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## Safety assessment of the process STF, based on EREMA Basic 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 STF (EU register number RECYC177) which uses the EREMA Basic 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 continuous reactor under vacuum before being extruded. The Panel concluded that the continuous reactor (step 2, for which a challenge test was provided), is critical in determining the decontamination efficiency of the process. The operating parameters that control the performance of this step 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 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, with or without hotfill. 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.

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**Keywords:** EREMA Basic, STF Recycling GmbH, food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

**Requestor:** Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany

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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 the recycled plastic is 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<sup>1</sup> 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<sup>2</sup> 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 competent authorities of Member States, 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 the evaluation of the recycling process STF, European Union (EU) register No RECYC177. The request has been listed in EFSA's register of received questions under the number EFSA-Q-2019-00384. The dossier was submitted on behalf of STF Recycling GmbH, 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 assessments of 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 STF 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 shall be submitted in accordance with Article 5 of the Regulation (EC) No 282/2008.

Additional information was provided by the applicant during the assessment process in response to a request from EFSA sent on 16 October 2019 and 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,

<sup>1</sup> 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.

<sup>2</sup> 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.

- 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 (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 a 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<sup>3</sup>

According to the applicant, the recycling process STF is intended to recycle food grade PET containers using the EREMA Basic technology. The recycled PET is intended to be used at up to 100% for the manufacture of materials and articles to be used in direct contact with all kinds of foodstuffs, such as bottles for mineral water, soft drink and beer, for long-term storage at room temperature, with or without hotfill.

### 3.2. Description of the process

#### 3.2.1. General description<sup>4</sup>

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

The recycling process comprises the three steps below.

#### Input

- In step 1, the post-consumer PET containers are processed into hot caustic washed and dried flakes. This step is performed by third parties.

#### Decontamination and production of recycled PET material

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

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

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

<sup>3</sup> Technical dossier, Section 3.1.1.

<sup>4</sup> Technical dossier, Section 3.2.1.

### 3.2.2. Characterisation of the input<sup>5</sup>

According to the applicant, the input material for the recycling process STF 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. According to the applicant, the proportion will be no more than 5%.

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

## 3.3. EREMA Basic technology

### 3.3.1. Description of the main steps<sup>6</sup>

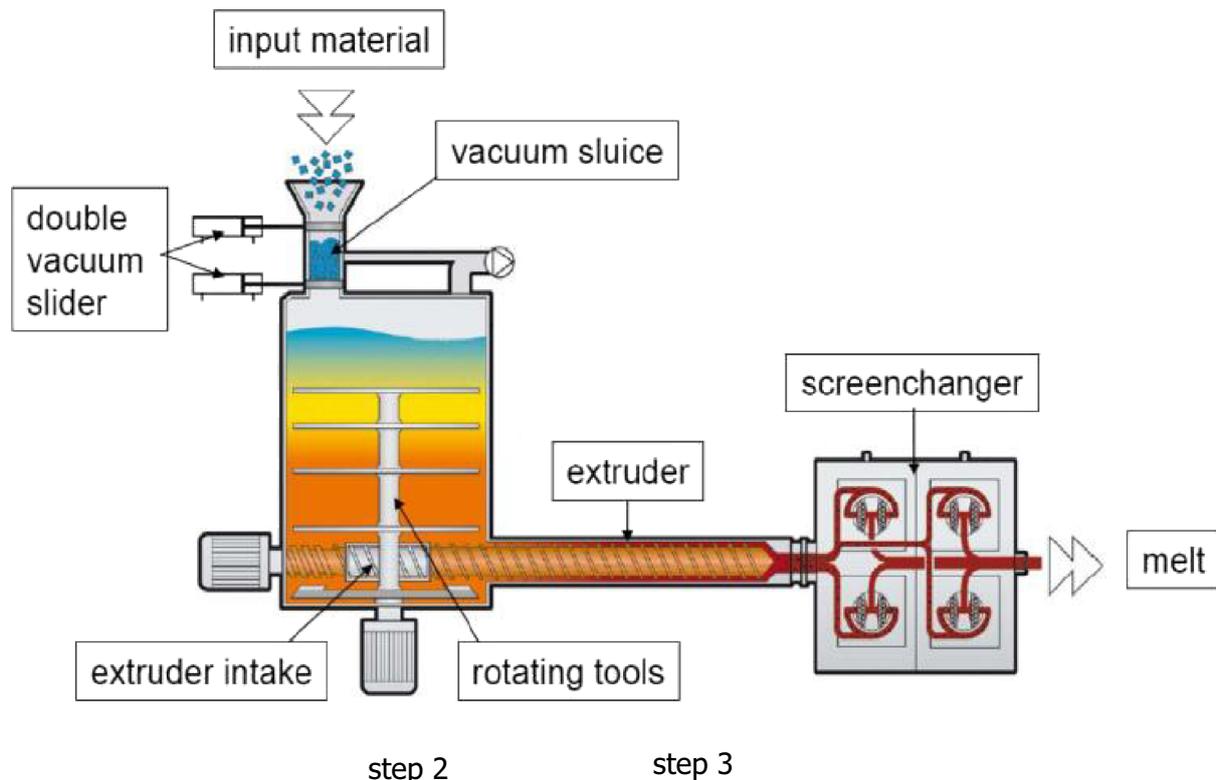
The general scheme of the EREMA Basic technology, as provided by the applicant, is reported in Figure 1. In step 1, not reported in the scheme, post-consumer PET containers are processed into hot caustic washed and dried flakes.

