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SCIENTIFIC OPINION

Safety assessment of the process Diamat SC 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 Diamat SC (EU register number RECYC334). The input is hot caustic washed and dried poly(ethylene terephthalate) (PET) flakes mainly originating from collected post-consumer PET containers, with no more than 5% PET from non-food consumer applications. The flakes are crystallised (step 2), dried (step 3) and extruded into sheets (step 4). Having examined the challenge test provided, the Panel concluded that the crystallisation, drying and extrusion steps (steps 2–4) are critical in determining the decontamination efficiency of the process. The operating parameters to control the efficiency of the process are the temperature and the residence time for all steps (steps 2–4), the air flow rate for step 3, the pressure and the characteristics of the extruder (step 4). 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 a 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, 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

Diamat GmbH, Diamat SC, 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 German competent authority (Federal Office of Consumer Protection and Food Safety), for evaluating the recycling process Diamat SC, European Union (EU) register No RECYC334. The request has been registered in the EFSA's register of received questions under the number EFSA-Q-2023-00393. The dossier was submitted on behalf of Diamat GmbH, Sinbronn-Amperestrasse 13 D-91550 Dinkelsbühl, Germany (see 'Documentation provided to EFSA').

1.2 | Terms of Reference

The German competent authority (Federal Office of Consumer Protection and Food Safety) requested the safety evaluation of the recycling process Diamat SC in compliance 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 25 June 2024 and on 16 April 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,[4] EFSA carried out a public consultation on the non-confidential version of the application from 12 July to 02 August 2024, 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-2023-16622.

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 of 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 Diamat SC 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 fruits and vegetables, eggs, meat, fish, dairy products and drinking water. The final articles are intended for long-term storage at room temperature or below, with or without hot-fill. The final articles are not intended to be used in microwave or conventional ovens.

3.2 | Description of the process

3.2.1 | General description[6]

The recycling process Diamat SC produces recycled PET sheets from PET materials originating from post-consumer collection systems.

Input

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

Decontamination and production of recycled PET material.

The decontamination process comprises the three steps below.

- In step 2, the flakes are crystallised.
- In step 3, the flakes are dried.
- In step 4, the flakes are melted and processed into sheets.

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

[5]Technical dossier, section 'Intended application in contact with food'.

[6]Technical dossier, sections 'Recycling process', 'Characterisation of the input' and 'Characterisation of the recycled plastic'.

3.2.2 | Characterisation of the preprocessed plastic input[7]

According to the applicant, the input material consists of hot caustic washed and dried flakes obtained from PET materials, e.g. bottles, previously used for food packaging, from post-consumer collection systems.[8] A small fraction may originate from non-food applications. According to the applicant, the proportion will be no more than 5%, as specified in Article 7 and Table 1 of Annex I of Commission Regulation (EU) 2022/1616.

Technical specifications on the hot washed and dried flakes are provided, such as on physical properties and residual contents of moisture, poly(vinyl chloride) (PVC), polyamide (PA), polyolefins, polycarbonate (PC), polystyrene (PS), glue, cellulose and metals (see Appendix A).

3.3 | Diamat SC process

3.3.1 | Description of the main steps[9]

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

- Crystallisation (step 2): The washed and dried flakes are introduced into a crystallisation tank, where the flakes are [redacted] for a predefined residence time.
- Drying (step 3): The flakes from the previous step are dried in a continuous reactor under [redacted] air flow [redacted].
- Extrusion (step 4): The dried flakes are continuously processed [redacted] in an extruder generating [redacted] melt exposed to vacuum [redacted]. The melted material is then transformed into sheets.

