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file: FDA-PVC

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November 7, 1986

RESPONSE REQUESTED BY NOVEMBER 20, 1986

To: SPI Vinyl Institute
SPI Plastic Bottle Institute
SPI Food, Drug and Cosmetic Packaging Materials Committee

Re: Status of FDA PVC Rulemaking

Highlights

1. We are planning to file supplemental comments with FDA addressing questions raised by the Agency's Environmental Group about the environmental impact of the proposed PVC regulation; the comments will also address various points raised in late-filed comments submitted by several environmental organizations. To help us prepare these supplemental comments, we would appreciate any additional information available on emissions during PVC waste incineration, adjuvants used in PVC products and the amount of PVC products, in the solid waste stream replacing glass, aluminum or paper.

2. In reaction to an indication of a possible immediate problem with the environmental assessment portion of the PVC Rulemaking, we have today filed a statement with FDA to correct a misstatement about anticipated PVC market penetration which appeared on page 5 of its assessment.

3. We are hereby urgently soliciting your comments on the attached draft of proposed revised regulatory language for the PVC regulation relating to the determination of residual vinyl chloride monomer levels. We are also requesting all interested companies to evaluate "typical" products using the proposed alternative compliance method set forth in the draft.

4. The Distilled Spirits and Tobacco Branch in the Bureau of Alcohol, Tobacco and Firearms (ATF) has forwarded a favorable recommendation on PVC liquor bottles to ATF's General Counsel who now plans to meet with FDA on the matter.

Ladies and Gentlemen:

This letter is intended to provide an update on the status of the Food and Drug Administration's (FDA) February, 1986, proposal reaffirming the safety of food contact applications of vinyl chloride polymers and copolymers (PVC). Although reasonable progress is being made to correct some of the deficiencies in the proposal, we are now very concerned that FDA may get sidetracked on environmental issues. As detailed below, we are concerned enough to be recommending here that substantial supplemental comments be filed with the Agency on this matter as soon as possible. Indeed, in reaction to an indication from FDA about a possible problem, and having conferred with Roy Gottesman and Pat Toner on the subject, we have already filed a statement to try to correct an apparent misconception (or miscalculation) on the part of the Environmental Group about anticipated PVC market penetration. (A copy of our letter on this point is enclosed.)

In addition to further comments on the environmental issue, we are recommending that the supplemental comments we have begun preparing include suggested regulatory language concerning a somewhat different basis for calculating residual vinyl chloride monomer levels. Since these are important matters, we are soliciting your comments on the enclosed draft language, as well as on the environmental concerns. So that we may address both the regulatory language and environmental issues in an expeditious manner, your comments are requested by

November 20, 1986. We are also taking this opportunity to report on the status of our September 15, 1986 letter to the Treasury Department's Bureau of Alcohol, Tobacco and Firearms (ATF) asking for clearance of PVC liquor bottles.

A. FDA PVC RULEMAKING

1. Environmental Impact Issue

a. FDA Concerns -- State solid waste officials have recently reported that FDA has been requesting information from them on the anticipated environmental impact of the Agency's proposed Food Additive Regulations. This prompted us to contact Dr. Buzz L. Hoffmann, Chief, Environmental Impact Section in FDA's Center for Food Safety and Applied Nutrition. Dr. Hoffman indicated that FDA was evaluating the comments, particularly the Environmental Protection Agency's (EPA) letter suggesting that FDA needed to study the environmental impact issue further, and that FDA's finding of no significant impact (FONSI) needed further support.

The issues of concern identified by Mr. Hoffmann in the order of their significance to him include:

(i) The potential for increased production of hydrogen chloride (HCl) and dioxins when PVC waste is incinerated.

(ii) The increased presence of adjuvants used in PVC products, such as phthalates, adipates, and epoxidized soybean oil, and the need to assess the impact of the increased presence of these materials. (We consider this point irrelevant to PVC's environmental assessment and will so note in our comments. Nonetheless, any thoughts you have would be welcome.)

(iii) Increased PVC products in the solid waste stream replacing what Mr. Hoffman is characterizing as "recyclable products" such as glass, aluminum and paper.

When asked how we might assist in this evaluation process, Mr. Hoffman suggested that any new or different information available to industry would be helpful.

b. Late-Filed Comments -- Although the comment period in the Docket formally closed in June, 1986, we recently became aware that five comments were filed in late September and early October relating solely to the environmental impact issue. The five commentors are: the Pennsylvania Department of Environmental Resources; the Environmental Defense Fund; the Environmental Action Coalition; Udall's Cove Preservation Committee, Inc.; and Konheim and Ketcham, an environmental consulting firm. Copies of their comments are attached.

