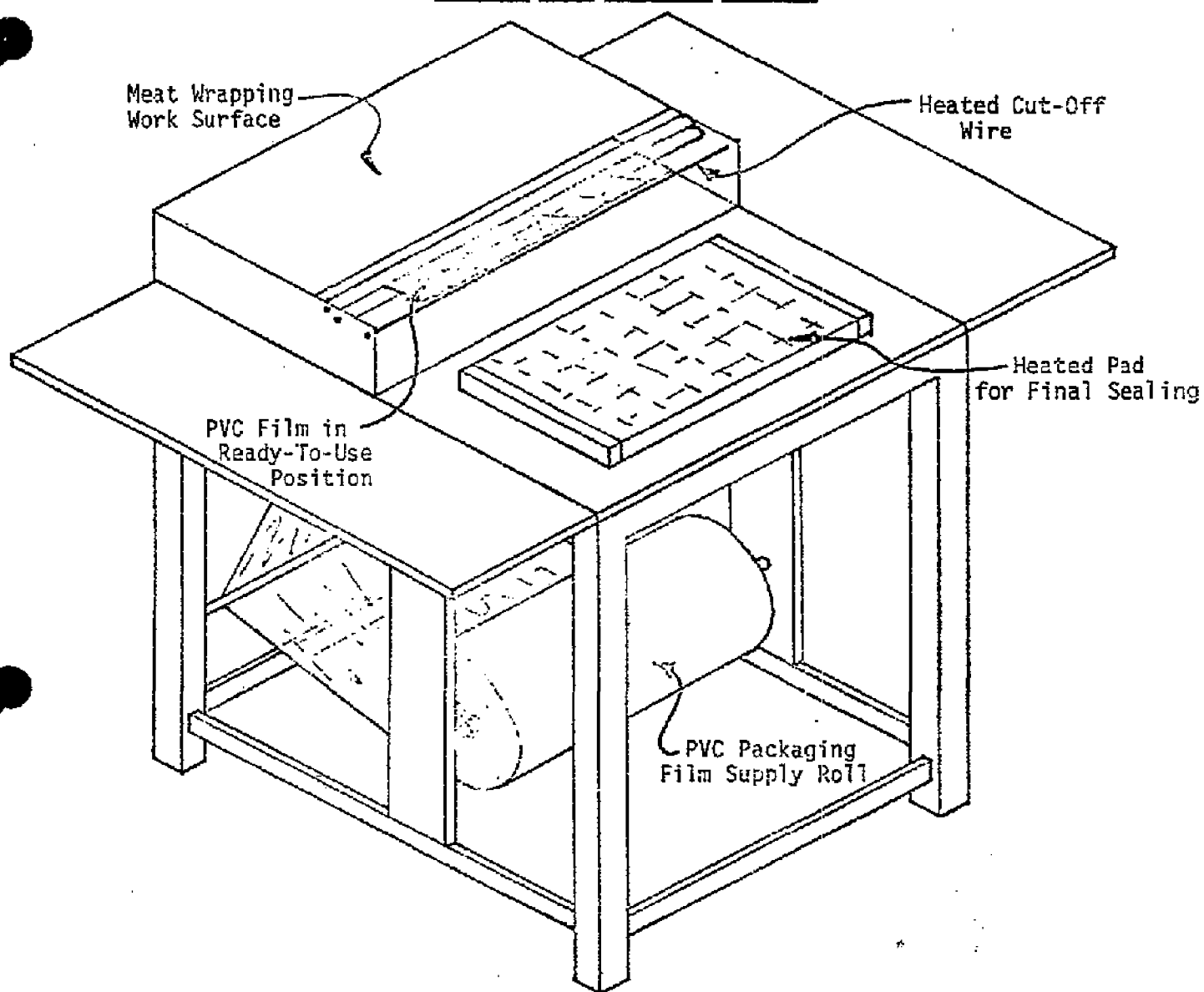
Air contaminants generated by the hot wire cutting of PVC packaging films and their alleged toxic effects on meat wrapping employees constitute the subject of this health hazard evaluation. There are approximately 75,000 meat wrapping employees in the United States, according to union and industry estimates.

