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## Safety assessment of the process Kalex Films, based on Starlinger deCON technology, used to recycle post-consumer PET into food contact materials

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### Abstract

The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) assessed the safety of the recycling process Kalex Films (EU register number RECYC244), which uses the Starlinger deCON technology. The input material is hot washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, e.g. bottles, including no more than 5% PET from non-food consumer applications. The flakes are preheated before being submitted to solid-state polycondensation (SSP) in a [REDACTED] reactor at high temperature under vacuum and [REDACTED]. Having examined the challenge test provided, the Panel concluded that the preheating (step 2) and the decontamination in the SSP reactor (step 3) are critical in determining the decontamination efficiency of the process. The operating parameters to control the performance of these critical steps are temperature, pressure, residence time and [REDACTED]. It was demonstrated that this recycling process is able to ensure a level of migration of potential unknown contaminants into food below the conservatively modelled migration of 0.1 µg/kg food. Therefore, the Panel concluded that the recycled PET obtained from this process is not considered to be of safety concern, when used at 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. The final articles made of this recycled PET are not intended to be used in microwave or conventional ovens and such uses are not covered by this evaluation.

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**Keywords:** Starlinger deCON, Kalex Films Ltd., food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

**Requestor:** Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany

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† Deceased.

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## 1. Introduction

### 1.1. Background

Recycled plastic materials and articles shall only be placed on the market if the recycled plastic is from an authorised recycling process. Before a recycling process is authorised, the European Food Safety Authority (EFSA)'s opinion on its safety is required. This procedure has been established in Article 5 of Regulation (EC) No 282/2008<sup>1</sup> 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<sup>2</sup> 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 the European Food Safety Authority (EFSA) for evaluation.

In this case, EFSA received an application, from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, for evaluation of the recycling process Kalex Films, European Union (EU) register No RECYC244. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2021-00302. The dossier was submitted on behalf of Kalex Films Ltd., United Kingdom (see [Documentation provided to EFSA](#)).

### 1.2. Terms of Reference

The Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, requested the safety evaluation of the recycling process Kalex Films, in compliance with Article 5 of Regulation (EC) No 282/2008.

### 1.3. Interpretation of the Terms of Reference

According to Article 5 of Regulation (EC) No 282/2008 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 is able to reduce the 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 are part of this evaluation.

## 2. Data and methodologies

### 2.1. Data

The applicant has submitted a confidential and a non-confidential version of 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 authorisation' (EFSA, 2008) and the 'Administrative guidance for the preparation of applications on recycling processes to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food' (EFSA, 2021). In accordance with Art. 38 of the Commission Regulation (EC) No 178/2002<sup>3</sup> and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation and of

<sup>1</sup> Commission 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.

<sup>2</sup> Commission 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.

<sup>3</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

the Decision of the EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,<sup>4</sup> the non-confidential version of the dossier is published on Open.EFSA.<sup>5</sup>

Additional information was sought from the applicant during the assessment process in response to a request from EFSA sent on 31 January 2022 and was subsequently provided (see '[Documentation provided to EFSA](#)').

According to Art. 32c(2) of Regulation (EC) No 178/2002, the non-confidential version of the application underwent a public consultation from 18 March to 8 April 2022, for which no comments were received.

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.

## 2.2. Methodologies

The risks associated with 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 (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  $\mu\text{g}/\text{kg}$  body weight (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 to be 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 guidance from the EFSA Scientific Committee.

<sup>4</sup> Decision available at <https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements>

<sup>5</sup> The non-confidential version of the dossier, following EFSA's assessment of the applicant's confidentiality requests, is published on Open.EFSA and is available at the following link: <https://open.efsa.europa.eu/dossier/FCM-2021-0244>

### 3. Assessment

#### 3.1. General information<sup>6</sup>

According to the applicant, the recycling process Kalex Films is intended to recycle food grade PET containers using the Starlinger deCON technology. The recycled PET is intended to be used at up to 100% for the manufacture of materials and articles for direct contact with all kinds of foodstuffs for long-term storage at room temperature, with or without hotfill, 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. The final articles are not intended to be used in microwave or conventional ovens.

#### 3.2. Description of the process

##### 3.2.1. General description<sup>6</sup>

The recycling process Kalex Films produces recycled PET flakes from PET containers from post-consumer collection systems (kerbside, deposit systems and mixed waste collection).

The recycling process comprises the three steps below.

