PVC SANCTION FOR LIQUOR BOTTLES WITH EXTRACTION LIMIT URGED

The Society for the Plastics Industry last week unveiled research showing no detectable migration from alcoholic beverage bottles, and said that this can be analytically checked.

In a comment, SPI endorsed the Food and Drug Administration's proposed prior sanction affirmation for PVC in food packaging, but opposed the proposed ban on use of PVC for packaging alcoholic beverages (See FOOD CHEMICAL NEWS, Oct. 15, Page 2).

"... It is now apparent that polyvinyl chloride compounds for rigid containers can be prepared on commercial equipment which will show no detectable migration of vinyl chloride monomer to distilled alcoholic spirits packaged therein," SPI said, enclosing a report of the scientific studies.

When the problem of possible migration arose, the Society said, "a concentrated effort was made by the major suppliers of such compounds to confirm and then take very possible and practical steps to eliminate the possibility of such unexpected migration."

PVC compounds, the comments said, have been "prepared by new technology to assure a low residual vinyl chloride monomer content," and have been processed into bottles and extracted with water, 3% acetic acid, 50% ethanol, and heptane.

".. It can be stated that for each manufacturer reporting the extraction studies at 120°F. for periods of time up to one month, no vinyl chloride monomer was detected in any of the solvents with methods ranging in sensitivity from 0.5 p p.m. to at least 0.05 p.p.m.," SPI wrote.

One bottle manufacturer performed extraction tests on bottles made from compounds supplied by two manufacturers, and no vinyl chloride monomers were detected with a method sensitive to at least 0 05 p.p.m., the letter said.

Two firms independently developed gas chromatographic methods for determining vinyl chloride content in the 50% ethanol solvent, SPI said, and it would appear "that either method can be used satisfactorily for the intended purpose."

Tests were made both of bottles made from virgin material and from 40% regrind, SPI said, with no vinyl chloride monomer detected using methods sensitive to 10 p.p.m "From this it can be concluded that there was no significant increase in residual monomer content as a result of processing and reuse," the letter said. SPI continued:

> "... The FDA can now be assured that manufacturers of PVC bottle compounds can provide formulations which, when used for packaging distilled spirits, will not yield detectable vinyl chloride monomer to the contents when tested with analytical methods sensitive to 0 05 p.p.m In light of the calculated no-effect level of 250 p.p.m for VCM in the total diet..., a finding of 'none detected' using methods sensitive to 0 05 p.p.m. is eminently suitable by a large safety factor to assure safety of such compounds when used to package distilled alcoholic spirits.

> "Accordingly, it is submitted that the industry has now clearly demonstrated that continuing to accord prior sanctioned status... to polyvinyl chloride resins in such a way as to encompass the use of such resins, when properly formulated, to package distilled alcoholic spirits would be wholly appropriate and consonant with the public interest."

In a separate letter, Dewey and Almy submitted to FDA the results of its extraction tests using PVC gaskets in 8% alcohol, 100% alcohol, and wine which was 12% alcohol. The firm said vinyl chloride monomer in each test was less than 50 p.p.b.

SPI recommended that a limit be placed on "the level of vinyl chloride monomer detectable in an appropriate food-simulating solvent when exposed under suitable test conditions," suggesting that the proposed §121.2009 prior sanction regulation read, as follows:

> "Polyvinyl chloride resins ... may be used as a component of food packaging material. As regards rigid containers made from polyvinyl chloride resins and intended for packaging of distilled alcoholic spirits, such containers shall show no detectable extraction (at the level of sensitivity of the method) of vinyl chloride monomer in a 50% solution by volume of ethyl alcohol in water when one pint containers containing such alcohol solutions are stored at 120°F. for 28 days and are tested with a procedure capable of detecting vinyl chloride monomer down to a sensitivity of 0.05 p.p.m. A suitable procedure is available from the Commissioner on request."

The Society said a ban on PVC for packaging alcoholic foods "is neither necessary nor appropriate," and that such a ban "would cause unnecessary hardship and economic loss..." SPI also said consumers "would be denied the choice of a safe and suitable packaging material."

The letter said that "any controls required should be directed not at PVC resins per se but rather, should be aimed at assuring that the compounds... used for packaging distilled alcoholic spirits are suitable for their intended use."

SPI also asked that FDA not use the phrase "alcoholic foods," noting that since any migration problem pertains only to distilled alcoholic spirits that any limitations should apply to "well identified problem areas." The term "alcoholic foods," the letter said "would be subject to wide variations in interpretation and could only lead to unnecessary and continuing confusion."

The American Conference of Governmental Industrial Hygienists have set a 200 p.p.m. limit for vinyl chloride monomer in air, SPI said, concluding from this that "250 p.p.m. in the total diet is without effect." The organization explained that the ACGIH figure was "based upon chronic exposure in man, not experimental animals, and the assumptions are quite 'conservative' on the side of safety..."

SPI also referred to limits on PVC set under two Food Additive Orders, §121.2514 for resinous and polymeric coatings and §121.2550 for sealing gaskets with closures for food containers. Extraction studies were conducted with PVC can liner enamels which have been cleared under the Orders, SPI said and the test results showed "no detection of vinyl chloride monomer in alcoholic beverages such as malt beverages and wine or in the spectrum of food-simulating solvents used to 'clear' other food packaging materials."

Regarding possible environmental effects, SPI recalled that the Bureau of Alcohol Tobacco and Firearms had filed a favorable Final Environmental Impact Statement which concluded that "PVC plastic is a suitable material for use in the manufacture of liquor bottles."

The Society endorsed FDA's proposal to affirm the PVC prior sanction, noting that this will be the first one listing a basic polymer "indirect additive." SPI called the affirmation "precedental."

Tracing the history of PVC use for alcoholic beverages SPI noted that BATF in 1968 permitted experimental use, and said:

> "At a very late and critical time when BATF had completed and published a favorable Final Impact Statement on the use of PVC liquor bottles so that it appeared routine commercial use would soon be allowed, it was reported to the FDA, to the surprise of most of those in the plastics and alcoholic beverages industries, that vinyl chloride monomer in the range of 10 to 20 p.p.m. was found in some experimentally packaged distilled alcoholic beverages."

SPI said it is "unaware of any contention that the presence of vinyl monomer in foods even at the 10 to 20 p.p.m. range presents a problem to public health or safety," and said it understands that the problem would be one of adulteration under §402 of FDA's law. The Society also noted "that the reports on detection of the presence of monomer in distilled alcoholic spirits came as a surprise to the scientific community because it had been generally assumed that the monomer, being a gas in nature, would most certainly volatilize off during the various manufacturing processes involved in compound and bottle production."

SPI said research was conducted into the "possible migration of vinyl chloride monomer to alcoholic beverages of lower alcohol content packaged in Japan," and that "no sample showed detectable vinyl chloride monomers." The letter added:

> "It is recognized that these results are at variance with those alluded to in the preamble of the subject proposed regulation wherein it is stated that vinyl chloride monomer was found in wine packaged in PVC containers. It is believed that any differences probably reflect differences in the vinyl chloride compounds which were used to prepare the bottles. In any case, it is submitted that these Japanese data -- the only information known to us directly relevant to lower alcohol content beverages -- adequately indicate that the distilled spirits situation is unique and should be treated in this light."