



August 29, 2019

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Re: Prenotification Consultation PNC 2372

Dear Dr. Welle:

This letter is in response to your submission (PNC 2372), received on May 23, 2019, requesting on behalf of EREMA Group GmbH (EREMA) a letter of no objection, confirming the capability of EREMA's secondary recycling process (a so-called as "super clean" process) in producing post-consumer recycled high-density polyethylene (PCR-HDPE) material that is suitable for food-contact. The PCR-HDPE material is intended for use at levels of up to 100% recycled content in manufacture of milk and juice bottles, meat trays, disposable tableware and cutlery under Conditions of Use (COU) E - F, as described in Table 2, which can be accessed from the Internet in the Packaging and Food Contact Substances section under the Food topic at www.fda.gov.

We reviewed the proposed recycling process as well as the results obtained from surrogate testing and other supporting information, which were submitted to demonstrate the capability of the proposed recycling process in removing potential contaminants from PCR-HDPE. Based on our review of these data, we determined that the proposed recycling process, as described in the subject submission, is effective in reducing potential contaminants from PCR-HDPE material to levels that do not migrate to food at a dietary concentration exceeding 0.5 ppb, FDA's threshold of regulatory concern. Therefore, we concluded that the finished PCR-HDPE material may be used at levels of up to 100% recycled content in manufacture of milk and juice bottles, meat trays, disposable tableware and cutlery under COU E - F, provided the feedstock consists of food-grade HDPE containers (*i.e.*, previously used for holding milk and juices only), and the PCR-HDPE complies with 21 CFR 177.1520 and other applicable authorizations. If the proposed recycling process is modified, new data may need to be re-evaluated.

The finished PCR-HDPE material 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.

U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
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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
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition