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Safety assessment of the process AMB, based on Bandera 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) evaluated the safety of the recycling process AMB (EU register number RECYC154). The input is washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers with no more than 5% PET from non-food applications. It is decontaminated in a reactor at high temperature under vacuum and extruded to sheets. Having examined the challenge test provided, the Panel concluded that two steps, the decontamination in the vacuum reactor (step 2) and the extrusion (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, residence time and pressure for step 2 and temperature, residence time, pressure and screw speed for step 3. 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 when used up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs for long-term storage at room temperature, with or without hotfill, is not considered of safety concern. Articles 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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Keywords: AMB, Bandera, food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

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Question number: EFSA-Q-2018-00375

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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 282/2008[1] 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 1935/2004[2] 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 Ministero della Salute, Italy, an application for evaluation of the recycling process AMB, European Union (EU) register No RECYC154. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2018-00375. The dossier was submitted on behalf of AMB S.p.A., Italy.

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 AMB 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.

Additional information was sought from the applicant during the assessment process in response to a request from EFSA sent on 22 March 2019 and was subsequently provided (see 'Documentation provided to EFSA').

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] 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.

2.2. Methodologies

The principles followed up 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 (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 AMB is intended to recycle food grade PET containers to produce recycled PET sheets using the Bandera technology. It is intended to use up to 100% recycled PET to manufacture new food packaging articles, typically thermoformed trays and containers, in direct contact with all kinds of foodstuffs for long-term storage at room temperature, with or without hotfill.

3.2. Description of the process

3.2.1. General description

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

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

Input

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

Decontamination and production of recycled PET sheets

- In step 2, the flakes are preheated and decontaminated in batch reactors under high temperature and vacuum. Two batch reactors are alternately used, resulting in a semi-continuous process: in the first reactor, the material is decontaminated, while the second reactor is loaded with input material, preparing for decontamination.
- In step 3, the flakes are decontaminated by extrusion, including atmospheric and vacuum degassing, and sheets of recycled PET are produced.

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

Extruded PET 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 thermoformed trays or containers used for hotfill and/or long-term storage at room temperature, for contact with all types of food. 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 AMB consists of hot caustic washed and dried flakes obtained from PET containers, previously used for food packaging, from post-consumer collection systems (kerbside and deposit systems). A small fraction may originate from non-food applications, such as bottles used for soap, mouth wash or kitchen hygiene agents. According to the applicant, the proportion of these non-food containers will be below 5%.

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

3.3. Bandera technology

3.3.1. Description of the main steps

The general scheme of the Bandera 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.

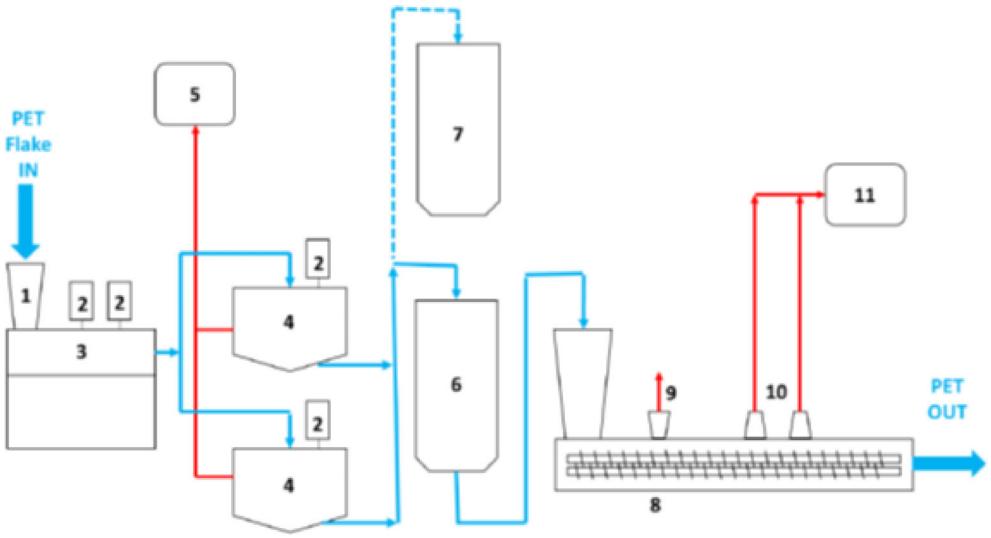

Figure 1: General scheme of the Bandera technology (provided by the applicant). (1 – Hopper, 2 – microwave devices, 3 – heating chamber, 4 – reactors, 5 – vacuum pump, 6 – ON-specification buffer for material complying with specified process parameters, 7 – OUT specification buffer for material not complying with specified process parameters and subsequently removed, 8 – co-rotating twin-screw extruder (Bandera), 9 – venting at atmospheric pressure, 10 – venting under vacuum, 11 – vacuum pump)

- In step 2, preheating and decontamination in vacuum reactors, the flakes are introduced continuously into a chamber for preheating. After preheating, two batch reactors operated under vacuum and high temperature are alternately used: While decontamination occurs in one reactor, preheated material is loaded in the second, which is in preparation for decontamination. Switching between the two reactors results in a semi-continuous process.
- In step 3, extrusion under vacuum, the flakes are fed into a twin-screw extruder with two degassing zones, one kept at ambient pressure (one venting point) and the other under vacuum (two venting points). Residual solid particles are filtered out before sheets are produced.

The process is operated under defined operating parameters[3] of temperature, pressure, residence time and extruder screw speed.

[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 European Commission (see Appendix C).

3.3.2. Decontamination efficiency of the recycling process

To demonstrate the decontamination efficiency of the recycling process AMB (Bandera technology), a challenge test performed in a small production unit was submitted to EFSA.

PET flakes were contaminated with toluene, chlorobenzene, 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 the preparation of the contaminated PET flakes, 120 kg of conventionally recycled[4] clear PET flakes was mixed with the surrogates and stored for 7 days at 50°C under periodical agitation. The procedure was repeated several times and the batches of flakes were combined. After washing, 600 kg contaminated flakes were introduced into the hopper (feeder). During the extrusion process, sheet samples were taken at regular intervals.

The decontamination efficiency was calculated from the concentrations of surrogates in PET material before introduction into the reactors (flakes) and after extrusion (sheets). The results are summarised below in Table 1.

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

Surrogates	Concentration of surrogates before step 2 (mg/kg PET)	Concentration of surrogates after step 3 (mg/kg PET)	Decontamination efficiency (%)
Toluene	507.8	< 0.1[(a)]	> 99.9
Chloroform	203.5	0.3	99.9
Chlorobenzene	645.8	< 0.1[(a)]	> 99.9
Phenylcyclohexane	375.8	1.3	99.7
Benzophenone	491.7	13.0	97.4
Methyl stearate	405.7	5.7	98.6

PET: poly(ethylene terephthalate).
(a): Not detected at the limit of detection given.

As shown in Table 1, the decontamination efficiency ranged from 97.4% for benzophenone to > 99.9% for toluene and chlorobenzene.

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, cellulose, metals and polyamides, were provided for the input materials (hot caustic washed and dried flakes, step 1). The input materials are produced from PET containers, previously used for food packaging, collected through post-consumer collection systems. However, a small fraction of the input may originate from non-food applications, such as bottles for soap, mouth wash and kitchen hygiene agents. According to the applicant, the process is managed in such a way that the proportion of these non-food containers will be lower than 5%, hence in accordance with the recommendations of 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 production of hot caustic washed and dried flakes from collected containers (step 1) is performed by third parties. The AMB process using the Bandera technology uses heat and vacuum in the decontamination reactors (step 2) and extrusion with degassing (step 3) to recycle the PET flakes into decontaminated PET sheets. The Panel noted that, in addition to the temperature, pressure and residence times, also the screw speed of the extruder plays a critical role on the performance of the recycling process. Differently sized Bandera extruders with the same ratio

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

of length over diameter in the different zones are covered by this evaluation. The operating parameters of temperature, pressure and residence time for steps 2 and 3 and the screw speed of the twin-screw extruder have been provided to EFSA.

To measure the decontamination efficiency of the process, a challenge test with contaminated flakes was conducted on step 2 (preheating and vacuum reactors) and step 3 (extrusion with degassing) at a small production unit. The challenge test was performed according to the recommendations in the EFSA Guidelines (EFSA, 2008). The contaminated flakes were washed before being subjected to step 2. The Panel considered that step 2 (preheating and vacuum reactors) and step 3 (extrusion with degassing under atmospheric pressure and vacuum) are critical for the decontamination efficiency of the process. Consequently, temperature, pressure and residence time of these steps as well as the screw speed of the twin-screw extruder should be controlled to guarantee the performance of the decontamination. These parameters have been provided to EFSA.

The decontamination efficiencies obtained for each surrogate in the challenge test, ranging from 97.4% to > 99.9%, have been used to calculate the residual concentrations of potential unknown contaminants in sheets (C_{res}) according to 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 percentages to the reference contamination level of 3 mg/kg PET, the C_{res} for the different surrogates in the challenge tests were obtained (Table 2).

Table 2: Decontamination efficiencies from challenge test, residual concentrations of surrogate contaminants in recycled PET (C_{res}) and calculated concentrations of surrogates in PET (C_{mod}) corresponding to a modelled migration of 0.1 μg/kg food after 1 year at 25°C

Surrogates	Decontamination efficiency (%)	C_{res} (mg/kg PET)	C_{mod} (mg/kg PET)
Toluene	> 99.98	0.001	0.09
Chloroform	99.9	0.004	0.10
Chlorobenzene	> 99.98	0.001	0.10
Phenylcyclohexane	99.7	0.010	0.14
Benzophenone	97.4	0.079	0.16
Methyl stearate	98.6	0.042	0.32

PET: poly(ethylene terephthalate).

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. 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.

The residual concentrations (C_{res}) of all surrogates in the decontaminated PET are below the corresponding modelled concentrations in PET (C_{mod}). Therefore, the Panel concluded that the recycling process under evaluation using the Bandera technology is able to ensure that the level of migration of potential unknown contaminants from the recycled PET into food is below the conservatively modelled migration of 0.1 μg/kg food, at which the risk to human health would be negligible.

4. Conclusions

The Panel considered that the process AMB 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 steps 2 (preheating and vacuum reactors) and 3 (extruder with degassing under atmospheric pressure and vacuum), are critical for the decontamination efficiency. The parameters to control its performance are temperature, residence time and pressure for step 2 and temperature, residence time, pressure and screw speed for the Bandera extruders. The Panel concluded that the recycling process AMB is able to reduce any foreseeable contamination of the 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 and contains no more than 5% of PET from non-food consumer applications.

Therefore, the recycled PET obtained from the process AMB intended to be used up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs for long-term storage at room temperature, with or without hotfill, is not considered of safety concern. Articles 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 "AMB". August 2018. Submitted on behalf of AMB SpA, Italy.
2) Additional information, June 2019. Submitted on behalf of AMB SpA, Italy.

References

EFSA (European Food Safety Authority), 2008. Guidelines for the submission of an application for safety evaluation by the EFSA of a recycling process to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food, prior to its authorisation. EFSA Journal 2008,6(7):717, 12 pp. https://doi.org/10.2903/j.efsa.2008.717

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EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)), 2011. 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 Journal 2011;9(7):2184, 25 pp. https://doi.org/10.2903/j.efsa.2011.2184

