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Safety assessment of the process Poly Recycling, based on Starlinger iV+ 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 Poly Recycling (EU register number RECYC171). The input is hot caustic washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, with no more than 5% PET from non-food consumer applications. The flakes are dried and crystallised in a reactor, then extruded into pellets which are further crystallised in a second reactor. Crystallised pellets are then preheated in a third reactor and fed to the solid-state polycondensation (SSP) reactor. Having examined the challenge test provided, the Panel concluded that the drying and crystallisation (step 2), extrusion and crystallisation (step 3) and SSP (step 4) are the critical steps that determine the decontamination efficiency of the process. The operating parameters to control the performance of these critical steps are temperature, gas flow and residence time for the drying and crystallisation step; temperature, pressure and residence time for the extrusion and crystallisation step as well as for the SSP step. It was demonstrated that this recycling process is able to ensure that the level of migration of potential unknown contaminants into food is 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 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. Trays made of this recycled PET are not intended to be used in microwave and conventional ovens and such use is not covered by this evaluation.

Keywords: Starlinger iV+, Poly Recycling AG, food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

Requestor: Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany

Question number: EFSA-Q-2018-01042

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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[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 the European Food Safety Authority (EFSA) for evaluation.

In this case, EFSA received from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany an application for the evaluation of the recycling process Poly Recycling, European Union (EU) register No RECYC171. The request has been registered in the EFSA's register of received questions under the number EFSA-Q-2018-01042. The dossier was submitted on behalf of Poly Recycling AG, Switzerland.

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 Poly Recycling 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.

Additional information was sought from the applicant during the assessment process in response to a request from EFSA sent on 22 March 2019 and was consequently provided (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] Regulation (EC) No 282/2008 of the European parliament and of the council of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006. OJ L 86, 28.3.2008, p. 9–18.

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

2.2. Methodologies

The principles followed 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 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 recycling process Poly Recycling is intended to recycle food grade PET containers to produce recycled PET pellets using the Starlinger iV+ technology. The recycled pellets are intended to be used up to 100% for the manufacture of recycled materials and articles that 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 Poly Recycling produces recycled PET pellets from PET containers of post-consumer collection systems (kerbside and deposit systems as well as mixed waste collection).

The recycling process comprises the four steps below. Step 1 may be performed by a third party or by the applicant.

Input

- In step 1, the post-consumer PET containers are processed into hot caustic washed and dried flakes.

Decontamination and production of recycled PET material

- In step 2, the flakes are dried and crystallised in a reactor under air flow at high temperature.
- In step 3, the flakes are extruded under vacuum at high temperature and then crystallised.
- In step 4, the crystallised pellets are preheated before being treated in a continuous solid-state polycondensation (SSP) reactor at high temperature and under vacuum.

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

The recycled pellets, the final product of the process, are checked against technical requirements, such as intrinsic viscosity, colour and black spots. They are intended to be converted by other companies into recycled articles used for hotfill and/or long-term storage at room temperature, for all types of food. The recycled pellets may be used for bottles or sheets, which are thermoformed to make food trays. They are not intended to be used in microwave and conventional ovens.

3.2.2. Characterisation of the input

According to the applicant, the input material for the recycling process Poly Recycling consists of hot washed and dried flakes obtained from PET containers, mainly bottles previously used for food packaging, from post-consumer collection systems (kerbside and deposit systems as well as mixed waste collection). A small fraction may originate from non-food applications. According to the applicant, its proportion is 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, poly(vinyl chloride) (PVC), polyolefins, other plastics than PET, dust and metals (see Appendix A).

3.3. Starlinger iV+ technology

3.3.1. Description of the main steps

The general scheme of the Starlinger iV+ technology, as provided by the applicant, is reported in Figure 1. In step 1, not reported in the scheme, post-consumer PET containers are processed into hot caustic washed and dried flakes.

