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SCIENTIFIC OPINION

Safety assessment of the process EREMA Vacurema Basic used to recycle post-consumer PET into food contact materials

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The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts.

Abstract

The EFSA Panel on Food Contact Materials (FCM) assessed the safety of the recycling process EREMA Vacurema Basic (EU register number RECYC 336). The input is washed and dried poly(ethylene terephthalate) (PET) flakes mainly originating from collected post-consumer PET containers, with below 5% PET from non-food consumer applications. The flakes are heated in a continuous flake reactor (step 2) under vacuum before being extruded. Having examined the challenge test provided, the Panel concluded that step 2 is critical in determining the decontamination efficiency of the process. The operating parameters to control the efficiency are the temperature, the pressure (vacuum) and the residence time. It was demonstrated that this recycling process ensures that the level of migration of potential unknown contaminants into food is below the conservatively modelled migration of 0.0481 or 0.0962 μg/kg food, depending on the molar mass of the contaminant substance. 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, and used for long-term storage at room temperature or below, with or without hot-fill. 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

EREMA Vacurema Basic, food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

CONTENTS

1 | INTRODUCTION

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 Articles 17 and 18 of Commission Regulation (EU) 2022/1616[1] on recycled plastic materials intended to come into contact with foods. More specifically, according to Article 18 of Commission Regulation (EU) 2022/1616 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, to evaluate the microbiological safety of these materials and articles and to deliver a scientific opinion on the recycling process examined.

According to this procedure, the process developers submit applications to the competent authorities of Member States, which transmit the applications to EFSA for evaluation. In this case, EFSA received an application from the Austrian Competent Authority (Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz), for evaluating the recycling process EREMA Vacurema Basic, European Union (EU) register No RECYC 336. The request has been registered in the EFSA's register of received questions under the number EFSA-Q-2024-00670. The dossier was submitted by EREMA Engineering Recycling Maschinen und Anlagen Ges.m.b.H., Unterfeldstraβe 3, 4052 Ansfelden, Austria (see 'Documentation provided to EFSA').

1.2 | Terms of Reference

The Austrian Competent Authority (Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz) requested the safety evaluation of the recycling process EREMA Vacurema Basic, in accordance with Article 17 of Commission Regulation (EU) 2022/1616. The recycling process uses the recycling technology number 1 of the list of suitable recycling technologies of Table 1 of Annex 1 of Commission Regulation (EU) 2022/1616.

2 | DATA AND METHODOLOGIES

2.1 | Data

The applicant submitted a confidential and a non-confidential version of a dossier, following EFSA's 'Scientific Guidance on the criteria for the evaluation and on the preparation of applications for the safety assessment of post-consumer mechanical PET recycling processes intended to be used for manufacture of materials and articles in contact with food' (EFSA CEP Panel, 2024) and EFSA's 'Administrative guidance for the preparation of applications for the authorisation of individual recycling processes to produce recycled plastics materials and articles intended to come into contact with food' (EFSA, 2024).

Additional information was received from the applicant during the assessment process, in response to requests from EFSA sent on 23 June 2025 (see 'Documentation provided to EFSA').

In accordance with Art. 38 of the Regulation (EC) No 178/2002[2] and taking into account the protection of confidential information and the personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of the EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[3] the non-confidential version of the dossier has been published on Open.EFSA.[4]

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, EFSA carried out a public consultation on the non-confidential version of the application from 18 August to 8 September 2025 for which no comments were received.

The following information on the recycling process was provided by the applicant and used for the evaluation (EFSA, 2024; EFSA CEP Panel, 2024):

- Recycling process,
- Determination of the decontamination efficiency of the recycling process,
- Table of operating parameters,
- Self-evaluation of the recycling process.

[1]Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Commission Regulation (EC) No 282/2008. OJ L 243, 20.9.2022, p. 3–46.

[2]Commission 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.

[3]Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements.

[4]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-2024-29770.

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 CEP Panel, 2024).

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 guidance developed by the EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (EFSA CEP Panel, 2024). The principle of the evaluation is to apply the decontamination efficiency of a recycling 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, considering different dietary exposure scenarios (EFSA CEP Panel, 2024). If the C_{res} is not higher than the C_{mod}, the recycled PET manufactured by such recycling process is not considered a safety concern for the defined conditions of use (EFSA CEP Panel, 2024).

