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Safety assessment of the process Cirrec Netherlands BV, based on the EREMA Basic 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 Cirrec Netherlands BV (EU register number RECYC283), which uses the EREMA Basic technology. The input material is hot caustic washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, including less than 5% PET from non-food consumer applications. The flakes are heated in a continuous reactor under vacuum before being extruded. Having examined the challenge test provided, the Panel concluded that the continuous decontamination (step 2), for which a challenge test was provided, is critical in determining the decontamination efficiency of the process. The operating parameters to control the performance of this step are temperature, pressure and residence time. It was demonstrated that this recycling process is able to ensure a level of migration of potential unknown contaminants into food below the conservatively modelled migration of 0.1 μg/kg food, derived from the exposure scenario for infants when such recycled PET is used at up to 100%. Therefore, the Panel concluded that the recycled PET obtained from this process is not considered to be of safety concern when used at up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs, including drinking water, for long-term storage at room temperature or below, with or without hotfill. This evaluation does not cover uses of the recycled PET in microwaves or conventional ovens.

Keywords: EREMA Basic, Cirrec Netherlands BV, food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

Requestor: Dutch competent authority (Ministry of Health, Welfare and Sport)

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† Deceased.

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1. Introduction

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 from the Dutch competent authority (Ministry of Health, Welfare and Sport), an application for evaluation of the recycling process Cirrec Netherlands BV, European Union (EU) register No RECYC283. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2021-00575. The dossier was submitted on behalf of Cirrec Netherlands BV, Roelofshoeveweg 43, 6921 RH Duiven, The Netherlands (see 'Documentation provided to EFSA').

1.2. Terms of Reference

The Dutch competent authority (Ministry of Health, Welfare and Sport) requested the safety evaluation of the recycling process Cirrec Netherlands BV, in accordance with Regulation (EC) No 282/2008.

1.3. Interpretation of the Terms of Reference

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

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

2. Data and methodologies

2.1. Data

The applicant has submitted a dossier following the 'EFSA guidelines for the submission of an application for the safety evaluation of a recycling process to produce recycled plastics intended to be used for the manufacture of materials and articles in contact with food, prior to its authorisation' (EFSA, 2008) and the 'Administrative guidance for the preparation of applications on recycling processes to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food' (EFSA, 2021). In accordance with Art. 38 of the Commission Regulation (EC) No 178/2002[4] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation and of the Decision of the EFSA's Executive

[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 the procedure set in 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.

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

Director laying down practical arrangements concerning transparency and confidentiality[5], the non-confidential version of the dossier is published on Open.EFSA[6].

According to Art. 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations[7], EFSA carried out a public consultation on the non-confidential version of the application from 24 April to 15 May 2023, for which no comments were received.

Additional information was provided by the applicant during the assessment process in response to a request from EFSA sent on 20 April 2022 and 4 November 2022 (see'Documentation provided to EFSA').

Following the request made by the applicant, a clarification teleconference was held on 29 March 2023.

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 to be of safety concern for the defined conditions of use (EFSA CEF Panel, 2011).

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

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

[6] The non-confidential version of the dossier, following EFSA's assessment of the applicant's confidentiality requests, is published on Open.EFSA and is available at the following link: https://open.efsa.europa.eu/dossier/FCM-2021-1532.

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

3. Assessment

3.1. General information[8]

According to the applicant, the recycling process Cirrec Netherlands BV is intended to recycle food grade PET containers using the EREMA Basic technology. The recycled PET is intended to be used at up to 100% for thermoformed trays or containers, e.g. for fruits, vegetables, dry foods, fresh meat, dairy products, food-to-go, cooked and/or pre-cooked food including ready-meals or bottles for mineral water and other beverages or for packaging food for infants. It is intended for long-term food storage at room temperature or below, with or without hotfill.[9]

3.2. Description of the process

3.2.1. General description[10]

The recycling process Cirrec Netherlands BV produces recycled PET pellets from used PET material and articles from post-consumer collection systems (kerbside and deposit systems) and/or from material and articles collected directly from food industry/food retailers.

It comprises the three steps below.

