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Safety assessment of the process rPET Aviv Shalam, based on the Starlinger iV+ 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 rPET Aviv Shalam (EU register number RECYC263), which uses the Starlinger iV+ technology. The input is 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 dried and crystallised in a first reactor, then extruded into pellets. These pellets are crystallised, preheated and treated in a solid-state polycondensation (SSP) reactor. Having examined the challenge test provided, the Panel concluded that the drying and crystallisation (step 2), extrusion and crystallisation (step 3) and SSP (step 4) are critical in determining the decontamination efficiency of the process. The operating parameters to control the performance of these critical steps are temperature, air/PET ratio and residence time for the drying and crystallisation step, and temperature, pressure and residence time for the extrusion and crystallisation step, as well as the SSP step. 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. 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.

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Keywords: Starlinger iV+, rPET Aviv Shalam Ltd., food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

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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] on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of Regulation (EC) No 1935/2004[2] 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 (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit) an application for evaluation of the recycling process rPET Aviv Shalam, European Union (EU) register No RECYC263. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2021-00468. The dossier was submitted on behalf of rPET Aviv Shalam Ltd., [redacted], Israel.

1.1.2. Terms of Reference

The German Competent Authority (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit) requested the safety evaluation of the recycling process rPET Aviv Shalam, according to the Articles 8, 9 and 10 of the Regulation (EC) No 1935/2004.

1.2. Interpretation of the Terms of Reference

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

According to Article 4 of Regulation (EC) No 282/2008, EFSA will evaluate whether it has been demonstrated in a challenge test, or by other appropriate scientific evidence, that the recycling process rPET Aviv Shalam is able to reduce the contamination of the plastic input to a concentration that does not pose a risk to human health. The poly(ethylene terephthalate) (PET) materials and articles used as input of the process as well as the conditions of use of the recycled PET are part of this evaluation.

2. Data and methodologies

2.1. Data

The applicant has submitted a confidential and a non-confidential version of a dossier following the 'EFSA guidelines for the submission of an application for the safety evaluation of a recycling process to produce recycled plastics intended to be used for the manufacture of materials and articles in contact with food, prior to its authorisation' (EFSA, 2008) and the 'Administrative guidance for the preparation of applications on recycling processes to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food' (EFSA, 2021).

Additional information was sought from the applicant during the assessment process in response to requests from EFSA sent on 28 October 2022 and was subsequently provided (see 'Documentation provided to EFSA').

[1] 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] 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.

In accordance with Art. 38 of the Regulation (EC) No 178/2002[3] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39 e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[4] the non-confidential version of the dossier has been published on Open.EFSA.[5]

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[2], EFSA carried out a public consultation on the non-confidential version of the application from 8 August to 29 August 2022 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.

[3] 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.

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

[5] 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-2021-1307

3. Assessment

3.1. General information[6]

According to the applicant, the recycling process rPET Aviv Shalam is intended to recycle food grade PET containers using the Starlinger iV+ 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 (including mineral water) for long-term storage at room temperature, with or without hotfill. The recycled pellets may also be used for sheets, which are thermoformed to make food trays. 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[7]

The recycling process rPET Aviv Shalam produces recycled PET pellets from PET containers (e.g. bottles), from post-consumer collection systems (kerbside, deposit systems and mixed waste collection).

The recycling process comprises the four steps below.

Input

- In step 1, the post-consumer PET containers are processed into hot caustic washed and dried flakes. This step may be performed by a third party or by the applicant.

Decontamination and production of recycled PET material

- In step 2, the flakes are dried and crystallised in a reactor under air flow at high temperature.
- In step 3, the flakes are extruded under vacuum at high temperature and then crystallised.
- In step 4, the crystallised pellets are preheated before being treated in a solid-state polycondensation (SSP) reactor at high temperature and under vacuum.

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, acetaldehyde, pellets size and bulk density.

3.2.2. Characterisation of the input[8]

According to the applicant, the input material for the recycling process rPET Aviv Shalam 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, deposit systems and mixed waste collection). A small fraction may originate from non-food applications. According to the applicant, the proportion will be no more than 5%.

