

AD HOC VCM/FDA COMMITTEE

Rigid Sheet and Blister Pack Sub-Committee

SPI Conference Room
New York, New York

10:00 A.M.
November 21, 1975

Attendees

C. E. Blades, Air Products & Chemicals Co., 1 Possumtown Rd., Piscataway, N.J. 08854
N. Bornstein, Cryovac, P.O. Box 464, Duncan, S. C. 29334
A. Cacciola, The Pantasote of N.Y., 26 Jefferson Street, Passaic, N.J. 07055
J. Floros, Great American Chemical, 650 Water Street, Fitchburg, Mass. 01420
J. Fleckenstein, Milprint, Inc. 4200 N. Holton St., Milwaukee, Wisconsin 53201
A. Fuhrman, Great American Chemical, 650 Water Street, Fitchburg, Mass. 01420
W. Gort, American Hoechst Corp., P. O. Box 340, Del. City, Del. 19707
E. Kruger, American Hoechst Corp., P.O. Box 340, Del. City, Del. 19707
R. Longarer, American Hoechst Corp., P.O. Box 340, Del. City, Del. 19707
J. Lawrence, SPI, 355 Lexington Avenue, New York, N.Y. 10017
G. Mantell, Air Products & Chemicals, P.O. Box 538, Allentown, Pa. 18105
H. Radloff, Oscar Mayer & Company, P.O. Box 1409, Madison, WI. 53701
W. Sacks, Allied Chemical, P.O. Box 1057R, Morristown, N.J. 07960
M. Saggese, Tenneco Chemicals, Inc., Nixon Lane, Nixon, N.J. 08818
J. Sibilia, Allied Chemical Corp., Columbia Rd., Morristown, N.J. 07960
F. Vincent, Jr., American Can Co., P.O. Box 702, Neenatt, WI. 54956

1. Mr. Gort reported that the round robin testing had been completed and called on Dr. Kruger to report on the results.

Dr. Kruger outlined the procedures used in the test program and stated the conclusion as follows:

"....that the analytical procedure obtained from the Food and Drug Administration can be used for the determination of the residual monomer content of commercial PVC sheet. Furthermore, the procedures appears to have a quantitative sensitivity in the range of 1 ppm and a detection limit in the range of approximately 0.3 ppm."

2. Extraction data is being developed by various companies and certain work has been reported on by several companies. It is expected that data will be available from the following:

Air Products - on 20 mil bottle material
Tenneco
American Hoechst
Cryovac - on Tenneco and American Hoechst product
Oscar Mayer
Pantasote

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

355 Lexington Avenue • New York, N.Y. 10017

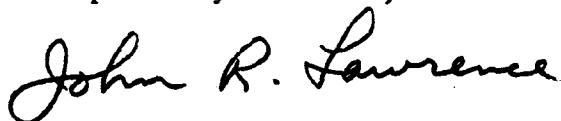
(212) 573-9400

SPI- 10263

In submitting data it is important that the report include chromatographs, calibration curves and data on spiked samples.

3. Mr. Gort read the draft of the preamble portion of the report he plans to submit on behalf of the committee for use in preparing the industry's comments on the FDA regulation. (Copy attached) Various comments were made that Mr. Gort will include in his final report. This report, including test data, will be put together at a meeting to be held on December 3.

Respectfully submitted,



John R. Lawrence
Technical Director

JRL:ctz
Attachment

The producers of rigid PVC sheet and blister packs cooperatively with the rest of the PVC industry have recently reduced by several orders of magnitude (data below) the level of vinyl chloride in all phases of food container manufacture. This reduction affords strong evidence that vinyl chloride cannot reasonably be expected to become a component of food when such food is in contact with articles recently made from the late production rigid PVC sheet and/or blister packs.

During the past months, several changes have occurred in the production of resin compounds and sheet which support this contention:

1. PVC suspension and mass polymerized resins, which in earlier times contained as much as 0.2 - 0.5% residual volatiles (vinyl chloride), are now being steam stripped of the residual monomer so that these same resins now contain 0.0004 - 0.0002% (4-20ppm).
2. PVC compounds are now being produced with residual vinyl chloride monomer of 0.0001% (1ppm) or less using a new hot-cold mixing system.
3. Rigid PVC sheet was formerly produced from powder blend or pellets using extrusion or calendering. Blending of the resin prior to extrusion or calendering was done by ribbon blenders, banbury mixers, or cold intensive mixers. Today, the low monomer resins are blended in hot-cold intensive mixers using time, temperature, and pressure (vacuum) controls to further reduce the vinyl monomer to the lowest level possible (non-detectable).
4. Much of the aforementioned process improvements were necessary to accommodate the OSHA regulations on vinyl chloride worker exposure, but as expected benefits were also realized in reducing the residual vinyl chloride content of the food contact articles.
5. During this period, gas chromatographic analysis was introduced to

measure the amount of vinyl chloride in plant environment and, subsequently, similar methodology was also developed to measure the vinyl chloride contained in resin, compound, rigid sheet, and thermoformed blister packs. Because this was a relatively new analytical tool for the industry, much research had to be conducted to develop the proper instrumentation, columns, standards, solvent purity, etc. Early this year, the detection capability of the methods was only 5ppm in resin and rigid sheet and blister packs. Improvements were continuously made in methodology so that the detection level was reduced to 1-2ppm and now it is believed that control methods have been developed which will detect vinyl chloride at 0.35ppm in rigid sheet and blister packs.

6. During the course of developing new and improved devolatilizing processes to remove the residual vinyl chloride from resin, compound and rigid sheet, data on diffusion rate and the effect of thermoforming, aging, etc., has also been accumulated. Consequently, it is the industry's position that today vinyl chloride cannot reasonably be expected to ^{suggest to} become a component of food.

Take FDA

Although the actual losses of vinyl chloride by processing, aging, diffusion, etc., are being developed, the following diagram certainly illustrates these losses dramatically. The most important fact, however, is that there is no logical or scientific expectation that, today, residual vinyl chloride could become a measurable component of food. ~~The data included in our comments which follow, are irrefutable.~~