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. Efsa Panel On Food Contact Materials, Enzymes, Flavourings And Processing Aids (cef), Vittorio Silano, Claudia Bolognesi, Laurence Castle, Jean Pierre J. P. Cravedi, Karl-heinz Engel, Paul Fowler, Konrad Grob, Rainer Gürtler, Trine Husøy, et al.

To cite this version:

. Efsa Panel On Food Contact Materials, Enzymes, Flavourings And Processing Aids (cef), Vittorio Silano, Claudia Bolognesi, Laurence Castle, Jean Pierre J. P. Cravedi, et al.. Safety assessment of the process 'Plastienvase', based on EREMA Basic technology, used to recycle post-consumer PET into food contact materials. EFSA Journal, 2017, 15 (6), 13 p. 10.2903/j.efsa.2017.4843 . hal-01604309

HAL Id: hal-01604309

https://hal.science/hal-01604309v1

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SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 4 May 2017

doi: 10.2903/j.efsa.2017.4843

Safety assessment of the process 'Plastienvase', based on EREMA Basic technology, used to recycle post-consumer PET into food contact materials

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), Vittorio Silano, Claudia Bolognesi, Laurence Castle, Jean-Pierre Cravedi, Karl-Heinz Engel, Paul Fowler, Konrad Grob, Rainer Gürtler, Trine Husøy, Sirpa Kärenlampi, Wim Mennes, André Penninks, Andrew Smith, Maria de Fátima Tavares Poças, Christina Tlustos, Detlef Wölfle, Holger Zorn, Corina-Aurelia Zugravu, Vincent Dudler, Nathalie Gontard, Eugenia Lampi, Cristina Nerin, Constantine Papaspyrides, Katharina Volk and Maria Rosaria Milana

Abstract

This scientific opinion of the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel) deals with the safety assessment of the Plastienvase recycling process (EU register number RECYC0138), which is based on the EREMA Basic technology. The input to this process is hot washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, containing no more than 5% PET from non-food consumer applications. In this technology, post-consumer washed and dried PET flakes are heated in a continuous reactor under vacuum before being extruded. Having examined the results of the challenge test provided, the Panel concluded that the continuous reactor step (step 2) is the critical step that determines the decontamination efficiency of the process. The operating parameters controlling its performance are well defined and are temperature, pressure and residence time. It was demonstrated that, depending on the operating conditions, the recycling process under evaluation is able to ensure that the level of migration of potential unknown contaminants into food is below a conservatively modelled migration of 0.15 μg/kg food, derived from the exposure scenario for toddlers. The Panel concluded that recycled PET obtained from the process is not of safety concern when the final thermoformed trays and containers manufactured with the recycled sheets and not used for packaging water contain up to 100% recycled post-consumer PET. These thermoformed trays are not intended to be used and should not be used in microwave and conventional ovens.

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Keywords: EREMA, Plastienvase, food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

Requestor: Ministero de Sanidad, Servicios Sociales e Igualdad, Agencia Española de Consumo, Seguridad Alimentaria y Nutrición, Spain

Question number: EFSA-Q-2016-00398

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Panel members: Claudia Bolognesi, Laurence Castle, Jean-Pierre Cravedi, Karl-Heinz Engel, Paul Fowler, Roland Franz, Konrad Grob, Rainer Gürtler, Trine Husøy, Sirpa Kärenlampi, Wim Mennes, Maria Rosaria Milana, André Penninks, Vittorio Silano, Andrew Smith, Maria de Fátima Tavares Poças, Christina Tlustos, Detlef Wölfle, Holger Zorn and Corina-Aurelia Zugravu.

Competing interests: In line with EFSA's policy on declarations of interest, Panel member Roland Franz did not participate in the development and adoption of this scientific output.

