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Safety assessment of the process Arcoplastica, based on the Bandera PURE 15 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 Arcoplastica (EU register number RECYC308), which uses the Bandera PURE15 technology. The input consists of hot caustic washed and dried poly(ethylene terephthalate) (PET) flakes mainly originating from post-consumer PET containers, with no more than 5% PET from non-food consumer applications. The flakes are

Having examined the challenge test provided, the Panel concluded that the

are critical for the decontamination efficiency. 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, including drinking water, for long-term storage at room temperature or below, with or without hotfill. The final 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.

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Table of contents

Abstract.....	1
1. Introduction.....	4
1.1. Background and Terms of Reference.....	4
1.1.1. Background	4
1.1.2. Terms of Reference	4
1.2. Interpretation of the Terms of Reference.....	4
2. Data and Methodologies	4
2.1. Data.....	4
2.2. Methodologies.....	5
3. Assessment.....	6
3.1. General information.....	6
3.2. Description of the process.....	6
3.2.1. General description.....	6
3.2.2. Characterisation of the input	6
3.3. Bandera PRe 15 technology	6
3.3.1. Description of the main steps.....	6
3.3.2. Decontamination efficiency of the recycling process	7
3.4. Discussion	8
4. Conclusions.....	9
5. Recommendation	9
6. Documentation as provided to EFSA	10
References.....	10
Abbreviations	10
Appendix A – Technical data of the washed flakes as provided by the applicant	11
Appendix B – Relationship between the key parameters for the evaluation scheme (EFSA CEF Panel, 2011)	12
Appendix C – Table of operational parameters	13

1. Introduction

1.1. Background and Terms of Reference

1.1.1. Background

Recycled plastic materials and articles shall only be placed on the market if the recycled plastic is from an authorised recycling process. Before a recycling process is authorised, the European Food Safety Authority (EFSA)'s opinion on its safety is required. This procedure has been established in Article 5 of Regulation (EC) No 282/2008^{1,2} on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of Regulation (EC) No 1935/2004³ 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 Italian competent authority (Ministero della Salute), an application for evaluation of the recycling process Arcoplastica, European Union (EU) register No RECYC308. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2022-00471. The dossier was submitted on behalf of Arcoplastica S.r.l., Via Chieri 79/A, 10020 Andezeno (TO), Italy.

1.1.2. Terms of Reference

The Italian competent authority (Ministero della Salute) requested the safety evaluation and the publication of an opinion of the recycling process Arcoplastica, according to the articles 8, 9 and 10 of the Regulation (EC) 1935/2004.

1.2. Interpretation of the Terms of Reference

According to Article 5 of Regulation (EC) No 282/2008 on recycled plastic materials intended to come into contact with foods, EFSA is required to carry out risk assessments on the risks originating from the migration of substances from recycled food contact plastic materials and articles into food and deliver a scientific opinion on the recycling process examined.

According to Article 4 of Regulation (EC) No 282/2008, EFSA will evaluate whether it has been demonstrated in a challenge test, or by other appropriate scientific evidence, that the recycling process Arcoplastica is able to reduce the contamination of the plastic input to a concentration that does not pose a risk to human health. The poly(ethylene terephthalate) (PET) materials and articles used as input of the process as well as the conditions of use of the recycled PET are part of this evaluation.

2. Data and Methodologies

2.1. Data

The applicant has submitted a confidential and a non-confidential version of a dossier following the 'EFSA guidelines for the submission of an application for the safety evaluation of a recycling process to produce recycled plastics intended to be used for the manufacture of materials and articles in contact with food, prior to its authorisation' (EFSA, 2008) and the 'Administrative guidance for the preparation of applications on recycling processes to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food' (EFSA, 2021).

Additional information was sought from the applicant during the assessment process in response to requests from EFSA sent on 15 December 2022 and was subsequently provided (see '[Documentation provided to EFSA](#)').

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 Commission Regulation (EC) No 282/2008 was repealed by Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008 (OJ L 243 20.9.2022, p. 3) which entered into force on 10 October 2022. Applications submitted to EU Member State competent authorities before the date of entry into force of Commission Regulation (EU) 2022/1616 are evaluated by EFSA in accordance with Commission Regulation (EC) No 282/2008.

³ 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.