The Pennsylvania Department of Environmental Resources (DER) noted the State's concern with recycling and incineration. While the DER comments acknowledge that recycling of plastics is feasible, it observed that the market is not well developed and that: "Public inclination is lacking to affect [sic] curbside separation and resource recovery facilities which pre-separate plastics are very scarce." Further, while recognizing that combustion efficiency is probably the most important factor in whether chlorinated dioxins or furans are formed during the incineration of chlorine-containing materials, DER concluded that there will be additional costs faced by an increased need for acid gas controls.

The Environmental Defense Fund (EDF) opposes any regulatory change "in the absence of a comprehensive environmental impact statement." EDF is contending that the National Environmental Protection Act (NEPA) requires a complete analysis, that no recycling market for post-consumer PVC scrap exists, and that this final regulation would result in the "substitution of non-recyclable plastic for recyclable glass, aluminum and cardboard." EDF also argues that increased hydrochloric acid would contribute to acid emissions as well as the formation of dioxin, that increased marine pollution from plastic litter will occur, and that local recyclers will be driven out of business.

The Environmental Action Coalition comments were not drafted for this rulemaking but consisted of a 1985 paper addressing the general question of thermoplastics in th post-consumer waste stream. The authors observed that "most modern

incinerators are designed to operate at optimum high temperatures and are fitted with anti-pollution devices such as electro-static precipitators, 'bag house' fabric filters and 'scrubbers' with limestone to neutralize the acid gases." While incineration had advantages, the capital investment, operating costs and anticipated air pollution were cited as disadvantages for incineration. The Coalition takes the position that "PVC is an undesirable component of mixed municipal refuse, if incineration is a disposal method." Coalition comments at p.11.

The comments submitted by Udall's Cove Preservation Committee are generally a diatribe, such as, "I find plastics as a whole and particularly in food packaging a scourge and a disaster to our earth! Our only home!"

Konheim and Ketcham is an environmental consulting firm for local governmental units. The firm apparently assists in the preparation of environmental assessments and environmental impact statements. It recommends that an environmental impact statement and risk assessment be performed to evaluate the impact of "a major new source of PVC and food containers," the impact on the recycling waste stream, and the effect of increased proportions of chlorinated plastics in the municipal waste load on emissions of hydrogen chloride, benzene, toluene, carbon monoxide, and carbon dioxide, dioxin and furans.

c. Need For Supplemental Comments -- This entire situation leads us to recommend that we prepare a supplemental s t of comments refuting the inaccuracies or misunderstandings reflected in the late-filed comments and ensuring that we have provided FDA with a complete review of the available scientific literature on the environmental issues. FDA is quite aware of the incineration study being conducted under the auspices of the New York State Environmental Resource and Development Authority (NYSERDA) and may well wish to await the results from that study before proceeding. So that you can better see precisely what we have in mind, we will prepare a draft set of comments and circulate them to you shortly. In the interim, we would appreciate your comments or any pertinent materials. We are coordinating this effort with Roy Gottesman, Executive Director of the Vinyl Institute, in light of Roy's earlier work on this subject.

2. Revisions to the Proposed PVC Regulation

Our original comments on the FDA proposed rule noted the need for several revisions. In particular, we were concerned with proposed language that would require determination of residual vinyl chloride monomer (RVCM) levels according to the percentage of the vinyl chloride polymer component of the food contact article. We argued vigorously that the RVCM level should be determined as a percentage of the entire food contact article rather than as a percent of the vinyl chloride polymer or copolymer component alone. To speed Agency action and to help assure that the final regulation will meet the industry's needs, we have prepared and are attaching an alternate text for the PVC regulation. We are asking that you provide your comments by November 17, so that, if you approve, we can advance the proposed language in the supplemental comments we plan to file.

Based on our assessment of the situation, we now consider it necessary to follow FDA's lead and base the vinyl chloride monomer limitation on the weight of the part of the package (e.g. a layer) that is made from a vinyl chloride polymer. However, we are attempting to make clear what we believe to be FDA's intent, that is that the basis for calculating should not be the weight of the vinyl chloride resin contained in such a part but, rather, the weight of the entire part.

In addition, to accommodate the problems noted heretofore by Occidental and Air Products regarding measuring RVCM in items like insoluble coatings, we have proposed an alternative compliance method based upon possible vinyl chloride migration. To be responsive to FDA concerns expressed to us, the extraction conditions are intended to provide for essentially complete migration of any contained vinyl chloride monomer into 50% ethanol followed by the determination of the vinyl chloride in the ethanol utilizing a method sensitive to 1 part per billion (ppb). Essentially complete extraction is required, according to FDA, to compensate for the fact that the analytical test prescribed has a 1 ppb lower detection limit. We are hereby asking the Occidental and Air Products recipients of this letter, as well as anyone else who is interested, to evaluate the proposed procedure with "typical" products by varying the extraction time and measuring the resultant amount of vinyl chloride that migrates so that an appropriate extraction time can be set. (We recognize that

those of you undertaking this work may not be able to complete it by November 20, but we would appreciate your providing us with an estimate of when you think you can provide reports.)