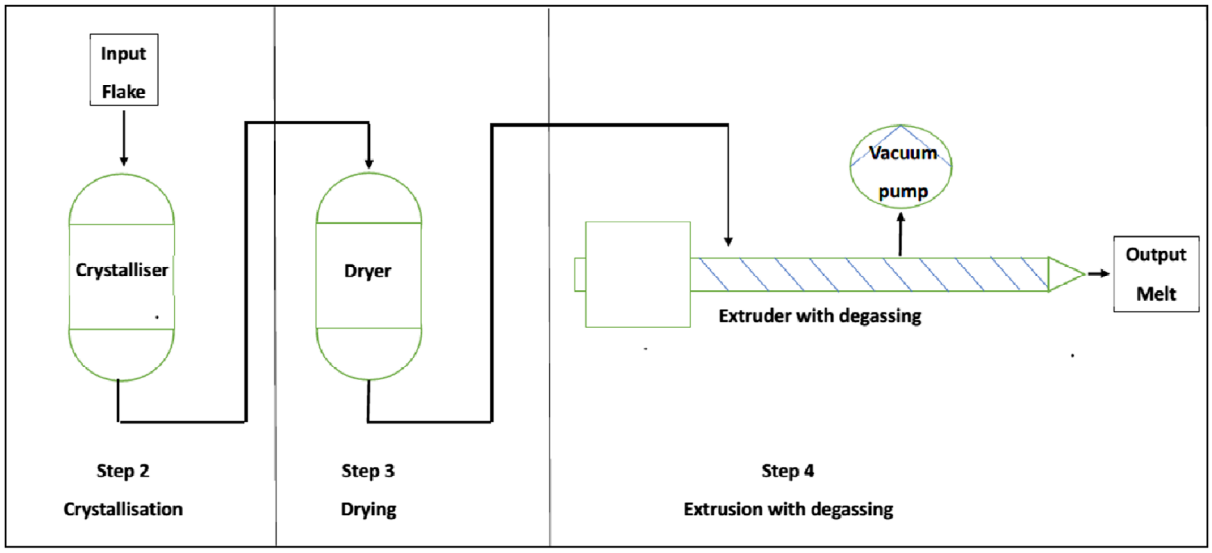

FIGURE 1 Process flow diagram of Diamat SC (provided by the applicant).

The process is run under defined operating parameters[10] of temperature, air flow rate (expressed as air/PET ratio in m^3 air/kg PET), pressure and residence time. All the parameters are automatically monitored. In case these parameters deviate from predefined threshold values, the produced material is labelled as not valid for direct food contact applications.[11]

According to the applicant, the extruded sheets, the final product of the process, are checked against technical requirements, such as intrinsic viscosity, transparency and clarity.[12]

[7]Technical dossier, section 'Characterisation of the input'.

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

[9]Technical dossier, sections 'Recycling process' and 'Determination of the decontamination efficiency of the recycling process'.

[10]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).

[11]Technical dossier, Sections 'Recycling process', 'Process analysis and evaluation' and 'Quality Assurance System'.

[12]Technical dossier, Section 'Characterisation of the recycled plastic'.

3.3.2 | Decontamination efficiency of the recycling process[13]

To demonstrate the decontamination efficiency of the recycling process, a challenge test performed at industrial scale on steps 2–4 was submitted to the EFSA. Step 4 was run at a throughput reduced to half while applying vacuum to only one of the two venting zones.

PET flakes were contaminated with toluene, chlorobenzene, chloroform, methyl salicylate, phenyl cyclohexane, benzophenone and methyl stearate, selected as surrogates in agreement with the EFSA Scientific Guidance (EFSA CEP Panel, 2024) and in accordance with the recommendations of the US Food and Drug Administration (FDA, 2021).

A batch of 200 kg PET flakes was divided into 10 barrels of 20 kg flakes each, to which 20 mL of the surrogate mixture was added. The barrels were kept at 50°C for 7 days with periodical agitation. The contaminated flakes were then rinsed with 10% ethanol. After the removal of the remaining 10% ethanol, the concentrations of the surrogates were determined.

The decontamination efficiency was calculated from the concentration differences of the surrogate substances in the flakes sampled before crystallisation (step 2) and in the sheets after extrusion (step 4). The results are summarised in Table 1.

TABLE 1 Efficiency of the decontamination of the Diamat SC process 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	403.5	0.3[a]	99.9
Chlorobenzene	699.2	0.6	99.9
Chloroform	148.3	0.7[a]	99.5
Methyl salicylate	855.8	0.3[a]	> 99.9[b]
Phenyl cyclohexane	720.1	2.7	99.6
Benzophenone	783.1	37.6[a]	95.2
Methyl stearate	831.3	21.4[a]	97.4

Abbreviations: PET, poly(ethylene terephthalate).

