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Safety assessment of the process Steinbeis PolyVert, based on the Vacunite (EREMA Basic and Polymetrix SSP V-LeaN) 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 Steinbeis PolyVert (EU register number RECYC280), which uses the VACUNITE (EREMA Basic and Polymetrix SSP V-leaN) technology. The input consists of hot caustic washed and dried poly(ethylene terephthalate) (PET) flakes, mainly originating from collected post-consumer PET containers, with no more than 5% PET from non-food consumer applications. The flakes are pre-decontaminated in a first [redacted] at high [redacted] under vacuum before being extruded, pelletised and crystallised. The pellets are then [redacted] and submitted to solid-state polycondensation (SSP) in two parallel [redacted] reactor lines at high [redacted] under [redacted] and [redacted]. Having examined the challenge test provided, the Panel concluded that step 2 ([redacted] reactor) and steps 4 and 5 ([redacted] and SSP) are critical for determining the decontamination efficiency of the process. The operating parameters to control the performance are temperature, pressure and residence time for steps 2, 4 and 5 as well as the gas velocity for steps 4 and 5. It was demonstrated that this recycling process is able to ensure that the level of migration of potential unknown contaminants into food is below the conservatively modelled migration of 0.1 μg/kg food. Therefore, the Panel concluded that the recycled PET obtained from this process is not of safety concern, when used at up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs, including drinking water, for long-term storage at room temperature, with or without hotfill. 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.

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† Deceased.

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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 1935/2004[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 an application from the Austrian Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz for evaluation of the recycling process Steinbeis PolyVert Vacunite (EREMA Vacurema Basic and Polymetrix SSP V-LeaN), European Union (EU) register No RECYC280. The request has been registered in EFSA's register of received questions under the number. The dossier was submitted on behalf of Steinbeis PolyVert GmbH, Werner-Heißenberg Straße 3, 9100, Völkermarkt, Austria (see 'Documentation provided to EFSA').

1.1.2. Terms of Reference

The Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz requested the safety evaluation of the recycling process Steinbeis PolyVert VACUNITE (EREMA Basic and Polymetrix SSP V-LeaN), in compliance with Article 5 of Regulation (EC) No 282/2008.

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 Steinbeis PolyVert 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).

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[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, p. 9–18.

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

[3] Regulation (EC) No 1935/2004 of the European parliament and of the council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4–17.

Additional information was sought from the applicant during the assessment process in response to requests from EFSA sent on 14 July 2022 and was subsequently provided (see 'Documentation provided to EFSA').

In accordance with Art. 38 of the Regulation (EC) No 178/2002[4] and taking into account the protection of confidential information and the 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 has been published on Open.EFSA.[6]

According to Art. 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations,[4] EFSA carried out a public consultation on the non-confidential version of the application from 19 January 2023 to 9 February 2023, for which no comments were received.

The following information on the recycling process was provided by the applicant and used for the evaluation:

- General information:
  - general description,
  - existing authorisations.
- Specific information:
  - recycling process,
  - characterisation of the input,
  - determination of the decontamination efficiency of the recycling process,
  - characterisation of the recycled plastic,
  - intended application in contact with food,
  - compliance with the relevant provisions on food contact materials and articles,
  - process analysis and evaluation,
  - operating parameters.

2.2. Methodologies

The risks associated with the use of recycled plastic materials and articles in contact with food come from the possible migration of chemicals into the food in amounts that would endanger human health. The quality of the input, the efficiency of the recycling process to remove contaminants as well as the intended use of the recycled plastic are crucial points for the risk assessment (EFSA, 2008).

The criteria for the safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for the manufacture of materials and articles in contact with food are described in the scientific opinion developed by the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (EFSA CEF Panel, 2011). The principle of the evaluation is to apply the decontamination efficiency of a recycling technology or process, obtained from a challenge test with surrogate contaminants, to a reference contamination level for post-consumer PET, conservatively set at 3 mg/kg PET for contaminants resulting from possible misuse. The resulting residual concentration of each surrogate contaminant in recycled PET (C_{res}) is compared with a modelled concentration of the surrogate contaminants in PET (C_{mod}). This C_{mod} is calculated using generally recognised conservative migration models so that the related migration does not give rise to a dietary exposure exceeding 0.0025 μg/kg body weight (bw) per day (i.e. the human exposure threshold value for chemicals with structural alerts for genotoxicity), below which the risk to human health would be negligible. If the C_{res} is not higher than the C_{mod}, the recycled PET manufactured by such recycling process is not considered 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.

