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Safety assessment of the process Concept Plastics Packaging, based on the Gneuss 2 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 Concept Plastics Packaging (EU register number RECYC300), which uses the Gneuss 2 technology. The input consists of 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 extruded into sheets. Having examined the challenge test provided, the Panel concluded that the decontamination in the extruder is critical in determining the decontamination efficiency of the process. The operating parameters to control the performance are the pressure, the temperature, the throughput, the rotor speed and the satellite screws speed. It was demonstrated that this recycling process is able to ensure a level of migration of potential unknown contaminants into food below the conservatively modelled migration of 0.10 µg/kg food, derived from the exposure scenario for infants, when such recycled PET is used at up to 90% in mixtures with virgin PET, and of 0.15 µg/kg food, derived from the exposure scenario for toddlers, when such recycled PET is used at up to 100%. Therefore, the Panel concluded that the recycled PET obtained from this process is not of safety concern when used for the manufacture of materials and articles at up to (a) 100% for contact with all types of foodstuffs except drinking water and (b) 90% in mixtures with virgin PET 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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† Deceased.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

1.1.1. Background

Recycled plastic materials and articles shall only be placed on the market if they contain recycled plastic obtained from an authorised recycling process. Before a recycling process is authorised, EFSA's opinion on its safety is required. This procedure has been established in Article 5 of Regulation (EC) No 282/2008^{1,2} of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of Regulation (EC) No 1935/2004³ of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the Member States Competent Authorities which transmit the applications to the European Food Safety Authority (EFSA) for evaluation.

In this case, EFSA received from the German Competent Authority (Federal Office of Consumer Protection and Food Safety) an application for evaluation of the recycling process Concept Plastics Packaging, EU register No RECYC300. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2021-00401. The dossier was submitted on behalf of CPP - Concept Plastics Packaging, Delves Rd, Heanor Gate Industrial Estate, Heanor DE75 7SJ, United Kingdom.

1.1.2. Terms of Reference

The German competent authority (Federal Office of Consumer Protection and Food Safety) requested the safety evaluation of the recycling process Concept Plastics, in accordance with Article 5 of Regulation (EC) No 282/2008.

1.1.3. Interpretation of the Terms of Reference

According to Article 5 of Regulation (EC) No 282/2008 of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods, EFSA is required to carry out risk assessments on the risks originating from the migration of substances from recycled food contact plastic materials and articles into food and deliver a scientific opinion on the recycling process examined.

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

2. Data and methodologies

2.1. Data

The applicant has submitted a 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).

¹ Commission Regulation (EC) No 282/2008 of the European parliament and of the council of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006. OJ L 86, 28.3.2008, p. 9–18.

² 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 Commission 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.

Additional information was sought from the applicant during the assessment process in response to requests from EFSA sent on 15 December 2022 and 3 May 2023 and was subsequently provided (see Section 6).

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,⁷ EFSA carried out a public consultation on the non-confidential version of the application from 27 June to 17 July 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,
 - operating parameters.

2.2. Methodologies

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

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

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.

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-2021-1187>

⁷ Decision available online: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf

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 information⁸

According to the applicant, the recycling process Concept Plastics Packaging is intended to recycle food grade PET containers using the Gneuss 2 technology. As requested by the applicant, the recycled PET is intended to be used at up to 80% for thermoformed trays/containers, e.g. for fruits, vegetables, cooked and uncooked meats, dairy products and desserts for long-term storage at room temperature or below, with or without hotfill. The final articles are not intended to be used in microwave or conventional ovens.

3.2. Description of the process

3.2.1. General description⁹

The recycling process Concept Plastics Packaging produces recycled sheets from PET containers (e.g. bottles) coming from post-consumer collection systems (kerbside and deposit systems). The recycling process comprises the two steps below.

Input

- In step 1, the 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 sheets.

- In step 2, the flakes are fed into an extruder, where they are melted, decontaminated [REDACTED] and finally transformed into sheets.

