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April 8, 1977

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for file of records
on each page.*

Dr. Howard R. Roberts
Acting Director
Bureau of Foods
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Re: Docket No. 75N-0190; Vinyl Chloride Polymers
in Contact With Food; Notice of Proposed Rule
Making, 40 Fed. Reg. 40529, September 3, 1975

Dear Dr. Roberts:

The purpose of this letter is to follow up on the January 5, 1977 conference between your staff and representatives of the Vinyl Chloride/Polyvinyl Chloride Producers Group of The Society of the Plastics Industry, Inc. (SPI). Responsive to the three requests made by members of your staff during that conference, we are herewith submitting the following:

(a) "raw data" to confirm and substantiate the submitted reports of the impressive achievements in reducing residual vinyl chloride monomer (RVCM) to insignificantly low levels in commercially available polyvinyl chloride products intended to contact food,

(b) descriptions of the analytical procedures employed to determine not only RVCM levels but also the levels of vinyl chloride (VCM) in food simulating solvents, and

22568001

BFG21587

Dr. Howard R. Roberts
April 8, 1977
Page Two

(c) a memorandum that provides a full rationale for the conclusion that no vinyl chloride can reasonably be expected to migrate from rigid and semirigid polyvinyl chloride food-contact products under intended conditions of use, provided said products are made in accordance with good manufacturing practices that limit RVCM to a level not exceeding 0.1 parts per million. 1/

It is respectfully submitted that the record, in its entirety, compels the determination that the public interest warrants the use of rigid and semirigid PVC food packaging materials produced in accordance with appropriate good manufacturing practices. Such PVC food packaging materials have been found environmentally preferred over many competing materials by the Bureau of Alcohol, Tobacco and Firearms (BATF) in its assessment of PVC bottles for liquor, 2/ and that determination is confirmed by FDA's findings in its Environmental Impact Statement relating to plastic containers for Beverages. 3/ In particular, the PVC containers provide important benefits with respect to freedom from breakability and the absence of problems with regard to safety.

We submit that it is fatuous to claim a risk to health exists when no vinyl chloride can be measured in food simulating solvents after exaggerated exposures using analytical procedures sensitive to 1 or 2 parts per billion. This is especially true when one considers that under no conceivable circumstances will as much as 10% of the diet be packaged in rigid and semirigid PVC products. The present level of analytical sensitivity is so low that the risk is less than approximately one ten-thousandth the risk deemed by FDA to be "safe" in an analogous context. 4/ This

1/ Due to manufacturing tolerances, a maximum limit of 0.1 ppm requires the average product to be well below that level.

2/ BATF, "Final Environmental Impact Statement, Polyvinyl Chloride Liquor Bottles," March 9, 1973.

3/ FDA, "Final Environmental Impact Statement, Plastic Bottles for Carbonated Beverages and Beer," September, 1976.

4/ 42 Fed. Reg. 10412

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level is at least three orders of magnitude lower than the level the Occupational Safety and Health Administration (OSHA) determined to be safe when it wrote its standard for occupational exposure to vinyl chloride. 5/

The data submitted to the Food and Drug Administration (FDA) during the pendency of the subject rule making has demonstrated that the polyvinyl chloride industry has reduced the residual vinyl chloride levels in rigid and semirigid products from levels in the range of approximately 500 parts per million, which were common before the possibility of migration of vinyl chloride was recognized, to levels well below 0.5 parts per million for many products, a thousand-fold reduction. Furthermore, some products can now be produced with levels of RVCM no greater than 0.1 part per million; and in some cases, particularly for sheet materials used in so-called blister packs, the levels do not exceed 0.05 parts per million. In other words, polyvinyl chloride rigid and semirigid products are now available to the food packaging industry with vanishing small levels of residual vinyl chloride and assure that there will be "no migration" 6/ of vinyl chloride to food packaged in such products when the foods are packed and otherwise handled in accordance with good manufacturing practices for the production and marketing of food products. 7/

5/ 29 C.F.R. 1910.1017

6/ The expression "no migration" is used as a convenient shorthand to mean "no reasonable expectation of becoming a component of food under the intended conditions of use."

7/ It is not claimed nor is it necessary that all rigid and semirigid polyvinyl chloride products be capable of showing no migration of vinyl chloride to food packaged therein; it is only necessary that those products which are offered as, and represented to be suitable for use as, food packaging materials comply with such requirements. Thus, the fact that all manufacturers may not now be offering materials which will provide a "no migration" package should not lead the FDA to ban all PVC products any more than the FDA would ban all paper from food packaging uses because some grades of paper are unsuitable for that purpose. See Natick Paperboard Corp. v. Weinberger, 525 F.2d 1103 (1st Cir. 1975). Accordingly, we urge, as we have in the past, that the FDA set appropriate standards in its good manufacturing practices regulations to assure, in light of the intended uses of such material, that there will be no migration of vinyl chloride to packaged food.

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BFG21589

Dr. Howard R. Roberts
April 8, 1977
Page Four

The raw data and descriptions of analytical procedures are presented in Appendices I through IV. Appendix I, supplied by the American Hoechst Corporation, Film Division, summarizes the residual vinyl chloride content of PVC resins received by American Hoechst during 1974 through 1976, provides a typical detailed report of lot-by-lot results for RVCN for the month of October 1976, provides typical chromatograms for a sampling of the individual lots reported for October 1976, demonstrates the reduction in RVCN achieved during the blending process wherein resin as purchased is converted to a product ready for formation into sheet product, provides typical chromatograms for material before and after blending, and, finally, sets forth the detailed analytical procedures that were employed.

Appendix II was submitted by the B. F. Goodrich Company. It includes an update of the RVCN levels in both resin and finished bottle compounds supplied by B.F. Goodrich during the last quarter of 1976. The gas chromatographic procedure employed by B. F. Goodrich for the determination of the residual vinyl chloride monomer content of polyvinyl chloride resins and wet cake samples is provided, as well as a report by J. A. Nikora and E. G. DeCapita entitled "Confirming the Presence of Vinyl Chloride in Food Simulating Solvents."

Appendix III supplied by Ethyl Corporation consists of information already supplied separately to FDA. It includes a document dated January 10, 1977, addressed to the Hearing Clerk, containing Addenda A through E as direct responses to the January 5, 1977 request for raw data and analytical methodology. In addition, there is a separate submission also addressed to the Hearing Clerk by means of a letter dated January 13, 1977, entitled "VCN Migration Studies with PVC Bottles Containing Low VCN Concentrations" dated January 10, 1977 written by Cannaday, Daniels, and Gaeke. This paper is particularly significant because it demonstrates that the chromatographic determination of vinyl chloride in food simulating solvents used to test low RVCN containers is subject to significant interferences and the consequent appearance of false positives. This same observation was reported by Tenneco in its independent submissions to FDA, and we understand similar effects have been observed by FDA scientists as well.

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Dr. Howard R. Roberts
April 8, 1977
Page Five

In order to provide more definitive evidence of interferences and to provide direct experimental evidence for setting a residual vinyl chloride level in bottles or bottle compounds that will assure "no migration," a protocol for a study was developed in consultation with FDA scientists; and samples of the experimental bottles have already been provided to the FDA staff. The test is now under way; and when the exposure time has been completed, samples of the extract will be supplied to the FDA scientists for their own independent analysis. The final results are expected soon, and will be reported by Ethyl Corporation as soon as they are available.

Appendix IV has been supplied by the Ruco Division of Hooker. This includes analytical procedures for the determination of RVCM in resins by either a solution procedure or by head space analysis, typical quality control chromatograms including standardizations, blank determinations and typical analyses of bottle compounds using both procedures, and the analysis of a compound deliberately "spiked" to show a large quantity of vinyl chloride.

The final attachment, Appendix V, is a memorandum that discusses in considerable detail why there is no reasonable expectation of migration of vinyl chloride into food under intended conditions of use from rigid and semirigid PVC food-contact materials that contain very low levels of residual vinyl chloride.

