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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), Vittorio Silano, Claudia Bolognesi, Laurence Castle, Kevin Chipman, Jean-Pierre Cravedi, Karl-Heinz Engel, Paul Fowler, Roland Franz, Konrad Grob, Rainer Gürtler, Trine Husøy, Sirpa Kärenlampi, Wim Mennes, Karla Pfaff, Gilles Riviere, Jannavi Srinivasan, Maria de Fátima Tavares Poças, Christina Tlustos, Detlef Wölfle, Holger Zorn, Vincent Dudler, Nathalie Gontard, Eugenia Lampi, Cristina Nerin, Constantine Papaspyrides, Cristina Croera and Maria Rosaria Milana

Abstract

This scientific opinion of the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel) deals with the safety evaluation of the recycling process BTB PET direct IV+ (EU register number RECYC0152). The input of the process is hot caustic washed and dried poly (ethylene terephthalate) (PET) flakes originating from collected post-consumer food contact PET containing no more than 5% of PET from non-food consumer applications. In this technology, washed PET flakes are extruded into pellets which are further crystallised. Crystallised pellets are then preheated and fed to the solid-state polycondensation (SSP) reactor. Having examined the challenge test provided, the Panel concluded that extrusion, crystallisation and SSP are the critical steps that determine the decontamination efficiency of the process. The operating parameters that control their performance are well defined and they are temperature, pressure and residence time. Under these conditions, it was demonstrated that the 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, 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. Trays made of this recycled PET are not intended to be used, and should not be used, in microwave and conventional ovens.

Keywords: PET direct IV+, BTB, food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

Requestor: Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany

Question number: EFSA-Q-2017-00224

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* Intrinsic Viscosity.

Panel members: Claudia Bolognesi, Laurence Castle, Kevin Chipman, Jean-Pierre Cravedi, Karl-Heinz Engel, Paul Fowler, Roland Franz, Konrad Grob, Rainer Gürtler, Trine Husøy, Sirpa Kärenlampi, Wim Mennes, Maria Rosaria Milana, Karla Pfaff, Gilles Riviere, Vittorio Silano, Jannavi Srinivasan, Maria de Fátima Tavares Poças, Christina Tlustos, Detlef Wölfle and Holger Zorn.

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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 for food contact 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 Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, an application for evaluation of the recycling process BTB PET direct IV+, EU register No RECYC0152. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2017-00224. The dossier was submitted on behalf of BTB GmbH & Co. KG, Germany.

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 processes 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 BTB PET direct IV+ 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 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 shall be 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.

[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 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 BTB PET direct IV+ is intended to recycle food grade PET materials to produce recycled PET pellets. The recycled PET pellets are intended to be used in a mass fraction up to 100% for the manufacture of recycled materials and articles. These final materials and articles are intended to be used 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 BTB PET direct IV+ produces recycled PET pellets from PET containers coming from post-consumer collection systems, such as deposit, kerbside and mixed waste collection. The recycling process comprises the steps below.

<u>Input</u>

- In step 1, post-consumer PET containers are sorted and processed into hot caustic washed and dried flakes, which are used as the input of the process (this step is made by the applicant or by third parties).

<u>Decontamination and production of recycled PET material</u>

- In step 2, the flakes are extruded into pellets under vacuum at high temperature.
- In step 3, the pellets are crystallised by heating with an inert gas flow. The crystallised pellets are then further heated to a higher temperature before the introduction into step 4.
- In step 4 the pellets are processed in the solid-state polycondensation (SSP) reactor at high temperature and under vacuum. More than one SSP reactor can be run in parallel.

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

Recycled PET pellets, the final product of the process, are checked against technical requirements on intrinsic viscosity, colour, black spots, etc. Recycled PET pellets are intended to be converted by other companies into recycled articles used for hotfill and/or long-term storage at room temperature. Trays made of this recycled PET 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 BTB PET direct IV+ consists of hot caustic washed and dried flakes obtained from PET materials (bottles, preforms, trays, sheets) previously used for food packaging, from post-consumer collection systems (kerbside and deposit systems) and mixed waste collection. A small fraction may originate from non-food applications, such as soap bottles, mouthwash bottles, kitchen hygiene bottles, etc. According to information from the applicant, the amount of this non-food container fraction will be kept below 5%.

Technical data for the washed and dried flakes are provided, such as information on residual content of poly(vinyl chloride) (PVC), polyolefins (PO), metals, dust and physical properties (see Appendix A).

