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Abstract

This scientific opinion of the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel) deals with the safety evaluation of the recycling process EstPak Plastik (EU register No RECYC150), which is based on the Starlinger Decon technology. The decontamination efficiency of the process was demonstrated by a challenge test. The input of this process is hot caustic washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, mainly bottles, containing no more than 5% of PET from non-food consumer applications. In this technology, washed and dried PET flakes are preheated before being submitted to solid-state polycondensation (SSP) in a continuous reactor (one single reactor or several reactors in parallel) at high temperature under vacuum and gas flow. Having examined the challenge test provided, the Panel concluded that the preheating (step 2) and the decontamination in the continuous SSP reactor (step 3) are the critical steps that determine the decontamination efficiency of the process. The operating parameters that control the performance of the process are well defined and are temperature, pressure, residence time and gas flow for steps 2 and 3. Under these conditions, it was demonstrated that the recycling process under evaluation, using the Starlinger Decon technology, is able to ensure that the level of migration of potential unknown contaminants into food is below a conservatively modelled migration of 0.1 μg/kg food. Therefore, the Panel concluded that the recycled PET obtained from this process intended to be used up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs for long-term storage at room temperature, with or without hotfill, is not considered of safety concern. Trays made of this PET are not intended to be used, and should not be used, in microwave and conventional ovens.

Keywords: Starlinger Decon technology, EstPak Plastik, food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Recycled plastic materials and articles shall only be placed on the market if they contain recycled plastic obtained from an authorised recycling process. Before a recycling process is authorised, EFSA's opinion on its safety is required. This procedure has been established in Article 5 of the Regulation (EC) No 282/2008[1] of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of Regulation (EC) No 1935/2004[2] of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the Member States Competent Authorities which transmit the applications to European Food Safety Authority (EFSA) for evaluation.

In this case, EFSA received, from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, an application for evaluation of the recycling process EstPak Plastik, EU register No RECYC150. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2017-00616. The dossier was submitted on behalf of EstPak Plastik A.S., Estonia.

According to Article 5 of Regulation (EC) No 282/2008 of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods, EFSA is required to carry out risk assessments on the risks originating from the migration of substances from recycled food contact plastic materials and articles into food and deliver a scientific opinion on the recycling process examined.

According to Article 4 of Regulation (EC) No 282/2008, EFSA will evaluate whether it has been demonstrated in a challenge test, or by other appropriate scientific evidence, that the recycling process EstPak Plastik is able to reduce any contamination of the plastic input to a concentration that does not pose a risk to human health. The poly(ethylene terephthalate) (PET) materials and articles used as input of the process as well as the conditions of use of the recycled PET make part of this evaluation.

2. Data and methodologies

2.1. Data

The applicant has submitted a dossier following the 'EFSA guidelines for the submission of an application for the safety evaluation of a recycling process to produce recycled plastics intended to be used for the manufacture of materials and articles in contact with food, prior to its authorization' (EFSA, 2008). Applications shall be submitted in accordance with Article 5 of the Regulation (EC) No 282/2008.

The following information on the recycling process was provided by the applicant and used for the evaluation:

- General information:
  - general description
  - existing authorisations
- Specific information:
  - recycling process
  - characterisation of the input
  - determination of the decontamination efficiency of the recycling process
  - characterisation of the recycled plastic
  - intended application in contact with food
  - compliance with the relevant provisions on food contact materials and articles
  - process analysis and evaluation
  - operating parameters.

[1] Regulation (EC) No 282/2008 of the European parliament and of the council of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006. OJ L 86, 28.3.2008, p. 9–18.

[2] Regulation (EC) No 1935/2004 of the European parliament and of the council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4–17.

2.2. Methodologies

The principles followed for the evaluation are described here. The risks associated to the use of recycled plastic materials and articles in contact with food come from the possible migration of chemicals into the food in amounts that would endanger human health. The quality of the input, the efficiency of the recycling process to remove contaminants, as well as the intended use of the recycled plastic, are crucial points for the risk assessment (see guidelines on recycling plastics; EFSA, 2008).

