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Safety assessment of the process EREMA, based on EREMA MPR + DS 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) assessed the safety of the recycling process EREMA (EU register number RECYC205), which uses the EREMA MPR + DS technology. The input material is hot caustic washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, including no more than 5% PET from non-food consumer applications. The flakes are heated in a [redacted] reactor under vacuum before being extruded. Having examined the challenge test provided, the Panel concluded that the [redacted] reactor (step 2) and the extruder (step 3) are critical in determining the decontamination efficiency. The operating parameters to control the performance of these steps are temperature, pressure and residence time. It was demonstrated that this recycling process is able to ensure a level of migration of potential unknown contaminants into food below the conservatively modelled migration of 0.1 μg/kg food, derived from the exposure scenario for infants when such recycled PET is used at up to 100%. Therefore, the Panel concluded that the recycled PET obtained from this process is not considered to be of safety concern when used at up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs, including drinking water, for long-term storage at room temperature. Articles made of this recycled PET are not intended to be used in microwave and conventional ovens and such uses are not covered by this evaluation.

Keywords: EREMA MPR + DS, food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

Requestor: Federal Ministry Republic of Austria - Labour, Social Affairs, Health and Consumer Protection, Austria

Question number: EFSA-Q-2019-00367

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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. Technical details on recycling steps 2 and 3 (Sections 3.3.1, 3.3.2, 3.4 and 4), details of the performed challenge test (Sections 3.3.2 and 3.4) as well as 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.

Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

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† Deceased.

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1. Introduction

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

Recycled plastic materials and articles shall only be placed on the market if the recycled plastic is from an authorised recycling process. Before a recycling process is authorised, the European Food Safety Authority (EFSA)'s opinion on its safety is required. This procedure has been established in Article 5 of Regulation (EC) No 282/2008[1] on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of Regulation (EC) No 1935/2004[2] on materials and articles intended to come into contact with food.

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

In this case, EFSA received from the Federal Ministry Republic of Austria - Labour, Social Affairs, Health and Consumer Protection, Austria, an application for evaluation of the recycling process EREMA (EREMA MPR + DS technology), European Union (EU) register No RECYC205. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2019-00367. The dossier was submitted on behalf of EREMA Engineering Recycling Maschinen und Anlagen Ges.m.b.H., Austria.

According to Article 5 of Regulation (EC) No 282/2008 on recycled plastic materials intended to come into contact with foods, EFSA is required to carry out risk assessments on the risks originating from the migration of substances from recycled food contact plastic materials and articles into food and deliver a scientific opinion on the recycling process examined.

According to Article 4 of Regulation (EC) No 282/2008, EFSA will evaluate whether it has been demonstrated in a challenge test, or by other appropriate scientific evidence, that the recycling process is able to reduce the contamination of the plastic input to a concentration that does not pose a risk to human health. The poly(ethylene terephthalate) (PET) materials and articles used as input of the process as well as the conditions of use of the recycled PET are part of this evaluation.

2. Data and methodologies

2.1. Data

The applicant has submitted a dossier following the 'EFSA guidelines for the submission of an application for the safety evaluation of a recycling process to produce recycled plastics intended to be used for the manufacture of materials and articles in contact with food, prior to its authorisation' (EFSA, 2008).

Additional information was provided by the applicant during the assessment process in response to requests from EFSA sent on 20 November 2020, 9 June 2021, 25 October 2021 and 17 December 2021, and was subsequently provided (see 'Documentation provided to EFSA').

Following the request by the Working Group, a technical hearing was held with the applicant on 26 May 2021.[3]

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,

[1] Commission Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006. OJ L 86, 28.3.2008, p. 9–18.

[2] Regulation (EC) No 1935/2004 of the European parliament and of the council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4–17.

[3] For further details, see minutes of the 25th meeting of the Working Group on Recycling Plastics 2018-2021, available under https://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/recycling-plastics-min.pdf

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

The criteria for the safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for the manufacture of materials and articles in contact with food are described in the scientific opinion developed by the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (EFSA CEF Panel, 2011). The principle of the evaluation is to apply the decontamination efficiency of a recycling technology or process, obtained from a challenge test with surrogate contaminants, to a reference contamination level for post-consumer PET, conservatively set at 3 mg/kg PET for contaminants resulting from possible misuse. The resulting residual concentration of each surrogate contaminant in recycled PET (C_{res}) is compared with a modelled concentration of the surrogate contaminants in PET (C_{mod}). This C_{mod} is calculated using generally recognised conservative migration models so that the related migration does not give rise to a dietary exposure exceeding 0.0025 μg/kg body weight (bw) per day (i.e. the human exposure threshold value for chemicals with structural alerts for genotoxicity), below which the risk to human health would be negligible. If the C_{res} is not higher than the C_{mod}, the recycled PET manufactured by such recycling process is not considered to be of safety concern for the defined conditions of use (EFSA CEF Panel, 2011).