Suggested citation: EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), Silano V, Bolognesi C, Castle L, Cravedi J-P, Engel K-H, Fowler P, Grob K, Gürtler R, Husøy T, Kärenlampi S, Mennes W, Penninks A, Smith A, Tavares Poças MF, Tlustos C, Wölfle D, Zorn H, Zugravu C-A, Dudler V, Gontard N, Lampi E, Nerin C, Papaspyrides C, Volk K and Milana MR, 2017. Scientific opinion on the safety assessment of the process 'Plastienvase', based on EREMA Basic technology, used to recycle post-consumer PET into food contact materials. EFSA Journal 2017; 15(6):4843, 13 pp. https://doi.org/10.2903/j.efsa.2017.4843

ISSN: 1831-4732

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

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Recycled plastic materials and articles shall only be placed on the market if they contain recycled plastic obtained from an authorised recycling process. Before a recycling process is authorised, EFSA's opinion on its safety is required. This procedure has been established in Article 5 of Regulation (EC) No 282/2008[1] of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of Regulation (EC) No 1935/2004[2] of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the Member States Competent Authorities which transmit the applications to the European Food Safety Authority (EFSA) for evaluation.

In this case, EFSA received, from the Ministerio de Sanidad, Sevicios Sociales e Igualdad, Agencia Española de Consumo, Seguridad Alimentaria y Nutrición, Spain, an application for evaluation of the recycling process Plastienvase, based on the EREMA Basic technology, EU register No RECYC0138. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2016-00398. The dossier was submitted on behalf of SP GROUP (The New Plastienvase), Spain.

According to Article 5 of Regulation (EC) No 282/2008 of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods, EFSA is required to carry out risk assessments on the risks originating from the migration of substances from recycled food contact plastic materials and articles into food and deliver a scientific opinion on the recycling process examined.

According to Article 4 of Regulation (EC) No 282/2008, EFSA will evaluate whether it has been demonstrated in a challenge test, or by other appropriate scientific evidence, that the recycling process Plastienvase, 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 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). Applications shall be submitted in accordance with Article 5 of the Regulation (EC) No 282/2008.

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.

[1] Regulation (EC) No 282/2008 of the European parliament and of the council of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006. OJ L 86, 28.3.2008, p. 9–18.

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

2.2. Methodologies

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

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

The assessment was conducted in line with the principles described in the EFSA Guidance on transparency in the scientific aspects of risk assessment (EFSA, 2009) and considering the relevant guidance from the EFSA Scientific Committee.

3. Assessment

3.1. General information

According to the applicant, the Plastienvase recycling process is intended to recycle food-grade PET containers to produce recycled PET using the EREMA Basic technology. This recycled PET is intended to be used in a mass fraction up to 100% to manufacture new food packaging articles, i.e. PET sheets for thermoformed trays and containers. These final materials and articles are intended to be used in direct contact with all kinds of foodstuffs for long-term storage at room temperature.

3.2. Description of the process

3.2.1. General description

The recycling process Plastienvase produces PET sheets from PET containers, mainly bottles, coming from post-consumer collection systems (kerbside and deposit systems). The recycling process comprises the three steps below.

- In step 1, post-consumer PET containers are ground and processed into washed and dried flakes, which are used as the input for the next steps. This step is performed by third parties.
- In step 2, the flakes are crystallised and decontaminated under high temperature and vacuum.
- In step 3, the decontaminated flakes are extruded to produce flat sheets.

Recycled flat sheets, the final product of the process, are checked against technical requirements on intrinsic viscosity, colour, black spots, etc. According to the applicant, this recycled PET is intended to be converted by other companies into recycled articles used for long-term storage at room temperature, i.e. extruded sheets which are thermoformed to make food trays/containers for food contact applications, such as for fruit, vegetables, cooked and uncooked meats, dairy products and desserts, etc. The trays are not intended to be used in microwaves or conventional ovens.