The criteria for the safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for the manufacture of materials and articles in contact with food are described in the scientific opinion developed by the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (EFSA CEF Panel, 2011). The principle of the evaluation is to apply the decontamination efficiency of a recycling technology or process, obtained from a challenge test with surrogate contaminants, to a reference contamination level for post-consumer PET, conservatively set at 3 mg/kg PET for contaminants resulting from possible misuse. The resulting residual concentration of each surrogate contaminant in recycled PET (C_{res}) is compared with a modelled concentration of the surrogate contaminants in PET (C_{mod}). This C_{mod} is calculated using generally recognised conservative migration models so that the related migration does not give rise to a dietary exposure exceeding 0.0025 μg/kg bodyweight (bw) per day (i.e. the human exposure threshold value for chemicals with structural alerts for genotoxicity), below which the risk to human health would be negligible. If the C_{res} is not higher than the C_{mod}, the recycled PET manufactured by such recycling process is not considered of safety concern for the defined conditions of use (EFSA CEF Panel, 2011).

The assessment was conducted in line with the principles described in the EFSA Guidance on transparency in the scientific aspects of risk assessment (EFSA, 2009) and considering the relevant existing guidance from the EFSA Scientific Committee.

3. Assessment

3.1. General information

According to the applicant, the recycling process EstPak Plastik is intended to recycle food grade PET containers to produce recycled PET flakes using the Starlinger Decon technology. The recycled flakes are intended to be used up to 100% for the manufacture of recycled materials and articles. These final materials and articles are intended to be used in direct contact with all kinds of foodstuffs for long-term storage at room temperature, with or without hotfill.

3.2. Description of the process

3.2.1. General description

The recycling process EstPak Plastik produces recycled PET flakes from PET containers, mainly bottles, coming from post-consumer collection systems (kerbside and deposit systems). The recycling process comprises of the three steps below. The first step may be performed by a third party or by the applicant.

<u>Input</u>

- In step 1, post-consumer PET containers, mainly bottles and trays, are processed into washed and dried flakes, which are used as input of the process.

<u>Decontamination and production of recycled PET material</u>

- In step 2, the flakes are pre-heated in one or several batch reactors with a flow of hot gas.
- In step 3, the preheated flakes are submitted to solid-state polycondensation (SSP) in a continuous reactor (one single reactor or several reactors) at high temperature using a combination of vacuum and gas flow.

The operating conditions of the process have been provided to EFSA.

Recycled flakes, the final product of the process, are checked against technical requirements on intrinsic viscosity, colour, black spots, etc. Recycled flakes are intended to be converted by the applicant or by other companies into recycled articles used for hotfill and/or long-term storage at room temperature, such as bottles for mineral water, soft drinks and beer. The recycled flakes may also be used for sheets which are thermoformed to make food trays. Trays made of this PET are not intended to be used in microwave and conventional ovens.

3.2.2. Characterisation of the input

According to the applicant, the input material for the recycling process EstPak Plastik is hot caustic washed and dried flakes obtained from PET containers, mainly bottles, previously used for food packaging, from post-consumer collection systems (kerbside and deposit systems). A small fraction may originate from non-food applications. On the basis of market share data, the applicant estimated that this fraction is below 5%.

Technical data for the washed and dried flakes are provided such as information on residual content of moisture, poly(vinyl chloride) (PVC), glue, wood/paper, metals, other plastics and physical properties (see Appendix A).

3.3. Starlinger Decon technology

3.3.1. Description of the main steps

To decontaminate post-consumer PET, the recycling process EstPak Plastik uses the Starlinger Decon technology as described below and for which the general scheme, provided by the applicant, is reported in Figure 1. In step 1, not reported in the scheme, post-consumer PET containers, mainly bottles, are processed into hot caustic washed and dried flakes from third parties or by the applicant.

- Preheating (step 2): The flakes are preheated in one or several batch reactors with a flow of hot gas up to the temperature of the next step, the main SSP reactors.
- Solid-state polycondensation (SSP) (step 3): The flakes from the batch preheater are fed into the SSP reactor. More than one SSP reactor can be run in parallel continuously under high temperature and using a combination of gas flow and vacuum for a predefined residence time. In particular, the SSP reactors remain under vacuum with values varying depending on the feeding mode, while gas flow is applied periodically to support the removal of the contaminants from the flakes. This step increases the intrinsic viscosity of the material and further decontaminates the PET flakes.

