

Safety assessment of the process Fucine Film, based on the Reifenhäuser 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 | Evgenia Lampi | 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 Fatima Poças | Alexandros Lioupis | Daniele Comandella | Elisa Savini | Evgenia Lampi

Correspondence: fip@efsa.europa.eu

Abstract

The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) assessed the safety of the recycling process Fucine Film (EU register number RECYC322), which uses the Reifenhäuser technology. The input material consists of hot caustic washed and dried poly(ethylene terephthalate) (PET) flakes mainly originating from collected post-consumer PET containers, including no more than 5% PET from non-food consumer applications. The flakes are extruded under vacuum into sheets. The recycled sheets are intended to be used at up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs, excluded drinking water and beverages, for long-term storage at room temperature, with or without hotfill. Based on the limited data available, the Panel concluded that the information submitted to EFSA was inadequate to demonstrate that the recycling process Fucine Film is able to reduce potential unknown contamination of the input PET flakes to a concentration that does not pose a risk to human health.

KEY WORDS

food contact materials, Fucine Film S.p.A., plastic, poly(ethylene terephthalate) (PET), recycling process, Reifenhäuser, safety assessment

This is an open access article under the terms of the [Creative Commons Attribution-NoDerivs](https://creativecommons.org/licenses/by-nd/4.0/) License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

© 2024 European Food Safety Authority. *EFSA Journal* published by Wiley-VCH GmbH on behalf of European Food Safety Authority.

CONTENTS

Abstract.....	1
1. Introduction	3
1.1. Background and Terms of Reference.....	3
1.1.1. Background	3
1.1.2. Terms of Reference.....	3
1.2. Interpretation of the Terms of Reference.....	3
2. Data and methodologies.....	3
2.1. Data.....	3
2.2. Methodologies.....	4
3. Assessment.....	4
3.1. General information.....	4
3.2. Description of the process.....	5
3.2.1. General description	5
3.2.2. Characterisation of the input	5
3.3. Reifenhäuser technology	5
3.3.1. Description of the main steps.....	5
3.3.2. Decontamination efficiency of the recycling process	6
4. Discussion.....	7
5. Conclusions.....	7
6. Documentation provided to EFSA	7
Abbreviations	8
Conflict of interest	8
Requestor.....	8
Question number.....	8
Copyright for non-EFSA content.....	8
Panel members	8
Waiver.....	8
Legal notice	8
References.....	8
Appendix A.....	10

1 | INTRODUCTION

1.1 | Background and Terms of Reference

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 1935/2004³ 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 an application from the Italian competent authority (Ministero della Salute) for evaluation of the recycling process Fucine Film, European Union (EU) register No RECYC322. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2021-00715. The dossier was submitted on behalf of Fucine Film S.p.A., Via dell'Artigianato n.6, 38,026 Fucine (TN), Italy (see '[Documentation provided to EFSA](#)').

1.1.2 | Terms of Reference

The Italian competent authority (Ministero della Salute) requested the safety evaluation of the recycling process Fucine Film, in accordance with Regulation (EC) No 282/2008 and Articles 9 and 10 of the 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 Fucine Film 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 provided by the applicant during the assessment process in response to a request from EFSA sent on 17 October 2022 and 20 December 2023 and was subsequently provided (see '[Documentation provided to EFSA](#)').

In accordance with Art. 38 of the Commission Regulation (EC) No 178/2002⁴ 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

¹Commission 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.

²Commission 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.

³Regulation (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.

⁴Commission 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.

Decision of the EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,⁵ the non-confidential version of the dossier is 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 25 July to 15 August 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.
 - quality assurance system (QAS).

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).

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 information⁸

According to the applicant, the recycling process Fucine Film is intended to recycle food grade PET containers using the Reifenhäuser 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, excluding drinking water and beverages, for long-term storage at room temperature or below, with or without hotfill. The final articles are not intended to be used in microwave or conventional ovens.

