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Safety assessment of the process 'General Plastic', based on Starlinger Decon 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 evaluation of the recycling process General Plastic (EU register No RECYC153), 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 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 process performance 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.

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Keywords: Starlinger Decon technology, General Plastic, 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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Table of Contents

Abstract 1
1. Introduction 4
1.1. Background and Terms of Reference as provided by the requestor 4
2. Data and methodologies 4
2.1. Data 4
2.2. Methodologies 4
3. Assessment 5
3.1. General information 5
3.2. Description of the process 5
3.2.1. General description 5
3.2.2. Characterisation of the input 6
3.3. Starlinger Decon technology 6
3.3.1. Description of the main steps 6
3.3.2. Decontamination efficiency of the recycling process 6
3.4. Discussion 7
4. Conclusions 8
5. Recommendations 9
Documentation provided to EFSA 9
References 9
Abbreviations 9
Appendix A – Technical data of the washed flakes as provided by the applicant 10
Appendix B – Relationship between the key parameters for the evaluation scheme (EFSA CEF Panel, 2011) 11
Appendix C – Table of Operational Parameters (Confidential Information) 12

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 General Plastic, EU register No RECYC153. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2017-00832. The dossier was submitted on behalf of General Plastic a.s., Slovakia.

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 General Plastic 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

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

[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.

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 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 existing guidance from the EFSA Scientific Committee.

3. Assessment

3.1. General information

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

Input

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

Decontamination and production of recycled PET material

- In step 2, the flakes are preheated 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 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 and different food grade specifications, etc. Recycled flakes are intended to be converted into recycled articles, such as bottles, used in direct contact with all types of foodstuffs (aqueous, carbonated soft drinks, dairy and fatty foodstuffs) for long-term storage at room temperature, with or without hotfill.

3.2.2. Characterisation of the input

According to the applicant, the input material for the recycling process General Plastic is hot caustic washed and dried flakes obtained from PET containers, mainly 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 amount of this non-food container fraction is kept below 5%.

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

3.3. Starlinger Decon technology

3.3.1. Description of the main steps

To decontaminate post-consumer PET, the recycling process General Plastic 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-batch reactor with a flow of hot gas up to the temperature of the next step, the SSP reactor. Several preheaters can be used alternatively depending on the amount intended to be recycled.
- SSP (step 3): The flakes from the batch preheater are fed into the SSP reactor. The SSP reactor remains under vacuum 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.

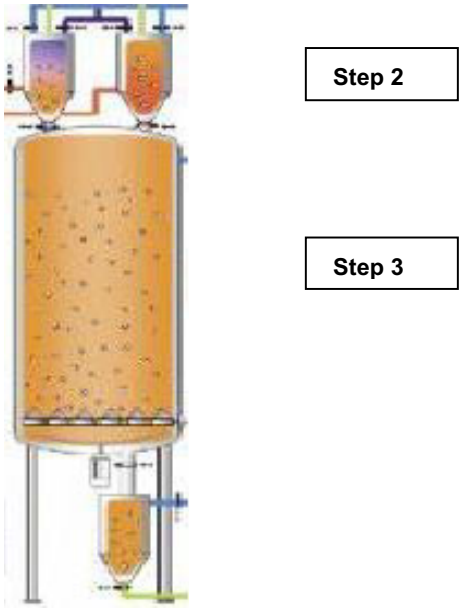

Figure 1: Starlinger Decon technology

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

3.3.2. Decontamination efficiency of the recycling process

To demonstrate the decontamination efficiency of the recycling process General Plastic, a challenge test on the Starlinger Decon technology was submitted to the 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

[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).

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. 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.

Since the challenge test was performed with only contaminated flakes, cross-contamination phenomena can be excluded.[5]

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, wood/paper, metals, other plastics and physical characteristics 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 window cleaner or shampoo bottles, etc. According to the applicant, the amount of this non-food container fraction depends on the collection system and it is kept 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

[4] Conventional recycling includes commonly sorting, grinding, washing and drying steps and produces washed and dried flakes.

[5] 'Cross-contamination', as meant in the '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' is the transfer of surrogate contaminants from the initially contaminated to the initially not contaminated material (EFSA CEF Panel, 2011).

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 step 2 and step 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.[6] 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.

4. Conclusions

The Panel considered that the process General Plastic 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 General Plastic is able to

[6] 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).

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 General Plastic 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 'General Plastic'. November 2017. Submitted on behalf of General Plastic a.s., Slovakia.
2) Clarification provided by the applicant on 20 April 2018.