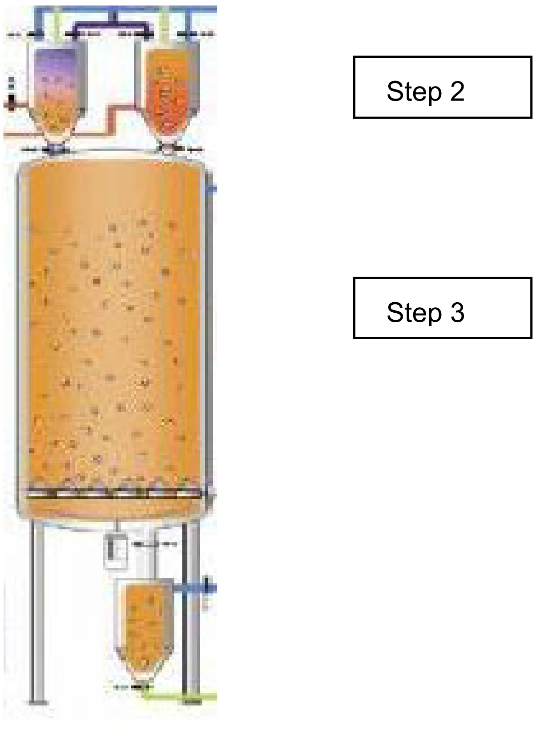

Figure 1: Starlinger Decon technology

The process is operated under defined operating parameters of temperature, pressure, gas flow and residence time.[3]

3.3.2. Decontamination efficiency of the recycling process

To demonstrate the decontamination efficiency of the recycling process EstPak Plastik, a challenge test on the Starlinger Decon technology was submitted to EFSA.

PET flakes were contaminated with toluene, chlorobenzene, phenylcyclohexane, chloroform, methyl salicylate, benzophenone and methylstearate, selected as surrogate contaminants. The surrogates were chosen in agreement with EFSA guidelines and in accordance with the recommendations of the US Food and Drug Administration. The surrogates include different molecular weights and polarities to cover possible chemical classes of contaminants of concern and were demonstrated to be suitable to monitor the behaviour of PET during recycling (EFSA, 2008).

For the preparation of the contaminated PET flakes, conventionally recycled[4] post-consumer PET flakes were soaked in a mixture of surrogates and stored for 7 days at 50°C with daily agitation. The contaminated PET flakes were washed with hot water and detergents then air dried. The concentrations of surrogates in this material were determined.

The Starlinger Decon technology was challenged at a pilot plant. The preheater reactor was filled with washed and dried contaminated flakes only (step 2). Preheated flakes were then fed into the SSP reactor (step 3). The flakes were analysed after each step for their residual concentrations of the applied surrogates. In both batch and continuous modes of operation, the surrogates diffuse through the flakes to the surface and they are constantly eliminated by the gas flow applied. Therefore, in this case, continuous working processes will result in equivalent cleaning efficiencies as batch processes, as long as the same temperature, pressure conditions, gas flow and residence time are applied.

The decontamination efficiency of the process was calculated taking into account the amount of the surrogates detected in washed contaminated flakes before the preheating (before step 2) and after SSP (step 3). The results are summarised below in Table 1.

Table 1: Efficiency of the decontamination of the Starlinger Decon technology in the challenge test

Surrogates	Concentration of surrogates before step 2 (mg/kg PET)	Concentration of surrogates after step 3 (mg/kg PET)	Decontamination efficiency (%)
Toluene	206.9	1.1	99.5
Chlorobenzene	393.1	2.1	99.5
Chloroform	120.2	3.4	97.2
Methyl salicylate	369	4.1	98.9
Phenylcyclohexane	404	6.9	98.3
Benzophenone	594.4	22.1	96.3
Methyl stearate	743.4	27.1	96.4

PET: poly(ethylene terephthalate).

As shown in Table 1, the decontamination efficiency ranged from 96.3% for benzophenone to 99.5% for toluene and chlorobenzene.

3.4. Discussion

Considering the high temperatures used during the process, the possibility of contamination by microorganisms can be discounted. Therefore, this evaluation focuses on the chemical safety of the final product.

Technical data such as information on residual content of PVC, glue, polyolefins, cellulose, metals, other plastics and physical properties are provided for the input materials (washed and dried flakes (step 1)), for the submitted recycling process. The input materials are produced from PET containers, mainly bottles, previously used for food packaging collected through post-consumer collection systems. However, a small fraction of the input may originate from non-food applications such as soap bottles, mouth wash bottles, kitchen hygiene bottles. According to the applicant, the amount of this non-food

[3] In accordance with Art. 9 and 20 of Regulation (EC) No 1935/2004 the parameters were provided to EFSA and made available to the applicant, the Member States and European Commission (see Appendix C).
[4] Conventional recycling includes commonly sorting, grinding, washing and drying steps and produces washed and dried flakes.

container fraction depends on the collection system and, on the basis of market share data it is below 5%, as recommended by the EFSA CEF Panel in its 'Scientific opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food' (EFSA CEF Panel, 2011).