Taken together, these appendices confirm current industry capability of producing PVC resins with residual monomer levels well below 0.5 parts per million, that producing compounds from these resins results in a loss of from 50% to more than 90% of the RVCM originally contained in the resin and that processing into finished products still further lowers the residual vinyl chloride level. In other words, rigid and semirigid PVC containers can be produced for food-contact purposes with residual monomer

22568005

BFG21591

Dr. Howard R. Roberts
April 8, 1977
Page Six

levels not exceeding 0.1 parts per million; and when such materials are used in food packaging, there is no reasonable expectation that vinyl chloride will become a component of food under the intended conditions of use. Accordingly, we urge the FDA to adopt final Regulations consistent with these facts.

Cordially yours,

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M E M O R A N D U M

THERE IS NO REASONABLE EXPECTATION THAT
VINYL CHLORIDE WILL BECOME A COMPONENT OF FOOD
IF THE RESIDUAL VINYL CHLORIDE CONTENT OF THE PACKAGING
MATERIAL DOES NOT EXCEED ONE-TENTH PART PER MILLION

Background

In its Notice of September 3, 1975 (Docket No. 75N-0190, Vinyl Chloride Polymers In Contact With Food) the Food and Drug Administration proposed to deal separately with polyvinyl chloride (PVC) food packaging materials in three categories:

1. Uses to be affirmed as prior sanctioned including coatings, gaskets, cap liners, flexible tubing, plasticized film and the like;
2. Potable water pipe; and
3. Rigid and semi-rigid materials.

SPI filed extensive Comments which included a comprehensive legal analysis of the meaning of the term "food additive" as defined in Section 201(s) of the Federal Food, Drug and Cosmetic Act, voluminous scientific data relating to residual monomer levels in rigid and semi-rigid PVC food contact materials, and the results of the migration studies conducted with such materials. Subsequent to the filing of these Comments, SPI and member companies thereof continued to provide to the Food and Drug Administration additional scientific data as they were being developed bearing on the possible migration of vinyl chloride (VCM) from rigid and semi-rigid PVC food packaging materials.

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In anticipation of the promulgation of final regulations in this proceeding ^{1/} the industry requested a meeting to bring the Food and Drug Administration completely up-to-date regarding the major improvements made by the PVC industry in reducing residual vinyl chloride (RVCM) levels in food contact materials to vanishingly low levels. This information was presented at a conference held in Washington, D.C. on January 5, 1977.

At the conclusion of the conference the Food and Drug Administration representatives requested (1) that the information supplied be supplemented with "raw data" bearing on the results that were reported, (2) that the analytical procedures employed be supplied, and (3) that explanatory information be furnished to provide a rationale for the industry conclusion that, from currently available rigid and semi-rigid materials, there would be no reasonable expectation of migration of vinyl chloride to food. The technical information requested is being supplied in separate documents which are being submitted at this time. The requested rationale forms the substance of this document.

^{1/} As a matter of internal management procedures it is understood the Food and Drug Administration attempts to promulgate final regulations or withdraw a proposed regulation within two years of the publication of a Notice of Proposed Rulemaking.

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Scientific--Technical Considerations

1. Clearly, the most significant factor leading to the conclusion of "no migration" ^{2/} is that no vinyl chloride could be detected in the appropriate test solvents using analytical procedures of extreme sensitivity, i.e., capable of quantifying vinyl chloride at a level of 1 or 2 parts per billion (ppb) when exaggerated extraction tests were conducted. In other words, rigid and semi-rigid PVC packaging materials containing the very low levels of residual VCM now being achieved in commerce were tested under conditions designed to reasonably exaggerate the likelihood of migration and no such migration could be detected. This demonstrable fact alone should be sufficient to confirm the validity of the conclusion reached by the industry scientists that there will be "no migration" of vinyl chloride into food under intended conditions of use of rigid and semi-rigid PVC packaging materials of the quality now being supplied. It should be borne in mind that conclusions in the physical sciences must be based on empirical evidence. Theory and speculation guide the choice and design of experiments but the experimental results are the only conclusions.

^{2/} It should be appreciated that the phrase "no migration" is used in this document as a convenient shorthand for the more lengthy statutory criteria embodied in §201(s) of the Act of "no reasonable expectation of becoming a component of food."

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2. The experimental data cited above are supported and reinforced by theoretical considerations. The "driving force" that makes a substance migrate from the interior of a container wall to the surface and, thereafter, into the container contents ^{3/} is the difference between the effective concentration of the substance in the container wall and its concentration in the food. When the level in the container wall is relatively high, a large differential in concentration exists; the resistance of the plastic to migration is overcome, and migration is rapid and extensive. As the level in the container wall is reduced, the concentration differential is reduced; and both the rate of migration and the quantity migrating diminish. Finally, when the concentration in the walls becomes vanishingly small, as is the case in the presently available PVC containers, the driving force cannot readily overcome the resistance; and both the rate of migration and the quantity migrating likewise become vanishingly small to the point where the substance cannot be detected even at extremely low levels. Indeed, there is no way of knowing that the resistance can

^{3/} It is recognized that migration from the container wall to the exterior will also occur. Data in the file show that of the RVCM actually migrating from "high" RVCM containers approximately one-third migrates into the contents and two-thirds migrates to the exterior.

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really be overcome at all and that any migration will occur. In short, when the concentration in the walls of a container becomes as small as it is now, there is no realistic expectation of migration.

3. This explanation is still further reinforced by the following considerations: If one were to consider a typical rigid container wall (0.020 inches thick) that contained 0.1 ppm of residual vinyl chloride, and make the totally unrealistic assumption that all the residual vinyl chloride available for migration into the contents did in fact migrate to food packaged in such a container, the maximum calculable concentration of vinyl chloride would be approximately 2 parts per billion (ppb), a quantity capable of analytically quantifiable measurement. The evidence cited above demonstrates that such total migration does not occur. Much scientific evidence already provided to the Food and Drug Administration has demonstrated with containers having high levels of RVCM that far less than the maximum potentially migratable quantity of vinyl chloride does in fact migrate even under exaggerated exposure conditions. It is apparent, therefore, that with containers made with the extremely low level of RVCM discussed here, there can be no realistic expectation of migration of vinyl chloride.

4. Summarizing then, scientific-technical considerations based upon available information and established scientific

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principles lead to the conclusion that there is no reasonable expectation of migration of vinyl chloride from container walls when the level of residual vinyl chloride in such walls is adequately low. The data presented in this docket indicate that 0.1 ppm is an "adequately low" level.

Practical Considerations

1. Since the chemical tests show "no migration" of vinyl chloride, the major practical consideration is whether the analytical procedures used to determine whether vinyl chloride migrates are sufficiently sensitive to assure the public health and safety when the "no migration" conclusion is relied upon. The Commissioner has answered this question in the affirmative in an analogous context, and we submit those same principles are clearly applicable here.

In his rulemaking on chemical compounds in food-producing animals, published in the Federal Register on February 22, 1977 (42 Fed. Reg. 10412), the Commissioner clearly embraced the concept that the Mantel-Bryan biostatistical procedure is suitable for specifying a level of analytical sensitivity for resolving the question as to whether or not carcinogenic drug residues are present in edible tissues of an animal to which that drug was fed. If no residue of the drug in issue can be detected in the edible tissues of animals fed such drug

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by means of an analytical procedure with a capability of detection at levels specified by the Mantel-Bryan procedure as adequate to assure the public health and safety, the Commissioner has determined that no drug residue is present. The same biostatistical extrapolation procedure, applied to vinyl chloride, will specify a detection sensitivity that will likewise assure that a finding that no vinyl chloride is present in food or food-simulating solvents will assure the safety of the general public. Such a finding should likewise lead to the conclusion that no vinyl chloride is present--that there has been "no migration" of vinyl chloride.

2. The file in this proceeding demonstrates that the application of the Mantel-Bryan procedure to the data available at the time our original Comments were filed shows that a minimum detection capability orders of magnitude higher than that actually available would be sufficient. In other words, a finding of no vinyl chloride in food-simulating solvents after suitably exaggerative exposures provides far greater assurance of no significant risk of harm than the Commissioner indicated would be sufficient in the case of animal drug residues, hence, a far sounder basis for reaching a "no migration" conclusion.

