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FYI
FDA
for VI

December 16, 1985

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

Re: Details of FDA PVC Proposal Reported

Ladies and Gentlemen:

At meetings earlier this month of the Vinyl Institute Executive Board and the Food, Drug and Cosmetic Packaging Materials Committee, we reported that the Office of the General Counsel and the Center for Food Safety and Applied Nutrition within the Food and Drug Administration finally had agreed on the language for a Federal Register notice and proposed rule regulating the food contact uses of polyvinyl chloride (PVC). While FDA Commissioner Young is expected to sign the proposal shortly, the extent of review by the Department of Health and Human Services (HHS) and the Office of Management and Budget (OMB) is undetermined. HHS and OMB involvement could range from an informal telephone call by FDA to full-blown, independent evaluations of FDA's work.

With the kind permission of the publisher, we are enclosing an article which highlights what may be expected in the proposed rule. Most of the article is consistent with our prior reports to you. As anticipated, a residual vinyl chloride monomer (RVCM) limit of 10 parts per billion (ppb) would be proposed for rigid and semi-rigid PVC. For PVC films and coating and plasticized uses such as flexible tubing and gaskets, a 5 ppb RVCM limit would be established. A limit of 50 ppb would be proposed for vinyl chloride-vinylidene chloride films. The proposal will apparently cover certain PVC copolymer applications as well.

R&S 029867

Assuming the Food Chemical News report is as accurate as they usually are--we hasten to note we have not seen and do not believe FCN's reporters have seen the official PVC document--besides reaffirming our earlier speculations on the proposal, there are two slightly surprising developments. First, FDA apparently discovered additional prior sanction correspondence for PVC in searching its files which will be added to the list of prior sanctioned uses. Second, the Food Chemical News article reports that the proposal would carry a 50 ppb RVCM limit for PVC water pipe. This is unexpected because the Environmental Protection Agency (EPA) generally takes the lead in the drinking water area under the authority of the Safe Drinking Water Act (SDWA). However, from our prior work with the EPA water staff, we know that EPA generally defers to FDA's health analysis and expertise here. Thus, EPA could conceivably adopt health or safety limits FDA deems appropriate.

The water pipe RVCM proposal is peculiar and leads us to surmise it may perhaps apply only to some limited application like food plant water systems because the National Sanitation Foundation (NSF) standard now calls for an RVCM level of 10 parts per million (ppm). We understand that manufacturers can produce PVC pipe around the 1 ppm level and that there is really no evidence of RVCM migrating from water pipe into the contained water. In any event, we consider this portion of the Food Chemical News report to be a bit disturbing but recommend you not consider the information "hard" until we can elicit more information from FDA on this matter. In so doing, if and when appropriate, we will also voice our disapproval if the Agency is disregarding the established working relationship between FDA and EPA under which EPA regulates all drinking-water materials used in general distribution systems.

We trust that this will bring you up-to-date on current developments in this area. If you have any comments or questions or if we can be of any assistance, please let us know.

Cordially yours,

Jerome H. Heckman

Enclosure

cc: Dr. Nina I. McClelland
National Sanitation Foundation

The most common reported symptom, reported in 23% of the total and 26% of the Type I complaints, was difficulty breathing. Five to seven percent of complaints in both groups concerned diarrhea, vomiting and nausea, abdominal pain and cramps, or wheezing.

Other symptoms reported with less frequency included: hives, dizziness or problems with balance, unconsciousness and coma, change in heart rate, fainting, itching, headache, change in body temperature, local swelling, difficulty swallowing, coughing, change in sensation, chese pain, and death.

FDA's analysis found no seasonal peaks associated with the reporting of reactions.

The number of sulfite adverse reactions reported to FDA continues to increase, and the agency currently has at least another 64 reports in the process of investigation, or with insufficient information for follow-up.

FDA POLYVINYL CHLORIDE PROPOSAL TO LIMIT VINYL CHLORIDE MONOMER RESIDUALS

The Food and Drug Administration is expected to shortly withdraw its proposal to restrict uses of vinyl chloride in contact with food (See FOOD CHEMICAL NEWS, Sept. 1, 1975, Page 34) and replace it with a proposal limiting residual vinyl chloride monomer both for packaging products covered by Food Additive Orders and those considered to be prior sanctioned.