Input

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

Decontamination and production of recycled PET material

- In step 2, the flakes are crystallised and decontaminated under high temperature and vacuum.
- In step 3, the decontaminated flakes are extruded to produce pellets.

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, haze, size, bulk density, melting point and moisture.

3.2.2. Characterisation of the input[11]

According to the applicant, the input material for the recycling process Cirrec Netherlands BV consists of hot washed and dried flakes obtained from PET containers, e.g. bottles, trays, etc., previously used for food packaging, from post-consumer collection systems (kerbside and deposit systems). The input material may also consist of materials or articles that have been collected directly from the food industry/food retailers. A small fraction may originate from non-food applications. According to the applicant, the proportion will be less than 5%.

Technical data on the hot washed and dried flakes are provided, such as on physical properties and residual contents of glue, labels, poly(vinyl chloride) (PVC), polypropylene (PP) as well as other plastics, cellulose and metals (see Appendix A).

3.3. EREMA Basic technology

3.3.1. Description of the main steps[12]

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

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8 Technical dossier, Section 'Recycling process', 'Intended application in contact with food', 'Compliance with the relevant provisions on food contact materials and articles'.

9 The application dossier also included the request for an evaluation of intended uses related to high temperature applications (i.e. microwave and conventional oven). Such uses do not currently fall under the definition of suitable technology described in row 1 of Table 1 of Annex I to Regulation (EU) 2022/1616. Therefore, as per Article 31(2) of Regulation (EU) 2022/1616 the part of the application covering these uses were deemed terminated as of the date of entry into force of this Regulation. Hence, the safety assessment was only carried out for the requested uses that are in scope of row 1 of Table 1 of Annex I to Regulation (EU) 2022/1616.

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

11 Technical dossier, Section 'Characterisation of the input'.

12 Technical dossier, Section 'Recycling process'.

- 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.

- Extrusion 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 to pellets.

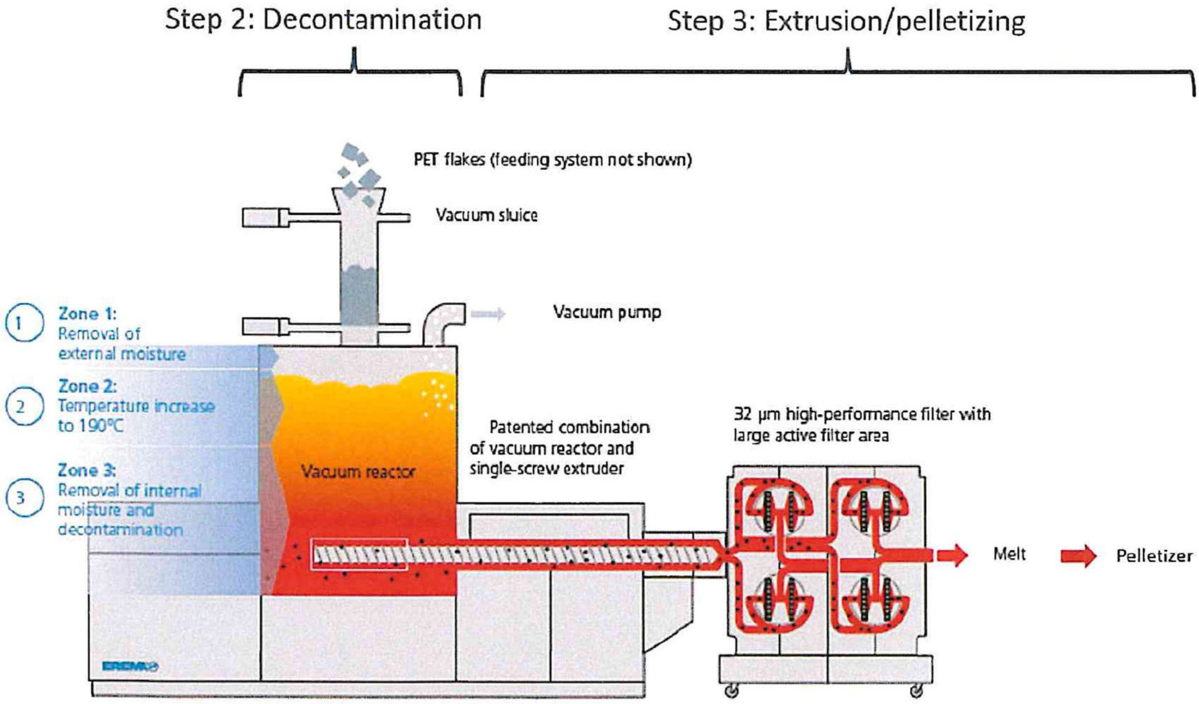

Figure 1: General scheme of the EREMA Basic technology (provided by the applicant)

The process is run under defined operating parameters[13] of temperature, pressure and residence time.

