



October 27, 2021

Dr. Frank Welle
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RE: Prenotification Consultation (PNC) 002679

Dear Dr. Welle:

This letter is in response to PNC 2679, received on August 16, 2021, requesting on behalf of Craemer GmbH (Craemer) a letter of no objection (LNO) confirming the capability of Craemer'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 up to 100% recycled content in the manufacture of crates/pallets in contact with all food types under Conditions of Use (COU) E through G, as described in Tables 1 and 2, respectively (see Enclosure 1).

We have reviewed the proposed recycling process and the provided supporting information, and we have determined that the subject recycling process is expected to produce PCR-HDPE of a suitable purity for the intended use specified above, provided that the feedstock is sourced from HDPE materials compliant with 21 CFR 177.1520 that were previously used for food-contact applications.

The finished articles should comply with all 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.

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)

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

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.