##### Input

- In step 1, the post-consumer PET containers are processed into washed and dried flakes. This step may be performed by a third party or by the applicant.

##### Decontamination and production of recycled PET material

- In step 2, the flakes are preheated in batch reactors [REDACTED]
- In step 3, the preheated flakes are submitted to solid-state polycondensation (SSP) in a [REDACTED] reactor at high temperature using a combination of vacuum [REDACTED]

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

Flakes, the final product of the process, are checked against technical requirements, such as the content of poly(vinyl chloride) (PVC), other plastics and glues.

##### 3.2.2. Characterisation of the input<sup>7</sup>

According to the applicant, the input material for the recycling process Kalex Films consists of hot washed and dried flakes obtained from PET containers, e.g. bottles, previously used for food packaging, from post-consumer collection systems (kerbside, deposit systems and mixed waste collection). A small fraction may originate from non-food applications. According to the applicant, the proportion will be no more than 5%.

Technical data for the hot washed and dried flakes are provided, such as information on physical properties and on residual contents of moisture, PVC, glues, other plastics than PET, wood, paper and metals (see Appendix A).

#### 3.3. Starlinger deCON technology

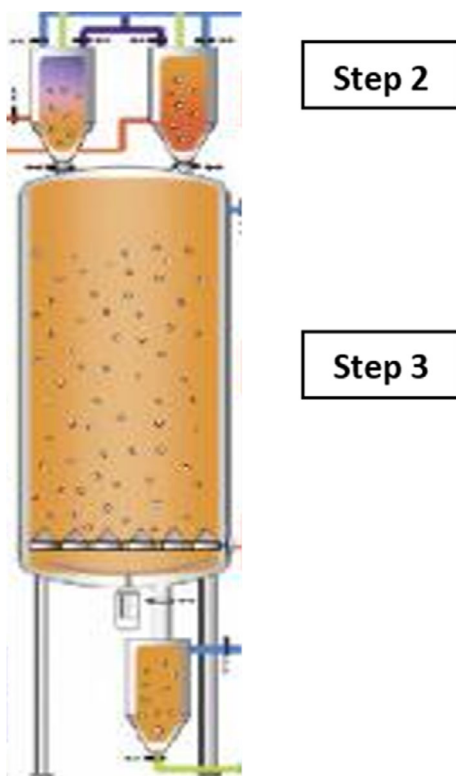
##### 3.3.1. Description of the main steps<sup>6</sup>

The general scheme of the Starlinger deCON technology, as provided by the applicant, is reported in Figure 1. The steps are:

- Preheating (step 2): The flakes are preheated in a batch reactor [REDACTED] up to the temperature of the next step, the SSP reactor. Several preheaters can be used alternately.
- SSP (step 3): The preheated flakes are fed into the SSP reactor running [REDACTED]. The SSP reactor remains under vacuum [REDACTED]

<sup>6</sup> Technical dossier, section 'Recycling process'.

<sup>7</sup> Technical dossier, section 'Characterisation of the input'.



**Figure 1:** General scheme of the technology (provided by the applicant)

The process is run under defined operating parameters<sup>8</sup> of temperature, pressure, [redacted] and residence time.

**3.3.2. Decontamination efficiency of the recycling process<sup>9</sup>**

To demonstrate the decontamination efficiency of the recycling process Kalex Films, a challenge test performed at [redacted] scale was submitted to EFSA.

PET flakes were contaminated with toluene, chlorobenzene, phenylcyclohexane, chloroform, methyl salicylate, benzophenone and methyl stearate, selected as surrogate contaminants in agreement with the EFSA guidelines (EFSA CEF Panel, 2011) and in accordance with the recommendations of the US Food and Drug Administration (FDA, 2006). The surrogates include different molecular masses 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).

[redacted] The concentration of the surrogates in these flakes was determined.

The preheater reactor was filled with [redacted] contaminated flakes (step 2). The 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.

The decontamination efficiency of the process was calculated from the concentrations of the surrogates measured in the washed contaminated flakes before the preheating (before step 2) and after SSP (step 3). The results are summarised in Table 1.

<sup>8</sup> In accordance with Art. 9 and 20 of Regulation (EC) No 1935/2004, the parameters were provided to EFSA by the applicant and made available to the Member States and the European Commission (see Appendix C).

<sup>9</sup> Technical dossier, section 'Determination of the decontamination efficiency of the recycling process'.