The process is well described. The washing and drying of flakes from collected PET containers (step 1) is conducted in different ways depending on the plant but, according to the applicant, this step is under control. The following steps are those of the Starlinger Decon technology used to recycle the PET flakes into decontaminated PET flakes: batch preheating (step 2) and continuous SSP (step 3). The operating parameters of temperature, residence time, pressure and gas flow for both steps have been provided to EFSA.

A challenge test was conducted at a pilot plant scale on process steps 2 and 3 (preheating and SSP reactor) to measure the decontamination efficiency. The Panel considered that the challenge test was performed correctly according to the recommendations in the EFSA guidelines (EFSA, 2008) and that the steps 2 and 3 are the critical steps for the decontamination efficiency of the process. Consequently, temperature, residence time, pressure and gas flow parameters of steps 2 and 3 of the process should be controlled to guarantee the performance of the decontamination. These parameters have been provided to EFSA.

The decontamination efficiencies obtained from for each surrogate contaminant from the challenge test performed on steps 2 and 3, ranging from 96.3% to 99.5%, have been used to calculate the residual concentrations of potential unknown contaminants in PET (C_{res}) according to the evaluation procedure described in the 'Scientific opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET' (EFSA CEF Panel, 2011; Appendix B). By applying the decontamination efficiency percentage to the reference contamination level of 3 mg/kg PET, the C_{res} for the different surrogates is obtained (Table 2).

According to the evaluation principles (EFSA CEF Panel, 2011), the C_{res} value should not be higher than a modelled concentration in PET (C_{mod}) corresponding to a migration, after 1 year at 25°C, which cannot give rise to a dietary exposure exceeding 0.0025 μg/kg bw per day, the exposure threshold below which the risk to human health would be negligible.[5] Because the recycled PET is intended for general use for the manufacturing of articles containing up to 100% recycled PET, the most conservative default scenario for infants has been applied. Therefore, the migration of 0.1 μg/kg into food has been used to calculate C_{mod} (EFSA CEF Panel, 2011). The results of these calculations are shown in Table 2. The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

Table 2: Decontamination efficiency from challenge test, residual concentration of surrogate contaminants in recycled PET (C_{res}) and calculated concentration of surrogate contaminants in PET (C_{mod}) corresponding to a modelled migration of 0.1 μg/kg food after 1 year at 25°C

Surrogates	Decontamination efficiency (%)	C_{res} (mg/kg PET)	C_{mod} (mg/kg PET)
Toluene	99.5	0.02	0.09
Chlorobenzene	99.5	0.02	0.10
Chloroform	97.2	0.08	0.10
Methyl salicylate	98.9	0.03	0.13
Phenylcyclohexane	98.3	0.05	0.14
Benzophenone	96.3	0.11	0.16
Methyl stearate	96.4	0.11	0.32

PET: poly(ethylene terephthalate).

The residual concentrations of all surrogates in PET after decontamination (C_{res}) are lower than the corresponding modelled concentrations in PET (C_{mod}). Therefore, the Panel considered that the recycling process under evaluation using the Starlinger Decon technology is able to ensure that the level of migration of unknown contaminants from the recycled PET into food is below the conservatively modelled migration of 0.1 μg/kg food at which the risk to human health would be negligible.

[5] 0.0025 μg/kg bw per day is the human exposure threshold value for chemicals with structural alerts raising concern for potential genotoxicity, below which the risk to human health would be negligible (EFSA CEF Panel, 2011).

4. Conclusions

The Panel considered that the process EstPak Plastik is well characterised and the main steps used to recycle the PET flakes into decontaminated PET flakes have been identified. Having examined the challenge test provided, the Panel concluded that the preheating (step 2) and the decontamination in the continuous SSP reactor (step 3) are the critical steps for the decontamination efficiency of the process. The operating parameters to control its performance are temperature, residence time, pressure and gas flow. The Panel considered that the recycling process EstPak Plastik is able to reduce any foreseeable accidental contamination of the post-consumer food contact PET to a concentration that does not give rise to concern for a risk to human health if:

i) it is operated under conditions that are at least as severe as those obtained from the challenge test used to measure the decontamination efficiency of the process;
ii) the input of the process is washed and dried post-consumer PET flakes originating from materials and articles that have been manufactured in accordance with the EU legislation on food contact materials containing no more than 5% of PET from non-food consumer applications.

