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Safety assessment of the process Quinn Packaging, based on Erema Basic technology, used to recycle post-consumer PET into food contact materials

EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP),
Vittorio Silano, José Manuel Barat Baviera, Claudia Bolognesi, Andrew Chesson,
Pier Sandro Cocconcelli, Riccardo Crebelli, David Michael Gott, Konrad Grob, Alicja Mortensen,
Gilles Riviere, Inger-Lise Steffensen, Christina Tlustos, Henk Van Loveren, Laurence Vernis,
Holger Zorn, Vincent Dudler, Maria Rosaria Milana, Constantine Papaspyrides,
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 Quinn Packaging (EU register number RECYC172). The input is hot caustic washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, with no more than 5% PET from non-food consumer applications. They are heated in a continuous reactor under vacuum before being extruded. Having examined the challenge test provided, the Panel concluded that the continuous reactor step (step 2) is the critical step that determines the decontamination efficiency of the process. The operating parameters to control the performance of this critical step are temperature, pressure 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 0.15 µg/kg food, derived from the exposure scenario for toddlers. Therefore, the Panel concluded that the recycled PET obtained from this process is not of safety concern when the final thermoformed trays and containers manufactured with the recycled sheets and not used for packaging water contain up to 100% recycled post-consumer PET. Trays made of this recycled PET are not intended to be used in microwave and conventional ovens and such use is not covered by this evaluation.

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Correspondence: fip@efsa.europa.eu

Panel members: Vittorio Silano, José Manuel Barat Baviera, Claudia Bolognesi, Andrew Chesson, Pier Sandro Cocconcelli, Riccardo Crebelli, David Michael Gott, Konrad Grob, Evgenia Lampi, Alicja Mortensen, Gilles Riviere, 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. The text and table on the operational parameters (Appendix C) have been provided under confidentiality and they are redacted awaiting the decision of the Commission.

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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 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 282/2008¹ 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 1935/2004² 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 Food Safety Authority of Ireland, an application for evaluation of the recycling process Quinn Packaging, European Union (EU) register No RECYC172.

The request has been registered in EFSA's register of received questions under the number EFSA-Q-2019-00085. The dossier was submitted on behalf of Quinn Packaging, Ireland.

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 Quinn Packaging 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 make 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). Applications are submitted in accordance with Article 5 of the Regulation (EC) No 282/2008.

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

¹ 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 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.

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 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 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

According to the applicant, the recycling process Quinn Packaging is intended to recycle food grade PET containers to produce recycled PET using the Erema Basic technology. The recycled PET is intended to be used at up to 100% for the manufacture of recycled materials and articles, i.e. PET sheets for thermoformed trays and containers that are intended to be used in direct contact with all kinds of foodstuffs for long-term storage at room temperature.

3.2. Description of the process

3.2.1. General description

The recycling process Quinn Packaging produces recycled PET sheets from PET containers, mainly bottles from post-consumer collection systems (kerbside and deposit systems).

The recycling process comprises the three steps below. Step 1 is performed by third parties.

Input

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

Decontamination and production of recycled PET material

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

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

Recycled sheets, the final product of the process, are checked against technical requirements, such as intrinsic viscosity, colour and black spots. They are intended to be converted by other companies into recycled articles used for long term storage at room temperature, i.e. extruded sheets which are thermoformed to make food trays/containers for food contact applications, such as for fruit, vegetables, cooked and uncooked meat, dairy products and desserts. They are not intended to be used in microwave and conventional ovens.

3.2.2. Characterisation of the input

According to the applicant, the input material for the recycling process Quinn Packaging consists of hot caustic washed and dried flakes obtained from PET containers, mainly 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 below 5%.

Technical data on the hot caustic washed and dried flakes are provided, such as information on physical properties and on residual contents of moisture, poly(vinyl chloride) (PVC), glue, polyolefins, polyamides, polyamide, cellulose and metals (see Appendix A).

3.3. Erema Basic technology

3.3.1. Description of the main steps

The general scheme of the Erema Basic technology, as provided by the applicant, is reported in Figure 1. In step 1, not reported in the scheme, post-consumer PET containers, are processed into hot caustic washed and dried flakes.