[a]Data corrected by the Panel taking into account the recovery.

[b]The Panel noted that methyl salicylate is likely to be unstable under the extrusion conditions.

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 no more than 5% in the input stream, as recommended by the EFSA CEP Panel in its Guidance (EFSA CEP Panel, 2024).

The Diamat SC process is adequately described. It comprises crystallisation (step 2), drying (step 3) and extrusion (step 4). The operating parameters of temperature, residence time, air flow rate and pressure have been provided to EFSA.

A challenge test to measure the decontamination efficiency was conducted at industrial scale on process steps 2–4. The Panel considered that it was performed correctly according to the recommendations of the EFSA Guidance (EFSA CEP Panel, 2024). The installation was operated under residence time, air flow, pressure and temperature conditions equivalent to those of the commercial process. Step 4 was run at a throughput reduced to half while applying vacuum to only one of the two venting zones. The Panel considered that it adequately represents the process conditions. Consequently, the pressure, the air flow rate, the temperature, the residence time (steps 2–4) and the characteristics of the extruder specified in Appendix C are to be controlled to guarantee the efficiency of the decontamination.

The decontamination efficiencies obtained for each surrogate, ranging from 95.2% to 99.9%, 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 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

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

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 mass of a contaminant substance[14] 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

TABLE 2 Decontamination efficiency 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 μg/kg 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	99.9	0.002	0.04
Chlorobenzene	99.9	0.003	0.05
Chloroform	99.5	0.01	0.05
Phenyl cyclohexane	99.6	0.01	0.13
Benzophenone	95.2	0.14	0.15
Methyl stearate	97.4	0.08	0.29

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

the key parameters for the evaluation scheme is reported in Appendix B.

On the basis of the provided data from the challenge test and the applied conservative assumptions, the Panel considered that, under the given operating conditions, the recycling process 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), for long-term storage at room temperature or below, with or without hot-fill.

4 | CONCLUSIONS

The Panel considered that the process Diamat SC is adequately characterised and that the main steps used to recycle the PET flakes into decontaminated PET material have been identified. Having examined the challenge test provided, the Panel concluded that the three steps (crystallisation, drying and extrusion) are critical for the decontamination efficiency. The parameters to control the process efficiency are the air flow rate (air/PET ratio), the pressure, the temperature, the residence time as well as the geometrical and operational characteristics of the extruder specified in Appendix C.

The Panel concluded that the recycling process Diamat SC 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 no more than 5% of PET from non-food consumer applications;
(iii) the recycled PET obtained from the process Diamat SC 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 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 no more than 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.

[14]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 PROVIDED TO EFSA

Dossier 'Diamat SC'. January 2024. Submitted on behalf of Diamat GmbH., Germany.
Additional information, February 2025. Submitted on behalf of Diamat GmbH., Germany.
Additional information, June 2025. Submitted on behalf of Diamat GmbH., Germany.

ABBREVIATIONS

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

REQUESTOR

German competent authority (Federal Office of Consumer Protection and Food Safety)

QUESTION NUMBER

EFSA-Q-2023-00393

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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 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.

REFERENCES

EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids). (2024). 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 Journal*, *22*(7), 8879. https://doi.org/10.2903/j.efsa.2024.8879

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APPENDIX A

Specifications of the preprocessed input material as provided by the applicant[15]

