## **No Objection Letter for Recycled Plastics #159**

Return to inventory: <u>Submissions on Post-Consumer Recycled (PCR) Plastics for Food-Contact Articles (https://wayback.archive-it.org/7993/20170607045144/http://www.accessdata.fda.gov/scripts/fdcc/?set=RecycledPlastics)</u>

## See also Recycled Plastics in Food Packaging

(/7993/20170607045144/https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/RecycledPlastics/ucm093435.htm)

May 25, 2012

William A. Olson, Ph.D. Center for Regulatory Services, Inc. 5200 Wolf Run Shoals Road Woodridge, VA 22192-5755 Email: <u>CFRSRV@aol.com (mailto:CFRSRV@aol.com)</u>

Re: Prenotification Consultation (PNC) 1122

Dear Dr. Olson:

This letter is in response to your submission, received on November 21, 2011 (PNC 1122), requesting on behalf of Utsumi Recycle Systems, Inc. (URS) (Osaka, Japan), a no objection letter confirming the capability of the proposed secondary recycling process (called super-clean) to produce post-consumer recycled polyethylene terephthalate (PCR-PET) pellets 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 C through H, as described in <u>Table 2</u> (/7993/20170607045144/https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/ucm109358.htm), which can be accessed from the Internet in the Food Ingredients and Packaging section under the Food topic of <u>www.fda.gov</u> (https://wayback.archive-it.org/7993/20170607045144/http://www.fda.gov/).

We have reviewed the proposed recycling process as well as the information obtained from surrogate testing which was submitted to demonstrate the capability of the proposed secondary recycling process in removing potential contaminants from PCR-PET. Based on our review of the testing data, we have determined that proposed 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 PET bottles previously used for beverage, alcoholic drinks and non-oil dressings only, 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 pellets 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 C through H, as described in **Table 2** 

(/7993/20170607045144/https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/ucm109358.htm), which can be accessed from the Internet in the Food Ingredients and Packaging section under the Food topic of <u>www.fda.gov</u> (https://wayback.archive-it.org/7993/20170607045144/http://www.fda.gov/). 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

More in <u>Recycled Plastics</u> <u>(/7993/20170607045144/https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/RecycledPlastics/default.htm)</u>