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

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

[6] The non-confidential version of the dossier has been published on Open.EFSA and is available at the following link: https://open.efsa.europa.eu/dossier/FCM-2022-3210

3. Assessment

3.1. General information[7]

According to the applicant, the recycling process Steinbeis PolyVert is intended to recycle food grade PET containers using the VACUNITE (EREMA Basic and Polymetrix SSP V-leaN) 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, such as bottles for mineral water, soft drinks, fruit juices and beer, for long-term storage at room temperature, with or without hotfill. The final articles are not intended to be used in microwave or conventional ovens.

3.2. Description of the process

3.2.1. General description[8]

The recycling process Steinbeis PolyVert produces recycled PET pellets from PET materials originating from post-consumer collection systems (kerbside and deposit collection systems). It comprises the four steps below.

Input

- In step 1, the post-consumer PET is sorted and processed into hot caustic washed and dried flakes. This step is performed by the applicant.

Decontamination and production of recycled PET material

- In step 2, the flakes are decontaminated under high [redacted] and [redacted].
- In step 3, the decontaminated flakes are extruded to produce pellets, [redacted].
- In steps 4 and 5, run in two parallel equivalent lines, the pellets are [redacted] to a [redacted] under [redacted] and then further decontaminated during solid-state polycondensation (SSP) under [redacted] and [redacted].

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

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

3.2.2. Characterisation of the input[9]

According to the applicant, the input material for the recycling process Steinbeis PolyVert consists of hot washed and dried flakes obtained from PET materials, e.g. bottles, previously used for food packaging, from post-consumer collection systems (kerbside and deposit systems). A small fraction may originate from non-food applications. According to the applicant, the proportion will be no more than 5%.

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

3.3. VACUNITE (EREMA Basic and Polymetrix SSP V-leaN) technology

3.3.1. Description of the main steps[10]

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

- Decontamination in a continuous reactor (step 2):

  The flakes are continuously fed into a reactor equipped with a rotating device, running under high temperature and vacuum for a pre-defined minimum residence time.

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

- Extrusion and [redacted] of the decontaminated flakes (step 3):

  The flakes, continuously introduced from the previous reactor, are molten in the extruder. Residual solid particles (e.g. paper or aluminium) are filtered out of the extruded plastic before the melt is converted into pellets. The pellets are then [redacted] and split to two [redacted].

- [redacted] SSP (steps 4 and 5):

  The crystallised pellets from each [redacted] are [redacted] to a [redacted] and fed to the respective continuous reactors running in parallel under high temperature, vacuum and countercurrent [redacted] for a predefined residence time.

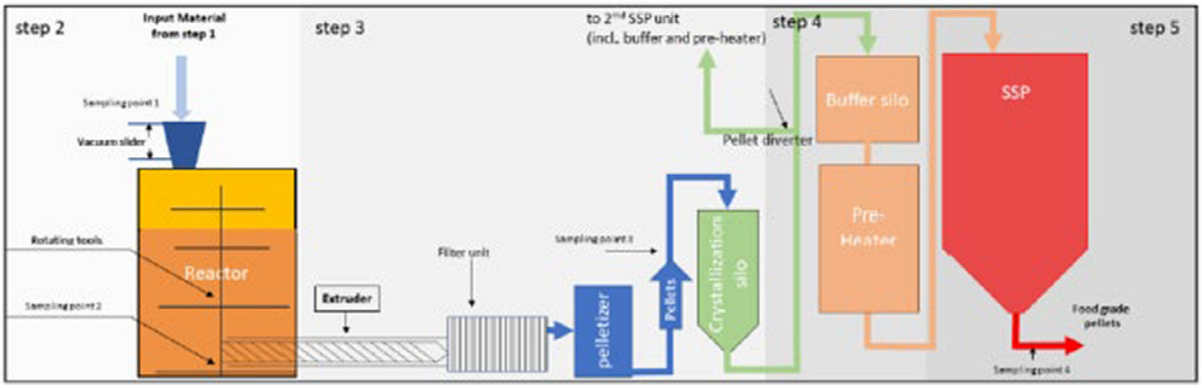


Figure 1: General scheme of the VACUNITE technology (provided by the applicant)

The process is run under defined operating parameters[11] of temperature, pressure, gas velocity and residence time.