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

⁶The non-confidential version of the dossier, following EFSA's assessment of the applicant's confidentiality requests, is published on Open.EFSA and is available at the following link: <https://open.efsa.europa.eu/dossier/FCM-2021-1890>.

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

⁸Technical dossier, sections 'Recycling process' and 'Intended application in contact with food'.

3.2 | Description of the process

3.2.1 | General description⁹

The recycling process Fucine Film produces recycled PET sheets from PET containers from post-consumer collection systems (kerbside and deposit systems).

The recycling process comprises the two steps below.

Input

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

Decontamination and production of recycled PET material

- In step 2, the flakes are melted inside a [REDACTED] extruder, decontaminated under [REDACTED] and vacuum and finally transformed into sheets.

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

Sheets, the final product of the process, are checked against technical requirements, such as intrinsic viscosity, haze and tensile strength. Furthermore, the annual control plan includes chemical analyses on PET sheets to determine the overall and specific migration.

3.2.2 | Characterisation of the input¹⁰

According to the applicant, the input material for the recycling process Fucine Film consists of hot washed and dried flakes obtained from PET containers previously used for food packaging, from post-consumer collection systems (kerbside and deposit systems). A small fraction may originate from non-food applications. According to the applicant, the proportion of this non-food container fraction depends on the collection system and will be no more than 5%.

Technical data on the hot washed and dried flakes were provided, such as on physical properties and residual contents of poly(vinyl chloride) (PVC), polyolefins, cellulose (paper, wood), metals and other substances.

3.3 | Reifenhäuser technology

3.3.1 | Description of the main steps¹¹

The general scheme of the Reifenhäuser technology, as provided by the applicant, is reported in [Figure 1](#). The decontamination step is:

- Decontamination and extrusion (step 2):

The flakes are continuously fed into a [REDACTED] extruder running at predefined throughput under [REDACTED] and vacuum. Then, the melt is converted into sheets.

⁹Technical dossier, sections 'Recycling process', 'Characterisation of the input' and 'Characterisation of the recycled plastic'.

¹⁰Technical dossier, section 'Characterisation of the input'.

¹¹Technical dossier, sections 'Recycling process' and 'Determination of the decontamination efficiency of the recycling process'.