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3. In the section on Scientific-Technical Considerations, calculations and conclusions were presented for a typical bottle wall thickness of 0.020 inches and a residual VCM content of 0.1 ppm. However, evidence has been presented showing that for many applications thinner walled containers and materials of much lower RVC are used. Furthermore, many applications exist involving refrigerated shipment and storage, as well as products with limited shelf life. To the extent that any of these considerations apply, there will be still greater assurance of "no migration"; to the extent that several are simultaneously effective, the degree of assurance will be again compounded.

4. One final practical consideration should be mentioned. Vinyl chloride is relatively insoluble in aqueous or even fatty foods: it tends to evaporate from food to the air which is in contact with that food. This phenomenon is the basis for the most sensitive analytical procedures now available since the vinyl chloride in a relatively large volume of food or solvent is readily transferred into and thus concentrated in a smaller quantity of air.

Thus, even if a measurable level of vinyl chloride were present in the contents of an actual food container, the vinyl chloride would tend to concentrate in the head space leaving only a very low level in the food itself. When the

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container is opened, the vinyl chloride in the head space will escape immediately. Upon reclosure the same redistribution phenomenon from food to head space would reoccur and upon reopening the second increment of vinyl chloride would escape. Likewise, food removed from such a container and exposed to air, stirred, heated or otherwise prepared would experience a rapid and substantially complete loss of any vinyl chloride it might have contained. In other words, where formerly used containers may have permitted the migration of vinyl chloride to a limited extent to the contents of such containers, the concentration of vinyl chloride that actually became a component of the diet was tremendously reduced. The application of this same principle to food packaged in the low RVCM containers adds still another major safety factor to assure there will be no vinyl chloride in food as consumed.

Legal

1. Comprehensive and well documented evidence has been submitted to the Commissioner demonstrating that there are no detectable extractives of vinyl chloride from food-contact articles into food-simulating solvents at a detection limit of approximately 0.001 part per million. It is respectfully submitted that this showing demands the conclusion there is no basis for regulating the residual vinyl chloride content of PVC food-contact articles as a Food Additive as defined

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in Section 201(s) of the Act. Failure to reach this conclusion would require the Commissioner to find that the mere presence of residual vinyl chloride monomer in the food-contact article is sufficient to determine that VCM in fact becomes or reasonably may be expected to become a component or otherwise affect the characteristics of any food irrespective of a factual basis for such a conclusion. It is respectfully submitted that such a determination is inconsistent with the governing statutory standard and the Commissioner's authority.

(2) The Food Additive definition in Section 201(s) of the Act entails essentially four (4) criteria:

- (a) That the substance becomes a component of food,
- (b) That the substance otherwise affects the characteristics of food,
- (c) That the substance may reasonably be expected to become a component of food, or
- (d) That the component may reasonably be expected to affect the characteristics of food.

The credible evidence before the Commissioner indicates that such residual vinyl chloride as may remain in PVC food contact articles neither becomes a component of food (i.e., is not a detectable component) nor affects the characteristic of any food. Furthermore, in that the known behavior of vinyl chloride in small but measurable quantities evidences that its presence in food does not affect the characteristics of such food, a

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fortiori, its possible presence in immeasurable quantities cannot affect the characteristics of food. Thus, the first, second and fourth criteria of Section 201(s) as stated above do not provide a basis for regulation as a food additive.

Accordingly, the issue presented is whether vinyl chloride present in PVC food-contact articles at a level not exceeding 0.1 ppm may reasonably be expected to become a component of any food. Obviously to reach an affirmative conclusion relies on a priori reasoning that necessarily ignores the only relevant scientific data, namely that there are no detectable extractives of vinyl chloride in the food-simulating solvents.

Recognizing that there are few, if any, absolutes with respect to food additive chemistry, the Congress established a standard based upon reasonable expectation rather than upon an absolute accounting for all potential contingencies under all undefined conditions. As discussed in SPI's December 19, 1975 Comments, hypothetical abstractions which cannot be proven do not give rise to reasonable expectations; in the absence of a clearly expressed congressional intent to the contrary, such hypothetical abstractions do not form the basis for the exercise of delegated regulatory authority.

Moreover, such a conclusion is not permissible under Section 201(s) which defines food additives in terms of "becoming a component or otherwise affecting the characteristics of any

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food. . . ." In that the phrase "or otherwise affecting the characteristics of any food" refers back to the "component" criteria, it thereby indicates a statutory intent that a component affect the characteristics of the food. Thus, to the extent that a component, in the statutory rather than theoretical sense, must affect the characteristics of any food, it must be measurable and perceptible in and of itself or in its effect. Otherwise stated, the effect of being a component is one of discernable physical presence. It is established, however, that vinyl chloride at levels less than 0.001 part per million does not have either an ascertainable physical presence or any other effect. Thus, it cannot reasonably be considered to be a component of any food. The Mantel-Bryan procedure adopted by the Commissioner in 42 Fed. Reg. 10412 confirms that FDA concurs with this position in an applicable analogous Section 409 situation.

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Re: Vinyl Chloride Polymers in
Contact With Food, Notice
Of Proposed Rulemaking; Docket
No. 75N-0190

Dear Dr. Roberts:

The purpose of this letter, sent in anticipation of our meeting with you and your associates on January 5, is to provide up-to-date information which we have elicited and received from key members of the VCM/PVC Producers Group of our client, The Society of the Plastics Industry, Inc. In light of the long pendency of the referenced rulemaking proceeding, we requested the meeting and have obtained these additional data because we consider it essential that the Food and Drug Administration be as fully advised as possible about the current state of the art vis-a-vis potential polyvinyl chloride food contact surface technology. In our opinion, and we are most hopeful that FDA's scientists will agree, the industry has now progressed to a point where it cannot be legitimately stated that polyvinyl chloride food contact surfaces, including such packages as PVC bottles and "blister pack," may reasonably be expected to result in vinyl chloride monomer becoming a component of food unless one gives the word "reasonable" a type of meaning that would amount to a reductio ad absurdum.

Before briefly summarizing and discussing the attached reports received from the members of the Society, it occurred to us that it might be best to restate a little of the background relevant to this situation although we are certainly aware that you and your associates are fully cognizant of where the matter stands.

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of data. One reports the residual monomer content of the PVC homopolymer resins it has been purchasing in the period from 1974 through 1976; the other provides an indication of the reduction of residual monomer content achieved by its new blending process in going from resin to finished compound before sheet formation.

Supplemental to the data on residual monomer levels supplied by each of the participants in this survey, we are also including a copy of an internal report prepared by C.A. Daniels of the B.F. Goodrich Company which provides predicted vinyl chloride migration data obtained from a predictive model developed by Goodrich. The data were developed for migration into 50% ethanol/water, a solvent known to be extremely aggressive in extracting vinyl chloride from PVC containers. These calculated results are considered to be conservative in that they are based on the assumption that the diffusion coefficient is constant and does not decrease as the concentration of residual monomer decreases (i.e. that the system does not show the so-called "Gilbert" effect.) Further conservatism is introduced into the assumptions of this model in that no allowance is made for loss through the seal, a phenomenon which appears to be real and ubiquitous and which tends to reduce the actual monomer level within a container below those calculated on the assumption that "leakage" does not occur.

In light of the fact that the information presented here has been developed independently and reports the discrete experience of the different reporting companies, it is our view that it is best to let the reports speak for themselves rather than attempt to provide any detailed characterizations of our own. Nevertheless, we believe it is fair to say the data demonstrate that the PVC industry can now provide, and is providing, bottle and sheet compounds with residual monomer levels sufficiently low as to warrant the conclusion of any ordinary, reasonable and prudent man that the likelihood of migration to foods, drugs or cosmetics is non-existent. Certainly, in light of data already provided to the Food and Drug Administration by Ethyl Corporation regarding samples which had been stored for longer than two years, data submitted in the Comments which showed no detectable VCM migration from bottles with approximately 0.35 ppm RVCM in the walls, and the predictive model data which is being provided herewith, we believe it would be

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ETHYL CORPORATION

J. R. LEES
DIRECTOR OF MARKETING
PLASTICS GROUP

December 23, 1976

Mr. Jerry Heckman
Keller & Heckman
1150 - 17th Street NW
Suite 1000
Washington, D. C. 20036

Dear Jerry:

Attached is our position paper a little in advance, but we think we can handle what it says. We will be available for conversation by phone all next week and are planning to attend the meeting on January 5.