3.3.2. Decontamination efficiency of the recycling process[12]

To demonstrate the decontamination efficiency of the recycling process Steinbeis PolyVert, challenge tests on steps 2 as well as 4 and 5 were submitted to the EFSA.

PET flakes were contaminated with toluene, chlorobenzene, chloroform, methyl salicylate, phenylcyclohexane, benzophenone and methyl stearate, selected as surrogates in agreement with the EFSA guidelines (EFSA CEF Panel, 2011) and in accordance with the recommendations of the US Food and Drug Administration (FDA, 2006). The surrogates include different molecular masses and polarities to cover possible chemical classes of contaminants of concern and were demonstrated to be suitable to monitor the behaviour of PET during recycling (EFSA, 2008).

For this purpose, 25 mL of each of the liquid surrogates (toluene, chlorobenzene, chloroform, methyl salicylate and phenyl cyclohexane) and 25 g of each of the solid surrogates (benzophenone and methyl stearate) were added to 25 kg of conventionally recycled[13] post-consumer PET flakes. Eight such batches were produced and stored for 7 days at 50°C with periodical agitation. Afterwards, the contaminated flakes were rinsed with 10% ethanol; the concentrations of the surrogates in this material were determined.

Step 2 of the VACUNITE technology was challenged at an industrial-scale plant. Contaminated flakes ([redacted] kg) were fed into the reactor. At the exit, sample was taken for analysis. Instead of being operated continuously, as in the industrial process, step 2 was run in batch mode. 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. In order to prove the representativeness of the residence time of the flakes in the challenge test in respect to the process, an additional challenge test running in continuous mode was provided. In this test, a mixture of green (contaminated) and clear (non-contaminated) flakes was challenged. At different residence times, the ratio of green and clear flakes exiting the reactor was determined. Based on the results provided, the Panel concluded

[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', Appendix E1 and E2.

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

that the residence time in the reactor ran in batch mode for the challenge test corresponded to the minimum residence time in the industrial continuous reactor.

The flakes were then extruded to pellets and [redacted] (step 3, which was not challenged).

Steps 4 and 5 ([redacted] SSP) were challenged at laboratory scale in batch mode, using 1 kg of the extruded pellets. Since the [redacted] SSP reactor in the process operates in the first-in, first-out mode, the Panel considered that this challenge test is representative of the process under the same operational conditions.

The decontamination efficiencies of step 2 (EREMA reactor) as well as step 4 ([redacted]) and 5 (SSP reactor) were calculated from the concentration of the surrogates before and after each reactor (Tables 1 and 2, respectively).

Table 1: Efficiency of the decontamination by the EREMA reactor in step 2 of 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	357.0	57.0	84.0
Chlorobenzene	641.1	100.6	84.3
Chloroform	165.6	78.0	52.9
Methyl salicylate	900.6	112.6	87.5
Phenylcyclohexane	588.2	140.1	76.2
Benzophenone	852.1	171.4	79.9
Methyl stearate	1279.9	205.2	84.0

PET: poly(ethylene terephthalate).

Table 2: Efficiency of the decontamination of the Polymetrix SSP reactor (steps 4 and 5) in the challenge test

Surrogates	Concentration of surrogates before step 4 (mg/kg PET)	Concentration of surrogates after step 5 (mg/kg PET)	Decontamination efficiency (%)
Toluene	12.6	< 0.4	> 96.8
Chlorobenzene	25.2	0.8	96.8
Chloroform	25.1	0.9	96.4
Methyl salicylate	7.9	0.1	98.7
Phenylcyclohexane	67.5	8.2	87.9
Benzophenone	100.9	9.4	90.7
Methyl stearate	100.4	2.0	98.0

PET: poly(ethylene terephthalate).

A combined decontamination efficiency of the process was then calculated from the decontamination efficiencies of steps 2, 4 and 5 (Table 3).

Table 3: Efficiency of the decontamination of the VACUNITE technology in the challenge test

Surrogates	Decontamination efficiency (%) step 2	Decontamination efficiency (%) steps 4 and 5	Combined decontamination efficiency (%)
Toluene	84.0	> 96.8	> 99.5
Chlorobenzene	84.3	96.8	99.5
Chloroform	52.9	96.4	98.3
Methyl salicylate	87.5	98.7	99.8
Phenylcyclohexane	76.2	87.9	97.1
Benzophenone	79.9	90.7	98.1
Methyl stearate	84.0	98.0	99.7

PET: poly(ethylene terephthalate).

