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## Safety assessment of the process Novapet, based on Protec technology, used to recycle post-consumer PET into food contact materials

EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP),  
Claude Lambré, José Manuel Barat Baviera, Claudia Bolognesi, Andrew Chesson,  
Pier Sandro Cocconcelli, Riccardo Crebelli, David Michael Gott, Konrad Grob,  
Marcel Mengelers, Alicja Mortensen, Gilles Rivière, Inger-Lise Steffensen, Christina Tlustos,  
Henk Van Loveren, Laurence Vernis, Holger Zorn, Vincent Dudler, Maria Rosaria Milana,  
Constantine Pappaspyrides, Maria de Fátima Tavares Poças, Alexandros Lioupis and  
Evgenia Lampi

### Abstract

The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) assessed the safety of the recycling process Novapet (EU register number RECYC208), which uses the Protec technology. The input is hot caustic washed and dried poly(ethylene terephthalate) (PET) flakes mainly originating from collected post-consumer PET containers, with no more than 5% PET from non-food consumer applications. The flakes are extruded into pellets, crystallised and treated in a solid-state polycondensation (SSP) reactor. Having examined the challenge test provided, the Panel concluded that the SSP (step 4) is critical in determining the decontamination efficiency of the process. The operating parameters to control the performance of this critical step 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 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 for long-term storage at room temperature, with or without hotfill. The final 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.

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**Keywords:** Protec, Novapet S.A., food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

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**Correspondence:** fip@efsa.europa.eu

**Panel members:** José Manuel Barat Baviera, Claudia Bolognesi, Andrew Chesson, Pier Sandro Coconcelli, Riccardo Crebelli, David Michael Gott, Konrad Grob, Claude Lambré, Evgenia Lampi, Marcel Mengelers, Alicja Mortensen, Gilles Rivière, Vittorio Silano (until 21 December 2020<sup>†</sup>), Inger-Lise Steffensen, Christina Tlustos, Henk Van Loveren, Laurence Vernis and Holger Zorn.

**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, 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<sup>1</sup> 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> 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 Agencia Española de Seguridad Alimentaria y Nutrición, an application for evaluation of the recycling process Novapet, European Union (EU) register No RECYC208. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2020-00554. The dossier was submitted on behalf of Novapet S.A., Spain.

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 Novapet 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).

Additional information was sought from the applicant during the assessment process in response to a request from EFSA sent on 27 January 2021 and was subsequently provided (see 'Documentation provided to EFSA').

The following information on the recycling process was provided by the applicant and used for the evaluation:

- General information:
  - general description,
  - existing authorisations.
- Specific information:
  - recycling process,
  - characterisation of the input,
  - determination of the decontamination efficiency of the recycling process,
  - characterisation of the recycled plastic,
  - intended application in contact with food,
  - compliance with the relevant provisions on food contact materials and articles,
  - process analysis and evaluation,
  - operating parameters.

<sup>1</sup> 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.

<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.

## 2.2. Methodologies

The principles followed up for the evaluation are described here. The risks associated with the use of recycled plastic materials and articles in contact with food come from the possible migration of chemicals into the food in amounts that would endanger human health. The quality of the input, the efficiency of the recycling process to remove contaminants as well as the intended use of the recycled plastic are crucial points for the risk assessment (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<sup>3</sup>

According to the applicant, the recycling process Novapet is intended to recycle food grade PET containers using the Protec technology. The recycled PET is intended to be used at up to 100% for the manufacture of materials and articles for direct contact with all kinds of foodstuffs for long-term storage at room temperature, with or without hotfill, such as bottles for mineral water and beverages. The recycled pellet may also be used for sheets, which are thermoformed to make food trays. 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<sup>4</sup>

The recycling process Novapet produces recycled PET pellets from PET containers (e.g. bottles), coming from post-consumer collection systems (kerbside and deposit systems).

The recycling process comprises the four 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 a third party.

#### Decontamination and production of recycled PET material

- In step 2, the flakes are extruded [REDACTED].
- In step 3, the pellets are crystallised for a [REDACTED] residence time.
- In step 4, the crystallised pellets are treated in a [REDACTED] solid-state polycondensation (SSP) reactor at high temperature and under vacuum.