- Drying and crystallisation (step 2): In a continuous process, the flakes are dried and crystallised in a reactor at high temperature and under air flow.
- Extrusion and crystallisation (step 3): The flakes from the previous step are fed into an extruder under high temperature and vacuum for a predefined residence time. The extruded pellets are then crystallised at high temperature in a further reactor under atmospheric pressure.
- SSP (step 4): The crystallised pellets are continuously preheated in a reactor before being introduced into the SSP reactor running under vacuum at a predefined high temperature and for a predefined residence time.

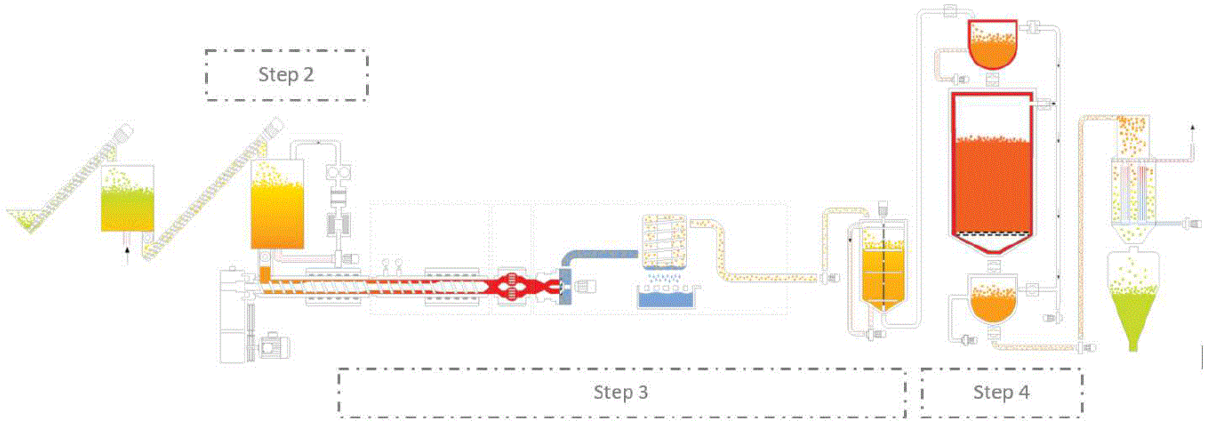


Figure 1: General scheme of the technology (provided by the applicant)

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 Poly Recycling, a challenge test was submitted to the EFSA that was performed in pilot plant scale.

PET flakes were contaminated with toluene, chloroform, phenylcyclohexane, benzophenone and lindane, 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 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).

[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 the European Commission (see Appendix C).

Conventionally recycled[4] post-consumer PET flakes were soaked in a heptane/isopropanol solution containing the surrogates and stored for 14 days at 40°C. The surrogate solution was decanted and PET flakes were rinsed with water and then air-dried. The concentration of surrogates in these flakes was determined.

The Starlinger iV+ technology was challenged in the Starlinger facilities in pilot plant scale and using only contaminated flakes. The contaminated flakes were introduced directly in the drier (step 2), then sampled after each step (2–4) of the process. The samples (flakes then pellets) were analysed for their residual concentrations of the applied surrogates. Instead of being processed continuously, the SSP reaction was run in batch mode. In both batch and continuous modes of operation, the surrogates diffuse through the pellets to the surface and are constantly eliminated by the vacuum applied. Therefore, such continuously working processes will result in the same cleaning efficiencies as batch processes, as long as the same temperature, pressure conditions and residence time are applied.

The decontamination efficiency of the process was calculated from the concentrations of the surrogates in the washed contaminated flakes before drying and crystallisation (before step 2) and after SSP (step 4). The results are summarised below in Table 1.

Table 1: Efficiency of the decontamination by the Starlinger iV+ technology in the challenge test

Surrogates	Concentration of surrogates before step 2 (mg/kg PET)	Concentration of surrogates after step 4 (mg/kg PET)	Decontamination efficiency (%)
Toluene	563	< 0.8[a]	> 99.9
Chloroform	1900	< 0.5[a]	> 99.9
Phenylcyclohexane	538	< 0.3[a]	> 99.9
Benzophenone	694	10.8	98.4
Lindane	373	33.9	90.9

PET: poly(ethylene terephthalate).
(a): Not detected at the limits of detection given

As shown in Table 1, the decontamination efficiency ranged from 90.9% for lindane to more than 99.9% for toluene, chloroform and phenylcyclohexane.

