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Safety assessment of the process 'Jász-Plasztik', based on Vacurema Prime 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 Panel) assessed the safety of the recycling process Jász-Plasztik (EU register number RECYC0157). The input are hot caustic washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers and containing no more than 5% PET from non-food applications. They are heated in a batch reactor under vacuum and then heated in a continuous reactor under vacuum before being extruded into pellets. Having examined the results of the challenge test provided, the Panel concluded that the decontamination in the batch reactors (step 2) and in the continuous reactor (step 3) are the critical steps that determine the decontamination efficiency of the process. The operating parameters to control the performance of these critical steps 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 0.1 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. 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.

Keywords: VACUREMA Prime, 'Jász-Plasztik, food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

Requestor: Hungarian Competent Authority (National Food Chain Safety Office), Hungary

Question number: EFSA-Q-2018-00529

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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 National Food Chain Safety Office), Hungary, an application for evaluation of the recycling process Jász-Plasztik, European Union (EU) register No RECYC0157. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2018-00529. The dossier was submitted on behalf of Jász-Plasztik Kft, Hungary.

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 Jász-Plasztik 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.

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

The criteria for the safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for the manufacture of materials and articles in contact with food are described in the scientific opinion developed by the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (EFSA CEF Panel, 2011). The principle of the evaluation is to apply the decontamination efficiency of a recycling technology or process, obtained from a challenge test with surrogate contaminants, to a reference contamination level for post-consumer PET, conservatively set at 3 mg/kg PET for contaminants resulting from possible misuse. The 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 Jász-Plasztik is intended to recycle food grade PET containers to produce recycled PET pellets using the VACUREMA Prime technology. It is intended to use up to 100% recycled PET to manufacture new food packaging 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 Jász-Plasztik produces recycled PET pellets from PET containers obtained from post-consumer collection systems (kerbside and deposit systems). The recycling process comprises four steps, as mentioned below.

<u>Input</u>

- In step 1, post-consumer PET containers are processed by third parties into hot caustic washed and dried flakes, which are used as input of the process.

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

- In step 2, the flakes are preheated in batch reactors under vacuum and the material is crystallised.
- In step 3, flakes are treated in a continuous reactor under high temperature and vacuum.
- In step 4, the material is extruded and pellets of recycled PET are produced.

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

Recycled pellets, 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 articles used for hotfill and/or long-term storage at room temperature, such as bottles for mineral water, soft drinks and beer. The recycled pellets may also be used for sheets, which are thermoformed to make food trays. 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 Jász-Plasztik 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 depends on the collection system and will be below 5%.

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

3.3. VACUREMA Prime technology

3.3.1. Description of the main steps

The general scheme of the VACUREMA Prime 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 and crystallisation in twin batch reactors (step 2):

- The flakes are introduced into twin batch reactors, where vacuum and heat are applied for a predefined residence time. These process conditions favour the vaporisation of possible contaminants and crystallisation of PET flakes. The twin reactors alternately feed a continuous reactor. The time for emptying one batch reactor is equal to the processing time in the other.

Decontamination in the continuous reactor (step 3):

- The flakes from the batch reactors are fed to a continuous reactor, running under high temperature and vacuum for a predefined residence time. Further decontamination occurs in this reactor.

Extrusion (step 4):

- The flakes continuously coming from the previous reactor are melted in the extruder and residual solid particles (e.g. paper, aluminium) are filtered out before pellets are produced.

