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To: All Members of SPI-VCM/PVC Mailings Lists

Letter Highlight

Enclosed is a copy of a letter from Mr. William Randolph, Acting Associate Commissioner for Compliance, FDA, declaring the Agency's intention to provide for additional public comment prior to any final action on the still-pending (since September 3, 1975) PVC Rule Making Proposal. Accordingly, PVC remains "prior sanctioned" for all food-contact applications and is likely to remain in this status for the foreseeable future.

Ladies and Gentlemen:

We have been reporting to you from time to time about the initiatives we have undertaken on behalf of SPI in both the regulatory and legislative arena. These have been motivated by the hope of limiting the "fallout" from the AN beverage container decision and clarifying the definition of the term "food additive" to permit the continued use of safe plastics packaging with a minimum of regulatory concern. Paralleling and supplementing these efforts, we have been informing you of the studies being conducted by Ethyl Corporation to establish a general "no migration" position for rigid and semirigid PVC products. The purpose of this letter is to supply you with additional information regarding what we consider to be a worthwhile thrust made by Tenneco Chemical Company and the encouraging results that this effort has yielded.

VVC 000006781

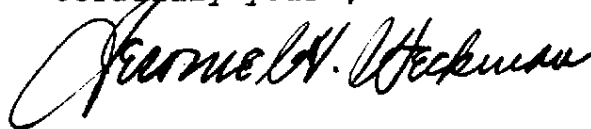
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In this connection, we are enclosing herewith copies of an exchange of correspondence between Eugene I. Lambert, Counsel for Tenneco, and William F. Randolph, Acting Associate Commissioner for Compliance at the Food and Drug Administration (FDA). The letter sent on behalf of Tenneco refers to the new analytical procedures developed by FDA, and rumors and hearsay (some of which we have reported) regarding the finding of very low levels of residual monomer (RVCM) in various PVC samples. It also asserts the need for reopening the comment period in connection with the proposed PVC Regulations. Replying specifically to this letter, but reflecting and confirming the change in thinking going on at FDA, the letter signed by Mr. Randolph commits the Agency to further consideration of the PVC regulatory proposals.

Although Mr. Randolph does not so state, we can report our contacts at FDA clearly expect that, in due course, the present PVC proposals will be withdrawn and new Regulations will be proposed with time for comment provided. We have no indication as to the precise timing of such action. However, we believe that it will not occur until at least internal agreement is reached upon an FDA position with regard to the Citizens Petition (7CP3313) we filed on behalf of SPI. You will recall that, in essence, our Petition asked for amendments to the regulatory definition of the term "food additive" that would effectively exempt from regulatory coverage minute or unmeasurable quantities of possible contaminants.

If you have any questions or comments at any time, please feel free to contact us.

Cordially yours,



Enclosure

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