May 05, 2020

Celina Martinez
Arpema Plásticos SA de CV
Rafael Navas Garcia No. 5 Lote 7
Colonia La Bomba
Lerma, Estado de Mexico
C.P. 52004
cmartinez@arpema.com.mx

Re: Pre-notification Consultation (PNC) No. 2444

Dear Ms. Martinez:

This letter is in response to your PNC 2444, received December 3, 2019, and amended on April 14, 2020, and April 24, 2020, submitted on behalf of Arpema Plásticos SA de CV (Arpema), requesting use of Arpema's secondary recycling process to produce post-consumer recycled (PCR) linear low-density polyethylene (LLDPE), low density polyethylene (LDPE), high-density polyethylene (HDPE) and polypropylene (PP) for food contact. The PCR-LLDPE, LDPE, HDPE, or PP is intended for use at a level of up to 100% recycled content in the manufacture of articles for food-contact at room and refrigerated temperatures, i.e., Conditions of Use (COU) E through F, as described in FDA's Food Types & Conditions of Use for Food Contact Substances, Table 2.[1]

You provided for our review the description of Arpema's proposed recycling process, which is a conventional secondary recycling process and involves sorting, washing, drying, and extrusion. The feedstock is sourced from bags, labels and flexible packaging used with foods, collected from a domestic supplier. You also provided the results of end tests for PCR-LDPE, LDPE, HDPE, and PP samples, suggesting the results meet the specifications and limitations as described in 21 CFR 177.1520[2] (Olefin polymers).

Based on the information provided, we determined that the proposed secondary recycling process described in the subject submission is similar to the process we have reviewed multiples times to produce recycled plastic for use in contact with fresh produce and shell eggs, under COU E - F. Therefore, the proposed recycling process described in this submission may be used to produce PCR- LLDPE, LDPE, HDPE, or PP for use at a level of up to 100% recycled content in the manufacture of articles to contact fresh produce and shell eggs for short contact time at low temperatures, under COU E - F, provided the feedstock comes from food grade materials,

[1] Table 2: https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances
[2] 21 CFR 177.1520 (Olefin polymers): https://www.ecfr.gov/cgi-bin/text-idx?SID=6ba0a6620c258cee683e814692be783d&mc=true&node=pt21.3.177&rgn=div5#se21.3.177_11520

excluding agricultural plastic material, and material sourced from chemical or industrial containers, and the finished recycled material complies with all applicable authorizations.

The recycled material should comply with all applicable authorizations, including 21 CFR 174.5 General provisions applicable to indirect food additives.[3] 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 -S

Digitally signed by Vanee Komolprasert -S
Date: 2020.09.21 13:37:15 -04'00'

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

[3] 21 CFR 174.5: https://www.ecfr.gov/cgi-bin/text-idx?SID=feeb4775aaf3def5f09163eac30176f0&mc=true&node=se21.3.174_15&rgn=div8