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SCIENTIFIC OPINION

Safety assessment of the process ENPLATER, based on the Kreyenborg IR clean+ 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 ENPLATER (EU register number RECYC316), which uses the Kreyenborg IR Clean+ technology. The input material is hot caustic washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, e.g. bottles, with no more than 5% PET from non-food consumer applications. The flakes are heated in a continuous IR dryer (step 2) before being processed in a finisher reactor (step 3). Having examined the challenge test provided, the Panel concluded that step 2 and step 3 are critical in determining the decontamination efficiency of the process. The operating parameters to control the performance of these critical steps are temperature, air/PET ratio and residence time. 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 0.10 and 0.15 μg/kg food, derived from the exposure scenario for infants and toddlers, respectively, when such recycled PET is used at up to 100%. Therefore, the Panel concluded that the recycled PET obtained from this process is not considered to be 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. 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

ENVASES PLASTICOS DEL TER, food contact materials, Kreyenborg IR Clean+, plastic, poly(ethylene terephthalate) (PET), recycling process, S.A., safety assessment

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CONTENTS

Abstract 1
1. Introduction 3
1.1. Background and Terms of Reference 3
1.1.1. Background 3
1.1.2. Terms of Reference 3
1.2. Interpretation of the Terms of Reference 3
2. Data and methodologies 3
2.1. Data 3
2.2. Methodologies 4
3. Assessment 4
3.1. General information 4
3.2. Description of the process 5
3.2.1. General description 5
3.2.2. Characterisation of the input 5
3.3. Kreyenborg IR clean+ technology 5
3.3.1. Description of the main steps 5
3.3.2. Decontamination efficiency of the recycling process 6
3.4. Discussion 7
4. Conclusions 8
5. Recommendations 8
6. Documentation provided to EFSA 8
Abbreviations 9
Conflict of interest 9
Requestor 9
Question number 9
Copyright for non-EFSA content 9
Panel members 9
Legal notice 9
References 9
Appendix A 10
Appendix B 11
Appendix C 12

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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 1935/2004[3] 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 an application from the Ministerio de Consumo, Spain for evaluation of the recycling process ENPLATER, European Union (EU) register No RECYC316. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2022-00744. The dossier was submitted on behalf of ENVASES PLASTICOS DEL TER, S.A., Caarrer de la Industrie 1, 17,257 Torroella de Montgri, Spain (see 'Documentation provided to EFSA').

1.1.2 | Terms of Reference

The Ministerio de Consumo, Spain, requested the safety evaluation of the recycling process ENPLATER, in compliance with Article 5 of Regulation (EC) No 282/2008.

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 ENPLATER 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 provided by the applicant during the assessment process in response to a request from EFSA sent on 15 June 2023 (see 'Documentation provided to EFSA').

In accordance with Art. 38 of the Commission Regulation (EC) No 178/2002[4] 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

[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.

[4]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.

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Decision of the EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[5] the non-confidential version of the dossier is 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 4 January to 25 January 2024 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,
  - 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 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 to be 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[7]

According to the applicant, the recycling process ENPLATER is intended to recycle food grade PET containers using the Kreyenborg IR Clean+ technology. The recycled PET is intended to be used at up to 100% for food contact applications, e.g. for fruits, vegetables, cooked and uncooked meat, dairy products and desserts, with or without hotfill. It is not intended to be used for packaging drinking water. The final articles are not intended to be used in microwave or conventional ovens.

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

[6]The non-confidential version of the dossier, following EFSA's assessment of the applicant's confidentiality requests, is published on Open.EFSA and is available at the following link: https://open.efsa.europa.eu/dossier/FCM-2022-8171

[7]Technical dossier, section 'Recycling process'.

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3.2 | Description of the process

3.2.1 | General description[8]

The recycling process ENPLATER produces recycled PET flakes from PET containers from post-consumer collection systems (kerbside and deposit systems).

The recycling process comprises the three steps below.

Input

- In step 1, the post-consumer PET containers are processed into 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] and decontaminated by means of an infrared (IR) [redacted] dryer under airflow, [redacted]
- In step 3, the flakes are further decontaminated in a finisher reactor under [redacted] air flow and [redacted] temperature.

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 input[9]

According to the applicant, the input material for the recycling process ENPLATER consists of hot caustic washed and dried flakes obtained from PET containers, e.g. bottles, previously used for food packaging, from post-consumer collection systems (kerbside and deposit systems). A small fraction may originate from non-food applications. According to the applicant, the proportion will be no more than 5%.

Technical specifications 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), glue, polyamide, polyolefins, cellulose and metals (see Appendix A).

