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April 8, 1977

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

> (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

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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

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.

The raw data and descriptions of analytical procedures are presented in Appendices I through IV. Appendix I, supplied by the American Hoechst Corporation, Film Divison, 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 RVCM for the month of October 1976, provides typical chromatograms for a sampling of the individual lots reported for October 1976, demonstrates the reduction in RVCM 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 RVCM 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 "VCM Migration Studies with PVC Bottles Containing Low VCM 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 RVCM 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.

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 chromatagrams 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

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,