

JUL 21 1998

Mr. Ralph A. Simmons  
Law Offices  
Keller and Heckman  
1001 G Street, N.W.  
Suite 500 West  
Washington, D.C. 20001

Re: Food Additive Master File No. 518

Dear Mr. Simmons:

This responds to your submission of October 17, 1996, regarding the use of post-consumer polyethylene terephthalate (PET) in the manufacturing of tri-laminated PET bottles consisting of at least 1 mil thick inner and outer layers of virgin PET complying with either 21 CFR 177.1630 or 21 CFR 177.1315, sandwiching a core layer of post-consumer recycled PET comprising approximately percent by weight of the tri-laminated PET bottles. Specifically, you requested that FDA confirm the safe use of these PET bottles for holding high-alcoholic and fatty foods under Condition of Use D (Hot filled or pasteurized below 150°F (66°C)), "subject to no other limitations."

We have reviewed the data in your submission and conclude the following:

- (1) The data do not support the safe use of your tri-laminated PET bottles for holding high-alcoholic and fatty foods under Condition of Use D (Hot filled or pasteurized below 150°F (66°C)), "subject to no other limitations," but
- (2) The data support the conclusion that a 1 mil thick food-contact layer of virgin PET acts as a functional barrier to artificially high levels of contamination under Condition of Use D, with room temperature storage for up to three months.

We have used theoretical modeling to determine potential contaminant migration through a 1 mil thick layer of virgin PET. We found that after one year, the dietary concentration of the contaminants would exceed our threshold of regulation limit (0.5 ppb). Thus the modeling data seem to support the view that a 1 mil thick layer of virgin PET can act as a functional barrier under Condition of Use D, only where storage does not exceed one year.

Based upon the modeling data, the agency can also conclude that the use of post-consumer PET (comprising approximately     percent by weight of the tri-laminated PET bottles) as the middle layer of tri-laminated food-contact articles would not require an amendment of the food additive regulations, provided this post-consumer recycled PET middle layer is sandwiched with 1 mil thick layers of virgin PET that comply with either 21 CFR 177.1630 or 21 CFR 177.1315. Such a tri-laminated bottle could be used to hold high-alcoholic and fatty foods under Condition of use D (Hot filled or pasteurized below 150°F (66°C)), with storage up to one year.

Although we have concluded that your intended use of post-consumer recycled PET does not require an amendment to the food additive regulations, you should be aware that we are currently developing a formal policy on the use of post-consumer recycled plastics in contact with food. Thus, the decisions set forth in this letter may need to be modified due to future deliberations on this matter.

If you have any further questions related to this letter, please do not hesitate to contact us.

Sincerely yours,



Eugene C. Coleman  
Director  
Division of Petition Control, HFS-215  
Center for Food Safety  
and Applied Nutrition