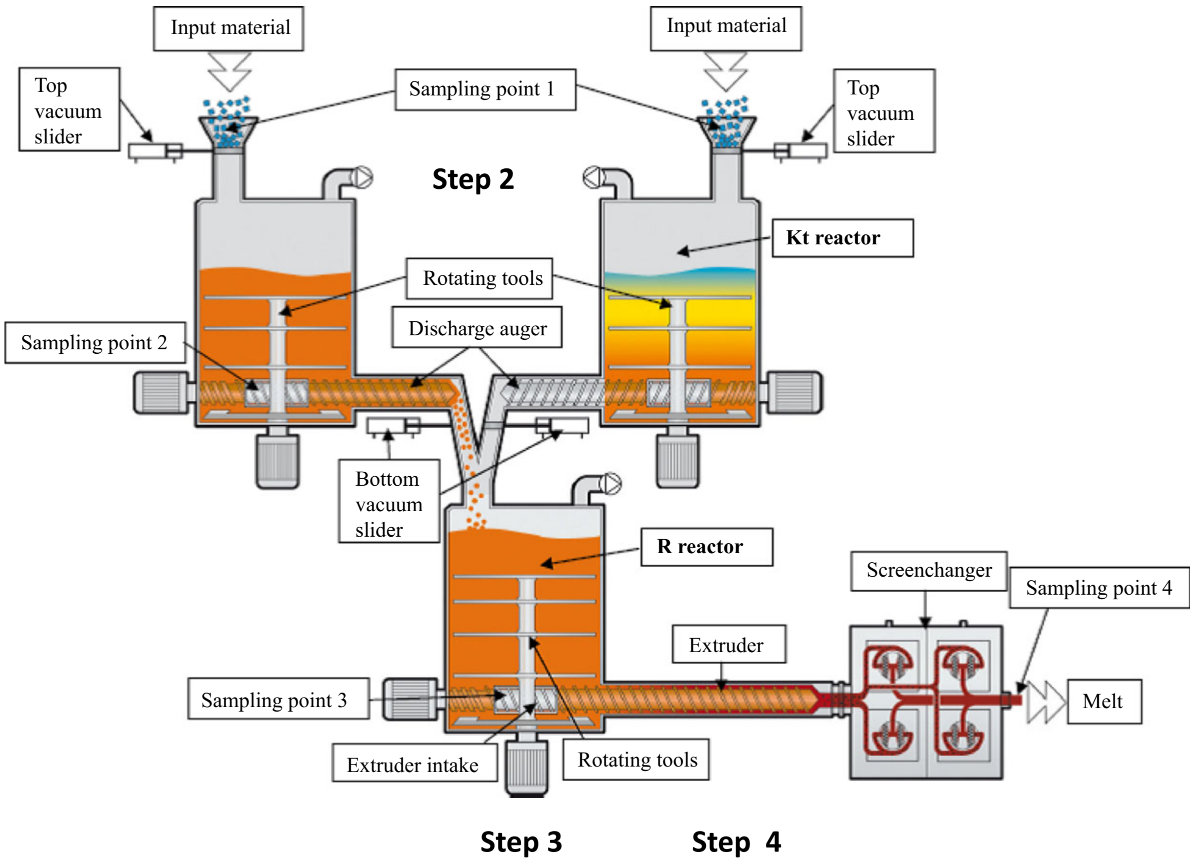


Figure 1: General scheme of the technology (provided by the applicant)

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

3.3.2. Decontamination efficiency of the recycling process

To demonstrate the decontamination efficiency of the recycling process Jász-Plasztik, a challenge test was submitted to the EFSA.

PET flakes were contaminated with toluene, chloroform, phenylcyclohexane, benzophenone and lindane, 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, 100 kg of conventionally recycled[4] post-consumer PET flakes of green colour was soaked in a heptane/isopropanol solution containing the surrogates and stored for 14 days at 40°C. The surrogates solution was decanted and PET flakes were rinsed with water and then air dried. The concentration of surrogates in this material was determined.

The VACUREMA Prime technology was challenged using a production plant of reduced capacity. The batch reactor was filled with washed and dried flakes, both white, non-contaminated, flakes and green flakes, contaminated with surrogate contaminants. White and green flakes were sampled at regular intervals after each step. After the batch and the continuous reactor (before extrusion), green flakes were isolated and analysed for their residual concentrations of the applied surrogates. In the extrusion process, contaminated material and non-contaminated material were melted together and at the end pellet samples were taken for analysis.

From the analysis of the samples, no more surrogates were detected in the green flakes after the continuous reactor. Thus, decontamination efficiency was calculated based on the concentrations of

[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).

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

the surrogates in green, contaminated, flakes before and after the batch reactor. The results are summarised in Table 1.

Table 1: Efficiency of the decontamination of the batch reactors (VACUREMA Prime, step 2) in the challenge test

Surrogates	Concentration[(a)] of surrogates before step 2 (mg/kg PET)	Concentration[(a)] of surrogates after step 2 (mg/kg PET)	Decontamination efficiency (%)
Toluene	1,190	< 0.7[(b)]	> 99.9
Chloroform	2,078	0.4	99.9
Phenylcyclohexane	113.3	0.2	99.8
Benzophenone	410	0.7	99.8
Lindane	95.2	1.6	98.3

PET: poly(ethylene terephthalate).
(a): Measured in green, contaminated, flakes.
(b): Not detected at the limit of detection given.

As shown in Table 1, the decontamination efficiency over step 2 ranged from 98.3% for lindane to more than 99.9% for toluene.

The decontamination efficiencies, as presented in Table 1, were calculated at the exit of the batch reactor (step 2) in the challenge test. After this step, surrogates levels were close to, or below, the detection limit. After the continuous reactor none of the surrogates could be detected. The vacuum and temperature in the continuous reactor are equivalent to, or more severe than, those in the batch reactor. Therefore, the ability of the continuous reactor (step 3) to decontaminate the PET is equivalent to that of the batch reactor. In plants operating the process, the residence time in the batch reactor plus the continuous reactor is equal to the residence time in the batch reactor in the challenge test. The decontamination efficiency of the batch reactor (step 2) in the challenge test represents that of both reactors (steps 2 and 3) in the process. The decontamination occurring during the time of the feeding of the continuous reactor and the extrusion step that may contribute further to the overall decontamination is not taken into account. Therefore, actual decontamination efficiencies are expected to be higher. Decontamination efficiencies were calculated by determining residual surrogates only in contaminated (green) flakes. Cross-contamination by diffusion of contaminants from green to white flakes may occur. However, considering the high decontamination rate of this process and the fact that contaminated and non-contaminated flakes are always under high temperature and under high vacuum conditions, a potential cross-contamination is expected to have a limited impact on the calculation of the final 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 residual content of PVC, glue, polyolefins, cellulose, metals, polyamides 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, mainly bottles, 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 soap bottles, mouth wash bottles, kitchen hygiene bottles, etc. According to the applicant, the proportion of this non-food container fraction depends on the collection system and the process is managed in such a way that in the input stream of the recycling process this amount 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 production of washed and dried flakes from collected containers (step 1) is conducted by third parties. The following steps are those of the VACUREMA Prime technology used to recycle the PET flakes into decontaminated PET pellets: batch decontamination reactors (step 2), continuous decontamination reactor (step 3) and extrusion (step 4). The operating parameters of temperature, pressure and residence time for steps 2 and 3 have been provided to EFSA. For step 4, the operating parameters of temperature and residence time are also provided.

A challenge test was conducted at a small production plant on process steps 2, 3 and 4 (batch decontamination reactor, continuous decontamination reactor and extrusion, respectively) to measure the decontamination efficiency. Surrogate concentrations after step 2 were close to, or below, the detection limit and were no longer detected in the flakes after the continuous reactor (step 3). In the challenge test, the batch reactor was operated under pressure and temperature conditions equivalent to those of the process, while the residence time was equal to the residence time of step 2 (batch reactor) plus step 3 (continuous reactor) of the process. The decontamination efficiency was determined in the challenge test from the batch reactor data (step 2), considered to be representative of steps 2 and 3 in the real plant. Because the continuous reactor is operated under pressure and temperature conditions equivalent to or more severe than the batch reactor, its ability to decontaminate PET is at least equivalent to that of the batch reactor. Therefore, the decontamination efficiency of the process is considered equivalent to that of the batch reactor as measured in the challenge test.

The decontamination efficiencies obtained from the challenge test data on step 2 for each surrogate contaminant, ranging from 98.3% to 99.9%, have been used to calculate the residual concentrations of potential unknown contaminants in PET (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, 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 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	0.003	0.10
Phenylcyclohexane	99.8	0.006	0.14
Benzophenone	99.8	0.006	0.16
Lindane	98.3	0.051	0.31

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 the recycling process under evaluation using the VACUREMA Prime 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 μg/kg food, at which the risk to human health would be negligible.

4. Conclusions

The Panel considered that the process Jász-Plasztik is well characterised and the main steps used to recycle the PET flakes into decontaminated PET pellets have been identified. Having examined the challenge tests provided, the Panel concluded that the decontamination in the batch reactors (step 2) and in the continuous reactor (step 3) are the critical steps for the decontamination efficiency of the

[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).

process. The operating parameters to control its performance are temperature, pressure and residence time.

The Panel considered that the recycling process Jász-Plasztik 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 applied in the challenge tests 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 Jász-Plasztik intended to be used at 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 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 "Jász-Plasztik". October 2018. Submitted on behalf of Jász-Plasztik Kft, Hungary.

