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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

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(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,

Appendix V

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.

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.

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."

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

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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.

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

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

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.

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 RVCM 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

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

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

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

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.