

DEC 29 1998

Mr. George G. Misko
Law Offices
Keller and Heckman LLP
1001 G Street, NW
Suite 500 West
Washington, D.C. 20001

Dear Mr. Misko:

This responds to your letters dated September 18, 1997, requesting that we confirm that Clean Tech. Inc.'s (CTI) post-consumer recycled (PCR) polyethylene terephthalate (PET) initially used to package food is suitable as food packaging material. The food packaging is intended to contact all types of food under Condition of Use A (high temperature heat-sterilized (e.g., over 212°F)) and less severe conditions. Your letters described

you our comments on the

This letter provides comments on the remaining

We presented
in a letter dated November 23, 1998.

We have reviewed the data submitted to demonstrate the suitability of CTI's to remove post-consumer contaminants from PCR-PET. You have provided analytical data and diffusion modeling results to demonstrate that surrogate contaminants intentionally added to PCR-PET to represent contaminated post-consumer feed material do not migrate in quantities that present regulatory concerns, when used in contact with all types of food under Condition of Use A (high temperature heat-sterilized (e.g., over 212°F)) and less severe conditions.

Based upon our review of these data and information, we agree that the dietary concentrations of possible contaminants in the PCR-PET resulting from CTI's processes would be below FDA's threshold level of concern. Therefore, we conclude that these recycling processes described in your September 18, 1997, letters will produce PCR-PET that is acceptable for use in contact with all types of food under Condition of Use A (high temperature heat-sterilized (e.g., over 212°F)) and less severe conditions, provided the PET complies with 21 CFR 177.1315, 177.1630, and other applicable regulations.

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Our conclusion applies only to PCR-PET collected and processed as described in your September 18, 1997, letters. If your recycling process is modified, new data would need to be evaluated.

Although we have concluded that the intended use of PCR-PET that has been collected and processed in the manner described in your submissions is acceptable, 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