The assessment was conducted in line with the principles described in the EFSA Guidance on transparency in the scientific aspects of risk assessment, considering the relevant guidance from the EFSA Scientific Committee (EFSA, 2009).

3 | ASSESSMENT

3.1 | General information[5]

According to the applicant, the recycling process EREMA Vacurema Basic is intended to recycle food-grade PET containers. 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, such as bottles for drinking water and soft drinks (carbonated and non-carbonated) as well as trays and containers for fruits, vegetables, cooked and uncooked meats, dairy products and desserts. The final articles are intended for long-term storage at room temperature. They are not intended to be used in microwave or conventional ovens.

3.2 | Description of the process

3.2.1 | General description[5]

The recycling process EREMA Vacurema Basic produces recycled PET pellets from PET materials originating from post-consumer collection systems.[6]

Input

- In step 1, the post-consumer PET is processed into washed and dried flakes.

Decontamination and production of recycled PET material

The decontamination process comprises the two steps below.

- In step 2, the flakes are decontaminated under high temperature and vacuum;
- In step 3, the decontaminated flakes are extruded to produce pellets.

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

3.2.2 | Characterisation of the preprocessed plastic input[7]

According to the applicant, the input material consists of hot caustic/surfactant-washed and dried flakes obtained from PET materials previously used for food packaging, from post-consumer collection systems.[6] A small fraction may originate

[5]Technical dossier, Section 'Recycling process'.

[6]The collected plastic waste should comply with Art. 6 of Reg. (EU) 2022/1616.

[7]Technical dossier, Section 'Recycling process', subsection 'Collection and pre-processing'.

from non-food applications. According to the applicant, the proportion will be below 5%, as specified in Article 7 and Table 1 of Annex I of Commission Regulation (EU) 2022/1616.

Technical specifications on the washed and dried flakes are provided, such as on physical properties and residual contents of poly(vinyl chloride) (PVC), polyamide (PA), polycarbonate (PC), polyolefin, paper, flakes containing residual glue, metals, moisture, dust and foreign polymer particles including polystyrene (PS) (see Appendix A).

3.3 | EREMA Vacurema Basic process

3.3.1 | Description of the main steps[8]

The process flow diagram, as provided by the applicant, is reported in Figure 1. The steps are:

- Decontamination in a flake reactor (step 2): The flakes are continuously fed into a reactor equipped with a rotating device, running under high temperature and vacuum for an averaged predefined residence time. The flakes are heated [redacted].
- Extrusion of the decontaminated flakes (step 3): The flakes are continuously fed from the previous reactor and molten in the extruder. Residual solid particles (e.g. paper or aluminium) are filtered out before the melt is converted to pellets.

