



Expert Opinion Document

on the

Food regulatory status of Sky Light Recycling
Process in relation to the German BfR and ILSI
guidelines for the safe recycling of post-consumer
PET into new food contact applications

Client: SKY-LIGHT A/S
Tømmervej 36
DK-6800 Varde
Denmark

Order No.: PA/4453/05

Date of order: 06.02.2008

The results relate to the investigated samples only.



DAP-PL-3909.00

1 Objective

Sky Light PET has installed EREMA multipurpose reactor for super-cleaning of post-consumer recycled PET (PCR PET). The output material is intended for being used for production of PET flat sheets for direct contact with different kinds of foodstuffs.

The intention of this document is to respond to Sky Light's request whether their recycling process can be considered as safe for this purpose and, in particular, whether their process would comply with the German BfR^[1] and the European ILSI^[2] guidelines for the use of mechanically recycled PET for manufacture of new food contact articles.

2 Available information about the Sky Light Recycling Process

To enable us to evaluate the recycling process, the customer provided the following documents:

- A description of the quality assurance system and the process parameters of the applied recycling process
- FDA Petitions of EREMA GmbH resulting in the FDA no objection letters of 17.11.2000 and amendments^[3]

In addition the customer had sent us 40 retain samples from the Sky Light recycling process for conducting an analytical screening for recycling related potential migrants. The results of this study have been reported^[4] and are suitable to assist our evaluation of the PCR PET product from this technology.

3 Requirements from the German BfR guidelines

The German BfR and the European ILSI Guidelines do not exclude mechanically recycled PET (R PET) from being used for new food contact applications but require that R PET must meet the same food regulatory requirements as virgin PET.

^[1]Bundesinstitut für Risikobewertung (BfR) as of 2000-10-01:
http://www.bfr.bund.de/cm/234/use_of_mechanically_recycled_plastic_made_from_polyethylene_terephthalate__pet__for_the_manufacture_of_articles_coming_into_contact_with_food.pdf

^[2]Recycling of plastics for food contact use. Guidelines prepared under the responsibility of the International Life Sciences Institute (ILSI) European Packaging Material Task Force. Brussels, 1998.

^[3]Fraunhofer IVV on behalf of EREMA, Recycled Poly(ethylene terephthalate) for direct food contact application, August 3, 1999.

^[4]Fraunhofer IVV test report PA/4072/08: " Analytical Screening of "post-consumer" PET recyclates for direct food contact applications ", February 29, 2008

The key elements of the BfR guidelines are:

- I. Control of material recovery logistics. In particular, it is requested that only food grade PET quality is used as a raw material which should be of a purity of at least 99% with respect to other PET qualities and materials.
- II. Testing and evaluation of the efficiency of cleaning steps in the recycling process. In particular, this should be done by means of a so-called challenge test using model contaminants at appropriate initial concentrations, and be based on the assessment criterion saying that the maximum migration of the model contaminants should not exceed 10 ppb ($\mu\text{g kg}^{-1}$) in the food.
- III. Analytical quality assurance. In particular, it is required to establish an analytical control system of the recycle production to ensure that any significant deviations of the product quality can be quickly recognised and corresponding measures be taken.

The European ILSI guidelines are very similar to the BfR guidelines, except point III. which is lacking in the ILSI guidelines.

4 Evaluation of Sky Light Recycling Process

From the above mentioned available documentation the applied recycling process for post-consumer PET bottles consists of the following decontamination and control steps:

- Input material is conventional recycled PET (R PET) flakes from post-consumer PET bottles. The conventional recycling process uses state-of-the-art recycling technology, which includes sorting, grinding and washing steps. The washing line uses hot-washing steps with surfactants.
- Further deep-cleansing of the washed flakes using EREMA multi-purpose reactor. The applied technology is approved by the US Food and Drug Administration (FDA)^[5] as well as by several other countries.
- Quality control steps are foreseen at the washed flakes and at the final product. Sky Light has installed a process control system, which warns the plant operator if the parameters set in the FDA petition running out of their specifications. All data related to production is being stored on the computer and automatically transferred to Sky Light's network server as documentation. The server has daily automatic backup as safety. Sky Light is certified according to ISO 9001 and ISO 14001. Gas chromatographic quality checks are foreseen in regular terms in order to guarantee the decontamination efficiency of the applied recycling process.
- The cleaning efficiency of the recycling process was determined by a so-called challenge test. Depending on the volatility of the surrogates, cleaning efficiencies of 77% up to 97% are established at input concentrations up to 500 ppm after washing. In the same document, migration data were provided with test bottles from contaminated and recycled PET. As a result, the migration of all surrogates was found to be below 10 ppb in 3% acetic acid, 10% ethanol and 95% ethanol after storage of the filled bottles for

^[5]FDA no objection letter CTS 66652 of November 17, 2000, and amendments

10 d weeks at 40 °C. In amendments of the FDA petition also hot-fill conditions are applied.

- In addition, the results of our analytical screening study^[4] to monitor representative samples from the Sky Light recycling process for migration-relevant compounds has demonstrated that the migration potential is not significantly higher than in virgin PET materials themselves.

5 Conclusions

Provided that the feedstock control assures 99% food grade PET input, the composition of the Sky Light recycling process product will be in compliance with EU Plastics Directive 2002/72/EC. In this context, we would like to emphasize that nearly all non-food bottles are manufactured from food grade PET material, too. From migration-theoretical considerations we come to the conclusion that the Sky light recycling process product will also meet the overall and specific migration limits for the applied monomers as required by EU Plastics Directive 2002/72/EC.

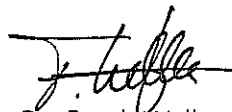
Taking account of the above discussion and considerations, we conclude that the Sky Light recycling process is capable to produce a R PET product which meets the requirements of the European ILSI and the German BfR guidelines and is in compliance with §§ 30 and 31(1) of the German Act on Foods, Feeds and Commodities (LFGB) when this product is used for the manufacture of PCR PET containing sheets and containers for direct contact with water and oily foodstuff.

Finally we conclude also that the requirements of Article 3 of EC Regulation 1935/2004 are met, being aware that a European Recycling Directive is currently in preparation.

Fraunhofer-Institut
für Verfahrenstechnik und Verpackung
Freising, March 18, 2008



Dr. Roland Franz
(Head of Dep. Product Safety and Analysis)



Dr. Frank Welle
(Scientist in Charge)