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## Safety assessment of the process 'Krones' used to recycle post-consumer PET into food contact materials

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### 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 Krones pellet (EU register number RECYC0149). The input to the process is washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers and containing no more than 5% PET from non-food consumer applications. In this technology, washed and dried PET flakes are extruded to pellets that are then crystallised and decontaminated in a reactor at high temperature under vacuum. Having examined the results of the challenge test provided, the Panel concluded that two steps, the extrusion (step 2) and the decontamination in the vacuum reactor (step 4), are the critical steps that determine the decontamination efficiency of the process. The operating parameters to control the performance of these critical steps are temperature, residence time and, for the vacuum reactor, also pressure. 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 the conservatively modelled migration of 0.1 µg/kg food. Therefore, the Panel concluded that the recycled PET obtained from this process when used 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.

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

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**Question number:** EFSA-Q-2016-704

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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 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<sup>1</sup> of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of Regulation (EC) No 1935/2004<sup>2</sup> of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the 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 Kronos, European Union (EU) register No RECYC0149. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2016-00704. The dossier was submitted on behalf of Kronos AG, 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 a challenge test, or by other appropriate scientific evidence, that the recycling process Kronos 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.

<sup>1</sup> Regulation (EC) No 282/2008 of the European parliament and of the council of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006. OJ L 86, 28.3.2008, p. 9–18.

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

## 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  $\mu\text{g}/\text{kg}$  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 recycling process Kronos is intended to recycle food grade PET containers to produce recycled PET using its own technology. This recycled PET is intended to be used in a mass fraction up to 100% to manufacture PET bottles for mineral water or other beverages and extruded PET sheets for thermoforming of trays/containers for food contact applications. Thermoformed trays are in general for single use only. PET trays for microwave applications are excluded.

### 3.2. Description of the process

#### 3.2.1. General description

The recycling process Kronos produces recycled PET pellets from PET containers, coming from post-consumer collection systems (kerbside or deposit systems).

The recycling process run is composed of the four steps below:

#### Input

- In step 1, post-consumer PET containers are ground and processed into hot washed and dried flakes which are used as input to the next steps.

#### Decontamination and production of recycled PET material

- In step 2, the flakes are extruded to pellets
- In step 3, the pellets are crystallised
- In step 4, the pellets are decontaminated at high temperature under vacuum.

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

Recycled pellets, the final product of the process, are checked against technical requirements on intrinsic viscosity, black spots and colour. Recycled pellets are intended to be converted by other companies into recycled articles, such as PET bottles for mineral water or other beverages and extruded PET sheets for thermoforming of trays/containers for food contact applications (e.g. for fruit, vegetables, cooked and uncooked meats, dairy products and desserts). The thermoformed trays are in general for single use only and are not intended to be used in microwave ovens.

### 3.2.2. Characterisation of the input

According to the applicant, the input for the recycling process Kronos consists of hot caustic washed, dried flakes obtained from PET containers previously used for food packaging, from post-consumer collection systems (kerbside or deposit systems). A small fraction may originate from non-food applications such as soap bottles, mouthwash bottles, kitchen hygiene bottles, etc.. According to information from the applicant, the amount of this non-food container fraction depends on the recollection system and will be between (nearly) 0% and 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, polyamides and physical properties (see Appendix A).