We look forward to receiving your compendium.

Very truly yours,

J. R. Lees

mar
attachment

of compound and bottles, the final VCM levels possible in bottle walls do not exceed 80% of the above compound values.

The compounding resin from which Ethyl bottle compound is produced is also rigidly controlled in regard to reduced VCM level. Our production specification for bottle grade resin is less than 10 ppm VCM content. To maintain this level in production also requires averages substantially lower than this number. Average bottle resin level during the latest 431 lots was 4.33 ppm.

It cannot be over emphasized that to maintain a rigid specification of 10 ppm maximum in bottle resin results in actual lot analyses covering a distribution of values whose mean must of necessity fall significantly below the control specification. The identical consideration applies to bottle compound produced from this resin. Thus, Ethyl starts with bottle resin produced with a distribution of values centering about a mean of about 4.0 ppm to maintain a maximum control specification of 10 ppm and converts this resin to bottle compound having in turn a distribution of values centering about a mean of 0.2 ppm (to maintain a maximum control specification in compound of <1 ppm VCM).

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submitted to the FDA extension long-term storage data representing today's commercial bottle compounds stored under exaggerated conditions. The bottles employed were small (2 oz.) and contained 41 ppm VCM in the wall. Results showed no detectable vinyl chloride monomer migration, after 27 months' room temperature storage, in standard FDA food-simulating solvents.

*Reference Ethyl Corporation submitted to Hearing Clerk, Food and Drug Administration, dated Sept. 27, 1976.

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STATEMENT BY UNION CARBIDE CORPORATION REGARDING VINYL
RESINS FOR RIGID AND SEMI-RIGID SHEET INTENDED FOR USE
IN FOOD CONTACT APPLICATIONS

This is essentially a condensation of that portion of our submission dated November 10, 1975, (Docket No. 75-N-0190) which deals with the use of Union Carbide Corporation solution and non-solvent resins in food contact applications.

Solution polymerized vinyl chloride-vinyl acetate resins are produced from monomers, solvent, and peroxide catalyst in a stirred autoclave under controlled conditions of temperature and pressure. Polymer formed is soluble in the solvent. Dissolved polymer is withdrawn, residual vinyl chloride monomer removed by a stripping process, and the polymer is precipitated by the addition of water and alcohol. Polymer is recovered by centrifugation, washed, and vacuum stripped. Wet resin is then ground, dried in a multi-stage dryer and packaged. This unique solvent polymerization precipitation recovery system results in relatively porous particles highly favorable to the efficient removal of residual vinyl chloride monomer. BAKELITE solvent polymerized resins contain no detectable vinyl chloride monomer when analyzed by a method sensitive to 0.2 ppm.

Non-solvent polymerized resins are produced by a continuous process in which fresh monomer is fed continuously to a pressurized autoclave and a mixture of polymer and monomer is continuously withdrawn. Other than catalyst and its carrier, no other materials are added. The monomer/resin slurry is discharged into hot water where monomer is boiled off and recovered. Suspended resin is continuously recovered by centrifugation, dried in a two stage flash drier, and packaged. This low conversion bulk polymerization process yields a small, very porous particle. These resins, as produced, contain less than 3 ppm of residual monomer but due to its small size and porous nature, within three days of manufacture the residual monomer content is reduced to 10% of its original value. Samples of resin as received by customers and analyzed by Union Carbide by a method sensitive to 0.2 ppm normally show no detectable vinyl chloride monomer.

Both solution and non-solvent vinyl resins are suitable for use in rigid and semi-rigid sheets for food packaging applications. The single-service jelly and jam container, which holds approximately 15 g of food and weighs approximately 600 mg, represents the most severe surface to volume ratio to be expected in a food packaging application. Assuming a residual vinyl chloride monomer content of <0.2 ppm, the 600 mg container would provide less than 0.00012 mg of monomer as a potential migrant to food. Assuming that half of this amount would migrate inward to the food, the monomer concentration in the 15 g of contained food would be less than 4.0 ppb.

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- 4) Based on the experimental test results which were submitted in our December, 1975 presentation to the Food and Drug Administration, as well as continuing work, it is established that PVC sheet of the kind currently being produced by Tenneco Chemicals, as well as the sheet that has been produced in the last twelve months, cannot reasonably be expected to cause VCM to become a component of food. We have further assured this on a continuing basis by the regular analysis of production samples of food grade rigid sheet.

It should be further noted that it has been established by the Department of Food Science at Rutgers University, that when the residual monomer in a rigid vinyl sheet is at 10 parts per billion or less reading on the gas chromatograph, subsequent analysis by G.C. mass fragmentography has been shown to be unable to identify this very minute amount as being vinyl chloride.

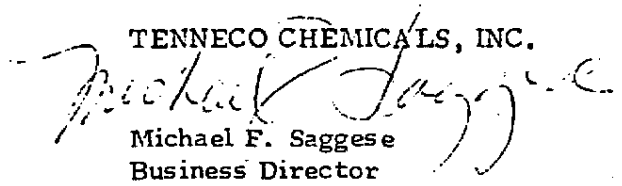
Our laboratories and manufacturing departments are continuing to work on ways and means of virtual elimination of vinyl chloride while continuing to use more and more sensitive tests. While this objective is currently underway, it now becomes evident as to the impracticality of the endeavor. We are speaking of such very low levels that we can find these levels in materials other than rigid vinyl.

We, therefore, conclude that establishment of a level of 30 parts per billion very adequately protects the consumer from any VCM ingestion by virtue of migration from the sheet, and based on our work and data we would suggest that a regulation be established at the 30 parts per billion level. However, we also feel that there is sufficient safety at the 50 parts per billion level residual monomer in the sheet.

I trust the foregoing adequately outlines our progress to date and our position regarding this matter. Should any further information or details be needed, we shall be glad to supply same.

Sincerely,

TENNECO CHEMICALS, INC.


Michael F. Saggese
Business Director

or

22569021

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TABLE I-A

Residual VCM Content of Resin Blends
Before and After New Blending Process

(American Hoechst Corporation Data)

<u>Control No. (1)</u>	<u>Residual VCM Level - ppm</u>	
	<u>Before Blending</u>	<u>After Blending (2)</u>
1	37.0	2.5
2	21.0	<1.5
3	13.0	<1.5
4	7.7	<1.5
5	7.7	0.50
6	6.5	0.34
7	5.7	0.19
8	4.9	0.16
9	4.2	0.11
10	4.0	ND (<0.10)
11	3.0	ND (<0.10)
12	2.0	ND (<0.10)
13	1.0	ND (<0.10)
14	0.5	0.020
15	0.25	ND (<0.01)
16	0.15	ND (<0.01)
17	0.10	ND (<0.01)

NOTES:

- (1) Samples no. 1-4 run by method with LDL of < 1.5 ppm; samples no. 5-13 run with new method with LDL of < 0.10 ppm; samples no. 14-17 run with revised method with LDL of < 0.01 ppm
- (2) After high intensity devolatilization blending technique which can be licensed from American Hoechst Corporation if desired.

RH:vel
12/10/76

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Another method of expressing the data is to choose a level of RVCM in the bottle compound, and to calculate the level of vinyl chloride contained in the bottle contents. For a one milligram per kilogram (ppm) pipe compound, for an 8 and 64 oz. bottle, 75°F, these tabulations are given in Table I. This distinctly shows the relationship between the size (volume) of the bottle and the migrating VCM levels, that is, the surface to volume ratio effect. Naturally, the smaller the volume of the bottle, the higher the VCM in the contents at a given time and RVCM in the bottle wall. The graph also shows the expected effect of temperature, namely that the higher temperatures produce higher vinyl chloride migration levels.

