

## SCIENTIFIC OPINION

### Scientific Opinion on the safety assessment of the process “MKF-Ergis”, used to recycle post-consumer PET into food contact materials<sup>1</sup>

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)<sup>2,3</sup>

European Food Safety Authority (EFSA), Parma, Italy

#### ABSTRACT

This scientific opinion of the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids deals with the safety assessment of the recycling process MKF-Ergis, EU register number RECYC021. The input for the process (step 1) is washed and dried PET flakes originating from collected post-consumer PET bottles containing no more than 1 % of PET from non-food consumer applications. The washed and dried flakes are crystallised (step 2) and then extruded at high temperature under vacuum into films (step 3). Having examined the challenge test provided, the Panel concluded that the two steps, the crystallisation (step 2) and the extrusion (step 3) are the critical steps that determine the decontamination efficiency of the process. The operating parameters to control their performance are well defined and are temperature, gas flow and residence time for the crystallisation and temperature, vacuum and residence time for the extrusion. The operating parameters of these steps in the process are at least as severe as those used in the challenge test. Under these conditions, it was demonstrated that the recycling process 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. Therefore the Panel concluded that the recycled PET obtained from this process intended for the manufacture of materials and articles for contact with all types of foodstuffs for long term storage at room temperature, with or without hotfill is not considered of safety concern. Trays made of this recycled PET should not be used in microwave and conventional ovens.

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#### KEY WORDS

MKF-Ergis, food contact materials, plastic, poly(ethylene terephthalate) PET, recycling process, safety evaluation

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<sup>2</sup> Panel members: Ulla Beckman Sundh, Mona-Lise Binderup, Claudia Bolognesi, Leon Brimer, Laurence Castle, Alessandro Di Domenico, Karl-Heinz Engel, Roland Franz, Nathalie Gontard, Rainer Gürtler, Trine Husøy, Klaus-Dieter Jany, Martine Kolf-Clauw, Catherine Leclercq (until July 2013), Jean-Claude Lhuguenot (until November 2012), Wim Mennes, Maria Rosaria Milana, Maria de Fátima Poças, Iona Pratt †, Kettil Svensson, Fidel Toldrá and Detlef Wölfle. One member of the Panel did not participate in the discussion on the subject referred to above because of potential conflicts of interest identified in accordance with the EFSA policy on declarations of interests. Correspondence: [fip@efsa.europa.eu](mailto:fip@efsa.europa.eu)

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† Deceased

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## SUMMARY

According to the Commission Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials intended to come into contact with foods, EFSA is requested to evaluate recycling process in which plastic waste is recycled. In this context, the CEF Panel evaluated the following process “MKF-Ergis”.

The Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, requested the evaluation of the recycling process “MKF-Ergis” submitted on behalf of MKF Ergis GmbH. The recycling process has been allocated the European Union register No RECYC021. It is deemed to recycle poly(ethylene terephthalate) (PET) obtained from PET bottles collected through post-consumer collection systems. The recycled films are intended to be used up to 100 % for the manufacture of food contact materials and articles intended to be used in direct contact with all kind of foodstuffs for long term storage at room temperature or below, with or without hotfill.

The process is composed of three steps. First in step 1, post-consumer PET articles are processed into washed and dried flakes which are used as input to the MKF-Ergis technology. In the step 2, the dried flakes are crystallised and then extruded in step 3.

Detailed specifications for the input materials are provided and the amount of non-food use containers is reported to be below 1 %.

A challenge test was conducted at the production plant at reduced capacity on the steps 2 and 3 (crystallisation and extrusion) to measure the decontamination efficiency of the process.

The decontamination efficiencies obtained for each surrogate contaminant from the challenge test, ranging from 93.61 % to above 99.97 %, have been used to calculate the residual concentrations of potential unknown contaminants in the recycled PET (*C<sub>res</sub>*) 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). According to these criteria, the recycling process under evaluation is able to reduce the level of unknown contaminants in recycled PET, represented by the surrogate contaminants, below a calculated concentration (*C<sub>mod</sub>*) corresponding to a modeled migration of 0.1 µg/kg food.

