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Safety assessment of the process Silver Plastics, based on the Reifenhäuser 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 Silver Plastics (EU register number RECYC299), 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. Having examined the challenge test provided, the Panel concluded that the decontamination in the extruder under vacuum degassing (step 2), for which a challenge test was provided, is critical in determining the decontamination efficiency of the process. The operating parameters to control the performance are temperature, pressure and throughput. The Panel concluded that this recycling process is able to ensure a level of exposure to potential unknown contaminants from food below 0.0025 μg/kg bw per day, when such recycled PET is used from 15% to 100% in mixtures with virgin PET, depending on the specific intended application. Therefore, the Panel concluded that the recycled PET obtained from this process is not considered to be of safety concern when used from 15% to 100% in mixtures with virgin PET for the manufacture of materials and articles depending on the specific intended application. 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: Reifenhäuser technology, Silver Plastics GmbH & Co KG, 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-2021-00744

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Table of contents

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 1935/2004[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 Silver Plastics, European Union (EU) register No RECYC299. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2021-00744. The dossier was submitted on behalf of Silver Plastics GmbH & Co KG, Godesberger Straße 9, 53842 Troisdorf, Germany (Section 6).

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.

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 Silver Plastics, 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 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 Silver Plastics 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 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

[1] Commission 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, pp. 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, pp. 4–17.

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 178/2002[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 is published on Open.EFSA.[6]

According to Article 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 01 February 2023 to 22 February 2023. No comments were received.

Additional information was provided by the applicant during the assessment process in response to requests from EFSA sent on 17 October 2022 and 22 February 2023 (see Section 6).

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}

[4] 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.

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

[6] The 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-2021-2358.

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

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 information[8]

According to the applicant, the recycling process Silver Plastics is intended to recycle food grade PET containers using the Reifenhäuser technology. As requested by the applicant, the recycled PET is intended to be used between 24% and 100% in mixture with virgin PET for thermoforming trays/ containers for food contact applications. According to the applicant, PET articles will be used in contact with specific food types under specific contact times and temperatures (Table 1). The final articles are not intended to be used in microwave or conventional ovens.

Table 1: Intended uses, contact times and temperatures as proposed by the applicant

	Intended use	Intended contact time	Intended contact temperature
1	Meat, fish and marinated grilled food, vegetable salads, fruit salads	up to 30 days	Cold chain
2	Meat products (like sausage, frankfurters, speck, etc.), sliced ham, sliced cheese, dairy products	up to 90 days	Cold chain
3	Vegetables and fruits	up to 90 days	Ambient temperature
4	Cakes, donuts, chocolates	up to 12 months	Ambient temperature
5	Confectionary (e.g. jelly babies)	up to 12 months	Ambient temperature
6	Confectionary (e.g. jelly babies)	up to 36 months	Ambient temperature

3.2. Description of the process

3.2.1. General description[8]

The recycling process Silver Plastics 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 fed into a [redacted] extruder where they are melted, decontaminated under [redacted] 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, colour and black spots.

3.2.2. Characterisation of the input[9]

According to the applicant, the input material for the recycling process Silver Plastics consists of hot caustic 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%.

[8] Technical dossier, Section 'Recycling Process'.
[9] Technical dossier, Section 'Characterisation of the input'.

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

3.3. Reifenhäuser technology

3.3.1. Description of the main steps[10]

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] vacuum. Then, the melt is converted into sheets.