The calculation capabilities are not limited to these sizes, temperatures or residence times. However, the diffusivity data are those published for specific, but typical, bottle compound compositions. Thus, we feel with certainty that these calculations accurately represent the expected migration levels from PVC bottles into 50% ethanol-water solutions.

Chuck

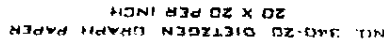
C. A. Daniels

CAD/dms

cc: J. R. Goots
A. P. Metzger
F. E. Krause
A. L. Schultz
E. A. Collins

22569025

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PREPRINT

(Accepted for May 1977 issue of JAOAC)

Gas-Liquid Chromatographic Headspace Procedure for Determination of
Vinyl Chloride in Vegetable Oil and Three Food Simulating Solvents.

By Gregory W. Diachenko, Charles V. Breder, Margaret Brown, and
J. Lawrence Dennison

Division of Chemical Technology, Bureau of Foods, Food and Drug
Administration, 200 "C" Street, S.W., Washington, D.C. 20204

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In early 1973, alcoholic liquors packaged in polyvinyl chloride (PVC) bottles were found to be contaminated with vinyl chloride (VC) migrating from the plastic (1). These findings, coupled with the demonstrated carcinogenicity of VC by inhalation (2), led to a great deal of concern about the possible migration of VC into foods. Several investigators subsequently detected VC in other foods such as vegetable oils, edible fats, and vinegars packaged in PVC bottles (2,3,4). These findings have increased significance in view of research by Maltoni et.al. (2), indicating the possibility that VC is also carcinogenic by ingestion.

PVC producers and converters have recently improved their manufacturing technology resulting in lower amounts of residual VC monomer in PVC resins and products. Several manufacturers have used new stripping technology to produce resin and finished rigid PVC articles with residual VC levels in the low ppm to low ppb range. Direct solution injection gas chromatographic (GLC) techniques generally do not have sufficient sensitivity to detect the small quantities of VC migrating from these materials. In view of this, it is desirable to have a more sensitive analytical procedure to detect and measure low levels of VC which may migrate from PVC into foods or food simulating solvents. Building on other GLC-headspace techniques (3,4,5) and the procedure of Breder et.al. (6), our laboratory has refined and developed procedures which permit the quantitative determination of VC at the 1 ppb level in food simulating solvents such as 50% ethanol, 3% acetic acid, n-heptane, and vegetable oil.

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(d) Gas Chromatograph.-Hewlett-Packard Model 7620A, or equivalent, equipped with temperature programmer and flame ionization detector. Operating conditions: temperatures (°C)-detector 260, injection port 200; flows (ml/min)-hydrogen 70, oxygen 480; electrometer setting, 1 or 2×10^{-12} amps full scale. Detector sensitivity: 0.7 ng VC gave 50% full scale deflection at retention time of 2.5 min and electrometer setting of 1×10^{-12} amps full scale.

(e) Chromatographic column.-Coiled stainless steel column 5'X2 mm id, packed with 60-80 mesh Chromosorb 104; temperature programmed (°C), 95 for 5 min, 95-250 at 30/min, hold for 6 min; helium carrier flow adjusted to give VC retention time of 2.0-3.5 min (ca 50 ml/min).

Preparation of Standards

Prepare stock VC solutions of ca 1 and 5 ppm concentrations in each of desired food simulating solvents as previously described (6). Check VC concentration by injecting solution into gas chromatograph and comparing area response with that obtained from equivalent amount of 1.00 ppm VC standard gas. Area measurements should agree within $\pm 5\%$. Prepare headspace standards by injecting calculated volumes of VC stock solution into 35 ml (1 oz) septum sealed bottles containing measured volumes of food simulating solvents. Volumes of sample and standard 35 ml septum sealed bottles should be matched within ± 0.5 ml.

Preparation of Sample and Analysis:

Invert solutions to be analyzed for VC several times to insure solution homogeneity. Analyze as described below.

Ethanol (50%) and acetic acid (3%)-Thoroughly purge 35 ml bottle with Nitrogen and seal with septum and cap. Using a 10 ml gas

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Discussion and Results

The high vapor pressure of VC (B.P.-14°C) makes it ideally suited for determination by a headspace technique. The favorable partitioning of VC into the headspace over a sample and the relatively clean matrix in the headspace enables GLC injections of larger percentages of the total VC in samples than could be obtained by direct solution injection. Detection levels by this headspace technique ranged from approximately 0.1 ppb (ng VC/ml) in 50% ethanol to 0.5 ppb in corn oil. These detection levels are 10 to 50 times lower than those obtainable using a direct solution injection technique for food simulating solvents (6).

Equilibration of the headspace/solvent system at 90°C is rapid. This was shown by the vinyl chloride concentration in the headspace remaining constant when analyzed at periods from 30 min to 2 hr. The experimentally determined concentrations of VC in the headspace over spiked solutions were used to calculate partition coefficients. By dividing the ng VC/ml of headspace by the ng VC/ml remaining in solution (obtained by difference), the following partition coefficients at 90° were calculated; 0.5 for 50% ethanol, 1 for 3% acetic acid, 0.09 for heptane, and 0.09 for corn oil.

Food simulating solvents spiked at concentrations ranging from 0.1 to 100 ppb with VC stock solutions in the same solvent gave linear calibration curves. The reproducibility in preparing and checking VC standards by this headspace technique was determined for corn oil and 50% ethanol. Three sets of standards, each consisting of 3 or 4 units, were prepared in each solvent, and quantitated using previously prepared

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were analyzed as previously described. Previous work in our laboratory showed that equilibrium was reached for similar PVC materials within these two time periods. Results of the headspace analyses of these solutions, shown in Table 2, gave average concentrations of 1.6 and 2.4 ppb VC in 50% ethanol and 2.5 and 4.8 ppb in corn oil for lots 1 and 2 respectively. These concentrations represent total migrations of approximately one third and one half of the residual VC from the PVC sheets into 50% ethanol and corn oil respectively.

Consistent losses of VC were obtained for the four 1 ppb standard solutions in each solvent subjected to the same conditions as the sample migration solutions. Average losses of VC were 64% (60, 63, 63, 68) from 50% ethanol standards and 37% (35, 35, 37, 41) from corn oil standards. These losses are suspected to be due to diffusion of VC through the Teflon lined septa used to seal the migration bottles. If one assumes that similar losses occurred from the PVC migration solutions, then the migration of much larger amounts of VC actually took place. The measured values might therefore be corrected for losses by applying correction factors derived from the standard solutions. These loss-corrected values would give percentages of maximum VC migration into corn oil and 50% ethanol ranging from about 2/3 to near complete migration. Although the GLC chromatograms of these solutions, shown in Figs. 5 and 6, are less than ideal, the data in Table 2 indicate they were adequate for reasonably reproducible quantitation. The chromatogram in Fig. 7, obtained in a previous VC migration study in our laboratory, illustrates the type of chromatogram obtained for migration solutions containing higher concentrations of VC and smaller amounts of extraneous chromatographable compounds. The presence and approximate amounts of VC in the 50% ethanol migration solutions were confirmed by GLC-MS.

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Acknowledgment

The authors thank Virgil Warren, Division of Chemical Technology,
Food and Drug Administration, Washington, D.C. for his GLC-MS confirmation
of VC in food simulating solvents.

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Table 2. VC Migration from PVC Sheets into 50% Ethanol and Corn Oil

Sample	Initial ppm VC in PVC	ppb VC Found in Migration Solutions		Z Maximum VC Migration *	
		50% Ethanol (19 days @ 120°F)	Corn Oil (54 Days @ 120°F)	50% ETOH (19 days @ 120°F)	Corn Oil (54 days @ 120°F)
1a	0.28	1.6	2.8 (2.6, 3.0)	28	50 (46, 54)
1b		1.5	2.2 (2.1, 2.2)	32	41 (40, 41)
2a	0.44	2.3	4.6 (4.5, 4.6)	31	60 (59, 60)
2b		2.5	4.9 (4.7, 5.1)	33	60 (58, 62)

*Uncorrected for VC losses from 1 ppb standards treated identically to the samples. See text for discussion.