The Panel considered that the process is well characterized and the main steps used to recycle the PET flakes into PET films are identified. After having examined the challenge test provided, the Panel concluded that the two steps, the crystallisation and the extrusion are the critical steps that determine the decontamination efficiency of the process. The operating parameters to control its performance are temperature, gas flow and residence time for the crystallisation and temperature, vacuum and residence time for the extrusion. Therefore, the Panel considered that the recycling process MKF-Ergis 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 obtained from the challenge test used to measure the decontamination efficiency of the processes and,
- ii) the input is washed and dried post-consumer PET flakes originating from materials and articles that have been manufactured in accordance with the Community legislation on food contact materials containing no more than 5 % of PET from non-food consumer applications.

The Panel concluded that the recycled PET obtained from the process MKF-Ergis intended to be used at up to 100 % for the manufacture of materials and articles for contact with all types of foodstuffs for long term storage at room temperature, with or without hotfill is not considered of safety concern. Trays made of this recycled PET should not be used in microwave and conventional ovens.

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

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## BACKGROUND AS PROVIDED BY THE LEGISLATION

Recycled plastic materials and articles shall only be placed on the market if they contain recycled plastic obtained from an authorised recycling process<sup>4</sup>. Before a recycling process is authorized, EFSA's opinion on its safety is required. This procedure has been established in Article 5 of the Regulation (EC) No 282/2008<sup>5</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 the Regulation (EC) No 1935/2004<sup>6</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 Member States competent Authorities which transmit the applications to EFSA for evaluation. Each application is supported by a technical dossier submitted by the industry following the EFSA 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 authorization (EFSA, 2008).

In this case, EFSA received from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, an application for evaluation of the recycling process MKF-Ergis. This application has been allocated the EU register No RECYC021.

## TERMS OF REFERENCE AS PROVIDED BY THE LEGISLATION

EFSA is required by 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 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 processes 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 MKF-Ergis is able to reduce any contamination of the plastic input to a concentration that does not pose a risk to human health. The 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.

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<sup>4</sup> Recycling pursuant to the definition in point 7 of Article 3 of European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste. OJ L 365, 31.12.1994, p.10–23

<sup>5</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, 28.03.2008, p.9-18

<sup>6</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

## ASSESSMENT

### 1. Introduction

The European Food Safety Authority was asked by the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany to evaluate the safety of the recycling process MKF-Ergis which has been allocated the EU register No RECYC021. The request has been registered in the EFSA's register of questions under the number EFSA-Q-2009-00964. The dossier was submitted on behalf of MKF-Ergis GmbH, Germany.

The dossier submitted for evaluation followed the EFSA 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, 2008).

### 2. General information

According to the applicant, the recycling process MKF-Ergis is intended to recycle post-consumer food grade poly(ethylene terephthalate) (PET) bottles to produce recycled PET film using the MKF-Ergis technology. The recycled films are intended to be used up to 100 % for the manufacture of recycled materials and articles intended to be used in direct contact with all types of foodstuffs for long term storage at room temperature or below, with or without hotfill.

### 3. Description of the process

#### 3.1. General description

The recycling process MKF-Ergis produces recycled PET film from PET bottles, coming from post-consumer collection systems (kerbside and deposit collection systems). The recycling process comprises the three steps below.

#### Input

- In Step 1, post-consumer PET bottles are processed into hot caustic washed and dried flakes. Step 1 is conducted by a third-party and the flakes are bought from approved suppliers.

#### Decontamination and production of recycled PET material

- In step 2, in a continuous process the PET flakes are dried and crystallised in a crystalliser equipped with a demister and using a hot air flow at ambient pressure followed by cooling to ambient temperature.
- In step 3, the precrystallised flakes are extruded in an extrusion unit which consists of a single screw extruder in the auger section operating at high temperature under vacuum, a planetary extruder operating at high temperature under vacuum and a second single screw extruder operating at melting temperature by loss of vacuum to produce a flat film.

Recycled film, the final product of the process, is checked against technical requirements on tensile impact strength, colour, etc. Recycled film is intended to be converted by other companies into recycled articles, used for hotfill and/or long term storage at room temperature for single or repeated use. The recycled film may also be used for sheets which are thermoformed to make food trays. Trays made of this recycled PET are not intended to be used in microwave and conventional ovens.