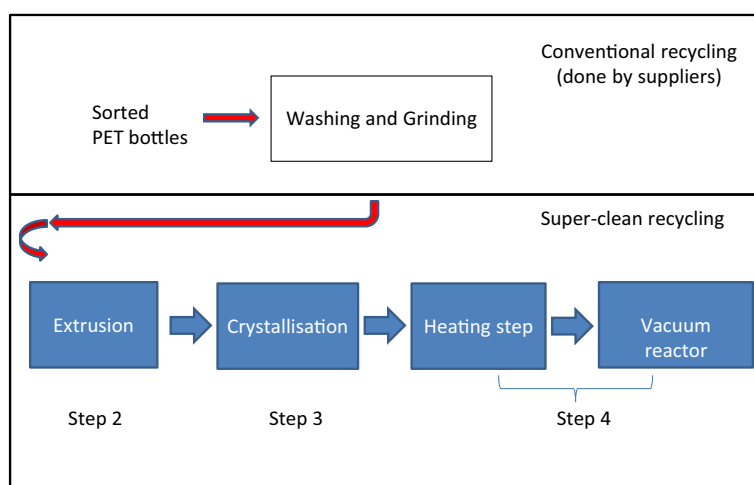
## 3.3. Technology

### 3.3.1. Description of the main steps

To decontaminate post-consumer PET, the recycling process Kronos uses its own Krone technology, as described below and for which the general scheme is reported in Figure 1.

The recycling process is composed of the four steps below.

- Step 1: Post-consumer PET containers are ground and processed into hot washed and dried flakes which are used as input to the next steps. This step is performed by third parties (flake suppliers).
- Step 2: The washed and dried flakes are extruded to pellets.
- Step 3: The pellets are crystallised.
- Step 4: The pellets are heated and decontaminated in a reactor at high temperature under vacuum for a defined residence time.



**Figure 1:** General scheme of the technology

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 recycling process Kronos, a challenge test on the technology used was submitted to EFSA.

PET flakes were contaminated with toluene, chlorobenzene, chloroform, methyl salicylate, phenylcyclohexane, benzophenone, lindane and methyl stearate, selected as surrogate contaminants in accordance with the EFSA guidelines and in agreement with the US Food and Drug Administration (FDA) recommendations. 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>3</sup> post-consumer PET flakes were mixed with a solution of the surrogates in isopropanol and stored in barrels for 7 days at 50°C with daily agitation. The contaminated flakes were first rinsed with 10% ethanol to remove surface contamination of the flakes, and subsequently, hot-caustic washed and dried before being decontaminated. The concentration of surrogates in this material was determined (before step 2).

For the challenge test, the contaminated flakes were submitted to extrusion (step 2), and then, the pellets were introduced in a batch reactor of reduced capacity able to simulate step 4 of the decontamination technology. The reactor was filled with pellets obtained from contaminated flakes only. After the steps 2 and 4, the pellets were analysed for the residual concentrations of the applied surrogates.

The decontamination efficiency was calculated based on the concentration of surrogates in the flakes before the extrusion (step 2) and in the pellets after the vacuum reactor (step 4). The results are summarised below in Table 1.

**Table 1:** Efficiency of the decontamination of the technology in the challenge test

Surrogates	Concentration before extrusion (step 2) (mg/kg PET flakes)	Concentration after extrusion (step 2) (mg/kg PET pellets)	Concentration after the vacuum reactor (step 4) (mg/kg PET pellets)	Overall decontamination efficiency (%)
Toluene	258.7	172.5	< 0.2 <sup>(a)</sup>	> 99.9
Chlorobenzene	369.8	142.2	1.6	99.6
Chloroform	117.7	58.9	0.9	99.2
Methyl salicylate	369.6	251.2	0.5	99.9
Phenylcyclohexane	444.9	273.3	21.2	95.2
Benzophenone	579.7	497.3	28.7	95.0
Lindane	331.3	227.5	21.2	93.6
Methyl stearate	257.6	201.6	9.1	96.5

PET: poly(ethylene terephthalate).

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

As shown in Table 1, the decontamination efficiency ranged from 93.6% for lindane to > 99.9% for toluene. Since the challenge test was performed with contaminated flakes only, cross-contamination<sup>4</sup> phenomena can be excluded.

### 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, 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, mouthwash bottles and kitchen hygiene bottles. 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).

<sup>3</sup> Conventional recycling generally includes sorting, grinding, washing and drying steps and produces washed and dried flakes.

<sup>4</sup> 'Cross-contamination', 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).

The process is well described. The production of washed and dried flakes from collected containers (step 1) is conducted by third parties. According to the applicant, this step is under the applicant's control. The Kronos technology uses the following steps to recycle the PET flakes into decontaminated PET pellets: extrusion of the washed and dried flakes to pellets (step 2), crystallisation (step 3) and decontamination at high temperature in a vacuum reactor (step 4). The operating parameters of temperature, pressure and residence time for steps 2, 3 and 4 have been provided to EFSA.

A challenge test was conducted in a pilot plant of reduced capacity on steps 2 and 4. This pilot plant can simulate the same conditions of temperature, pressure and residence time as those operated in the process at the production plant. It can be concluded that the decontamination parameters applied in the commercial process are equally severe than the ones in the challenge test.

The challenge test was performed according to the recommendations in the EFSA guidelines (EFSA, 2008). The Panel considered that two steps (steps 2 and 4) are the critical ones for the decontamination efficiency of the process. Consequently, the operating parameters of the process, temperature and residence time for step 2 and temperature, pressure and residence time for step 4, should be controlled to guarantee the performance of the decontamination.

The decontamination efficiencies obtained for each surrogate contaminant from the challenge test, ranging from 93.6% to 99.9%, have been used to calculate the residual concentrations of potential unknown contaminants in flakes ( $C_{res}$ ) 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 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 1 year at 25°C, which cannot give rise to a dietary exposure exceeding 0.0025 µg/kg bw per day, the exposure threshold below which the risk to human health would be negligible.<sup>5</sup> Because the recycled PET is intended for general use in 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 per 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.

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

Surrogates	Decontamination efficiency (%)	$C_{res}$ (mg/kg PET)	$C_{mod}$ (mg/kg PET)
Toluene	> 99.9	< 0.003	0.09
Chlorobenzene	99.6	0.01	0.10
Chloroform	99.2	0.02	0.10
Methyl salicylate	99.9	0.003	0.13
Phenylcyclohexane	95.2	0.14	0.14
Benzophenone	95.0	0.15	0.16
Lindane	93.6	0.19	0.31
Methyl stearate	96.5	0.11	0.32

PET: poly(ethylene terephthalate).

The residual concentrations of all surrogates in PET after the decontamination ( $C_{res}$ ) are not higher than the corresponding modelled concentrations in PET ( $C_{mod}$ ). 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.

<sup>5</sup> 0.0025 µg/kg bw per 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 CEF Panel, 2011).



## 4. Conclusions

The Panel considered that the process Krones is well characterised and the main steps used to decontaminate the PET flakes are identified. Having examined the challenge test provided, the Panel concluded that two steps, the extrusion of flakes to pellets (step 2) and the decontamination in the vacuum reactor (step 4), are critical for the decontamination efficiency of the process. The operating parameters to control their performance are temperature and residence time for step 2, and temperature, pressure and residence time for step 4. Therefore, the Panel considered that the recycling process Krones 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 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 and contain no more than 5% PET from non-food consumer applications.

Therefore, the recycled PET obtained from the process Krones, when used up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs for hotfill and/or long-term storage at room temperature, is not considered of safety concern. Trays made of this recycled PET should not be used in microwave and conventional ovens.

## 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 "Krones Pellet Recycling Process". December 2016. Submitted on behalf of Krones AG, Germany.
- 2) Clarification on dossier "Krones Pellet Recycling Process". June and July 2017. Submitted on behalf of Krones AG, Germany.

## References

- EFSA (European Food Safety Authority), 2008. Guidelines for the submission of an application for safety evaluation by the EFSA of a recycling process to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food, prior to its authorisation. *EFSA Journal* 2008;6(7):717, 12 pp. <https://doi.org/10.2903/j.efsa.2008.717>
- EFSA (European Food Safety Authority), 2009. Guidance of the Scientific Committee on transparency in the scientific aspects of risk assessments carried out by EFSA. Part 2: 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 (CEF), 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>