The assessment was conducted in line with the principles described in the EFSA Guidance on transparency in the scientific aspects of risk assessment (EFSA, 2009) and considering the relevant guidance from the EFSA Scientific Committee.

3. Assessment

3.1. General information[4]

According to the applicant, the recycling process EREMA using the EREMA MPR + DS technology is intended to recycle food-grade PET containers. The recycled PET is intended to be used at up to 100% for (i) thermoformed trays/containers, e.g. for fruits, vegetables, cooked and uncooked meats, dairy products and desserts, and (ii) the manufacture of bottles for mineral water, soft drinks, juices and beer, for long-term food storage at room temperature. The final articles are not intended to be used in microwave or conventional ovens.

3.2. Description of the process

3.2.1. General description[5]

The recycling process EREMA (EREMA MPR + DS) produces recycled PET pellets or sheets from PET containers from post-consumer collection systems (kerbside and deposit systems).

The recycling process comprises the three steps below.

<u>Input</u>

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

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

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

[4] Technical dossier, Sections 3.1.1 and 3.2.5.
[5] Technical dossier, Sections 3.1.1, 3.2.1 and 3.2.4.

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

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

3.2.2. Characterisation of the input[6]

According to the applicant, the input material for the recycling process EREMA using the EREMA MPR + DS technology consists of hot washed and dried flakes obtained from PET containers, e.g. bottles, previously used for food packaging, from post-consumer collection systems (kerbside and deposit systems). A small fraction may originate from non-food applications. The proportion should be no more than 5%.

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

3.3. EREMA MPR + DS technology

3.3.1. Description of the main steps[7]

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

- Decontamination in a [redacted] reactor (step 2):

The flakes are [redacted] fed into a reactor equipped with a rotating device, running under high temperature and vacuum for a pre-defined minimum residence time.

- Extrusion of the decontaminated flakes (step 3):

The flakes, [redacted] introduced from the previous reactor, are molten in the double-screw extruder. [redacted]

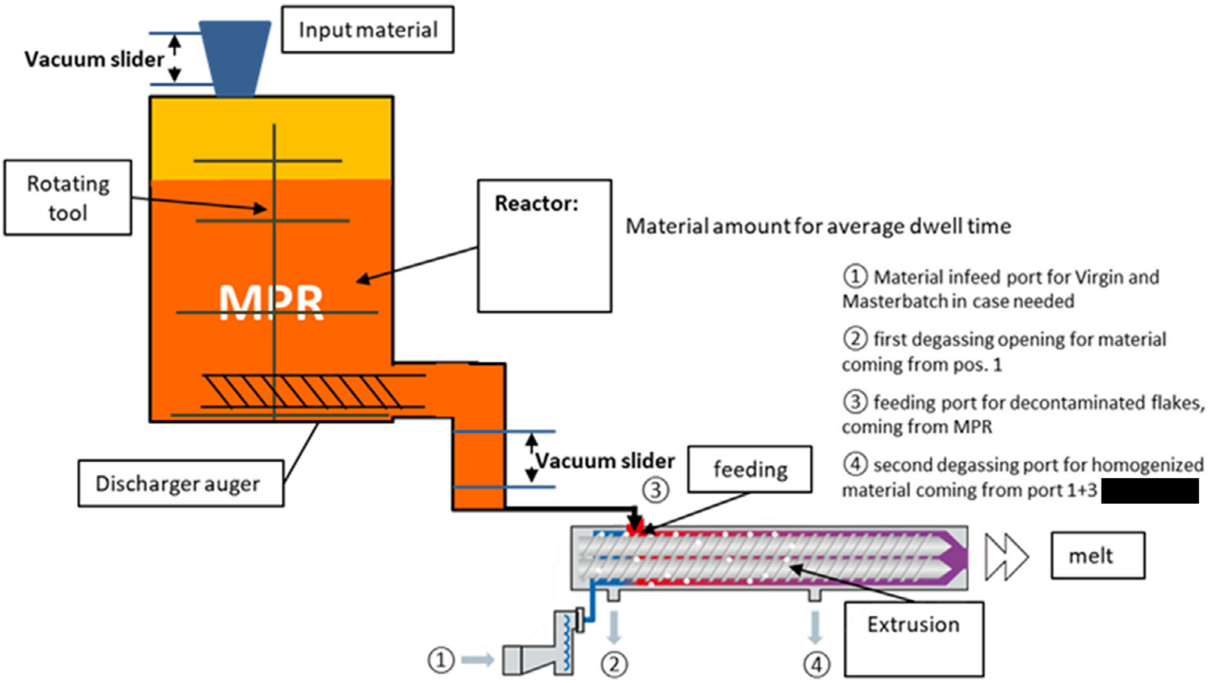

Figure 1: General scheme of the technology (provided by the applicant)

[6] Technical dossier, Section 3.2.2.
[7] Technical dossier, Sections 3.1.1 and 3.2.1.