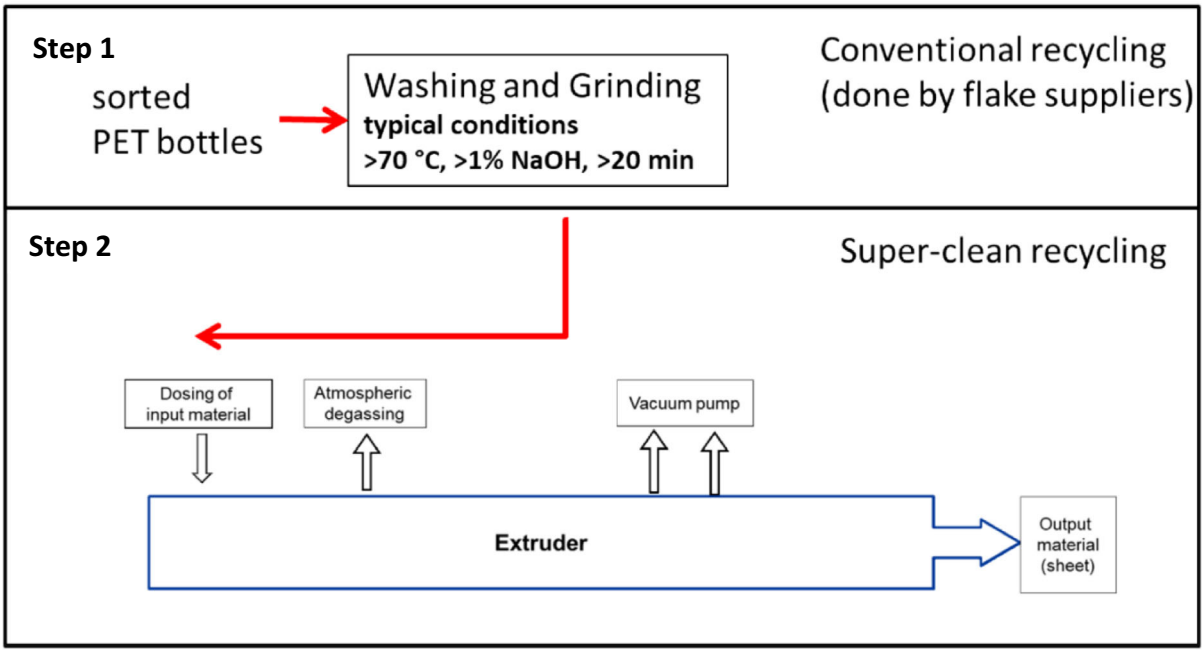


Figure 1: General scheme of the Reifenhäuser technology (provided by the applicant)

The process is run under defined operating parameters[11] of temperature, pressure and throughput.

3.3.2. Decontamination efficiency of the recycling process[12]

To demonstrate the decontamination efficiency of the recycling process Silver Plastics, 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).

Solid surrogates (benzophenone and methyl stearate) were mixed with liquid surrogates (toluene, chlorobenzene, chloroform, methyl salicylate and phenylcyclohexane) and added to conventionally recycled[13] post-consumer PET flakes. Batches of contaminated PET were stored for 7 days at 50°C

[10] Technical dossier, Section 'Recycling Process'.
[11] 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).
[12] Technical dossier, Section 'Determination of the decontamination efficiency of the recycling process'.
[13] Conventional recycling commonly includes sorting, grinding, washing and drying steps and produces washed and dried flakes.

with periodical agitation. Then, the PET flakes were washed with hot caustic water at high temperature, rinsed with water and centrifuged to low water content. Finally, the concentration of the surrogates in PET was determined.

Step 2 of the Reifenhäuser technology was challenged [redacted]. The contaminated flakes were fed into the decontamination extruder. Samples were taken at the exit of the extruder, then analysed to determine the concentrations of the applied surrogates.

The decontamination efficiency of the process was calculated from the concentrations of the surrogates measured in the hot caustic washed contaminated flakes inserted and those exiting the Reifenhäuser extruder (step 2). The results are summarised in Table 2.

Table 2: Efficiency of the decontamination of the extruder (step 2) in the challenge test

Surrogates	Concentration of surrogates before step 2 (mg/kg PET)	Concentration of surrogates after step 2 (mg/kg rPET)	Decontamination efficiency (%)
Toluene	228.1	14.8	93.4
Chlorobenzene	349.2	28.7	91.8
Chloroform	177.6	12.9	92.7
Methyl salicylate[(a)]	357.7	< 0.1[(b)]	> 99.9
Phenylcyclohexane	398.5	72.4	81.8
Benzophenone	449.5	140.4	68.7
Methyl stearate	239.0	50.0	79.1

PET: poly(ethylene terephthalate). rPET: recycled poly(ethylene terephthalate).
(a): This surrogate is reactive at the [redacted] temperature of extrusion. Therefore, it was not considered in the evaluation of the decontamination efficiency.
(b): Not detected at the limits of detection given.