Technical data for the hot washed and dried flakes are provided, such as information on physical properties and on residual contents of moisture, metal, poly(vinyl chloride) (PVC), polyolefins and plastics other than PET (see Appendix A).

3.3. Starlinger iV+ technology

3.3.1. Description of the main steps[9]

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

- Drying and crystallisation (step 2): In a continuous process, the flakes are dried and crystallised in a reactor at high temperature and under air flow.

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

- Extrusion and crystallisation (step 3): The flakes from the previous step are fed into an extruder under high temperature and vacuum for a predefined residence time. The pellets are then crystallised at high temperature in a continuous reactor under atmospheric pressure.
- SSP (step 4): The crystallised pellets are preheated in a reactor before being introduced into a semi-continuous SSP reactor running under vacuum at a high temperature and for a predefined residence time.

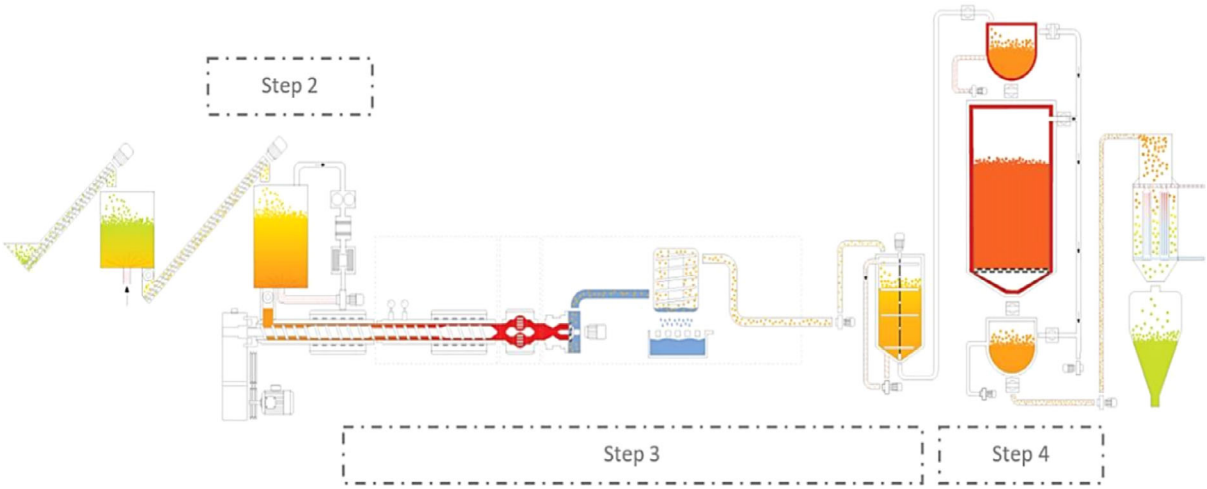

Figure 1: General scheme of the Starlinger iV+ technology (provided by the applicant)

The process is run under defined operating parameters[10] of temperature, pressure, air/PET ratio and residence time.

3.3.2. Decontamination efficiency of the recycling process[11]

To demonstrate the decontamination efficiency of the recycling process rPET Aviv Shalam, a challenge test performed at pilot plant scale was submitted to EFSA.

PET flakes were contaminated with toluene, chloroform, phenylcyclohexane, benzophenone and lindane, 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).

Conventionally recycled[12] post-consumer PET flakes were soaked in a heptane/isopropanol solution containing the surrogates and stored for 14 days at 40°C. After decanting the surrogate solution, the flakes were rinsed with water and air-dried. The concentration of surrogates in these flakes was determined.

The Starlinger IV+ technology was challenged at the Starlinger facilities in pilot plant scale. The contaminated flakes were introduced directly into the drier (step 2), then sampled after each step (2–4) to measure the residual concentrations of the applied surrogates. Instead of being processed continuously, the SSP reactor was run in batch mode. However, since the reactor in the process works practically with no mixing, the Panel agreed that the batch reactor in the challenge test provided the same cleaning efficiency when run at the same temperature, pressure and residence time.

