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Safety assessment of the process Petainer Lidköping, based on the Kreyenborg IR Clean+ 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 Petainer Lidköping (EU register number RECYC254), which uses the Kreyenborg IR Clean+ technology. The input material is hot caustic washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, including no more than 5% PET from non-food consumer applications. The flakes are heated in a [redacted] IR dryer (step 2) before being processed by the finisher (step 3). Having examined the challenge test provided, the Panel concluded that step 2 and step 3 are critical in determining the decontamination efficiency of the process. The operating parameters to control the performance of this step are temperature, airflow and residence time. 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 0.10 μg/kg food, derived from the exposure scenario for infants when such recycled PET is used at up to 100%. Therefore, the Panel concluded that the recycled PET obtained from this process is not of safety concern when used at up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs, including drinking water, for long-term storage at room temperature, with or without hotfill. Articles made of this recycled PET are not intended to be used in microwave and conventional ovens and such uses are not covered by this evaluation.

Keywords: Kreyenborg IR Clean+, Petainer Lidköping AB, food contact materials, plastic, poly (ethylene terephthalate) (PET), recycling process, safety assessment

Requestor: Sweedish Competent Authority (Livsmedelsverket Swedish Food Agency)

Question number: EFSA-Q-2020-00703

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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. Technical details on recycling steps 2 and 3, details of the performed challenge test (sections 3.2.1, 3.3.1, 3.3.2 and 3.4) and 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.

Declarations of interest: If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

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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 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[1] on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of Regulation (EC) No 1935/2004[2] on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the competent authorities of Member States, which transmit the applications to EFSA for evaluation.

In this case, EFSA received from the Swedish Competent Authority (Livsmedelsverket Swedish Food Agency), an application for evaluation of the recycling process Petainer Lidköping, European Union (EU) register No RECYC254. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2020-00703. The dossier was submitted on behalf of Petainer Lidköping AB, Sweden (see 'Documentation provided to EFSA').

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).

Additional information was provided by the applicant during the assessment process in response to a request from EFSA sent on 29 July 2021, 22 December 2021 and 17 May 2022 (see 'Documentation provided to EFSA').

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] Commission Regulation (EC) No 282/2008 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 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 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 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.

3. Assessment

3.1. General information[3]

According to the applicant, the recycling process Petainer Lidköping is intended to recycle food grade PET containers using the Kreyenborg IR Clean+ technology. The recycled PET is intended to be used at up to 100% for thermoformed containers, e.g. PET one-way and refillable containers for mineral water, sparkling water, carbonated soft drinks, coffee, Kombucha, beer, wine (alcoholic beverages under 15% ethanol) and fruit juices, with or without hotfill. 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[4]

The recycling process Petainer Lidköping produces recycled PET flakes from PET containers from post-consumer collection systems (kerbside and deposit systems).

The recycling process comprises the three steps below.

Input

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

Decontamination and production of recycled PET material

- In step 2, the flakes are heated and decontaminated by means of an infrared (IR) rotary dryer under airflow, up to a defined temperature.
- In step 3, the flakes are further decontaminated in a finisher under [redacted] airflow and high temperature.

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 intrinsic viscosity, colour and black spots.

[3] Technical dossier, Section 3.1.1.
[4] Technical dossier, Section 3.1.1, 3.2.1, 3.2.2 and 3.2.4.

3.2.2. Characterisation of the input[5]

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

Technical specifications on the hot washed and dried flakes were provided, such as information on physical properties and on residual contents of moisture, poly(vinyl chloride) (PVC), glue, polyolefins, polyamides, cellulose and metals (see Appendix A).

3.3. Kreyenborg IR Clean+ technology

3.3.1. Description of the main steps[6]

The general scheme of the Kreyenborg IR Clean+ technology, as provided by the applicant, is reported in Figure 1. Washed and air-dried flakes from step 1 are used as input to the next two steps, which are:

- Decontamination by means of an IR dryer (step 2):

The flakes are [redacted] fed into a dryer where they are treated by IR radiation under defined conditions of airflow, temperature and residence time.

- Decontamination of the flakes in a finisher (step 3):

The flakes from the IR dryer are [redacted] introduced into the finisher under defined conditions of [redacted] airflow, temperature and residence time.