The process is run under defined operating parameters[8] of temperature, pressure and residence time.

3.3.2. Decontamination efficiency of the recycling process[9]

To demonstrate the decontamination efficiency of the recycling process, a challenge test on steps 2 and 3 was submitted to the EFSA.

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 (EFSA CEF Panel, 2011) and in accordance with the recommendations of the US Food and Drug Administration (FDA, 2006). The surrogates include different molecular masses and polarities to cover possible chemical classes of contaminants of concern and were demonstrated to be suitable to monitor the behaviour of PET during recycling (EFSA, 2008).

For this purpose, 20 mL each of the liquid surrogates (toluene, chlorobenzene, chloroform, methyl salicylate and phenylcyclohexane) were mixed with 20 g each of the solid surrogates (benzophenone and methyl stearate). This surrogate mix was given to a batch of 20 kg of conventionally recycled[10] post-consumer PET flakes. Ten such batches were produced and stored for 7 days at 50°C with periodical agitation. Afterwards, the contaminated flakes were washed and rinsed with 10% ethanol, and the concentration of surrogates in this material was determined.

The challenge test was performed in two separate stages, both at an industrial reactor. Two hundred kg of contaminated flakes were introduced in the decontamination reactor (step 2). [redacted] Samples were taken at the outlet of the reactor at regular intervals and the flakes were analysed for their residual concentrations of the applied surrogates. [redacted] Samples were taken at the outlet of the extruder and were then analysed for their residual concentrations of the applied surrogates.

Instead of being operated [redacted] (as in the industrial process), the step 2 of the challenge test was run in [redacted] mode. The Panel considered that the [redacted] reactor ran at the same temperature and pressure as is foreseen for the industrial process. In order to prove the representativeness of the residence time of the flakes in the challenge test, two additional challenge tests running in continuous mode were provided. In these tests, a mixture of green (contaminated) and clear (non-contaminated) flakes was challenged and the ratio of green and clear flakes at the exit of the reactor at different residence times was determined. Based on these results, the Panel concluded that the residence time in the challenge test [redacted] reactor corresponded to the minimum residence time in the industrial [redacted] reactor.

The decontamination efficiency of the process was calculated from the concentrations of the surrogates measured in the washed contaminated flakes introduced in the reactor (step 2) and those exiting the extruder (step 3). The results are summarised in Table 1.

Table 1: Efficiency of the decontamination of the process (step 2 followed by step 3) 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	185.9	1.9[(a)]	99.0
Chlorobenzene	421.9	1.9	99.5
Chloroform	150.6	1.3	99.1
Methyl salicylate	620.0	< 0.1	100
Phenylcyclohexane	345.2	7.6	97.8
Benzophenone	756.1	25.6	96.6
Methyl stearate	889.5	10.6	98.8

PET: poly(ethylene terephthalate).
(a): Value after step 2.

[8] In accordance with Art. 9 and 20 of Regulation (EC) No 1935/2004 the parameters were provided to EFSA by the applicant and made available to the Member States and the European Commission (see Appendix C).
[9] Technical dossier, Sections 3.2.1 and 3.2.3 and Appendices E1, E2 and E3.
[10] Conventional recycling commonly includes sorting, grinding, washing and drying steps and produces washed and dried flakes.

The decontamination efficiency ranged from 96.6% for benzophenone up to 100% for methyl salicylate.

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 specifications, such as information on physical properties and residual contents of moisture, PVC, glue, polyolefins, polyamides, cellulose and metals, were provided for the input materials (i.e. hot caustic washed and dried flakes, step 1). These are produced from PET containers, e.g. bottles, previously used for food packaging, collected through post-consumer collection systems. However, a small fraction may originate from non-food applications, such as bottles for soap, mouth wash or kitchen hygiene agents. The collection system and the process are to be managed in such a way that in the input stream this fraction will be no more than 5%, as recommended by the EFSA CEF Panel in its 'Scientific opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food' (EFSA CEF Panel, 2011).