The decontamination efficiency of the process was calculated from the concentrations of the surrogates measured in the washed contaminated flakes before drying and crystallisation (before step 2) and after SSP (step 4). The results are summarised in Table 1.

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

Table 1: Efficiency of the decontamination of the Starlinger iV+ technology in the challenge test

Surrogates	Concentration of surrogates before step 2 (mg/kg PET)	Concentration of surrogates after step 4 (mg/kg PET)	Decontamination efficiency (%)
Toluene	563	< 0.8[(a)]	> 99.9
Chloroform	1,900	< 0.5[(a)]	> 99.9
Phenylcyclohexane	538	< 0.3[(a)]	> 99.9
Benzophenone	694	10.8	98.4
Lindane	373	33.9	90.9

PET, poly(ethylene terephthalate).
(a): Not detected at the limits of detection given.

As shown in Table 1, the decontamination efficiency ranged from 90.9% for lindane to more than 99.9% for toluene, chloroform and phenylcyclohexane.

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 physical properties and residual contents of PVC, polyolefins and metals, were provided for the input materials (i.e. washed and dried flakes, step 1). These are produced mainly 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, e.g. bottles from window cleaner or shampoo. According to the applicant, the collection system and the process are managed in such a way that in the input stream this fraction will be no more 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 adequately described. The washing and drying of the flakes from the collected PET (step 1) is conducted in different ways, depending on the plant, and, according to the applicant, this step is under control. The Starlinger iV+ technology comprises drying and crystallisation (step 2), extrusion and crystallisation (step 3) and SSP (step 4). The operating parameters of temperature, residence time, pressure and air/PET ratio have been provided to EFSA.

A challenge test to measure the decontamination efficiency was conducted at pilot plant scale on process steps 2–4. The Panel considered that this challenge test was performed correctly according to the recommendations in the EFSA guidelines (EFSA, 2008). The fourth step is expected to be the most critical step for the decontamination, but drying and crystallisation (step 2) as well as extrusion and crystallisation (step 3) are relevant, too. Therefore, the Panel considered that these three steps (drying and crystallisation, extrusion and crystallisation, SSP) were critical for the decontamination efficiency of the process. Consequently, the temperature, the air/PET ratio and the residence time for the drying and crystallisation (step 2), as well as the temperature, the pressure and the residence time for extrusion and crystallisation (step 3) and SSP (step 4) should be controlled to guarantee the performance of the decontamination (Appendix C).

The decontamination efficiencies obtained for each surrogate, ranging from 90.9% to > 99.9%, have been used to calculate the residual concentrations of potential unknown contaminants in PET (C_{res}) according to the evaluation procedure described in the 'Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET' (EFSA CEF Panel, 2011; Appendix B). By applying the decontamination percentages to the reference contamination level of 3 mg/kg PET, the C_{res} for the different surrogates was obtained (Table 2).

According to the evaluation principles (EFSA CEF Panel, 2011), the dietary exposure must not exceed 0.0025 μg/kg bw per day, below which the risk to human health is considered negligible. The C_{res} value should not exceed the modelled concentration in PET (C_{mod}) that, after 1 year at 25°C, results in a migration giving rise to a dietary exposure of 0.0025 μg/kg bw per day. Because the recycled PET is 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 into food and has been used to calculate C_{mod} (EFSA CEF Panel, 2011). The results of these calculations are shown in Table 2. The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

Table 2: Decontamination efficiency from the challenge test, residual concentrations of the surrogates in the recycled PET (C_{res}) and calculated concentrations of the surrogates in PET (C_{mod}) corresponding to a modelled migration of 0.1 μg/kg food after 1 year at 25°C

Surrogates	Decontamination efficiency (%)	C_{res} for 100% rPET (mg/kg PET)	C_{mod} (mg/kg PET)
Toluene	> 99.9	< 0.003	0.09
Chloroform	> 99.9	< 0.003	0.10
Phenylcyclohexane	> 99.9	< 0.003	0.14
Benzophenone	98.4	0.048	0.16
Lindane	90.9	0.273	0.31

PET, poly(ethylene terephthalate).
rPET, recycled poly(ethylene terephthalate).