As shown in Table 3, the decontamination efficiency ranged from 97.1% for phenylcyclohexane to 99.8% 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 moisture, poly(vinyl chloride) (PVC), polyolefins, glue, polyamide, other thermoplastics, cellulose and aluminium, were provided for the input materials (i.e. washed and dried flakes, step 1). The flakes 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, mouthwash or kitchen hygiene agents. According to the applicant, the collection system and the sorting 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 the 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 VACUNITE technology comprises the continuous decontamination reactor in step 2, extrusion and [redacted] (step 3), [redacted] (step 4) and decontamination in SSP reactors (step 5). The operating parameters of temperature, pressure, residence time and gas velocity have been provided to EFSA.

The challenge tests to measure the decontamination efficiency were conducted in a small industrial scale reactor for step 2 and a laboratory SSP reactor for steps 4 and 5. The reactors were operated under pressure, temperature and [redacted] conditions as well as residence time equivalent to or less severe than those of the commercial process. The Panel considered that these challenge tests were performed correctly according to the recommendations of the EFSA guidelines (EFSA, 2008) and that step 2 as well as steps 4 and 5 are critical for the decontamination efficiency of the process. Consequently, temperature, pressure and residence time of steps 2, 4 and 5 as well as the [redacted] or [redacted] of steps 4 and 5 of the process should be controlled to guarantee the performance of the decontamination (Appendix C).

The decontamination efficiencies obtained for each surrogate, ranging from 97.1% to 99.8%, have been used to calculate the residual concentrations of potential unknown contaminants in PET (C_{res}) according to the evaluation procedure described in the 'Scientific opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET' (EFSA CEF Panel, 2011; Appendix B). By applying the decontamination efficiency percentage to the reference contamination level of 3 mg/kg PET, the C_{res} for the different surrogates was obtained (Table 4).

According to the evaluation principles (EFSA CEF Panel, 2011), the dietary exposure must not exceed 0.0025 μg/kg bw per day, below which the risk to human health is considered negligible. The C_{res} value should not exceed the modelled concentration in PET (C_{mod}) that, after 1 year at 25°C, results in a migration giving rise to a dietary exposure of 0.0025 μg/kg bw per day. Because the recycled PET is intended for the manufacturing of articles (e.g. bottles) to be used in direct contact with drinking water, the exposure scenario for infants has been applied (water could be used to prepare infant formula). A maximum dietary exposure of 0.0025 μg/kg bw per day corresponds to a maximum migration of 0.1 μg/kg of a contaminant substance into the infant's food and has been used to calculate C_{mod} (EFSA CEF Panel, 2011). C_{res} reported in Table 4 is calculated for 100% recycled PET, for which the risk to human health is demonstrated to be negligible. The results of these calculations are shown in Table 4. The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

Table 4: Decontamination efficiencies from the combined challenge tests on steps 2, 4 and 5, residual concentrations of the surrogates (C_{res}) related to the reference contamination level and calculated concentrations of the surrogates in PET corresponding to a modelled migration of 0.1 μg/kg food after 1 year at 25°C (C_{mod})

Surrogates	Decontamination efficiency (%)	C_{res} for 100% rPET (mg/kg PET)	C_{mod} (mg/kg PET)
Toluene	> 99.5	< 0.02	0.09
Chlorobenzene	99.5	0.02	0.09
Chloroform	98.3	0.05	0.10
Methyl salicylate	99.8	0.01	0.13
Phenyl cyclohexane	97.1	0.09	0.14
Benzophenone	98.1	0.06	0.16
Methyl stearate	99.7	0.01	0.32

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 concluded that under the given operating conditions the recycling process Steinbeis PolyVert using the VACUNITE technology is able to ensure that the level of migration of unknown contaminants from the recycled PET into food is below the conservatively modelled migration of 0.1 μg/kg food. At this level, the risk to human health is considered negligible when the recycled PET is used at up to 100% to produce materials and articles intended for contact with all types of foodstuffs, including drinking water, for long-term storage at room temperature, with or without hotfill.