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FIG. 1 - Gas-liquid chromatograms of 3.0 ml headspace aliquots from over 50% ethanol solutions: A, Blank; B, 0.5 ppb VC standard solution, ca 0.5 ng VC injected; 2×10^{-12} afs.

FIG. 2 - Gas-liquid chromatogram of 3.0 ml headspace aliquot from over 50% ethanol solution; 5.8 ppb VC standard; ca 6.2 ng VC injected; 8×10^{-12} afs.

FIG. 3 - Gas-liquid chromatograms of 4.0 ml headspace aliquots from over corn oil solutions: A, Blank; B, 1.0 ppb VC standard solution; ca 0.35 ng VC injected; 2×10^{-12} afs.

FIG. 4 - Gas-liquid chromatogram of 4.0 ml headspace aliquot from over corn oil; 5.7 ppb VC standard solution; ca 1.9 ng VC injected; 2×10^{-12} afs.

FIG. 5 - Gas-liquid chromatogram of 3.0 ml headspace aliquot from over 50% ethanol migration solution; PVC lot 1b, representing ca 1.4 ng VC; 2×10^{-12} afs.

FIG. 6 - Gas-liquid chromatogram of 4.0 ml headspace aliquot from over corn oil migration solution; PVC lot 1a, representing ca 1.1 ng VC; 2×10^{-12} afs.

FIG. 7 - Gas-liquid chromatogram of 3.0 ml headspace aliquot from over 50% ethanol migration solution; PVC sheet contained 0.54 ppm residual VC monomer before migration; concentration in solution ca 10.7 ppb; 16×10^{-12} afs.

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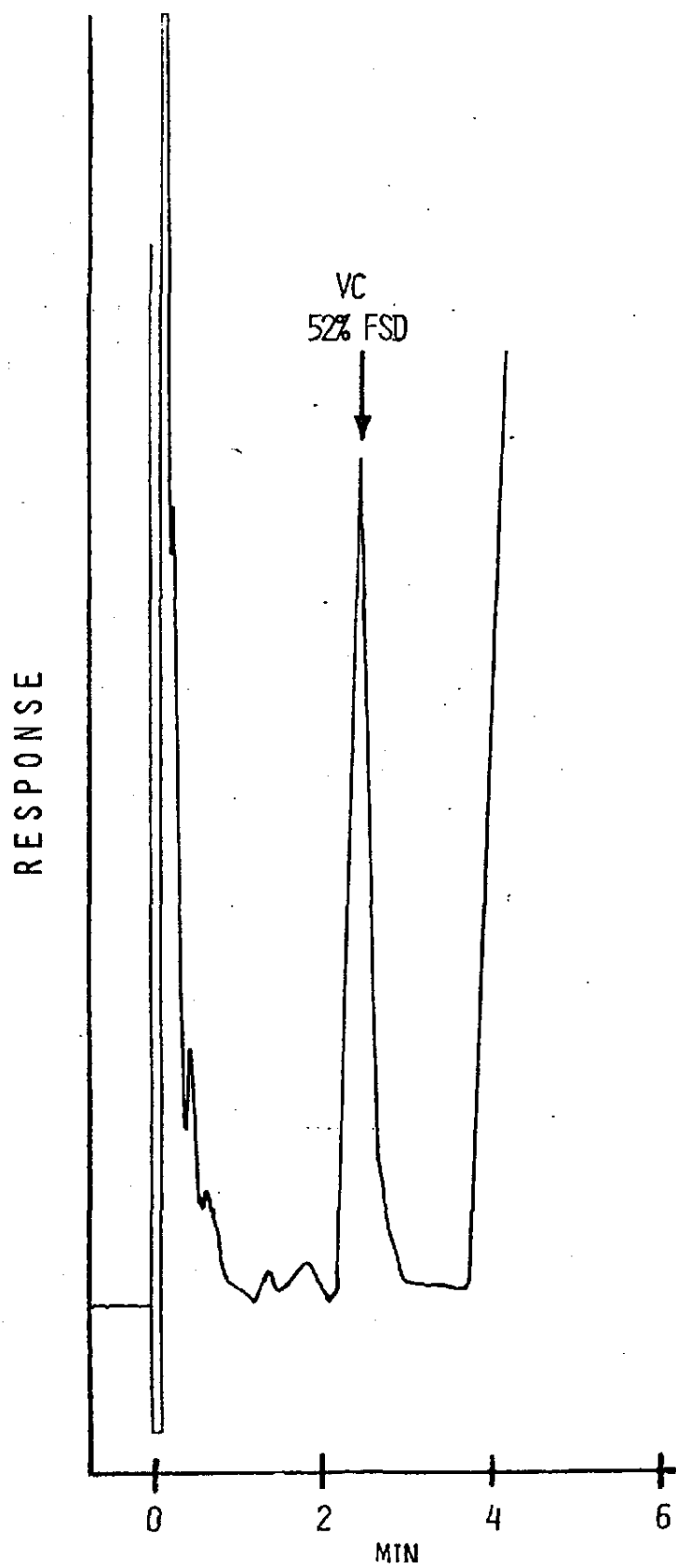
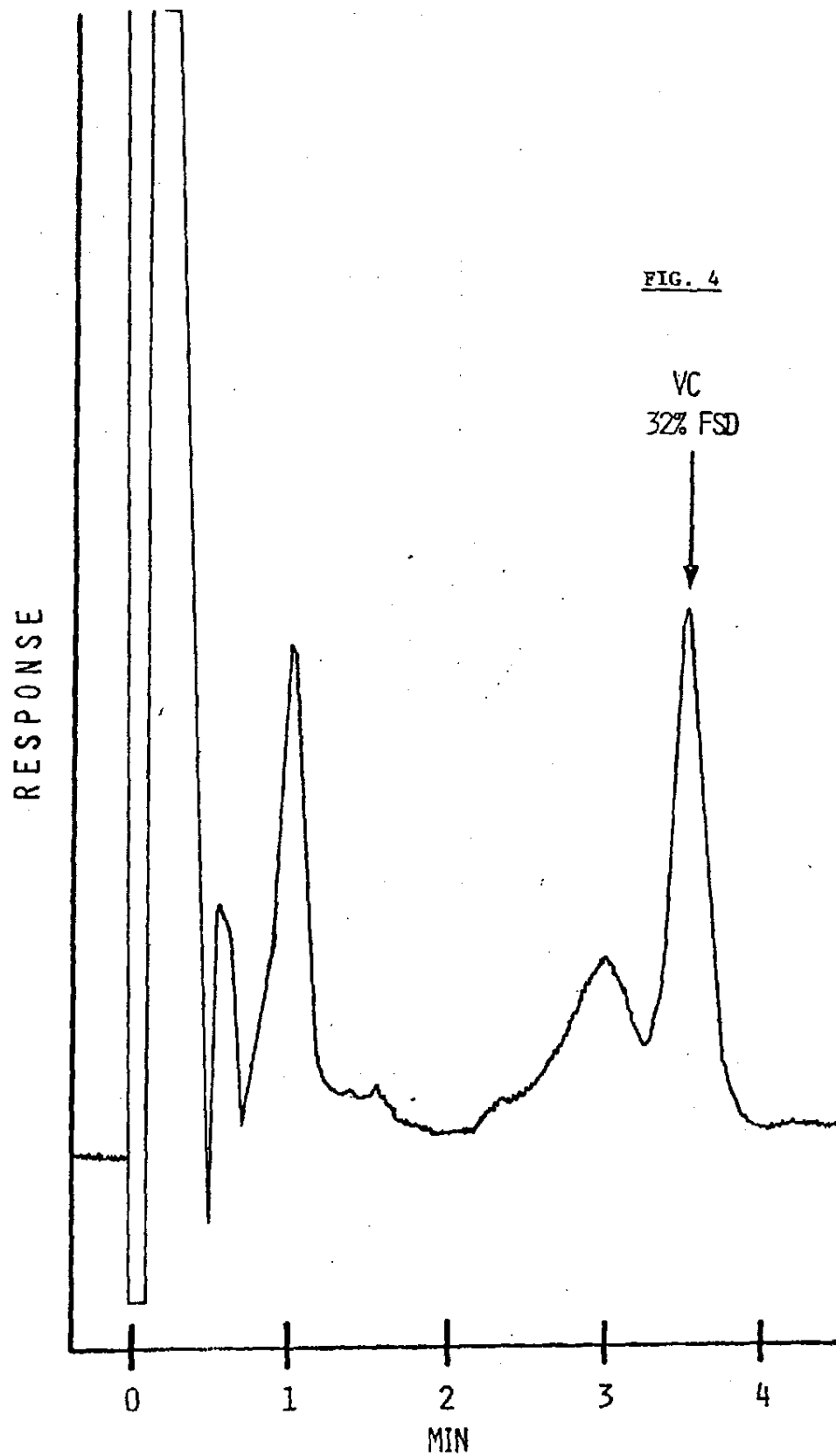