- Decontamination in a continuous reactor (step 2):

The flakes are continuously fed into a reactor equipped with a bottom-mounted rotating mixing device, running under high temperature and vacuum for a predefined average residence time.

- Extrusion of the decontaminated flakes (step 3):

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



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

<sup>5</sup> Technical dossier, Section 3.2.2.

<sup>6</sup> Technical dossier, Section 3.2.1.

The process is operated under defined operating parameters<sup>7</sup> of temperature, pressure and average residence time.

### 3.3.2. Decontamination efficiency of the recycling process<sup>8</sup>

To demonstrate the decontamination efficiency of the recycling process STF, a challenge test on step 2 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 and in accordance with the recommendations of the US Food and Drug Administration. 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).

Solid surrogates (benzophenone and methyl stearate) were mixed with liquid surrogates (toluene, chlorobenzene, chloroform, methyl salicylate and phenyl cyclohexane) and admixed to 5 kg conventionally recycled<sup>9</sup> post-consumer PET flakes. This masterbatch was added to approximately 50 kg PET flakes and stored for 7 days at 50°C with periodical agitation. The contaminated flakes were washed and rinsed in a batch process at pilot plant scale. The concentration of surrogates in this material was determined.

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

The Panel noted that decontamination efficiencies, calculated only on the basis of residual surrogates in the contaminated (green-coloured) flakes, could be overestimated. In fact, cross-contamination<sup>10</sup> by transfer of contaminants from green to white flakes does occur (EFSA CEF Panel, 2011).

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

- The mass fraction of green to white flakes at various residence time points was derived from the data provided. A best fitting mass fraction/residence time distribution curve was used to calculate the percentage of green and white flakes at given residence times.
- From the residual concentrations of surrogates in the green flakes at different residence times (provided by the applicant), a best fitting curve was derived and used to interpolate the residual concentrations in green flakes at different residence times.
- It was assumed that cross-contamination of surrogates from green to white flakes in the reactor occurred to the extent that the surrogate concentration in the white flakes reached 10% of the residual concentration measured in the green flakes. This percentage reflects the experience from previous evaluations.
- A new study was provided by the applicant. Based on the results provided as an Annex of the technical dossier and subsequently published (Welle, 2016), cross-contamination was found at low mixing (dilution) ratios (e.g. 1:1), but the author argued that moving to higher mixing (dilution) ratios (e.g. 1:50) does not play a significant role. Therefore, the applicant requested that the 10% cross-contamination should not apply for the industrial process STF under evaluation. However, the Panel noted that this study had some shortcomings and the conclusion

<sup>7</sup> In accordance with Art. 9 and 20 of Regulation (EC) No 1935/2004, the parameters were provided to EFSA and made available to the applicant, the Member States and the European Commission (see Appendix C).

<sup>8</sup> Technical dossier, Section 3.2.3 and Appendix E.

<sup>9</sup> Conventional recycling includes sorting, grinding, washing and drying steps and produces washed and dried flakes.

<sup>10</sup> 'Cross-contamination' (partitioning between green and white flakes), as meant in the Scientific Opinion on 'the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food', is the transfer of surrogate contaminants from the initially contaminated to the initially not contaminated material (EFSA CEF Panel, 2011).

that cross-contamination was negligible was questioned due to the poor detection limits of the analytical method used, as it had a major impact on calculations at a high mixing (dilution) ratio. Moreover, the Panel considered that the laboratory tests to investigate cross-contamination were not representative of the industrial process under evaluation: different technologies (types of equipment and operational conditions) were used, for example in terms of heating technique (hot gas vs friction) and removal of contaminants from the reactor (inert gas vs vacuum). Therefore, the provided study allows neither to exclude cross-contamination from the calculation of the decontamination efficiency nor to refine the previous estimate of 10%.

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

The decontamination efficiencies presented in Table 1 were calculated for the average residence time in the continuous reactor (step 2) in the challenge test.

