



August 24, 2018

Frank Welle, Ph.D.  
Fraunhofer-Institute for Process Engineering and Packaging (IVV)  
Giggenhauser Straße 35  
85354 Freising  
GERMANY

Re: Prenotification Consultation PNC 2236

Dear Dr. Welle:

This letter is in response to your electronic submission (PNC 2236), received on July 27, 2018, requesting on behalf of Veolia Beteiligungsgesellschaft mbH (Veolia), an Agency's letter of no objection (LNO), confirming the capability of Veolia's secondary recycling process (a so-called "super clean" process) in cleaning and producing post-consumer recycled polyethylene terephthalate (PCR-PET) material that is suitable for food-contact. The PCR-PET material is intended for use at levels of up to 100% recycled content in manufacturing PET articles that may contact 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 & Packaging section under the Food topic at [www.fda.gov](http://www.fda.gov).

We have reviewed the results of surrogate testing and migration modeling, which were submitted to demonstrate the capability of the proposed recycling process in removing potential contaminants from PCR-PET material. Based on our review of these data, we have determined that the proposed recycling process, as described in the subject submission, is effective in reducing potential contaminants from PCR-PET material to levels that do not migrate to food at a dietary concentration exceeding 0.5 ppb, FDA's threshold of regulatory concern. Therefore, we concluded that the PCR-PET material may be used for food-contact under the intended use conditions, as described above. This determination covers the use of PCR-PET derived from the feedstock that consists of food and non-food PET containers, compliant with 21 CFR § 177.1630 (polyethylene phthalate polymers) and other applicable authorizations. The feedstock excludes industrial/chemical containers. If the proposed recycling process is modified, new data may need to be evaluated.

The recycled 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 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.

**U.S. Food and Drug Administration**  
**Center for Food Safety & Applied Nutrition**  
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[www.fda.gov](http://www.fda.gov)

Sincerely,

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Consumer Safety Officer  
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and Applied Nutrition