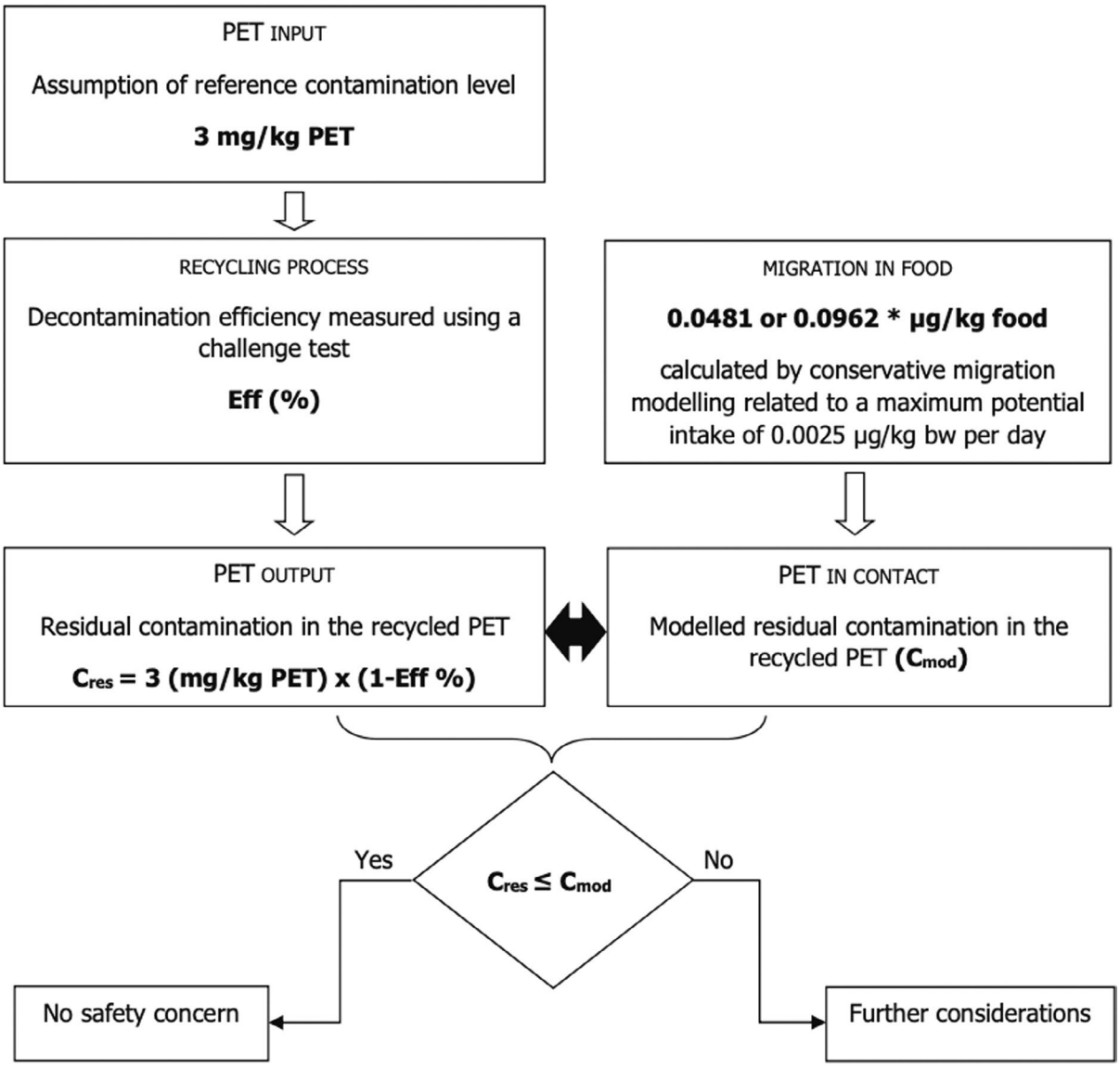
Parameter	Value
Moisture	≤ 1%
Bulk density	250–700 kg/m^3
PVC	≤ 100 mg/kg
Polyolefins	≤ 300 mg/kg
PA	≤ 100 mg/kg
PC	≤ 100 mg/kg
PS	≤ 100 mg/kg
Glue	≤ 100 mg/kg
Cellulose (paper, wood)	≤ 100 mg/kg
Metals	≤ 100 mg/kg

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

[15]Technical dossier, Section 'Characterisation of the input'.

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[16]

[redacted]

Process Diamat SC (RECYC334)	Step 2 (crystallisation)			Step 3 (drying)				Step 4 (extrusion)**		
	t (min)	*P* (mbar)	*T* (°C)	*t* (min)	*P* (mbar)	*T* (°C)	Air/PET ratio (m^3 air/kg PET)	*t* (s)	*P* (mbar)	*T* (°C)
Challenge test (PA/1812/23)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]*	[redacted]	[redacted]	[redacted]
	Continuous			Continuous				Continuous		
Process	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Continuous			Continuous				Continuous		

* [redacted]

** Characteristics of the extruder.

	Challenge test	Industrial process
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

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