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

### 3.2. Characterisation of the input

According to the applicant, the input for the recycling process MKF-Ergis is hot caustic-washed flakes obtained from PET bottles previously used for food packaging, from post-consumer collection systems (kerbside and deposit collection systems). However, a small fraction may originate from non-food applications such as soap bottles, mouth wash bottles, kitchen cleaning product bottles, etc. According to the applicant, the non-food container fraction depends on the re-collection system. On the basis of qualified suppliers and quality control system, the applicant assures this fraction is kept below 1 %.

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

## 4. MKF-ERGIS technology

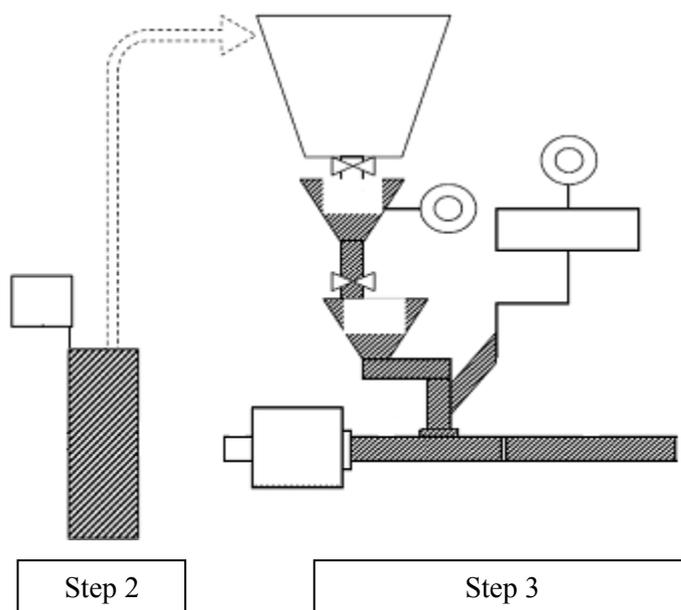
### 4.1. Description of the main steps

To decontaminate post-consumer PET, the recycling process under evaluation uses the technology MKF-Ergis which is described below and for which the general scheme is reported in figure 1. Step 1 is the washing step performed by a third party and described above.

Crystallisation of flakes in a continuous reactor: In step 2, PET flakes are introduced in a continuous reactor, heated by a hot air stream and then cooled to ambient temperature in an air stream.

Extrusion of flakes into film: In step 3, the crystallised flakes are fed in an extrusion unit which consists of a single screw extruder in the auger section operating at high temperature under vacuum followed by a planetary extruder with central spindle operating at higher temperature under vacuum and then by a single screw extrusion unit operating at melting point temperature at atmospheric pressure.

Steps 2 and 3 are operated under defined parameters of temperature, pressure and residence time.



**Figure 1:** General scheme of the MKF-Ergis technology

### 4.2. Decontamination efficiency of the recycling process

To demonstrate the decontamination efficiency of the recycling process, a challenge test on the steps 2 and 3 (crystallisation and extrusion) were submitted to EFSA.

PET flakes were contaminated with selected chemicals, toluene, chloroform, chlorobenzene, phenyl cyclohexane, methyl salicylate, benzophenone and methyl stearate, used as surrogate contaminants. The surrogates were chosen in accordance with EFSA guidelines and the recommendations of the US Food and Drug Administration (FDA). The surrogates are of 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 plastic during recycling (EFSA, 2008).

For the preparation of the contaminated PET flakes, conventionally recycled<sup>7</sup>, post-consumer PET flakes were soaked in a mixture of surrogates and stored for seven days at 50 °C with daily stirring. The contaminated PET flakes were hot washed, rinsed and dried as on a standard washing line (i.e. step 1). The concentration of surrogates in these flakes after washing and drying was determined.

The MKF-Ergis technology was challenged using the production plant at a reduced capacity and operating in continuous mode, using only contaminated flakes. Flakes were sampled after each step. Film samples were taken at regular time intervals after the extrusion step 3. The film consisted of three layers, the internal layer from recycled PET constituting the 90 % of the material and two outer layers from virgin PET constituting the 10 % of the material.

Thus decontamination efficiency was calculated based on the concentration of surrogates in the flakes after washing and drying and in the film after extrusion. The residual concentration values determined analytically by extraction from the multi-layer PET film were multiplied by a factor of 1.11 (100/90) to take into account the presence of the 10 % virgin PET in the film samples analysed.