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 the intrinsic viscosity, colour and black spots.

<sup>3</sup> Technical dossier, Section 3.1.

<sup>4</sup> Technical dossier, Section 3.1.1.

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

According to the applicant, the input material for the recycling process Novapet consists of hot washed and dried flakes obtained from PET containers, mainly bottles 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 of this non-food container fraction depends on the collection system and will be no more than 5%.

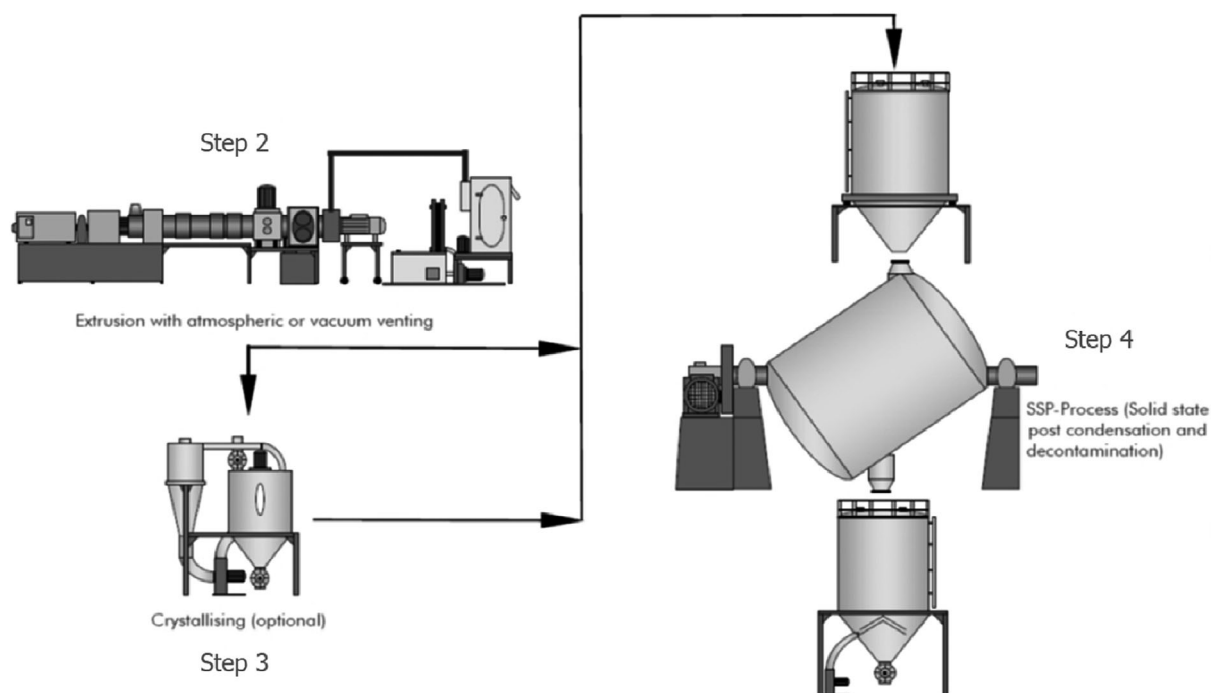
Technical data for the hot washed and dried flakes are provided, such as information on physical properties and on residual contents of moisture, poly(vinyl chloride) (PVC), glue, polyolefins, cellulose, metals and polyamide (see Appendix A).

## 3.3. Protec technology

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

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

- Extrusion (step 2): The flakes are fed into an extruder operating [REDACTED].
- Crystallisation (step 3): The extruded pellets are crystallised [REDACTED] for a predefined residence time. Alternatively, crystallisation of the amorphous pellets can take place inside the tumble reactor of the next step followed by heating to the final decontamination temperature (of step 4).
- SSP (step 4): The crystallised pellets are introduced into a tumble dryer for solid state polycondensation (SSP) at a high temperature under vacuum and for a predefined residence time. The step may be operated under two different combinations of temperature and residence time, ( $t_1, T_1$  and  $t_2, T_2$ , where  $t_1 > t_2$  and  $T_1 < T_2$ ).



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

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

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

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

<sup>7</sup> 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).