FIG. 2

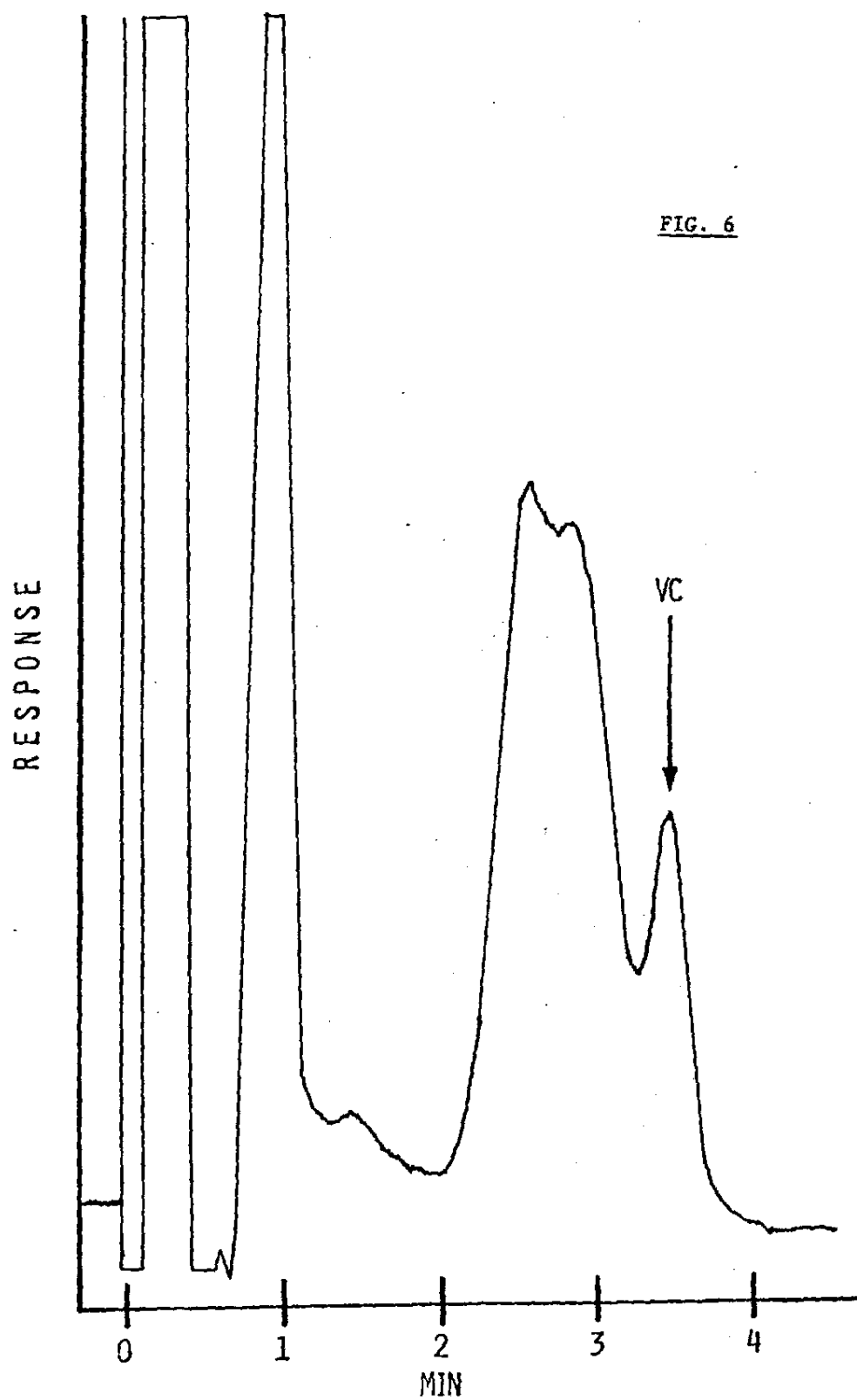
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December 13, 1976

TELEPHONE
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CABLE ADDRESS "KELMAN"
WRITERS DIRECT DIAL NUMBER
457-1110

Mr. Richard J. Ronk
Director
Division of Food and
Color Additives
Food and Drug Administration
200 "C" Street, S.W.
Washington, D.C. 20204

Re: PVC; 90-Week Interim Report of
Two-Year Oral Toxicity Study
Conducted by CIVO-TNO

Dear Mr. Ronk:

Following up on my telephone report to you last week, we are enclosing herewith a copy of the 90-week interim report concerning the chronic oral toxicity study of vinyl chloride now underway at the Central Institute for Nutrition and Food Research (CIVO-TNO) in Holland. Although we received this copy on a confidential basis through informal channels, we felt it necessary and desirable to advise you about it immediately.

Despite the fact that we can see no immediate relevance of a report on a feeding study to the interest of the Environmental Protection Agency or the National Institute of Occupational Safety and Health insofar as their regulatory responsibilities with respect to vinyl chloride monomer are concerned, rather than take any risk that a reporting omission might somehow be misconstrued as constituting some attempt to withhold pertinent data, you will note that copies of this letter and the enclosure have today been sent to the Administrator of the Environmental Protection Agency, Mr. Russell Train, and the Director of the National Institute of Occupational Safety and Health, Dr. John Finklea.

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Chronic (two-year) oral toxicity study with vinyl chloride in rats

(Interim information III)

1. Conduct of the study

See Interim Information of 15th December 1975, given in Enclosure 1.

Vinyl chloride-treatment by gavage was discontinued in week 84 because the condition of the rats given 300 mg vinylchloride/kg body weight was rapidly declining and mortality in this group was high (55 %). Moreover, most of the rats of this group that died or were killed in extremis showed extensive liver damage (haemorrhages, focal necrosis), liver tumours or tumours at other sites.

2. Results available after a test period of 90 weeks2.1. Body weights

Not affected.

2.2. Food consumption

Not distinctly affected.

2.3. Mortality

VCM (mg/kg body wt)	Total number of deaths*) at week 90	
	males	females
0	2	5
1	3	4
3	6	16
9	20	40
300 (by gavage)	46	44

*) Initial number of rats: 60 animals/sex/group

2.4. Haematology

Slightly decreased haemoglobin values in males of the 9 mg/kg group after 78 weeks.

2.5. Blood biochemistry

No indications of an adverse effect of vinyl chloride.

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9 mg/kg group:	Liver nodules (tumours ?)
	Pancreas tumour
	Thymic tumour
	Lymphoreticular tumour
	Mammary tumour
	Pituitary tumour
	Subcutaneous tumour
300 mg/kg group:	Liver nodules/haemorrhagic cysts (tumours ??)
	Pancreas tumour
	Pituitary tumour
	Lymphoreticular tumour
	Pulmonary nodules/haemorrhagic lesions (tumour)
	Nodules aer-duct area
	Abdominal tumour
	Mammary tumour
	Kidney mass (tumour ?)

