



October 17, 2017

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Email: [MMarrapese@wileyrein.com](mailto:MMarrapese@wileyrein.com)

Re: Prenotification Consultation PNC 2071

Dear Ms. Marrapese:

This letter is in response to your electronic submission (PNC 2071), received on August 23, 2017, requesting on behalf of KW Plastics (Troy, AL) a letter of no objection, confirming the capability of the KW Plastics secondary recycling process in producing post-consumer recycled high-density polyethylene (PCR-HDPE) that is suitable for food-contact. The PCR-HDPE material is intended for use at levels of up to 100% recycled content in the fabrication of articles that contact all food types at room temperature and below (*i.e.*, Conditions of Use E-G), as described in Tables 1 and 2, accessible 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 supporting information you submitted to demonstrate the capability of the proposed recycling process in removing potential contaminants from PCR-HDPE. Based on our review of the supporting information, we have determined that the proposed recycling process, as described in the subject submission, is effective in reducing potential contaminants from PCR-HDPE to levels that do not migrate to food at a dietary concentration of exceeding 0.5 ppb, FDA's threshold of regulatory concern. Therefore, the PCR-HDPE material may be used at levels of up to 100% recycled content in the fabrication of articles that contact all food types at room temperature and below, (*i.e.*, Conditions of Use E-G). This determination covers the use of PCR-HDPE derived from the feedstock that consists of clear food-grade HDPE containers (*e.g.*, those that hold milk, water and juice), complying with all applicable authorizations. The feedstock excludes industrial/chemical containers. If the proposed recycling process is modified, new supporting information may need to be re-evaluated.

The resultant PCR-HDPE must 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.

U.S. Food & Drug Administration  
Center for Food Safety & Applied Nutrition  
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Sincerely,

Vanee Komolprasert, Ph.D., P.E.  
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