As C_{res} values are lower than the corresponding modelled concentrations in PET (C_{mod}), the Panel considered that under the given operating conditions the recycling process rPET Aviv Shalam using the Starlinger iV+ 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 which the risk to human health is considered negligible.

The Panel noted that the input of the process originates from Israel. In the absence of data on misuse contamination of this input, the Panel used the reference contamination of 3 mg/kg PET (EFSA CEF Panel, 2011) that was derived from experimental data from an EU survey. Accordingly, the recycling process under evaluation using a Starlinger iV+ technology is able to ensure that the level of unknown contaminants in recycled PET is below a calculated concentration (C_{mod}) corresponding to a modelled migration of 0.1 μg/kg food.

4. Conclusions

The Panel considered that the process rPET Aviv Shalam using the Starlinger iV+ 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, the Panel concluded that the three steps (drying and crystallisation, extrusion and crystallisation, and SSP) are critical for the decontamination efficiency. The operating parameters to control its performance are the temperature, the air/PET ratio and the residence time for the drying and crystallisation (step 2), as well as the temperature, the pressure and the residence time for extrusion and crystallisation (step 3) and SSP (step 4).

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

i) it is operated under conditions that are at least as severe as those applied in the challenge test used to measure the decontamination efficiency of the process;
ii) the input material of the process is washed and dried post-consumer PET flakes originating from materials and articles that have been manufactured in accordance with the EU legislation on food contact materials and contain no more than 5% of PET from non-food consumer applications.
iii) the recycled PET obtained from the process rPET Aviv Shalam is 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.

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 as provided to EFSA

Dossier 'rPET Aviv Shalam'. August 2021. Submitted on behalf of rPET Aviv Shalam Ltd., Israel.
Additional information. October 2022. Submitted on behalf of rPET Aviv Shalam Ltd., Israel.