3.3. PET direct IV+ technology

3.3.1. Description of the main steps

To decontaminate post-consumer PET, the recycling process BTB PET direct IV+ uses the PET direct IV+® technology as described below and for which the general scheme, provided by the applicant is reported in Figure 1. Figure 1 starts at step 2. The washing step (step 1) may be performed by the applicant or by third parts.

- Extrusion (step 2): The flakes from the previous step are fed into an extruder under high temperature and vacuum for a predefined residence time.
- Crystallisation (step 3): The extruded pellets are crystallised at high temperature in a further reactor under inert gas at atmospheric pressure.
- SSP (step 4): The crystallised pellets are continuously preheated in a reactor before being introduced into the SSP reactor(s) running under vacuum, at a predefined high temperature and for a predefined residence time. More than one SSP reactor can run in parallel.

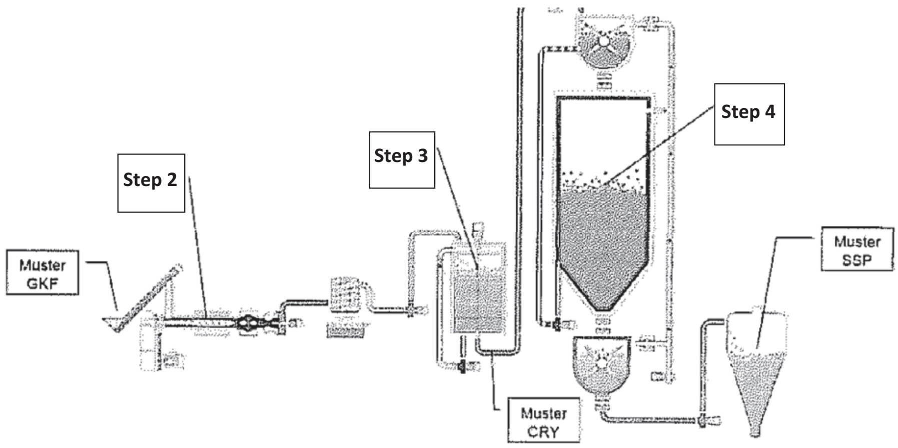


Figure 1: General scheme of the PET direct IV+ technology

The process is operated under defined operating parameters[3] of temperature, pressure, gas flow and residence time.

3.3.2. Decontamination efficiency of the recycling process

To demonstrate the decontamination efficiency of the recycling process BTB PET direct IV+, a challenge test on the PET direct IV+ technology was submitted to EFSA.

[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).

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

The surrogates were chosen in agreement with 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). The batches of contaminated PET were stored in a closed steel container for 7 days at 50°C with periodical agitation. The surrogates were decanted and PET flakes were rinsed with water and then air-dried. The concentration of surrogates in this material was determined.

The PET direct IV+ technology was challenged in a pilot plant of the Starlinger facilities, using only contaminated flakes. The contaminated flakes were extruded into pellets (step 2), crystallised (step 3) and then submitted to a SSP reaction (step 4). The samples (flakes then pellets) were analysed for their residual concentrations of the applied surrogates. Instead of being processed continuously, the SSP reaction was run in batch mode. In both batch and continuous modes of operation, the surrogates diffuse through the pellets to the surface and they are constantly eliminated by the vacuum applied. Therefore, continuous working processes will result in the same cleaning efficiencies as batch processes, as long as the same temperature, pressure conditions and residence time are applied.

The decontamination efficiency of the process was calculated taking into account the amount of the surrogates detected in washed and dried contaminated flakes before extrusion (before step 2) and in pellets after SSP (step 4). When not detected, the limit of detection was considered for the calculation of the decontamination efficiency. The results are summarised below in Table 1.

Table 1: Efficiency of the decontamination by the PET direct IV+ technology in the challenge test

Surrogates	Concentration of surrogates before step 2 (mg/kg PET)	Concentration of surrogates after step 4 (mg/kg PET)	Decontamination efficiency (%)
Toluene	267.8	< 0.2[(a)]	> 99.9
Chloroform	376.5	< 0.1[(a)]	> 99.9
Chlorobenzene	467.8	0.7	99.9
Phenylcyclohexane	572.4	5.7	99.0
Methyl salicylate	410.9	0.4	99.9
Benzophenone	719.4	8.8	98.8
Methyl stearate	505.2	3.2	99.4

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

As shown in Table 1, the decontamination efficiency ranged from 98.8% for benzophenone to more than 99.9% for toluene and chloroform.

Since the challenge test was performed with contaminated flakes only, cross-contamination[4] phenomena can be excluded.