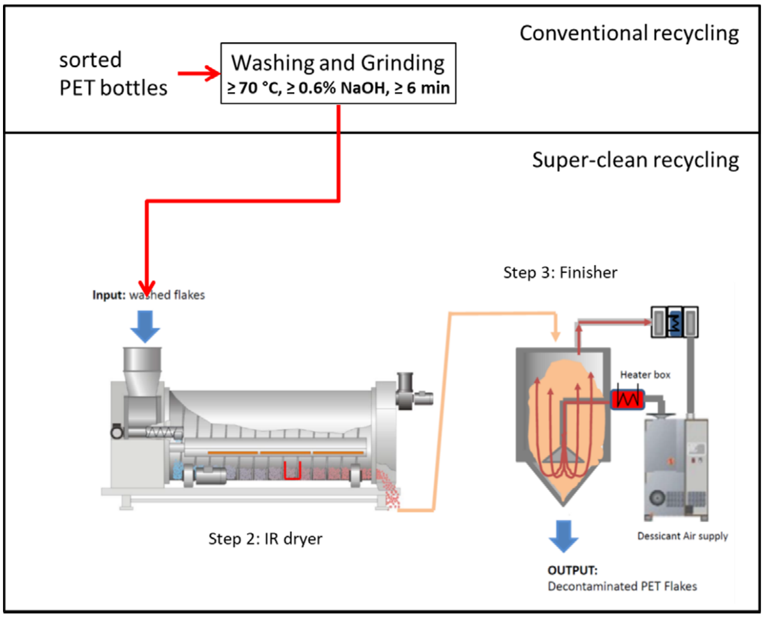


Figure 1: General scheme of the **Kreyenborg IR Clean +** technology (provided by the applicant)

The process is run under defined operating parameters[7] of temperature, airflow and residence time.

[5] Technical dossier, Section 3.2.2.
[6] Technical dossier, Section 3.2.1.
[7] 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).

3.3.2. Decontamination efficiency of the recycling process[8]

To demonstrate the decontamination efficiency of the recycling process Petainer Lidköping, a challenge test on steps 2 and 3 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 (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).

A mixture of solid surrogates (benzophenone and methyl stearate) and liquid surrogates (toluene, chlorobenzene, chloroform, methyl salicylate and phenyl cyclohexane) was added in a barrel to 25 kg of conventionally recycled[9] post-consumer PET flakes. Four such barrels were prepared and stored for 7 days at 50°C with periodical agitation. Afterwards, the contaminated flakes were rinsed with 10% ethanol and air-dried (step 1). For each batch, the concentrations of surrogates were determined, before and after air-drying. The barrels were merged into one batch of 100 kg.

Steps 2 and 3 of the Kreyenborg IR Clean+ technology were challenged at a production plant scale. To process a sufficiently large amount of material compatible with the high capacity of the [redacted] plant, the IR dryer was initially fed with blue non-contaminated flakes and, after process conditions were reached, with the 100 kg contaminated, colourless flakes. These were [redacted] fed into the IR dryer (step 2) and subsequently into the finisher (step 3). The colourless flakes were sampled after step 3 to measure the residual concentrations of the applied surrogates. The decontamination efficiency of the process was calculated from the concentrations of the surrogates measured in the air-dried contaminated flakes before entering the IR dryer (step 2) and after exiting the finisher (step 3). The results are summarised in Table 1.

Table 1: Efficiency of the decontamination of the Kreyenborg IR Clean+ technology in the challenge test

Surrogates	Concentration[(a)] of surrogates before step 2 (mg/kg PET)	Concentration[(b)] of surrogates after step 3 (mg/kg PET)	Decontamination efficiency (%)
Toluene	162.7	< 0.1	> 99.9
Chlorobenzene	330.8	1.4	99.6
Chloroform	113.7	1.1	99.0
Methyl salicylate	411.4	4.3	99.0
Phenylcyclohexane	294.5	6.6	97.8
Benzophenone	617.1	30.7	95.0
Methyl stearate	798.3	31.7	96.0

PET: poly(ethylene terephthalate).
(a): Initial concentration in the contaminated air-dried PET flakes.
(b): Residual concentration measured in the colourless flakes after decontamination.

The decontamination efficiency ranged from 95.0% for benzophenone up to > 99.9% for toluene.

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 specifications, such as information on physical properties and residual contents of PVC, glue, polyolefins and metals, were provided for the input materials (i.e. hot caustic 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 bottles.

[8] Technical dossier, Section 3.2.3 and Appendix E.
[9] Conventional recycling commonly includes sorting, grinding, washing and drying steps. It produces washed and dried flakes.