Therefore, the recycled PET obtained from the process EstPak Plastik intended to be used up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs for long-term storage at room temperature, with or without hotfill, is not considered of safety concern. Trays made of this recycled PET are not intended to be used, and should not be used, in microwave and conventional ovens.

5. Recommendations

The Panel recommended periodic verification that the input to be recycled originates from materials and articles that have been manufactured in accordance with the EU legislation on food contact materials and that the proportion of PET from non-food consumer applications is no more than 5%. This adheres to good manufacturing practice and Regulation (EC) No 282/2008, Art. 4b. Critical steps in recycling should be monitored and kept under control. In addition, supporting documentation should be available on how it is ensured that the critical steps are operated under conditions at least as severe as those in the challenge test used to measure the decontamination efficiency of the process.

Documentation provided to EFSA

1) Dossier "EstPak Plastik". July 2017. Submitted on behalf of EstPak Plastik A. S., Estonia.

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Abbreviations

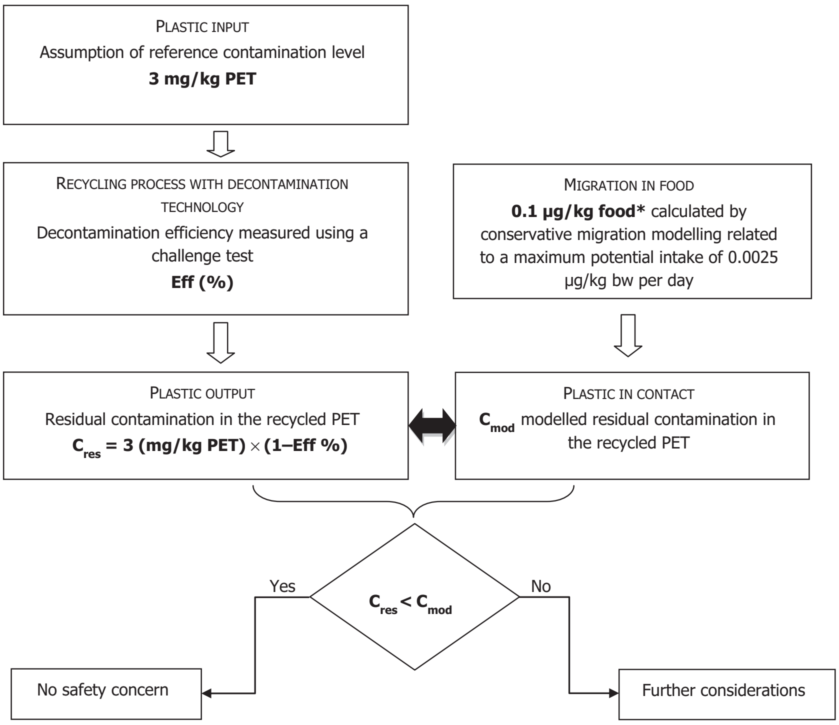
bw	body weight
CEF Panel	EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
C_{mod}	modelled concentration in PET
C_{res}	residual concentration in PET
FDA	US Food and Drug Administration
iV	intrinsic viscosity
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)
SSP	solid-state polycondensation

Appendix A – Technical data of the washed flakes as provided by the applicant

Parameter	Value
Moisture	< 2%
PVC content	< 100 ppm
Other plastics than PET (multilayer (polyamide))	< 750 ppm
Flakes with glue content	< 4,000 ppm
Metal content (aluminium, ferrous, others)	< 500 ppm
Wood, paper content	< 100 ppm
iV[(a)]	0.65–1.2 dL/g
Total contamination other than water	< 2,000 ppm
Bulk density	250–750 kg/m^3
Flakes size	1–15 mm
Flakes thickness	50–1,200 μm

PVC: poly(vinyl chloride); PET: poly(ethylene terephthalate); iV: intrinsic viscosity.
(a): Value refers to food grade PET flakes, after the recycling process.

Appendix B – Relationship between the key parameters for the evaluation scheme (EFSA CEF Panel, 2011)



*Default scenario (infant). For adults and toddlers, the migration criterion will be 0.75 and 0.15 µg/kg food, respectively.

Appendix C – Table of Operational Parameters (Confidential Information)