4. Conclusions

The Panel considered that the process Steinbeis PolyVert, using the VACUNITE (EREMA Basic and Polymetrix SSP V-leaN) technology, is adequately characterised and that the main steps used to recycle the PET flakes into decontaminated PET pellets have been identified. Having examined the challenge test provided, it concluded that temperature, pressure and residence time in the continuous reactors of steps 2, 4 and 5 as well as the gas velocity in steps 4 and 5 are critical for the decontamination efficiency.

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

i) it is operated under conditions that are at least as severe as those applied in the challenge test used to measure the decontamination efficiency of the process;
ii) the input material of the process is washed and dried post-consumer PET flakes originating from materials and articles that have been manufactured in accordance with the EU legislation on food contact materials and contains no more than 5% of PET from non-food consumer applications;
iii) the recycled PET obtained from the process Steinbeis PolyVert VACUNITE (EREMA Basic and Polymetrix SSP V-LeaN) is used at up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs, including drinking water, soft drinks, juices, tea, milk, oil and alcoholic beverages, for long-term storage at room temperature, with or without hotfill.

The final articles made of this recycled PET are not intended to be used in microwave and conventional ovens and such uses are not covered by this evaluation.

5. Recommendation

The Panel recommended periodic verification that the input to be recycled originates from materials and articles that have been manufactured in accordance with the EU legislation on food contact materials and that the proportion of PET from non-food consumer applications is no more than 5%. This adheres to good manufacturing practice and the Regulation (EC) No 282/2008, Art. 4b. Critical steps in recycling should be monitored and kept under control. In addition, supporting documentation should be available on how it is ensured that the critical steps are operated under conditions at least as severe as those in the challenge test used to measure the decontamination efficiency of the process.

6. Documentation provided to EFSA

Dossier 'Steinbeis PolyVert GmbH_VACUNITE® (EREMA Vacurema® Basic + Polymetrix SSP V-LeaN)'. May 2022. Submitted on behalf of Steinbeis PolyVert GmbH, Austria.

Additional information, November 2022. Submitted on behalf of Steinbeis PolyVert GmbH, Austria.

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. Part 2: general principles. EFSA Journal 2009;7(5):1051, 22 pp. https://doi.org/10.2903/j.efsa.2009.1051

EFSA (European Food Safety Authority), 2021. Administrative guidance for the preparation of applications on recycling processes to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food. EFSA Journal 2021;18(3):EN-6512, 30 pp. https://doi.org/10.2903/sp.efsa.2021.EN-6512

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

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

Abbreviations

bw	body weight
CEF	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP	Panel on Food Contact Materials, Enzymes and Processing Aids
C_{mod}	modelled concentration in PET
C_{res}	residual concentration in PET
iV	intrinsic viscosity
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)
SSP	solid-state polycondensation