3.3 | Kreyenborg IR clean+ technology

3.3.1 | Description of the main steps[10]

The general scheme of the Kreyenborg IR Clean+ technology, as provided by the applicant, is reported in Figure 1. Washed and air-dried flakes from step 1 are used as input to the next two steps, which are:

- Decontamination by means of an IR dryer (step 2):

  The flakes are continuously fed into a dryer where they are treated by IR radiation under defined conditions of air flow, temperature and residence time.

- Decontamination of the flakes in a finisher reactor (step 3):

  The flakes from the IR dryer are continuously introduce™d into the finisher reactor under defined conditions of [redacted] air flow, temperature and residence time.

[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, sections 'Recycling process' and 'Determination of the decontamination efficiency of the recycling process'.

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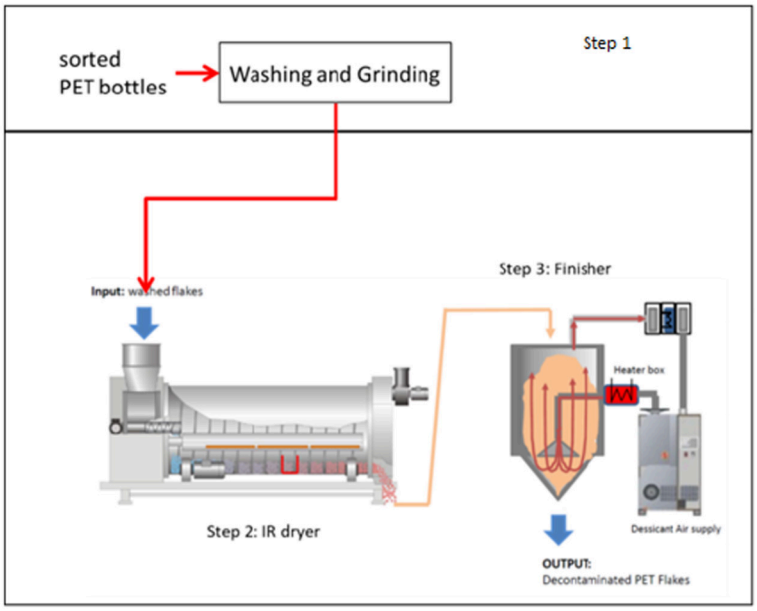

FIGURE 1 General scheme of the Kreyenborg IR Clean+ technology (provided by the applicant).

The process is run under defined operating parameters[11] of temperature, air/PET ratio and residence time.

3.3.2 | Decontamination efficiency of the recycling process[12]

To demonstrate the decontamination efficiency of the recycling process ENPLATER, a challenge test on steps 2 and 3 was submitted to EFSA.

PET flakes were contaminated with toluene, chlorobenzene, phenylcyclohexane, chloroform, methyl salicylate, 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).

A mixture of solid surrogates (benzophenone and methyl stearate) and liquid surrogates (toluene, chlorobenzene, chloroform, methyl salicylate and phenylcyclohexane) was added in a barrel to 25 kg of conventionally recycled[13] post-consumer PET flakes. Four such barrels were prepared and stored for 7 days at 50°C with periodical agitation. Afterwards, the contaminated flakes were rinsed with 10% ethanol and air-dried. For each batch, the concentration of surrogates was determined, before and after air-drying. The barrels were merged into one batch of 100 kg.

Steps 2 and 3 of the Kreyenborg IR Clean+ technology were challenged at a production plant scale. To process a sufficiently large amount of material compatible with the high capacity of the continuous industrial plant, the IR dryer was initially fed with blue non-contaminated flakes and, after process conditions were reached, with the 100 kg contaminated, colourless flakes. These were continuously fed into the IR dryer (step 2) and subsequently into the finisher reactor (step 3). The colourless flakes were sampled after step 3 to measure the residual concentrations of the applied surrogates. The decontamination efficiency of the process was calculated from the concentrations of the surrogates measured in the air-dried contaminated flakes before entering the IR dryer (step 2) and after exiting the finisher reactor (step 3). The results are summarised in Table 1.

[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'.

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

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TABLE 1 Efficiency of the decontamination of the Kreyenborg IR Clean+ technology in the challenge test.

Surrogates	Concentration[a] of surrogates before step 2 (mg/kg PET)	Concentration[b] of surrogates after step 3 (mg/kg PET)	Decontamination efficiency (%)
Toluene	162.7	< 0.1	> 99.9
Chlorobenzene	330.8	1.4	99.6
Chloroform	113.7	1.1	99.0
Methyl salicylate	411.4	4.3	99.0
Phenylcyclohexane	294.5	6.6	97.8
Benzophenone	617.1	30.7	95.0
Methyl stearate	798.3	31.7	96.0

Abbreviation: PET, poly(ethylene terephthalate).

[a]Initial concentration in the contaminated air-dried PET flakes.

[b]Residual concentration measured in the colourless flakes after decontamination.

As shown in Table 1, the decontamination efficiency ranged from 95.0% for benzophenone up to > 99.9% for toluene.

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 on residual contents of moisture, poly(vinyl chloride) (PVC), glue, polyamide, polyolefins, cellulose and metals, were provided for the input materials (i.e. washed and dried flakes, step 1). 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, mouth wash 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 no more than 5% in 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 the 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 containers (step 1) is conducted in different conditions depending on the plant and, according to the applicant, this step is under control. The Kreyenborg IR Clean+ technology comprises the IR dryer (step 2) and the finisher reactor (step 3). The operating parameters of temperature, residence time and air/PET ratio have been provided to EFSA.

A challenge test to measure the decontamination efficiency was conducted at industrial plant scale on process steps 2 and 3. The IR dryer (step 2) and the finisher reactor (step 3) were operated in continuous mode under air flow and temperature conditions equivalent to or less severe than those of the commercial process. The Panel considered that this challenge test was performed correctly according to the recommendations of the EFSA guidelines (EFSA, 2008). The Panel considered that steps 2 and 3 were critical for the decontamination efficiency of the process. Consequently, temperature, residence time and air/PET ratio should be controlled to guarantee the performance of the decontamination (Appendix C).

The decontamination efficiencies obtained for each surrogate, ranging from 95.0% to > 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 efficiency percentage 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 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. Because the recycled PET is intended to manufacture trays and containers, not to pack water, the exposure scenario for toddlers has been applied. A maximum dietary exposure of 0.0025 µg/kg bw per day corresponds to a maximum migration of 0.15 µg/kg of the contaminant into the toddler's food has been used to calculate C_{mod} (EFSA CEF Panel, 2011). The results of these calculations are shown in Table 2. C_{res} reported in Table 2 is calculated for 100% recycled PET, for which the risk to human health is demonstrated to be negligible.

The Panel noted that benzophenone was close to the limit, but considering the conservative assumption made in the calculation of the C_{mod}, the process results in a decontamination efficiency that would allow for the application of the exposure scenario for infants, corresponding to a maximum migration of 0.1 µg/kg food, for 100% recycled PET (Table 2), i.e. for packaging drinking water (which may be used for preparing infant formula). The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

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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 0.1 and 0.15 μg/kg food (infant and toddler scenario, respectively) after 1 year at 25°C.

Surrogates	Decontamination efficiency (%)	C_{res} for 100% rPET (mg/kg PET)	C_{mod} (mg/kg PET); infant scenario	C_{mod} (mg/kg PET); toddler scenario
Toluene	> 99.9	< 0.01	0.09	0.13
Chlorobenzene	99.6	0.01	0.09	0.15
Chloroform	99.0	0.03	0.10	0.15
Methyl salicylate	99.0	0.03	0.13	0.20
Phenylcyclohexane	97.8	0.07	0.14	0.21
Benzophenone	95.0	0.15	0.16	0.24
Methyl stearate	96.0	0.12	0.32	0.47

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, Panel concluded that, under the given operating conditions, the recycling process ENPLATER using the Kreyenborg IR Clean+ technology is able to ensure that the level of migration of unknown contaminants from the recycled PET into food is below the conservatively modelled migrations of 0.10 and 0.15 μg/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.

4 | CONCLUSIONS

The Panel considered that the process ENPLATER using the Kreyenborg IR Clean+ 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 temperature, residence time and air/PETratio of the IR dryer (step 2) and the finisher reactor (step 3) are critical for the decontamination efficiency.

The Panel concluded that the recycling process ENPLATER 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 no more than 5% of PET from non-food consumer applications;
(iii) The recycled PET obtained from the process ENPLATER is 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 or below, with or without hotfill. It may also be used for drinking water.

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 | RECOMMENDATIONS

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 PROVIDED TO EFSA

Dossier 'ENPLATER'. August 2022. Submitted on behalf of ENVASES PLASTICOS DEL TER, S.A., Spain.
Additional information, June 2023. Submitted on behalf of ENVASES PLASTICOS DEL TER, S.A., Spain.

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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
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)
rPET	recycled poly(ethylene terephthalate)

CONFLICT OF INTEREST

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REQUESTOR

Ministerio de Consumo, Spain.

QUESTION NUMBER

EFSA-Q-2022-00744

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[†]Deceased.

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APPENDIX A

Technical data of the washed flakes as provided by the applicant [14]

Parameter	Value
Moisture max.	1.0%
Moisture variation	± 0.3%
Bulk density	270–350 kg/m^3
Bulk density variation	± 150 kg/m^3/h
Material temperature	5–40°C
Material temperature variation	± 10°C/h
PVC max.	100 mg/kg
Glue max.	100 mg/kg (inclusive flakes)
Polyolefins max.	100 mg/kg
Cellulose (paper, wood)	100 mg/kg
Metals max.	50 mg/kg
Polyamide max.	50 mg/kg

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

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

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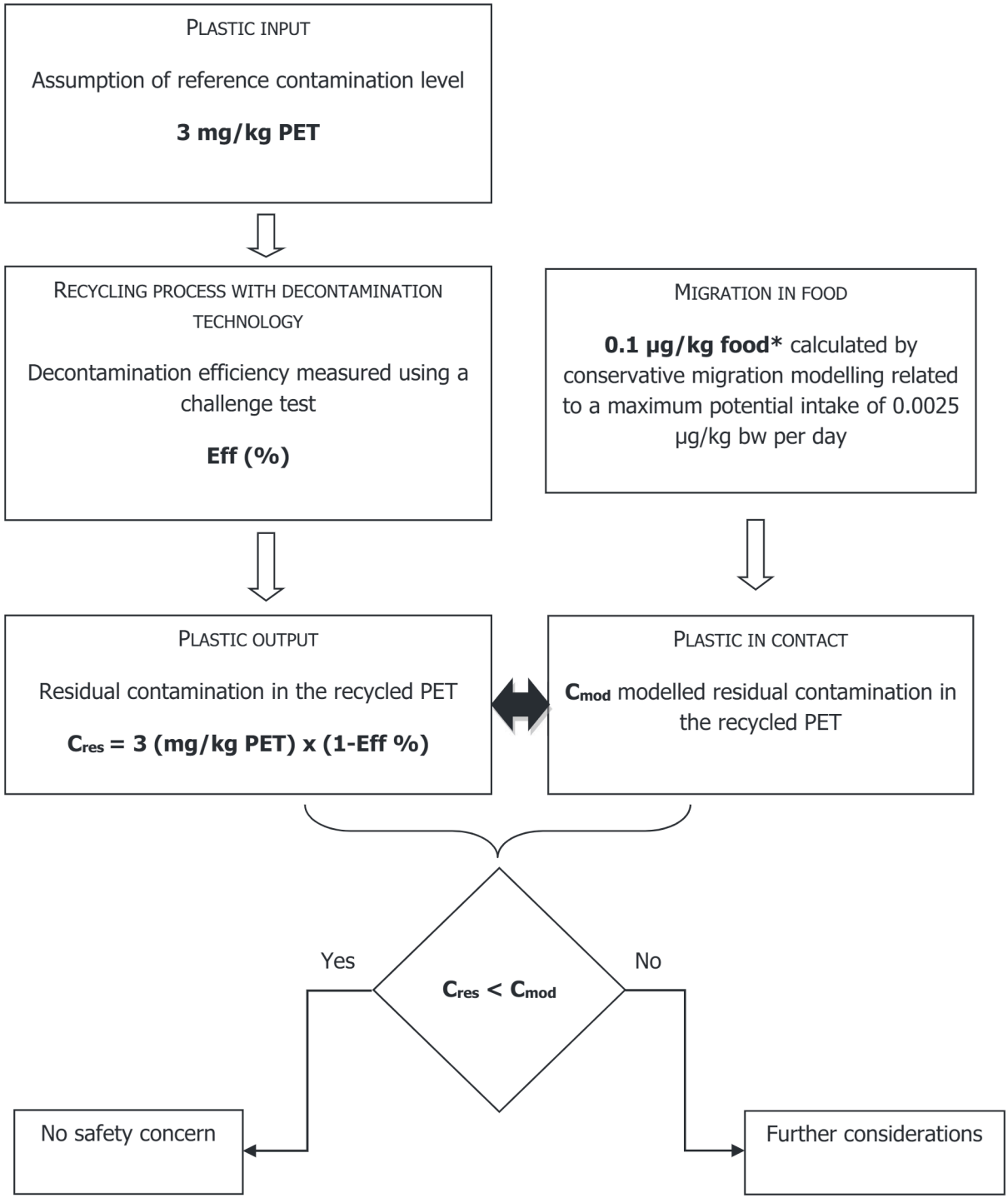
APPENDIX B

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.

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APPENDIX C

Table of operational parameters[15]

[redacted]

	Process ENPLATER (RECYC316) based on the Kreyenborg IR Clean+ technology					
	Step 2: IR dryer			Step 3: Finisher reactor		
Parameters	t (min)	T (°C)	Air/PET ratio (m^3/h) per (kg/h)	t (min)	T (°C)	Air/PET ratio (m^3/h) per (kg/h)
Challenge test [redacted]	[redacted] (cont.)	[redacted]	[redacted]	[redacted] (cont.)	[redacted]	[redacted]
Process	≥ [redacted] (cont.)	≥ [redacted]*	≥ 1	≥ 120 (cont.)	≥ [redacted]	≥ [redacted]

* [redacted]

[15]Technical report, section 'Table of operating Parameters'.

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