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Safety assessment of the process ISKO, based on Gneuss 4 technology, used to recycle post-consumer PET into food contact materials

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Abstract

The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) assessed the safety of the recycling process ISKO (EU register number RECYC287), which uses the Gneuss 4 technology. The input consists of 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 melted in an extruder (step 2), decontaminated during a melt-state polycondensation step [redacted] and vacuum (step 3) and finally pelletised. Having examined the challenge test provided, the Panel concluded that the melt-state polycondensation (step 3) is critical in determining the decontamination efficiency of the process. The operating parameters to control the performance of the critical step are the pressure, the temperature, the residence time and the characteristics of the reactor. It was demonstrated by the challenge test 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, including drinking water, for long-term storage at room temperature or below, with or without hotfill. The final articles made of this recycled PET are not intended to be used in microwave and conventional ovens and such uses are not covered by this evaluation.

Keywords: Gneuss 4, ISKO, food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

Requestor: German Competent Authority (Federal Office of Consumer Protection and Food Safety)

Question number: EFSA-Q-2022-00187

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

1.1.1. Background

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, the 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[1,2] on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of Regulation (EC) No 1935/2004[3] 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 EFSA for evaluation.

In this case, EFSA received from the German Competent Authority (Federal Office of Consumer Protection and Food Safety), an application for evaluation of the recycling process ISKO, European Union (EU) register No RECYC287. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2022-00187. The dossier was submitted on behalf of SANKO TEKSTİL İŞLETMELERİ SANAYİ VE TICARET A.Ş ISKO ŞB (ISKO), Organize Sanayi Bölgesi 3.Cadde Inegol/Bursa, Türkiye (see 'Documentation provided to EFSA').

1.1.2. Terms of Reference

The German Competent Authority (Federal Office of Consumer Protection and Food Safety) requested the safety evaluation of the recycling process ISKO, in accordance with Regulation (EC) No 282/2008 and articles 8, 9 and 10 of Regulation (EC) 1935/2004.

1.2. Interpretation of the Terms of Reference

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 ISKO 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 are part of this evaluation.

2. Data and methodologies

2.1. Data

The applicant has submitted a confidential and a non-confidential version of 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) and the 'Administrative guidance for the preparation of applications on recycling processes to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food' (EFSA, 2021).

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[1] 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.

[2] Commission Regulation (EC) No 282/2008 was repealed by Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008 (OJ L 243 20.9.2022, p. 3) which entered into force on 10 October 2022. Applications submitted to EU Member State competent authorities before the date of entry into force of Commission Regulation (EU) 2022/1616 are evaluated by EFSA in accordance with Commission Regulation (EC) No 282/2008.

[3] 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.

Additional information was sought from the applicant during the assessment process in response to requests from EFSA sent on 11 November 2022 and was subsequently provided (see 'Documentation provided to EFSA').

In accordance with Art. 38 of the Regulation (EC) No 178/2002[4] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[5] the non-confidential version of the dossier has been published on Open.EFSA.[6]

According to Art. 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations,[7] EFSA carried out a public consultation on the non-confidential version of the application from 16 May 2023 to 06 June 2023, for which no comments were received.

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.

2.2. Methodologies

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 to be of safety concern for the defined conditions of use (EFSA CEF Panel, 2011).

[4] Commission Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p.1–48.

[5] Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements.

[6] The non-confidential version of the dossier has been published on Open.EFSA and is available at the following link: https://open.efsa.europa.eu/dossier/FCM-2022-4232.

[7] Decision available at: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf.

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[8]

According to the applicant, the recycling process ISKO is intended to recycle food grade PET containers using the Gneuss 4 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. 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[9]

The recycling process ISKO 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 three steps below.

Input

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

Decontamination and production of recycled PET material

- In step 2, the flakes are extruded.
- In step 3, the material is decontaminated in a melt-state polycondensation process.

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

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

3.2.2. Characterisation of the input[10]

According to the applicant, the input material for the recycling process ISKO consists of hot washed and dried flakes obtained from PET containers, e.g. 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 will be no more than 5%.

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

3.3. Gneuss 4 technology

3.3.1. Description of the main steps[11]

The general scheme of the Gneuss 4 technology, as provided by the applicant, is reported in Figure 1. The steps are:

- Extrusion (step 2): The hot washed and dried flakes are melted, extruded under vacuum and filtered. The extruder used ([redacted]) comprises [redacted] and residence time. The residual solid particles (e.g. paper, aluminium) are filtered out before being pumped into the reactor of step 3.

[8] Technical dossier, sections 'Recycling process' and 'Intended application in contact with food'.
[9] Technical dossier, 'Recycling process', 'Characterisation of the input' and 'Characterisation of the recycled plastic'.
[10] Technical dossier, section 'Characterisation of the input'.
[11] Technical dossier, section 'Recycling process' and 'Determination of the decontamination efficiency of the recycling process'.

- Melt-state polycondensation (step 3): The melt is decontaminated under [redacted] and vacuum. The reactor consists of [redacted], then the melt is processed to pellets.

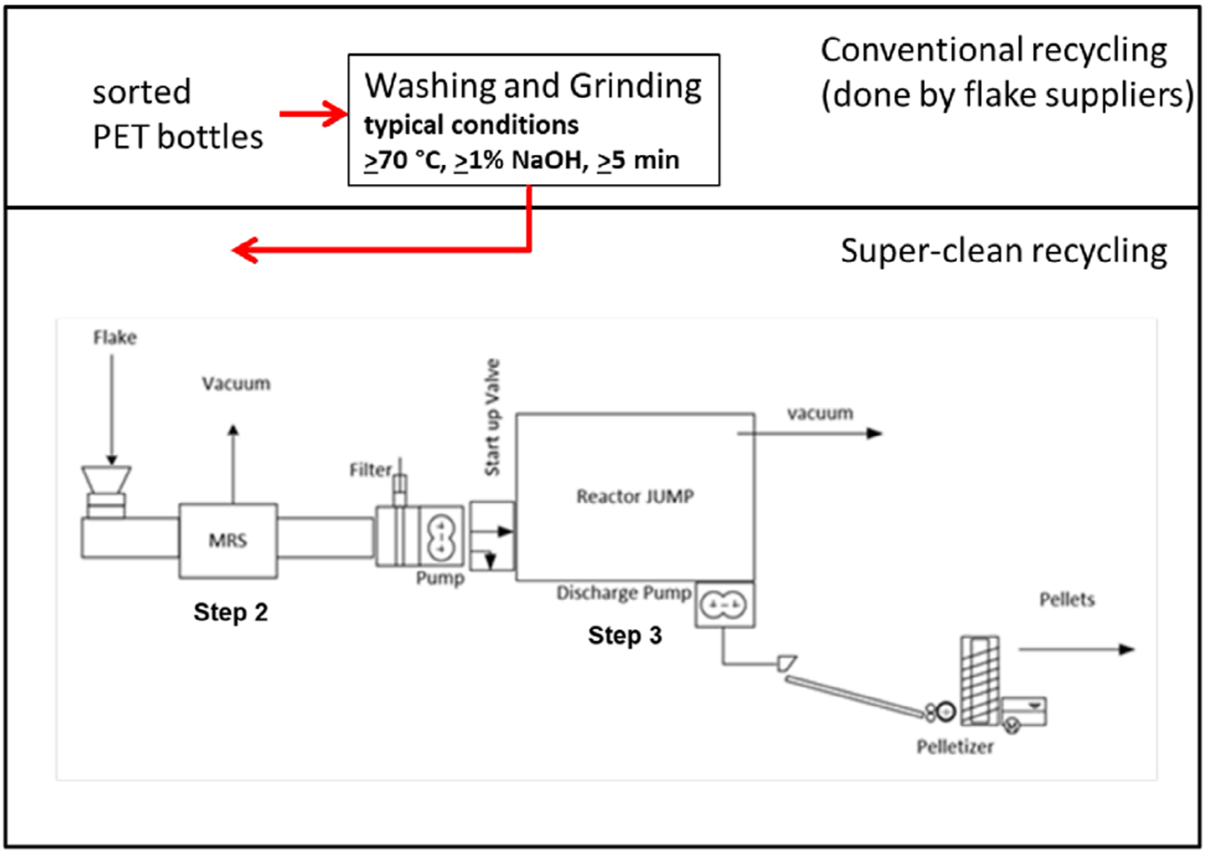

Figure 1: General scheme of the Gneuss 4 technology (provided by the applicant)

The process is run under defined operating parameters[12] of temperature, pressure and residence time.

3.3.2. Decontamination efficiency of the recycling process[13]

To demonstrate the decontamination efficiency of the recycling process ISKO, a challenge test performed at [redacted] was submitted to EFSA.

PET was contaminated with toluene, chloroform, chlorobenzene, phenylcyclohexane, methyl salicylate, 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). The mixture of these surrogates was spiked into the PET flakes during the extrusion (step 2). The extruder used in the challenge test was a standard single screw extruder without satellite screws, degassing section and vacuum applied.

The Gneuss 4 technology was challenged at the Gneuss facilities [redacted]. The decontamination efficiency was then calculated from the concentration differences before the

[12] 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).
[13] Technical dossier, section 'Determination of the decontamination efficiency of the recycling process' and Appendix E.

melt-state polycondensation (step 3) and after pelletisation. When surrogates were not detected, the limit of detection was considered for the calculation of the decontamination efficiency. The results are summarised in Table 1.

Table 1: Efficiency of the decontamination of the Gneuss 4 technology in the challenge test

Surrogates	Concentration of surrogates before step 3 (mg/kg PET)	Concentration of surrogates after step 3 (mg/kg PET)	Decontamination efficiency (%)
Toluene	545.0	< 0.5[a]	> 99.9
Chloroform	108.1	< 0.2[a]	> 99.8
Chlorobenzene	508.1	< 0.1[a]	> 99.9
Phenylcyclohexane	516.4	< 0.1[a]	> 99.9
Methyl salicylate	323.3	< 0.1[a]	> 99.9
Benzophenone	439.7	2.1	99.5
Methyl stearate	510.9	< 0.1[a]	> 99.9

PET: poly(ethylene terephthalate).
(a): Not detected at the limits of detection given.

As shown in Table 1, the decontamination efficiency ranged from 99.5% for benzophenone to more than 99.9% for all the other surrogates.

Contrary to the recommendations of the EFSA guideline (EFSA, 2008), the contaminated flakes were not rinsed before being introduced in the recycling process. As the flakes were contaminated during the extrusion process, before the material is subjected to vacuum, the Panel agreed that the surrogate substances were homogeneously distributed in the PET material before the decontamination started. Therefore, the results from the challenge test can be used to calculate the decontamination efficiency.

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 on physical properties and residual contents of PVC, glues, polyolefins, wood, paper and metals, were provided for the input materials (i.e. washed and dried flakes, step 1). These are mainly 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, mouth wash or kitchen hygiene agents. According to the applicant, the collection system and the process are managed in such a way that this fraction will be no more than 5% in the input stream, as recommended by the EFSA CEF Panel in its 'Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food' (EFSA CEF Panel, 2011).

The process is adequately described. The washing and drying of the flakes from the collected PET containers (step 1) is conducted by the applicant or by third parties. According to the applicant, this step is under control. The Gneuss 4 technology comprises extrusion (step 2) and melt-state polycondensation (step 3). 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 the Gneuss facilities [redacted] on process step 3. The Panel considered that this challenge test was performed correctly according to the recommendations of the EFSA guidelines (EFSA, 2008). The decontamination of the material in the vacuum reactor by melt-state polycondensation (step 3) is critical and depends on the specific surface area of the melt exposed to the vacuum, the residence time, the pressure and the temperature. [redacted]. Consequently, the pressure, the temperature, the residence time ([redacted]) and the characteristics of the reactor specified in Appendix C should be controlled to guarantee the performance of the decontamination.

The decontamination efficiencies obtained from the challenge test, being from 99.5% for benzophenone and more than 99.9% for the other surrogates, 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 efficiency percentage 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 μg/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, results in a migration giving rise to a dietary exposure of 0.0025 μg/kg bw per day. Because the recycled PET is intended for the manufacturing of articles (e.g. bottles) to be used in direct contact with drinking water, the exposure scenario for infants has been applied (water could be used to prepare infant formula). 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 the challenge test, residual concentrations of the surrogates (C_{res}) related to the reference contamination level and calculated concentrations of the surrogates 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} for 100% rPET(mg/kg PET)	C_{mod}(mg/kg PET)
Toluene	> 99.9	0.003	0.080
Chloroform	> 99.8	0.006	0.099
Chlorobenzene	> 99.9	0.001	0.095
Phenylcyclohexane	> 99.9	0.001	0.133
Methyl salicylate	> 99.9	0.001	0.126
Benzophenone	99.5	0.014	0.154
Methyl stearate	> 99.9	0.001	0.290

PET: poly(ethylene terephthalate). rPET: recycled 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 ISKO using the Gneuss 4 technology 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 this level, the risk to human health is considered negligible, when the recycled PET is used at up to 100% to produce materials and articles intended for contact with all types of foodstuffs for long-term storage at room temperature or below, with or without hotfill.

