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September 16, 1977

To: Plastic Bottle Institute
Plastic Beverage Container Group
PET Safety Group
Food, Drug and Cosmetic Packaging
Materials Committee
PVC Safety Group
AN Safety Group

Re: AN Beverage Container-PVC Regulations Interactions

Letter Highlights

1. At a recent meeting to discuss information relevant to the PVC rulemaking proceeding, FDA-Bureau of Foods personnel indicated that they are apparently preparing to apply what we consider to be erroneous basic concepts advanced by the government's attorneys in the AN beverage container case. Although recent trade press reports reflect an FDA "topside" view that no basic shifts are contemplated, the communications gap appears to be so wide that those who actually deal with incidental additives matters are at least vocalizing the theory that, henceforth, to be consistent with the proposition advanced by FDA's legal staff, they will need to take the position that any substance intended to contact food is a "food additive" because theoretical projections, or the laws of physics could always be used to show there must be some migration, no matter how "unmeasurable."

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Ladies and Gentlemen:

You may recall that, in our letter dated August 25, 1977, we indicated our deep concern over the likelihood that Commissioner Kennedy might accept Judge Davidson's and the Bureau's attorneys argument that food contact of any type must, by application of the laws of physics, result in some migration from the contacting material to the food and, thus, trigger full scale food additive treatment for every food contact surface component. Should this develop, we indicated that a major portion of the regulatory folklore developed to deal with "non-additives" will have been jeopardized, and that debilitating confusion among both the regulators and regulated could be the inevitable result.

Unfortunately, our concerns in this respect have now been intensified as a result of statements made at a meeting between representatives of Ethyl Corporation and the Food and Drug Administration's (FDA) Bureau of Foods (Bureau) held on September 8, 1977. Ethyl Corporation had previously submitted information to FDA which it believed demonstrated that migration, if any, from bottles with low levels of residual vinyl chloride monomer is "vanishingly small". Ethyl representatives met with the scientific-technical staff members of the Bureau to summarize the migration versus residual VCM data that had been presented to FDA piecemeal as it was developed, and to exchange views regarding the validity and significance of the data. At that meeting, attended at Ethyl's request by Dr. Dixler of our office, the Bureau staff explicitly enunciated the doctrine--and referred to the AN case as the justification for so doing--that mathematical equations predict that migration will occur if any level of residual vinyl chloride remains in container walls.

Collaterally, but during the same general time period, persons designated as "spokesmen" for the Food and Drug Administration apparently informed Food Chemical News that the AN beverage container situation is not to be interpreted as being applicable to other materials. (We are enclosing a copy of pages 9 and 10 of the September 12, issue of Food Chemical News with the kind permission of the publisher so that you can review the FCN story.)

It is disturbing to us to note once again the apparent rather persistent lack of communication that seems to exist on a continuing basis between the staff of the Bureau working on direct implementation of the Food Additive Regulations and others who presumably speak for the Food and Drug Administration regarding the import of its major decisions on related problems.

We hope this review of the present Bureau of Foods position vis a vis the application of the AN beverage container case reasoning will serve to keep you aware of the basis for our deep concerns regarding the possible fallout from the acrylonitrile beverage container hearing. We shall follow the situation as closely as possible and will continue to report to you promptly. In the meantime, if you have any questions, please to not hesitate to contact us.

Cordially yours,

Jerome H. Heckman

Enclosures

Just for your information, attached hereto is a copy of a letter one member of SPI recently sent to Commissioner Kennedy on his own initiative. Suffice it to say that I think Frank Harris has at least expressed some of the frustration that many of us feel.

JHH

KENNEDY ORDERS REVIEW OF FDA'S RESEARCH PRIORITIES

The Food and Drug Administration has not had a satisfactory internal mechanism for establishing research needs and priorities, according to Food and Drugs Commissioner Dr. Donald Kennedy.

Responding to a series of questions posed by Robert B. Choate, Chairman of th Council on Children, Media and Merchandising (See FOOD CHEMICAL NEWS, Sept. 5, Page 58), Kennedy said he has directed FDA to develop such a plan over the next year. The aim will be to enable the agency to determine which n ds can be met in FDA's laboratories, through agreements with other governm nt agencies, and by contracting or awarding grants to non-government scientists.

