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Safety assessment of the process rPET InWaste, based on the NGR technology, used to recycle post-consumer PET into food contact materials

EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP),
Claude Lambré, José Manuel Barat Baviera, Claudia Bolognesi, Andrew Chesson,
Pier Sandro Cocconcelli, Riccardo Crebelli, David Michael Gott, Konrad Grob,
Marcel Mengelers, Alicja Mortensen, Gilles Rivière, Inger-Lise Steffensen, Christina Tlustos,
Henk Van Loveren, Laurence Vernis, Holger Zorn, Vincent Dudler, Maria Rosaria Milana,
Constantine Paspaspyrides, Maria de Fátima Tavares Poças, Alexandros Lioupis and
Evgenia Lampi

Abstract

The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) assessed the safety of the recycling process rPET InWaste (EU register number RECYC231), which uses the NGR technology. The input is 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 dried (step 2), melted in an extruder (step 3) and decontaminated during a melt-state polycondensation step under high temperature and vacuum (step 4). In step 5, the melt material is granulated. Having examined the challenge test provided, the Panel concluded that the melt-state polycondensation (step 4) is critical in determining the decontamination efficiency of the process. The operating parameters to control the performance of the critical steps are the pressure, the temperature, the residence time (depending on the mass and throughput of the melt) and the characteristics of the reactor. It was demonstrated that this recycling process is able to ensure that the level of migration of potential unknown contaminants into food is below the conservatively modelled migration of 0.1 µg/kg food. Therefore, the Panel concluded that the recycled PET obtained from this process is not of safety concern, when used at up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs, including drinking water, for long-term storage at room temperature, 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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Requestor: Czech Competent Authority (National Institute of Public Health)

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Correspondence: fip@efsa.europa.eu

Panel members: José Manuel Barat Baviera, Claudia Bolognesi, Andrew Chesson, Pier Sandro Cocconcelli, Riccardo Crebelli, David Michael Gott, Konrad Grob, Claude Lambré, Evgenia Lampi, Marcel Mengelers, Alicja Mortensen, Gilles Rivière, Vittorio Silano (until 21 December 2020 †), Inger-Lise Steffensen, Christina Tlustos, Henk Van Loveren, Laurence Vernis and Holger Zorn.

Note: The full opinion will be published in accordance with Article 10(6) of Regulation (EC) No 1935/2004 once the decision on confidentiality, in line with Article 20(3) of the Regulation, will be received from the European Commission. Technical details on recycling steps 3 and 4 (Section 3.3.1), details of the performed challenge test (Section 3.4), the text and table on the operational parameters as well as reactor characteristics and schemes (Appendix C) have been provided under confidentiality and they are redacted awaiting the decision of the Commission.

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† Deceased.

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1. Introduction

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

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 282/2008¹ on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of Regulation (EC) No 1935/2004² on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the competent authorities of Member States, which transmit the applications to EFSA for evaluation.

In this case, EFSA received, from the Czech Competent Authority (National Institute of Public Health), an application for evaluation of the recycling process rPET InWaste, European Union (EU) register No RECYC231. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2020-00526. The dossier was submitted on behalf of rPET InWaste, s.r.o., Czech Republic.

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 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 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).

Additional information was provided by the applicant during the assessment process in response to a request from EFSA sent on 29 April 2021, 6 July 2021 and 16 November 2021 (see 'Documentation provided to EFSA'). Following the request for additional data sent by EFSA on 6 July 2021, the applicant requested a clarification teleconference, which was held on 2 September 2021.

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.

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 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.

2.2. Methodologies

The principles followed for the evaluation are described here. 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 information³

According to the applicant, the recycling process rPET InWaste is intended to recycle food grade PET containers using the NGR technology. The recycled PET is intended to be used at up to 100% for the manufacture of materials and articles for direct contact with all kinds of foodstuffs for long-term storage at room temperature, with or without hotfill, such as bottles for mineral water and beverages. The final articles are not intended to be used in microwave or conventional ovens.

3.2. Description of the process

3.2.1. General description⁴

The recycling process rPET InWaste produces recycled PET pellets from PET containers (e.g. bottles), coming from post-consumer collection systems (kerbside and deposit systems).

The recycling process comprises the five steps below.

Input

- In step 1, the post-consumer PET containers are processed into washed and dried flakes. This step is performed by a third party.