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 by third parties and, according to the applicant, this step is under control. The Kreyenborg IR Clean+ technology comprises the IR dryer (step 2) and the finisher (step 3). The operating parameters of temperature, airflow and residence time have been provided to EFSA.

A challenge test to measure the decontamination efficiency was conducted at industrial plant scale on the process steps 2 and 3. The IR dryer (step 2) and the finisher (step 3) were operated in [redacted] mode under airflow and temperature conditions equivalent to or less severe than those of the commercial process. The Panel considered that this challenge test was performed correctly according to the recommendations of the EFSA guidelines (EFSA, 2008) and that steps 2 and 3 were critical for the decontamination efficiency of the process. Consequently, temperature, airflow rate and residence time of steps 2 and 3 of the process should be controlled to guarantee the performance of the decontamination (Appendix C).

The decontamination efficiencies obtained for each surrogate, ranging from 95% to more than 99.9%, 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 percentages to the reference contamination level of 3 mg/kg PET, the C_{res} for the different surrogates was obtained (Table 2).

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 μg/kg food (infant scenario) after 1 year at 25°C

Surrogates	Decontamination efficiency (%)	C_{res} for 100% rPET (mg/kg PET)	C_{mod} (mg/kg PET) infant scenario
Toluene	> 99.9	< 0.01	0.09
Chlorobenzene	99.6	0.01	0.09
Chloroform	99.0	0.03	0.10
Methyl salicylate	99.0	0.03	0.13
Phenylcyclohexane	97.8	0.07	0.14
Benzophenone	95.0	0.15	0.16
Methyl stearate	96.0	0.12	0.32

PET: poly(ethylene terephthalate); rPET: recycled poly(ethylene terephthalate).

According to the evaluation principles (EFSA CEF Panel, 2011), the dietary exposure must not exceed 0.0025 μg/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 could result, after 1 year at 25°C, in a migration giving rise to a dietary exposure exceeding 0.0025 μg/kg bw per day. Because the recycled PET is intended to manufacture bottles and containers (also for drinking water), the exposure scenario for infants has been applied (in which water is considered to prepare infant formula). A maximum dietary exposure of 0.0025 μg/kg bw per day corresponds to a maximum migration of 0.1 μg/kg of the contaminant into the infant's food and has been used to calculate C_{mod} (EFSA CEF Panel, 2011). C_{res} reported in Table 2 is calculated for 100% recycled PET, for which the risk to human health is demonstrated to be negligible. The Panel noted that benzophenone was close to the limit, but considering the conservative assumption made in the calculation of the C_{mod}, the process resulted in a decontamination efficiency that allows for the application of the exposure scenario for infants. The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

On the basis of the provided data from the challenge test and the applied conservative assumptions, the Panel concluded that under the given operating conditions the recycling process Petainer Lidköping using the Kreyenborg IR Clean+ technology is able to ensure that the level of migration of unknown contaminants from the recycled PET into food is below the conservatively modelled migrations of 0.10 μg/kg food. At this level, the risk to human health is considered negligible when the recycled PET is used at up to 100% to produce materials and articles intended for contact with all types of foodstuffs including drinking water.

4. Conclusions

The Panel considered that the process Petainer Lidköping using the Kreyenborg IR Clean+ 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 and airflow of the IR dryer (step 2) and the finisher (step 3) are critical for the decontamination efficiency.

The Panel concluded that the recycling process Petainer Lidköping 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 Petainer Lidköping is used at up to 100% for the manufacture of materials and articles for contact with all types of foodstuff, including drinking water, 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 'Petainer Lidköping'. October 2020. Submitted on behalf of Petainer Lidköping AB, Sweeden.
Additional information, November 2021. Submitted on behalf of Petainer Lidköping AB, Sweeden.
Additional information, April 2022. Submitted on behalf of Petainer Lidköping AB, Sweden.
Additional information, May 2022. Submitted on behalf of Petainer Lidköping AB, Sweden.

