



July 31, 2019

Martha E. Marrapese
Wiley & Rein LLP
1776 K Street, NW
Washington, DC 20006
mmarrapese@wileyrein.com

Re: Prenotification Consultation PNC 2364

Dear Ms. Marrapese:

This letter is in response to your electronic submission (PNC 2364), received on May 8, 2019, on behalf of Envision Plastics Inc. (Envision), requesting an Agency's no objection letter to confirm the capability of Envision's secondary recycling process to produce post-consumer recycled high-density polyethylene (PCR-HDPE) that is suitable for food-contact. The PCR-HDPE is intended for use at levels of up to 100% recycled content in manufacture of articles for use in contact with aqueous and/or acidic foods under Conditions of Use (COU) C through H, and with fatty foods and/or alcohol-containing foods under COU D through G, as described in Tables 1- 2, which can be accessed from the Internet in the Ingredients and Packaging section under the Food topic at www.fda.gov.

You provided for our review the description of the proposed secondary recycling process, which emphasizes strict source control, sortation of the feedstock, and decontamination of PCR-HDPE. The feedstock is composed of clear/opaque, food-grade HDPE milk, water and juice bottles only. The sourced HDPE material and the adjuvants present in HDPE comply with all applicable authorizations. Food-grade additives may be added to the PCR-HDPE during Envision's recycling process. The proposed recycling process includes modifications of the secondary recycling process, which is the subject of our review and two letters dated January 16, 1998, and June 1, 2017.

We reviewed the information you provided and determined that the proposed secondary recycling process as described in the subject submission is effective to produce PCR-HDPE material that is suitable for food-contact. Therefore, the PCR-HDPE material generated from the subject process may be used at levels of up to 100% recycled content in manufacture of articles for use in contact with aqueous and/or acidic foods under COU C through H, and with fatty foods and/or alcohol-containing foods under COU D through G.

The resultant 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

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Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740
www.fda.gov

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., P.E.
Consumer Safety Officer
Division of Food Contact Substances HFS-275
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition