SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 27 October 2022

doi: 10.2903/j.efsa.2022.7653

Safety assessment of the process Ester Industries, based on the recoSTAR PET FG technology, used to recycle post-consumer PET into food contact materials

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

Abstract

The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) assessed the safety of the recycling process Ester Industries (EU register number RECYC261) using the recoSTAR PET FG technology. The input is hot washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, mainly bottles, with no more than 5% PET from non-food consumer applications. The flakes are processed continuously under an inert gas flow. They are dried and crystallised in a first reactor and then further heated in a second reactor before being extruded into pellets. Having examined the challenge test provided, the Panel concluded that the drying and crystallisation (step 2), and the heating of the crystallised flakes (step 3) 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 gas flow rate. It was demonstrated that this recycling process is able to ensure that the level of migration of potential unknown contaminants into food is below the conservatively modelled migration of 0.1 μg/kg food. Therefore, the Panel concluded that the recycled PET obtained from this process is not of safety concern, when used at up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs for long-term storage at room temperature, with or without hotfill. Trays 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.

Keywords: recoSTAR PET FG, Ester Industries, food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

Requestor: German Competent Authority (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, BVL)

Question number: EFSA-Q-2021-00396

Correspondence: fip@efsa.europa.eu

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

Note: The full opinion is published in accordance with Article 10(6) of Regulation (EC) No 1935/2004, and it implements EFSA's decision on confidentiality, in accordance with Article 20 of the said Regulation. Certain Technical details have been awarded confidential status by EFSA and consequently withheld from public disclosure by redaction.This opinion may be subject to editing once the confidentiality decision making on the additional information received is completed.

Declarations of interest: If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

Suggested citation: EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids), Lambré C, Barat Baviera JM, Bolognesi C, Chesson A, Cocconcelli PS, Crebelli R, Gott DM, Grob K, Mengelers M, Mortensen A, Rivière G, Steffensen I-L, Tlustos C, Van Loveren H, Vernis L, Zorn H, Dudler V, Milana MR, Papaspyrides C, Tavares Poças MF, Lioupis A, Tsochatzis E and Lampi E, 2022. Scientific Opinion on the safety assessment of the process Ester Industries, based on the recoSTAR PET FG technology, used to recycle post-consumer PET into food contact materials. EFSA Journal 2022;20(12):7653, 13 pp. https://doi.org/10.2903/j.efsa.2022.7653

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.

† Deceased.

Table of contents

Abstract 1
1. Introduction 4
1.1. Background and Terms of Reference as provided by the requestor 4
1.2. Terms of Reference 4
1.3. Interpretation of the Terms of Reference 4
2. Data and methodologies 4
2.1. Data 4
2.2. Methodologies 5
3. Assessment 5
3.1. General information 5
3.2. Description of the process 6
3.2.1. General description 6
3.2.2. Characterisation of the input 6
3.3. recoSTAR PET FG technology 6
3.3.1. Description of the main steps 6
3.3.2. Decontamination efficiency of the recycling process 7
3.4. Discussion 8
4. Conclusions 9
5. Recommendations 9
6. Documentation provided to EFSA 10
References 10
Abbreviations 10
Appendix A – Technical data of the washed flakes as provided by the applicant 11
Appendix B – Relationship between the key parameters for the evaluation scheme (EFSA CEF Panel, 2011) 12
Appendix C – Table on Operational parameters (Confidential Information) 13

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[1] 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[2] 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, an application for evaluation of the recycling process Ester Industries, European Union (EU) register No RECYC261. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2021-00396. The dossier was submitted on behalf of Ester Industries Ltd, Gurgaon, 122001, India (see 'Documentation provided to EFSA').

1.2. Terms of Reference

The Bundesamt für Verbraucherschutz und Lebensmittelsicherheit requested the safety evaluation of the recycling process Ester Industries, in accordance with Article 5 of Regulation (EC) No 282/2008.

1.3. Interpretation of the Terms of Reference

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 Ester Industries 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 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).

Additional information was sought from the applicant during the assessment process in response to requests from EFSA sent on 2 May 2022 and 8 July 2022 and was subsequently provided (see 'Documentation provided to EFSA').

[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, pp. 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, pp. 4–17.

In accordance with Art. 38 of the Regulation (EC) No 178/2002[3] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39 e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[4] the non-confidential version of the dossier has been published on Open.EFSA.[5]

According to Art. 32c(2) of Regulation (EC) No 178/2002, the non-confidential version of the application underwent a public consultation from 18 March to 8 April 2022, 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 principles followed for the evaluation are described here. The risks associated with the use of recycled plastic materials and articles in contact with food come from the possible migration of chemicals into the food in amounts that would endanger human health. The quality of the input, the efficiency of the recycling process to remove contaminants as well as the intended use of the recycled plastic are crucial points for the risk assessment (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] 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, pp.1–48.

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

[5] 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-2021-1167

3. Assessment

3.1. General information[6]

According to the applicant, the recycling process Ester Industries is intended to recycle food grade PET containers to produce recycled PET pellets using the recoSTAR PET FG technology. The recycled PET is intended to be used at up to 100% for the manufacture of materials and articles to be used in direct contact with all kinds of foodstuffs, including water, for long-term storage at room temperature, with or without hotfill. The final articles are not intended to be used in microwave and conventional ovens.

3.2. Description of the process

3.2.1. General description[7]

The recycling process Ester Industries produces recycled PET pellets from PET containers, coming from post-consumer collection systems (kerbside and deposit systems and mixed waste collection).

The recycling process is composed of the four steps below.

Input

- In step 1, the post-consumer PET containers are processed into [redacted] and dried flakes. This step may be performed by a third party or by the applicant.

Decontamination and production of recycled PET material

- In step 2, the flakes are preheated in a [redacted] reactor under [redacted] and the material is crystallised.
- In step 3, the flakes are heated in a continuous reactor under [redacted] and [redacted].
- In step 4, the material is extruded and pellets of recycled PET are produced.

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

The recycled pellets, the final product of the process, are checked against technical requirements, such as intrinsic viscosity, size and bulk density.

3.2.2. Characterisation of the input[8]

According to the applicant, the input material for the recycling process Ester Industries consists of [redacted] and dried flakes obtained from PET containers, mainly bottles, previously used for food packaging, from post-consumer collection systems (kerbside and deposit systems as well as mixed waste collection). A small fraction may originate from non-food applications. According to the applicant, this proportion will be no more than 5%.

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

3.3. recoSTAR PET FG technology

3.3.1. Description of the main steps[9]

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

- Drying and crystallisation in a [redacted] reactor (step 2): The flakes are introduced into a continuous reactor where they are heated and crystallised at high temperature with preheated inert gas for a predefined residence time.

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

- Heating of the crystallised flakes in a [redacted] reactor (step 3): The crystallised flakes are continuously fed into a reactor under [redacted] with preheated [redacted] for a predefined [redacted].
- Extrusion (step 4): The flakes continuously coming from the previous reactor are melted in the extruder. The molten material is pelletised or used for in-line production.

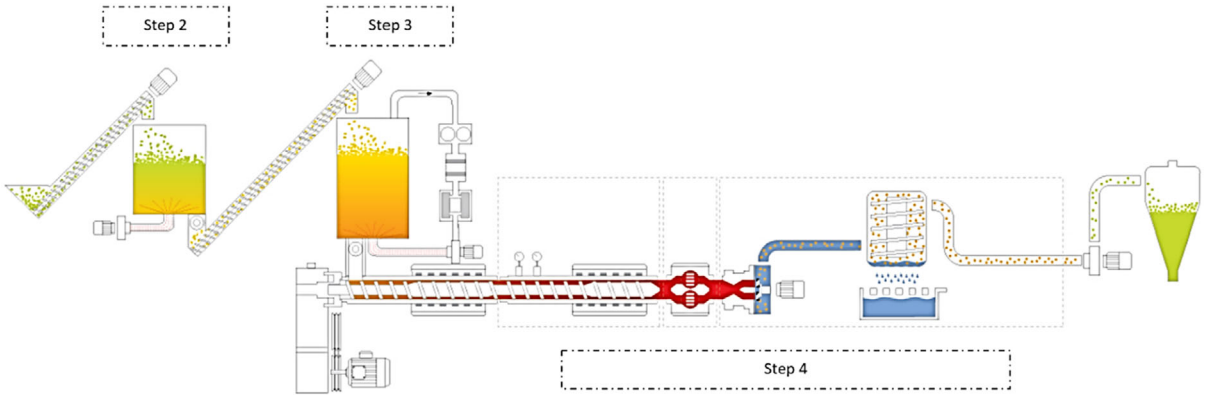


Figure 1: General scheme of the technology (provided by the applicant)

The process is operated under defined operating parameters[10] of temperature, gas flow rate and residence time.

3.3.2. Decontamination efficiency of the recycling process[11]

To demonstrate the decontamination efficiency of the recycling process Ester Industries, a challenge test was submitted to the EFSA that was performed at laboratory scale in batch mode.

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, 2006). The surrogates include different molecular masses and polarities to cover possible chemical classes of contaminants of concern and were demonstrated to be suitable to monitor the behaviour of PET during recycling (EFSA, 2008).

Conventionally recycled[12] post-consumer PET flakes were soaked in a mixture of surrogates and stored for 7 days at 50°C with periodical agitation. The contaminated PET flakes were washed and the concentrations of the surrogates in these flakes determined.

The laboratory reactor was filled with washed and dried contaminated flakes and operated steps 2 and 3 successively. The flakes were analysed before step 2 and after step 3 for the residual surrogate concentrations. The recoSTAR PET FG technology was challenged at laboratory scale on process steps 2 and 3. The contaminated flakes were introduced directly into the drier (step 2), then sampled after the reactor for heating and crystallisation (step 3) to measure the residual concentrations of the applied surrogates. Instead of being processed continuously, the reactor was run in batch mode. However, since the reactor in the process works practically with no mixing, the Panel agreed that the batch reactor in the challenge test provided the same cleaning efficiency when run at the same temperature, gas flow rate and residence time.

The decontamination efficiency of the process was calculated taking into account the amount of the surrogates detected in washed contaminated flakes before the drying and crystallisation reactor (before step 2) and after the heating (step 3). The results are summarised below in Table 1.

[10] 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 the European Commission (see Appendix C).
[11] Technical dossier, section 'Determination of the decontamination efficiency of the recycling process'.
[12] Conventional recycling includes commonly sorting, grinding, washing and drying steps and produces washed and dried flakes.

Table 1: Efficiency of the decontamination by the recoSTAR PET FG technology in the challenge test

Surrogates	Concentration of surrogates before step 2 (mg/kg PET)	Concentration of surrogates after step 3 (mg/kg PET)	Decontamination Efficiency (%)
Toluene	260.9	3.5	98.7
Chlorobenzene	452.7	7.0	98.5
Chloroform	401.5	6.8	98.3
Methyl salicylate	575.6	8.7	98.5
Phenylcyclohexane	356.7	12.8	96.4
Benzophenone	535.7	22.2	95.9
Methyl stearate	525.6	11.9	97.7

PET: poly(ethylene terephthalate).

As shown in Table 1, the decontamination efficiency ranged from 95.9% for benzophenone to 98.7% for toluene.

3.4. Discussion

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

Technical data, such as information on physical properties and residual contents of PVC, polyolefins, other plastics and metals, were provided for the input materials (washed and dried flakes, step 1). These are produced from PET containers, 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 in the input stream, this fraction will be no more than 5%, as recommended by the EFSA CEF Panel in its 'Scientific opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food' (EFSA CEF Panel, 2011).The process is adequately described. The washing and drying of the flakes from the collected PET containers (step 1) is conducted in different ways depending on the plant but, according to the applicant, this step is under control. The following steps are those of the recoSTAR PET FG technology used to recycle the PET flakes into decontaminated PET pellets: drying and crystallisation (step 2), heating the crystallised flakes (step 3) and extrusion (step 4). The operating parameters of temperature, gas flow rate and residence time for the steps 2 and 3 have been provided to EFSA.

A challenge test to measure the decontamination efficiency was conducted at laboratory scale on process steps 2 and 3. The Panel considered that the challenge test was performed correctly according to the recommendations in the EFSA guidelines (EFSA, 2008) and that steps 2 and 3 are critical for the decontamination efficiency of the process. Consequently, temperature, residence time and gas flow rate parameters of steps 2 and 3 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 95.9% to 98.7%, have been used to calculate the residual concentrations of potential unknown contaminants in PET (C_{res}) according to the evaluation procedure described in the 'Scientific opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET' (EFSA CEF Panel, 2011; Appendix B). By applying the decontamination percentages to the reference contamination level of 3 mg/kg PET, the C_{res} for the different surrogates was obtained (Table 2).