B. Study Background and Design

Polyvinyl chloride and wrapping film is made from pure PVC resin and a variety of additives. All additives must be approved by the federal Food and Drug Administration for use in meat packaging materials. These additives include plasticizers, stabilizers, antifog agents, lubricants, and colorants. Plasticizers (dioctyl adipate - di-2-ethyl hexyl adipate, and epoxidized soya or soybean oil) can comprise up to 30% of the film. Stabilizers (calcium-zinc stearate) antifog agents (e.g., polyoxyethylene derivatives of sorbitan monooleate), lubricants (e.g., stearic acid), and colorants together makeup roughly 2-6% of the film.

Several investigators have attempted to identify and quantitate air contaminants generated by the hot wire cutting of PVC film in the meat wrapping environment. Early field measurements for hydrogen chloride (HCl) detected trace amounts (less than 1 ppm) in the vicinity of meat wrapping operations.² A later laboratory study of air contaminants from hot wire cutting of PVC film confirmed the presence of HCl and related its rate of generation together with the rate of generation of particulate to the operating temperature of the hot wire.³ As would be expected, the production of both HCl and airborne particulate increase with increasing wire temperature.

FIGURE 1: Typical Hand-Wrapping Machine



Manufacturers of Wrapping Equipment: Automatic, Semi-Automatic, and Hand Wrapping

Cleveland-Detroit Corporation, Clamco Division
J. B. Dove and Sons, Incorporated
Heat Sealing Equipment Manufacturing Company
The Hobart Manufacturing Company
Package Machinery Company
Reliance Electric Company, Toledo Scales and Systems

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To date, three researchers have found the film plasticizer to be the predominant contaminant generated by the thermal decomposition of PVC meat wrapping film.³⁻⁵ The oral toxicity of di-2-ethyl hexyl adipate, as determined by animal experimentation, is relatively low. However, no data are currently available regarding the inhalation toxicity of di-2-ethyl hexyl adipate. It is interesting to note that one researcher, Bovee, et al. identified the plasticizer to be diisooctyl adipate while the other two (Van Houten and Jaeger) found di-2-ethyl hexyl adipate. Diisooctyl adipate has exactly the same molecular weight as di-2-ethyl hexyl adipate and possesses very similar physical properties.

Hydrogen chloride is possibly the second most important degradation product. HCl can be detected at concentrations of 1-5 ppm and is disagreeable at concentrations of 5-10 ppm.

Other film degradation products have been identified, but are present in small quantities when compared to the film plasticizer. These other materials include chlorinated hydrocarbons and breakdown products of film additives.

Workplace concentrations of PVC film decomposition products are difficult to measure. As previously, stated, HCl has been found in very low concentrations in the meat wrapping environment. Laboratory experiments by Van Houten et al. suggest that airborne concentrations of HCl in the plume of "smoke" directly over the hot wire can reach 2 ppm. These measurements were made during "artificially severe operating conditions," which would rarely occur during actual meat wrapping. (It should also be noted that an employee's exposure would be to a significantly lower concentration than that found in the plume close to the wire. In the same study plasticizer concentrations in the plume were found as high as 13 mg/M³. Again, this value was found during artificially severe operating conditions.

Clinical complaints allegedly resulting from exposure to air contaminants from PVC meat wrapping film were first referenced in an unpublished study conducted by NIOSH's predecessor the Bureau of Occupational Safety and Health.² According to that investigation, state health officials in Virginia became involved with complaints from meat wrappers in the summer of 1969. Since that time complaints have come in by letter and telephone from several cities across the Nation. Due to the informal nature of most of the reports, it is difficult to accurately estimate the true number of individuals involved. However, a small group of medical investigators scattered throughout the Nation have reported approximately 50-75 cases of pronounced clinical symptoms.

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Subjective estimates from union officials, university investigators, medical professionals, and meat wrappers suggest that a large number of meat wrappers are less seriously affected.

To better delineate the clinical manifestations of exposure to contaminants from PVC film decomposition a preliminary survey of meat wrapping operations was made. Five retail stores in and around Seattle, Washington were visited during August 7-9, 1972. Meat wrapping operations were observed in each retail store and eighteen meat wrappers with varied work experience with PVC films were interviewed. Each worker was questioned in an attempt to elicit symptoms of upper respiratory tract irritation, irritation of the eyes, nose, and throat, and occupational dermatoses. Spirometric measurements were obtained from thirteen of the meat wrappers.