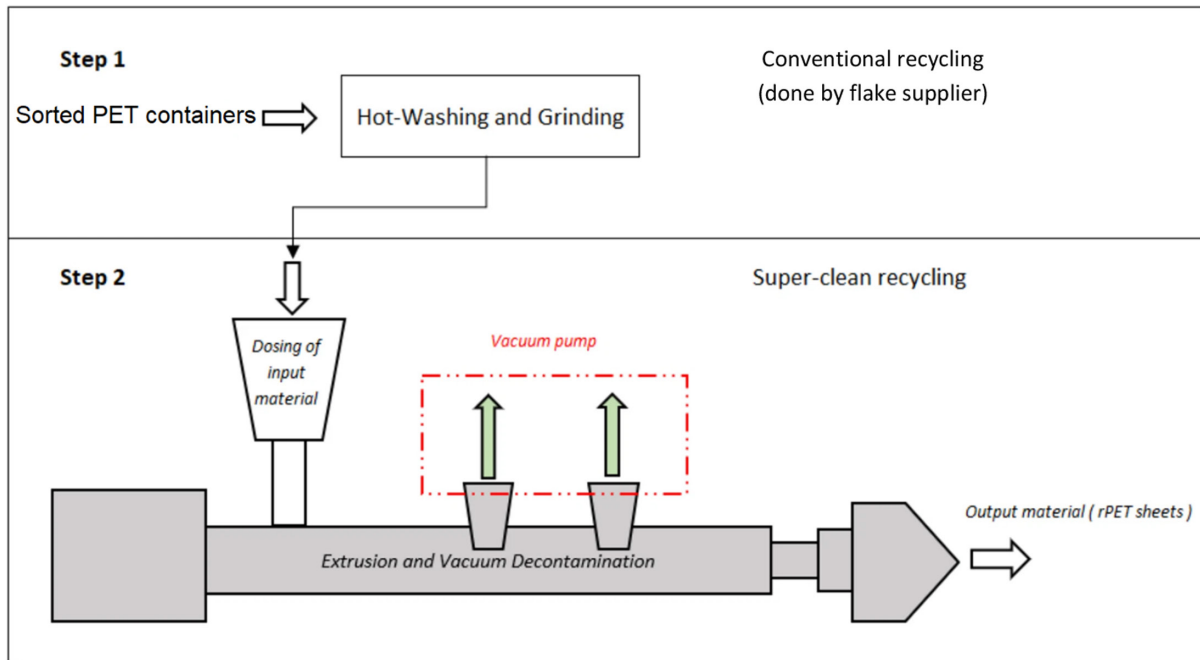


FIGURE 1 General scheme of the Reifenhäuser technology (provided by the applicant).

The process is run under defined operating parameters¹² of temperature, pressure and throughput.

3.3.2 | Decontamination efficiency of the recycling process¹³

To demonstrate the decontamination efficiency of the recycling process Fucine Film, two challenge tests on step 2 were submitted to EFSA.

In the first challenge test, conventionally recycled post-consumer¹⁴ 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 (EFSA CEF Panel, 2011) and in accordance with the recommendations of the US Food and Drug Administration (FDA, 2006). Batches of contaminated PET were stored for 7 days at 50°C with periodical agitation, then washed with hot caustic water. Finally, the concentration of the surrogates in PET was determined. Step 2 of the Reifenhäuser technology was challenged at [REDACTED]. The vacuum level applied represented the lower value of the range of vacuum that is intended to be applied in the industrial process. Samples taken at the exit of the extruder were analysed to determine the concentrations of the surrogates. However, the applicant did not provide the supporting raw data for the chemical analysis.

The decontamination efficiency of the process was calculated from the concentrations of the surrogates measured in the hot caustic washed contaminated flakes and in those exiting the Reifenhäuser extruder (step 2). The decontamination efficiency ranged from 68.7% for benzophenone up to 93.4% for toluene.

After a request for additional information, the applicant provided a second challenge test. In this challenge test, conventionally recycled¹⁵ post-consumer PET was contaminated with toluene, chlorobenzene, methyl salicylate, phenylcyclohexane, benzophenone and methyl stearate. The amount of the contaminated material and its form (i.e. flakes or pellets) were not clearly indicated. Batches of contaminated PET were stored for 10 days at 35°C with periodical agitation. The Panel noted that these conditions are not sufficient to ensure the absorption of surrogates into PET to a level simulating the contamination after potential misuse of PET containers. The concentration of the surrogates in the contaminated PET was determined without a prior washing or rinsing step, hence without the removal of surrogates remaining on the PET surface. Step 2 of the Reifenhäuser technology was challenged at [REDACTED] at [REDACTED] used in the industrial process. Samples were taken at the exit of the extruder and then analysed to determine the residual concentrations of surrogates. The applicant did not provide all the necessary supporting data on the chemical analysis of the surrogates and on the validation of the method according to the EFSA guidelines. Moreover, the Panel did not consider the applied method enough performant to fully extract surrogates from PET.

¹²In 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.

¹³Technical dossier, section 'Determination of the decontamination efficiency of the recycling process'.

¹⁴Conventional recycling commonly includes sorting, grinding, washing and drying steps and produces washed and dried flakes.

¹⁵Conventional recycling commonly includes sorting, grinding, washing and drying steps and produces washed and dried flakes.

The decontamination efficiency of the process was calculated from the concentrations of the surrogates measured in the contaminated PET material before extrusion and in the PET exiting the Reifenhäuser extruder (step 2). The decontamination efficiency of this second challenge test ranged from 98.2% for benzophenone up to >99.9% for toluene. The Panel noted that the decontamination efficiency resulting from this challenge test was far higher than that resulting from the first one despite applying less severe decontamination conditions.