3. Preliminary conclusion

From the results so far available it appears that the administration vinyl chloride monomer to rats at levels of 9 (as PVC-powder in diet) and 300 mg/kg body weight (in soyaoil by gavage) resulted in obvious liver changes which in many cases seem to be neoplastic in nature. Moreover, there are indications that similar lesions also occur at the 3 mg/kg level, but so far are absent at the 1 mg/kg level.

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**The Society of the
Plastics Industry, Inc.**



355 Lexington Avenue
New York, New York 10017
(212) 573 9400

February 23, 1976

Mr. Don R. Goodwin
Emission Standards & Engineering Division
Environmental Protection Agency
Research Triangle Park, North Carolina 27711

Dear Mr. Goodwin:

Enclosed herewith, on behalf of the Vinyl Chloride and Polyvinyl Chloride Producers Group of The Society of the Plastics Industry, Inc. (SPI), are comments on the Proposed Standard for Vinyl Chloride published in 40 Fed. Reg. 59532 on December 4, 1975. As we testified at the public hearing on the Proposed Standard on February 3, 1976, we commend the Agency for adopting an approach which allowed an open exchange of information between the technical people of the Agency, the industry, and other interested parties. We also support the Agency's utilization of a Quantitative Risk Assessment Analysis in determining the appropriate control technology, although as I also testified we believe the Agency did not weigh finely enough the costs against the benefits likely to be achieved in protecting public health.

Although there is much with which we agree, there are also a number of individual statements and assertions in the Proposed Standard and supporting documents which we consider erroneous. The two documents I am enclosing to spell out our differences are as follows:

1. Comments on the Standard and its supporting documents prepared by the Technical Subcommittee of the Vinyl Chloride and Polyvinyl Chloride Producers Group; and
2. Comments by the Health Subcommittee of the Vinyl Chloride and Polyvinyl Chloride Producers Group.

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We urge the Agency to take these comments into account before the final Standard is promulgated; to correct the errors noted in the attached statements; and to weigh more carefully some of the control requirements whose costs we believe far exceed any potential benefit.

There were four specific matters raised when the EPA panel was questioning me during the public hearing on February 3. To complete the record, the following comments are respectfully submitted.

1. We were asked by Mr. Farmer (Transcript of Proceedings, hereinafter: "Tr." page 68) to comment on "...the uses of PVC and then the possible substitutes for PVC in all these end use applications." EPA's own reports on this question have already covered the widespread and diversified uses of PVC in the medical, construction, appliance, electrical, transportation, packaging and many other industries.

As to the concept itself, we respectfully submit that substitutability per se is not a valid issue. First, our legal research confirms Dr. Kuzmack's observation that there is no authority in the Clean Air Act for EPA to ban selected uses of PVC (Tr. 52). Secondly, under the proposed Standard, the level of VCM emissions would be reduced by 95 percent; at such low levels there is no clearly established health risk and, hence, no danger to the public health which must be further obviated. Finally, even given exhaustive investigation of questions interrelating safety, costs, availability of raw materials, production and technological capability, capital investment and other related issues, as a practical matter substitutability remains an imponderable. Thus, under the circumstances of this case, we do not believe it would be fruitful for EPA to explore these issues further.

2. In response to Dr. Knelson's question (Tr. 71) about dialysis machines, the principal usage of PVC is in the extensive tubing which circulates the patient's blood through the machine.

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3. To Dr. Marcus (Tr. 76) I promised to clarify the dates ". . . when Maltoni first informed industry and industry first informed EPA . . ." about the preliminary results of Maltoni's inhalation studies with rats. Industry was first informed at a technical symposium in Bologna, Italy held from April 9 to April 12, 1973. This can be confirmed by Dr. Saffiotti of NIOSH who was in the audience. The USA VCM/PVC industry representatives did not report to EPA; this information was reported to NIOSH as required by regulations promulgated under §20 of the Occupational Safety and Health Act.

4. Dr. Marcus also asked (Tr. 82) for a response on SPI's position regarding toxic substances legislation. We generally support the moderate, responsible approach of the McCollister Bill (H.R. 7664).

Finally, we want to re-emphasize our belief that EPA leadership is needed to develop a vinyl chloride health research program under the joint sponsorship of expert representatives from government, industry, labor and other interested groups. A further reason for this approach was provided on the very day of the EPA hearing on the Vinyl Chloride Standard by way of the sensationalized disclosure of a new study relating to whether vinyl chloride is a potential mutagen. The report in question was not available to any of the industry representatives who testified at the hearings, nor was it made a part of the record. Instead, it was released directly to the press by the Health Research Group, under circumstances which did not permit rational discussion of the information or informed industry comment. We comment in more detail on this subject in the attached Comments.

Thus, while the vinyl chloride and polyvinyl chloride producers obviously believe that the concerns raised in the study should be explored further, they do not believe that a press release provides the best means to evaluate the risks involved nor the further precautions, if any, which should be observed.

The producers have expressed their willingness to provide their full share of the costs of jointly-sponsored research in the best interests of the general public and

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of the workers directly involved. The questions involved are too important to be dealt with by acrimonious and sensationalized debate. Unfortunately, recent history indicates that until the government exercises leadership in bringing all interested parties together, we are all too likely to see more time and money wasted on disputed research and incomplete or even biased discussion of scientific evidence.

In closing our written submission to EPA, we again want to express appreciation for the careful manner in which EPA is handling the development of this Standard. We would be pleased to respond to any further questions you might have or which might arise as a result of the comments of others.

Respectfully submitted,

Ralph L. Harding, Jr.
President

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U.S. DEPARTMENT OF LABOR
Occupational Safety and Health Administration
WASHINGTON, D.C. 20210



FEB 13 1976

Howard L. Watson, Administrative
Manager Manufacturing
Air Products and Chemicals, Inc.
Chemicals Group
Five Executive Mall
Swedesford Road
Wayne, Pennsylvania 19087

Dear Mr. Watson:

In response to your letter of September 2, 1975, this Office has reviewed your interoffice memorandum dated April 1, 1975 to R. Fleming at Valley Forge. The subject of the memorandum is: VCM MEDICAL EXAMINATIONS - Persons required to be covered by annual or semi-annual physicals.

In regard to the program proposed by you, Mr. John Barr, and Mr. John Novak for application to the occasional visitor from outside your plants, the Occupational Safety and Health Administration (OSHA) agrees you need not provide medical surveillance as mandated by CFR 1910.1017(k) if the duration of the visitor's exposure is so limited that he will not be exposed to vinyl chloride in excess of the action level. However, a few words of caution are in order:

- (1) Stationary monitors may not provide a very accurate indication of actual exposures.
- (2) Should a visitor remain in the regulated area for a duration of 45 minutes, setting the alarm at 5 ppm leaves very little margin for error.
- (3) Exposure in excess of 5 ppm averaged over a 15 minute time span is a violation of the permissible exposure limit.

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The rest of your proposal appears to be satisfactory.
Thank you for taking the initiative in this important
matter.

Sincerely,

Richard P. Wilson

for Barry J. White
Associate Assistant Secretary
for Regional Programs

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CABLE ADDRESS "KELMAN"

January 19, 1976

Mr. Ellis Rottman, Editor
FDA Consumer
HFI-20
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Dear Mr. Rottman:

While we certainly have no quarrel with your printing an article which recites the chronology and rationale for FDA action on polyvinyl chloride, we strongly question the timing and content of "Polyvinyl Chloride: Why FDA Acted" which appeared in the December/January issue of FDA Consumer.

Should the official magazine of FDA publish an article on the vinyl chloride regulations prior to the completion of that process? We think not. In fact, we believe that the published article could suggest that FDA has prejudged the case and decided to ban several important types of polyvinyl chloride packaging prior to reviewing new industry data which shows that these products present no hazard to public health.

We also find it difficult to understand why author Wayne Pines' otherwise excellent chronology fails to mention:

- 1) Commissioner Schmidt's finding that polyvinyl chloride packaging presents no immediate hazard.
- 2) The December 19 filing of 900 pages of Comment by The Society of the Plastics Industry documenting industry's contention that there is no reasonable expectation of vinyl chloride monomer migration from any PVC product.

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