The decontamination efficiency ranged from 68.7% for benzophenone up to 93.4% 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 specifications, such as on physical properties and residual contents of PVC, glue, polyolefins, polyamides, cellulose and metals, were provided for the input materials (i.e. hot caustic washed and dried flakes, step 1). These are 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) are conducted by third parties and, according to the applicant, this step is under control. The Reifenhäuser technology comprises a vacuum extrusion (step 2) with production of sheets. The operating parameters of temperature, pressure and throughput, as well as the geometrical characteristics, have been provided to EFSA.

A challenge test to measure the decontamination efficiency was conducted [redacted] on the process step 2 (vacuum extruder). The Panel considered that the extruder was operated under conditions (pressure, temperature, throughput) and geometrical characteristics equivalent to or less severe than those of the commercial process, and that this challenge test was performed correctly according to the recommendations of the EFSA guidelines (EFSA, 2008). The Panel considered that the decontamination in step 2 is critical for the decontamination efficiency of the process. Consequently, temperature, pressure and throughput parameters of step 2 of the process should be controlled to guarantee the performance of the decontamination (Appendix C).

The decontamination efficiencies obtained for each surrogate, ranging from 68.7% to 93.4%, 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 (Tables 3–6).

According to the evaluation principles (EFSA CEF Panel, 2011), the dietary exposure must not exceed 0.0025 μg/kg body weight (bw) per day, below which the risk to human health is considered negligible. 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 considered. For a general use, the C_{res} value should not exceed the modelled concentration in PET (C_{mod}) that could result, after 1 year at 25°C, in a migration giving rise to a dietary exposure exceeding 0.0025 μg/kg bw per day. 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 to be used to calculate C_{mod} under general use applications (EFSA CEF Panel, 2011). The relationship between the key parameters for the evaluation scheme is reported in Appendix B. If new articles produced with 100% recycled PET cannot fulfil these requirements, the recycled PET should be mixed with virgin PET to ensure that the C_{res} value does not exceed the C_{mod} value. Furthermore, in the case of specific uses with different contact conditions and/or food consumptions, adapted figures of maximum migration could be considered and C_{mod} recalculated accordingly (EFSA CEF Panel, 2011).

The Panel noted that the applicant

- requested six specific uses, excluding contact with drinking water, and proposed the related C_{mod} using conditions reported in Table 1. However, migration time and temperature conditions should be selected according to the Regulation (EU) 10/2011, as specified by the EFSA CEF Panel (EFSA CEF Panel, 2011). Therefore, the Panel selected the migration conditions from Regulation (EU) 10/2011 corresponding to the specific uses proposed by the applicant (Appendix D). Then, the Panel determined C_{mod} by using currently validated migration models (Hoekstra et al., 2015).
- proposed a maximum migration of 0.625 μg/kg of the contaminant into the toddler's food specifically for PET articles intended for contact with confectionary (intended use number 5 and 6 in Table 1). This value was determined based on the food consumption for Food Category 4 (20 g/kg bw per day) proposed by the EFSA CEF Panel (EFSA CEF Panel, 2016), applying the human exposure threshold value of 0.0025 μg/kg bw per day and the overestimation factor of 5 for modelling (EFSA CEF Panel, 2011). The Panel accepted this approach, but only for the specific intended uses (number 5 and 6 in Table 1).

Tables 3–6 report C_{mod} and C_{res} values determined by the Panel for the scenario of toddlers for the six specific uses, considering that some specific uses (1 and 2, and 5 and 6 in Table 1) correspond to the same migration conditions (see Appendix D). For each specific use, C_{res} was calculated for a given percentage of recycled PET, for which the risk to human health was demonstrated to be negligible ($C_{res} < C_{mod}$). Then, the percentage of recycled PET was rounded down to the nearest multiple of 5 and C_{res} calculated again.