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

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

3.2.2. Characterisation of the input¹⁰

According to the applicant, the input material for the recycling process Concept Plastics Packaging consists of hot 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 data for the hot washed and dried flakes are provided, such as on physical properties and residual contents of moisture, poly(vinyl chloride) (PVC), polyolefins, glue, polyamide, cellulose and metals (see Appendix A).

3.3. Gneuss technology

3.3.1. Description of the main step¹¹

The general scheme of the Gneuss 2 technology, as provided by the applicant, is reported in Figure 1. The decontamination step is:

Extrusion (step 2): the hot washed and dried flakes are melted, extruded [REDACTED] and filtered. [REDACTED]

⁸ Technical dossier, sections 'Recycling process' and 'Intended application in contact with food'.

⁹ Technical dossier, sections 'Recycling process', 'Characterisation of the input' and 'Characterisation of the recycled plastic'.

¹⁰ Technical dossier, section 'Characterisation of the input'.

¹¹ Technical dossier, sections 'Recycling process' and 'Determination of the decontamination efficiency of the recycling process'.

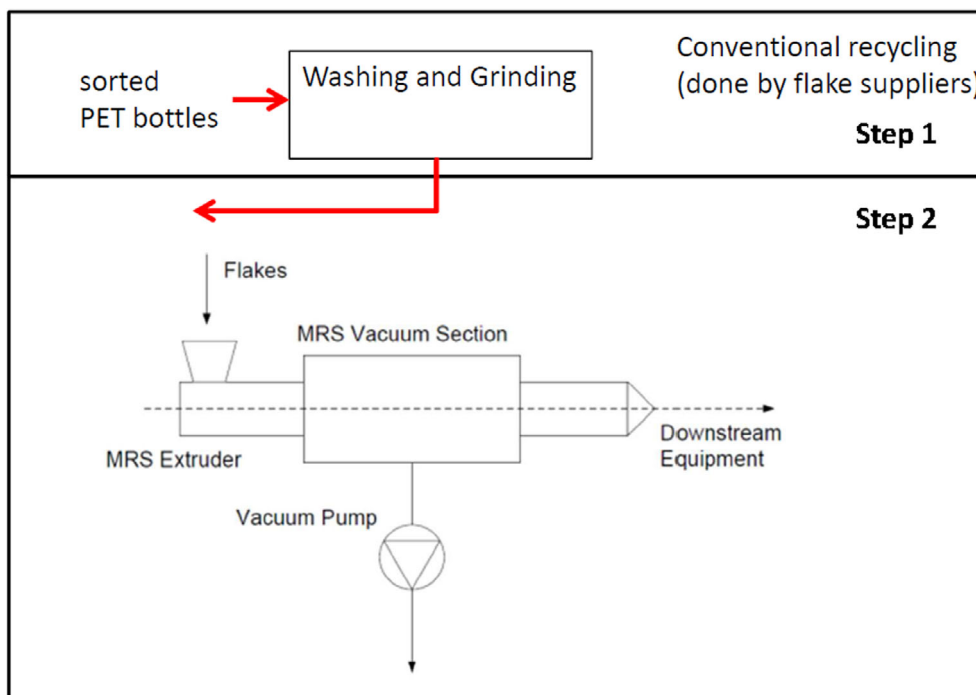


Figure 1: General scheme of the Gneuss 2 technology (provided by the applicant)

The process is operated under defined operating parameters¹² of temperature, pressure and residence time.

3.3.2. Decontamination efficiency of the recycling process¹³

To demonstrate the decontamination efficiency of the recycling process Concept Plastics Packaging, a challenge test performed at industrial plant scale was submitted to EFSA.

PET flakes were contaminated with toluene, chloroform, chlorobenzene, phenylcyclohexane, methyl salicylate, benzophenone and methyl stearate, selected as surrogates 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).

For the preparation of the contaminated PET flakes, 60 kg washed and dried conventionally recycled green PET flakes were mixed with the surrogates and stored for 7 days at 50°C under regular agitation. The contaminated flakes were rinsed with 10% ethanol and the concentration of the surrogates in this material was determined. Then, the flakes were introduced into the extruder.

The Concept Plastics Packaging process was challenged at the Gneuss facilities using the extruder [REDACTED]. The process was running first with non-contaminated transparent flakes for around 1 h. Subsequently, 30 kg of contaminated green flakes were introduced into the hopper (feeder). When the extruder was entirely filled (100%) with green contaminated flakes, samples were taken and the concentration of the surrogates determined.

The decontamination efficiency was calculated based on the concentration of surrogates in PET material before (flakes) and after the extrusion (sheets). The results are summarised in Table 1.

¹² In accordance with Art. 9 and 20 of Regulation (EC) No 1935/2004 the parameters were provided to EFSA and made available to the applicant, the Member States and European Commission (see Appendix C).

¹³ Technical dossier, sections 'Recycling process' and 'Determination of the decontamination efficiency of the recycling process'.

Table 1: Efficiency of the decontamination of the Gneuss 2 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 efficiency (%)
Toluene	256	< 0.2 ^(a)	> 99.9
Chloroform	311	1.1	99.6
Chlorobenzene	537	3.6	99.3
Phenylcyclohexane	411	12.3	97.0
Methyl salicylate ^(b)	736	< 0.1 ^(a)	> 99.9
Benzophenone	762	43.1	94.3
Methyl stearate	966	27.1	97.2

PET: poly(ethylene terephthalate).

(a): Not detected at the limits of detection given.


(b): Reactive at the high temperature of the extruder. Therefore, it was not considered in the evaluation of the decontamination efficiency.





As shown in Table 1, the decontamination efficiency ranged from 94.3% for benzophenone to above 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 residual contents of PVC, glue, polyolefins, polyamides, cellulose and metals, were provided for the input material, i.e. hot caustic washed and dried flakes (step 1). These 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 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) are conducted by third parties and, according to the applicant, this step is under control. The Gneuss 2 technology is based on  extrusion (step 2) with a production of sheets. The operating parameters of temperature, pressure, residence time, throughput, rotor speed and satellite screws speed have been provided to EFSA.

A challenge test to measure the decontamination efficiency was conducted at industrial plant scale on the process step 2. The extruder was operated under conditions equivalent to or less severe than those of the commercial process. The equivalence of the decontamination efficiency of the  (challenge test) and  (process) was demonstrated by modelling. The Panel considered that this challenge test was performed correctly according to the recommendations of the EFSA guidelines (EFSA, 2008). The Panel considered that the critical parameters for the decontamination of the melt are the surface area, the thickness of the melt exposed to the  and the duration of the exposure to the , which are critically affected by the throughput rate, the rotor speed and the satellite screws speed. Consequently, the temperature, pressure, throughput rate, rotor speed and satellite screws speed of the extrusion should be controlled to guarantee the performance of the decontamination. These parameters have been provided to EFSA (Appendix C).

The decontamination efficiencies obtained from the challenge test on step 2, ranging from 94.3% 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 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 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 not intended for the manufacturing of articles to be used in direct contact with drinking water, the exposure scenario for toddlers has been applied. A maximum dietary exposure of 0.0025 µg/kg bw per day, corresponding 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). C_{res} reported in Table 2 (scenario for toddlers) is calculated for 100% recycled PET, for which the risk to human health is demonstrated to be negligible. The Panel noted that the process results in a decontamination efficiency that allows the exposure scenario for infants (including exposure from drinking water that could be used to prepare infant formula), corresponding to a maximum migration of 0.1 µg/kg food, for 90% recycled PET (Table 2). The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

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 modelled migrations of 0.10 and 0.15 µg/kg food after 1 year at 25°C (C_{mod})

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	0.002 (0.002)*	0.09	0.13
Chlorobenzene	99.3	0.021 (0.018)*	0.10	0.15
Chloroform	99.7	0.011 (0.010)*	0.10	0.15
Phenylcyclohexane	97.0	0.090 (0.0080)*	0.14	0.21
Methyl salicylate	> 99.9	0.0004 (0.0004)*	0.13	0.20
Benzophenone	94.3	0.17 (0.153)*	0.16	0.24
Methyl stearate	97.2	0.084 (0.076)*	0.32	0.47

PET: poly(ethylene terephthalate).

*: values between brackets are for 90% use recycle.

As 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 Concept Plastics Packaging using the Gneuss 2 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 excluding drinking water, and up to 90% for contact with drinking water, for long-term storage at room temperature or below, with or without hotfill.

4. Conclusions

The Panel considered that the process Concept Plastics Packaging, using the Gneuss 2 technology, is adequately characterised and that the main steps used to recycle the PET flakes into decontaminated PET sheets have been identified. Having examined the challenge test provided, the Panel concluded that the extrusion (step 2) is critical for the decontamination efficiency. The operating parameters to control its performance are the pressure, the temperature, the throughput rate as well as the rotor speed and the satellite screw speed, as specified in Appendix C.

The Panel considered that the recycling process Concept Plastics Packaging 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:

- 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;
- 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 contains no more than 5% of PET from non-food consumer applications.

- iii) the recycled PET obtained from the process Concept Plastics Packaging is used at up to (a) 100% for the manufacture of materials and articles for contact with all types of foodstuffs excluding drinking water or (b) 90% for contact with drinking water, for long-term storage at room temperature and 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. 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

- 1) Dossier "Concept Plastics Packaging", July 2021. Submitted on behalf of CPP - Concept Plastics Packaging, United Kingdom.
- 2) Additional information for the dossier "Concept Plastics Packaging", April 2023. Submitted on behalf of CPP - Concept Plastics Packaging, United Kingdom.
- 3) Additional information for the dossier "Concept Plastics Packaging", May 2023. Submitted on behalf of CPP - Concept Plastics Packaging, United Kingdom.

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Abbreviations

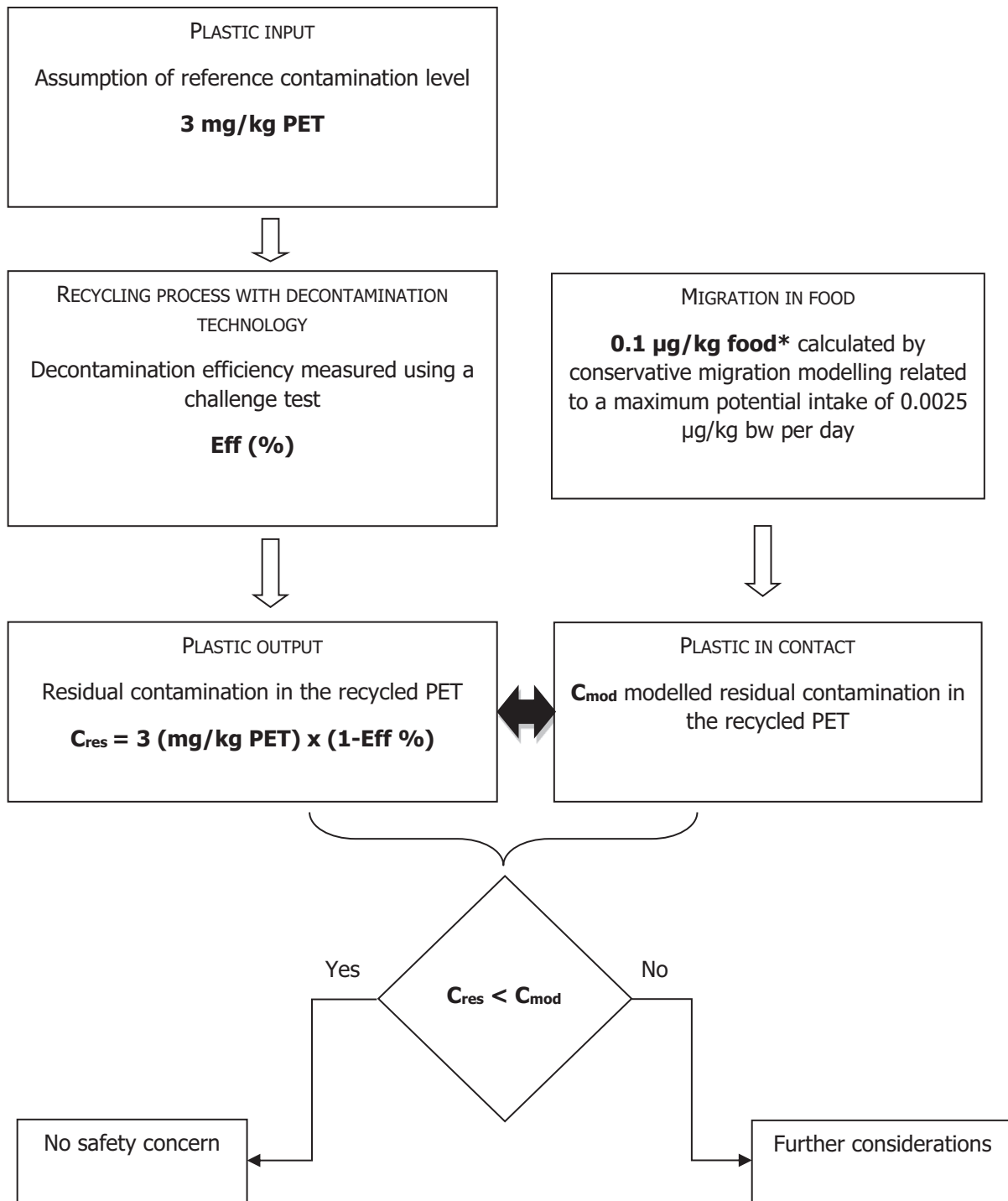
bw	body weight
CEF Panel	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP Panel	Panel on Food Contact Materials, Enzymes and Processing Aids
C_{mod}	modelled concentration in PET
C_{res}	residual concentration in PET
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)
rPET	recycled poly(ethylene terephthalate)

Appendix A – Technical data of the washed flakes as provided by the applicant¹⁴

Parameter	Value
Moisture max.	1.0%
Bulk density	200–850 kg m ⁻³
PVC max.	200 mg/kg
Glue max.	100 mg/kg
Polyolefins max.	300 mg/kg
Cellulose (paper, wood)	100 mg/kg
Metal max.	100 mg/kg
Polyamide max.	100 mg/kg

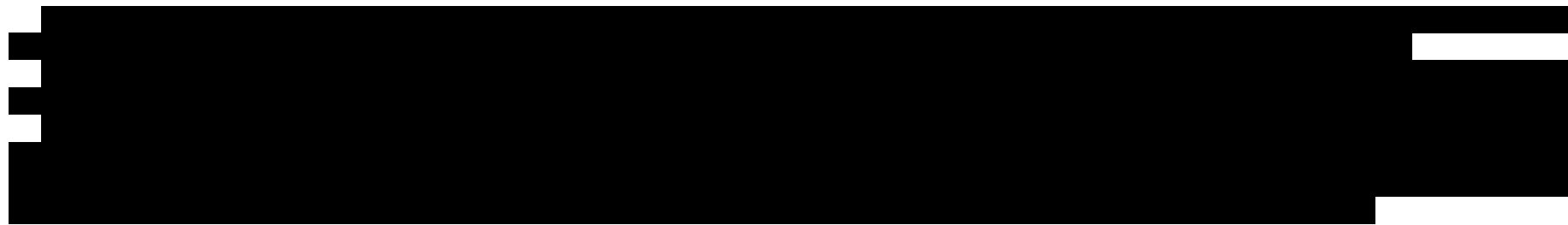
¹⁴ Technical dossier, section 'Characterisation of the input'.

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 on operational parameters¹⁵



Process Concept Plastics Packaging (register number RECYC300) based on the Gneuss 2 technology

Parameters	Step 2 (decontamination)*					
	t (s)	P (mbar)	T (°C)	Throughput (kg h ⁻¹)	Rotor speed (min ⁻¹)	Satellite screw speed (min ⁻¹)
Challenge test (Report No. PA/4729/10)	█	█	█	█	█	█
Process	█	█	█	█	█	█

*Characteristics of the extruder in the challenge test and the industrial process

	(challenge test)	(industrial process)
█	█	█
█	█	█
█	█	█
█	█	█
█	█	█
█	█	█

¹⁵ Technical dossier, section 'Table of operating parameters'.