

U.S. Food & Drug Administration



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No Objection Letter for Recycled Plastics #156

November 10, 2011

Joan Sylvain Baughan
1001 G Street, NW
Suite 500 West
Washington, DC 20001

Re: Prenotification Consultation (PNC) 1086

Dear Ms. Baughan:

This letter is in response to your submission, received on August 9, 2011 (PNC 1086), requesting on behalf of Engineering Recycling Maschinen und Anlagen GmbH (EREMA), a no objection letter confirming the capability of the proposed secondary recycling process to produce post-consumer recycled polyethylene terephthalate (PCR-PET) flakes that are suitable for use at levels of up to 100% recycled content in the manufacture of PET containers for contact with all food types under Conditions of Use A through H, and J¹, as described in Table 2², which can be accessed from the Internet in the Food Ingredients and Packaging section under the Food topic of www.fda.gov³.

We previously reviewed the same recycling process and issued letters of no objection dated November 18, 2009, which allowed for expanded use of PCR-PET at levels up to 100% recycled content in the manufacture of containers for contact with all food types under Conditions of Use C through G⁴, when the feedstock consists of post-consumer food and/or non-food containers (excluding industrial PET containers).

We have reviewed the information you referenced in the previous submission, including migration data and migration modeling, which were submitted to demonstrate the capability of EREMA's secondary recycling process to remove potential contaminants from PCR-PET. Based on our review of these data, we have determined that EREMA's secondary recycling process, as described in the subject submission, would be effective in reducing potential contaminants from PCR-PET materials to levels that result in dietary concentrations not to exceed 0.5 ppb, FDA's threshold of regulatory concern. This determination covers the use of PCR-PET derived from the feedstock that consists of post-consumer food and non-food PET containers (excluding industrial PET containers), and the PCR-PET complies with the existing applicable authorizations.

We have concluded that the proposed secondary recycling process, as described in the subject submission, would produce PCR-PET flakes that are suitable for use at levels of up to 100% recycled content in the manufacture of articles for contact with all food types under Conditions of Use A through H, and J⁵, as described in Table 2⁶, which can be accessed from the Internet in the Food Ingredients and Packaging section under the Food topic of www.fda.gov⁷. If the proposed recycling process is modified, new data may need to be evaluated.

The resultant PCR-PET material must comply with all applicable authorizations including 21 CFR § 174.5 General provisions applicable to indirect food additives. For example, in accordance with section 402(a)(3) of the Federal Food, Drug and Cosmetic Act, use of the recycled PCR-PET material should not impart odor or taste to food rendering it unfit for human consumption.

If you have any questions concerning this matter, please do not hesitate to contact us.

Sincerely,

Vanee Komolprasert, Ph.D., P.E.
Consumer Safety Officer
Division of Food Contact Notifications, HFS-275
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

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