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Monsanto

P. R. Graham - B3NA-General Office

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VCM *File*

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FDA Status of PVC

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For over a year now, the FDA Bureau of Foods has opted to delay official reaction to the VCM issue. However, strong rumors are again pointing to imminent regulatory changes which are a direct consequence of the recent public insistence of the Health Research Group that the Delaney amendment be invoked by the FDA since VCM is a "proven" carcinogen. The following are the expected FDA action according to these most recent rumors:

1) Flexible (Plasticized) PVC Regulations

The FDA is expected to reaffirm the prior sanction status of PVC for applications employing film of thicknesses of 2 mils or less. These would include meat wrap film, can liners, most closures and cap liners. Therefore, effect on our plasticizer business would be minimal or even zero.

2) Rigid and Semi-rigid Thermoformed Containers

These uses include blown bottles, vacuum formed containers and bubble-packs which are generally of relatively heavier wall thicknesses. It is anticipated that the FDA will remove the prior sanctioned status for these uses. New petitions covering specific food surface formulations will have to be filed by individuals to obtain regulations. The petitioner will have to show "zero" VCM migration using a test sensitive to 50 ppb. This action will also have very little effect on our plasticizer business.

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3) Potable Water Pipe

The FDA is not likely to immediately curtail the use of PVC potable water pipe. But rather, an interim regulation is expected which will control the amount of VCM in the pipe to a level which will minimize the risk until data are in hand to show the amount of VCM which could be expected to migrate from this instantaneous contact use. The interim regulation would be replaced by a final regulation after the data are evaluated. Again, this would have no effect on our plasticizer business.

Regardless of the form the FDA action takes, immediate bans, or abrupt regulation changes are not possible. At least six months would be necessary before a regulatory change could be effected.

These predictions are based on information from Keller and Heckman Law Offices, Ethyl Corporation and friends at the FDA.

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