

Safety assessment of the process Lietpak, based on the EREMA MPR 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 | Vasiliki Sfika | 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 Lietpak (EU register number RECYC319), which uses the EREMA MPR technology. The input material is hot caustic washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, including no more than 5% PET from non-food consumer applications. The flakes are heated [REDACTED] under vacuum (step 2). Having examined the challenge test provided, the Panel concluded that this step 2, for which the challenge test was provided, is critical in determining the decontamination efficiency of the process. The operating parameters to control the performance of this step are temperature, pressure and residence time. It was demonstrated that this recycling process is able to ensure a level of migration of potential unknown contaminants into food below the conservatively modelled migration of 0.15 µg/kg food, derived from the exposure scenario for toddlers, when such recycled PET is used at up to 100%. Therefore, the Panel concluded that the recycled PET obtained from this process is not considered to be of safety concern when used at up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs, except drinking water, for long-term storage at room temperature or below, with or without hot fill. 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.

KEYWORDS

EREMA MPR, food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment, UAB Lietpak

This is an open access article under the terms of the [Creative Commons Attribution-NoDerivs](https://creativecommons.org/licenses/by/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 as provided by the requestor.....	3
1.2. Terms of Reference	3
1.3. 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. EREMA MPR technology	5
3.3.1. Description of the main steps.....	5
3.3.2. Decontamination efficiency of the recycling process	6
3.4. Discussion	7
4. Conclusions.....	8
5. Recommendation.....	8
6. Documentation provided to EFSA	8
Abbreviations	8
Conflict of interest	9
Requestor.....	9
Question number	9
Copyright for non-EFSA Content.....	9
Panel members	9
Legal notice	9
References.....	9
Appendix A.....	10
Appendix B	11
Appendix C	12

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 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 from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, an application for evaluation of the recycling process Lietpak, European Union (EU) register No RECYC319. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2022-00535. The dossier was submitted on behalf of UAB Lietpak, Adomo Mickevičiaus g. 165, Čekoniškių k., Zujūnų sen., 14207 Vilnius R. Sav., Lithuania (see '[Documentation provided to EFSA](#)').

1.2 | Terms of Reference

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

1.3 | 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 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 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). 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 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

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.

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-2022-8832>

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 03 January to 24 January 2024, for which no comments were received.

Additional information was provided by the applicant during the assessment process in response to a request from EFSA sent on 24 March 2019 (see 'Documentation provided to EFSA').

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} , then 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 Lietpak is intended to recycle food-grade PET containers using the EREMA MPR technology. The recycled PET is intended to be used at up to 100% by converters for thermoformed trays/containers, for example, for fruits, vegetables, cooked and uncooked meats, dairy products and desserts, for long-term food storage at room temperature, with or without hot fill. The final articles are not intended to be used in microwave or conventional ovens.

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 Lietpak produces recycled PET flakes from PET containers from post-consumer collection systems (kerbside and deposit systems).

It 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 may be performed by third parties.

Decontamination and production of recycled PET material.

- In step 2, the flakes are [REDACTED] and decontaminated under [REDACTED] temperature and vacuum.

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

3.2.2 | Characterisation of the input¹⁰

According to the applicant, the input material for the recycling process Lietpak consists of hot washed and dried flakes obtained from PET containers, for example, 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 on the hot washed and dried flakes are provided, such as on physical properties and residual contents of moisture, poly(vinyl chloride) (PVC), glue, polyolefins, other thermoplastics, polyamide, cellulose, aluminium and PET dust (see Appendix A).

3.3 | EREMA MPR technology

3.3.1 | Description of the main steps¹¹

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

- Decontamination in a [REDACTED] reactor (step 2):
The flakes are continuously fed into a reactor equipped with a rotating device, running under [REDACTED] temperature and vacuum for a pre-defined minimum residence time.

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

¹⁰Technical dossier, 'Characterisation of the input'.