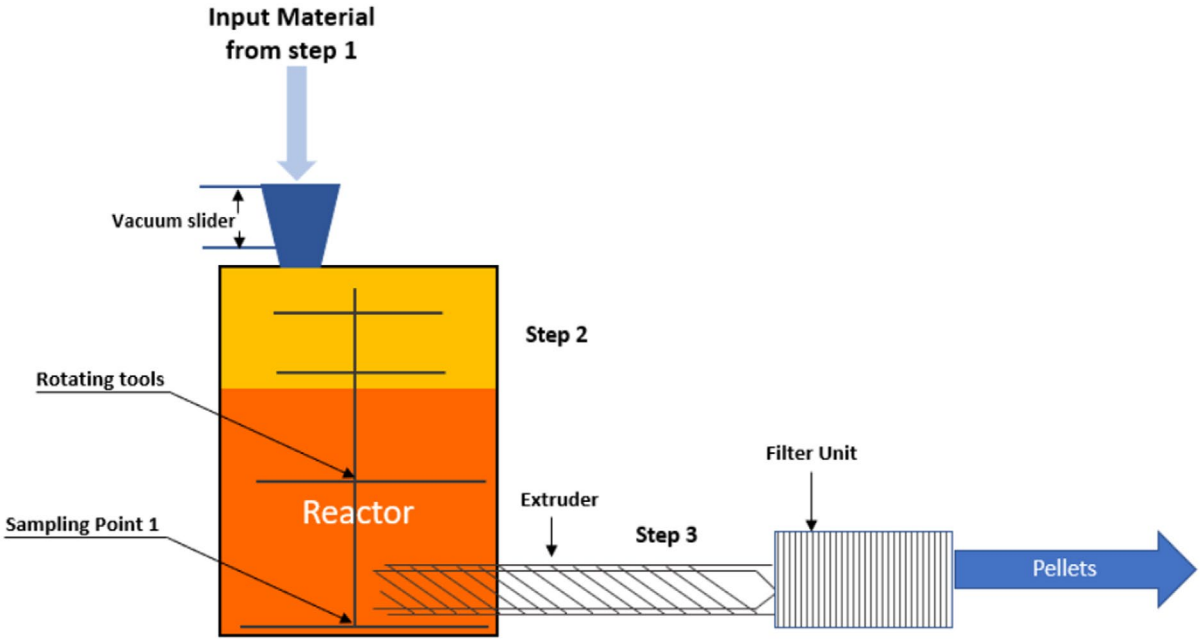

FIGURE 1 Process flow diagram of the EREMA Vacurema Basic process (provided by the applicant).

The process is run under defined operating parameters[9] of temperature, pressure (vacuum) and residence time (Appendix C). All critical parameters are automatically monitored. A dedicated software checks their values and in case of failure, the exiting material is not used for direct food contact applications.[8]

According to the applicant, the pellets, the final product of the process, are checked against technical requirements, such as intrinsic viscosity, black spots, colour, size, bulk density or moisture.[10]

3.3.2 | Decontamination efficiency of the recycling process[11]

To demonstrate the decontamination efficiency of the recycling process EREMA Vacurema Basic, a challenge test performed at pilot-plant scale on step 2 was submitted to the EFSA.

PET flakes were contaminated with toluene, chlorobenzene, methyl salicylate, phenylcyclohexane, benzophenone and methyl stearate, selected as surrogates in agreement with the EFSA Scientific Guidance (EFSA CEP Panel, 2024) and in

[8]Technical dossier, section 'Recycling process', subsection 'Decontamination process'.

[9]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).

[10]Technical dossier, section 'Recycling process', subsection 'Post processing and intended uses'.

[11]Technical dossier, Section 'Determination of the decontamination efficiency of the recycling process'.

accordance with the recommendations of the US Food and Drug Administration (FDA, 2021). A batch of [redacted] kg green PET flakes was divided into [redacted] barrels of about [redacted] kg flakes. [redacted] millilitres of each liquid surrogate and [redacted] g of each solid surrogate were added to each barrel. The barrels were kept at [redacted]°C for [redacted] days with daily agitation. The contaminated flakes were rinsed with 10% ethanol at room temperature to remove surface contamination. After removal of the remaining ethanol by centrifugation, the concentrations of the surrogates were determined in the flakes.

The flake reactor was initially fed with [redacted] kg of non-contaminated colourless flakes. After the process conditions were stabilised, [redacted] kg of contaminated green flakes was introduced as one batch. Samples were taken at the bottom of the reactor at regular intervals. The contaminated (green) flakes were separated from the non-contaminated (colourless) flakes and analysed. Cross-contamination from the contaminated to the non-contaminated flakes was accounted for by assuming a concentration of the surrogates in the non-contaminated flakes of 10% of the concentration in the contaminated ones.

The decontamination efficiencies presented in Table 1 were calculated for the average residence time in the continuous flake reactor (step 2). When surrogates were not detected, the limit of detection was considered for the calculation of the decontamination efficiency.

TABLE 1 Efficiency of the decontamination in the EREMA Vacurema Basic challenge test.

Surrogates	Concentration of surrogates before step 2 (mg/kg PET)	Concentration of surrogates after step 2[a] (mg/kg PET)	Decontamination efficiency[b] (%)
Toluene	243.0	< 0.6	> 99.2
Chlorobenzene	543.5	< 1.6	> 99.0
Methyl salicylate	567.3	< 1.2	> 99.3
Phenylcyclohexane	430.3	4.4	96.4
Benzophenone	779.0	7.1	97.6
Methyl stearate	905.0	6.3	98.0

Abbreviation: PET, poly(ethylene terephthalate).

