



December 13, 2010

Frank Welle
Fraunhofer Institut
Verfahrenstechnik und Verpackung
Giggenhauser Str. 35
D-85354 Freising
GERMANY

Re: Prenotification Consultation (PNC) 958

Dear Mr. Welle:

This letter is in response to your electronic submission, received on August 5, 2010 (PNC 958), requesting on behalf of Starlinger & Co. GmbH (Starlinger) an opinion letter from FDA confirming the capability of Starlinger's secondary recycling process (a so-called "super clean" process) (referred to as "Starlinger iV+") to produce post-consumer recycled polyethylene terephthalate (PCR-PET) pellets that are suitable for use at levels up to 100% recycled content in the manufacture of PET containers for contact with all food types under Conditions of Use C through H, as described in [Table 2](#), which can be accessed from the Internet in the Ingredients and Packaging section under the Food topic of www.fda.gov.

We have previously reviewed the same recycling process and issued a letter of no objection dated October 29, 2007, which allowed for 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 G 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 the Starlinger's secondary recycling process to remove potential contaminants from PCR-PET. Based on our review of these data, we have determined that Starlinger's secondary recycling process, as described in the subject submission, would be effective in reducing potential contaminants from PCR-PET 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 all existing applicable authorizations.

We have concluded that Starlinger's secondary recycling process, as described in the subject submission, would produce PCR-PET pellets that are suitable for use at levels up to 100% recycled content in the manufacture of articles for contact with all food types under Conditions of Use C through H, as described in [Table 2](#), which can be accessed from the Internet in the Ingredients and Packaging section under the Food topic of www.fda.gov. If Starlinger's 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 PET should not impart odor or taste to food rendering it unfit for human consumption.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Vanee Komolprasert". The signature is fluid and cursive, with the first name "Vanee" and last name "Komolprasert" clearly distinguishable.

Vanee Komolprasert, Ph.D., P.E.
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