Safety assessment of the process Texplast, based on EREMA Advanced 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 Texplast recycling process (EU register number RECYC158), which is based on the EREMA Advanced technology. The input is washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, containing no more than 5% PET from non-food consumer applications. They are heated in a continuous reactor under vacuum. Having examined the results of the challenge test provided, the Panel concluded that this continuous reactor step (step 3) is the critical step that determines the decontamination efficiency of the process. The operating parameters controlling its performance are temperature, pressure and residence time. It was demonstrated that, depending on the operating conditions, the recycling process under evaluation is able to ensure that the level of migration of potential unknown contaminants into food is below a conservatively modelled migration of 0.1 μg/kg food, derived from the exposure scenario for infants. Therefore, the Panel concluded that recycled PET obtained from the process is not of safety concern when used to manufacture articles intended for food contact applications if it is produced in compliance with the conditions specified in the conclusion of this opinion. Articles 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.

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

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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 for food contact if they contain recycled plastic obtained from an authorised recycling process. Before a recycling process is authorised, EFSA’s opinion on its safety is required. This procedure has been established in Article 5 of Regulation (EC) No 282/2008 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 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the Member States Competent Authorities which transmit the applications to the European Food Safety Authority (EFSA) for evaluation.

In this case, EFSA received, from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, an application for evaluation of the recycling process Texplast, EREMA Advanced, European Union (EU) register No RECYC158. The request has been registered in EFSA’s register of received questions under the number EFSA-Q-2018-00642. The dossier was submitted on behalf of Texplast 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 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 challenge test, or by other appropriate scientific evidence, that the recycling process Texplast, 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.

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.

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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 resulting residual concentration of each surrogate contaminant in recycled PET ($C_{res}$) is compared with a modelled concentration of the surrogate contaminants in PET ($C_{mod}$). This $C_{mod}$ is calculated using generally recognised conservative migration models so that the related migration does not give rise to a dietary exposure exceeding 0.0025 µg/kg body weight (bw) per day (i.e. the human exposure threshold value for chemicals with structural alerts for genotoxicity), below which the risk to human health would be negligible. If the $C_{res}$ is not higher than the $C_{mod}$, the recycled PET manufactured by such recycling process is not considered of safety concern for the defined conditions of use (EFSA CEF Panel, 2011).

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

3. Assessment

3.1. General information

According to the applicant, the Texplast recycling process is intended to recycle food-grade PET containers to produce recycled PET using the EREMA Advanced technology. It is intended to use up to 100% recycled PET, to manufacture new food packaging articles, typically bottles for all kind of foodstuffs. 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.

3.2. Description of the process

3.2.1. General description

The recycling process Texplast produces recycled PET pellets, from PET containers, mainly bottles, coming from post-consumer collection systems (kerbside and deposit systems). The recycling process comprises the four steps mentioned below.

- In step 1, post-consumer PET containers are ground and processed in-house into hot caustic washed and dried flakes, which are used as the input to the process.
- In step 2, the flakes are treated in a continuous reactor at high temperature.
- In step 3, after the first reactor, the flakes are decontaminated in a second continuous reactor at a higher temperature and under vacuum.
- In step 4, the decontaminated flakes from the previous step are extruded at high temperature to produce pellets.

After step 4, the amorphous pellets are recrystallised.

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

Recycled PET pellets, the final products 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 recycled articles used for hotfill and/or long-term storage at room temperature, such as bottles for mineral water, soft drinks and beer.
3.2.2. Characterisation of the input

According to the applicant, the input material for the Texplast recycling process 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 information from the applicant, the amount of this non-food container fraction depends on the collection system and will be below 5%.

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

3.3. EREMA Advanced technology

3.3.1. Description of the main steps

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

- **Pre-decontamination in a continuous reactor (step 2):** The flakes are introduced into a continuous reactor with a bottom-mounted rotating mixing device in which high temperature is applied for a predefined residence time.