Decontamination and production of recycled PET material

- In step 2, the flakes are dried under gas flow at high temperature.
- In step 3, the flakes are extruded.
- In step 4, the material is decontaminated in a melt-state polycondensation process.
- In step 5, the melt is cooled down and granulated.

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

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

³ Technical dossier, Section 3.1.

⁴ Technical dossier, Section 3.1.1.

3.2.2. Characterisation of the input⁵

According to the applicant, the input material for the recycling process rPET InWaste consists of 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 information on residual contents of moisture, poly(vinyl chloride) (PVC), polyolefins, polyamide, glue, wood, paper and metals (see Appendix A).

3.3. NGR technology

3.3.1. Description of the main steps⁶

The general scheme of the NGR technology, as provided by the applicant, is reported in Figure 1. The steps are:

- Drying (step 2): The flakes are dried under high temperature and gas flow.
- Extrusion (step 3): The flakes from the previous step are melted in an extruder. The melt is to the top of the reactor of step 4.
- Melt-state polycondensation (step 4): The material is decontaminated during a melt-state polycondensation under high temperature and vacuum.

- Granulation (step 5): The melt material is cooled down and pelletised.

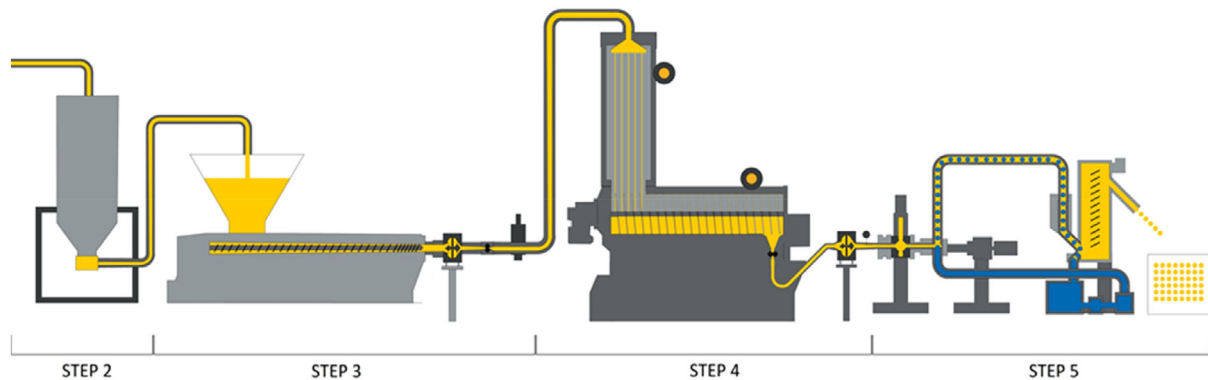


Figure 1: General scheme of the technology (provided by the applicant)

The process is run under defined operating parameters⁷ of temperature, pressure, gas flow and residence time.

3.3.2. Decontamination efficiency of the recycling process⁸

To demonstrate the decontamination efficiency of the recycling process rPET InWaste, a challenge test performed at pilot plant scale was submitted to EFSA.

⁵ Technical dossier, Section 3.2.2.

⁶ Technical dossier, Section 3.2.1.

⁷ 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).

⁸ Technical dossier, Section 3.2.3 and Appendix E.

PET was contaminated with toluene, chlorobenzene, phenylcyclohexane, 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). The mixture of these surrogates was spiked into the dried PET flakes entering the extruder (before step 3).

The NGR technology was challenged at the NGR facilities at pilot plant scale. The decontamination efficiency was then calculated from the concentration difference before the melt-state polycondensation (step 4) and after pelletisation (step 5). When surrogates were not detected, the limit of detection was considered for the calculation of the decontamination efficiency. The results are summarised in Table 1.

Table 1: Efficiency of the decontamination of the NGR technology in the challenge test

Surrogates	Concentration of surrogates before step 4 (mg/kg PET)	Concentration of surrogates after step 5 (mg/kg PET)	Decontamination efficiency (%)
Toluene	69.7	< 0.1 ^(a)	> 99.9
Chlorobenzene	153.5	< 0.1 ^(a)	> 99.9
Phenylcyclohexane	249.1	0.3	99.9
Benzophenone	292.1	10.3	96.5
Methyl stearate	122.3	0.3	99.8

PET: poly(ethylene terephthalate).