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

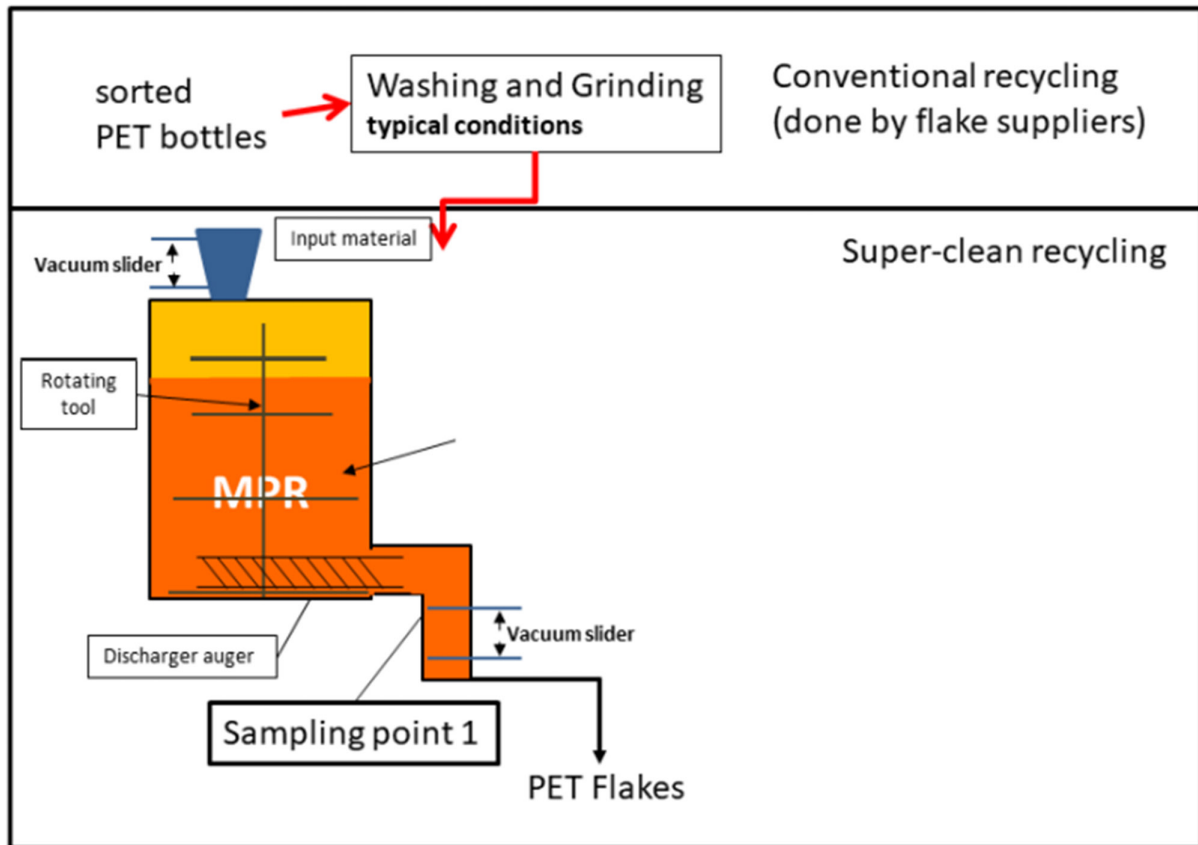


FIGURE 1 General scheme of the EREMA MPR technology (provided by the applicant).

The process is run under defined operating parameters¹² of [REDACTED]

3.3.2 | Decontamination efficiency of the recycling process¹³

To demonstrate the decontamination efficiency of the recycling process Lietpak, a challenge test on step 2 was submitted to the EFSA.

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). 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).

[REDACTED]
[REDACTED]
[REDACTED]¹⁴ [REDACTED]
[REDACTED]
[REDACTED] and the concentration of surrogates in this material was determined.

The challenge test was performed [REDACTED]. [REDACTED]

[REDACTED] Samples were [REDACTED] analysed for their residual concentrations of the applied surrogates.

[REDACTED] The Panel considered that the reactor ran at residence time, temperature and pressure conditions equal to or less severe than those foreseen for the industrial process. [REDACTED]

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 (see Appendix C).

¹³Technical dossier, '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.

The decontamination efficiency of the process was calculated from the concentrations of the surrogates measured in the washed contaminated flakes introduced and those exiting the EREMA MPR reactor (step 2). The results are summarised in [Table 1](#).

TABLE 1 Efficiency of the decontamination of step 2 in the challenge test.

Surrogates	Concentration of surrogates before step 2 (mg/kg PET)	Concentration of surrogates after step 2 (mg/kg PET)	Decontamination efficiency (%)
Toluene	185.9	1.9	99.0
Chlorobenzene	421.9	4.8	98.9
Chloroform	150.6	6.9	95.4
Methyl salicylate	620.0	2.1	99.7
Phenylcyclohexane	345.2	9.5	97.3
Benzophenone	756.1	23.3	96.9
Methyl stearate	889.5	18.8	97.9

Abbreviation: PET: poly(ethylene terephthalate).