- **Decontamination in a continuous reactor (step 3):** The flakes from step 2 are fed into a continuous reactor equipped with a bottom-mounted rotating mixing device, running under higher temperature and vacuum for a pre-defined average residence time. These process conditions favour the desorption of contaminants from PET and the crystallisation of PET flakes.

- **Extrusion of the decontaminated flakes (step 4):** The flakes continuously introduced from the previous reactor are molten in the extruder at atmospheric pressure. The residual solid particles (e.g. paper, aluminium, etc.) are filtered out of the extruded plastic before the final pellets are produced.

*Figure 1:* General scheme of the EREMA Advanced technology (provided by the applicant)
The process is operated under defined operating parameters of temperature, pressure and residence time.

### 3.3.2. Decontamination efficiency of the recycling process

To demonstrate the decontamination efficiency of the Texplast recycling process, a challenge test was submitted to EFSA that was performed at the EREMA facilities at industrial scale.

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 (FDA). The surrogates include different molecular weights and polarities to cover possible chemical classes of contaminants of concern and were demonstrated to be suitable to monitor the behaviour of PET during recycling (EFSA, 2008).

For this purpose, solid surrogates (benzophenone and methyl stearate) were mixed with liquid surrogates (toluene, chlorobenzene, chloroform, methyl salicylate and phenyl cyclohexane). This surrogate mixture was admixed with 5 kg of conventionally recycled post-consumer PET flakes (masterbatch). The masterbatch was mixed with another portion of approx. 50 kg of PET flakes and stored for 7 days at 50°C with periodical agitation. The contaminated flakes were washed and rinsed in a batch process in pilot plant scale. The concentration of surrogates in this material was determined.

The EREMA Advanced technology was challenged using 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 then 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 contaminated (green coloured) flakes could be overestimated. In fact, cross-contamination by transfer of contaminants from green to white flakes does occur (EFSA CEF Panel, 2011).

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

- 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 derived from the experimental data and was used to calculate the percentage of green and white flakes at given different residence times.
- The residual concentrations of surrogates in the green flakes after decontamination were derived for the different residence time points from the data provided. A best fitting curve was derived from the experimental data and was used to interpolate the residual concentrations in green flakes at different residence times.
- The Panel made the assumption 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 gained from previous evaluations.

To take into account the cross-contamination between green and white flakes, the total residual surrogate content at the outlet of the continuous reactor (step 3) as a function of residence time was calculated by adding the amounts transferred into the white flakes (based on the assumption of 10% of the concentration measured in the green flakes) to the amounts measured in the green ones, taking

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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.
5 '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).
into account the mass fraction of green and white flakes. Correspondingly corrected concentrations of the surrogates after decontamination were compared with their initial concentrations in green flakes at the inlet of the reactor to derive the decontamination efficiencies (see Table 1).

**Table 1:** Efficiency of the decontamination of the continuous reactor (EREMA Advanced, step 3) in the challenge test

| Surrogates       | Concentration<sup>a</sup> of surrogates before step 3 (mg/kg PET) | Concentration<sup>b</sup> of surrogates after step 3 (mg/kg PET) | Decontamination efficiency<sup>c</sup> (%) |
|------------------|---------------------------------------------------------------|-------------------------------------------------|--------------------------------------------|
| Toluene          | 202                                                          | 0.18                                           | 99.0                                       |
| Chlorobenzene    | 361                                                          | 0.36                                           | 98.9                                       |
| Chloroform       | 291                                                          | 0.23                                           | 99.1                                       |
| Methyl salicylate| 143                                                          | 0.47                                           | 96.4                                       |
| Phenylcyclohexane| 364                                                          | 1.35                                           | 96.0                                       |
| Benzophenone     | 480                                                          | 2.40                                           | 94.6                                       |
| Methyl stearate  | 360                                                          | 1.03                                           | 96.9                                       |

PET: poly(ethylene terephthalate).

<sup>a</sup>: Initial concentration in the contaminated PET flakes.

<sup>b</sup>: Residual concentration calculated for green flakes after decontamination.