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 residual content of PVC, polyolefins, metals, dust and physical properties, are provided for the input materials (washed and dried flakes (step 1)) for the submitted recycling process. The input materials are produced from PET containers previously used for food packaging collected through post-consumer collection systems, from post-consumer collection systems and mixed waste collection. However, a small fraction may originate from non-food applications, such as soap bottles, mouthwash bottles, kitchen hygiene bottles, etc. According to the

[4] 'Cross-contamination', 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).

applicant, the amount of this non-food container fraction is kept below 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 containers (step 1) is done either by the applicant or by third parties; according to the applicant, this step is under control. The following steps are those of the PET direct IV+ technology used to recycle the PET flakes into decontaminated PET pellets: extrusion into pellets (step 2), crystallisation (step 3) and SSP (step 4). In the current application, several SSP reactors (six) run in parallel. The operating parameters of temperature, pressure, residence time and gas flow have been provided to EFSA.

A challenge test was conducted at pilot plant scale, on process steps 2–4 (extrusion, crystallisation and SSP reactor) to measure the decontamination efficiency. The operating parameters of these steps in the process are at least as severe as those operated for the challenge test. The Panel considered that the challenge test was performed correctly according to EFSA guidelines (EFSA, 2008). Although the fourth step is expected to be most critical for the decontamination, crystallisation (step 3) is relevant too. Therefore, the Panel considered that the three steps (extrusion, crystallisation, and SSP) are the critical steps for the decontamination efficiency of the process. Consequently, the temperature for extrusion (step 2), the temperature, the gas flow and the residence time for crystallisation (step 3) and the temperature, the pressure and the residence time for SSP (step 4) 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 98.8% to above 99.9%, have been used to calculate the residual concentrations of potential unknown contaminants in pellets (C_{res}) in accordance with 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 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.[5] Because the recycled PET is intended for general use for the manufacturing of articles containing up to 100% recycled PET, the most conservative default scenario for infants has been applied. Therefore, the migration of 0.1 μg/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 concentration of surrogate contaminants in recycled PET (C_{res}) and calculated concentration of surrogate contaminants 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	> 99.9	< 0.003	0.09
Chloroform	> 99.9	< 0.024	0.10
Chlorobenzene	99.9	0.003	0.10
Phenylcyclohexane	99.0	0.030	0.14
Methyl salicylate	99.9	0.003	0.13
Benzophenone	98.8	0.006	0.16
Methyl stearate	99.4	0.018	0.32

PET: poly(ethylene terephthalate).

The residual concentrations of all surrogates in PET after decontamination (C_{res}) are lower than the corresponding modelled concentrations in PET (C_{mod}). Therefore, the Panel considered that the recycling process BTB PET direct IV+ is able to ensure that the level of migration of unknown

[5] 0.0025 μg/kg bw per day is the human exposure threshold value for chemicals with structural alerts raising concern for potential genotoxicity, below which the risk to human health would be negligible (EFSA CEF Panel, 2011).

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 CEF Panel considered that the process BTB PET direct IV+ is well characterised and the main steps used to recycle PET flakes into decontaminated PET pellets have been identified. Having examined the challenge test provided, the Panel concluded that the three steps (extrusion, crystallisation and SSP) are critical for the decontamination efficiency of the process. The operating parameters to control its performance are the temperature for extrusion (step 2), the temperature, the gas flow and the residence time for crystallisation (step 3) and the temperature, the pressure and the residence time for SSP (step 4).

The Panel considered that the recycling process BTB PET direct IV+ is able to reduce any foreseeable accidental 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 obtained from the challenge test used to measure the decontamination efficiency of the process; and
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 European Union (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 BTB PET direct IV+ 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. Trays made of this recycled PET are not intended to be used, and should not be used, in microwave and conventional ovens.

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 'BTB PET direct IV+'. May 2017. Submitted on behalf of BTB GmbH & Co. KG, Germany.
2) Additional data on the dossier 'BTB PET direct IV+'. November 2017. Submitted on behalf of BTB GmbH & Co. KG, Germany.
3) Additional data on the dossier 'BTB PET direct IV+'. January 2018. Submitted on behalf of BTB GmbH & Co. KG, Germany.