The average results are summarized below in table 1.

**Table 1:** Efficiency of the decontamination of the crystallisation and extrusion steps 2 and 3

Surrogates	Concentration of surrogates before crystallisation (step 2) (mg/Kg PET)	Concentration of surrogates in the film after extrusion (step3) (mg/Kg PET)	Decontamination Efficiency (%)
Toluene	262.2	< 0.44*	>99.83
Chloroform	109.0	0.81	99.28
Chlorobenzene	407.3	1.1	99.73
Phenyl cyclohexane	350.3	8.43	97.59
Methyl salicylate	319.9	< 0.11*	>99.97
Benzophenone	381.4	18.87	95.05
Methyl stearate	185.0	11.81	93.61

(\*): Not detected at the limit of detection

As shown above, the decontamination efficiency ranged from 93.61 % for methyl stearate to above 99.97 % for methyl salicylate.

## 5. 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, metals, acetic aldehydes and physical properties are provided for the hot-caustic washed and dried flakes (step 1), the input materials for the recycling process. The input materials are produced from PET bottles previously used for food packaging collected through post-consumer collection systems. However, a

<sup>7</sup> Conventional recycling includes commonly sorting, grinding, washing and drying steps and produces washed and dried flakes.

small fraction may originate from non-food applications such as soap bottles, mouth wash bottles, kitchen cleaning products bottles, etc. According to the applicant, the amount of this non-food container fraction, on the basis of predefined specifications and quality control is below 1 % even below of 5 % as recommended by the 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. Washed and dried flakes from collected containers (step 1) are bought from flakes suppliers according to agreed quality specifications. The following steps are those of the MKF-Ergis technology used to recycle the PET flakes into decontaminated PET film: crystallisation (step 2) and extrusion (step 3) under vacuum. The operating parameters, temperature, gas flow and residence time for the crystallisation (step 2) and temperature, pressure and residence time for the extrusion (step 3) have been provided to EFSA.

A challenge test was conducted using the industrial plant at reduced capacity on the process steps 2 and 3 (crystallisation and extrusion) to measure the decontamination efficiency. The challenge test was performed according to the EFSA guidelines (EFSA, 2008). Therefore, the Panel considered that the two steps, crystallisation and extrusion are the critical steps for the decontamination efficiency of the process. Consequently the temperature, gas flow and the residence time for the crystallisation (step 2) and the temperature, the pressure and the residence time for extrusion (step 3) should be controlled to guarantee the performance of the decontamination. These parameters have been provided to EFSA.

The challenge test used an industrial plant which was set-up to make a 3-layer film with the recycled PET as the inner layer. This evaluation is however based on the scenario that the recycled PET was a monolayer and intended for direct food contact applications. Consequently this evaluation of the recycling process is not limited to the use of the recycled PET in multilayers.

The decontamination efficiencies obtained for each surrogate contaminant from the challenge test, ranging 93.61 % to above 99.97 % have been used to calculate the residual concentrations of potential unknown contaminants in the film ( $C_{res}$ ) 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, 2011; Appendix B). By applying the decontamination efficiency percentage to the reference contamination level of 3 mg/kg PET, the  $C_{res}$  for the different surrogates is obtained (Table 2).

According to the evaluation principles (EFSA CEF Panel, 2011), the  $C_{res}$  should not be higher than a modelled concentration in PET ( $C_{mod}$ ) corresponding to a migration, after one year at 25 °C, which cannot give rise to a dietary exposure exceeding 0.0025 µg/kg bw/day, the exposure threshold below which the risk to human health would be negligible<sup>8</sup>. Because the recycled PET is intended for general use for the manufacturing of articles containing up to 100 % recycled PET, the most conservative default scenario for infants has been applied, where a maximum dietary exposure of 0.0025 µg/kg bw/day corresponds to a maximum migration of 0.1 µg/kg of a contaminant substance into the infant’s food. Therefore, the migration of 0.1 µg/kg into food has been used to calculate  $C_{mod}$  (EFSA CEF Panel, 2011). The results of these calculations are shown in Table 2. The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

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<sup>8</sup> 0.0025 µg/kg bw/day is the human exposure threshold value for chemicals with structural alerts raising concern for potential genotoxicity, below which the risk to human health would be negligible (EFSA Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), 2011).