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

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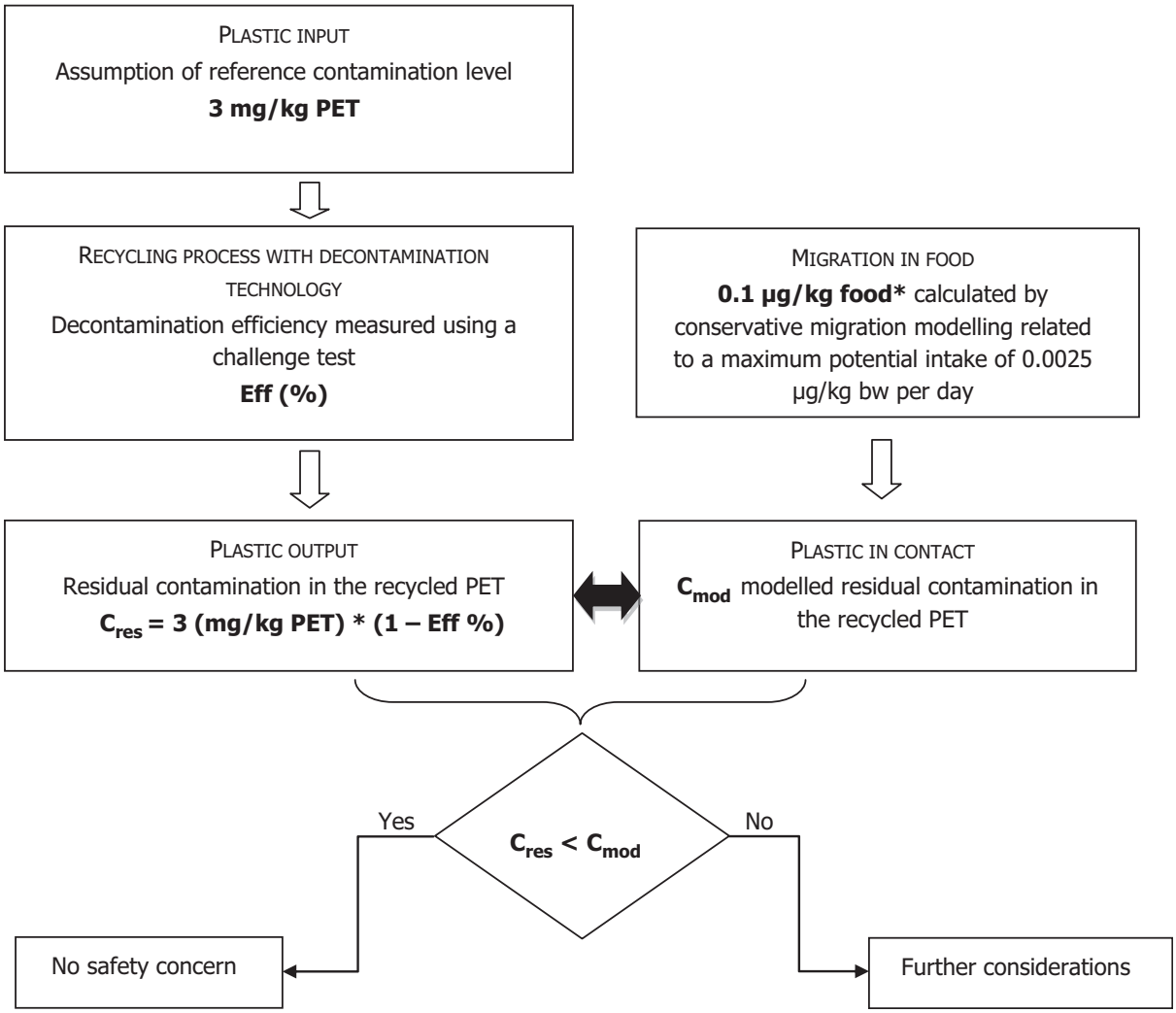
Abbreviations

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
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 mg/kg
Other plastics than PET	< 500 mg/kg
Flakes with glue content	< 4000 mg/kg
Metal content (aluminium, ferrous, others)	< 500 mg/kg
Wood, paper content	< 100 mg/kg
Total contamination other than water	< 2000 mg/kg
Bulk density	250–750 kg/m^3
Flakes size	1–15 mm
Flakes thickness	50–1200 μm

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)

[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]

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