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

EFSA (European Food Safety Authority), 2009. Guidance of the Scientific Committee on transparency in the scientific aspects of risk assessments carried out by EFSA. Part 2: general principles. EFSA Journal 2009;7(5):1051, 22 pp. https://doi.org/10.2903/j.efsa.2009.1051

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

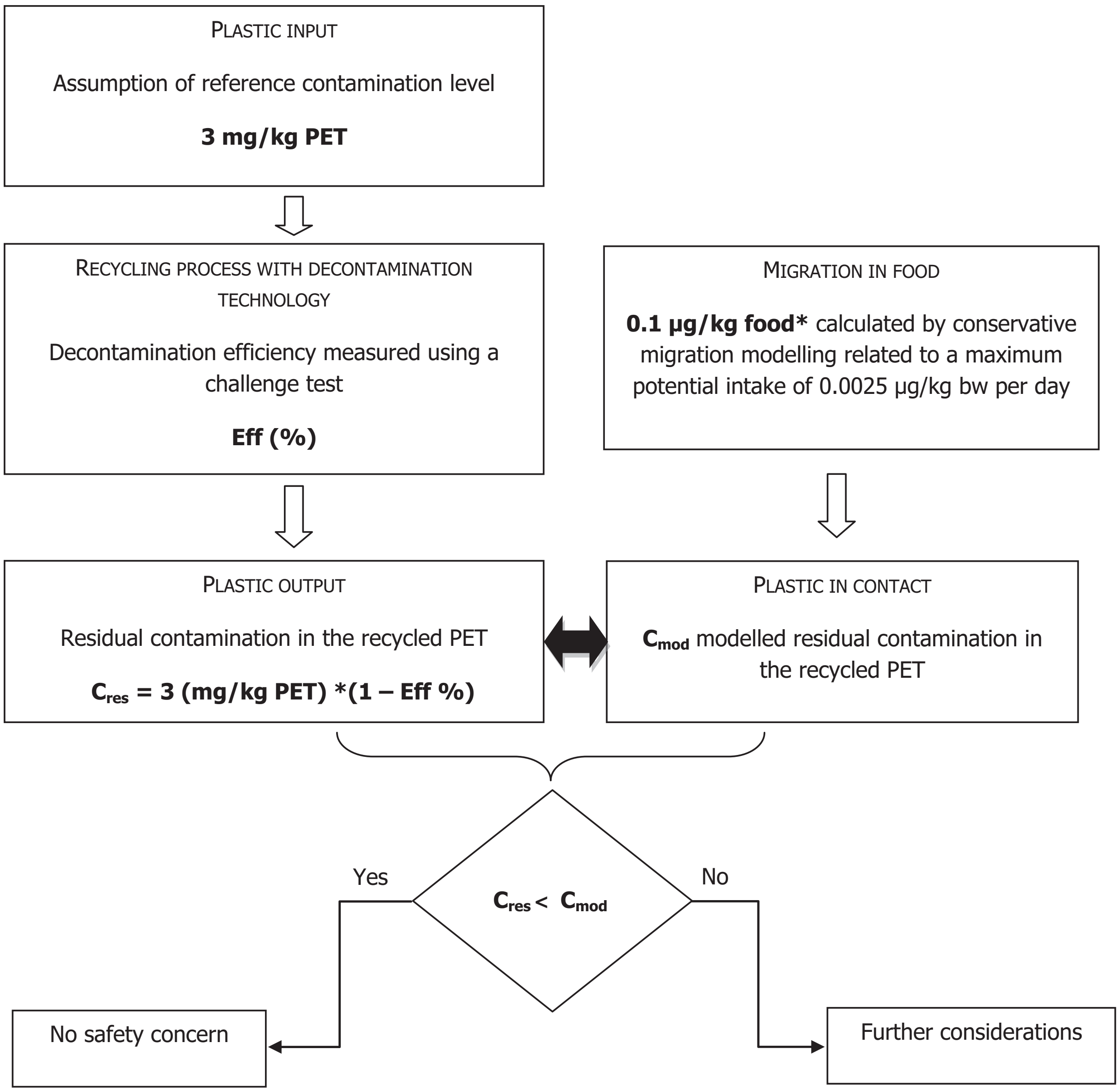
bw	body weight
CEF	Food Contact Materials, Enzymes, Flavourings and Processing Aids
C_{mod}	modelled concentration in PET
C_{res}	residual concentrations in PET
IV	Intrinsic Viscosity
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)
SSP	solid-state polycondensation

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

Parameter	Value
Moisture max.	< 2.5%
Bulk density	200–300 kg/m^3
PVC	< 200 ppm
Polyolefins	< 100 ppm
Metals	< 300 ppm
Dust	< 1.5%

PVC: poly(vinyl chloride).

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 of Operational Parameters (Confidential Information)