

VCM-FDA

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March 18, 1974

Handwritten signature/initials.

TO: All Members of:

SPI Food, Drug and Cosmetic
Packaging Materials Committee;
General Polyvinyl Chloride Interest
Mailing List */;
Ad Hoc Liquor Bottle Committee;
Plastic Pipe Institute
(Executive Board);
Plastic Bottle Division
(Voting Representatives);
SPI Executive Committee;
SPI Public Affairs Committee

RE: Prior Sanctioned PVC Status;
Proposed Rule Making

Gentlemen:

Following up on our letter of March 12 which, I am sure you all know, has lead to great concern among everyone interested in the polyvinyl chloride problem as it has developed at the Food and Drug Administration, and also to our being virtually swamped with telephone calls for further information, the purpose of this letter is to try to keep all interested parties as up to date as possible. In so doing, we are following the explicit instructions of the President of SPI, Ralph Harding, who, like we, is hopeful that our posting you as responsibly

*/ We are substituting this designation for the one heretofore used on correspondence of this type because, obviously, the PVC problem has transcended the original interest which was centered on liquor bottles and the Bureau of Alcohol, Tobacco and Firearms. Continuing to use the misnomer "BATF Mailing List" is no longer really appropriate and no harm would seem to be caused by changing the designation since the mailing list did not constitute an official SPI group.

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as we can will calm some unnecessary fears and delimit much of the rumoring and erroneous hearsay being generated by the telephone contacts. This process might also suggest to many of you the desirability of avoiding the telephoning of the Food and Drug Administration's Staff since we doubt that this will be helpful to you or FDA in the effort being made to maintain perspective on the case.

Turning more specifically to the problem, firstly we are enclosing herewith, with the permission of the editors, reproductions of pages 23 and 24 from this week's edition of Food Chemical News. As many of you know, but some may not, Food Chemical News is the basic reference publication for Food and Drug Administration developments in the food additives and other related areas. This will probably explain to you why the report is, in our opinion, quite objective and as reasonably low-key as may be expected from a responsible publication under the circumstances. The point here is that "the unofficial word is out" although official action has not yet been taken.

Today we spoke at some length with Dick Ronk of the Division of Food and Color Additives who, as you know from our previous letters, is pretty much heading up the FDA activity on PVC at this time. We were advised that work is going forward on a draft Order which will propose removal of the "prior-sanction" on PVC and propose replacing the prior-sanction with an Interim Food Additive Regulation along the lines described in our last letter.

The thinking at FDA has not progressed to the point where we can be any more definitive than this except that we can tell you we have been asked to stand by to help with the drafting activity, especially as it might relate to including proposed test methodology for the Interim Food Additive Regulation. We might also note that there is an outside possibility that FDA will invoke emergency powers to make the Order effective immediately, instead of simply proposing the action and receiving comments before moving. We say this is an outside possibility

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because Mr. Ronk informed us that the more likely approach will be to propose, receive comments, and then take action in promulgating an Interim Food Additive Regulation. During the course of this process, please understand that the prior-sanction will remain in effect so as to leave the marketplace in tact, at least legally and scientifically.

As far as timing is concerned, Gerard Mccowin of Mr. Ronk's Staff is working on the project. Mr. Ronk advises that he is unlikely to have even a first draft for internal consideration before the end of this week. The matter would then have to be considered at a number of levels in FDA so the prediction at the moment is that nothing definite is likely to appear in the Federal Register in less than three or four weeks. Again, please understand that the prior-sanction remains in effect during this time. Moreover, there is no valid reason for those in such industries as the plastic pipe industry, or the supplying of cosmetic containers, to be unduly concerned. There is every likelihood that the present use of PVC in these areas will not be affected, at least until such time as toxicological work is completed, the anticipation being that this might require as much as two or three years. Furthermore, many of those knowledgeable about the toxicological situation have given us reason to believe that appropriately conducted studies might well lead to a satisfactory conclusion of the toxicology issue.

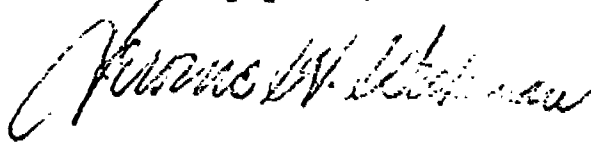
The one circumstance which might have to change more rapidly is that, if FDA adopts an Order limiting residual monomer in food contact surfaces, the type or quality of PVC compound used for all applications may have to be changed to take this into account, i.e. compounds with lower residual monomer may have to be employed by those using them for food containers, film, potable water pip, etc.

As far as any meetings or other follow-up activity are concerned, discussions have been taking place but it has been generally agreed that no useful purpose would be served by calling sessions until such time as the Food and Drug Administration does issue something definitive. You

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have already been alerted to the fact that a meeting might need to be called on short notice. In the meantime, we will simply try to keep you fully briefed by letters such as this one.

Cordially yours,

A handwritten signature in cursive script, appearing to read "James W. Whitman".

Enclosure

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