Table 3: Decontamination efficiency from the challenge test, residual concentrations of the surrogates in the recycled PET ($C_{res,}$ calculated for 100% recycled PET) and calculated concentrations of the surrogates in PET (C_{mod}) corresponding to a modelled migration of 0.15 μg/kg food (scenario for toddlers) after 10 days at 20°C (specific use number 1 and 2 in Table 1)

Surrogates	Decontamination efficiency (%)	C_{res} for 100% rPET (mg/kg PET)	C_{mod} (mg/kg PET); toddler scenario
Toluene	93.4	0.20	1.04
Chlorobenzene	91.8	0.25	1.22
Chloroform	92.7	0.22	1.29
Methyl salicylate	> 99.9	< 0.003	1.64
Phenylcyclohexane	81.8	0.55	1.73
Benzophenone	68.7	0.94	2.00
Methyl stearate	79.1	0.63	3.19

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

Table 4: Decontamination efficiency from the challenge test, residual concentrations of the surrogates in the recycled PET ($C_{res,}$ calculated for 55% recycled PET in virgin PET) and calculated concentrations of the surrogates in PET (C_{mod}) corresponding to a modelled migration of 0.15 μg/kg food (scenario for toddlers) after 10 days at 40°C (specific use number 3 in Table 1)

Surrogates	Decontamination efficiency (%)	C_{res} for 55% rPET (mg/kg PET)	C_{mod} (mg/kg PET); toddler scenario
Toluene	93.4	0.11	0.28
Chlorobenzene	91.8	0.14	0.33
Chloroform	92.7	0.12	0.35
Methyl salicylate	> 99.9	< 0.002	0.44
Phenylcyclohexane	81.8	0.30	0.47
Benzophenone	68.7	0.52	0.54
Methyl stearate	79.1	0.34	1.06

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

Table 5: Decontamination efficiency from the challenge test, residual concentrations of the surrogates in the recycled PET ($C_{res,}$ calculated for 15% recycled PET in virgin PET) and calculated concentrations of the surrogates in PET (C_{mod}) corresponding to a modelled migration of 0.15 μg/kg food (scenario for toddlers) after 10 days at 60°C (specific use number 4 in Table 1)

Surrogates	Decontamination efficiency (%)	C_{res} for 15% rPET (mg/kg PET)	C_{mod} (mg/kg PET); toddler scenario
Toluene	93.4	0.03	0.09
Chlorobenzene	91.8	0.04	0.10
Chloroform	92.7	0.03	0.11
Methyl salicylate	> 99.9	< 0.0005	0.14
Phenylcyclohexane	81.8	0.08	0.15
Benzophenone	68.7	0.14	0.17
Methyl stearate	79.1	0.09	0.33

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

Table 6: Decontamination efficiency from the challenge test, residual concentrations of the surrogates in the recycled PET ($C_{res,}$ calculated for 75% recycled PET in virgin PET) and calculated concentrations of the surrogates in PET (C_{mod}) corresponding to a modelled migration of 0.625 μg/kg food (scenario for toddlers) after 10 days at 60°C (specific use number 5 and 6 in Table 1)

Surrogates	Decontamination efficiency (%)	C_{res} for 75% rPET (mg/kg PET)	C_{mod} (mg/kg PET); toddler scenario
Toluene	93.4	0.15	0.37
Chlorobenzene	91.8	0.18	0.43
Chloroform	92.7	0.16	0.46
Methyl salicylate	> 99.9	< 0.002	0.58
Phenylcyclohexane	81.8	0.41	0.61
Benzophenone	68.7	0.70	0.71
Methyl stearate	79.1	0.47	1.39

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

Based on the provided data from the challenge test and the applied conservative assumptions, the Panel considered that, under the given operating conditions, the recycling process Silver Plastics, using the Reifenhäuser technology, is able to ensure that the level of exposure to potential unknown contaminants from the recycled PET is below 0.0025 μg/kg bw per day.

At this level, the risk to human health is considered negligible when the recycled PET is used to produce materials and articles at up to

- 100% for contact with meat, fish, marinated grilled food as well as vegetable and fruit salads up to 30 days at 10°C,
- 100% for contact with meat and dairy products up to 90 days at 10°C,
- 55% in virgin PET for contact with vegetables and fruits up to 90 days at 25°C,
- 15% in virgin PET for contact with cakes, donuts and chocolates up to 365 days at 25°C,
- 75% in virgin PET for contact with confectionary up to 1080 days at 25°C.

4. Conclusions

The Panel considered that the Silver Plastics recycling process using the Reifenhäuser 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 temperature, pressure and throughput in the extruder (step 2) are critical for the decontamination efficiency.