**Table 1:** Efficiency of the decontamination by the continuous reactor (step 2) in the challenge test

Surrogates	Concentration <sup>(a)</sup> of surrogates before step 2 (mg/kg PET)	Concentration <sup>(b)</sup> of surrogates after step 2 (mg/kg PET)	Decontamination efficiency <sup>(c)</sup> (%)
Toluene	202	0.14	99.2
Chlorobenzene	361	0.28	99.1
Chloroform	291	0.18	99.2
Methyl salicylate	143	0.36	97.0
Phenylcyclohexane	364	1.12	96.3
Benzophenone	480	1.96	95.1
Methyl stearate	360	0.84	97.2

PET: poly(ethylene terephthalate).

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

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

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

The decontamination efficiency ranged from 95.1% for benzophenone up to 99.2% for toluene and chloroform.

### 3.4. Discussion

Considering the high temperatures used during the process, the possibility of contamination by microorganisms can be discounted. Therefore, this evaluation focuses on the chemical safety of the final product.

Technical data, such as information on physical properties and residual contents of PVC, glue, polyolefins and metals, were provided for the input materials (hot caustic washed and dried flakes, step 1). These flakes are produced from PET containers, previously used for food packaging and collected through post-consumer collection systems. However, a small fraction may originate from non-food applications, such as bottles for soap, mouth wash or kitchen hygiene agents. According to the applicant, the collection system and the process are managed in such a way that in the input stream this fraction will be lower than 5%, as recommended by the EFSA CEF Panel in its 'Scientific opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food' (EFSA CEF Panel, 2011).

The process is adequately described. The washing and drying of the flakes from the collected PET containers (step 1) is conducted by third parties and according to quality control parameters. The EREMA Basic technology comprises the continuous decontamination reactor (step 2) and extrusion (step 3). The operating parameters of temperature, pressure and residence time have been provided to EFSA.

A challenge test to measure the decontamination efficiency was conducted at industrial plant scale on the process step 2 (continuous decontamination reactor) according to the recommendations in the EFSA guidelines (EFSA, 2008). The reactor was operated under pressure and temperature conditions equivalent to those of the commercial process. Since a mixture of non-contaminated (white) and contaminated (green) flakes was collected at the outlet of the reactor, the Panel calculated the decontamination efficiencies taking into account also the amount possibly transferred to the white flakes due to cross-contamination. The Panel considered that the decontamination in the continuous reactor (step 2) is the critical step for the decontamination efficiency of the process. Consequently, the temperature, the pressure and the residence time parameters of the step 2 of the process should be controlled to guarantee the performance of the decontamination. These parameters have been provided to EFSA.

The decontamination efficiencies obtained for each surrogate, ranging from 95.1% to 99.2%, 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  $\mu\text{g}/\text{kg}$  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 in a migration giving rise to a dietary exposure exceeding the 0.0025  $\mu\text{g}/\text{kg}$  bw per day, after 1 year at 25°C. Because the recycled PET is intended for manufacture of bottles, the scenario for infants has been applied, since water could be used to prepare infant formula. A maximum dietary exposure of 0.0025  $\mu\text{g}/\text{kg}$  bw per day corresponds to a maximum migration of 0.1  $\mu\text{g}/\text{kg}$  of a contaminant substance into the infant's food and has been used to calculate  $C_{mod}$  (EFSA CEF Panel, 2011).  $C_{res}$  reported in Table 2 (scenario for infants) 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  $\mu\text{g}/\text{kg}$  food after 1 year at 25°C

Surrogates	Decontamination efficiency (%)	$C_{res}$ for 100% rPET (mg/kg PET)	$C_{mod}$ (mg/kg PET)
Toluene	99.2	0.03	0.09
Chlorobenzene	99.1	0.03	0.09
Chloroform	99.2	0.02	0.10
Methyl salicylate	97.0	0.09	0.13
Phenylcyclohexane	96.3	0.11	0.14
Benzophenone	95.1	0.15	0.16
Methyl stearate	97.2	0.08	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 the STF recycling process under the given operating conditions is able to ensure that the level of migration of unknown contaminants from the recycled PET into food is below the conservatively modelled migration of 0.1  $\mu\text{g}/\text{kg}$  food. At this level, the risk to human health is considered negligible when the recycled PET is used at up to 100% to produce bottles intended for contact with all types of foodstuffs, including drinking water.

## 4. Conclusions

The Panel considered that the STF recycling process using the EREMA Basic technology is adequately characterised and the critical step to decontaminate the PET is identified. Temperature, pressure and residence time in the continuous reactor of step 2, which was included in the challenge test, are critical for the decontamination efficiency.

The Panel concluded that the recycling process STF 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 no more than 5% of this 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 kinds of foodstuff, 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.

