

March 22, 2018

Frank Welle, Ph.D.

Fraunhofer-Institute for Process Engineering and Packaging (IWW)

Giggenhauser StraRe 35

85354 Freising

Germany

Re: Prenotification Consultation PNC 2121

Dear Dr. Welle:

This letter is in response to your electronic submission (PNC 2121), received on December 5, 2017, requesting on behalf of Reifenhäuser Cast Sheet Coating GmbH & Co. KG (Reifenhäuser), a letter of no objection, confirming the capability of Reifenhäuser's secondary recycling process (a so-called as "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 sheets for use in production of PET containers that may contact all food types under Conditions of Use C-G, as described in Tables 1 and 2, which can be accessed from the Internet in the Ingredients, Packaging & Labeling section under the Food topic at [www.fda.gov](http://www.fda.gov).

We have reviewed the proposed recycling process as well as the information you obtained from surrogate testing and migration modeling, which were submitted to demonstrate the capability of the proposed recycling process in removing potential contaminants from PCR-PET. 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 produced from the proposed recycling process may be used 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, which comply 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 re-evaluated.

The PCR-PET material should comply with all other 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

Sincerely,

Vanee Komolprasert, Ph.D., PE.

Consumer Safety Officer

Division of Food Contact Notifications, HFS-275

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

## Food Types & Conditions of Use for Food Contact Substances

CFSAN/Office of Food Additive Safety

These tables were created for easy reference for notifications relating to a food contact substance

### Table 1—Types of Raw and Processed Foods

- I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0)
- II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
- III. Aqueous, acid or nonacid products containing free oil or fat: may contain salt, and including water-in-oil emulsions of low- or high-fat content
- IV. Dairy products and modification:
  - A. Water-in-oil emulsions, high- or low-fat.
  - B. Oil-in-water emulsions, high- or low-fat
- V. Low-moisture fats and oil
- VI. Beverages:
  - A. Containing up to 8 percent of alcohol
  - B. Nonalcoholic.
  - C. Containing more than 8 percent alcohol
- VII. Bakery products other than those included under Types VIII or IX of this table:
  - A. Moist bakery products with surface containing free fat or oil
  - B. Moist bakery products with surface containing no free fat or oil
- VIII. Dry solids with the surface containing no free fat or oil (no end test required)
- IX. Dry solids with the surface containing free fat or oil

### Table 2—Condition of use

- A. High temperature heat-sterilized (e.g., over 212 deg.F).
- B. Boiling water sterilized.
- C. Hot filled or pasteurized above 150 deg.F
- D. Hot filled or pasteurized below 150 deg.F
- E. Room temperature filled and stored (no thermal treatment in the container)
- F. Refrigerated storage (no thermal treatment in the container)
- G. Frozen storage (no thermal treatment in the container)
- H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:
  - A. Aqueous or oil-in-water emulsion of high- or low-fat.
  - B. Aqueous, high- or low-tree oil or fat.
- I. Irradiation
- J. Cooking at temperatures exceeding 250 deg.F.



## FDA Letter of no objection for direct food contact with REItruder Technology N.O.L. #209

### FDA - Letter of No Objection

Reifenhäuser-CSC received confirmation of compliance of its process with EFSA criteria, as well as the N.O.L. #209.

The NOL #209 to Reifenhäuser-CSC was officially published on the FDA website:

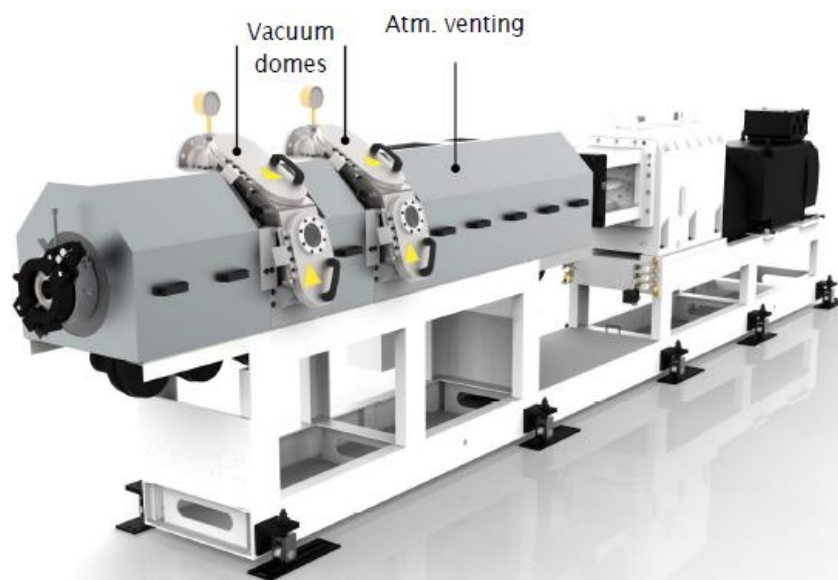
<https://www.accessdata.fda.gov/scripts/fdcc/?set=recycledplastics>

### Condition of use Table 2

- C. Hot filled or pasteurized above 150 deg. F (65,5°C).
- D. Hot filled or pasteurized below 150 deg. F (65,5°C).
- E. Room temperature filled and stored (no thermal treatment in the container).
- F. Refrigerated storage (no thermal treatment in the container).
- G. Frozen storage (no thermal treatment in the container).

<https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsOfUse/default.htm>

### REItruder for PET processing



Configuration RH-CSC PET extrusion process for FDA conform process