The decontamination efficiency ranged from 95.4% for chloroform up to 99.7% for methyl salicylate.

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, glue, polyolefins and metals, were provided for the input material (i.e. hot caustic washed and dried flakes, step 1). The flakes are produced from PET containers, for example, 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 [REDACTED] and, according to the applicant, this step is under control. The EREMA MPR technology is based on the continuous decontamination in step 2. The operating parameters of temperature, pressure and residence time for this step have been provided to EFSA.

A challenge test to measure the decontamination efficiency was conducted at [REDACTED] on step 2. The reactor was operated under pressure and temperature conditions as well as residence time equivalent to or less severe than those of the commercial process. The Panel considered that this challenge test was performed correctly according to the recommendations of the EFSA guidelines (EFSA, 2008) and concluded that step 2 was critical for the decontamination efficiency of the process. Consequently, temperature, pressure and residence time of step 2 should be controlled to guarantee the performance of the decontamination. These parameters have been provided to EFSA (Appendix C).

The decontamination efficiencies obtained from the challenge test, ranging from 95.4% to 99.7%, 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 not intended for the manufacturing of articles to be used in direct contact with drinking water, the exposure scenario for toddlers has been applied. A maximum dietary exposure of 0.0025 µg/kg bw per day corresponds to a maximum migration of 0.15 µg/kg of the contaminant into the toddler's food and has been used to calculate C_{mod} (EFSA CEF Panel, 2011). C_{res} reported in Table 2 is 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 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 0.15 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); toddler scenario
Toluene	99.0	0.031	0.13
Chlorobenzene	98.9	0.034	0.15
Chloroform	95.4	0.137	0.15
Methyl salicylate	99.7	0.102	0.20
Phenylcyclohexane	97.3	0.083	0.21
Benzophenone	96.9	0.092	0.24
Methyl stearate	97.9	0.063	0.47

Abbreviations: PET, poly(ethylene terephthalate); rPET, recycled poly(ethylene terephthalate).

On the basis of the provided data from the challenge test and the applied conservative assumptions, the Panel considered that under the given operating conditions the recycling process Lietpak using the EREMA MPR 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 0.15 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 (except drinking water) for long-term storage at room temperature or below, with or without hot fill.

4 | CONCLUSIONS

The Panel considered that the Lietpak recycling process using the EREMA MPR technology is adequately characterised and that the critical step to decontaminate the PET is identified. Having examined the challenge test provided, the Panel concluded that the temperature, the pressure and the residence time in the continuous reactor of step 2 are critical for the decontamination efficiency of the process. Therefore, these are the operating parameters to be controlled.

The Panel concluded that the recycling process Lietpak 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 contain 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 foodstuffs, except drinking water, for long-term storage at room temperature or below, with or without hot fill.

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 | RECOMMENDATION

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 'Lietpak'. August 2022. Submitted on behalf of UAB Lietpak, Lithuania.

Additional information, June 2023. Submitted on behalf of UAB Lietpak, Lithuania.

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 concentration 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

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany

QUESTION NUMBER

EFSA-Q-2022-00535

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, Vittorio Silano (until 21 December 2020[†]), Inger-Lise Steffensen, Christina Tlustos, Henk Van Loveren, Laurence Vernis, and Holger Zorn.

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. Part 2: 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). (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., Mengelers, M., Mortensen, A., Rivière, G., Steffensen, I.-L., Tlustos, C., Van Loveren, H., Vernis, L., Zorn, H., Dudler, V., Milana, M. R., ... Lampi, E. (2024). Safety assessment of the process Lietpak, based on the EREMA MPR technology, used to recycle post-consumer PET into food contact materials. *EFSA Journal*, 22(3), e8609. <https://doi.org/10.2903/j.efsa.2024.8609>

[†]Deceased.

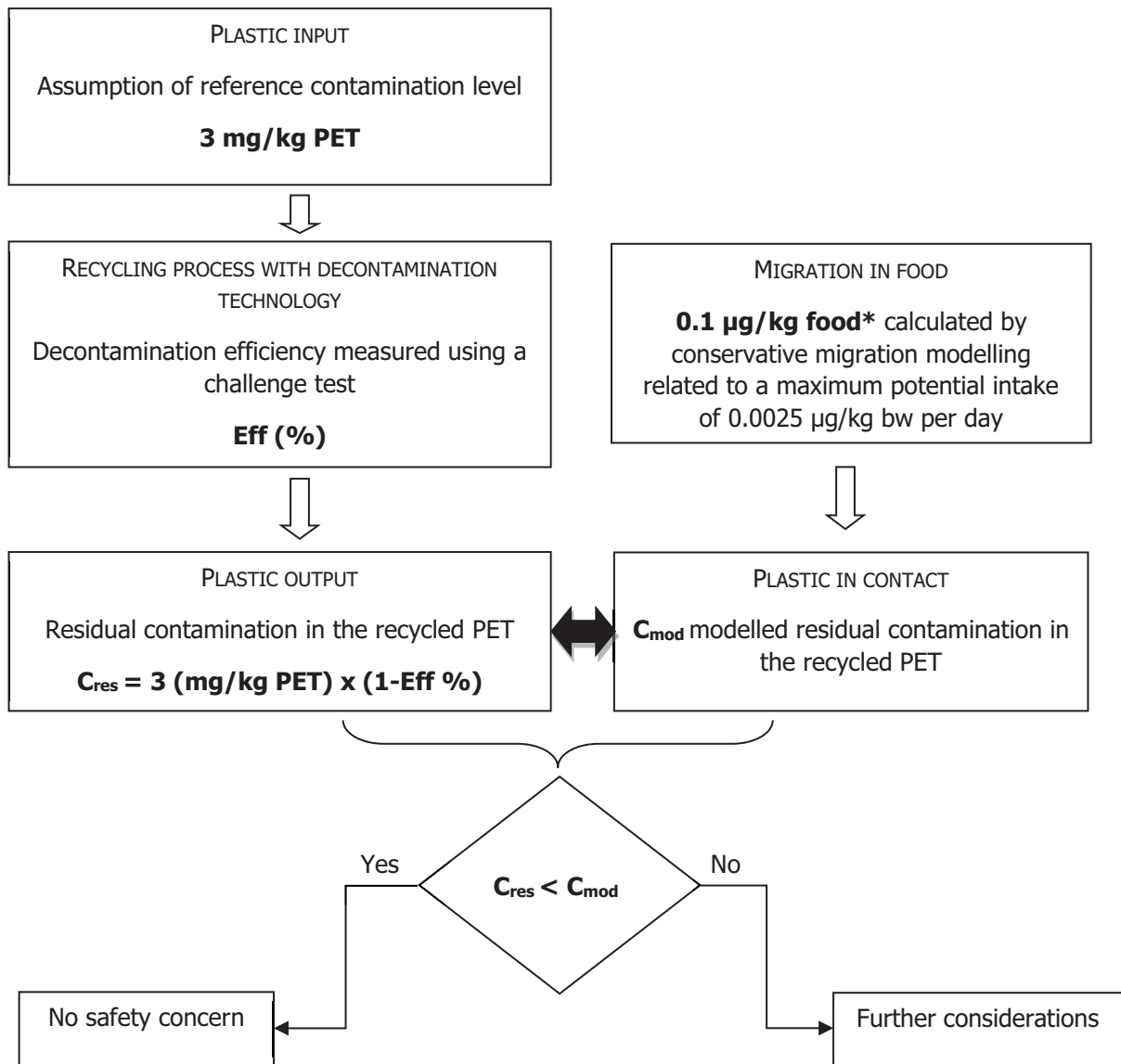
APPENDIX A**Technical data of the washed flakes as provided by the applicant¹⁵**

Parameter	Value
Moisture max.	1.0%
Bulk density	250–500 kg/m ³
Bulk density variation	±150 kg/m ³
Material temperature	10–60°C
PVC max.	50 mg/kg
Glue max.	20 mg/kg
Polyolefins max.	25 mg/kg
Other thermoplastics	300 mg/kg
Polyamide	20 mg/kg
Cellulose (paper, wood)	2 mg/kg
Aluminium max.	20 mg/kg
PET dust max.	1%

¹⁵Technical 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 of operational parameters¹⁶

[Redacted Table Content]

Process Lietpak (RECYC319) based on the EREMA MPR technology			
Parameters	Step 2 MPR Reactor		
	t [min]	P [mbar]	T [°C]
Challenge test	[Redacted]	[Redacted]	[Redacted]
Process	[Redacted]	[Redacted]	[Redacted]

¹⁶Technical report, Section 'Table of operating parameters'.