The Panel concluded that the recycling process Silver Plastics 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 hot caustic 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 contact with meat, fish, marinated grilled food as well as vegetable and fruit salads up to 30 days at 10°C,
- 100% for contact with meat and dairy products up to 90 days at 10°C,
- 55% in virgin PET for contact with vegetables and fruits up to 90 days at 25°C,
- 15% in virgin PET for contact with cakes, donuts, chocolates up to 365 days at 25°C,
- 75% in virgin PET for contact with confectionary up to 1080 days at 25°C.

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

1) Dossier 'Silver Plastics'. July 2022. Submitted on behalf of Silver Plastics GmbH & Co KG, Germany.
2) Additional information, January 2023. Submitted on behalf of Silver Plastics GmbH & Co KG, Germany.
3) Additional information, May 2023. Submitted on behalf of Silver Plastics GmbH & Co KG, Germany.
4) Additional information, June 2023. Submitted on behalf of Silver Plastics GmbH & Co KG, Germany.

References

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

EFSA (European Food Safety Authority), 2009. Guidance of the Scientific Committee on transparency in the scientific aspects of risk assessments carried out by EFSA. 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 supporting publication 2021;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

EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2016. Recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials. EFSA Journal 2016;14(1):4357.

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

Hoekstra EJ, Brandsch R, Dequatre C, Mercea P, Milana MR, Störmer A, Trier X, Vitrac O, Schäfer A and Simoneau C, 2015. Practical guidelines on the application of migration modelling for the estimation of specific migration. Publications Office of the European Union, EUR 27529 EN. https://doi.org/10.2788/04517

Abbreviations

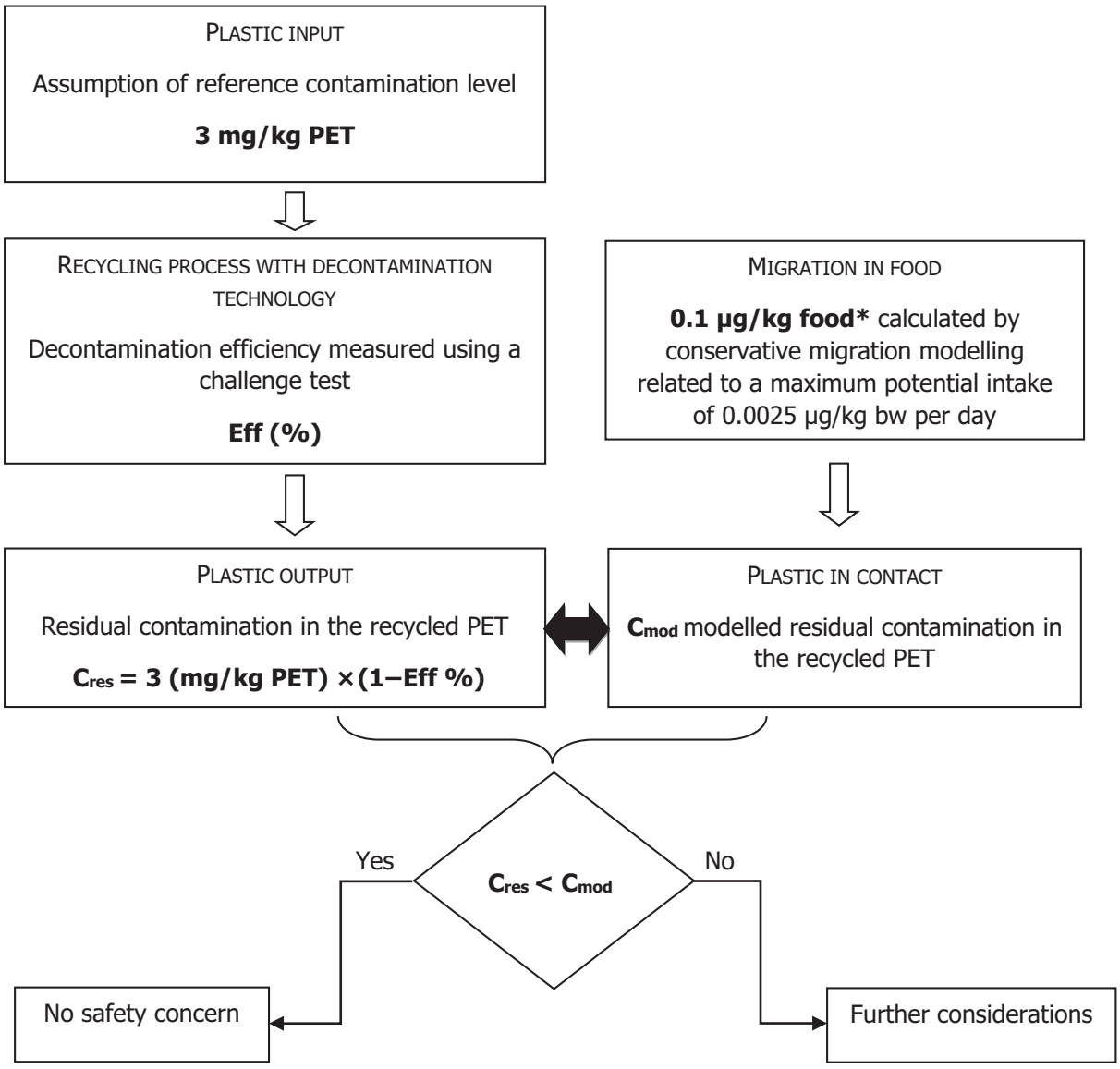
bw	body weight
CEF Panel	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP Panel	Panel on Food Contact Materials, Enzymes and Processing Aids
C_{mod}	modelled concentration in PET
C_{res}	residual concentration in PET
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)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