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

3.2.2. Characterisation of the input

According to the applicant, the input material for the Plastienvase recycling process consists of washed and dried flakes obtained from PET containers, mainly bottles, previously used for food

packaging, from post-consumer collection systems (kerbside and deposit systems). A small fraction may originate from non-food applications such as soap bottles, mouth wash bottles, kitchen hygiene bottles, etc. According to information from the applicant, the amount of this non-food container fraction depends on the re-collection system and will be between (nearly) 0% and about 5%.

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

3.3. EREMA Basic technology

3.3.1. Description of the main steps

To decontaminate post-consumer PET, the recycling process Plastienvase uses the EREMA Basic technology, which is described below and for which the general scheme provided by the applicant is reported in Figure 1. Washed and dried flakes from step 1 are used as input to the next two steps, which are:

- Decontamination and crystallisation in a continuous reactor (step 2): In this step, the flakes are introduced into a continuous reactor equipped with a bottom-mounted rotating mixing device, in which vacuum and temperature are applied for a predefined residence time. These process conditions favour the desorption of possible contaminants from PET and the crystallisation of PET flakes.
- Extrusion of the decontaminated flakes (step 3): The flakes continuously coming from the previous reactor are melted in the extruder at atmospheric pressure. Residual solid particles (e.g. paper, aluminium, etc.) are filtered out of the extruded plastic before the final flat sheets are produced.

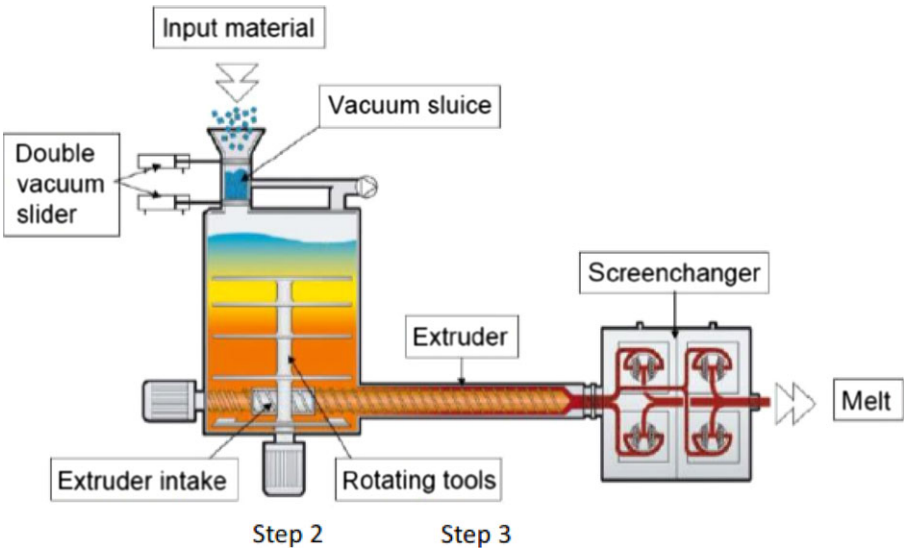

Figure 1: General scheme of the EREMA Basic technology

The process is operated under defined operating parameters of temperature, pressure and residence time.

3.3.2. Decontamination efficiency of the recycling process

To demonstrate the decontamination efficiency of the Plastienvase process, a challenge test was submitted to EFSA. According to the applicant, it was performed at the EREMA facilities at industrial scale.

PET flakes were contaminated with toluene, chlorobenzene, chloroform, methyl salicylate, phenylcyclohexane, benzophenone and methyl stearate, selected as surrogate contaminants in agreement with the EFSA guidelines and in accordance with the recommendations of the US Food and Drug Administration. The surrogates include different molecular weights 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, solid surrogates (benzophenone and methyl stearate) were mixed with liquid surrogates (toluene, chlorobenzene, chloroform, methyl salicylate and phenylcyclohexane). This mixture was admixed to 5 kg recycled post-consumer green PET flakes (masterbatch). The masterbatch was mixed with approx. 50 kg of green PET flakes and stored for 7 days at 50°C with periodical agitation. The contaminated flakes were washed and rinsed in a batch process in pilot plant scale. The concentration of surrogates in this material was determined.

The EREMA technology was challenged on the reactor of step 2 only, using an industrial-scale plant. To process a sufficiently large amount of material compatible with the high capacity of the continuous industrial plant, the reactor was fed initially with non-contaminated flakes (white colour) and, after process conditions are stabilised, with a defined amount of contaminated flakes (green colour) and then with a much larger quantity of non-contaminated flakes. The flakes were continuously fed into the reactor. The ratio between contaminated and non-contaminated flakes was approximately 1:22. Samples were taken at the outlet of the reactor at regular intervals. The green flakes were separated from the white flakes and the evolution of the fraction of green flakes with time (residence time distribution curve) was determined by weighing. The green flakes were then analysed for their residual concentrations of the applied surrogates.

The Panel noted that decontamination efficiencies, calculated only on the basis of residual surrogates in contaminated (green coloured) flakes could be overestimated. In fact, based on EFSA CEF Panel (2011), cross-contamination[3] by transfer of contaminants from green to white flakes does occur.

Therefore to take into account the cross-contamination phenomenon, the following considerations and assumptions were made:

- The mass fraction of green to white flakes at various residence time points was derived from the data provided. A best fitting mass fraction/residence time distribution curve was derived from the experimental data and was used to calculate the percentage of green and white flakes at given different residence times.
- The residual concentrations of surrogates in the green flakes after decontamination were derived for the different residence time points from the data provided. A best fitting curve was derived from the experimental data and was used to interpolate the residual concentrations in green flakes at different residence times.
- The Panel made the assumption that cross-contamination of surrogates from green to white flakes in the reactor occurred to the extent of 10% of the residual concentration measured in the green flakes. This percentage reflects the experience gained from previous evaluations.
- A new study was provided by the applicant. Based on the results provided as an Annex of the technical dossier and subsequently published (Welle, 2016), cross-contamination was found at low mixing (dilution) ratios (e.g. 1:1), but the author argued that moving to higher mixing (dilution) ratios (e.g. 1:50) cross-contamination does no longer play a significant role. Therefore, the applicant requested that the 10% cross-contamination should not apply for the industrial process Plastienvase (EREMA basic) under evaluation.
- The Panel noted that the test (Welle, 2016) had shortcomings and the conclusion that cross-contamination was negligible had to be questioned due to the poor detection limits of the analytical method used as it had a major impact on calculations for the high mixing (dilution) ratio. Moreover, the Panel considered that the laboratory tests to investigate cross-contamination were not representative of the industrial process under evaluation: different technologies (types of equipment and operational conditions) were used, for example in terms of heating technique (hot gas vs friction) and removal of contaminants from the reactor (inert gas vs vacuum). The Panel concluded that the argumentation is insufficiently supported. Therefore, the provided study allows neither to exclude cross-contamination from the calculation of the decontamination efficiency nor to refine the previous estimate of 10%.

To take into account the cross-contamination between green and white flakes, the evolution of the total residual surrogate content at the outlet of the continuous reactor (step 2) as a function of residence time was calculated by adding the amounts transferred into the white flakes (based on the

[3] 'Cross-contamination', (partitioning between green and white flakes) as meant in the 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', is the transfer of surrogate contaminants from the initially contaminated to the initially not contaminated material (EFSA CEF Panel, 2011).

assumption of 10% of the concentration measured in the green flakes) to the amounts measured in the green ones, taking into account the mass fractions of green and white flakes.

Correspondingly corrected concentrations of the surrogates after decontamination were compared with their initial concentrations in green flakes at the inlet of the reactor to derive the decontamination efficiencies taking into account the residence time in the step 2 reactor as specified by the applicant (see Table 1).

