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Answering letter date

Subject

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You will be interested in the attached
excerpt from Food Chemical News.

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SPI MAKES CASE FOR REAFFIRMATION OF PVC PRIOR SANCTION

The Society for the Plastics Industry has urged the Food and Drug Administration to reaffirm the "prior sanction" for polyvinyl chloride, with a limit on the level of vinyl chloride monomer.

The SPI position was spelled out in a July 18 meeting between FDA Commissioner Schmidt and other FDA-ers and SPI representatives. The SPI position was advanced at the meeting by Jerome H. Heckman, of the Washington law firm of Keller and Heckman. The SPI General Counsel also furnished the FDA-ers with a memo setting forth his position.

The meeting was held on a rush basis after reports that FDA might propose restrictions on some PVC containers (See FOOD CHEMICAL NEWS, July 14, Page 65) led to some industry panic. The memo of the FDA-SPI meeting, written by Associate Commissioner for Compliance Sam D. Fine, said:

"Word has just reached Mr. Heckman that a customer of one PVC bottle manufacturer, who had been using PVC bottles for packaging salad oil, has cancelled his usual order for such bottles. The cancellation was said to be due to a news report that FDA was changing its views about PVC in contact with food, as a result of evaluation of the petition submitted by the Health Research Group."

Apparently the panic in the industry was caused by FDA thinking in regard to PVC bottles - - which must have been misinterpreted by someone as meaning that there would be an overnight ban on PVC bottles. Action on any FDA proposal will take time.

The latest draft of a PVC proposal is now wending its way through FDA, where there is an urgency inspired by the HRG petition. How soon a proposal will be published depends in part on whether the agency holds up the document until Schmidt returns from his vacation.

The SPI position presented at the meeting, according to Fine's memo, was that industry "has so radically changed the manufacturing procedure for PVC that for all practical purposes there is no problem of the monomer vinyl chloride (VCM) migrating to food." The memo continued:

"It is the position of SPI that, if by using the most sensitive methodology under exaggerated conditions, the monomer cannot be found, then FDA should recognize there is no problem. SPI believes that the FDA in its forthcoming proposal on PVC for use in food packaging should reaffirm the prior sanction for PVC. Reference was made by the SPI spokesman to the fact that PVC itself has been

fed extensively to experimental animals (rats) and found safe. It was pointed out that this was the so-called 'old' resin. The studies were made in 1948. It is the belief of SPI that the 1948 resin contained far more of the monomer than does resin manufactured in 1975."

Industry May Fund VCM Feeding Study

Heckman told the FDA-ers that industry has decided to "fund an extensive toxicological study on feeding VCM to rats," the FDA memo said, adding that the protocol for the study has been sent to the agency's Bureau of Foods for approval. The testing is to be conducted by Food and Drug Research Laboratories.

The memo added: "However, it is Mr. Heckman's view that if FDA goes forward with a regulation that does not reaffirm the prior sanction for PVC, industry may well decide to cancel its support for such a study."

In his memo, Heckman urged "that the prior sanction be reaffirmed but that limitations be spelled out for the first time to assure that there will be no vinyl monomer (which is not prior sanctioned) in the food supply." He proposed - -

". . . That a prior sanction reaffirmation regulation be proposed and that it (1) indicate that all forms of PVC packaging or processing equipment are considered prior sanctioned and safe provided there is no detectable monomer extractable from them using extraction procedures that reasonably exaggerate intended conditions of use, and (2) that a suitable method for analyzing extractability be set forth in such a reaffirmation regulation."

Such an analytical method "must obviously be one that has been satisfactorily validated and will be reliable for practical day-to-day application," Heckman wrote, adding that FDA has developed "such a method which can be incorporated in a reaffirmation proposal."

Noting that any analytical method has a "finite detection limit," Heckman said that, "If the extraction test properly exaggerates any possibility of migration, and with this exaggerated exposure none is detected, one is not relying on the detection sensitivity to assure lack of migration but rather the exaggerated exposure test assures that there is no reasonable expectation of migration under actual intended conditions of use."

The attorney said SPI's proposal would be "responsive" to the HRG petition "in that such action will assure that no vinyl chloride monomer enters the food supply." Heckman said the FDA-proposed limits "would be far more severe than those which have already been imposed by the Occupational Safety and Health Administration in circumstances where exposure to vinyl chloride monomer is not a remote conceptual possibility, but is an absolute certainty."

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The OSHA standard permits worker exposure of up to 1 p.p.m. a day, he explained, saying "this is roughly equivalent to permitting 10 p.p.m. of vinyl chloride in the total diet to be ingested daily, if such were possible, which it is obviously not." Heckman added that HRG "participated fully in the OSHA proceedings which led to adoption of its standards."

Expressing concern about the "uncertainty" regarding the status of PVC, Heckman said any FDA proposal which "adds to the unfavorable climate will undoubtedly cause grossly unjustified damage vis-a-vis the public's sense of security about the food supply."

He wrote that current resins and compounds "differ very significantly from the basic materials that were in the marketplace at the time the HRG referenced extraction data were submitted." Use of the "new materials," Heckman said, "will assure there can be no reasonable expectation that PVC packaging materials will lead to vinyl monomer becoming a component of foods, or will be ingested."

Noting that many firms have advised FDA about changes made in their food packaging materials, Heckman said that, "If more data is needed, . . . we can ask that it be supplied and would urge that the FDA receive the same before it takes any precipitous action that might injure the industry's reputation irreparably."

The SPI attorney urged that, in the preamble to its proposal, FDA "explain carefully that while vinyl monomer may be a carcinogen, and is not the subject of a prior sanction. . . , PVC is an entirely different material in the same way that toxic chlorine gas is not sodium chloride (table salt)." Heckman said PVC is inert and has been shown in testing to be "harmless when ingested. . ."

In a footnote, SPI said that while VCM is a carcinogen when "inhaled in high doses over long periods of time," there is "no conclusive data to indicate that the same is true as regards ingestion of vinyl monomer. . ." Therefore, Heckman said it does not fall under the Delaney anti-cancer clause, since it has not been "found to induce cancer after tests 'appropriate for the evaluation of the safety of food additives.'"

Contending that PVC is exempted from the Food Additive Law under its "prior sanction" so that no action at all is necessary, Heckman said that in view of the concern expressed and the confusion between PVC and VCM "it would appear to us that reaffirmation of the PVC prior sanction would be worthwhile." He added:

"Industry, therefore, could be counted upon to support such action, rather than contest FDA jurisdiction on this score, providing any limitations imposed in the process of reaffirmation are appropriately designed to make it clear that the presence of vinyl monomer in foods will not be tolerated."

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