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Abbreviations

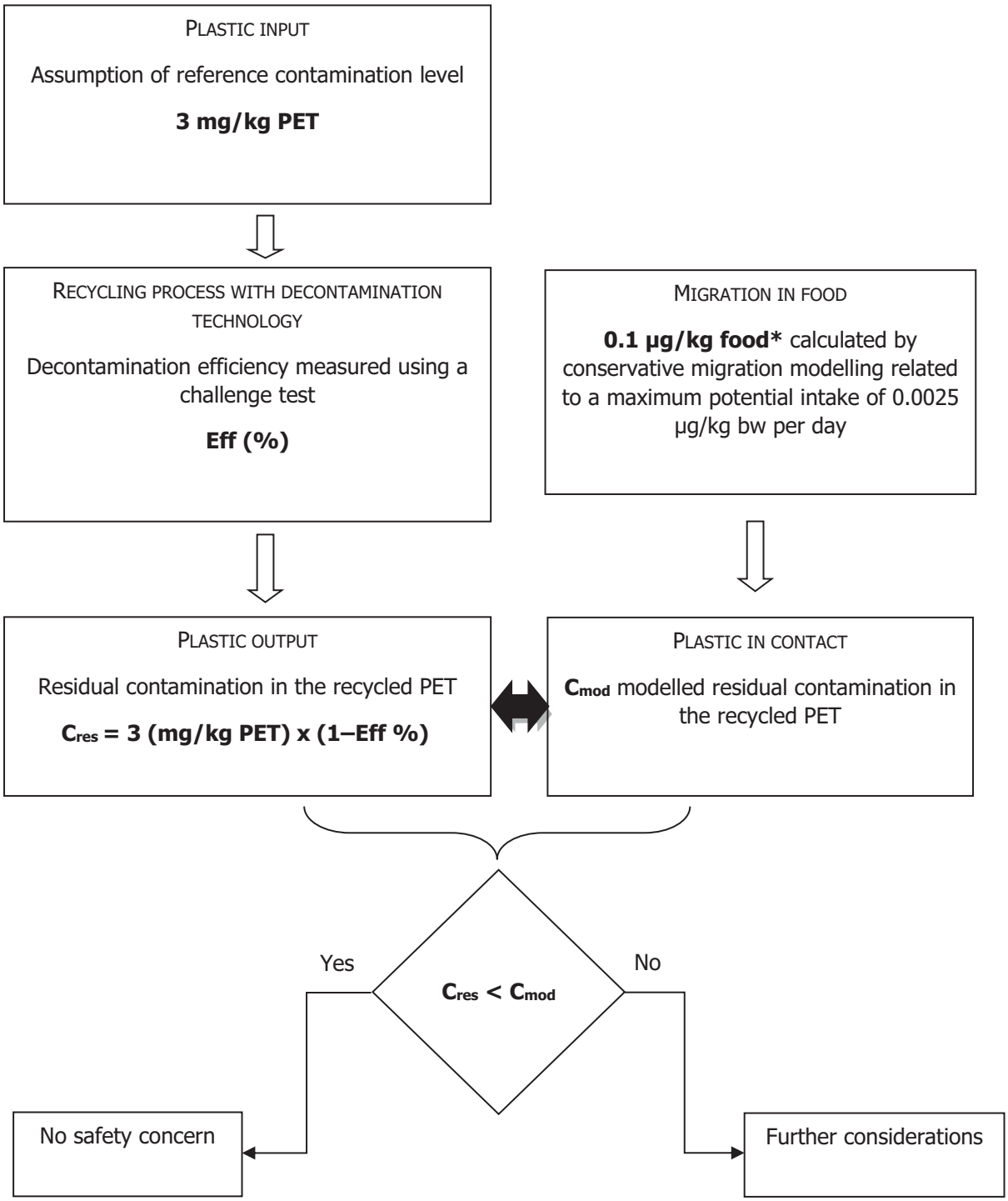
bw	body weight
CEF Panel	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP Panel	Panel on Food Contact Materials, Enzymes and Processing Aids
C_{mod}	modelled concentration in PET
C_{res}	residual concentrations in PET
iV	intrinsic viscosity
PET	poly(ethylene terephthalate)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

Appendix A – Technical data of the washed flakes as provided by the applicant[8]

Parameter	Value
PVC content	< 200 mg/kg
Polyolefin content	< 100 mg/kg
Metal content (aluminium, ferrous, others)	< 200 mg/kg
Other Plastics	< 200 mg/kg
Dust	< 1.5%
Moisture	< 2.5%
Bulk density	200–600 kg/m^3
Amount of non-food application PET	< 5%

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

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[13]

[redacted]

Process rPET Aviv Shalam (RECYC263) based on the Starlinger iV+ technology									
	Step 2, Drying and crystallisation			Step 3, Extrusion + vacuum degassing: 1st line, Crystallisation: 2nd line			Step 4, SSP process		
Parameters	**t (min)**	**Air/PET ratio (m^3/kg)**	**T (°C)**	**t**	**P (mbar)**	**T (°C)**	**t (h)**	**P (mbar)**	**T (°C)**
Challenge test (Fraunhofer report 4452/05)	[redacted] (batch)	approx. [redacted]	[redacted]	[redacted] s [redacted] min (crystallisation: batch)	[redacted] atmospheric	[redacted] [redacted]	[redacted] (batch)	[redacted]	[redacted]
Process	≥ [redacted] (continuous)	approx. [redacted]*	≥ [redacted]	[redacted] s ≥ [redacted] min (crystallisation: continuous)	≤ [redacted] atmospheric	≥ [redacted] ≥ [redacted]	≥ [redacted] (semi-continuous)	≤ [redacted]	≥ [redacted]

*Throughput = [redacted] kg/h, gas flow rate = [redacted] m^3/h.

[13] Technical dossier, section 'Table of operating parameters'.