According to the evaluation principles (EFSA CEF Panel, 2011), the dietary exposure must not exceed 0.0025 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 manufacture of bottles for water and beverages, the scenario for infants has been applied (water could be used to prepare infant formula). 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 and has been used to calculate C_{mod} (EFSA CEF Panel, 2011). C_{res} reported in Table 4 are calculated for 100% recycled PET, for which the risk to human health is demonstrated to be negligible. The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

Table 2: Decontamination efficiencies from the challenge test, residual concentrations of the surrogates in the recycled PET (C_{res}) and calculated concentrations of the surrogates in PET (C_{mod}) corresponding to a modelled migration of 0.1 μg/kg food after 1 year at 25°C

Surrogates	Decontamination efficiency (%)	C_{res} (mg/kg PET)	C_{mod} (mg/kg PET)
Toluene	98.7	0.04	0.09
Chlorobenzene	98.5	0.05	0.10
Chloroform	98.3	0.05	0.10
Methyl salicylate	98.5	0.05	0.13
Phenylcyclohexane	96.4	0.11	0.14
Benzophenone	95.9	0.12	0.16
Methyl stearate	97.7	0.07	0.32

PET: poly(ethylene terephthalate).

As the residual concentrations (C_{res}) of all surrogates in the decontaminated PET are below the corresponding modelled concentrations in PET (C_{mod}), the Panel concluded that the recycling process using the recoSTAR PET FG technology is able to ensure that the migration of unknown contaminants from the recycled PET into food is below the conservatively modelled value of 0.1 μg/kg food, at which the risk to human health is considered negligible.

The Panel noted that the input of the process originates from India. 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 recoSTAR PET FG 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 Ester Industries using the recoSTAR PET FG 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 drying and crystallisation (step 2) and the heating of the crystallised flakes (step 3) are critical for the decontamination efficiency. The operating parameters to control its performance are temperature, residence time and gas flow rate.

The Panel concluded that the recycling process Ester Industries 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 of the process is washed and dried post-consumer PET flakes originating from materials and articles that have been manufactured in accordance with the EU legislation on food contact materials containing no more than 5% of PET from non-food consumer applications.
iii) the recycled PET is used at up to 100% for the manufacture of materials and articles for contact with all types of foodstuff, for long-term storage at room temperature, with or without hotfill.

The final articles made of this recycled PET are not intended to be used in microwave 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.

6. Documentation provided to EFSA

1) Dossier 'Ester Industries'. November 2021. Submitted on behalf of Ester Industries.
2) Additional information, May 2022. Submitted on behalf of Ester Industries.
3) Additional information, July 2022. Submitted on behalf of Ester Industries

References

EFSA (European Food Safety Authority), 2008. Guidelines for the submission of an application for safety evaluation by the EFSA of a recycling process to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food, prior to its authorisation. EFSA Journal 2008;6(7):717, 12 pp. https://doi.org/10.2903/j.efsa.2008.717

EFSA (European Food Safety Authority), 2009. Guidance of the Scientific Committee on transparency in the scientific aspects of risk assessments carried out by EFSA. Part2: General principles. EFSA Journal 2009;7 (5):1051, 22 pp. https://doi.org/10.2903/j.efsa.2009.1051

EFSA (European Food Safety Authority), 2021. 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 Journal 2021;18(3):EN-6512, 30 pp. https://doi.org/10.2903/sp.efsa.2021.EN-6512

EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2011. Scientific opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food. EFSA Journal 2011;9(7):2184, 25 pp. https://doi.org/10.2903/j.efsa.2011.2184

FDA (Food and Drug Administration), 2006. Guidance for Industry: Use of Recycled Plastics in Food Packaging: Chemistry Considerations. Available online: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-use-recycled-plastics-food-packaging-chemistry-considerations