4 | DISCUSSION

Considering the ██████████ 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 specifications, such as information on physical properties and residual contents of poly(vinyl chloride) (PVC), polyolefins, cellulose (paper, wood), metals and more, were provided for the input materials (i.e. hot caustic 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 less 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).

To demonstrate the decontamination efficiency of the process, two challenge tests were provided. The information provided on both challenge tests showed data gaps, inconsistencies and discrepancies that were not accounted for even after requests for clarification. Hence, the process was evaluated on the basis of the information provided. Based on this information, the Panel could not conclude on the safety of the process due to the following observations:

For the first challenge test:

- The vacuum level applied represented the lower end of the range of vacuum levels that are intended to be applied in the industrial process. Therefore, the challenge test did not represent the worst-case scenario with respect to decontamination efficiency.
- The applicant did not provide all the necessary supporting data on the chemical analysis of the surrogates (as requested by the EFSA guidelines).

For the second challenge test:

- The amount and the form of the material (i.e. flakes or pellets) used in the challenge test were not clearly specified.
- The conditions at which the contamination was conducted cannot be considered sufficient to ensure the bulk absorption of the surrogates and the homogeneous contamination of the material.
- The contaminated material was not rinsed or washed before the analysis of the initial contamination level.
- The method applied to extract surrogates from PET prior to chemical analysis did not ensure the complete extraction of surrogates.
- The applicant did not provide all the necessary supporting data on the chemical analysis of the surrogates and on the validation of the method (as requested by the EFSA guidelines, EFSA, 2008). Therefore, the results of the decontamination efficiency cannot be considered reliable.

The Panel noted that the decontamination efficiency resulting from the second challenge test was far higher than that resulting from the first challenge test despite applying less severe decontamination conditions. This is considered to be the result of the poor reliability of the second challenge test.

The Panel noted that the dossier does not satisfy the requirements of the EFSA guidelines (EFSA, 2008) and 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 intended to come in contact with food (EFSA CEF Panel, 2011).

5 | CONCLUSIONS

The Panel concluded that the information submitted to EFSA was inadequate to demonstrate that the recycling process is able to reduce a potential contamination of the input PET flakes to a concentration that does not pose a risk to human health.

6 | DOCUMENTATION PROVIDED TO EFSA

Dossier 'Fucine Film'. July 2022. Submitted on behalf of Fucine Film S.p.A., Italy.

Additional information, May 2023. Submitted on behalf of Fucine Film S.p.A., Italy.

Additional information, April 2024. Submitted on behalf of Fucine Film S.p.A., Italy.

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)

CONFLICT 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.

REQUESTOR

Italian competent authority (Ministero della Salute)

QUESTION NUMBER

EFSA-Q-2021-00715

COPYRIGHT FOR NON-EFSA CONTENT

EFSA may include images or other content for which it does not hold copyright. In such cases, EFSA indicates the copyright holder and users should seek permission to reproduce the content from the original source.

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, Inger-Lise Steffensen, Christina Tlustos, Henk Van Loveren, Laurence Vernis and Holger Zorn.

WAIVER

In accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management a waiver was granted to an expert of the Working Group. Pursuant to Article 21(6) of the aforementioned Decision, the concerned expert was allowed to take part in the preparation and discussion of the scientific output but was not allowed to take up the role of rapporteur within that time frame. Any competing interests are recorded in the respective minutes of the meetings of the CEP Panel Working Group on Recycling Plastics.

LEGAL NOTICE

Relevant information or parts of this scientific output have been blackened in accordance with the confidentiality requests formulated by the applicant pending a decision thereon by EFSA. The full output has been shared with the European Commission, EU Member States (if applicable) and the applicant. The blackening may be subject to review once the decision on the confidentiality requests is adopted by EFSA and in case it rejects some of the confidentiality requests.