<sup>10</sup> [redacted]

**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	369.0	4.1	98.9
Phenylcyclohexane	404.0	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 physical properties and residual contents of PVC, glues, plastics other than PET, wood, paper and metals, were provided for the input materials (i.e. washed and dried flakes, step 1). These are produced from PET containers, e.g. bottles, previously used for food packaging, collected through post-consumer collection systems. However, a small fraction may originate from non-food applications, such as bottles for soap, mouth wash or kitchen hygiene agents. According to the applicant, the collection system and the process are managed in such a way that in the input stream, this fraction will be no more than 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 adequately described. The washing and drying of the flakes from the collected PET containers (step 1) is conducted in different ways depending on the plant and, according to the applicant, this step is under control. The Starlinger deCON technology comprises the batch preheating (step 2) and ██████████ SSP (step 3). The operating parameters of temperature, residence time, pressure and ██████████ for both steps have been provided to EFSA.

A challenge test to measure the decontamination efficiency was conducted at ██████████ scale on process steps 2 and 3. The Panel considered that this challenge test was performed correctly according to the recommendations of the EFSA guidelines (EFSA, 2008). The Panel considered that steps 2 and 3 were critical for the decontamination efficiency of the process. Consequently, temperature, residence time, pressure and ██████████ parameters of steps 2 and 3 should be controlled to guarantee the performance of the decontamination (Appendix C).

The decontamination efficiencies obtained for each surrogate, 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 was obtained (Table 2).

According to the evaluation principles (EFSA CEF Panel, 2011), the dietary exposure must not exceed 0.0025  $\mu\text{g}/\text{kg}$  bw per day, below which the risk to human health is considered negligible. The  $C_{res}$  value should not exceed the modelled concentration in PET ( $C_{mod}$ ) that, after 1 year at 25°C, could result in a migration giving rise to a dietary exposure exceeding 0.0025  $\mu\text{g}/\text{kg}$  bw per day. Because the recycled PET is intended for the manufacturing of articles containing up to 100% recycled PET, the scenario for infants has been applied. Therefore, the migration of 0.1  $\mu\text{g}/\text{kg}$  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 the challenge test, residual concentrations of the surrogates in the recycled PET ( $C_{res}$ ) and calculated concentrations of the surrogates in PET ( $C_{mod}$ ) corresponding to a modelled migration of 0.1  $\mu\text{g}/\text{kg}$  food after 1 year at 25°C

Surrogates	Decontamination efficiency (%)	$C_{res}$ for 100% rPET (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); rPET: recycled poly(ethylene terephthalate).

As  $C_{res}$  values are lower than the corresponding modelled concentrations in PET ( $C_{mod}$ ), the Panel considered that under the given operating conditions the recycling process Kalex Films 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  $\mu\text{g}/\text{kg}$  food, at which the risk to human health would be negligible.

#### 4. Conclusions

The Panel considered that the process Kalex Films using the Starlinger deCON technology is adequately characterised and that 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 temperature, residence time, pressure and [REDACTED] of the preheating (step 2) and the decontamination in the [REDACTED] SSP reactor (step 3), which were included in the challenge test, are critical for the decontamination efficiency.

The Panel concluded that the recycling process Kalex Films is able to reduce foreseeable accidental contamination of 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 applied in the challenge test used to measure the decontamination efficiency of the process;
- ii) the input material 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 and contain no more than 5% of PET from non-food consumer applications;
- iii) the recycled PET obtained from the process Kalex Films is used at 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.

The final articles made of this recycled PET are not intended to be used in microwave or conventional ovens and such uses are not covered by this evaluation.

#### 5. Recommendations

The Panel recommended periodic verification that the input material 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 the 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.

## 6. Documentation provided to EFSA

Dossier 'Kalex Films'. April 2021. Submitted on behalf of Kalex Films Ltd., United Kingdom.  
Additional information, March 2022. Submitted on behalf of Kalex Films Ltd., United Kingdom.