- Decontamination in a continuous reactor (step 2):

The flakes are fed into a continuous reactor equipped with a bottom-mounted rotating mixing device, running under higher temperature and vacuum for a pre-defined average residence time. These process conditions favour the desorption of contaminants from PET and the crystallisation of PET flakes.

- Extrusion of the decontaminated flakes (step 3):

The flakes continuously introduced from the previous reactor are molten in the extruder at atmospheric pressure. The residual solid particles (e.g. paper, aluminium, etc.) are filtered out of the extruded plastic before the melt is converted into sheets.

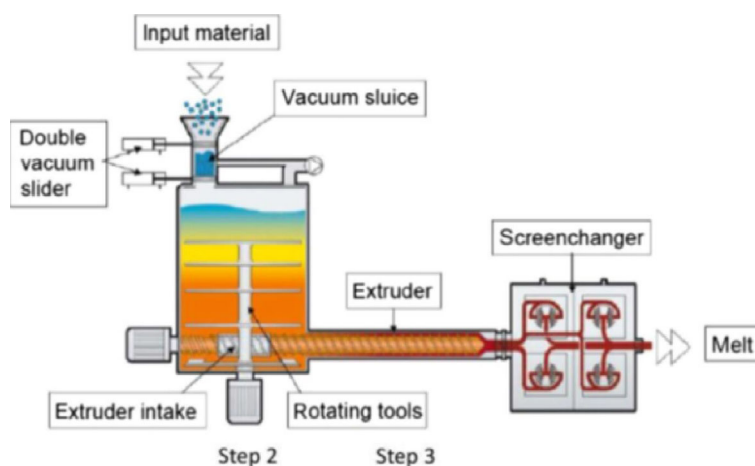


Figure 1: General scheme of the technology (provided by the applicant)

The process is operated under defined operating parameters³ of temperature, pressure and residence time.

3.3.2. Decontamination efficiency of the recycling process

To demonstrate the decontamination efficiency of the recycling process Quinn Packaging, a challenge test was submitted to the EFSA that was performed at the EREMA facilities at industrial scale.

PET flakes were contaminated with toluene, chlorobenzene, chloroform, methyl salicylate, phenylcyclohexane, benzophenone and methyl stearate, selected as surrogate contaminants in agreement with the EFSA guidelines and in accordance with the recommendations of the US Food and Drug Administration. The surrogates include different molecular weights 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 this purpose, solid surrogates (benzophenone and methyl stearate) were mixed with liquid surrogates (toluene, chlorobenzene, chloroform, methyl salicylate and phenyl cyclohexane). This surrogate mixture was admixed with 5 kg of conventionally recycled⁴ post-consumer PET flakes

³ 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 the European Commission (see Appendix C).

⁴ Conventional recycling includes commonly sorting, grinding, washing and drying steps and produces washed and dried flakes.

(masterbatch). The masterbatch was mixed with another portion of approx. 50 kg of PET flakes and stored for 7 days at 50°C with periodical agitation. The contaminated flakes were washed and rinsed in a batch process in pilot plant scale. The concentration of surrogates in this material was determined.

The Erema Basic technology was challenged using an industrial-scale plant. To process a sufficiently large amount of material compatible with the high capacity of the continuous industrial plant, the reactor was initially fed with non-contaminated flakes (white colour) and, after process conditions were stabilised, with a defined amount of contaminated flakes (green colour) and then with a much larger quantity of non-contaminated flakes. The flakes were continuously fed into the reactor. Samples were taken at the outlet of the reactor at regular intervals. The green flakes were separated from the white flakes and the evolution of the fraction of green flakes over time (residence time distribution curve) was determined by weighing. The green flakes were then analysed for their residual concentrations of the applied surrogates.