Abbreviations

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

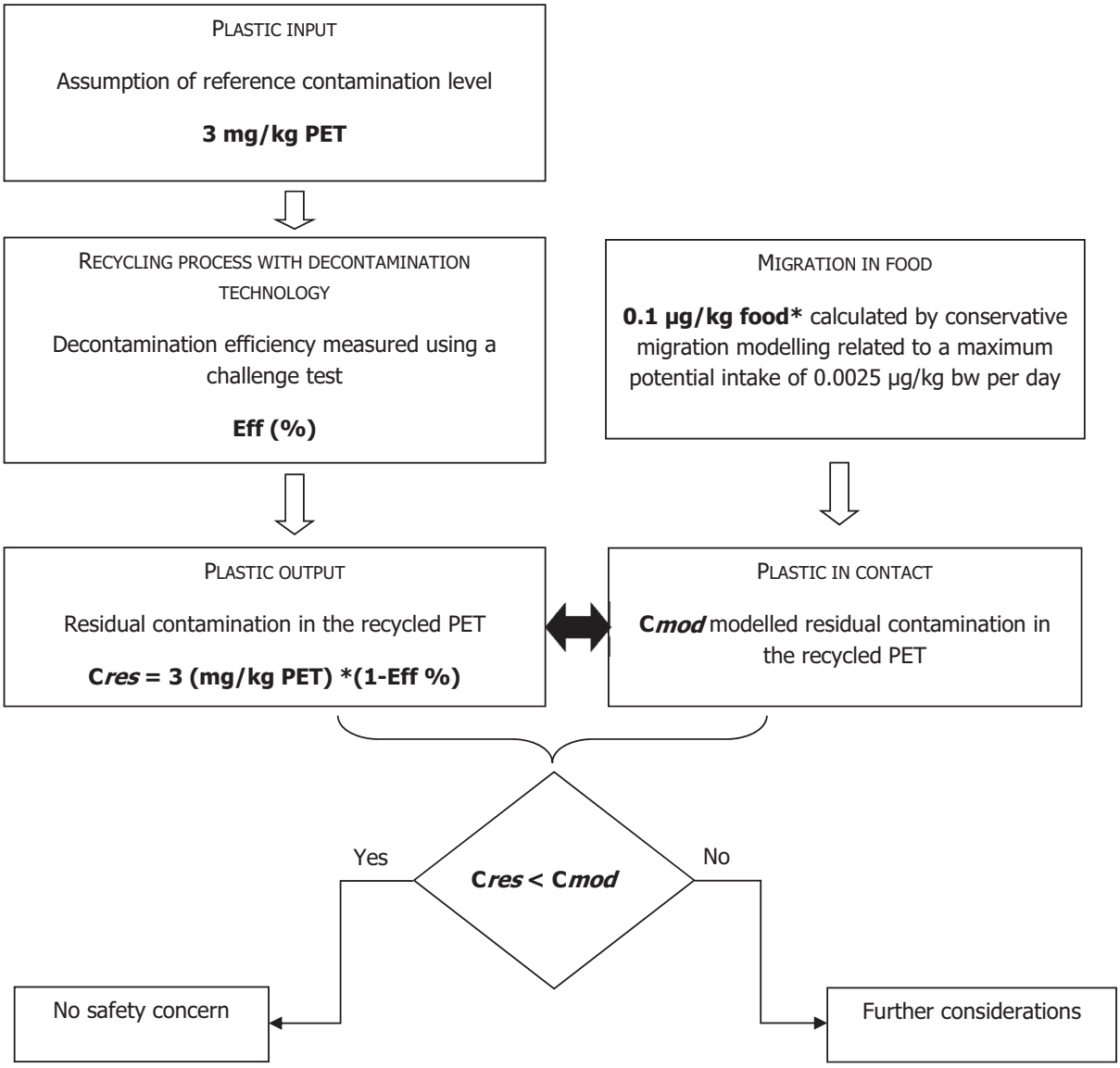
Appendix A – Technical data of the washed flakes as provided by the applicant[13]

Parameter	Value
Moisture	< 2.5%
Dust	< 1.5%
Metal content (aluminium, ferrous, others)	< 200 mg/kg
PVC content	< 200 mg/kg
Polyolefin content	< 100 mg/kg
Other plastics	< 200 mg/kg
Amount of non-food application PET	< 5%

PVC: poly(vinyl chloride); PET: poly(ethylene terephthalate).

[13] 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 TTC value of 0.0025 µg/kg bw per day applying a factor of 5 due to the overestimation of modelling.

Appendix C – Table on Operational parameters (Confidential Information)[14]

[redacted]

Process Ester Industries (RECYC261) based on the recoSTAR PET FG technology									
Parameters	**Step 2: 1st reactor (drying and crystallisation)**			**Step 3: 2nd reactor (heating of crystallised flakes)**			**Step 4: Extrusion**		
	t [min]	**Inert gas flow rate [m3/h per kg PET]**	**T [°C]**	**t [min]**	**Inert gas flow rate [m3/h per kg PET]**	**T [°C]**	**t [min]**	**Pressure (P) (mbar)**	**T [°C]**
Challenge test (Fraunhofer Report PA/4255/08)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Not challenged		
Process	≥ [redacted]	≥ [redacted]*	≥ [redacted]	≥ [redacted]	≥ [redacted]**	≥ [redacted]	Not measured	Not measured	≥ [redacted]°C

*: The gas flow rate of 1.85 m^3/h per kg PET corresponds to [redacted] m^3/h (flow) for a constant throughput of [redacted] kg/h.

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