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- FDA (Food and Drug Administration), 2006. Guidance for Industry: Use of Recycled Plastics in Food Packaging: Chemistry Considerations. Available online: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-use-recycled-plastics-food-packaging-chemistry-considerations>

## Abbreviations

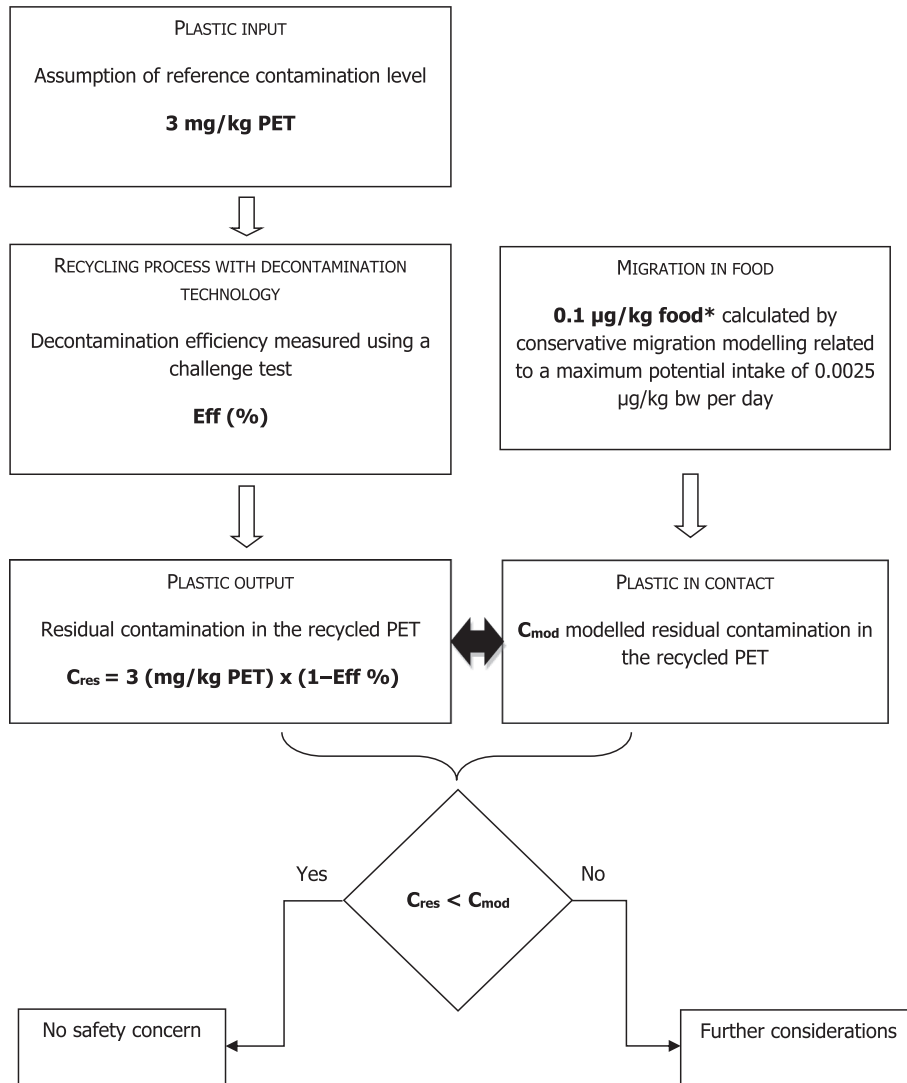
bw	body weight
CEF Panel	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP Panel	Panel on Food Contact Materials, Enzymes and Processing Aids
$C_{\text{mod}}$	modelled concentration in PET
$C_{\text{res}}$	residual concentrations in PET
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)
rPET	recycled poly(ethylene terephthalate)
SSP	solid-state polycondensation

## Appendix A – Technical data of the washed flakes as provided by the applicant<sup>7</sup>

Parameter	Value
Moisture	< 2%
Particle size	1–15 mm
Bulk density	250–750 kg/m <sup>3</sup>
Thickness	50–1,200 µm
Other materials than PET	< 500 mg/kg
Flakes with adhesive	< 4,000 mg/kg
Wood, paper	< 100 mg/kg
Metal content	< 500 mg/kg
PVC content	< 100 mg/kg
Contamination other than water	< 2,000 mg/kg
PET from non-food applications	≤ 5%

PVC: poly(vinyl chloride); PET: poly(ethylene terephthalate).

## 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. The figures are derived from the application of the human exposure threshold value of 0.0025 µg/kg bw per day applying a factor of 5 related to the overestimation of modelling.

### Appendix C – Table of operational parameters (Confidential Information)<sup>11</sup>

[Redacted text]

[Redacted]								
[Redacted]	[Redacted]				[Redacted]			
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]

[Redacted text]

<sup>11</sup> Technical report, section 'Table of operating Parameters'.