The Panel noted that decontamination efficiencies, calculated only on the basis of residual surrogates in contaminated (green-coloured) flakes could be overestimated. In fact, cross-contamination⁵ by transfer of contaminants from green to white flakes does occur (EFSA CEF Panel, 2011)

Therefore, to take into account the cross-contamination phenomenon, some assumptions and considerations were made:

- The mass fraction of green to white flakes at various residence time points was derived from the data provided. A best fitting mass fraction/residence time distribution curve was derived from the experimental data and was used to calculate the percentage of green and white flakes at given different residence times.
- The residual concentrations of surrogates in the green flakes after decontamination were derived for the different residence time points from the data provided. A best fitting curve was derived from the experimental data and was used to interpolate the residual concentrations in green flakes at different residence times.
- The Panel made the assumption that cross-contamination of surrogates from green to white flakes in the reactor occurred to the extent that the surrogate concentration in the white flakes reached 10% of the residual concentration measured in the green flakes. This percentage reflects the experience gained from previous evaluations.
- A new study was provided by the applicant. Based on the results provided as an Annex of the technical dossier and subsequently published (Welle, 2016), cross-contamination was found at low mixing (dilution) ratios (e.g. 1:1), but the author argued that moving to higher mixing (dilution) ratios (e.g. 1:50) it does not play a significant role. Therefore, the applicant requested that the 10% cross-contamination should not apply for the industrial process Quinn Packaging (Erema Basic) under evaluation.
- The Panel noted that the test (Welle, 2016) had some shortcomings and the conclusion that cross-contamination was negligible had to be questioned due to the poor detection limits of the analytical method used as it had a major impact on calculations at a high mixing (dilution) ratio. Moreover, the Panel considered that the laboratory tests to investigate cross-contamination were not representative of the industrial process under evaluation: different technologies (types of equipment and different operational conditions) were used, for example in terms of heating technique (hot gas vs. friction) and removal of contaminants from the reactor (inert gas vs. vacuum). The Panel concluded that the argumentation is insufficiently supported. Therefore, the provided study allows neither to exclude cross-contamination from the calculation of the decontamination efficiency nor to refine the previous estimate of 10%.

To take into account the cross-contamination between green and white flakes, the evolution of the total residual surrogate content at the outlet of the continuous reactor (step 2) as a function of residence time was calculated by adding the amounts transferred into the white flakes (based on the assumption of 10% of the concentration measured in the green flakes) to the amounts measured in the green ones, taking into account the mass fraction of green and white flakes. Correspondingly corrected concentrations of the surrogates after decontamination were compared with their initial concentrations in green flakes at the inlet of the reactor to derive the decontamination efficiencies (see Table 1).

⁵ 'Cross-contamination' (partitioning between green and white flakes), as meant in the 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', is the transfer of surrogate contaminants from the initially contaminated to the initially not contaminated material (EFSA CEF Panel, 2011).

Table 1: Efficiency of the decontamination of the continuous reactor (Erema Basic, step 2) in the challenge test

Surrogates	Concentration ^(a) of surrogates before step 2 (mg/kg PET)	Concentration ^(b) of surrogates after step 2 (mg/kg PET)	Decontamination efficiency ^(c) (%)
Toluene	202	0.4	98.4
Chlorobenzene	361	0.76	98.3
Chloroform	291	0.48	98.6
Methyl salicylate	143	1.03	94.0
Phenylcyclohexane	364	2.31	94.7
Benzophenone	480	4.37	92.4
Methyl stearate	360	1.93	95.5

PET: poly(ethylene terephthalate).

(a): Initial concentration in the contaminated PET flakes.

(b): Residual concentration calculated for green flakes after decontamination.

(c): Decontamination efficiency of the step 2 reactor in the challenge test and after correction for cross-contamination (see text).

The decontamination efficiencies as presented in Table 1 were calculated at the time of exit from the continuous reactor (step 2) in the challenge test. The decontamination efficiency ranged from 92.4% for benzophenone up to 98.6% for chloroform.

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 and metals, were provided for the input materials (hot caustic washed and dried flakes, step 1). These are produced from PET containers, 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 lower 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 well described. The washing and drying of flakes from collected PET containers (step 1) is conducted by third parties and this step is under control. The following steps are those of the Erema Basic technology used to recycle the PET flakes into decontaminated PET sheets: continuous decontamination reactor (step 2) and extrusion (step 3). The operating parameters of temperature, pressure and residence time have been provided to EFSA.

A challenge test was conducted at industrial plant scale on the process step 2 (continuous decontamination reactor) to measure the decontamination efficiency. In this challenge test, the continuous decontamination reactor was operated under pressure and temperature conditions equivalent to those of the commercial process. The challenge test was performed according to the recommendations in the EFSA guidelines (EFSA, 2008). Since a mixture of flakes not contaminated with surrogates (white) and contaminated flakes (green, spiked with surrogates) was collected at the outlet of the reactor used for this challenge test, the Panel calculated the decontamination efficiencies taking into account also the amount possibly transferred to the white flakes due to cross contamination phenomena during the challenge test. The Panel considered that the decontamination in continuous reactor (step 2) is the critical step for the decontamination efficiency of the process. Consequently temperature, pressure and residence time parameters of the step 2 of the process should be controlled to guarantee the performance of the decontamination. These parameters have been provided to EFSA.

The decontamination efficiencies obtained for each surrogate contaminant from the challenge test, ranging from 92.4% to 98.6%, 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 is obtained (Table 2).

According to the evaluation principles (EFSA CEF Panel, 2011), the C_{res} value should not be higher than a modelled concentration in PET (C_{mod}) corresponding to a migration, after 1 year at 25°C, which cannot give rise to a dietary exposure exceeding 0.0025 µg/kg bw per day, the exposure threshold below which the risk to human health would be negligible. Because the recycled PET is intended to be used in the manufacture of trays and containers and not used to pack water (since water could be used to prepare infant formula), the exposure scenario for toddlers has been applied as worst case, where 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. Therefore, the corresponding migration of 0.15 µg/kg (scenario of toddlers) into food has been used to calculate C_{mod} (EFSA CEF Panel, 2011). If the PET produced by a recycling process is used up to 100% to produce new articles and they do not meet these targets, recycled PET should be mixed with virgin PET to make sure that the C_{res} value does not exceed the C_{mod} value. This percentage is reported in Table 2 for the scenario of toddlers. The percentage of recycled PET reported in Table 2 is, therefore, the maximum percentage for which the risk to human health is demonstrated to be negligible and may differ from the initial request from the applicant. The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

Table 2: Decontamination efficiencies from the challenge test, residual concentrations of the surrogates in the recycled PET (C_{res}) and calculated concentrations of the surrogates in PET (C_{mod}) corresponding to a modelled migration of 0.15 µg/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	98.4	0.05	0.13
Chlorobenzene	98.3	0.05	0.15
Chloroform	98.6	0.04	0.15
Methyl salicylate	94.0	0.18	0.20
Phenylcyclohexane	94.7	0.16	0.21
Benzophenone	92.4	0.23	0.24
Methyl stearate	95.5	0.13	0.47

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

On the basis of the provided data from the challenge test and the applied conservative assumptions, the Panel considered that the recycling process under evaluation using the EREMA Basic technology under the given operating conditions 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 0.15 µg/kg food at which the risk to human health would be negligible when the recycled sheets are used for trays and containers intended for contact with all types of foodstuffs except packaged water (scenario of toddlers) and when the recycled PET from the Quinn Packaging recycling process is used up to 100%.

4. Conclusions

The Panel considered that the Quinn Packaging recycling process is well characterised and 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 decontamination in the continuous reactor of step 2 is the critical step for the decontamination efficiency. The operating parameters to control its performance are temperature, pressure and residence time.

The Panel considered that the recycling process Quinn Packaging is able to reduce any 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 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 containing no more than 5% of PET from non-food consumer applications.

Therefore, the recycled PET obtained from the process Quinn Packaging intended to be used up to 100% for the manufacture of thermoformed trays and containers for contact with all types of foodstuff, except packaged water, for long-term storage at room temperature, is not considered of safety concern. Trays made of this recycled PET are not intended to be used in microwave and conventional ovens and such use is not covered by this evaluation.

5. Recommendations

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 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.

Documentation provided to EFSA

- 1) Dossier 'Quinn Packaging'. February 2019. Submitted on behalf of Quinn Packaging, Ireland.

