



No Objection Letter for Recycled Plastics #95

March 15, 2005

Ralph A. Simmons
Keller and Heckman LLP
1001 G Street, N.W.
Suite 500 West
Washington, DC 20001

Re: Prenotification Consultation (PNC) 258

Dear Mr. Simmons:

This responds to your inquiry of December 8, 2003 (referred as PNC 258 in our files), requesting on behalf of United Resource Recovery Company (URRC) an opinion letter from the FDA confirming that URRC's modified recycling process can produce post-consumer recycled polyethylene terephthalate (PCR-PET) of suitable purity for use in the manufacture of articles to contact all types of food listed in Table 1 of 21CFR§176.170 (c) under Conditions of Use C through G listed in Table 2 of 21CFR§176.170(c), provided that the PCR-PET complies with 21CFR§177.1630 and §177.1315.

We have reviewed URRC's modified recycling process and their previous recycling process submitted in 1998 (Letter No. 60), as well as the information obtained from surrogate testing, migration studies and migration modeling that was submitted to demonstrate the capability of the URRC's modified recycling process to remove potential contaminants from PCR-PET. Based on our review of these data, we have concluded that URRC's modified recycling process, as described in the December 8, 2003 submission, would be effective in reducing potential contaminants to levels that would result in dietary concentrations below 0.5 ppb, FDA's threshold of regulatory concern. Therefore, we have concluded that URRC's modified recycling process will produce PCR-PET that is of a purity suitable for use in the manufacture of articles in contact with all types of food listed in Table 1 of 21CFR§176.170 (c) under Conditions of Use C through G listed in Table 2 of 21CFR§176.170(c), provided that the PCR-PET complies with 21CFR§177.1630 and §177.1315.

If you have any further 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

<http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/UCM155210>