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## Safety assessment of the process 'Linpac', based on Linpac super clean technology, used to recycle post-consumer PET into food contact materials

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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 assessment of the Linpac recycling process (EU register number RECYC0148), which is based on the Linpac super clean technology. The input to this process is hot washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, containing no more than 5% PET from non-food consumer applications. In this technology post-consumer washed and dried PET flakes are heated in continuous driers under gas flow before being extruded. Having examined the results of the challenge test provided, the Panel concluded that the decontamination in the driers (steps 2 and 3) are the critical steps that determine the decontamination efficiency of the process. The operating parameters controlling its performance are well defined and are residence time, 'air flow per mass of flakes' and temperature in the driers. It was demonstrated that, depending on the operating conditions, the recycling process under evaluation is able to ensure that the level of migration of potential unknown contaminants into food is below a conservatively modelled migration of 0.15 µg/kg food, derived from the exposure scenario for toddlers. The Panel concluded that recycled PET obtained from the process is not of safety concern when used at up to 100% to make articles intended for contact with all types of foodstuffs, except packaged water. These articles should be used at conditions covered by migration testing of 10 days at 20°C. The articles are not intended to be used, and should not be used, in microwave and conventional ovens.

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**Keywords:** Linpac, food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

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**Note:** The full opinion will be published in accordance with Article 10(6) of Regulation (EC) No 1935/2004 once the decision on confidentiality, in line with Article 20(3) of the Regulation, will be received from the European Commission. The text and table on the operational parameters (appendix C) have been provided under confidentiality and they are redacted awaiting the decision of the Commission.

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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 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, from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, an application for evaluation of the recycling process Linpac, based on the Linpac super clean technology, EU register No RECYC0148. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2016-00550. The dossier was submitted on behalf of LINPAC Packaging GmbH, Germany.

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 Linpac, 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 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 authorisation' (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.

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<sup>1</sup> 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> 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 up 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 (CT) 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 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 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.

## 3. Assessment

### 3.1. General information

According to the applicant, the Linpac recycling process is intended to recycle food grade PET containers to produce recycled PET using its own technology. This recycled PET is intended to be used in a mass fraction up to 100% to manufacture single use PET trays for fresh food (e.g. meat) with maximum storage conditions of 30 days at 6°C.

### 3.2. Description of the process

#### 3.2.1. General description

The recycling process Linpac produces PET trays from PET containers, mainly bottles, coming from post-consumer collection systems (kerbside and deposit systems). The recycling process comprises the steps below:

- In step 1, post-consumer PET containers are ground and processed into washed and dried flakes. This step is performed by the flake suppliers.
- In step 2, the flakes are treated by means of an infrared (IR) rotary dryer, in three zones with increasing temperature.
- In step 3, the flakes are treated by means of 1,800 L 'dryer 1'.
- In step 4, the decontaminated flakes are extruded to produce flat sheets under vacuum.

The operating conditions of residence time, gas flow and temperature of the process (steps 2 and 3) have been provided to EFSA. Additionally, the parameter 'air flow per mass of flakes' was provided. Recycled flat sheets, the final product of the process, are checked against technical requirements on intrinsic viscosity, colour, black spots, etc. According to the applicant, this recycled PET is intended to be converted to produce single use PET trays for fresh food contact (e.g. meat) with maximum storage conditions of 30 days at 6°C with up to about 100% recycle. The trays are not intended to be used in microwave or conventional ovens.

#### 3.2.2. Characterisation of the input

According to the applicant, the input material for the Linpac recycling process consists of 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 such as soap bottles, mouth wash bottles, kitchen hygiene bottles, etc. According to information from the applicant, the amount of this non-food container fraction depends on the collection system and will be below 5%.

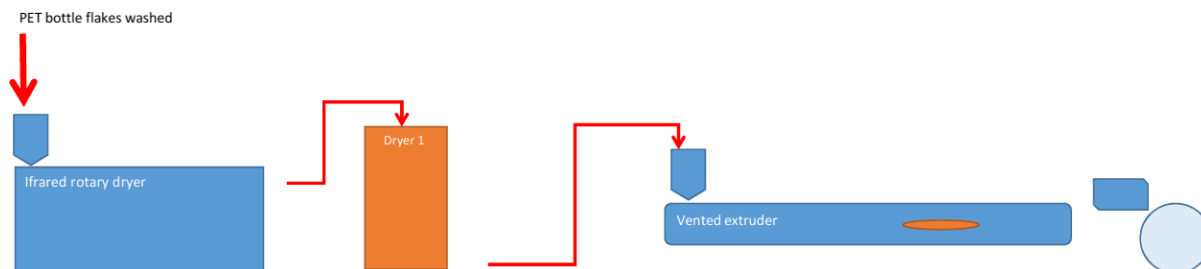
Technical data for the hot washed and dried flakes are provided, such as information on residual content of poly(vinyl chloride) (PVC), glue, other plastics, cellulose, metals and physical properties (see Appendix A).

