



January 26, 2011

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

Re: Prenotification Consultation (PNC) 991

Dear Mr. Welle:

This letter is in response to your electronic submission, received on October 20, 2010 (PNC 991), requesting on behalf of Gneuss Kunststofftechnik GmbH (Gneuss) a non objection letter from FDA confirming the capability of Gneuss's secondary recycling process (a so-called "Super Clean" process) 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 G, 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 reviewed Gneuss's recycling process as well as the information obtained from surrogate testing and migration modeling which were submitted to demonstrate the capability of the Gneuss's secondary recycling process to remove potential contaminants from PCR-PET. Based on our review of these data, we have determined that Gneuss'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 the existing applicable authorizations.

We have concluded that Gneuss'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 G, 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 Gneuss'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 PCR-PET material 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,

Vane 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