The process is adequately described. The EREMA MPR + DS technology comprises the [redacted] 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 to measure the decontamination efficiency was conducted at industrial plant scale in a decontamination reactor operating in [redacted] mode (step 2) and in an extruder (step 3). The reactor and extruder were operated under temperature, pressure and residence time conditions equivalent to or less severe than those of the commercial process. Since both steps 2 and 3 were conducted with only contaminated flakes and pellets, respectively, cross-contamination could not occur. The Panel considered that this challenge test was performed correctly according to the recommendations of the EFSA guidelines (EFSA, 2008) and that steps 2 and 3 were critical for the decontamination efficiency of the process. Consequently, temperature, pressure and residence time of steps 2 and 3 of the process should be controlled to guarantee the performance of the decontamination (Appendix C).

The decontamination efficiencies obtained for each surrogate, ranging from 96.6% to 100% 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 was obtained (Table 2).

According to the evaluation principles (EFSA CEF Panel, 2011), the dietary exposure must not exceed 0.0025 μg/kg bw per day, below which the risk to human health is considered negligible. The C_{res} value should not exceed the modelled concentration in PET (C_{mod}) that could result, after 1 year at 25°C, in a migration giving rise to a dietary exposure exceeding 0.0025 μg/kg bw per day. Because the recycled PET is intended for the manufacture of trays and containers as well as bottles for drinking water, the exposure scenario for infants has been applied (since water could be used to prepare infant formula). A maximum dietary exposure of 0.0025 μg/kg bw per day corresponds to a maximum migration of 0.1 μg/kg of the contaminant into the infant's food and has been used to calculate C_{mod} (EFSA CEF Panel, 2011).

C_{res} reported in Table 2 is calculated for 100% recycled PET, for which the risk to human health is demonstrated to be negligible. The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

Table 2: Decontamination efficiency from the challenge test, residual concentrations of the surrogates in the recycled PET (C_{res}) and calculated concentrations of the surrogates in PET (C_{mod}) corresponding to a modelled migration of 0.1 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	99.0	0.030	0.09
Chlorobenzene	99.5	0.015	0.09

Surrogates	Decontamination efficiency (%)	C_{res} for 100% rPET (mg/kg PET)	C_{mod} (mg/kg PET)
Chloroform	99.1	0.027	0.10
Methyl salicylate	100	0	0.13
Phenylcyclohexane	97.8	0.066	0.14
Benzophenone	96.6	0.102	0.16
Methyl stearate	98.8	0.036	0.32

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 under the given operating conditions the recycling process EREMA using the EREMA MPR + DS 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 this level, the risk to human health would be negligible when the recycled PET is used at up to 100% for materials and articles intended for contact with all types of foodstuffs including drinking water.

4. Conclusions

The Panel considered that the recycling process EREMA using the EREMA MPR + DS technology is adequately characterised and that the critical step to decontaminate the PET is identified. Having examined the challenge test provided, the Panel concluded that temperature, pressure and residence time in the [redacted] reactor of step 2 as well as temperature, pressure and residence time of the extruder of step 3, which were both included in the challenge test, are critical for the decontamination efficiency.

The Panel concluded that the recycling process EREMA using the EREMA MPR + DS technology is able to reduce foreseeable accidental contamination of post-consumer food contact PET to a concentration that does not give rise to concern for a risk to human health if:

i) it is operated under conditions that are at least as severe as those applied in the challenge test used to measure the decontamination efficiency of the process;
ii) the input material of the process is washed and dried post-consumer PET flakes originating from materials and articles that have been manufactured in accordance with the EU legislation on food contact materials and contain no more than 5% of PET is from non-food consumer applications;
iii) the recycled PET is used at up to 100% for the manufacture of materials and articles for contact with all types of foodstuff, including drinking water, for long-term storage at room temperature, with or without hotfill.

Articles made of this recycled PET are not intended to be used in microwave or conventional ovens and such uses are not covered by this evaluation.

5. Recommendations

The Panel recommended periodic verification that the input material to be recycled originates from materials and articles that have been manufactured in accordance with the EU legislation on food contact materials and that the proportion of PET from non-food consumer applications is no more than 5%. This adheres to good manufacturing practice and the Regulation (EC) No 282/2008, Art. 4b. Critical steps in recycling should be monitored and kept under control. In addition, supporting documentation should be available on how it is ensured that the critical steps are operated under conditions at least as severe as those in the challenge test used to measure the decontamination efficiency of the process.