### 3.3. Linpac super clean technology

#### 3.3.1. Description of the main steps

According to the applicant, to decontaminate post-consumer PET, the recycling process Linpac uses its own technology, which is described below and for which the general scheme, provided by the applicant, is reported in Figure 1. Washed and dried flakes from step 1 are used as input to the next three steps, which are:

- Treatment of flakes by means of an IR dryer (step 2): in this step, the washed flakes are continuously feed into IR drier where they are treated by IR radiation under fixed conditions of 'air flow per mass of flakes', residence time and temperature.
- Treatment of flakes by means of a 1,800 L 'dryer 1' (step 3): the flakes are treated with hot air, under fixed conditions of residence time, 'air flow per mass of flakes' and temperature.
- Extrusion of the decontaminated flakes into sheets (step 4): The flakes are melted in the extruder with vacuum degassing. There is a range of downstream equipment to produce mono or thin-film-laminated flat sheets with degassing under vacuum.



**Figure 1:** General scheme of the Linpac super clean technology

The process is operated under defined operating parameters<sup>3</sup> of residence time, 'air flow per mass of flakes' and temperature.

#### 3.3.2. Decontamination efficiency of the recycling process

To demonstrate the decontamination efficiency of the Linpac process, a CT was submitted to EFSA.

PET flakes were contaminated with toluene, chlorobenzene, chloroform, methyl salicylate, phenylcyclohexane, benzophenone and methyl stearate, selected as surrogate contaminants in agreement with the 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 this purpose, solid surrogates (benzophenone and methyl stearate) were mixed with liquid surrogates (toluene, chlorobenzene, chloroform, methyl salicylate and phenyl cyclohexane). The batches were stored in a closed steel container for 7 days at 50°C with periodical agitation. Subsequently the contaminated flakes were rinsed with 10% ethanol and shipped in a sealed steel container to the washing plant. The contaminated flakes were washed using a hot solution of alkali and detergent, and subsequently rinsed with water and hot-air dried. The concentration of the surrogates in this material was determined.

<sup>3</sup> 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).

The CT was performed in the production plant only with contaminated flakes. The contaminated flakes were introduced directly in step 2. After step 3 (before extrusion), flakes were collected and analysed for their residual concentrations of the applied surrogates. The decontamination efficiency was then calculated from the concentration difference before and after these steps. Step 4 (extrusion) was not included in the challenge test.

The process runs in steps 2 and 3 at conditions of air flow per mass of flakes, residence time and temperature equal to the ones used in the challenge test.

As shown in Table 1, the decontamination efficiency ranged from 87.5% for benzophenone to 97.5% for toluene.

The Panel noted that only steps 2 and 3 were submitted to the challenge test. During the extrusion, degassing under vacuum takes place, which is expected to contribute further to the overall decontamination. Therefore, actual decontamination efficiencies are expected to be higher than those reported in Table 1.

**Table 1:** Efficiency of the decontamination of the Linpac super clean 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	203.6 ± 19.8	5.0 ± 0.1	97.5
Chlorobenzene	329.9 ± 31.7	9.0 ± 0.1	97.3
Chloroform	109.5 ± 23.6	8.0 ± 0.1	92.7
Methyl salicylate	254.7 ± 28.9	15.8 ± 0.1	93.8
Phenylcyclohexane	414.4 ± 46.4	23.3 ± 0.2	94.4
Benzophenone	464.6 ± 52.2	58.3 ± 0.3	87.5
Methyl stearate	207.3 ± 22.8	22.1 ± 0.1	89.3

PET: poly(ethylene terephthalate).

### 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, other plastics, cellulose, metals 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, etc. According to the applicant, the proportion of this non-food container fraction depends on the collection system and the process is managed in such a way that in the input stream of the recycling process this amount will be lower 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 production of washed and dried flakes from collected containers (step 1) is conducted by flake suppliers. According to the applicant, the suppliers use state-of-art washing processes. The following steps are those of Linpac super clean technology used to recycle the PET flakes into decontaminated PET flakes: treatment of flakes by means of IR dryer (step 2), treatment of flakes by means of 1,800 L dryer (step 3) and extrusion (step 4).

A CT was conducted at industrial plant scale on the process steps 2 and 3 to measure the decontamination efficiency. The CT was conducted with only contaminated flakes. Therefore cross contamination does not need to be addressed.