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

To demonstrate the decontamination efficiency of the recycling process Novapet, a challenge test performed at pilot plant scale was submitted to the EFSA.

PET flakes were contaminated with toluene, chloroform, chlorobenzene, phenylcyclohexane, benzophenone and methyl stearate, selected as surrogates 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).

Conventionally recycled<sup>9</sup> post-consumer PET flakes were soaked in a mixture containing the surrogates and stored for 7 days at 50°C. The PET flakes were rinsed and the concentration of surrogates in these flakes was determined.

The challenge test was performed in pilot plant on steps 2 and 4 (extrusion and SSP reactor). The crystallisation step 3 was not challenged. In the challenge test, the extruder was fed with only contaminated flakes and the extruded pellets were fed to the tumble dryer. The pellets were sampled before the SSP reactor and at regular intervals after the reactor and analysed for their residual concentrations of the applied surrogates.

The decontamination efficiency of the process was calculated from the concentrations of the surrogates measured in the contaminated flakes before and after SSP (step 4). The results are summarised below in Table 1.

**Table 1:** Efficiency of the decontamination by the Protec technology in the challenge test. Calculations for two different conditions of operation of the SSP reactor (t1, T1 and t2, T2) are provided

| Surrogates        | Concentration of surrogates before step 4 (mg/kg PET) (t1, T1) | Concentration of surrogates before step 4 (mg/kg PET) (t2, T2) | Concentration of surrogates after step 4 (mg/kg PET) (t1, T1) | Concentration of surrogates after step 4 (mg/kg PET) (t2, T2) | Decontamination efficiency (%) (t1, T1) | Decontamination efficiency (%) (t2, T2) |
|-------------------|--|--|---|---|---|---|
| Toluene           | 36.9   | 34.8   | < 0.1 <sup>(a)</sup>  | < 0.1 <sup>(a)</sup>  | > 99.7                                  | > 99.7                                  |
| Chloroform        | 14.8   | 14.5   | < 0.2 <sup>(a)</sup>  | < 0.2 <sup>(a)</sup>  | > 98.6                                  | > 98.6                                  |
| Chlorobenzene     | 73.4   | 71.9   | < 0.1 <sup>(a)</sup>  | < 0.1 <sup>(a)</sup>  | > 99.9                                  | > 99.9                                  |
| Phenylcyclohexane | 174.5  | 170.3  | 7.6   | 6.4   | 95.6                                    | 96.2                                    |
| Benzophenone      | 385.2  | 370.3  | 11.7  | 10.6  | 97.0                                    | 97.1                                    |
| Methyl stearate   | 271.1  | 258.1  | 3.1   | 2.9   | 98.9                                    | 98.9                                    |

PET: poly(ethylene terephthalate).

(a): Not detected at the limits of detection given.

As shown in Table 1, the decontamination efficiency ranged from 95.6% for phenylcyclohexane to more than 99.9% for chlorobenzene.

### 3.4. Discussion

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

Technical data, such as information on physical properties and residual contents of PVC, glue, polyolefins, cellulose, metals and polyamide, were provided for the input materials (i.e. 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, mouthwash 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 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

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

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

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 in different ways depending on the plant and, according to the applicant, this step is under control. The Protec technology comprises extrusion (step 2), crystallisation (step 3) and SSP (step 4). The operating parameters of temperature, residence time and pressure have been provided to EFSA.

A challenge test to measure the decontamination efficiency was conducted at pilot plant scale on process steps 2 and 4. The Panel considered that this challenge test was performed correctly according to the recommendations in the EFSA guidelines (EFSA, 2008). The Panel considered that step 4 (SSP) was critical for the decontamination efficiency of the process. Consequently, the temperature, the pressure and the residence time for SSP (step 4) should be controlled to guarantee the performance of the decontamination (Appendix C).

