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No. 28

TO: All Members of SPI-PVC/VCM Mailing List

Letter Highlights

1. Latest information from FDA suggests that no final PVC Regulation can be expected before the end of 1976 at the earliest.

2. The new EPA emissions standards pose major economic burdens; but there are few technological shocks.

Ladies and Gentlemen:

The primary purpose of this letter is to bring you up to date on our latest information regarding the timing of the Food and Drug Administration's (FDA) final regulations on polyvinyl chloride. Secondly, it will confirm the Environmental Protection Agency's (EPA) promulgation of its regulations governing vinyl chloride emissions, regulations which affect only manufacturers of vinyl chloride monomer, polyvinyl resin per se, and certain related products.

FDA

ASI 000015023

As many of you may already know, FDA's Bureau of Foods, the branch of the Administration responsible for the promulgation of the polyvinyl chloride Food Additive Regulations, is involved in a rather major reorganization and a redefinition of long range goals. In addition,

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the Division of Food and Color Additives, the division with specific responsibility for the PVC regulation, is also facing a move from its current location at 200 C Street, S.W. to the Donahue Building on 6th and D Streets, S.W. As a result of pressures on the staff to complete planning in both of those connections, our latest information is that it is unlikely that any final polyvinyl chloride regulations will be promulgated this year; if such regulations appear at all, there seems to be no possibility that they will be promulgated before the very end of December.

To the best of our knowledge, concerned personnel at FDA now have a major portion of their time allocated to the development of long term plans for implementing FDA's projected overall additives safety review. This will involve the addition of perhaps 75 new people to work in the Division of Food and Color Additives where only ten are now employed in a comparable capacity. The program is intended ultimately to provide a review of the safety of all presently regulated direct and indirect additives in light of present standards. It will supplement the GRAS and prior sanction reviews now well under way. In addition, the move to the new quarters is also demanding planning attention and has resulted in initial packing of records and the like.

These two factors, combined with the need to prepare for Hearings on Color Additives have meant (we gather) that the polyvinyl chloride Regulations have received almost no attention and are not likely to receive any significant amount of attention, at least until the move has been accomplished. Since the move was originally scheduled for the end of October, then the end of November, then the end of December and now the end of November again, perhaps this will help you understand the basis for our "guesstimate" as to timing on "final" PVC regulations.

As to the substance of the Regulations, there is nothing that we can add to our past reports because so little attention has been given to this at FDA Staff level. Nevertheless, we are continuing to maintain close

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contact with the Staff in the event that any presently unanticipated activity develops.

EPA

With respect to the Environmental Protection Agency's new standards on vinyl chloride emissions, the Regulations contained no real shocks. This is not surprising in light of the procedures used by EPA which include consulting with and informing all interested parties concerning the substance of drafts of the Regulations. This helps to insure that the ultimate Regulations are as feasible as possible and are based upon up-to-date knowledge of the industry.

Despite the fact that the regulation will impose serious economic burdens on the VC/PVC industry, the requirements seem to be within the realm of known technology and are in most respects believed to be attainable. In most of those areas where the goals have not already been reached, it is anticipated that they will be achieved within the time period allowed. We report this for general interest mainly, because those who are directly affected by the Regulations are well aware of the detailed requirements and implications.

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Once again we want to assure you that we will follow the various aspects of interest to the vinyl chloride/polyvinyl chloride industry as closely as we can and will continue to report to you promptly.

Cordially yours,

James H. Brown

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ERRATUM

This letter should be identified as
No. 29 not No. 28.

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