The Panel considered that the decontamination in steps for crystallising/drying and subsequent drying (steps 2 and 3) should be considered together for the decontamination efficiency of the process. The parameters residence time, 'air flow per mass of flakes' and temperature of the steps 2 and 3 of the process have been provided to EFSA and were indicated by the applicant as fixed and



equal to the ones applied in the challenge test. Additionally to these parameters, other industrial process parameters provided were the bulk density and the throughput of the flakes, the driers capacity and their filling level. In the industrial process, these parameters are not fixed and may assume a range of values. The Panel noted that those parameters influence the parameter 'air flow per mass of flakes' in each drier, which is expected to be critical for the decontamination efficiency.

In accordance with the recommendations in the EFSA Guidelines (EFSA, 2008), the CT should be conducted in conditions allowing for concluding that in the industrial operating conditions the same or a higher decontamination efficiency is achieved. Therefore, the specific parameters residence time, 'air flow per mass of flakes' and temperature used in the CT should be controlled and followed in the industrial process.

The decontamination efficiencies obtained for each surrogate contaminant from the challenge test, ranging from 87.5% to 97.5%, have been used to calculate the residual concentrations of potential unknown contaminants ( $C_{res}$ ) 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 percentages to the reference contamination level of 3 mg/kg PET, the  $C_{res}$  values for the different surrogates are obtained (see Table 2).

According to the evaluation principles (EFSA CEF Panel, 2011), the  $C_{res}$  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.<sup>4</sup>

The recycled PET is intended to be used in the manufacture of new single use PET trays for fresh food (e.g. meat), with up to about 100% recycle content to be used in storage conditions corresponding to standard migration testing conditions of 10 days at 20°C.<sup>5</sup> The most conservative default scenario for toddlers has been applied. Therefore the migration of 0.15 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 0.15 µg/kg food after 10 days at 20°C

Surrogates	Decontamination efficiency (%)	$C_{res}$ (mg/kg PET)	$C_{mod}$ (mg/kg PET)
Toluene	97.5	0.075	1.08
Chlorobenzene	97.3	0.081	1.26
Chloroform	92.7	0.219	1.32
Methyl salicylate	93.8	0.186	1.67
Phenylcyclohexane	94.4	0.160	1.77
Benzophenone	87.5	0.375	2.04
Methyl stearate	89.3	0.321	4.05

PET: poly(ethylene terephthalate).

On the basis of the provided data from the CT and the applied conservative assumptions, the Panel considered that the recycling process under evaluation using the Linpac super clean technology, under the given operating conditions, 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 0.15 µg/kg food, at which the risk to human health would be negligible when the recycled sheets are used for trays and containers intended for contact with all types of foodstuffs (except packaged water), at the intended conditions (corresponding to those for which the migration determination is for 10 days at 20°C) and when the recycled PET from the Linpac recycling process is used up to 100%.

<sup>4</sup> 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).

<sup>5</sup> Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0010&from=EN>)



## 4. Conclusions

The Panel considered that the main steps and parameters used to recycle the PET flakes into decontaminated PET sheets, by the recycling process Linpac, have been identified. Having examined the challenge test provided, the Panel concluded that the decontamination in the dryers (steps 2 and 3) are the critical steps for the decontamination efficiency of the process. The operating parameters to control their performance are residence time, 'air flow per mass of flakes' and temperature in the driers. The Panel considered that the recycling process Linpac 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 Linpac, when used up to 100% for the manufacture of articles intended for contact with all food, except packaged water, with storage conditions corresponding to those for which the migration testing is for 10 days at 20°C<sup>5</sup>, is not considered of safety concern. The thermoformed 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 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.

### Documentation provided to EFSA

- 1) Dossier 'Linpac Recycling Process'. August 2016. Submitted on behalf of LINPAC Packaging GmbH, Germany.
- 2) Additional data on the dossier 'Linpac Recycling Process' received on 13 September 2017. Submitted on behalf of LINPAC Packaging GmbH, Germany.
- 3) Additional data on the dossier 'Linpac Recycling Process' received on 17 April 2018. Submitted on behalf of LINPAC Packaging GmbH, Germany.

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- EFSA (European Food Safety Authority), 2008. Guidelines for the submission of an application for safety evaluation by the EFSA of a recycling process to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food, prior to its authorisation. EFSA Journal 2008;6(7):717, 12 pp. <https://doi.org/10.2903/j.efsa.2008.717>
- EFSA (European Food Safety Authority), 2009. Guidance of the Scientific Committee on transparency in the scientific aspects of risk assessments carried out by EFSA. Part 2: general principles. EFSA Journal 2009; 7(5):1051, 22 pp. <https://doi.org/10.2903/j.efsa.2009.1051>
- EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2011. 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 Journal 2011;9(7):2184, 25 pp. <https://doi.org/10.2903/j.efsa.2011.2184>