3.3.2. Decontamination efficiency of the recycling process[14]

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

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

Solid surrogates (benzophenone and methyl stearate) and liquid surrogates (toluene, chlorobenzene, chloroform, methyl salicylate and phenylcyclohexane) were added to 25 kg of conventionally recycled[15] post-consumer PET flakes. Sixteen such barrels were prepared and stored for 7 days at 50°C with periodical agitation. Afterwards, the contaminated flakes were rinsed with 10% ethanol. For each barrel, the concentrations of the surrogates in the flakes were determined. The barrels were shipped to the

[13] 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).
[14] Technical dossier, Sections 'Recycling process' and 'Determination of the decontamination efficiency of the recycling process'.
[15] Conventional recycling commonly includes sorting, grinding, washing and drying steps and produces washed and dried flakes.

EREMA facilities, where they were merged into [redacted], one of which was used for the challenge test.

The step 2 of the EREMA Basic technology was challenged at industrial scale. The contaminated flakes ([redacted]) were fed into the decontamination reactor. Samples were taken [redacted], then analysed for their concentrations of the applied surrogates.

Instead of being operated continuously (as in the industrial process), the challenge test was run in [redacted] 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. For the residence time, in order to prove the representativeness of the challenge test for 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 these results, the Panel concluded that the residence time in the challenge test [redacted] reactor corresponded to the minimum residence time in the industrial continuous reactor.

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

Table 1: Efficiency of the decontamination of the reactor (step 2) in the challenge test

Surrogates	Concentration of surrogates before step 2 (mg/kg PET)	Concentration of surrogates after step 2 (mg/kg PET)	Decontamination efficiency (%)
Toluene	391.3	0.6	99.8
Chlorobenzene	699.5	1.9	99.7
Chloroform	166.7	2.7	98.4
Methyl salicylate	982.6	5.7	99.4
Phenylcyclohexane	625.3	11.2	98.2
Benzophenone	927.1	15.2	98.4
Methyl stearate	1,599.1	9.7	99.4

PET: poly(ethylene terephthalate).

The decontamination efficiency ranged from 98.2% for phenylcyclohexane up to 99.8% for toluene.

3.4. Discussion

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

Technical data, such as on physical properties and residual contents of glue, labels, poly(vinyl chloride) (PVC), polypropylene (PP) as well as other plastics, cellulose and metals, were provided for the input materials (i.e. hot caustic 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, mouth wash or kitchen hygiene agents. According to the applicant, the collection system and the process are managed in such a way that this fraction will be less than 5% in the input stream, as recommended by the EFSA CEF Panel in its 'Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food' (EFSA CEF Panel, 2011).

The process is adequately described. The washing and drying of the flakes from the collected PET containers (step 1) is conducted in house and, according to the applicant, this step is under control. The EREMA Basic technology comprises the continuous decontamination (step 2) and the extrusion (step 3). The operating parameters of temperature, pressure and residence time for these steps have been provided to EFSA.

A challenge test to measure the decontamination efficiency was conducted at industrial plant scale on step 2. The reactor was operated under pressure and temperature conditions as well as residence time equivalent to or less severe than those of the commercial process. The Panel considered that this challenge test was performed correctly according to the recommendations of the EFSA guidelines (EFSA, 2008) and concluded that step 2 was critical for the decontamination efficiency of the process.

Consequently, temperature, pressure and residence time of step 2 should be controlled to guarantee the performance of the decontamination. These parameters have been provided to EFSA (Appendix C).