At the completion of this preliminary survey it was clear that a more detailed scientific study would be necessary to elucidate the full ramifications of the potential health problems associated with the use of PVC films. The assistance of the Amalgamated Meat Cutters and Butcher Workmen of North America was solicited to facilitate the location of metropolitan areas where sizeable numbers of meat wrappers were allegedly being adversely affected by air contaminants from PVC films. Following a nationwide search, the City of Louisville, Kentucky was selected as a site for further investigatory research.

A research protocol was developed under the guidance of pulmonary specialists from the NIOSH Appalachian Laboratory of Occupational Respiratory Diseases. The protocol called for the administration of a health questionnaire and the conduction of pulmonary function testing on meat wrappers and suitable controls. The orientation of the questionnaire and the subsequent interview with a NIOSH physician placed emphasis on occupationally related health problems, especially respiratory health problems.

On January 22, 1973, in Louisville, Kentucky, seventeen meat wrappers and twenty non-meat wrappers (office personnel serving as controls) completed medical questionnaires and participated in pre- and post-workshift pulmonary function testing. Technical problems regarding environmental sampling prevented evaluation of employee exposures on the day of testing. As observed in a number of retail establishments, meat wrappers' exposures to contaminants from hot wire cutting of PVC meat packaging film are intermittent and highly variable. To be useful in interpreting employee symptoms, breathing zone air samples would have to reflect both average and short term exposures. Although these contaminants have been measured in undiluted form near the source of generation³, there is at present no suitable method of sufficient sensitivity to measure variable breathing zone concentrations.

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C. Evaluation Methods

1. Medical Questionnaire

The medical questionnaire consisted of twenty-six sets of questions. Its purpose as to gather pertinent information concerning an individual's past medical history, smoking history, past occupational exposures, current respiratory status and adverse effects allegedly arising from exposure to air contaminants from PVC films.

2. Pulmonary Function Testing

Each pulmonary function test required the employee to make three forced expiratory volume practice maneuvers after which three forced expiratory volume maneuvers (reproducible within 5%) were recorded as flow volume loops. A waterless, high fidelity spirometer equipped with an air temperature probe was used. The flow volume loops were displayed on a storage oscilloscope and recorded on magnetic tape. A photograph of each oscilloscope display was taken for backup. Computer analysis of flow volume loops provided the following parameters forced expiratory volume in one second (FEV₁), and flow rates at 25,50,75 and 90 per cent of forced vital capacity (FVC).

D. Evaluation Results

1. Preliminary Survey (Seattle, Washington and vicinity)

Sixteen of the eighteen meat wrappers interviewed in the preliminary survey were known to have suffered ill effects from air contaminants from PVC films. Only two workers were free of any clinical symptomatology. Eight had similar case histories and admitted experiencing varying degrees of sneezing, rhinorrhea, and eye irritation. Most individuals gave a like story that the ill effects came on from one to three hours after the commencement of meat wrapping in the morning. The workers stated that as the workday progressed the prodromal manifestations increased in intensity. The sneezing, rhinorrhea, and throat and eye irritation would abate in the evening hours and would be non-existent during weekends and vacations.

Five workers experienced more severe clinical symptomatology necessitating physician intervention and, on occasion, hospitalization. These individuals seemed to suffer with "occupational bronchiolitis." They suffered at times with severe dyspnea, productive cough, and nasal congestion. Onset of these symptoms was from one-half to two and one-half hours after commencement of work. These ill effects led to increased absenteeism. All were on one form of medication or another. This group also stated that a period of several days away from the meat wrapping environment was required for them to feel like their normal selves.

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Four of these workers had fifteen or more pack-years of cigarette smoking behind them.

Three meat wrappers had pre-existing susceptibility to upper respiratory symptomatology caused by severe disease processes (rheumatic fever, chronic obstructive pulmonary disease, and lung abscess).

2. Medical Questionnaires (Louisville Study)

Seventeen meat wrappers and a control population of twenty individuals completed the questionnaire. None of the controls reported any adverse clinical symptomatology associated with their particular form of employment. The majority of the controls worked as clerks in retail grocery stores.