The decontamination efficiencies obtained for each surrogate, ranging from 95.6% to > 99.9%, 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, after 1 year at 25°C, could result in a migration giving rise to a dietary exposure exceeding 0.0025  $\mu\text{g}/\text{kg}$  bw per day. Because the recycled PET is intended for the manufacturing of articles containing up to 100% recycled PET, the scenario for infants has been applied. Therefore, the migration of 0.1  $\mu\text{g}/\text{kg}$  into food has been used to calculate  $C_{mod}$  (EFSA CEF Panel, 2011). The results of these calculations are shown in Tables 2 and 3. The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

**Table 2:** Decontamination efficiencies 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, under SSP conditions t1, T1

| Surrogates        | Decontamination efficiency (%) | $C_{res}$ for 100% rPET (mg/kg PET) | $C_{mod}$ (mg/kg PET) |
|-------------------|--------------------------------|-------------------------------------|-----------------------|
| Toluene           | > 99.7                         | < 0.01                              | 0.09                  |
| Chloroform        | > 98.6                         | < 0.04                              | 0.18                  |
| Chlorobenzene     | > 99.9                         | < 0.01                              | 0.09                  |
| Phenylcyclohexane | 95.6                           | 0.13                                | 0.14                  |
| Benzophenone      | 97.0                           | 0.09                                | 0.16                  |
| Methyl stearate   | 98.9                           | 0.03                                | 0.32                  |

PET: poly(ethylene terephthalate).

**Table 3:** Decontamination efficiencies 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, under SSP conditions t2, T2

| Surrogates        | Decontamination efficiency (%) | $C_{res}$ for 100% rPET (mg/kg PET) | $C_{mod}$ (mg/kg PET) |
|-------------------|--------------------------------|-------------------------------------|-----------------------|
| Toluene           | > 99.7                         | < 0.01                              | 0.09                  |
| Chloroform        | > 98.6                         | < 0.04                              | 0.18                  |
| Chlorobenzene     | > 99.9                         | < 0.01                              | 0.09                  |
| Phenylcyclohexane | 96.2                           | 0.11                                | 0.14                  |
| Benzophenone      | 97.1                           | 0.09                                | 0.16                  |
| Methyl stearate   | 98.9                           | 0.03                                | 0.32                  |

PET: poly(ethylene terephthalate).



As  $C_{res}$  values are lower than the corresponding modelled concentrations in PET ( $C_{mod}$ ), the Panel considered that under the given operating conditions the recycling process Novapet using the Protec technology is able to ensure that the level of migration of unknown contaminants from the recycled PET into food is below the conservatively modelled value of 0.1  $\mu\text{g}/\text{kg}$  food, at which the risk to human health is considered negligible.

#### 4. Conclusions

The Panel considered that the process Novapet using the Protec technology is adequately characterised and that the main steps used to recycle the PET flakes into decontaminated PET pellets have been identified. Having examined the challenge test provided, the Panel concluded that the two steps (extrusion and SSP) are critical for the decontamination efficiency. The operating parameters to control its performance are temperature, the pressure and the residence time for the SSP (step 4).

The Panel concluded that the recycling process Novapet 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 containing no more than 5% of PET from non-food consumer applications;
- iii) the recycled PET obtained from the process Novapet is 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.

The final 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 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 'Novapet'. June 2020. Submitted on behalf of Novapet S.A., Spain.
- 2) Additional information, May 2021. Submitted on behalf of Novapet S.A., Spain.

#### 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>
- FDA (Food and Drug Administration), 2006. Guidance for industry: use of recycled plastics in food packaging: chemistry considerations. Available online: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-use-recycled-plastics-food-packaging-chemistry-considerations>