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

The decontamination efficiencies, as presented in Table 1, were calculated at the time of exit from the continuous reactor (step 3) in the challenge test. The decontamination efficiency ranged from 94.6% for benzophenone to 99.1% for 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 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 hot caustic washed and dried flakes from collected containers (step 1) is conducted in-house. The following steps are those of the EREMA Advanced technology used to recycle the PET flakes into decontaminated PET pellets: first continuous reactor (step 2), second continuous reactor (step 3) and extrusion (step 4). The operating parameters of temperature, pressure and residence time for steps 2 to 4 have been provided to EFSA.

A challenge test on step 3 (continuous decontamination reactor) of the process was carried out in an industrial-scale plant to measure the decontamination efficiency. In this challenge test, the continuous decontamination reactor was operated under pressure and temperature conditions equivalent to those of the commercial process. The challenge test was performed according to the recommendations in the EFSA Guidelines (EFSA, 2008). Since a mixture of flakes not contaminated with surrogates (white) and contaminated flakes (green, spiked with surrogates) was collected at the outlet of the reactor used for this challenge test, the Panel calculated the decontamination efficiencies taking into account also the amount possibly transferred to the white flakes due to cross-contamination phenomena during the challenge test. The Panel considered that the decontamination in the continuous reactor (step 3) is the critical step for the decontamination efficiency of the process. Consequently, temperature, pressure and residence time parameters of the step 3 of the processes
should be controlled to guarantee the performance of the decontamination. These parameters have been provided to EFSA.

The decontamination efficiencies obtained for each surrogate contaminant from the challenge test, ranging from 94.6% to 99.1%, have been used to calculate the residual concentrations of potential unknown contaminants in flakes (\(C_{\text{res}}\)) 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 intended to be used for manufacture of materials and articles in contact with food’ (EFSA CEF Panel, 2011; Appendix B). By applying the decontamination efficiency percentages to the reference contamination level of 3 mg/kg PET, the \(C_{\text{res}}\) values for the different surrogates are obtained (see Table 2).

According to the evaluation principles (EFSA CEF Panel, 2011), the \(C_{\text{res}}\) value should not be higher than a modelled concentration in PET (\(C_{\text{mod}}\)) corresponding to a migration, after 1 year at 25°C, which cannot give rise to a dietary exposure exceeding 0.0025 \(\mu\)g/kg bw per day, the exposure threshold below which the risk to human health would be negligible. For recycled PET intended to be used in the manufacture of bottles, the default exposure scenario for infants has been applied as a worst case. A maximum dietary exposure of 0.0025 \(\mu\)g/kg bw per day corresponds to a maximum migration of 0.1 \(\mu\)g/kg of a contaminant substance into an infant’s food, as calculated by conservative migration modelling. Therefore, the corresponding migration of 0.1 \(\mu\)g/kg (scenario for infants) into food has been used to calculate the \(C_{\text{mod}}\) value (EFSA CEF Panel, 2011). If the PET produced by a recycling process is used up to 100% to produce new articles and they do not meet these targets, recycled PET should be mixed with virgin PET to make sure that the \(C_{\text{res}}\) value does not exceed the \(C_{\text{mod}}\) value. The Panel established the maximum percentage of recycled PET in final articles for which the risk to human health is demonstrated to be negligible. This percentage is reported in Table 2 for the scenario of infants. The percentage of recycled PET reported in Table 2 is, therefore, the maximum percentage for which the risk to human health is demonstrated to be negligible and may differ from the initial request from the applicant. The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

| Surrogates            | Decontamination efficiency (%) | \(C_{\text{res}}\) for 100% rPET (mg/kg PET) | \(C_{\text{mod}}\) (mg/kg PET) |
|-----------------------|--------------------------------|---------------------------------------------|--------------------------------|
| Toluene               | 99.0                           | 0.03                                        | 0.09                           |
| Chlorobenzene         | 98.9                           | 0.03                                        | 0.10                           |
| Chloroform            | 99.1                           | 0.03                                        | 0.10                           |
| Methyl salicylate     | 96.4                           | 0.11                                        | 0.13                           |
| Phenylcyclohexane     | 96.0                           | 0.12                                        | 0.14                           |
| Benzenophene          | 94.6                           | 0.16                                        | 0.16                           |
| Methyl stearate       | 96.9                           | 0.09                                        | 0.32                           |

PET: poly(ethylene terephthalate).