## 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 'STF'. August 2019. Submitted on behalf of STF Recycling GmbH, Germany.
- 2) Additional information, November 2019. Submitted on behalf of STF Recycling GmbH, 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. Part2: 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), 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>
- Welle F, 2016. Investigation into cross-contamination during cleaning efficiency testing in PET recycling. *Resources, Conservation and Recycling*, 112, 65–72. <https://doi.org/10.1016/j.resconrec.2016.05.003>

### Abbreviations

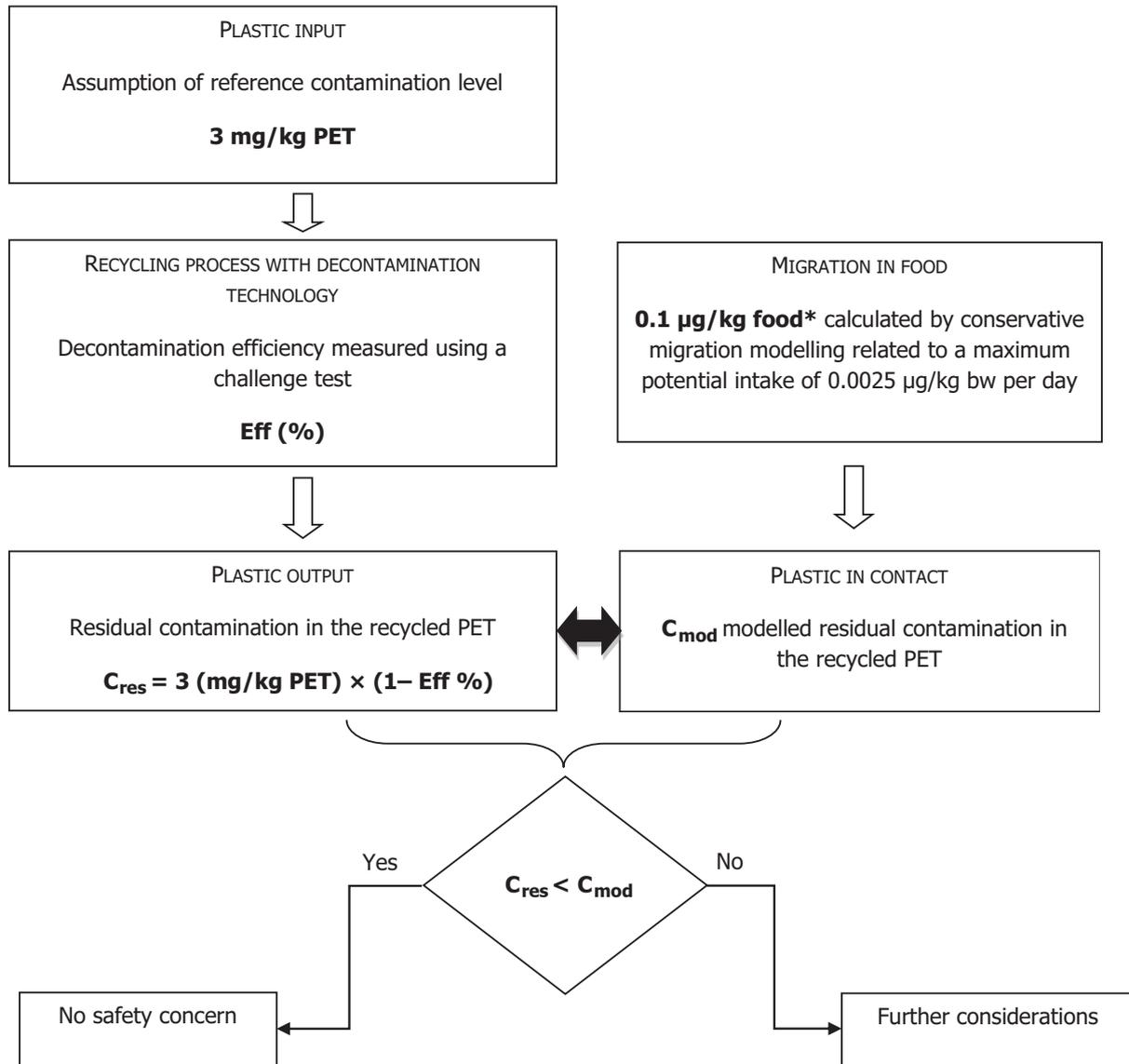
bw	body weight
CEF	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP	Panel on Food Contact Materials, Enzymes and Processing Aids
$C_{\text{mod}}$	modelled concentration in PET
$C_{\text{res}}$	residual concentration in PET
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)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

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

Parameter	Value
Moisture max.	1.0%
Moisture variation	±0.3%/h
Bulk density	250–400 kg/m <sup>3</sup>
Material temperature	5–40°C
Material temperature variation	±10°C/h
PVC max.	10 mg/kg
Glue max.	100 mg/kg
Polyolefins max.	50 mg/kg
Cellulose (paper, wood)	50 mg/kg
Metals max.	10 mg/kg
Polyamides 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 is 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 on operational parameters (Confidential Information)

[Redacted Table Content]