[a]Residual concentration derived from green flakes after decontamination.

[b]Calculated considering cross-contamination.

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.

Specifications on the input material (i.e. washed and dried flakes, step 1) are listed in Appendix A.

The flakes 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, mouthwash or kitchen hygiene agents. According to the applicant, the collection system and the sorting are managed in such a way that this fraction will be below 5% in the input,[12] as recommended by the EFSA CEP Panel in its Guidance (EFSA CEP Panel, 2024).

The process is adequately described. It comprises the decontamination (step 2) and extrusion (step 3). The operating parameters of temperature, residence time and pressure have been provided to EFSA.

A challenge test to measure the decontamination efficiency was conducted at pilot-plant scale on process step 2. The Panel considered that the pilot plant design resulted in worst-case conditions compared to the process in respect to the decontamination efficiency. The challenge test was conducted under temperature, residence time as well as pressure (vacuum) equivalent to or less severe than those of the commercial process.

The Panel considered that it was performed correctly according to the recommendations of the EFSA Guidance (EFSA CEP Panel, 2024) and that step 2 was critical for the decontamination efficiency of the process. Consequently, the temperature, the residence time and the pressure (vacuum) are to be controlled to guarantee the efficiency of the decontamination.

The decontamination efficiencies obtained for each surrogate, ranging from 96.4% to above 99.3%, have been used to calculate the residual concentrations of potential unknown contaminants in PET (C_{res}). By applying the decontamination efficiency percentage to the reference contamination level of 3 mg/kg PET, the C_{res} values shown in Table 2 were obtained.

According to the evaluation principles (EFSA CEP Panel, 2024), 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, after 1 year at 25°C, results in a migration giving rise to a dietary exposure of 0.0025 μg/kg bw per day. As the recycled PET is intended for the manufacturing of articles (e.g. bottles) to be used in direct contact with drinking water, the exposure scenario for infants has been applied for the calculation of C_{mod} (exposure scenario A; water could be used to prepare infant formula). A maximum dietary exposure of 0.0025 μg/kg bw per day corresponds to a maximum migration of 0.0481 μg/kg (= 5 × 0.00962 μg/kg) or 0.0962 μg/kg (= 10 × 0.00962 μg/kg), depending on the molar

[12]In accordance with Annex I, Table 1 of Regulation 2022/1616.

mass of a contaminant substance[13] into infants' food and has been used to calculate C_{mod} (EFSA CEP Panel, 2024). C_{res} reported in Table 2 is calculated for 100% recycled PET. 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 0.0481 or 0.0962 µg/kg after 1 year at 25°C (C_{mod}).

Surrogates	Decontamination efficiency (%)	C_{res} for 100% rPET (mg/kg PET)	C_{mod} (mg/kg PET) Scenario A
Toluene	> 99.2	0.025	0.04
Chlorobenzene	> 99.0	0.030	0.05
Methyl salicylate	> 99.3	0.022	0.12
Phenylcyclohexane	96.4	0.108	0.13
Benzophenone	97.6	0.071	0.15
Methyl stearate	98.0	0.060	0.29

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

On the basis of the provided data from the challenge test and the applied conservative assumptions, the Panel considered that, under the given operating conditions, the recycling process EREMA Vacurema Basic 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 0.0481 or 0.0962 µg/kg, depending on the molar mass of a contaminant substance into infant's 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 (exposure scenario A), and used for long-term storage at room temperature or below, with or without hot-fill.

4 | CONCLUSIONS

The Panel considered that the process EREMA Vacurema Basic is adequately 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 step 2 is critical for the decontamination efficiency. The parameters to control the process efficiency are the temperature, the residence time and the pressure (vacuum), as specified in Appendix C.

The Panel concluded that the process is capable of reducing 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 below 5% of PET from non-food consumer applications;
(iii) the recycled PET is used at up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs, including drinking water, and used for long-term storage at room temperature or below, with or without hot-fill.

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.

5 | RECOMMENDATION

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 below 5%. This adheres to good manufacturing practice and the Commission Regulation (EU) 2022/1616. 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.

[13]Correction factors of 5 and 10 are applied for contaminants with molecular masses ≤ 150 Da and > 150 Da, respectively (EFSA CEP Panel, 2024).