Appendix A – Technical specifications of the hot caustic washed flakes as provided by the applicant[14]

Parameter	Value
Moisture max.	< 1%
Bulk density	230–850 kg/m^3
PVC max.	< 100 mg/kg
Glue max.	< 100 mg/kg
Polyolefins max.	< 100 mg/kg
Cellulose (paper, wood)	< 100 mg/kg
Metals max.	< 50 mg/kg
Polyamide max.	< 50 mg/kg

[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 of operational parameters[15]

Process Silver Plastics (RECYC299) based on the Reifenhäuser technology			
Parameters	**Step 2 (decontamination)***		
	P (mbar)	**T (°C)**	**Throughput (kg/h)**
Challenge test (PA/4079/17)			
Process			

Based on the provided information and data, a maximum proportion of recycled PET from 15% to 100% in the final food contact material was derived by the Panel.

*__Characteristics of the extruder__ in the challenge test and the industrial process.

	Challenge test	**Industrial process**

[15] Technical report, Section 'Table of Operating Parameters'.

Appendix D – Modelling parameters used by the Panel to calculate concentration in PET (C_{mod}) corresponding to a dietary exposure of 0.0025 μg/kg bw per day

Contact times and temperatures were taken from Reg. (EU) 10/2011, selecting the migration conditions corresponding to the specific uses proposed by the applicant:

	Intended use	Contact conditions proposed by the applicant	Corresponding contact conditions in Reg. (EU) 10/2011
1	Meat, fish and marinated grilled food, vegetable salads, fruit salads	Up to 30 days at 10°C	10 days at 20°C
2	Meat products (like sausage, frankfurters, speck, etc.), sliced ham, sliced cheese, dairy products	Up to 90 days at 10°C	10 days at 20°C
3	Vegetables and fruits	Up to 90 days at 25°C	10 days at 40°C
4	Cakes, donuts, chocolates	Up to 365 days at 25°C	10 days 60°C
5	Confectionary (e.g. jelly babies)	Up to 365 days at 25°C	10 days 60°C
6	Confectionary (e.g. jelly babies)	Up to 1080 days at 25°C	10 days 60°C

The modelling parameters are the following:
- Good solubility of the migrant in food simulant is assumed ($K_{p,F}$ = 1).
- A food contact material or article made entirely with 100% recycled PET.
- A surface area to volume ratio of 6 dm^2 PET to 1 kg food/drink.
- A material thickness of 300 μm is assumed.
- For the calculation of the diffusion coefficient in PET for contact temperatures below or equal to 70°C as a modelling parameter Ap' = 3.1 is used and τ = 1,577 (Hoekstra et al., 2015).
- Density of PET is 1.375 g/cm^3.