## Abbreviations

bw body weight

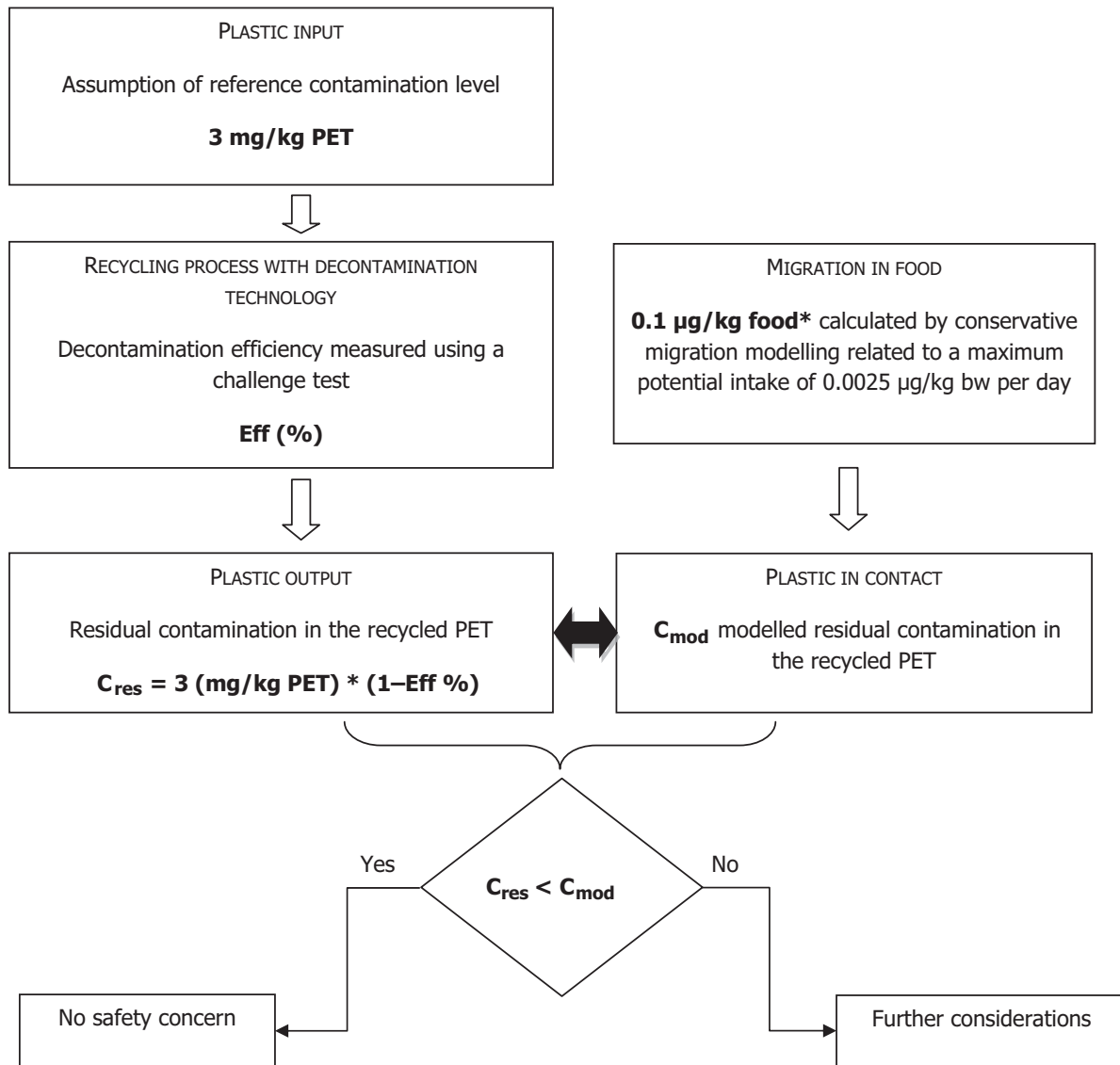
CEF Panel EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids

$C_{\text{mod}}$	modelled concentration in PET
$C_{\text{res}}$	residual concentration in PET
CT	challenge test
IR	infrared
MPR	Multi-Purpose Reactor
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)

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

Parameter	Value
Moisture max.	1.0%
Moisture variation	$\pm 0.1\% \text{ h}^{-1}$
Bulk density	$325 \text{ kg m}^{-3}$
Bulk density variation	$\pm 50 \text{ kg m}^{-3} \text{ h}^{-1}$
Material temperature	15–50°C
Material temp. variation	$\pm 5^\circ\text{C h}^{-1}$
PVC max.	500 ppm
Glue max.	50 ppm
Other plastics max.	1,000 ppm
Cellulose (paper, wood) max	5%
Metals max.	1,000 ppm

## 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 on critical parameters (Confidential Information)

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