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, polyolefins, other plastics, dust and metals, were provided for the input materials (hot washed and dried flakes, step 1). These are produced from PET containers previously used for food packaging and collected through post-consumer collection systems. However, a small fraction may originate from non-food applications, such as bottles for soap, mouthwash and 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 is 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 well described. The washing and drying of the flakes from the collected PET containers (step 1) is conducted in different ways, depending on the plant, but, according to the applicant, this step is under control. The following steps are those of the Starlinger iV+ technology used to recycle the PET flakes into decontaminated PET pellets: drying and crystallisation (step 2), extrusion and crystallisation (step 3) and SSP (step 4). The operating parameters of temperature, residence time, pressure and gas flow have been provided to EFSA.

A challenge test to measure the decontamination efficiency was conducted at pilot plant scale on process steps 2, 3 and 4 (drying, extrusion and crystallisation and SSP). The operating parameters were at least as severe as those operated for the challenge test. The Panel considered that the challenge test was performed correctly according to the recommendations in the EFSA guidelines (EFSA, 2008). Although the fourth step is expected to be most critical for the decontamination, drying

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

and crystallisation (step 2) and extrusion (step 3) are relevant, too. Therefore, the Panel considered that the three steps (drying and crystallisation, extrusion and crystallisation and SSP) are critical for the decontamination efficiency of the process. Consequently, the temperature, the gas flow and the residence time for the drying and crystallisation (step 2), as well as the temperature, the pressure and the residence time for extrusion and crystallisation (step 3) and SSP (step 4) should be controlled to guarantee the performance of the decontamination. These parameters have been provided to EFSA.

The decontamination efficiencies obtained for each surrogate contaminant from the challenge test, ranging from 90.9% 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).

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. 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 efficiencies 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 after 1 year at 25°C

Surrogates	Decontamination efficiency (%)	C_{res} (mg/kg PET)	C_{mod} (mg/kg PET)
Toluene	> 99.9	< 0.003	0.09
Chloroform	> 99.9	< 0.003	0.10
Phenylcyclohexane	> 99.9	< 0.003	0.14
Benzophenone	98.4	0.048	0.16
Lindane	90.9	0.273	0.31

PET: poly(ethylene terephthalate).

As the residual concentrations (C_{res}) of all surrogates in the decontaminated PET are below the corresponding modelled concentrations in PET (C_{mod}), the Panel concluded that the recycling process using the Starlinger iV+ technology is able to ensure that the migration of unknown contaminants from the recycled PET into food is below the conservatively modelled value of 0.1 μg/kg food, at which the risk to human health is considered negligible.

4. Conclusions

The Panel considered the process Poly Recycling well characterised and that the main steps used to recycle the PET flakes into decontaminated PET pellets have been identified. Having examined the challenge test provided, the Panel concluded that the three steps (drying and crystallisation, extrusion and crystallisation and SSP) are critical for the decontamination efficiency. The operating parameters to control its performance are temperature, gas flow and residence time for the drying and crystallisation (step 2) and temperature, pressure and residence time for extrusion and crystallisation (step 3) and SSP (step 4).

The Panel concluded that the recycling process Poly Recycling 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 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 Poly Recycling 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 in microwave and conventional ovens and such use is not covered by this evaluation.

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 'Poly Recycling'. April 2019. Submitted on behalf of Poly Recycling AG, Switzerland.
2) Additional information, July 2019. Submitted on behalf of Poly recycling AG, Switzerland.

