



April 8, 2021

Mitzi Ng Clark
Keller and Heckman LLP
Three Embarcadero Center
Suite 1420
San Francisco, CA 94111
clark@khlaw.com

RE: Prenotification Consultation (PNC) 002616

Dear Ms. Clark:

This letter is in response to your submission, PNC 2616, received on March 8, 2021, submitted on behalf of Fresh Pak Corporation (Fresh Pak) requesting the Agency's letter of no objection (LNO) confirming the capability of Fresh Pak's secondary recycling process for producing post-consumer recycled high density polyethylene (PCR-HDPE) material that is suitable for food-contact applications. The PCR-HDPE material is intended for use at levels of up to 100% as raw material for the fabrication of articles in contact with all food types under Conditions of Use (COU) A through H, as described in Tables 1 and 2, respectively (see Enclosure 1).

You provided a description of the proposed recycling process, which is a typical physical recycling process, involving washing, drying, and extrusion/film production. The feedstock is comprised of HDPE material that is collected from the sources specified in your submission and is certified as complying with 21 CFR 177.1520. The feedstock is inspected and will be rejected if it does not meet the quality specifications.

Based on our review of the proposed process and the intended use for the finished PCR-HDPE material, we determined that because of strict source control there is little likelihood of unacceptable contaminant levels in the PCR-HDPE material. Therefore, we concluded that the proposed recycling process as described in the subject submission may be used to produce PCR-HDPE material that is intended for use at levels of up to 100% as raw material for the fabrication of articles in contact with all food types under COU A through H, provided that the feedstock contains only HDPE collected from the sources specified in your submission, and the recycled materials comply with 21 CFR 177.1520 and other applicable authorizations applied to adjuvants present in the finished recycled material.

The finished recycled 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.

U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740
www.fda.gov

Sincerely,

Sean Fischer, Ph.D.
Consumer Safety Officer
Division of Food Contact Substances
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

Enclosure (1)

Enclosure 1

Definitions of Food Types and Conditions of Use for Food Contact Substances

These tables were created for easy reference for notifications relating to a food contact substance.

Table 1--Types of Raw and Processed Foods

- I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
- II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
- III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
- IV. Dairy products and modifications:
 - A. Water-in-oil emulsions, high- or low-fat.
 - B. Oil-in-water emulsions, high- or low-fat.
- V. Low-moisture fats and oil.
- VI. Beverages:
 - A. Containing up to 8 percent of alcohol.
 - B. Nonalcoholic.
 - C. Containing more than 8 percent alcohol.
- VII. Bakery products other than those included under Types VIII or IX of this table:
 - A. Moist bakery products with surface containing free fat or oil.
 - B. Moist bakery products with surface containing no free fat or oil.
- VIII. Dry solids with the surface containing no free fat or oil (no end test required).
- IX. Dry solids with the surface containing free fat or oil.

Table 2--Condition of use

- A. High temperature heat-sterilized (*e.g.*, over 212 deg. F).
- B. Boiling water sterilized.
- C. Hot filled or pasteurized above 150 deg. F.
- D. Hot filled or pasteurized below 150 deg. F.
- E. Room temperature filled and stored (no thermal treatment in the container).
- F. Refrigerated storage (no thermal treatment in the container).
- G. Frozen storage (no thermal treatment in the container).
- H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:
 1. Aqueous or oil-in-water emulsion of high- or low-fat.
 2. Aqueous, high- or low-free oil or fat.
- I. Irradiation.
- J. Cooking at temperatures exceeding 250 deg. F.