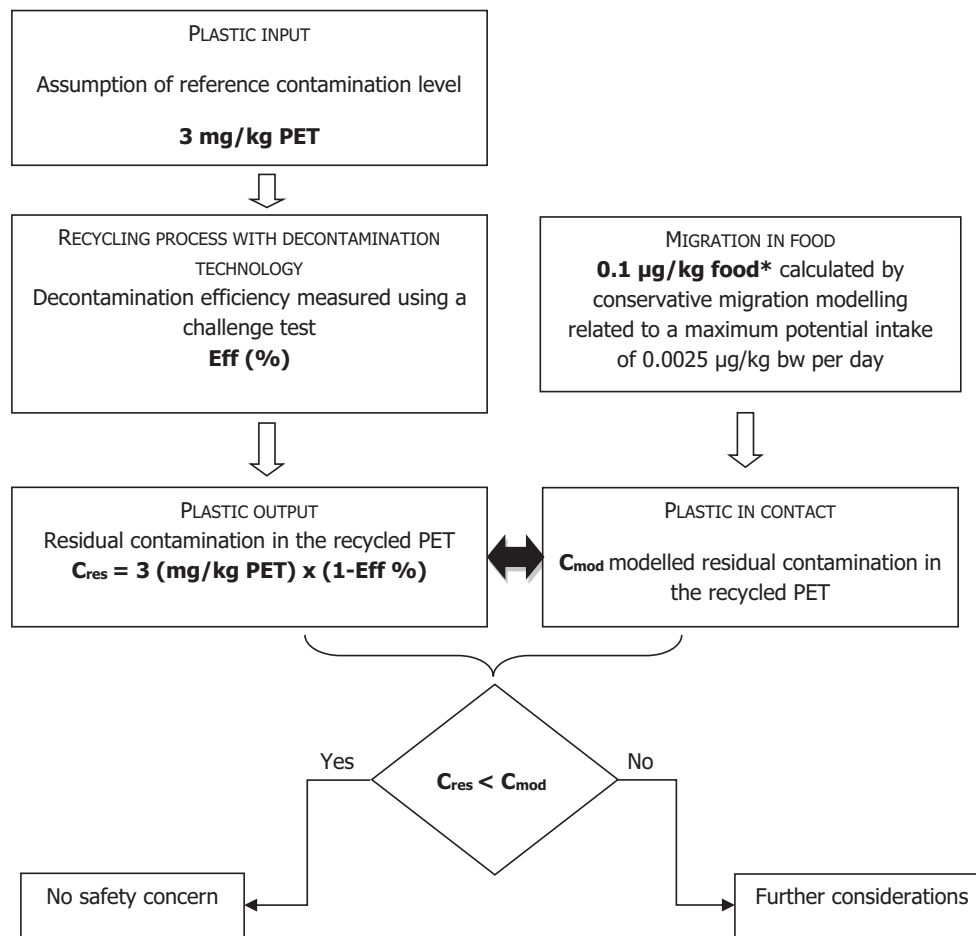
REFERENCES

- 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*, 6(7), 717. <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*, 7(5), 1051. <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*, 18(3), EN-6512. <https://doi.org/10.2903/sp.efsa.2021.EN-6512>
- 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*, 9(7), 2184. <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*. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-use-recycled-plastics-food-packaging-chemistry-considerations>

How to cite this article: EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids), Lambré, C., Barat Baviera, J. M., Bolognesi, C., Chesson, A., Cocconcelli, P. S., Crebelli, R., Gott, D. M., Grob, K., Lampi, E., Mengelers, M., Mortensen, A., Rivière, G., Steffensen, I.-L., Tlustos, C., Van Loveren, H., Vernis, L., Zorn, H., Dudler, V., ... Lampi, E. (2024). Safety assessment of the process Fucine Film, based on the Reifenhäuser technology, used to recycle post-consumer PET into food contact materials. *EFSA Journal*, 22(7), e8878. <https://doi.org/10.2903/j.efsa.2024.8878>

APPENDIX A

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.