June 13, 2019

Mitzi Ng Clark
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Re: Prenotification Consultation PNC 2334

Dear Ms. Clark:

This letter is in response to your electronic submission (PNC 2334) received on March 1, 2019, requesting on behalf of Global Holdings and Development LLC (GHD) an Agency's letter of no objection (LNO), confirming the capability of GHD's secondary recycling process to produce 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 for the following use conditions.

1. Articles (e.g., single layer trays, containers, and clamshells) intended to contact raw fruits and vegetables and shell eggs at room temperature and below, i.e., under Conditions of Use (COU) E through G, as described in Table 2.[1]
2. Non-food contact layer in multilayer packaging intended to be used at room temperature and below, i.e., under COU E through G, provided the PCR-PET is separated from food by a ≥ 25 µm (~0.001 in) thick layer of virgin PET complying with 21 CFR. 177.1630 (Polyethylene phthalate polymers) and all applicable food additive regulations.
3. Non-food contact layer in multilayer packaging intended to be used at higher temperatures, i.e., COU A through H, provided the PCR-PET is separated from food by a ≥ 50 µm (~0.002 in) thick layer of virgin PET complying with 21 CFR 177.1630 and all applicable food additive regulations. This includes use as a dual-ovenable container for cooking food at 150°C for 30 minutes.

You provided description of the proposed recycling process, which is a typical physical recycling process. The feedstock is comprised of only colorless PET water and soda bottles. The feedstock excludes colored bottles, sports drink bottles and similar items with multilayer structures that may contain non-PET material. Because of strict source control, there is little likelihood of unacceptable contaminant levels in the recycled PET material. Therefore, we concluded that the proposed recycling process as described in the subject submission may be used to produce PCR-

[1] Table 2 (Conditions of Use) is available at https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances

PET for use in manufacture of single layer articles used in direct contact only with raw fruits and vegetables and shell eggs at room temperature and below, provided that the feedstock comes from only colorless PET water and soda bottles complying with 21 CFR 177.1630, and other applicable authorizations.

You also intend to use PCR-PET as a non-food contact layer in multilayer packaging, provided that the food contact layer is made of virgin PET layer, complying with 21 CFR 177.1630, at a thickness of ≥ 25 µm for use at room temperature and below, and at ≥ 50 µm for use at higher temperatures, i.e., COU A-H, as described in Table 2,[1] including use as a dual-ovenable container for cooking food at 150°C for 30 min. Because these two use conditions follow the recommendations as described in Section VII (Use of an effective barrier) of Guidance for Industry,[2] we concluded that the PCR-PET material generated from the recycling process described in the subject submission may be used as a non-food contact layer in multilayer food packages under the intended use conditions 2 and 3, above.

The finished PCR-PET material should also comply with 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., P.E.
Consumer Safety Officer
Division of Food Contact Substances HFS-275
Office of Food Additive Safety
Center for Food Safety
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[2] Guidance is available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-use-recycled-plastics-food-packaging-chemistry-considerations