Choate had complained that FDA does not make known its areas of interest, suggesting that a priority list of 25 to 50 research issues be published quarterly to attract applicants.

Kennedy said the FDA review of priorities will also help the agency better " xpress our research funding requirements during the budget process."

Once the review is completed, the Commissioner said the agency's needs will be made known publicly through the Federal Register, Commerce's Business Daily, the National Institutes of Health Guide for Grants and Contracts and scientific journals.

If these expressions of interest are backed by a reliable source of funds, he continued, "I don't believe the rejection of some proposals because of lack of technical merit will squelch interest in a field that we are truly committed to supporting."

Choate had pointed out that FDA's rejection of a grant for the study of carcinogens in heavily burned meat might indicate the agency's lack of interest in the area.

The consumer advocate is a member of the National Advisory Food and Drug Committee, which is slated for abolition by the Carter Administration (See FOOD CHEMICAL NEWS, Aug. 29, Page 35). It is understood that FDA is asking for Office of Management and Budget reconsideration of the plans to scrap NAFDC, the Toxicology Advisory Committee, the Science Advisory Board to the National Center for Toxicological Research, and the Board of Tea Experts.

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FDA-ERS SEE NO CHANGE IN BASIC INDIRECT ADDITIVE POSITION ☆

Food and Drug Administration spokespersons have informally indicated that there has been no change in the agency's long-held position that packaging materials are to be regulated as "food additives" only if they migrate to food.

An FDA bri f filed in the acrylonitrile hearing has be n interpreted by industry representatives as changing the groundrules for packaging materials (S e FOOD

CHEMICAL NEWS, Aug. 29, Page 26). The industry representatives read the FDA position as constituting an expectation of migration into food of any packaging material which is suspected of carcinogenicity, regardless of measurable migration.

FDA-ers said there was no intention of changing FDA's policy, explaining that the brief which has upset industry was designed only to reply to exceptions filed by industry to Administrative Law Judge Daniel Davidson's initial decision. Some spokespersons characterized the responses as being necessarily cursory.

The FDA-ers stress that there was no intention of changing FDA's basic position on packaging materials as it was stated in the agency's major brief in the acrylonitrile hearing (See FOOD CHEMICAL NEWS, July 18, Page 57).

Kennedy is Preparing Acrylonitrile Decision

FDA Commissioner Kennedy, who has declined to hear oral arguments from the manufacturing parties to the hearing (See FOOD CHEMICAL NEWS, Sept. 5, Page 2), is believed to be preparing a decision in the matter.

Industry representatives, on the basis of the FDA reply to the exceptions, have expressed the belief that Kennedy is faced with ruling on whether a packaging material is to be regulated as a "food additive" regardless of measurable migration if there is any toxicological concern. They fear the application of this kind of interpretation to polyvinyl chloride and other packaging materials.

The spokespersons for the firms express concern that a change in FDA's policy on packaging materials would mean that the agency could ban can linings, glass, paper components, and other substances at any time, since trace amounts of carcinogens could be expected.

If Kennedy accepts Davidson's initial decision, the companies can be expected to appeal the agency decision in court. Failing a reversal of FDA on appeal, industry spokespersons have indicated they will push for Congressional adoption of a principle of toxicological insignificance. One bill is pending in Congress on this subject.

However, it is expected that FDA may move on a toxicological insignificance petition submitted by the Society of the Plastics Industry. If so, adoption of the SPI proposal -- or a variation of it -- could affect future FDA actions regarding packaging materials, but would probably be too late for acrylonitrile and PVC.

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CANADA UPDATES PROVISIONS FOR COLORS IN DRUGS AND COSMETICS

The Canadian regulations on colors permitted for use in drugs and cosmetics were updated by the Canadian Health Protection Branch recently in Information Letter No. 504, issued Aug. 19.

HPB amended the drug regulations to "require notification of the identity and concentration of all colouring agents us d in drug formulations," effective Sept. 30, 1977.