**Table 2:** Decontamination efficiency from challenge test, residual concentration of surrogate contaminants in recycled PET (*C<sub>res</sub>*) and calculated concentration of surrogate contaminants in PET (*C<sub>mod</sub>*) corresponding to a modelled migration of 0.1 µg/kg food after 1 year at 25 °C

Surrogates	Decontamination efficiency (%)	<i>C<sub>res</sub></i> (mg/kg PET)	<i>C<sub>mod</sub></i> (mg/kg PET)
Toluene	>99.83	0.005	0.09
Chloroform	99.28	0.022	0.10
Chlorobenzene	99.73	0.008	0.10
Phenyl cyclohexane	97.59	0.072	0.14
Methyl salicylate	>99.97	0.001	0.13
Benzophenone	95.05	0.148	0.16
Methyl stearate	93.61	0.192	0.32

The residual concentrations of all surrogates in PET after the decontamination (*C<sub>res</sub>*) are lower than the corresponding modelled concentrations in PET (*C<sub>mod</sub>*). Therefore, the Panel considered the recycling process under evaluation is able to ensure that the level of migration of unknown contaminants from the recycled PET into food is below the conservatively modelled migration of 0.1 µg/kg food at which the risk to human health would be negligible.

## CONCLUSIONS AND RECOMMENDATIONS

### CONCLUSIONS

The Panel considered that the process MKF-Ergis is well characterised and the main steps used to recycle the PET flakes into PET film are identified. Having examined the challenge test provided, the Panel concluded that the two continuous steps, the crystallisation (step 2) and the extrusion under vacuum (step 3) are the critical steps for the decontamination efficiency of the process. The operating parameters to control their performance are temperature, gas flow and residence time for crystallisation (step 2) and temperature, pressure and residence time for extrusion (step 3). Therefore, the Panel considered that the recycling process MKF-Ergis 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 obtained from the challenge test used to measure the decontamination efficiency of the processes and,
- ii) the input to the process is washed and dried post-consumer PET flakes originating from materials and articles that have been manufactured in accordance with the Community 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 MKF-Ergis intended to be used at up to 100 % for the manufacture of materials and articles for contact with all types of foodstuffs for long term storage at room temperature, with or without hotfill is not considered of safety concern. Trays made of this recycled PET should not be used in microwave and conventional ovens. The Panel notes that a limitation to use in multilayer systems only is not necessary.

### RECOMMENDATIONS

The Panel recommends that it should be verified periodically, as part of the good manufacturing practice (GMP), that as foreseen in the Regulation (EC) No 282/2008, art. 4b, the input originates from materials and articles that have been manufactured in accordance with the Community legislation on food contact materials and that the proportion of PET from non-food consumer applications is no

more than 5 % in the input to be recycled. Critical steps should be monitored and kept under control; supporting documentation describing how it will be ensured that the critical steps are operated under conditions at least as severe as those obtained from the challenge test used to measure the decontamination efficiency of the process should be available.

#### **DOCUMENTATION PROVIDED TO EFSA**

1. Dossier “MKF-Ergis”. November 2009. Submitted behalf of MKF Ergis GmbH.
2. Additional data for Dossier “MKF-Ergis”. November 2013. Submitted on behalf of MKF Ergis GmbH.