On the basis of the provided data from the challenge test and the applied conservative assumptions, the Panel considered that the recycling process under evaluation using the EREMA Advanced Recycling technology 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 \(\mu\)g/kg food (derived from the exposure scenario for infants), when the recycled pellets are used for bottles intended for contact with all types of foodstuffs, when the recycled PET is used up to 100%, at which level the risk to human health would be negligible.

4. Conclusions

The Panel considered that the process Texplast 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 continuous reactor of step 3 is the critical step for the decontamination efficiency of the process. The operating parameters
to control its performance are temperature, pressure and residence time. The Panel considered that the recycling process Texplast 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 test 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 Texplast intended to be used at up to 100% for the manufacture of materials and articles intended for contact with all types of foodstuffs, for long-term storage at room temperature, with or without hotfill, is not considered of safety concern. Articles 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 ‘Texplast Recycling Process’. December 2018. Submitted on behalf of Texplast GmbH.

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

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Abbreviations

bw body weight
CEF Panel Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP Panel on Food Contact Materials, Enzymes and Processing Aids
C_{mod} modelled concentration in PET
C_{res} residual concentration in PET
FDA US Food and Drug Administration
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.                 | 1.5%      |
| Moisture variation            | ±0.5%/h   |
| Bulk density                  | 250-500 kg/m³ |
| Material temperature          | 10–60°C   |
| PVC max.                      | 50 mg/kg  |
| Glue max.                     | 1,000 mg/kg |
| Polylefins max.               | 100 mg/kg |
| Cellulose (paper, wood)       | 100 mg/kg |
| Metals max.                   | 100 mg/kg |
| PET dust max.                 | 0.5%      |

PVC: poly(vinyl chloride); PET: poly(ethylene terephthalate).
Appendix B – Relationship between the key parameters for the evaluation scheme (EFSA CEF Panel, 2011)

- **PLASTIC INPUT**
  - Assumption of reference contamination level
  - 3 mg/kg PET

- **RECYCLING PROCESS WITH DECONTAMINATION TECHNOLOGY**
  - Decontamination efficiency measured using a challenge test
  - \( \text{Eff} \) (%)

- **PLASTIC OUTPUT**
  - Residual contamination in the recycled PET
  - \( C_{\text{res}} = 3 \text{ (mg/kg PET)} \times (1 - \text{Eff} \%) \)

- **MIGRATION IN FOOD**
  - 0.1 \( \mu \text{g/kg food} \)* calculated by conservative migration modelling related to a maximum potential intake of 0.0025 \( \mu \text{g/kg bw per day} \)

- **PLASTIC IN CONTACT**
  - \( C_{\text{mod}} \) modelled residual contamination in the recycled PET

- \( C_{\text{res}} < C_{\text{mod}} \)

  - **Yes**
    - No safety concern
  
  - **No**
    - Further considerations

*Default scenario (infant). For adults and toddlers, the migration criterion will be 0.75 and 0.15 \( \mu \text{g/kg food} \), respectively.
Appendix C – Table of operational parameters (confidential information)

| Parameter  | Value 1 | Value 2 | Value 3 | Value 4 | Value 5 |
|------------|---------|---------|---------|---------|---------|
| Parameter A | Value A1 | Value A2 | Value A3 | Value A4 | Value A5 |
| Parameter B | Value B1 | Value B2 | Value B3 | Value B4 | Value B5 |
| Parameter C | Value C1 | Value C2 | Value C3 | Value C4 | Value C5 |
| Parameter D | Value D1 | Value D2 | Value D3 | Value D4 | Value D5 |
| Parameter E | Value E1 | Value E2 | Value E3 | Value E4 | Value E5 |
| Parameter F | Value F1 | Value F2 | Value F3 | Value F4 | Value F5 |

Note: Some values are redacted for confidentiality.