In accordance with Art. 38 of the Regulation (EC) No 178/2002⁴ and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,⁵ the non-confidential version of the dossier has been published on Open.EFSA.⁶

According to Art. 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations,⁵ EFSA carried out a public consultation on the non-confidential version of the application from 25 July to 15 August 2023, for which no comments were received.

The following information on the recycling process was provided by the applicant and used for the evaluation:

- General information:
 - general description,
 - existing authorisations.
- Specific information:
 - recycling process,
 - characterisation of the input,
 - determination of the decontamination efficiency of the recycling process,
 - characterisation of the recycled plastic,
 - intended application in contact with food,
 - compliance with the relevant provisions on food contact materials and articles,
 - process analysis and evaluation,
 - quality assurance system,
 - operating parameters.

2.2. Methodologies

The risks associated with the use of recycled plastic materials and articles in contact with food come from the possible migration of chemicals into the food in amounts that would endanger human health. The quality of the input, the efficiency of the recycling process to remove contaminants as well as the intended use of the recycled plastic are crucial points for the risk assessment (EFSA, 2008).

The criteria for the safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for the manufacture of materials and articles in contact with food are described in the scientific opinion developed by the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (EFSA CEF Panel, 2011). The principle of the evaluation is to apply the decontamination efficiency of a recycling technology or process, obtained from a challenge test with surrogate contaminants, to a reference contamination level for post-consumer PET, conservatively set at 3 mg/kg PET for contaminants resulting from possible misuse. The resulting residual concentration of each surrogate contaminant in recycled PET (C_{res}) is compared with a modelled concentration of the surrogate contaminants in PET (C_{mod}). This C_{mod} is calculated using generally recognised conservative migration models so that the related migration does not give rise to a dietary exposure exceeding 0.0025 $\mu\text{g}/\text{kg}$ body weight (bw) per day (i.e. the human exposure threshold value for chemicals with structural alerts for genotoxicity), below which the risk to human health would be negligible. If the C_{res} is not higher than the C_{mod} , the recycled PET manufactured by such recycling process is not considered 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.

⁴ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

⁵ Decision available online: <https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements>

⁶ The non-confidential version of the dossier has been published on Open.EFSA and is available at the following link: <https://open.efsa.europa.eu/dossier/FCM-2022-7670>

3. Assessment

3.1. General information⁷

According to the applicant, the recycling process Arcoplastica is intended to recycle food grade PET containers using the Bandera PURE 15 technology. The recycled PET is intended to be used at up to 100% for the manufacture of materials and articles for direct contact with all kinds of foodstuffs, except mineral water, e.g. fruit, vegetables, cooked and uncooked meats, dairy products and desserts, for long-term storage at room temperature. The recycled flakes may be used for sheets thermoformed to make food trays/containers. The final articles are not intended to be used in microwave or conventional ovens.

3.2. Description of the process

3.2.1. General description⁸

The recycling process Arcoplastica produces recycled PET flakes from PET containers from post-consumer collection systems (kerbside and deposit systems). It comprises the two steps below.

Input

- In step 1, post-consumer PET containers are processed into hot caustic washed and dried flakes. This step is performed by third parties.

Decontamination and production of recycled PET material

- In step 2, the flakes are [REDACTED], then decontaminated [REDACTED]

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

Flakes, the final product of the process, are checked against technical requirements, such as intrinsic viscosity, colour and black spots.

3.2.2. Characterisation of the input⁹

According to the applicant, the input material for the recycling process Arcoplastica consists of hot caustic washed and dried flakes obtained from PET containers 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 bottles used for soap, mouth wash or kitchen hygiene agents. According to the applicant, the proportion will be below 5%.

Technical data for the hot washed and dried flakes were provided, such as on physical properties and residual contents of poly(vinyl chloride) (PVC), polyolefins, polyamide, glue, cellulose (paper, wood) and metals (see Appendix A).

3.3. Bandera PURE 15 technology

3.3.1. Description of the main steps¹⁰

The general scheme of the Bandera PURE 15 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.

In the decontamination step 2, the flakes are [REDACTED] introduced [REDACTED]. Then they are [REDACTED]. [REDACTED]. Switching between the two reactors results in a semi-continuous process.

⁷ Technical dossier, section 'Intended application in contact with food'.

⁸ Technical dossier, sections 'Recycling process', 'Characterisation of the input' and 'Characterisation of the recycled plastic'.

