



November 13, 2019

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Re: Prenotification Consultation PNC 2407

Dear Dr. Welle:

This letter is in response to your submission (PNC 2407), received on September 3, 2019, requesting on behalf of SML Maschinengesellschaft mbH (SML) a letter of no objection, confirming the capability of SML's secondary recycling process (a so-called as "super clean" process) in producing 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 in manufacture of PET containers for all food types under Conditions of Use (COU) C through G, 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 migration modeling, which were submitted to demonstrate the capability of the proposed recycling process in removing potential contaminants from PCR-PET. Based on our review of these data, we determined that the proposed recycling process, as described in the subject submission, is effective in removing potential contaminants from PCR-PET 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-PET material may be used at levels of up to 100% recycled content in manufacture of PET containers for all food types under COU C-G, provided the feedstock comes from food-grade PET containers and the PCR-PET complies with 21 CFR 177.1630 and other applicable authorizations. If the proposed recycling process is modified, new data may need to be re-evaluated.

The finished PCR-PET 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.

If you have any further questions concerning this matter, please do not hesitate to contact us.

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Sincerely,

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