The decontamination efficiencies obtained from the challenge test on step 2, ranging from 98.2% 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 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 of the contaminant into the infant's food and has been used to calculate C_{mod} (EFSA CEF Panel, 2011). C_{res} reported in Table 2 is calculated for 100% recycled PET, for which the risk to human health is demonstrated to be negligible. The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

The Panel noted that the applicant

- also proposed a maximum migration of 0.625 μg/kg food for trays/containers not intended for contact with drinking water. This value corresponds to the food consumption according to Food Category 4 (20 g/kg bw per day; EFSA CEF Panel, 2016), applying the human exposure threshold value of 0.0025 μg/kg bw per day and the overestimation factor of 5 for modelling (EFSA CEF Panel, 2011);
- calculated concentrations by modelling for conditions different than 1 year at 25°C, namely 10 days at 40°C and 10 days at 60°C for tray/containers applications below and at room temperature, respectively.

These alternative scenarios were not considered relevant by the Panel in the context of the evaluation of this recycling process, as the process passes for 100% rPET even for the scenario related to a maximum migration of 0.1 μg/kg food and modelling conditions of 1 year at 25°C.

Table 2: Decontamination efficiency from the challenge test, residual concentrations of the surrogates (C_{res}) related to the reference contamination level and calculated concentrations of the surrogates in PET (C_{mod}) corresponding to a modelled migration of 0.1 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); infant scenario
Toluene	99.8	0.01	0.09
Chlorobenzene	99.7	0.01	0.09
Chloroform	98.4	0.05	0.10
Methyl salicylate	99.4	0.02	0.13
Phenylcyclohexane	98.2	0.05	0.14
Benzophenone	98.4	0.05	0.16
Methyl stearate	99.4	0.02	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 considered that under the given operating conditions the recycling process Cirrec Netherlands BV, using the EREMA Basic 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 or below, with or without hotfill.

4. Conclusions

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

The Panel concluded that the recycling process Cirrec Netherlands BV 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 less than 5% of PET from non-food consumer applications;
iii) the recycled PET is used at up to 100% for the manufacture of materials and articles for contact with all types of foodstuff, including drinking water, for long-term storage at room temperature or below, with or without hotfill.

This evaluation does not cover uses of the recycled PET in microwave or conventional ovens.

5. Recommendation

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

6. Documentation provided to EFSA

1) Dossier 'Cirrec Netherlands BV'. November 2021. Submitted on behalf of Cirrec Netherlands BV, The Netherlands.
2) Additional information, July 2022. Submitted on behalf of Cirrec Netherlands BV, The Netherlands.
3) Additional information, December 2022. Submitted on behalf of Cirrec Netherlands BV, The Netherlands.

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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. 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