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

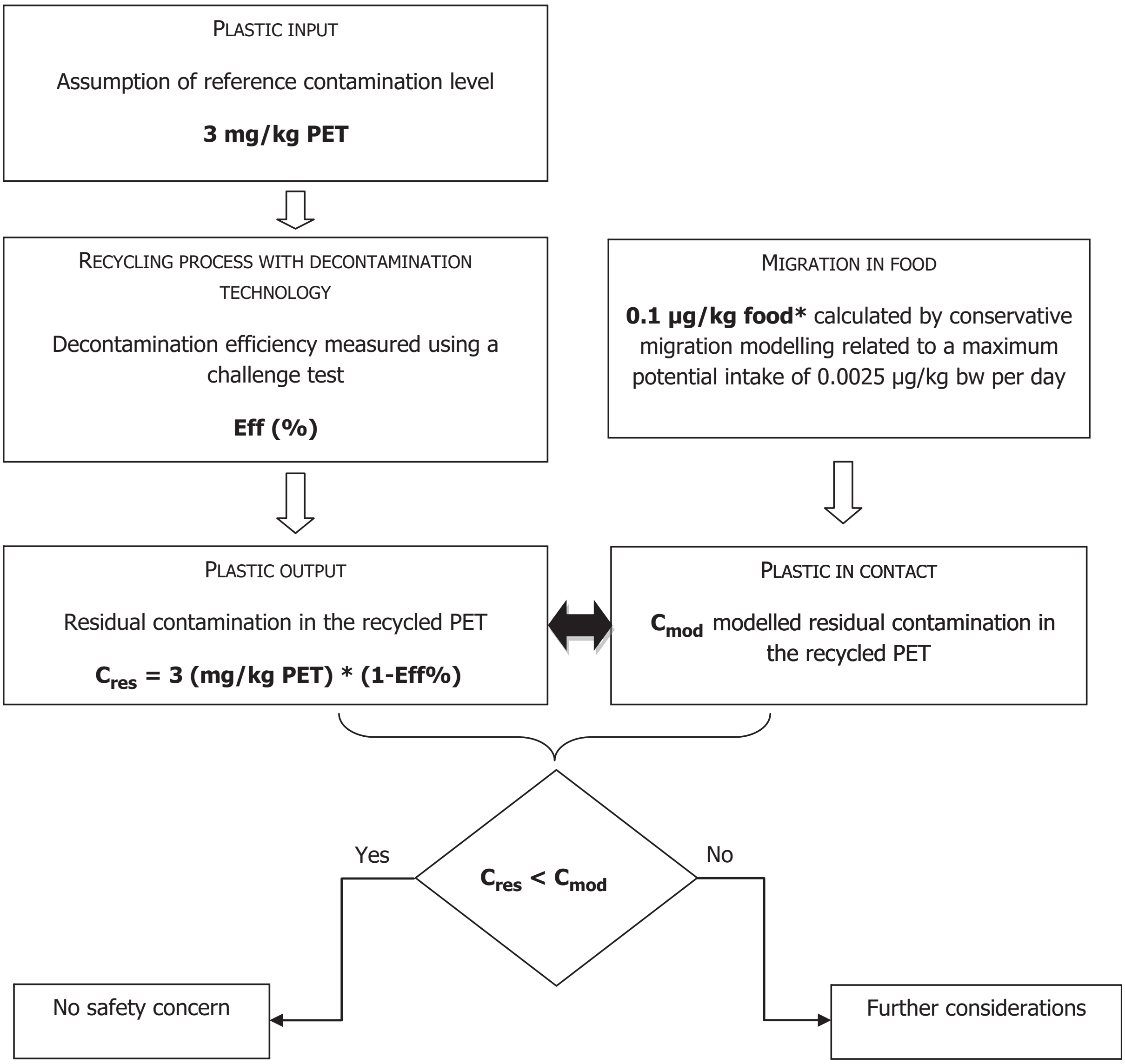
bw	body weight
CEF	Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP	Food Contact Materials, Enzymes and Processing Aids
C_{mod}	modelled concentration in PET
C_{res}	residual concentrations in PET
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)

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

Parameter	Value
Moisture max.	1.5%
Moisture variation	$\pm$ 0.3% h^{-1}
Bulk density	330 kg/m^3
Bulk density variation	$\pm$ 40 $kg/(h*m^3)$
Material temperature	30–60°C
PVC max.	15 mg/kg
Glue max.	20 mg/kg
Polyolefins max.	20 mg/kg
Cellulose (paper, wood)	20 mg/kg
Metal max.	10 mg/kg
Polyamide max.	10 mg/kg

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 on Operational parameters (Confidential Information)

[redacted]

[redacted]

	[redacted]			[redacted]			[redacted]		
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
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