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 (CEF), 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

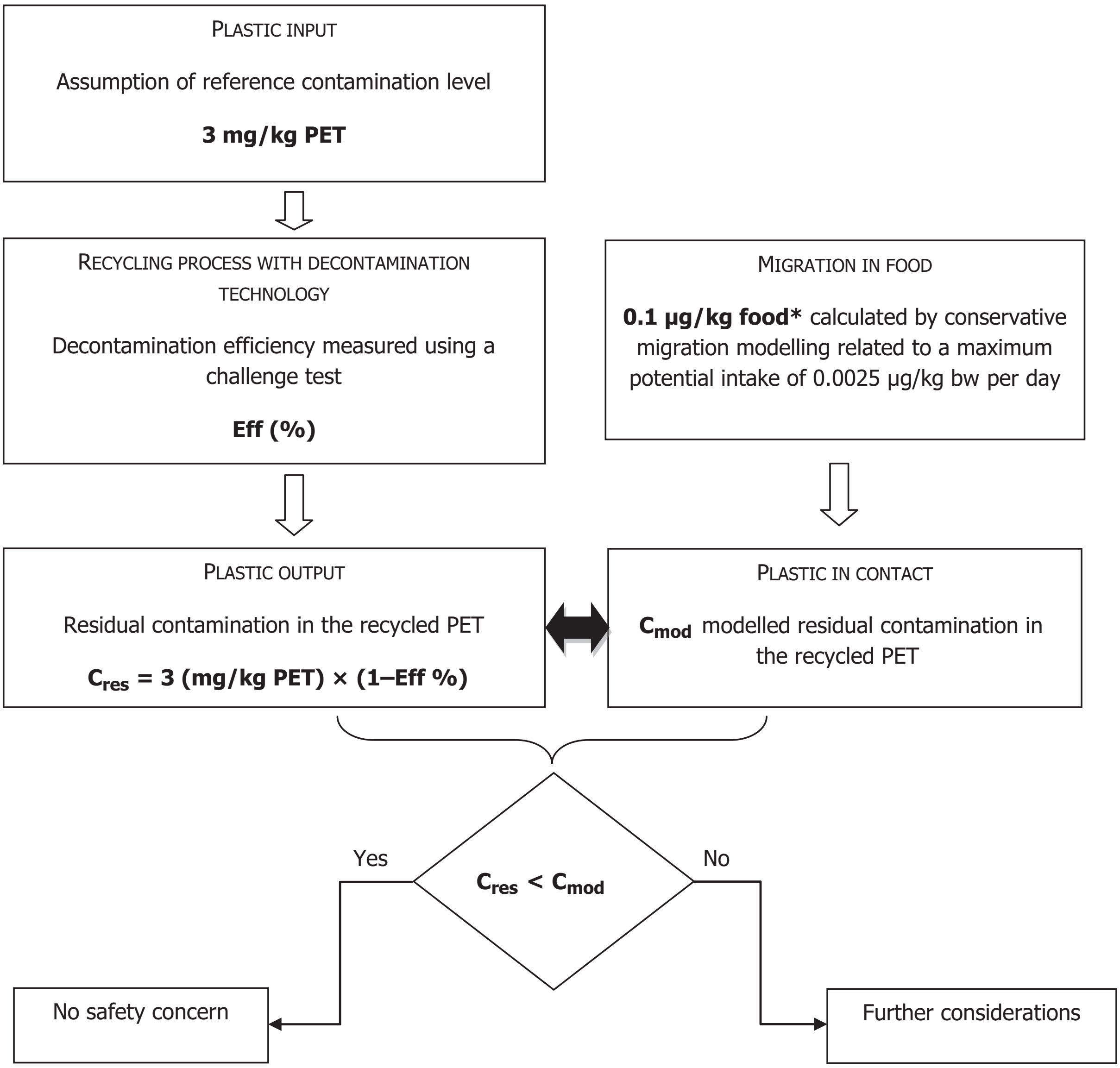
Abbreviations

bw	body weight
CEF	Panel 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 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
PVC content	< 200 mg/kg
Polyolefins content	< 100 mg/kg
Metal content (Aluminium, ferrous, others)	< 200 mg/kg
Other Plastics	< 200 mg/kg
Dust	< 1,5%
Moisture	2.5%
Bulk density	200–600 kg/m^3

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 Operational parameters (Confidential Information)

[redacted]

[redacted]

	[redacted]			[redacted]						[redacted]		
				[redacted]			[redacted]					
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
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