⁹ Technical dossier, section 'Characterisation of the input'.

¹⁰ Technical dossier, section 'Recycling process'.

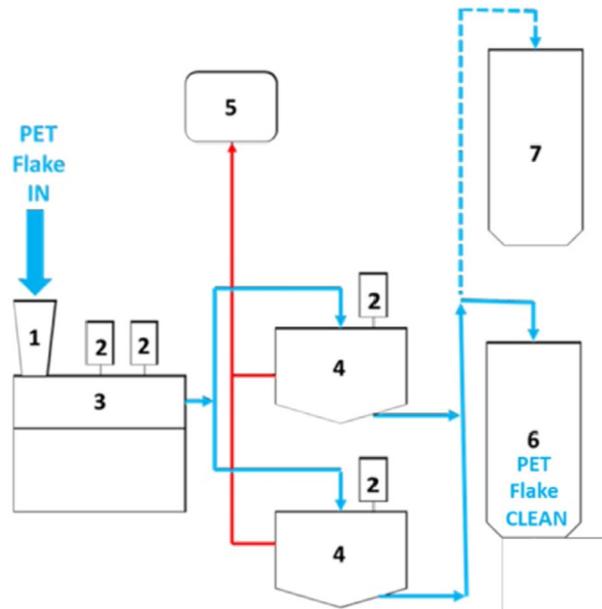


Figure 1: General scheme of the Bandera PURE 15 technology (provided by the applicant): 1 hopper, 2 microwave devices, 3 heating chamber, 4 decontamination reactors, 5 vacuum pump, 6 silo for material complying with the process parameters specified for food contact, 7 silo for material not complying with these parameters

The process is run under defined operating parameters¹¹ of [REDACTED]

3.3.2. Decontamination efficiency of the recycling process¹²

To demonstrate the decontamination efficiency of the recycling process Arcoplastica, a challenge test performed in a small-scale plant was submitted to EFSA.

PET flakes were contaminated with toluene, chlorobenzene, chloroform, 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).

Post-consumer PET flakes (120 kg) were mixed with the surrogates and stored for 7 days at 50°C with continuous mixing. The procedure was repeated six times. After washing, 600 kg of contaminated flakes were introduced into the hopper (feeder). The first 150 kg were discarded, as they served to bring the decontamination process into a steady state.

The decontamination efficiency of the process was calculated from the concentrations of the surrogates measured in the washed contaminated flakes before preheating and after decontamination reactor. The results are summarised in Table 1.

Table 1: Efficiency of the decontamination by the Bandera PURE 15 technology in the challenge test

Surrogates	Concentration of surrogates before step 2 (mg/kg PET)	Concentration of surrogates after step 2 (mg/kg PET)	Decontamination efficiencies (%)
Toluene	563.7	1.7	99.7
Chloroform	165.9	2.5	98.5
Chlorobenzene	699.2	2.1	99.7

¹¹ 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).

¹² Technical dossier, section 'Determination of the decontamination efficiency of the recycling process' and 'Recycling process'.

Surrogates	Concentration of surrogates before step 2 (mg/kg PET)	Concentration of surrogates after step 2 (mg/kg PET)	Decontamination efficiencies (%)
Phenylcyclohexane	362.6	4.0	98.9
Benzophenone	592.5	26.3	95.6
Methyl stearate	569.2	24.9	95.6

PET: poly(ethylene terephthalate).

As shown in Table 1, the decontamination efficiency ranged from 95.6% for benzophenone and methyl stearate to 99.7% for toluene and chlorobenzene.

3.4. Discussion

Considering the high temperatures used during the process, the possibility of contamination by microorganisms can be discounted. Therefore, this evaluation focuses on the chemical safety of the final product.

Technical data, such as on physical properties and residual contents of PVC, polyolefins, polyamide, glue, cellulose (paper, wood) and metals, were provided for the input materials (i.e. hot caustic washed and dried flakes, step 1). The flakes are produced mainly 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 or kitchen hygiene agents. According to the applicant, the collection system and the process are managed in such a way that this fraction will be lower than 5% of the input stream, 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 are conducted by third parties. According to the applicant, this step is under control. In the Bandera PRe 15 recycling technology, the flakes are

are applied. The operating parameters of have been provided to EFSA.

