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February 10, 1986

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

IMMEDIATE ATTENTION AND RESPONSE REQUESTED

Re: **FDA PVC Rulemaking; Interpretation of Residual Monomer Limitations**

Ladies and Gentlemen:

Our letter of February 4, 1986, provided a preliminary analysis of the Food and Drug Administration's (FDA) rulemaking actions concerning vinyl chloride polymers. As indicated in that letter, it was our intent to advise you about any nuances in interpretation that might occur to us, or be called to our attention, after the initial mailing.

While there may yet be further questions about interpretation raised hereafter, one point requiring consideration and action has already been raised quite forcefully with us. The problem could be one of semantics, but we decided that, at the very least, it deserved immediate investigation so we have been conferring informally with the FDA staff about it. The following is an attempt to try to explain the issue, a somewhat difficult thing to do.

As we heard the preliminary reports about the way in which the vinyl chloride rulemaking criteria would be established (and as we reported to you at an early stage even before

the December 16, 1985, Food Chemical News article), we have consistently been given the impression that the residual vinyl chloride monomer (RVCM) limitations FDA would impose would relate to RVCM in finished food contact surfaces. Prompted by calls from Dick LaRue of Occidental on February 6, and Gene Skeist of Borden on February 7, we have now had the time to examine more closely the language used in the formal indirect food additives rulemaking sections that begin on page 4185 of the Federal Register (Feb. 3, 1986).

In so doing, we have duly noted what is at best an ambiguity that appears throughout the proposals, and what could be, at worst, an unexpectedly severe limitation. The conflict flows from the fact that almost all the proposed regulations speak in terms of a 5 or 10 parts per billion (ppb) RVCM maximum (as anticipated), but then go on to state that the limitation shall be "5 [or 10] ppb by weight of the vinyl chloride homo- or copolymer component." (Emphasis supplied.)

Having now spoken with the FDA staff about this matter, we realize that the Agency (or at least its attorneys) was apparently attempting to make it clear that, if a given package consists of a laminate of PVC and some other substance, compliance with the 5 [10] ppb RVCM limitation would be determined by analysis of the PVC layer only. In other words, FDA was trying to say that, for example, if the construct were 50% PVC film and 50% polyethylene film, you would not be permitted to have 10 ppb in the PVC film and claim that the 5 ppb RVCM limitation had been satisfied. In and of itself, this objective seems reasonable.

Unfortunately, by carrying the same language throughout all of the regulations, what has been proposed is likely to be read to mean that the limitation, for example, of 5 ppb in coatings, will require that companies not only make certain a finished coating contains no more than 5 ppb RVCM, but that they will also have to determine how much of the coating is a PVC resin. They would then have to make certain in some way that the RVCM in the final food contact surface does not exceed the equivalent of 5 [10] ppb by weight of the resin, not 5 ppb of the total coating.

We are now assured that this convolution is not and was not FDA's intent so we are presented with a semantical

problem. Assuming we can develop suitable language to accommodate the two interests implicit in the foregoing examples, we are reasonably confident that we will have the cooperation of the Agency in clarifying this matter. For example, we might recommend that the proposed regulations be changed to read:

> " . . . 5 ppb RVCM in the [article: film, coating, sheet]. In the case of multilayer structures, the RVCM limit relates to the amount of RVCM in the vinyl chloride homo- or copolymer layer."

Our informal talks with the FDA staff lead us to believe that the potential problems with these issues and those noted in our February 4 letter should not be difficult to resolve and need not occasion any long delay in finalizing the February 3 rulemaking proposal. Thus, your suggestions on how the clarification might best be accomplished are being solicited, our special interest being in getting your input as to whether a change is needed in all the rules, or only a few.

Instead of simply suggesting deletion of the "by weight of the vinyl chloride homo- or copolymer component" everywhere it appears, we are requesting your advice because we do not know as of this writing whether or not the problem we are calling to your attention is really a practical one. If everyone is capable of making homo- and co-polymer resins or compounds that will meet the limitations as written, and is prepared to certify their resin or compound accordingly, there may be no problem with the proposed regulations. Our suspicion, however, is that this is not the case and that most manufacturers have been assuming that higher RVCM resins or compounds can be employed to make films or coatings since processing will remove the excess. This concept might still be valid, but we would then need to know how one could be assured that the PVC component of a coating or film will not contain more than 5 ppb RVCM after the end product is fabricated.

Along with any other comments you might care to give us, we would appreciate your thoughts on this unhappy little wrinkle that has developed. I am reasonably certain we can resolve the issue with suitable language, but information on commercially feasible RVCM levels is needed to guide any further discussions we might have with FDA and the development of a suitable approach for the SPI Comments.

As an aside--but one that could become an important part of any comments we file for the industry--we should probably note here that, while we may seemingly have accepted the notion of RVCM limitations on polyvinyl chloride products, we have never been of the view nor are we now of the view that this is a correct approach to regulating any packaging material. It may be a politically expedient way to move, or even one that, properly stated, would be easier to administer scientifically. In our opinion, however, it is inappropriate to regulate a packaging material by the way in which it is made. What the law really requires is that the Food and Drug Administration regulate what gets into food. In keeping with this philosophy, had the Agency imposed extraction limitations for PVC applications instead of customized RVCM limits, it seems to us that the presently presented problem and many of the other complications in the various proposed regulations could be avoided.

We may not put undue emphasis on this point again in our comments since to do so could delay what I believe we all most urgently desire, rapid FDA final action. However, unless you instruct us to the contrary, you will probably see comments or a footnote in any draft we send you that reflects these ideas.

As of this time we have reason to believe that we will certainly be commenting on this matter, on the RVCM content of PVC pipe for food plant use provisions, and on the question of the suitability of the FDA RVCM test method. We are thinking in terms of the sort of comments that will have to be filed on these subjects and will continue to be in touch with you as we proceed.

Cordially yours,

Jerome H. Heckman