Table 1: Efficiencies of the decontamination of the continuous reactor (step 2)

Surrogates	Concentration[(a)] of surrogates before step 2 (mg/kg PET)	Concentration[(b)] of surrogates after step 2 (mg/kg PET)	Decontamination efficiency[(c)] (%)
Toluene	202	0.40	98.4
Chlorobenzene	361	0.76	98.3
Chloroform	291	0.48	98.6
Methyl salicylate	143	1.03	94.0
Phenylcyclohexane	364	2.31	94.7
Benzophenone	480	4.37	92.4
Methyl stearate	360	1.93	95.5

PET: poly(ethylene terephthalate).
(a): Initial concentration in the contaminated PET flakes.
(b): Residual concentration calculated for green flakes after decontamination.
(c): Decontamination efficiency of the step 2 reactor in the challenge test and after correction for cross-contamination (see text).

The decontamination efficiencies as presented in Table 1 were calculated at the time(s) of exit from the continuous reactor (step 2) in the challenge test. The decontamination efficiency ranged from 92.4% for benzophenone up to 98.6% for chloroform.

3.4. Discussion

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

Technical data such as information on residual content of PVC, glue, polyolefins, cellulose, metals, polyamides and physical properties are provided for the input materials (washed and dried flakes (step 1)), for the submitted recycling process. The input materials are produced from PET containers, mainly bottles, previously used for food packaging collected through post-consumer collection systems. However, a small fraction of the input may originate from non-food applications such as soap bottles, mouth wash bottles, kitchen hygiene bottles, etc. According to the applicant, the proportion of this non-food container fraction depends on the collection system and the process is managed in such a way that in the input stream of the recycling process this amount will be lower than 5%, as recommended by the EFSA CEF Panel in its 'Scientific opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food' (EFSA CEF Panel, 2011).

The process is well described. The production of washed and dried flakes from collected containers (step 1) is conducted by third parties. According to the applicant, this step is under control. The following steps are those of the EREMA Basic technology used to recycle the PET flakes into decontaminated PET flakes: continuous decontamination reactor (step 2) and extrusion (step 3). The operating parameters of temperature, pressure and residence time for the steps 2–3 have been provided to EFSA.

A challenge test was conducted at industrial plant scale on the process step 2 (continuous decontamination reactor) to measure the decontamination efficiency. In the challenge test, the continuous decontamination reactor was operated under pressure and temperature conditions equivalent to those of the commercial process. The challenge test was performed according to the recommendations in the EFSA Guidelines (EFSA, 2008). Since a mixture of flakes not contaminated with surrogates (white) and contaminated flakes (green, spiked with surrogates) was collected at the outlet of the reactor used for this challenge test, the Panel calculated the decontamination efficiencies taking into account also the amount possibly transferred to the white flakes due to cross contamination phenomena during the challenge test. The Panel considered that the decontamination in continuous reactor (step 2)

is the critical step for the decontamination efficiency of the process. Consequently, temperature, pressure and residence time parameters of the step 2 of the process should be controlled to guarantee the performance of the decontamination. These parameters have been provided to EFSA.

The decontamination efficiencies obtained for each surrogate contaminant from the challenge test, ranging from 92.4% to 98.6%, have been used to calculate the residual concentrations of potential unknown contaminants (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 percentages to the reference contamination level of 3 mg/kg PET, the C_{res} values for the different surrogates are obtained (see Table 2).

According to the evaluation principles (EFSA CEF Panel, 2011), the C_{res} should not be higher than a modelled concentration in PET (C_{mod}) corresponding to a migration, after 1 year at 25°C, which cannot give rise to a dietary exposure exceeding 0.0025 μg/kg bw per day, the exposure threshold below which the risk to human health would be negligible.[4] Because the recycled PET is intended to be used in the manufacture of trays and containers and not used to pack water (since water could be used to prepare infant formula), the exposure scenario for toddlers has been applied as worst case, where 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. Therefore, the corresponding migration of 0.15 μg/kg (scenario of toddlers) into food has been used to calculate C_{mod} (EFSA CEF Panel, 2011). If the PET produced by a recycling process is used up to 100% to produce new articles and they do not meet these targets, recycled PET should be mixed with virgin PET to make sure that the C_{res} value does not exceed the C_{mod} value. The Panel established the maximum percentage of recycled PET in final articles for which the risk to human health is demonstrated to be negligible. This percentage is reported in Table 2 for the scenario of toddlers. The percentage of recycled PET reported in Table 2 is, therefore, the maximum percentage for which the risk to human health is demonstrated to be negligible and may differ from the initial request from the applicant. The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

