File VC

The Society of the
Plastics Industry, Inc.

355 Lexington Ave
New York, New York 10017
(212) 573-9400

SPI

H. Jewett claims the 0.5-1.0 RVCM level is not feasible with existing stripping equipment. 40 ppm is the norm currently. We expect 40 ppm level for RVCM in V-50. Some changes made in colloid and other recipe changes to improve down from 40. 1 ppM would be v. difficult. Dick.

URGENT--IMMEDIATE RESPONSE FROM AFFECTED MEMBERS ESSENTIAL

RECEIVED
OCT 28 1982
R. W. Laundrie

October 25, 1982

TO: SPI Public Affairs Committee
SPI PVC Safety Group
SPI Food, Drug, and Cosmetic Packaging Materials Committee
SPI AN Polymers Group
SPI Plastic Bottle Institute
SPI Plastic Beverage Container Division

RE: FDA Request for Marketing Data on PVC

GENC 015825

Ladies and Gentlemen:

The purpose of this letter is to determine whether we may instruct counsel to advise the Food and Drug Administration (FDA) that manufacturers of rigid and semi-rigid polyvinyl chloride (PVC) food packaging materials can meet a residual vinyl chloride monomer (RVCM) limitation of [redacted] For the reasons discussed below, [redacted]

To put this request for your opinion in perspective, please recall that FDA is developing proposals on the food contact use of acrylonitrile (AN) and vinyl chloride polymers under

According to Phil Freedman of PVC Containers Corp., this translates into a need to be at 0.5-1.0 ppm in the resin from which the compounding step reduces it further. The compound procedure is a stripping step done actually under vacuum conditions. Ethyl + Hooker have such a set up for bottle compounds. Dick.

its new constitutents policy. Prior to taking any action, FDA requested that The Society of the Plastics Industry, Inc. (SPI) provide information on: (1) current marketing data for the regulated and prior-sanctioned food contact uses of the polymers, (2) projected future markets as food contact materials, and (3) current data on residual monomer levels and extraction data for food grade polymers.

Subsequently, it was decided that the AN Polymers Group and the PVC Safety Group would proceed independently to respond to FDA's request. The AN Polymers Group will be meeting on October 26, 1982 to review their situation.

In a letter dated September 15, 1982, John Lawrence, SPI's Technical Director, requested that information relevant to PVC be sent directly to Keller and Heckman by October 1, 1982. The plan at that time was to have Keller and Heckman collect and compile the data for submission to FDA. Thus far, Keller and Heckman has received good data from two companies representing rigid and semi-rigid PVC interests.

It seems unlikely that FDA would consider this data base sufficient for determining the amount of the diet packaged in PVC or commercially-feasible RVCM levels. In the absence of adequate data, we have been considering alternative approaches because interested members have indicated their desire that FDA quickly resolve the PVC issue. While PVC is prior-sanctioned for food packaging, it is our understanding that PVC may be disadvantaged in certain markets, such as that for liquor bottles, if FDA does not move forward promptly.

As for the liquor bottle situation, the Bureau of Alcohol, Tobacco and Firearms (ATF) will not act in the absence of an FDA statement that PVC is acceptable for alcoholic beverages. We have been working diligently to obtain fair treatment for PVC in this area and others are supporting this through independent efforts. Nevertheless, some industry response to FDA's request must be forth-coming shortly.

Based on the constitutents policy, FDA is in the process of establishing an acceptable daily intake (ADI) for vinyl chloride monomer. We have been informally advised that the tentative calculation for the vinyl chloride ADI will be approximately 0.25 ug/day. The marketing data that FDA requested would pro-

vide the basis for determining a consumption factor, that is, the percentage of the diet expected to be packaged in PVC. With both the ADI and the consumption factor, FDA can calculate a permissible RVCM level based on VCM migration rates and shelf life data. Without substantial support for a specific consumption factor, FDA is likely to assume that the entire diet will be packaged in PVC. Assuming that the ADI for vinyl chloride is 0.25 ug/per day, we calculate that the RVCM level in food-grade resin for rigid and semi-rigid PVC would need to be 10 parts per billion (ppb) or less to keep the estimated daily intake (EDI) below the ADI.

To help resolve the regulatory problems facing PVC we urgently need a response from affected members of the PVC Safety Group, Plastic Bottle Institute, and Food, Drug, and Cosmetic Packaging Materials Committee. Then we can inform FDA that manufacturers of rigid and semi-rigid PVC can produce a product with a 10 ppb RVCM level. This, in turn, should eliminate any public health concerns even if one assumes that the entire diet is packaged in PVC.

We understand that this a sensitive issue, and we are extremely interested in receiving your views on this matter. Please contact Keller and Heckman by November 8, 1982. They will keep the identity of individual submissions in strict confidence to avoid any antitrust or other difficulties. We look forward to hearing from you.

Cordially yours,

G. R. Munger