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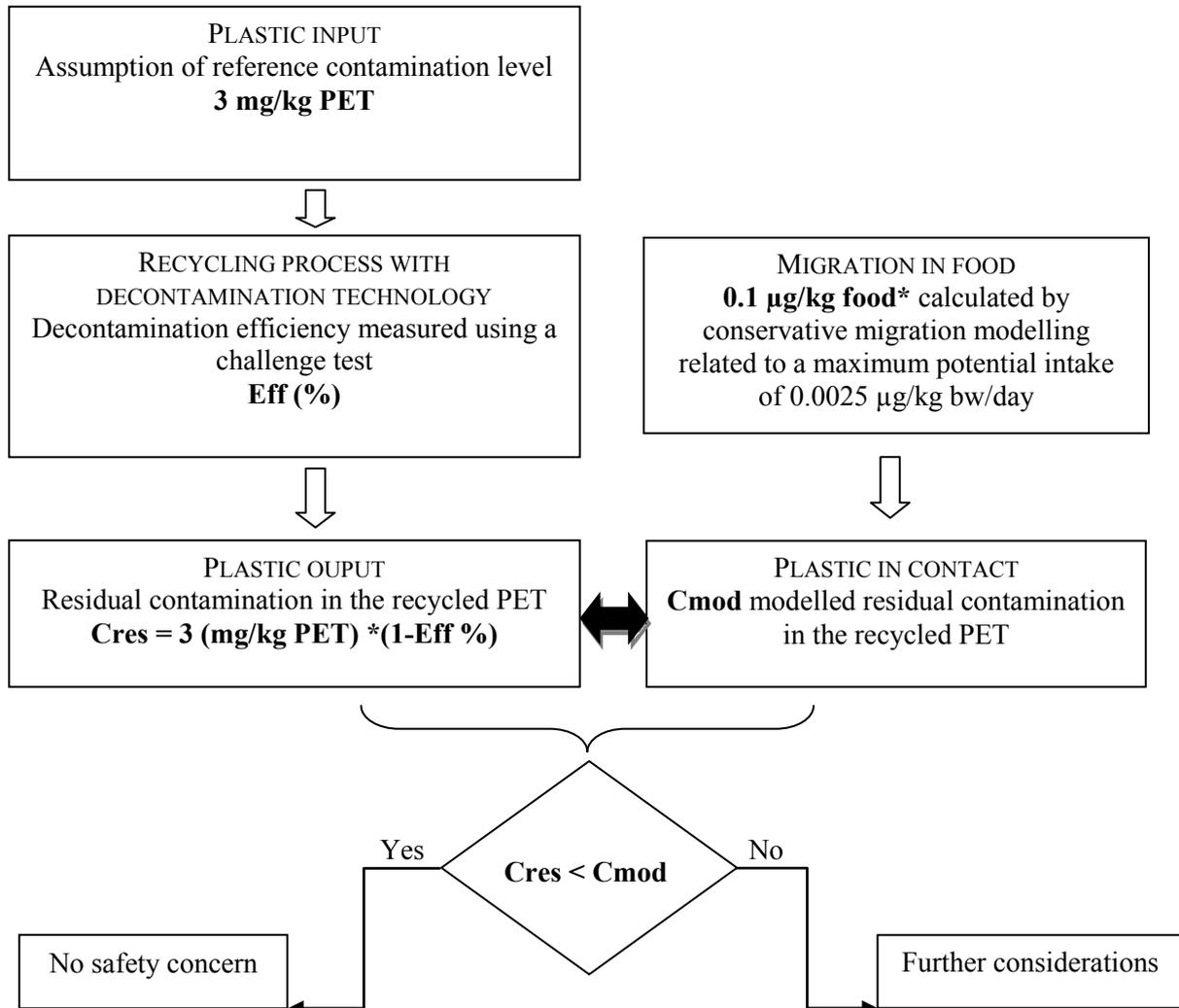
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**APPENDICES**

**Appendix A. Technical data of the washed and dried flakes as provided by the applicant**

<b>Characteristic</b>	<b>Value</b>
Source density	1,33 g/cm <sup>3</sup>
Bulk density	>250 g/l
Pieces size	<10 mm
Small particles (<3mm )	<3 %
Big particles (>10mm )	<5 %
Dust	<0,5 %
Moisture	<1 %
Acetaldehyde	max. 1 ppm
PVC	<20 ppm
Metal	<10 ppm
Glue	<5 ppm
Polyolefins	<50 ppm
Colour PET-Flakes	<500 ppm
Others	<25 ppm
Total (without colour Flakes)	<50 ppm

**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.

## ABBREVIATIONS

CEF	Food Contact Materials, Enzymes, Flavourings and Processing Aids
<i>C<sub>mod</sub></i>	Modelled concentration in PET
C <sub>res</sub>	Residual concentrations in PET
EC	European Commission
EFSA	European Food Safety Authority
GMP	Good manufacturing practice
PET	Poly(ethylene terephthalate)
PVC	Poly(vinyl chloride)
US-FDA	United States-Food and Drug Administration