The analytical procedure for determining vinyl chloride in the 50% ethanol extractant discussed above was the subject of round robin testing by a task group established by the Food, Drug and Cosmetic Packaging Materials Committee and included the Food and Drug Administration as a participant in the tests. Those of you who want copies of the procedure can obtain them by contacting us or Dennis Burgess at the SPI Washington office.

3. FDA Analytical Work

FDA proposed that an analytical method developed by its staff and published in the Journal of the Association of Official Analytical Chemists, Inc. (AOAC) be employed to determine residual vinyl chloride monomer levels. Our comments recommended that a test promulgated by the American Society for Testing and Materials, Inc. (ASTM) be substituted. We understand that the FDA staff is receptive to this change. However, the Agency concluded that its own laboratories should conduct analyses validating the equivalency of the ASTM and AOAC procedures. This work is underway. Unfortunately, due to accidental injuries, the FDA analytical staff has fallen behind schedule in completing its validation work. However, we do not anticipate that this will cause a further substantial delay.

B. PVC LIQUOR BOTTLE EFFORTS

As reported in our letter of September 19, 1986, last month we wrote to the Treasury Department's Bureau of Alcohol, Tobacco and Firearms (ATF) requesting an opinion from ATF that PVC liquor containers "protect the revenue adequately" so that manufacturers of distilled spirits may again market their products in PVC bottles. The request was based on FDA's proposed rule which constitutes an advisory opinion that rigid PVC containers are safe for food and liquor packaging so long as residual vinyl chloride monomer is kept within permissible limits.

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We can now report that the Distilled Spirits and Tobacco Branch in ATF has made a favorable recommendation on the matter and has forwarded it to its General Counsel for additional review. John Dubeck of our office has been in contact with John Manfrieda, ATF's General Counsel, and has learned that his office is planning to meet with FDA to obtain clarification regarding the status of PVC for liquor packaging. We reaffirmed to ATF the importance of approaching those people in FDA's Center for Food Safety and Applied Nutrition who are most knowledgeable on this subject, i.e., Dr. Sanford Miller and Robert Lake. Unfortunately, it appears that, unless our information is incorrect, or he changes his mind, ATF's counsel is likely to insist that FDA provide specific written confirmation that PVC may be used for liquor bottles before ATF will clear PVC bottles for distilled spirits. FDA can not realistically be expected to provide such a letter prior to promulgation of a final food additive regulation. In any case, ATF is expected to make its decision as to whether to require a specific written confirmation or simply rely upon the advisory opinion status of the preamble of the proposal within a few weeks.

* * *

We trust this will bring you up to date. We will circulate a draft of supplemental comments to FDA on the environmental issues shortly. In the interim, we look forward to your comments on the enclosed draft language and your views on the environmental issue by November 20, 1986.

Cordially yours,

Jerome H. Heckman

Enclosures

cc: Charles E. O'Connell
Lewis R. Freeman, Jr.
Dr. Roy T. Gottesman
John Malloy
Dennis Burgess

Proposed Paragraphs for Vinyl Chloride Polymer Rulemaking: Docket No. 84N-0334

One element of the Federal Food, Drug and Cosmetic Act's (Act) definition for the term "food additive" dictates that a component of a food contact article must reasonably be expected to become a component of the contained food to be subject to Section 409 of the Act. Section 201(s) of the Act, 21 U.S.C. § 321(s). This criterion is discussed in 21 C.F.R. § 170.3(e). Due to enforcement and administrative convenience concerns, the February 1986 proposal governing the use of vinyl chloride polymers and copolymers focused on the amount of residual vinyl chloride monomer in a food contact article as a regulatory surrogate for migration.

Under the proposal, the sole avenue for demonstrating compliance with residual monomer limitations was a test method published in the Journal of the Association of Official Analytical Chemists, Inc. (AOAC). As discussed elsewhere in this preamble, and in response to many comments, FDA has modified the final rule to provide for the use of an alternative residual monomer test issued by the American Society for Testing and Materials (ASTM). Even so, in some cases neither the AOAC nor the ASTM methods can be utilized. As explained more fully below, when neither method can be employed to verify the residual vinyl chloride monomer level, compliance of a food

c ntact article is to be determined by subjecting the article to an extraction test and examining the test solvents for the presence of vinyl chloride after appropriate exposure.