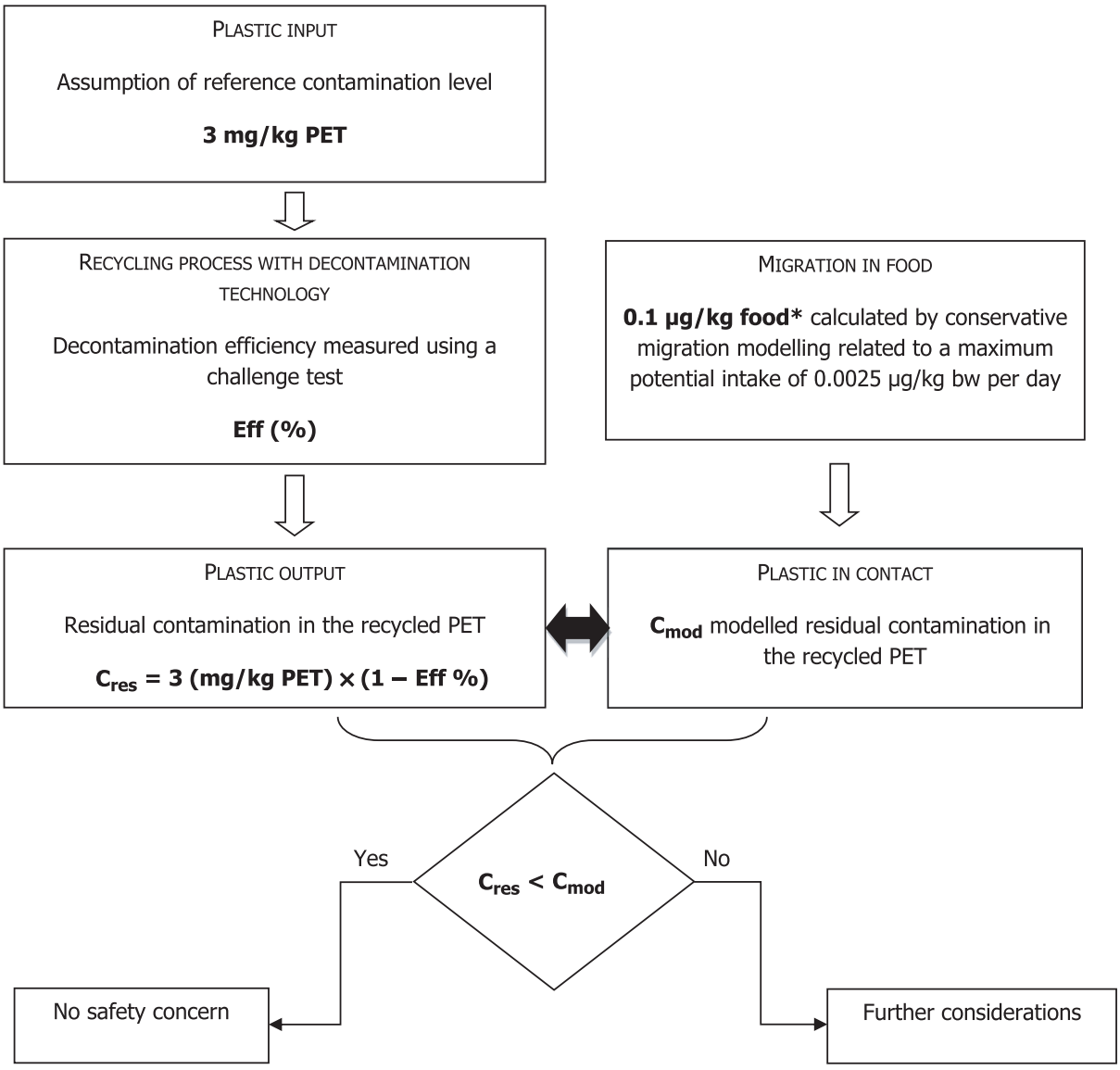
Abbreviations

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

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

Parameter	Value
Moisture max.	1.0%
Moisture variation	± 0.3% h^{-1}
Bulk density	200–850 kg/m^3
Bulk density variation	± 150 kg/(m^3h)
PVC max.	500 mg/kg
Glue max.	100 mg/kg
Polyolefins max.	300 mg/kg
Cellulose (paper, wood)	200 mg/kg
Metal max.	100 mg/kg
Polyamide max.	100 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)