The Panel noted that the input of the process originates from Türkiye. In the absence of data on misuse contamination of this input, the Panel used the reference contamination of 3 mg/kg PET (EFSA CEF Panel, 2011) that was derived from experimental data from an EU survey. Accordingly, the recycling process under evaluation using a Gneuss 4 technology is able to ensure that the level of unknown contaminants in recycled PET is below a calculated concentration (C_{mod}) corresponding to a modelled migration of 0.1 μg/kg food.

4. Conclusions

The Panel considered that the process ISKO, using the Gneuss 4 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 melt-state polycondensation (step 3) is critical for the decontamination efficiency. The operating parameters to control its performance are the pressure, the temperature, the residence time and the characteristics of the reactor specified in Appendix C.

The Panel considered that the recycling process ISKO is able to reduce foreseeable accidental contamination of post-consumer food contact PET to a concentration that does not give rise to concern for a risk to human health if:

i) it is operated under conditions that are at least as severe as those applied in the challenge test used to measure the decontamination efficiency of the process;
ii) the input material of the process is washed and dried post-consumer PET flakes originating from materials and articles that have been manufactured in accordance with the EU legislation on food contact materials and contains no more than 5% of PET from non-food consumer applications;
iii) the recycled PET obtained from the process ISKO is used at up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs, including drinking water, for long-term storage at room temperature or below, 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 material to be recycled originates from materials and articles that have been manufactured in accordance with the EU legislation on food contact materials and that the proportion of PET from non-food consumer applications is no more than 5%. This adheres to good manufacturing practice and the Regulation (EC) No 282/2008, Art. 4b. Critical steps in recycling should be monitored and kept under control. In addition, supporting documentation should be available on how it is ensured that the critical steps are operated under conditions at least as severe as those in the challenge test used to measure the decontamination efficiency of the process.

6. Documentation provided to EFSA

Dossier 'ISKO'. March 2022. Submitted on behalf of SANKO TEKSTİL İŞLETMELERİ SANAYİ VE TICARET A.Ş ISKO ŞB (ISKO), Türkiye.

Additional information, March 2023. Submitted on behalf of SANKO TEKSTİL İŞLETMELERİ SANAYİ VE TICARET A.Ş ISKO ŞB (ISKO), Türkiye.

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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

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Abbreviations

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

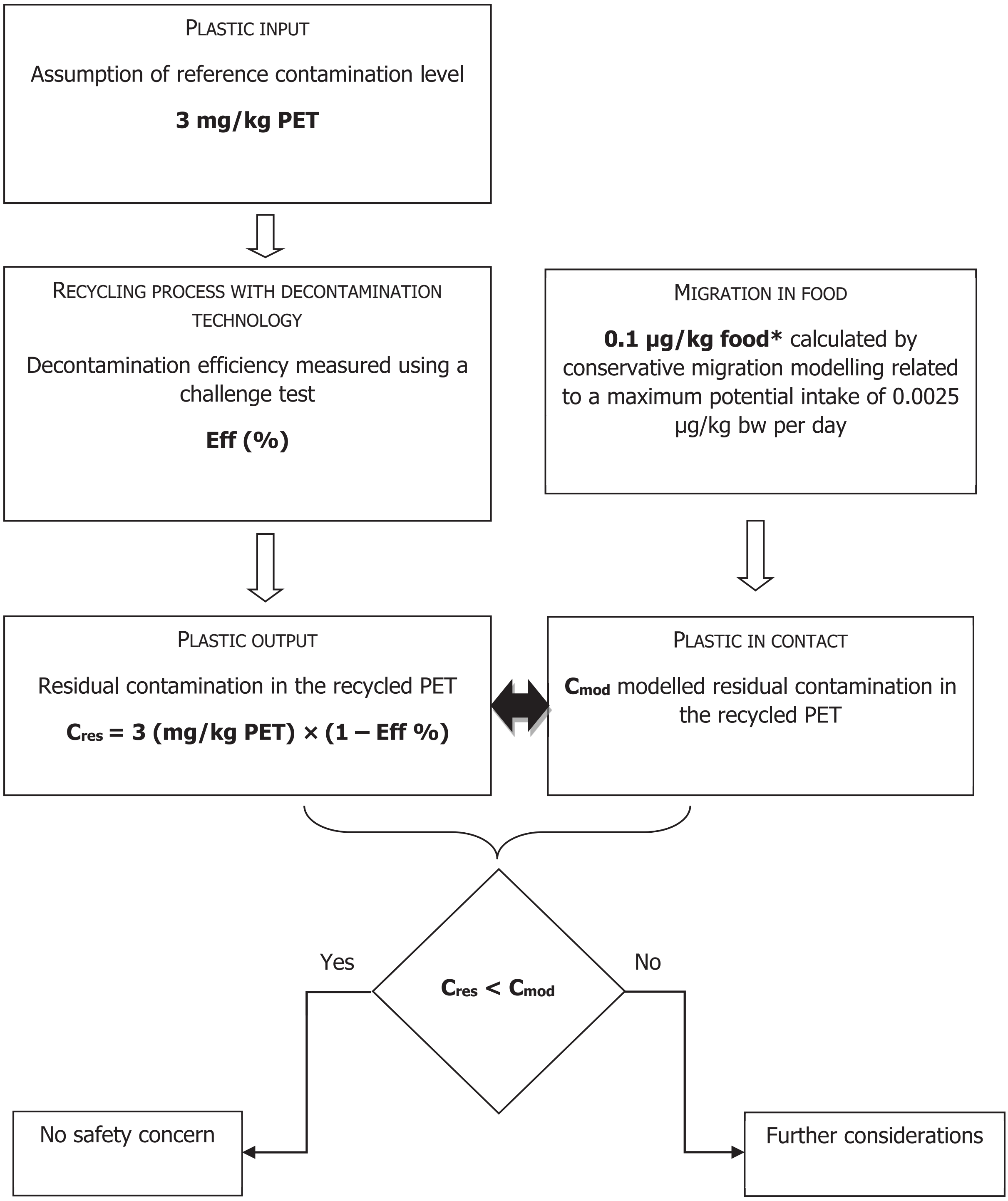
Appendix A – Technical data of the washed flakes as provided by the applicant[14]

Parameter	Value
Moisture max.	5.0%
Bulk density	200–850 kg m^{-3}
PVC max.	200 mg/kg
Glue max.	100 mg/kg
Polyolefins max.	300 mg/kg
Metals max.	100 mg/kg
Cellulose (paper, wood) max.	100 mg/kg
Polyamide max.	100 mg/kg

PVC: poly(vinyl chloride).

[14] Technical dossier, section 'Characterisation of the input'.

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[15]

Although the operational parameters are reported for all the process steps, the critical steps and the corresponding parameters of the challenge test/ process, considered for the evaluation of the process and for which it has been concluded that the process is safe, are highlighted in green.

The process should be operated at conditions at least as severe as the ones indicated in green in the table (e.g. lower pressures are more severe than higher, higher temperatures are more severe than lower, longer times are more severe than shorter, higher gas flows generally are more severe than lower).

The official enforcement control shall verify that the recycling plant is operating in a way that complies with its authorisation. Depending on the technology, some of the parameters are inter-related and changing one parameter to a more severe value may impact another parameter into a less severe value. Therefore, eventual deviations from the values of the parameters indicated as critical (marked in green in the table) should be demonstrated not impacting significantly on the safety assessment. The table does not necessarily report all the tolerances for the operational parameters.

	Recycling Process ISKO (recycling number RECYC287) based on the Gneuss 4 technology					
	Step 2 (Extrusion)			**Step 3 (Decontamination)***		
	t (sec)	**P (mbar)**	**T (°C)**	**t (min)**	**P (mbar)**	**T (°C)**
Challenge test (PA/4499a/20)	Not challenged			[redacted] Cont.	[redacted]	[redacted]
Process	[redacted] Cont.	[redacted]	[redacted]	[redacted] Cont.	[redacted]	[redacted]

*: **Characteristics of the reactor** in the challenge test and the industrial process.

	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[15] Technical dossier, section 'Table of operating parameters'.