In doing so, the agency will rely on its carcinogenic impurity doctrine, upheld by the courts in the D&C Green 5 case, which will enable it to circumvent the Delaney clause for the vinyl chloride monomer, which the agency has concluded is a carcinogen and is likely to migrate to food from packaging materials.

The agency has concluded that there is an individual lifetime risk of cancer from exposure to vinyl chloride monomer at 25 nanograms per day of less than 1 in 10 million, and that lifetime-averaged individual exposure is likely to be substantially less than 25 nanograms per day.

A new Food Additive Order will be proposed to allow the use of vinyl chloride polymer resins, rigid and semirigid, for manufacturing bottles, a use that some had felt was covered by prior sanction.

The agency will explain that it now believes vinyl chloride polymers can be approved for use not only with dry food but also with aqueous, alcoholic and fatty foods.

Four new prior sanction uses, discovered by the agency in its search of the files, will be added to those previously recognized.

Residual vinyl chloride monomer will be limited in the prior sanctioned uses to 5 p.p.b. in plasticized vinyl chloride for use as flexible tubing and as gaskets and bottle or jar liners and in vinyl chloride homo- or copolymer films and coatings, except that it would be limited to 50 p.p.b. in vinyl chloride-vinylidene chloride films and to 10 p.p.b. in rigid vinyl chloride polymer sheet.

The 50 p.p.b. limit would also apply to vinyl chloride polymer waterpipe, also covered by a prior sanction.

For the vinyl chloride polymer resins, rigid and semirigid, the residual vinyl chloride monomer limit would be 10 p.p.b. by weight of the vinyl chloride polymer, a limitation that would

also apply for vinyl chloride-ethylene copolymers, vinyl chloride-hexene-1 copolymers, vinyl chloride-lauryl vinyl ether copolymers, and vinyl chloride-propylene copolymers.

A limit of 5 p.p.b. residual vinyl chloride monomer would be used for adhesives, resinous and polymeric coatings, components of paper and paperboard, acrylic and modified acrylic plastics, cellophane, polyethylene phthalate polymers, closures with sealing gaskets, and packaging materials for use during the irradiation of prepackaged foods.

Vinyl chloride-vinylidene chloride copolymers would be deleted from the list of materials that may be used as coatings on fresh citrus fruit.

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RELIANCE ON SCIENCE IN ANY EEC DECISION ON HORMONE USE IN ANIMALS URGED

"The decision on the use of hormone growth promoters should be based on all available scientific evidence," the Animal Health Institute urged in a letter to Secretary of State George P. Schultz.

The Nov. 8 letter has been credited with activating the United States' successful efforts to bring about a delay in action by the European Economic Community's Council of Ministers on a proposal to ban the use of growth promoting hormones in food-producing animals (See FOOD CHEMICAL NEWS, Dec. 9, Page 2).

AHI President Fred H. Holt urged that the decision be delayed until the Codex Committee on Veterinary Medicine considers the use of hormones in animal production during its first meeting, scheduled for the fall of 1986, and until "all relevant information, including the final report of the Lamming Committee which was commissioned by the EEC to evaluate the safety of hormonal implants, has been thoroughly examined."

The ban, Holt wrote, would "create a serious non-tariff trade barrier to the EEC's importation of U. S. meat and meat products derived from animals that had been treated with hormones."

Alleging that the ban "would . . . result primarily from political pressures," Holt said "the EEC would be establishing an approach to safety assessment of hormone products which would be disruptive to regulatory agencies throughout the world and create confusion among consumers."

"An EEC ban," he concluded, "would not be consistent" with the "various activities of intergovernmental bodies in the past few years directed in part at eliminating, or at least diminishing, the differences in the way various countries address the safety assessment of animal health products."

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FSIS COMMITTEES DEVELOPING RESPONSES TO NAS INSPECTION RECOMMENDATIONS

Nine "planning committees" are being formed by the Agriculture Department's Food Safety and Inspection Service to develop the agency's response to recommendations made last summer by a National Academy of Sciences' committee reviewing the scientific basis for meat and poultry inspection (See FOOD CHEMICAL NEWS, July 22, Pages 3, 4, and 7).

FSIS Administrator Dr. Donald L. Houston has said that his staff will develop plans to implement each one of the NAS recommendations, but will leave the decision on which will be implemented up to political officials of the Department (See FOOD CHEMICAL NEWS,