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

As shown in Table 1, the decontamination efficiency ranged from 96.5% for benzophenone to above 99.9% for toluene and chlorobenzene.

Contrary to the recommendations of the EFSA guidelines (EFSA, 2008), the contaminated flakes were not rinsed before being introduced in the recycling process. As the flakes are contaminated at the beginning of the extrusion process, before the material is subjected to vacuum, it can be estimated that surrogates are homogeneously distributed in the PET material when the decontamination starts. Therefore, the Panel concluded that the results from the challenge test could be used to calculate the decontamination efficiency.

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 information on physical properties and residual contents of PVC, glue, polyolefins, polyamides, metals and moisture, were provided for the input materials (i.e. 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 in the input stream, this fraction will be no more than 5%, 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) is conducted by third parties. According to the applicant, this step is under control. The NGR technology comprises drying (step 2), extrusion (step 3), melt-state polycondensation (step 4) and granulation (step 5). The operating parameters of temperature, residence time, pressure and gas flow have been provided to EFSA.

A challenge test to measure the decontamination efficiency was conducted at pilot plant scale on process steps 4 and 5. The Panel considered that this challenge test was performed correctly

according to the recommendations of the EFSA guidelines (EFSA, 2008). The decontamination of the material in a vacuum reactor by melt-state polycondensation (step 4) is critical

Consequently, the pressure, the temperature, the residence time (depending on the mass and throughput of the melt) and the characteristics of the reactor specified in Appendix C should be controlled to guarantee the performance of the decontamination.

The decontamination efficiencies obtained for each surrogate, ranging from 96.5% to more than 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 $\mu\text{g}/\text{kg}$ bw per day, below which the risk to human health is considered negligible. The C_{res} value should not exceed the modelled concentration in PET (C_{mod}) that, after 1 year at 25°C, could result in a migration giving rise to a dietary exposure exceeding 0.0025 $\mu\text{g}/\text{kg}$ bw per day. Because the recycled PET is intended for the manufacturing of articles containing up to 100% recycled PET, the scenario for infants has been applied (water could be used to prepare infant formula). Therefore, the migration of 0.1 $\mu\text{g}/\text{kg}$ into food has been used to calculate C_{mod} (EFSA CEF Panel, 2011). The results of these calculations are shown in Table 2. The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

Table 2: Decontamination efficiency from the challenge test, residual concentrations of the surrogates in the recycled PET (C_{res}) and calculated concentrations of the surrogates in PET (C_{mod}) corresponding to a modelled migration of 0.1 $\mu\text{g}/\text{kg}$ food after 1 year at 25°C

Surrogates	Decontamination efficiency (%)	C_{res} for 100% rPET (mg/kg PET)	C_{mod} (mg/kg PET)
Toluene	> 99.9	< 0.004	0.09
Chlorobenzene	> 99.9	< 0.002	0.09
Phenylcyclohexane	99.9	0.004	0.14
Benzophenone	96.5	0.106	0.16
Methyl stearate	99.8	0.007	0.32

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

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 rPET InWaste using the NGR technology is able to ensure that the level of migration of unknown contaminants from the recycled PET into food is below the conservatively modelled migration of 0.1 $\mu\text{g}/\text{kg}$ food, at which the risk to human health would be negligible.

4. Conclusions

The Panel considered that the process rPET InWaste using the NGR technology 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 the melt-state polycondensation (step 4), is critical for the decontamination efficiency. The operating parameters to control its performance are the pressure, the temperature, the residence time (depending on the mass and throughput of the melt) and the characteristics of the reactor specified in Appendix C.

The Panel considered that the recycling process rPET InWaste 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 rPET InWaste 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, 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

Dossier 'rPET InWaste'. January 2021. Submitted on behalf of rPET InWaste, s.r.o., Czech Republic.

Additional information, May 2021. Submitted on behalf of rPET InWaste, s.r.o., Czech Republic.

Additional information, September 2021. Submitted on behalf of rPET InWaste, s.r.o., Czech Republic.

Additional information, December 2021. Submitted on behalf of rPET InWaste, s.r.o., Czech Republic.