Table 2: Calculated concentration of surrogate contaminants in PET (C_{mod}) corresponding to a modelled migration of 0.15 μg/kg food after 1 year at 25°C, decontamination efficiencies from the challenge test, residual concentration (C_{res}) of surrogate contaminants in PET consisting of 100% recycled PET (rPET)

Surrogates	Decontamination efficiency (%)	C_{res} for 100% rPET (mg/kg PET)	C_{mod} (mg/kg PET)
Toluene	98.3	0.05	0.13
Chlorobenzene	98.2	0.05	0.15
Chloroform	98.6	0.04	0.15
Methyl salicylate	94.0	0.18	0.20
Phenylcyclohexane	94.7	0.16	0.21
Benzophenone	92.4	0.23	0.24
Methyl stearate	95.5	0.13	0.47

PET: poly(ethylene terephthalate).

On the basis of the provided data from the challenge test and the applied conservative assumptions, the Panel considered that the recycling process under evaluation using the EREMA Basic technology under the given operating conditions 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 which the risk to human health would be negligible when the recycled sheets are used for trays and containers intended for contact with all types of foodstuffs except packaged water (scenario of toddlers) and when the recycled PET from the Plastienvase recycling process is used up to 100%.

[4] 0.0025 μg/kg bw per day is the human exposure threshold value for chemicals with structural alerts raising concern for potential genotoxicity, below which the risk to human health would be negligible (EFSA CEF Panel, 2011).

4. Conclusions

The Panel considered that the Plastienvase recycling process is well characterised and the main steps used to recycle the PET flakes into decontaminated PET sheets have been identified. Having examined the challenge test provided, the Panel concluded that the decontamination in the continuous reactor of step 2 is the critical step for the decontamination efficiency of the process. The operating parameters to control its performance are the temperature, the pressure and the residence time. Therefore, the Panel considered that the recycling process Plastienvase is able to reduce any foreseeable accidental contamination of the 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 obtained from the challenge test used to measure the decontamination efficiency of the process,
ii) the input of the process is washed and dried post-consumer PET flakes originating from materials and articles that have been manufactured in accordance with the European Union (EU) legislation on food contact materials containing no more than 5% of PET from non-food consumer applications.

The Panel concluded that the recycled PET obtained from the process Plastienvase and intended for the manufacture of thermoformed trays and containers for contact with all types of foodstuff, except packaged water, for long-term storage at room temperature, is not considered of safety concern, when made with up to 100% recycled post-consumer PET. These thermoformed trays are not intended to be used and should not be used in microwaves and conventional ovens.

5. Recommendations

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

Documentation provided to EFSA

1) Dossier "Plastienvase Recycling Process". June 2016. Submitted on behalf of SP GROUP (The New Plastienvase), Spain.
2) Additional information. January 2017. Submitted on behalf of SP GROUP (The New Plastienvase), Spain.

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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

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Welle F, 2016. Investigation into cross-contamination during cleaning efficiency testing in PET recycling. Resources, Conservation and Recycling, 112, 65–72.