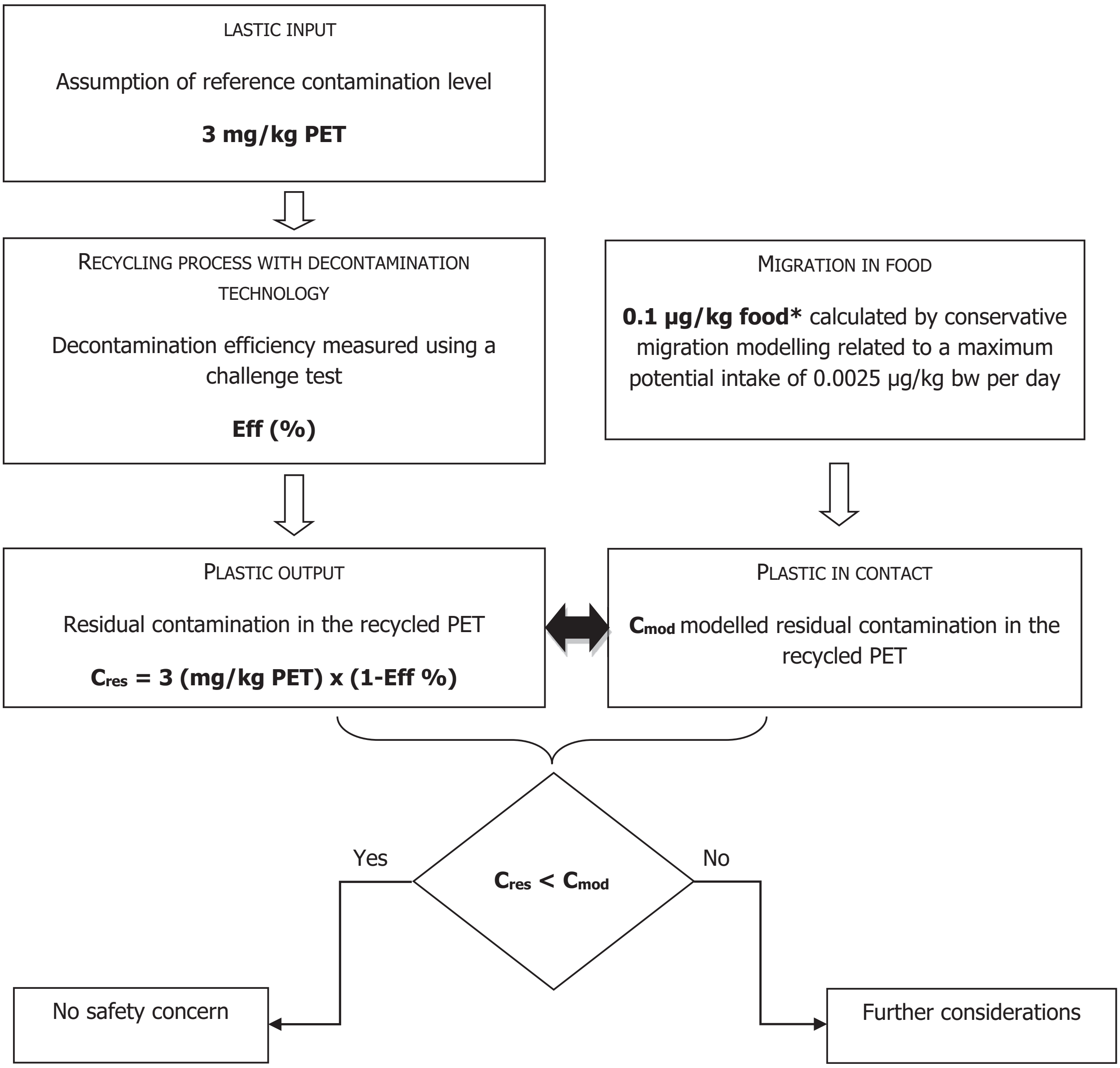
Appendix A – Technical data of the washed flakes as provided by the applicant[14]

Parameter	Value
Moisture max.	1.5%
Moisture variation	± 0.3%
Bulk density	250–500 kg/m^3
Material temperature	10–60°C
PVC max.	100 mg/kg
Glue max.	500 mg/kg
Polyolefins max.	500 mg/kg
Other thermoplastics	300 mg/kg
Polyamide	1,000 mg/kg
Cellulose (paper, wood)	500 mg/kg
Aluminium max.	400 mg/kg
PET dust max.	1%

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

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

Appendix B – Relationship between the key parameters for the evaluation scheme (EFSA CEF Panel, 2011)



*: Default scenario (infant). For adults and toddlers, the migration criterion will be 0.75 and 0.15 μg/kg food, respectively. The figures are derived from the application of the human exposure threshold value of 0.0025 μg/kg bw per day applying a factor of 5 related to the overestimation of modelling.

Appendix C – Table on operational parameters[15]

[redacted]

Process Steinbeis PolyVert (RECYC280) based on the VACUNITE (EREMA Basic and Polymetrix SSP V-leaN) technology

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

*Without external heating in a crystallisation silo; temperature > [redacted], > [redacted].
**Under vacuum in the first section of the screw of the extruder because of the connection to the reactor. The profile of pressure was not provided.
***Applicable only to SSP. Preheating is done at atmospheric pressure.
****There is experimental evidence (Huang and Walch 1998, Polymer, 93, p. 6991–9; Solid State Polymerization, ed. C.Papaspyrides and N. Vouyiouka, J. Wiley & Sons Inc., 2009) that above a minimal gas flow, the velocity of the gas has no longer influences on the rate of SSP process. Taking into account the gas flow in plant and the size of pellets, the gas flow used in the challenge test is considered representative of the one used in the plant. The gas velocity values of [redacted] m/s (challenge test) and ≥[redacted] m/s (process) correspond to gas flows of [redacted] m^3/h (challenge test) and > [redacted] m^3/h (process, [redacted] m^3 capacity reactor).

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