6 | DOCUMENTATION AS PROVIDED TO EFSA

Dossier EREMA Vacurema Basic. May 2025. Submitted by EREMA Engineering Recycling Maschinen und Anlagen Ges.m.b.H., Austria.

Additional information. September 2025. Submitted by EREMA Engineering Recycling Maschinen und Anlagen Ges.m.b.H., Austria.

ABBREVIATIONS

bw	body weight
CEP	Panel on Food Contact Materials, Enzymes and Processing Aids
C_{mod}	modelled concentration in PET
C_{res}	residual concentration in PET
FCM	food contact materials
PET	poly(ethylene terephthalate)
rPET	recycled poly(ethylene terephthalate)

REQUESTOR

Austrian Competent Authority (Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz).

QUESTION NUMBER

EFSA-Q-2024-00670

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PANEL MEMBERS

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WAIVER

In accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management, a waiver was granted to an expert of the Working Group. Pursuant to Article 21(6) of the aforementioned Decision, the concerned expert was allowed to take part in the preparation and in the discussion of the scientific output but was not allowed to take up the role of rapporteur within that time frame. Any competing interests are recorded in the respective minutes of the meetings of the FCM Panel Working Group on Recycling Plastics.

LEGAL NOTICE

Relevant information or parts of this scientific output have been blackened in accordance with the confidentiality requests formulated by the applicant pending a decision thereon by EFSA. The full output has been shared with the European Commission, EU Member States (if applicable) and the applicant. The blackening may be subject to review once the decision on the confidentiality requests is adopted by EFSA and in case it rejects some of the confidentiality requests.

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APPENDIX A

Specifications of the preprocessed input material* as provided by the applicant.[14]

Parameter	Value
PVC	< 50 mg/kg
PA	< 10 mg/kg
PC	< 25 mg/kg
Polyolefins	< 80 mg/kg
Paper	< 20 mg/kg
Flakes containing residual glue (incl. mass of PET flakes)	< 4000 mg/kg
Metals	< 25 mg/kg
Moisture	< 1%
Bulk density	250–500 kg/m^3
Bulk density variation	50 kg/m^{3}h
PET flake size	3–12 mm
Flake thickness max.	3 mm
Flake content oversized (> 12 mm)	4%
Dust (<0.5 mm)	< 500 ppm
Foreign polymer particles including PS	< 80 ppm