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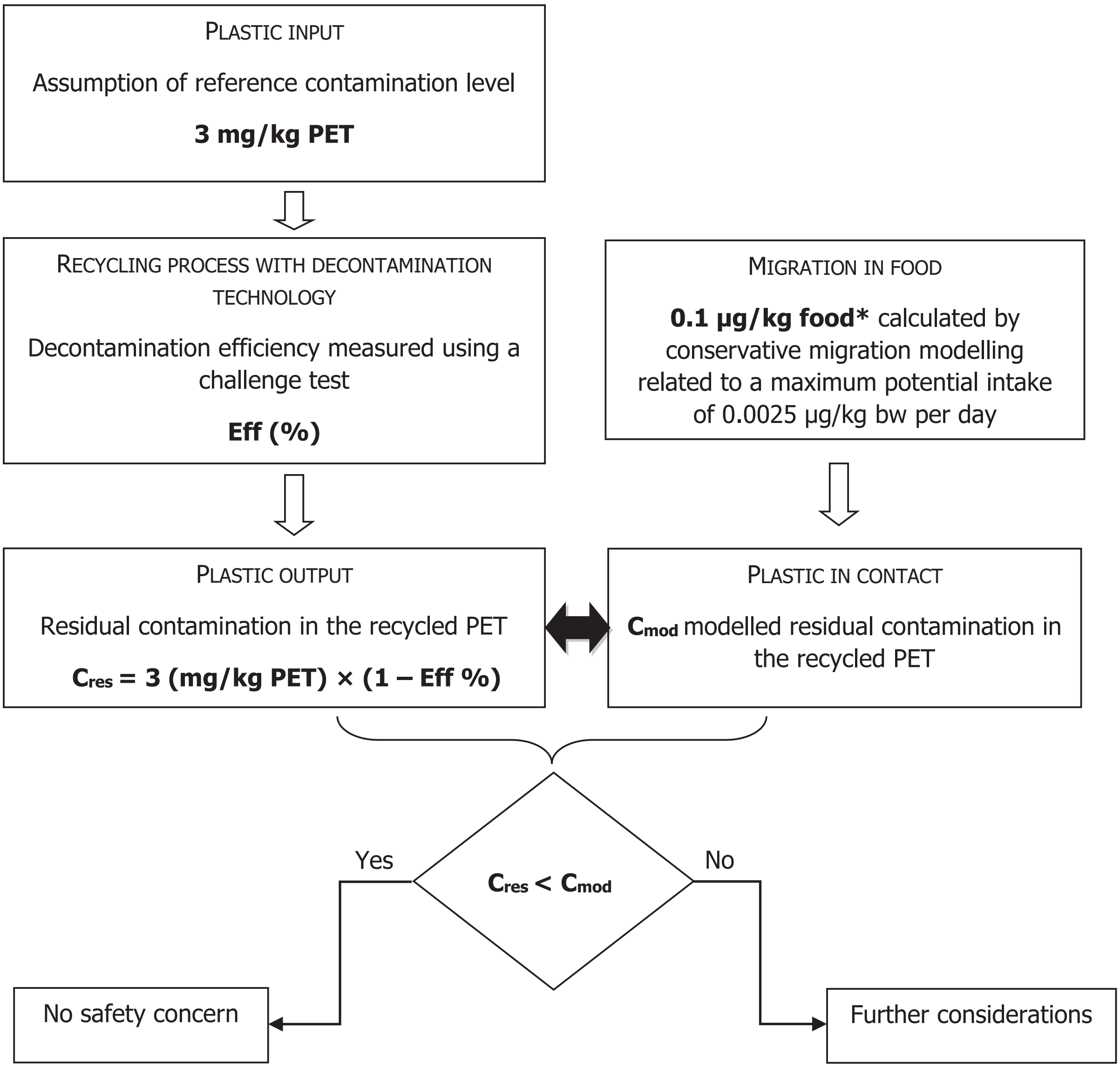
Abbreviations

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 concentration in PET
IV	intrinsic viscosity
PET	poly(ethylene terephthalate)
PP	Polypropylene
PVC	poly(vinyl chloride)
rPET	recycled poly(ethylene terephthalate)

Appendix A – Standard technical specifications for hot washed flakes as provided by the applicant[10]

Parameter	Value
PET purity min.	99%
Total non-PET contamination max.	1%
Intrinsic viscosity	0.55–0.8 dL/g
Moisture max.	1.0%
Bulk density min.	250 kg/m^3
Flake size	1–10 mm
Glue max.	350 mg/kg
Labels max.	300 mg/kg
PVC max.	600 mg/kg
PP max.	3,000 mg/kg
PE max.	6,000 mg/kg
PS max.	3,000 mg/kg
PA/EVOH multilayer max.	50 mg/kg
Other plastics (PA, PC, MXD6, etc.) max.	70 mg/kg
Cellulose (paper and wood fibres) max.	5 mg/kg
Metals max.	10 mg/kg
Other contaminants (particulates) max.	5 mg/kg

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[16]

[redacted]

Process Cirrec Netherlands BV (RECYC283) based on the EREMA Basic technology						
	Step 2 ***Reactor***			**Step 3** ***Extrusion***		
Parameters	**t [min]**	**P [mbar]**	**T [°C]**	**t [s]**	**P [mbar]***	**T [°C]**
Challenge test (Fraunhofer report PA/4111/19)	[redacted] [redacted]	[redacted]	[redacted]		[redacted]	
Process	[redacted] [redacted]	[redacted]	[redacted]	[redacted] [redacted]		[redacted]

[redacted]

[16] Technical dossier, Sections 'Recycling process' and 'Table of operating parameters'.