References

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. Part2: 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

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

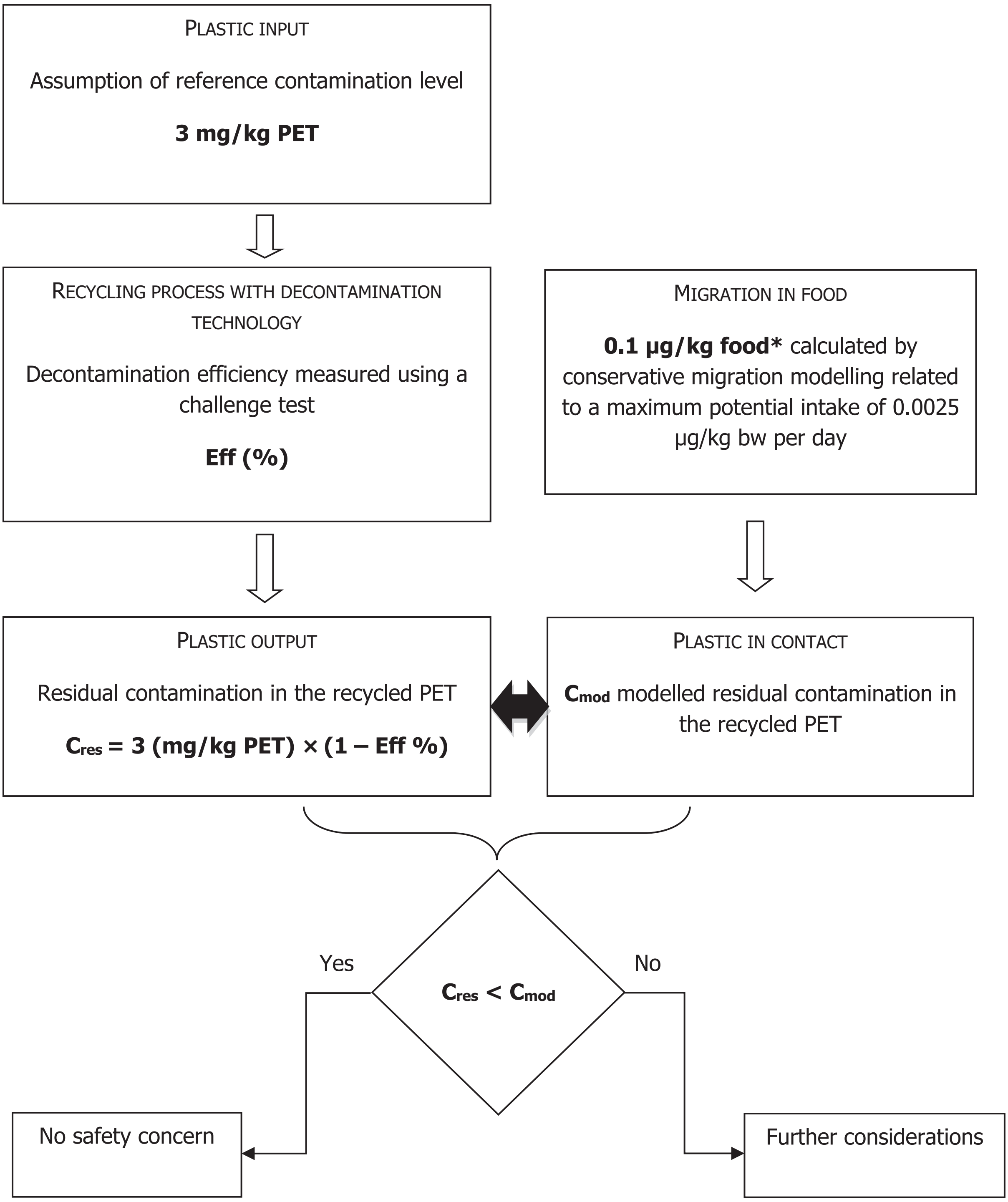
bw	body weight
CEF Panel	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP Panel	Panel on Food Contact Materials, Enzymes and Processing Aids
C_{mod}	modelled concentration in PET
C_{res}	residual concentrations in PET
iV	intrinsic viscosity
PET	poly(ethylene terephthalate)
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[5]

Parameter	Value
Moisture max.	1.0%
Moisture variation	± 0.3%
Bulk density	230–850 kg/m^3
Bulk density variation	± 150 kg/m^3 per h
Material temperature	5–40°C
Material temperature variation	± 10°C/h
PVC max.	100 mg/kg
Glue max.	100 mg/kg
Polyolefins max.	100 mg/kg
Cellulose (paper, wood)	100 mg/kg
Metals max.	50 mg/kg
Polyamide max.	50 mg/kg

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)[10]

[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]

*: In the process the temperatures are measured at four residence time points of 5 min difference, corresponding to temperatures of 80°C, 120°C, 150°C and 170°C. The temperature of ≥ 170°C in the flakes is reached during the last quarter of the residence time.

[10] Technical dossier, Section 3.10.