Documentation provided to EFSA

1) Dossier 'EREMA Engineering Recycling Maschinen und Anlagen recycling process (EREMA "MPR + DS")'. May 2019. Submitted on behalf of EREMA Engineering Recycling Maschinen und Anlagen Ges.m.b.H., Austria.

2) Additional information, March 2021. Submitted on behalf of EREMA Engineering Recycling Maschinen und Anlagen Ges.m.b.H., Austria.
3) Additional information, September 2021. Submitted on behalf of EREMA Engineering Recycling Maschinen und Anlagen Ges.m.b.H., Austria.
4) Additional information, December 2021. Submitted on behalf of EREMA Engineering Recycling Maschinen und Anlagen Ges.m.b.H., Austria.
5) Additional information, March 2022. Submitted on behalf of EREMA Engineering Recycling Maschinen und Anlagen Ges.m.b.H., Austria.

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Abbreviations

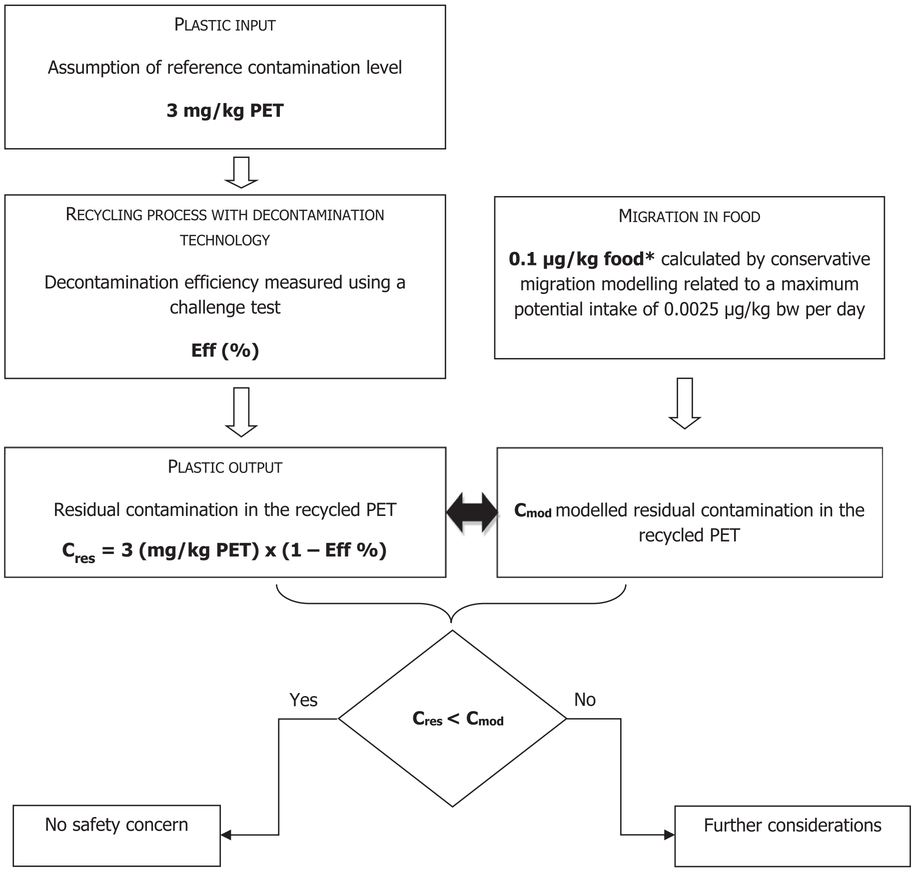
bw	body weight
CEF Panel	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP Panel	Panel on Food Contact Materials, Enzymes and Processing Aids
C_{mod}	modelled concentration in PET
C_{res}	residual concentration in PET
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)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

Appendix A – Technical specifications of the washed flakes as provided by the applicant[6]

Parameter	Value
Moisture max.	1.0%
Moisture variation	± 0.3%/h
Bulk density	250–400 kg/m^3
Bulk density variation	± 150 $kg/(m^3*h)$
Material temperature	10–60°C
Material temperature variation	± 10°C/h
PVC max.	200 mg/kg
Glue max.	100 mg/kg
Polyolefins max.	300 mg/kg
Cellulose (paper, wood)	100 mg/kg
Metals max.	100 mg/kg
Polyamide max	100 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. The figures are derived from the application of the human exposure threshold value of 0.0025 µg/kg bw per day applying a factor of 5 related to the overestimation of modelling.

Appendix C – Table of operational parameters (Confidential Information)[11]

[redacted]

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

[11] Technical dossier, Section 3.10 (Appendix F) and Appendix E1.