Vinyl chloride polymers and copolymers are used in a wide variety of applications. As the comments and the Agency's own regulations attest, many coatings for paper and paperboard, can enamels, adhesives, and binders are comprised only in part of vinyl chloride-based formulations that contain residual vinyl chloride monomer. Some of these products can be analyzed so that the vinyl chloride content of the portion containing the vinyl chloride-based formulation can be calculated. However, many of these compositions are insoluble or cannot be made into workable samples that permit the measuring either of the residual monomer content of the sample, or the percentage of the sample that is comprised of the vinyl chloride-based formulation. This will preclude the application of the ASTM or AOAC methods for determining the monomer levels in such products.

It is important to note that these types of food contact substances have long been considered of no consequence as far as dietary intake is concerned. Thus, FDA's 1975

proposal to prohibit the use of some polyvinyl chloride food-contact materials included the following observation:

> The available data indicate that certain applications of vinyl chloride do not present a realistic possibility of vinyl chloride migration. The Commissioner is unaware of any findings of vinyl chloride migration from film, cap liners, coatings, gaskets, or flexible tubing. Results of analyses of extractives from such articles have shown no detectible vinyl chloride. 40 Fed. Reg. 40,529, 40,531 (Sept. 3, 1975).

Although analytical methods have advanced over the last decade, no comments filed in this docket or in the course of the Agency's investigation even suggest that these conclusions do not remain essentially valid. Thus, it is eminently reasonable and will in no way impinge upon the risk assessment basis for the proposed rules if an extraction study is used as an alternate regulatory method to verify that the residual monomer levels of food contact articles are sufficiently low when the food contact surface to be tested cannot be dissolved in the

appropriate test solvents, or when reasonably sized samples cannot be prepared for testing by the ASTM or AOAC methods.

In keeping with this discussion, the final rules issued by the Agency today and set forth below:

(1) mandate that residual vinyl chloride monomer content be determined and meet the limits set forth in the rules when it is possible to apply the ASTM or AOAC methods to the food contact article; and

(2) permit as an alternative the use of extraction tests to determine the residual monomer levels for paper and paperboard coatings, can enamels, binders, or similar food contact articles when the vinyl chloride-based component and/or residual monomer contents thereof are not measurable using the ASTM or AOAC methods because they cannot be dissolved in the test solvents, or because the preparation of samples would be a practical impossibility.

Suggested Revisions to Proposed § 177.1975

(c) Limitations

(1)(i) When a formulation of the vinyl chloride polymer resin is used as a homogeneous food-contact article, the residual vinyl chloride content shall not exceed 10 ppb if the article is rigid or semi-rigid, and shall not exceed 5 ppb if the article is non-rigid, plasticized.

(ii) When a formulation of the vinyl chloride polymer resin is used as a distinguishable component of a food-contact article, e.g., as a sheet, layer, coating or similar component of the food-contact article, the residual vinyl chloride content of the distinguishable component shall not exceed 10 ppb if the distinguishable component is rigid or semi-rigid, and shall not exceed 5 ppb if the distinguishable component is non-rigid, plasticized.

(iii) The residual vinyl chloride content of the homogeneous food-contact article described in subparagraph (c)(1)(i) of this section, or of the distinguishable component of a food-contact article described in subparagraph (c)(1)(ii) of this section shall

be determined [specify the test method]. If the distinguishable component of a food-contact layer cannot be separated for testing, the same component, separately prepared or fabricated, may be tested for compliance with this section.

(2)(i) If there is no feasible way to determine the residual vinyl chloride content in accordance with subsection (1), either because the test samples are insoluble in the solvents used in the prescribed method or other inherent limitation (e.g., an impractical sample size would be required), the finished food-contact article shall be tested as described below, and the quantity of vinyl chloride extracted shall not exceed 1.0 ppb.

(ii) The extraction test shall be conducted by exposing the food-contact surface of the article (or immersing the article) in a 50% ethanol solution at 70°C for 24 hours under conditions that preclude loss of vinyl chloride from the test solution. Ten ml of alcohol shall be used for each square inch of surface of the food-contact article where this ratio is feasible. If this is not feasible, a different ratio may be used, but the results obtained shall be calculated on

the basis that 10 ml of solvent will contact each square inch of surface. After exposure, the solution shall be cooled to room temperature, the sample shall be carefully removed from the solvent to minimize the loss of vinyl chloride by volatilization. A measured volume of the solvent shall be carefully transferred to . . . and the vinyl chloride content analyzed by . . .