A challenge test to measure the decontamination efficiency was conducted in small plant scale. The Panel considered that it was performed correctly according to the recommendations in the EFSA guidelines (EFSA, 2008). The contaminated flakes were washed before decontamination (step 1). The Panel considered that the step 2 (and) is critical for the decontamination efficiency of the process. The

equivalent to or less severe than those of the commercial process. Consequently, these parameters should be controlled to guarantee the performance of the decontamination (Appendix C).

The decontamination efficiencies obtained for each surrogate, ranging from 95.6% to 99.7%, 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 dietary exposure must not exceed 0.0025 $\mu\text{g}/\text{kg}$ bw per day, below which the risk to human health is considered negligible. The C_{res} value should not exceed the modelled concentration in PET (C_{mod}) that, after 1 year at 25°C, results in a migration giving rise to a dietary exposure of 0.0025 $\mu\text{g}/\text{kg}$ bw per day. The Panel noted that the challenge test resulted in a decontamination efficiency that allows applying the exposure scenario for infants, corresponding to a maximum migration of 0.1 $\mu\text{g}/\text{kg}$ food for 100% recycled PET (Table 2), i.e. for packaging drinking water (which may be used for preparing infant formula). A maximum dietary exposure of 0.0025 $\mu\text{g}/\text{kg}$ bw per day corresponds to a maximum migration of 0.1 $\mu\text{g}/\text{kg}$ into food and 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 (C_{res}) related to the reference contamination level and calculated concentrations of the surrogates in PET (C_{mod}) corresponding to a modelled migration of 0.1 $\mu\text{g}/\text{kg}$ food after 1 year at 25°C

Surrogates	Decontamination efficiencies (%)	C_{res} for 100% rPET (mg/kg PET)	C_{mod} (mg/kg PET)
Toluene	99.7	0.009	0.09
Chloroform	98.5	0.045	0.10
Chlorobenzene	99.7	0.009	0.09
Phenylcyclohexane	98.9	0.033	0.14
Benzophenone	95.6	0.133	0.16
Methyl stearate	95.6	0.131	0.32

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

As the C_{res} values are lower than the corresponding modelled concentrations in PET (C_{mod}), the Panel considered that under the given operating conditions the recycling process Arcoplastica using the Bandera PURE 15 technology is able to ensure that the level of migration of unknown contaminants from the recycled PET into food is below the conservatively modelled migration of 0.1 $\mu\text{g}/\text{kg}$ food. At 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, for long-term storage at room temperature or below, with or without hotfill.

4. Conclusions

The Panel considered that the process Arcoplastica using the Bandera PURE 15 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 the [REDACTED]

[REDACTED] are critical for the decontamination efficiency.

The Panel concluded that the recycling process Arcoplastica 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 less than 5% of PET from non-food consumer applications.
- iii) the recycled PET obtained from the process Arcoplastica is 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 or below, 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. Recommendation

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 as provided to EFSA

Dossier 'Arcoplastica'. July 2022. Submitted on behalf of Arcoplastica S.r.l., Italy.
Additional information, March 2023. Submitted on behalf of Arcoplastica S.r.l., Italy.

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

Abbreviations

bw	body weight
CEF Panel	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP Panel	Panel on Food Contact Materials, Enzymes and Processing Aids
C_{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