## Abbreviations

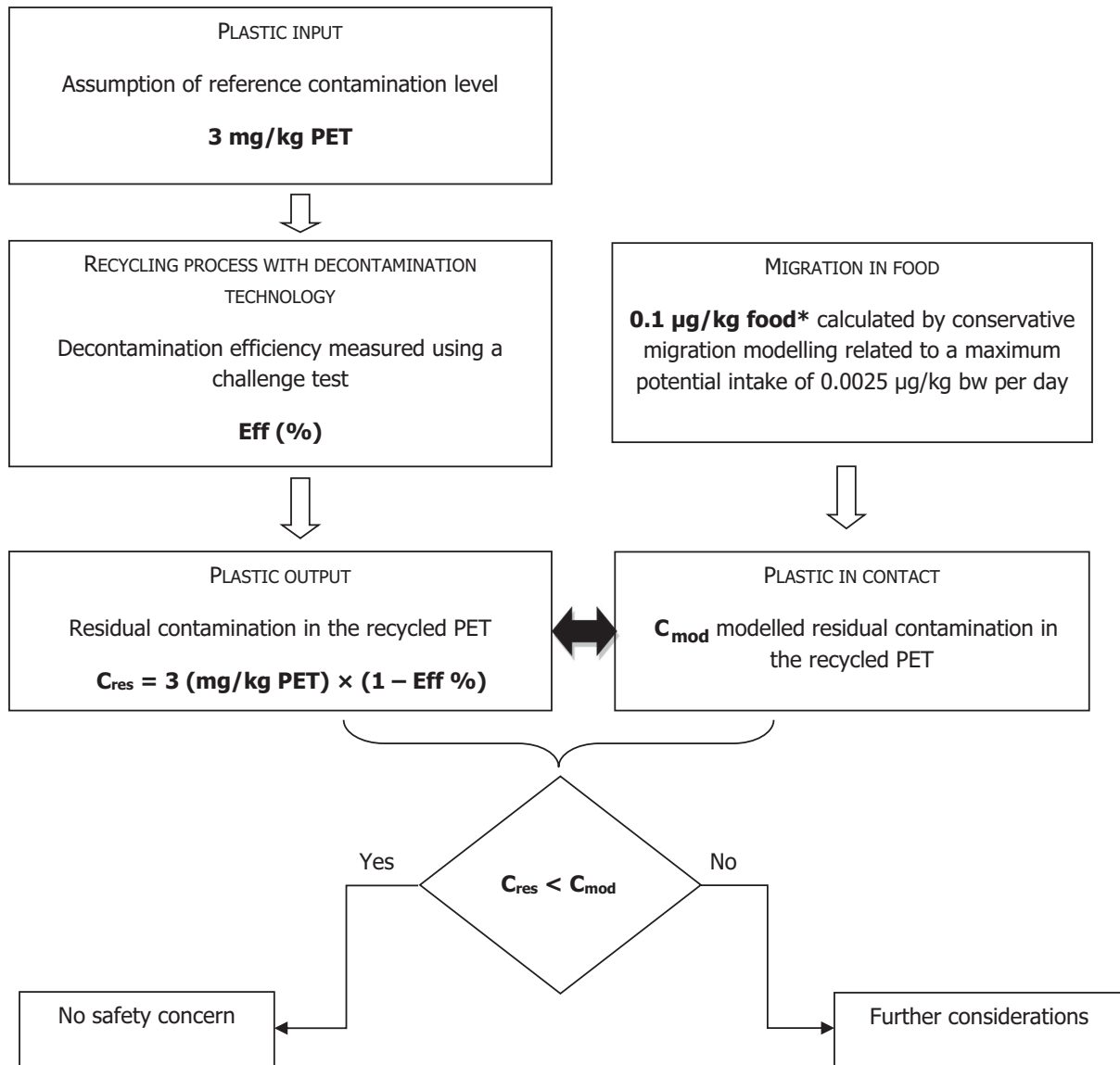
|                  |   |
|------------------|---|
| bw               | body weight   |
| CEF              | Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids |
| CEP              | Panel on Food Contact Materials, Enzymes and Processing Aids              |
| $C_{\text{mod}}$ | modelled concentration in PET   |
| $C_{\text{res}}$ | residual concentration in PET   |
| 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.           | < 1.5%                    |
| Bulk density            | 200–500 kg/m <sup>3</sup> |
| Material temperature    | 10–60°C                   |
| PVC max.                | 50 mg/kg                  |
| Glue max.               | 50 mg/kg                  |
| Polyolefins max.        | 200 mg/kg                 |
| Cellulose (paper, wood) | 50 mg/kg                  |
| Metals max.             | 20 mg/kg                  |
| Polyamide max.          | 500 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 on Operational parameters (Confidential Information)

[Redacted content]

| [Redacted] |            |            |            |            |            |            |            |            |            |
|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|
| [Redacted] | [Redacted] |            |            | [Redacted] |            |            | [Redacted] |            |            |
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[Redacted content]