As a group the seventeen meat wrappers averaged nine years and three months of experience in the meat wrapping profession. Forty-five per cent of these meat wrappers complained of irritation from film contaminants which resulted in watering and itching eyes. Thirty per cent of the wrappers complained of burning or dryness of the throat. Three wrappers (18%) stated that they experienced "painful breathing" and shortness of breath while working with PVC meat wrap. It is important to note that these same three individuals had a history of allergies, were on medication and were under physician care.

3. Pulmonary Function Testing (Louisville Study)

All pulmonary function data were analyzed by bio-statisticians at the NIOSH Appalachian Laboratory for Respiratory Diseases. The data can be summarized by examining the following statistical tests:

Note: df = degrees of freedom (number of employees tested minus one)

P = probability that a difference occurred by chance alone.

The "student t test" was used to determine whether there were significant differences between groups of individuals with respect to changes in FEV₁'s and FVC's. To be significant, a difference between groups would have a probability of occurring by chance of less than 5% or P less than 0.05.

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Test No. 1 - When all exposed (meat wrappers) were compared with all non-exposed (controls) with respect to any differences between pre- and post-workshift values of FEV₁ and FVC, there was no significant difference at the 95% confidence level (i.e. P less than 0.05).

TFEV ₁ (35df)	= -0.35	P = 0.73
TFVC (35df)	= -0.42	P = 0.67

Test No. 2 - When exposed smokers were compared with non-exposed smokers, there was no significant difference.

TFEV ₁ (11df)	= 0.22	P = 0.83
TFVC (11df)	= 0.31	P = 0.76

Test No. 3 - When exposed non-smokers were compared with non-exposed non-smokers there was no significant difference.

TFEV ₁ (22df)	= 0.55	P = 0.59
TFVC (22df)	= 0.11	P = 0.90

Test No. 4 - Test No. 1 was repeated with respect to peak flow and flow at 25,50,75 and 90% of FVC. There was a significant difference for F90.

TPF (35df)	= 0.47	P = 0.64
TF25 (35df)	= 0.38	P = 0.71
TF50 (35df)	= 0.01	P = 0.99
TF75 (35df)	= 0.11	P = 0.91
TF90 (35df)	= 2.39	P = 0.02

Test No. 5 - Test No. 2 was repeated with respect to the preceding parameters and there was a significant difference for F50.

TPF (11df)	= 0.08	P = 0.94
TF25 (11df)	= 1.36	P = 0.20
TF50 (11df)	= 2.31	P = 0.04
TF75 (11df)	= 0.88	P = 0.40
TF90 (11df)	= 0.54	P = 0.60

Test No. 6 - Test No. 3 was repeated with respect to the preceding parameters and there were significant differences for F75 and F90.

TPF (22df)	= 1.14	P = 0.27
TF25 (22df)	= 0.98	P = 0.34
TF50 (22df)	= 1.61	P = 0.12
TF75 (22df)	= 2.26	P = 0.03
TF90 (22df)	= 2.87	P = 0.01

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In summary, pulmonary function tests of this small, randomly selected population of meat wrappers revealed no gross pulmonary effects in comparison to a control population after one workshift of meat wrapping. Furthermore, it must be stated that this exposed study group was of general good health and free of serious symptomatology.

E. Discussion

A study of meat wrapping employees is beset by various intrinsic problems from the onset. These include the following:

- a) Low density dispersal of meat wrappers in any geographic area.
- b) No more than two or three meat wrappers employed at any typical retail store.
- c) Meat wrapping work environments, although similar, are not strictly uniform. Differences can exist in packaging equipment (i.e., operating parameters), type of wrapping material ambient environmental conditions (temperature, humidity), general ventilation provisions, work practices, and volume of meat wrapping performed.
- d) Work shifts for meat wrapping employees are highly variable.
- e) There is a lack of suitable sampling and analytical methodology for the evaluation of employee exposures to PVC film decomposition products encountered in retail meat wrapping. At present, methods are not sensitive enough to characterize intermittent exposures or variable constant exposure via breathing zone sampling techniques.

The above problems interrupted the completion of this preliminary controlled scientific study. At this point, a limited amount of data have been compiled for a population of basically healthy meat wrappers. There remains the necessity to study a sizeable population of seriously affected meat wrappers. It is felt that such a population exists based upon scattered reports of clinical symptomatology from various medical investigators throughout the Nation.

V. REFERENCES

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