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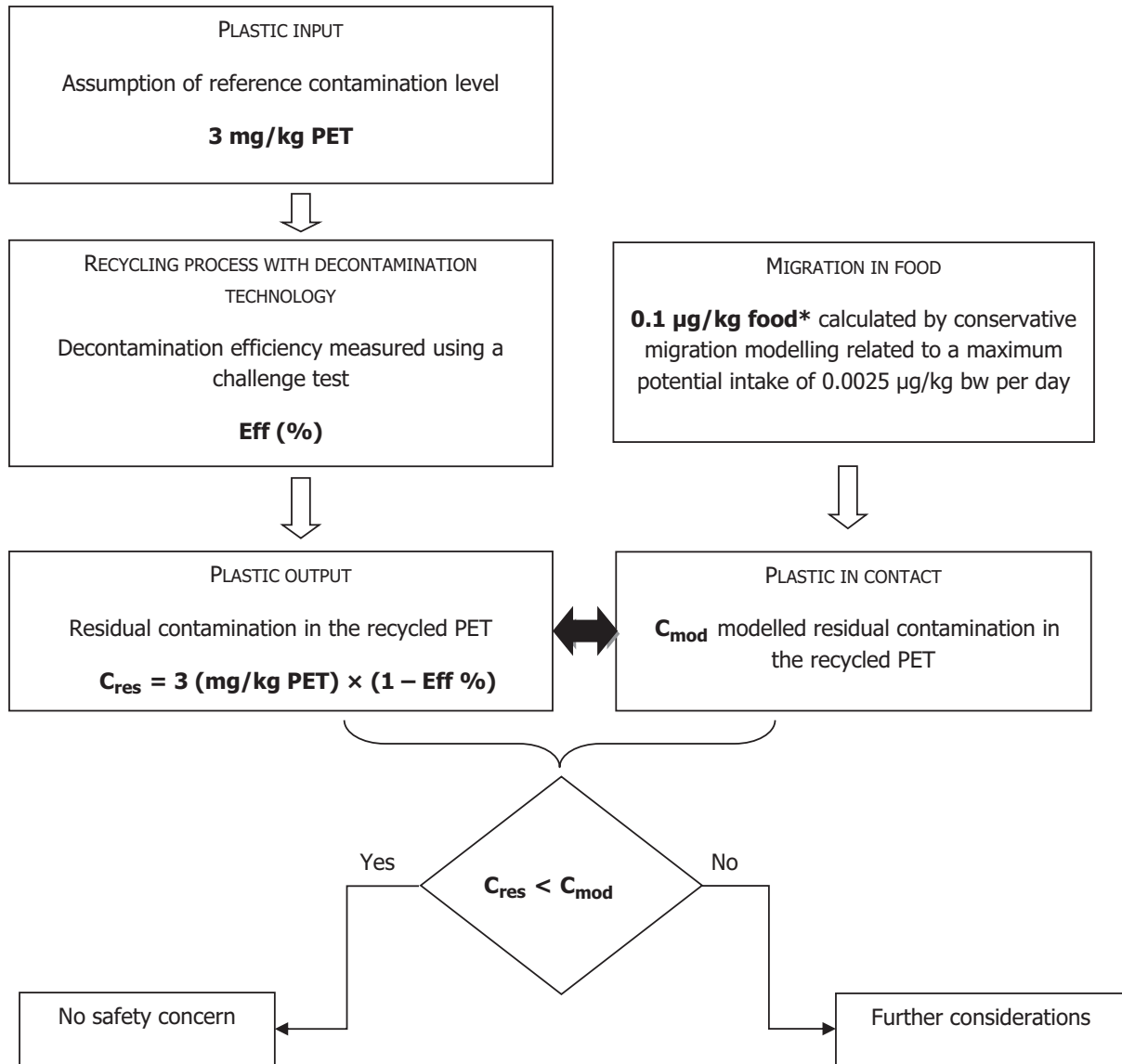
Abbreviations

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 applicant

Parameter	Value
Moisture max.	1.0 %
Moisture variation	± 0.3%/h
Bulk density	230–850 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
Polyolefins max.	100 mg/kg
cellulose (paper, wood)	100 mg/kg
Metals max.	50 mg/kg
Polyamide max.	50 mg/kg

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.

Appendix C – Table on Operational parameters (Confidential Information)

[Redacted Table Content]