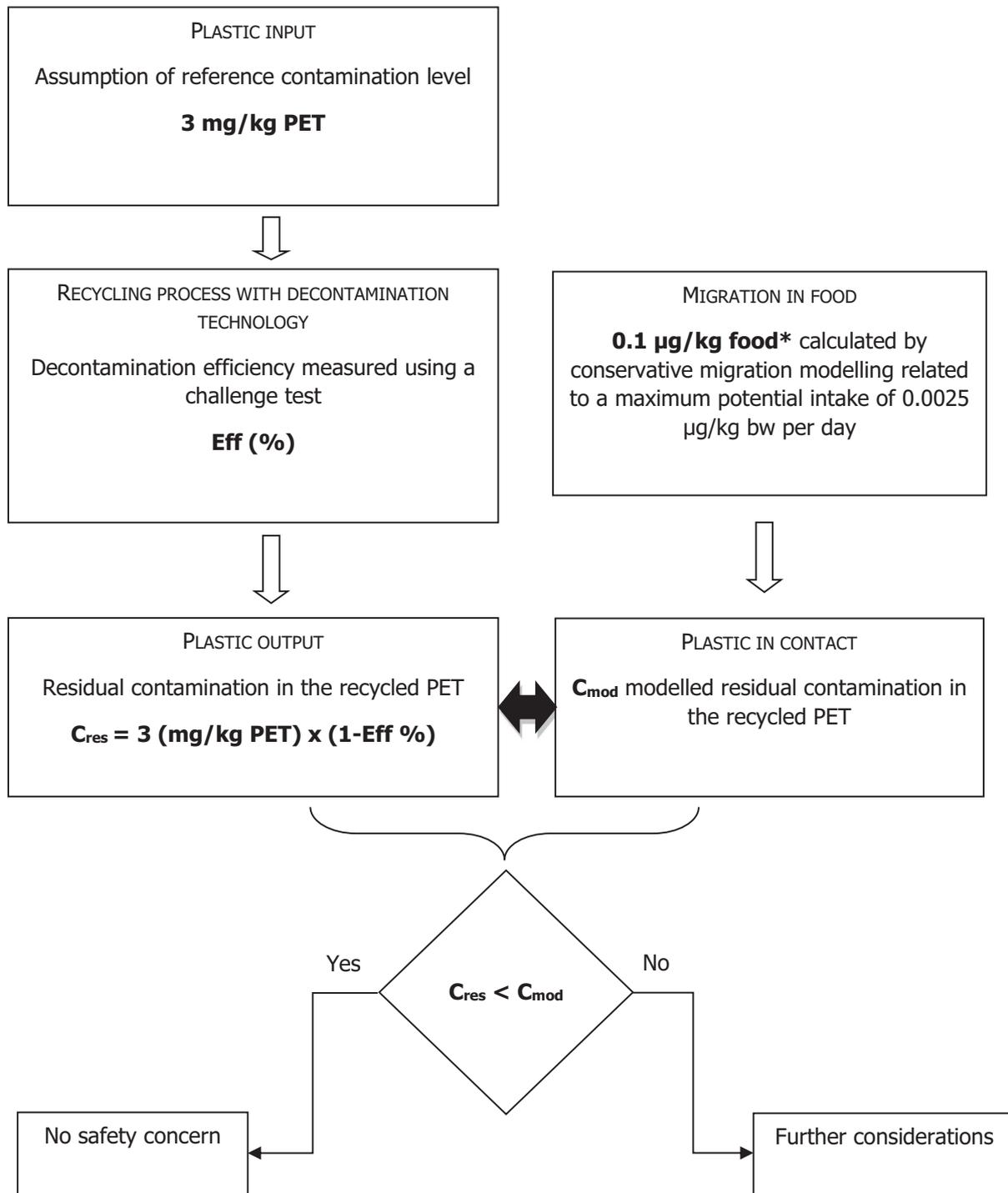
Appendix A – Technical data of the washed flakes as provided by the applicant¹³

Parameter	Value
Moisture max.	1.0%
Moisture variation	± 0.3%
Bulk density	250–500 kg/m ³
Bulk density variation	± 150 kg/m ³
PVC max.	60 mg/kg
Glue max.	100 mg/kg
Polyolefins max.	30 mg/kg
Metal max.	25 mg/kg
Polyamide max.	20 mg/kg
Cellulose (paper, wood)	20 mg/kg

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

¹³ Technical dossier, section 'Characterisation of the input' and 'Quality assurance system'.

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 parameters¹⁴



Process Arcoplastica (RECYC308) based on the Bandera PURE 15 technology

Parameters	Step 2: Decontamination			
	t (min)	P (mbar)*	T (°C)	Air flow rate (m ³ /h)
Challenge test (Fraunhofer report 4964/19)	[REDACTED]		[REDACTED]	[REDACTED]
	[REDACTED] (semi-continuous)	[REDACTED]	[REDACTED]	[REDACTED]
Process	[REDACTED]		[REDACTED]	[REDACTED]
	[REDACTED] (semi-continuous)	[REDACTED]	[REDACTED]	[REDACTED]

*: In the [REDACTED]
 **: [REDACTED] for a throughput of [REDACTED] kg/h (capacity of the [REDACTED] kg PET).
 ***: [REDACTED] for a throughput of [REDACTED] kg/h (capacity of the [REDACTED] kg PET).

¹⁴ Technical dossier, section 'Table of operating parameters'.