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Abbreviations

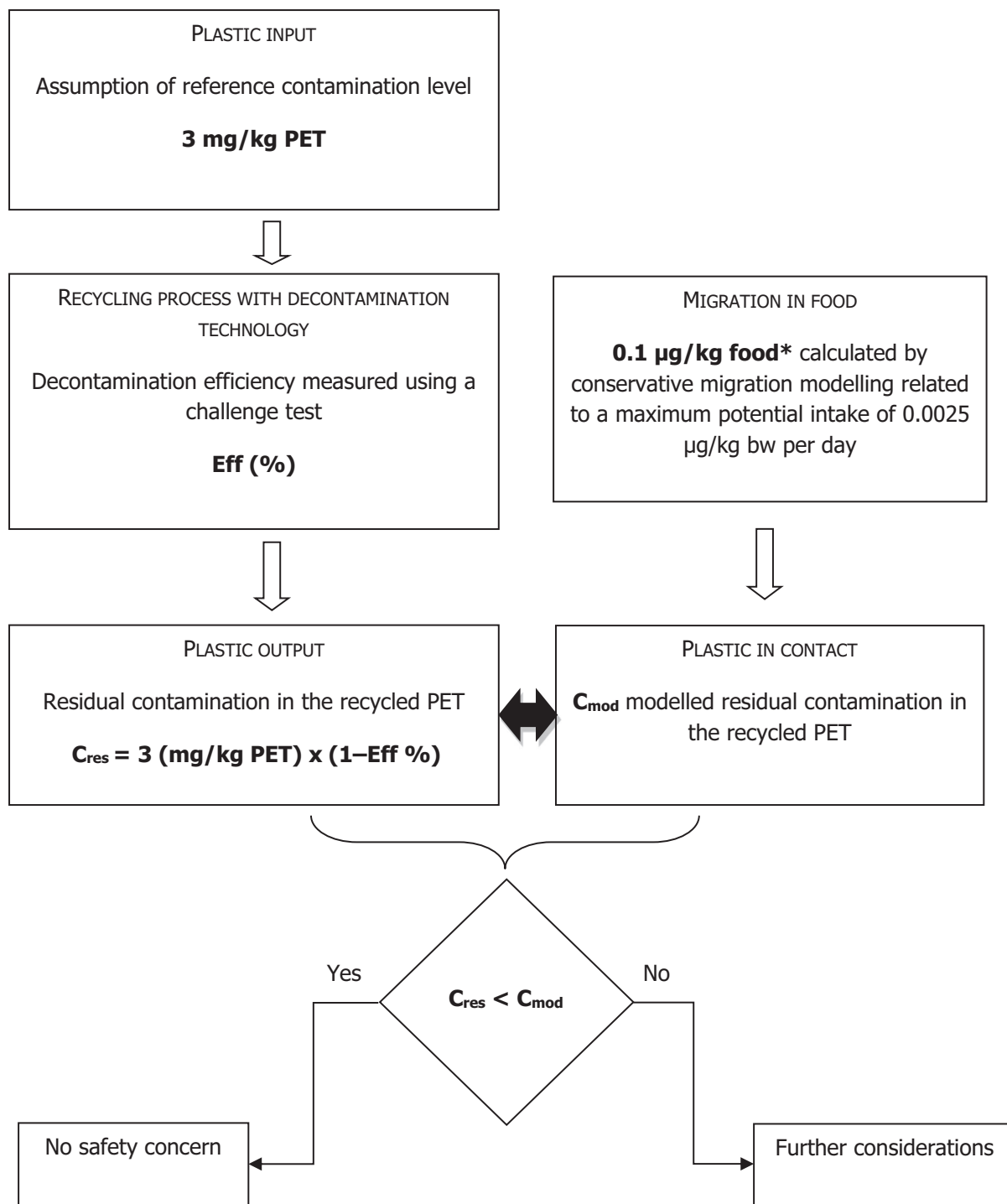
bw	body weight
CEF Panel	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP Panel	Panel on Food Contact Materials, Enzymes and Processing Aids
C_{mod}	modelled concentration in PET
C_{res}	residual concentrations in PET
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)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

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

Parameter	Value
Moisture	< 10,000 mg/kg
PVC content	< 50 mg/kg
Glue max. PET flakes with glue content	< 500 mg/kg
Polyolefins content	< 100 mg/kg
Polyamide content	< 50 mg/kg
Metals max.	< 50 mg/kg
Wood, paper, cellulose	< 50 mg/kg

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

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 parameters (Confidential Information)⁹

[Redacted content]

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⁹ Technical report, Section 3.2.1 and Appendix F.