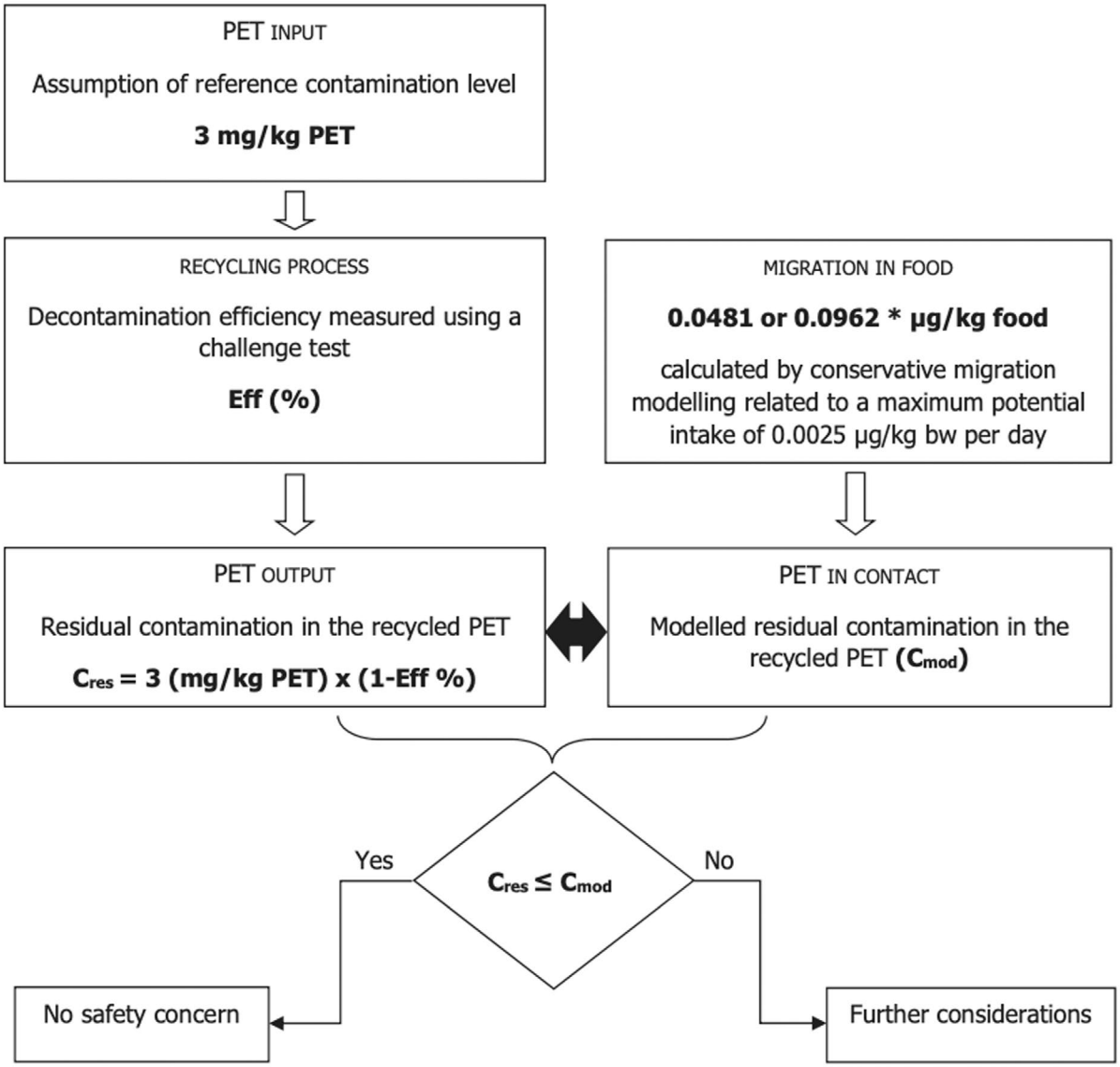
Abbreviations: PA, polyamide; PC, polycarbonate; PS, polystyrene; PVC, poly(vinyl chloride).

*Foreign plastics in the flakes were determined by 'oven testing'.

[14]Technical dossier, Section 'Recycling process', Subsection 'Collection and preprocessing'.

APPENDIX B

Relationship between the key parameters for the evaluation scheme, based on the most conservative scenario A (EFSA CEP Panel, 2024)



*Depending on the molecular mass of the surrogate substance. The figures are derived from the application of the human exposure threshold value of 0.0025 µg/kg bw per day applying the factors of 5 and 10 related to the overestimation of modelling (most conservative Scenario A).

APPENDIX C

Table of operational parameters[15]

Although the operational parameters are reported for all the process steps, the critical steps and the corresponding parameters of the challenge test/process, considered for the evaluation of the process and for which it has been concluded that the process is safe, are highlighted in green.

The process should be operated at conditions at least as severe as the ones indicated in green in the table (e.g. lower pressures are more severe than higher, higher temperatures are more severe than lower, longer times are more severe than shorter, higher gas flows generally are more severe than lower).

The official enforcement control shall verify that the recycling plant is operating in a way that complies with its authorisation. Depending on the technology, some of the parameters are interrelated, and changing one parameter to a more severe value may impact another parameter into a less severe value. Therefore, eventual deviations from the values of the parameters indicated as critical (marked in green in the table) should be demonstrated not to impact significantly on the safety assessment. The table does not necessarily report all the tolerances for the operational parameters.

	Step 2 Decontamination flake reactor			Step 3 Extrusion		
Parameters	***t* (min)**	***P* (mbar)**	***T* (°C)**	***t* (s)**	***P* (mbar)**	***T* (°C)**
Challenge test PA-1328i-22	[redacted] Continuous	[redacted]	[redacted]	Not challenged		
Process EREMA Vacurema Basic	≥ [redacted] Continuous	≤ [redacted]	≥ [redacted]	≥ [redacted] Continuous	< [redacted]	≥ [redacted]

[15]Technical dossier, Sections 'Table of operating Parameters' and 'Recycling process'.