## Abbreviations

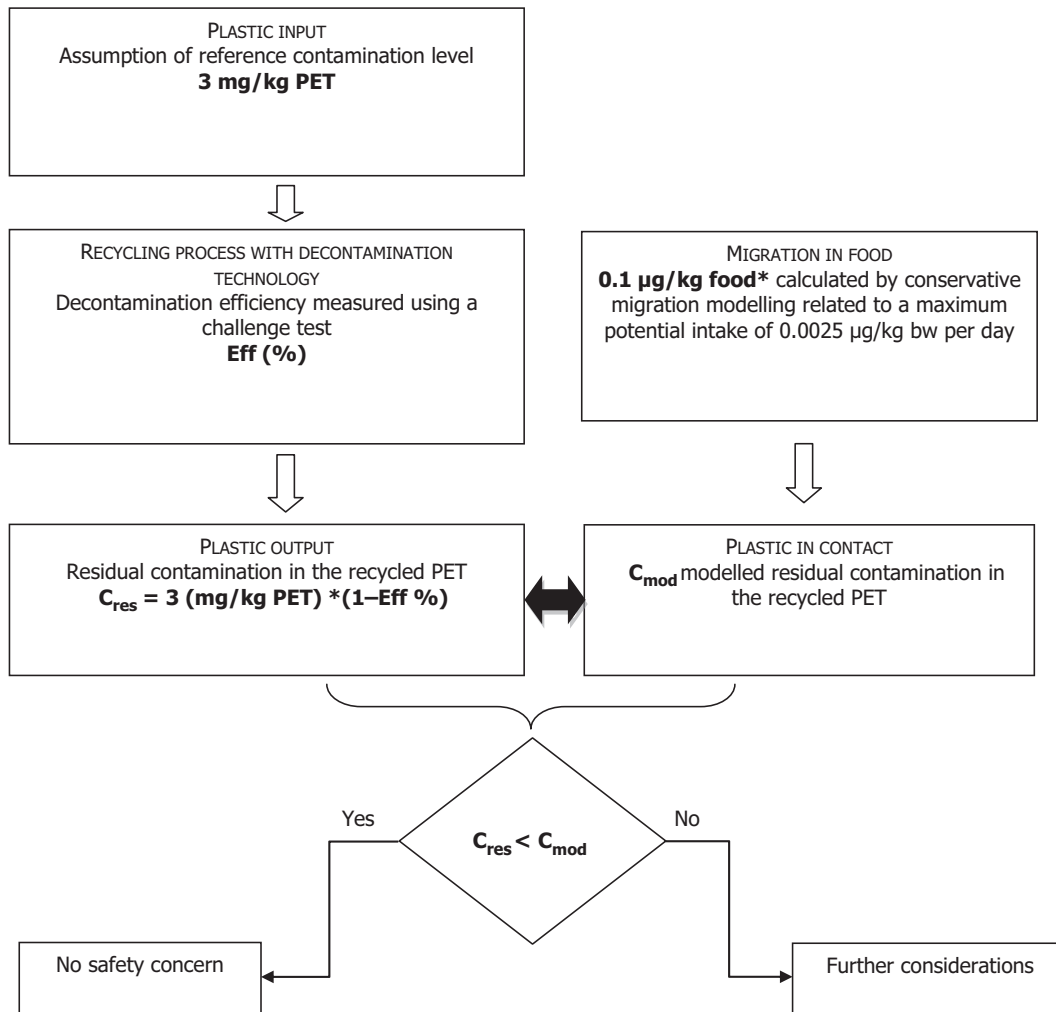
- bw body weight  
CEF Panel EFSA Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids  
C<sub>mod</sub> modelled concentration in PET

$C_{res}$  residual concentrations in PET  
FDA Food and Drug Administration  
PET poly(ethylene terephthalate)  
PVC poly(vinyl chloride)

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

Parameter	Value
Moisture max.	1.0%
Moisture variation	$\pm 0.3 \text{ h}^{-1}$
Bulk density	$200\text{--}400 \text{ kg m}^{-3}$
Bulk density variation	$\pm 150 \text{ kg m}^{-3} \text{ h}^{-1}$
PVC max.	200 ppm
Glue max.	100 ppm
Polyolefins max.	300 ppm
cellulose (paper, wood)	100 ppm
metals max.	100 ppm
polyamide max.	100 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.