

JAN 9 1991

Mr. Ralph A. Simmons
Law Offices
Keller and Heckman
1150 17th Street, N.W.
Suite 1000
Washington, D.C. 20036

Re: FAMF 428

Dear Mr. Simmons:

This responds to your submissions of May 25, August 2, August 16, and December 21, 1990, on behalf of Hoechst Celanese, concerning the use of post-consumer polyethylene terephthalate (PET) two-liter bottles to produce regenerated dimethyl terephthalate (DMT) for further use as a component in the manufacture of PET beverage bottles. By "regenerated", we mean that DMT is chemically recovered from PET that has been depolymerized to its constituent monomers.

We have reviewed the data that you have provided on the Hoechst isolation and purification process to produce regenerated DMT from depolymerized PET bottles. In particular, you have provided chromatography and mass spectrometry data demonstrating that regenerated DMT is as pure as "virgin" DMT, and that marker contaminants purposefully added to the original PET bottles are removed during processing. Based upon our review of these data, we believe that DMT produced by this process will be of a purity suitable for use in the production of PET intended for use in contact with food, in accordance with 21 CFR 174.5. Therefore, we do not object to the use of DMT regenerated by this process as a component in the manufacture of PET beverage bottles or other PET food-contact articles, provided that its use in making such articles is in compliance with 21 CFR 177.1630.

We recognize that the use of PET bottles as a source of DMT regenerated by the Hoechst process may be broadly referred to by some as "recycling". We wish to emphasize, however, that we do not consider this process to be "recycling". The Hoechst process recovers regenerated DMT from depolymerized PET through a chemical process. The Hoechst process thus can be distinguished from either the physical reuse of a regulated article, such as the reuse of a bottle by washing and refilling, or the physical recycling of a regulated polymer obtained, for example, by grinding and remolding a plastic article. In addition, PET articles, because they are free of adjuvants, such as antioxidants, that are typically present in other types of plastic food-contact articles, present a special case. Because of the absence of such adjuvants, their fate during Hoechst's reprocessing of PET bottles need not be considered. This would

not be the case, however, with many other plastics approved for food-contact use.

We believe that it is important to differentiate the Hoechst process for regenerating DMT from recycling because the data that you submitted and we reviewed, and the opinion set forth in this letter, address only the use of regenerated DMT from the Hoechst process. Thus, this opinion does not authorize or approve the reuse of PET or other food-contact polymers, or of PET bottles, through the physical reuse or recycling described above. Indeed, in the near future, FDA intends to issue food additive regulations to supplement 21 CFR 174.5 that will establish requirements for the use of recycled polymers in contact with food. These regulations will address issues such as the source of materials to be recycled and the methods for assuring that recycled materials do not contain unacceptable levels of contaminants. Requests for the use of regenerated materials like DMT or other components of food-contact articles will be addressed on a case-by-case basis.

In summary, we are issuing this letter addressing the Hoechst process because, based on the data that you have submitted, we believe that the use of regenerated DMT produced by this process from depolymerized PET bottles to manufacture PET food-contact articles is within the purview of existing regulations (21 CFR §§174.5 and 177.1630).

We trust that this letter responds fully to your request on this matter. If you have any further questions, please do not hesitate to contact me.

Sincerely yours,

/s/
Alan M. Rulis, Ph.D.
Director
Division of Food and Color Additives
Center for Food Safety
and Applied Nutrition