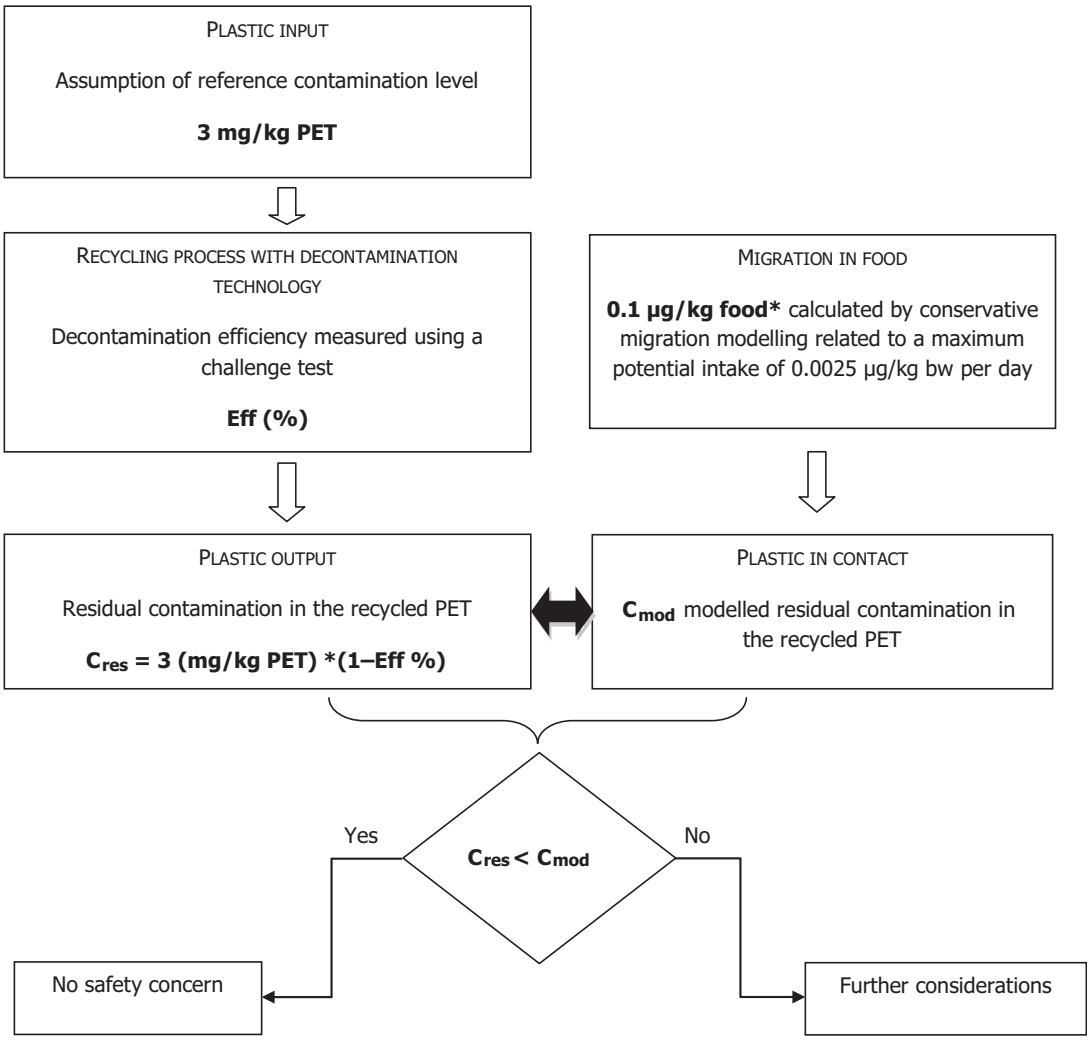
Abbreviations

bw	body weight
CEF Panel	EFSA Panel on Food Contact Materials, Enzymes, Flavourings 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 data of the washed flakes as provided by the applicant

Parameter	Value
Moisture max.	1.0%
Moisture variation	$\pm$ 0.1% h^{-1}
Bulk density	350–850 kg m^{-3}
Bulk density variation	$\pm$ 50 kg m^{-3} h^{-1}
Material temperature	15–50°C
Material temp. variation	$\pm$ 5°C h^{-1}
Glue max.	50 ppm
Polyolefins max.	25 ppm
Cellulose (paper, wood)	50 ppm
Metals max.	2 ppm
Polyamide max.	5 ppm

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.