JOSEPH E. KELLER
JEROME H. HECKMAN
CHARLES M. MEEHAN
WILLIAM H. BORGHESANI, JR.
ROBERT R. TIERNAN
WAYNE V. BLACK
DAVID L. HILL
MARTIN W. BERCOVICI
PETER M. NEMKOV
JOSEPH E. HADLEY, JR.
CAROLE C. HARRIS
MICHAEL F. MORRONE
LARRY S. SOLOMON
JOHN B. DUBECK
CHRISTINE A. MEAGHER
SHIRLEY S. FUJIMOTO
JOHN S. ELDRED
LAWRENCE P. HALPRIN

LAW OFFICES
KELLER AND HECKMAN
1150 17TH STREET, N.W.
SUITE 1000
WASHINGTON, D.C. 20036

TELEPHONE
202 457-1100
CABLE ADDRESS "KELMAN"
WRITER'S DIRECT DIAL NUMBER
202/457-1110

H. J. ROBINSON

SEP 15 1978

August 29, 1978

PRODUCT SAFETY

AUG 31 1978

J. P. CHARM

Letter No. 43

cc JWA
ETKuba
H.J. Robinson
D M Aviado
A T Plantamura
T.D. Kent
Frank J. B. Clarke

To: All Members of:

SPI-VCM/PVC Mailing List
Plastic Bottle Institute
Plastic Beverage Container Group
AN Polymers Group
PET Safety Group
Food, Drug and Cosmetic Packaging
Materials Committee
PVC Safety Group
Ad Hoc SPI Packaging Risk
Assessment Committee

Re: Risk Assessment for Vinyl Chloride Monomer

Letter Highlights

In an anticipated proposal regarding carcinogenic animal drug residues, FDA is expected to conclude that vinyl chloride in food at a level below approximately 6.5 ppb would be "safe." Since present PVC packaging assures "non-detectable" VCM in food simulating solvents at far lower levels, the SOM proposal lends support to the conclusion that FDA will ultimately apply risk assessment procedures to clear PVC and other packaging materials components.

Ladies and Gentlemen:

As all of you know, SPI has been urging for many years[1/] that FDA explicitly set a level of migration below which most substances will not even be considered indirect food additives and, in the case of substances that may raise concerns of irreversible toxicity, use a specified risk assessment procedure to determine that level. We have also been reporting to you regarding FDA activities in the general area of risk assessment relating to food additives and especially on the tie-in between residues of animal drugs in edible tissues and indirect additives. Very recently, we have learned from what we consider very reliable sources that FDA is now "putting the final touches" on a new proposal regarding carcinogenic animal drug residues; it is expected to specify that the required sensitivity of analytical method (SOM) be based upon a linear extrapolation procedure. Of more direct interest we have reason to believe that the present draft of this proposal presents, as an example in the use of the method only, a calculation for vinyl chloride monomer that shows approximately 6.7 parts per billion (ppb) of VCM in the food simulating extract would be deemed "safe" if and when the methodology is officially adopted and then made applicable, e.g., to animal drugs and packaging materials components.

The previous SOM Regulations which utilized the improved Mantel-Bryan (M-B) procedure were invalidated by a United States District Court[2/] on the grounds that the final Regulation deviated too widely from the proposed Regulation in that the final rules specified the improved M-B procedure whereas the proposed rule referred to the original M-B procedure. Among the options the Court's decision left open for FDA was the reproposal of the Regulation. This is the procedural route it selected, but

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1/ Tangible examples are the Comments filed on the Food and Drug Administration (FDA) 1973 rule making proposal regarding vinyl chloride monomer, statements made in support of the Ashley and Sisk Bills, [H.R. 6979 and H.R. 9602, respectively] and the SPI Citizen Petition No. 7CP3313, Docket No. 77P-0122 filed with the Food and Drug Administration in 1977.

2/ Animal Health Institute v. FDA (DCDC. 1978). Food, Drug and Cosmetic Law Reporter (CCH), paragraph 38, 154.

instead of reproposing any Mantel-Bryan procedure, we have now been told that the new draft will propose utilization of the more severe linear extrapolation method; like the earlier SOM regulation, the new method does "adjust" the observed animal toxicology data to provide a 99% confidence level for the predictions.

Although, strictly speaking, the proposal will be designated as one to set forth methodology immediately applicable only to animal drug residues, it is our understanding that FDA is showing several exemplary calculations drawn from other areas to demonstrate how the procedure works. As indicated, among them the present draft is believed to present a calculation of the "safe" level for vinyl chloride. Based upon the 1975 Maltoni data (for inhalation), the linear risk assessment method shows that a level of somewhat less than 7 ppb of vinyl chloride in the total diet for a lifetime assures that the possible risk of cancer will be less than 1 in 1,000,000. This risk level was utilized in the old SOM document and we believe will appear in the new proposal as being sufficiently low as to cause no public health concern.

If the same criteria were to be applied to indirect additives as the SOM document will propose for drug residues, and we are told this is a likely eventuality, a finding of "non-detected" with a validated analytical procedure capable of detecting approximately 6.5 ppb in food simulating solvents would lead to the regulatory conclusion that there is no reasonable expectation of vinyl chloride extraction into food. Thus, there would be no basis for a ban of such PVC packaging material. In fact, present PVC products show "non-detected" in food simulating solvents at far lower levels of analytical sensitivity.

Obviously, we have a long way to go before FDA formally agrees to apply the soon-to-be-proposed SOM procedure or any other SOM procedure to the threshold determination of what constitutes a food additive. Nevertheless, FDA's use of vinyl chloride as an example in the new SOM proposal it is developing suggests that the Agency is moving toward an acknowledgement that the animal drug residues and monomer residues in plastics should be dealt with in comparable ways. At the very least, it will make it very difficult for FDA to try to effect a ban of useful PVC products which it had already admitted were safe. Thus, we believe this anticipated FDA action provides a further indication that FDA is actively considering ways to withdraw its proposed ban of certain PVC products.

We shall, of course, continue to follow developments and keep you promptly informed. In the meantime, if you have any questions, please do not hesitate to contact us.

Cordially yours,

James W. Hickman