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Safety assessment of the process Acepolymer, based on the Vacurema Prime technology, used to recycle post-consumer PET into food contact materials

EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP),
Claude Lambré, José Manuel Barat Baviera, Claudia Bolognesi, Andrew Chesson,
Pier Sandro Cocconcelli, Riccardo Crebelli, David Michael Gott, Konrad Grob,
Marcel Mengelers, Alicja Mortensen, Gilles Rivière, Inger-Lise Steffensen, Christina Tlustos,
Henk Van Loveren, Laurence Vernis, Holger Zorn, Vincent Dudler, Maria Rosaria Milana,
Constantine Pappaspyrides, Maria de Fátima Tavares Poças, Emmanouil Tsochatzis and
Evgenia Lampi

Abstract

The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) assessed the safety of the recycling process Acepolymer (EU register number RECYC305), which uses the Vacurema Prime 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 heated in a batch reactor (Step 2) under vacuum and then treated at higher temperature in a continuous reactor (Step 3) under vacuum before being extruded into pellets. Having examined the challenge test provided, the Panel concluded that Steps 2 and 3 are critical in determining the decontamination efficiency of the process. The operating parameters to control the performance of these steps are temperature, pressure and residence time. 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, soft drinks, juices, tea, milk, oil, alcoholic beverages and other food products, for long-term storage at room temperature or below, with or without hot fill. 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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Correspondence: fip@efsa.europa.eu

Panel members: José Manuel Barat Baviera, Claudia Bolognesi, Andrew Chesson, Pier Sandro Coconcelli, Riccardo Crebelli, David Michael Gott, Konrad Grob, Claude Lambré, Evgenia Lampi, Marcel Mengelers, Alicja Mortensen, Gilles Rivière, Vittorio Silano (until 21 December 2020[†]), Inger-Lise Steffensen, Christina Tlustos, Henk Van Loveren, Laurence Vernis and Holger Zorn.

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[†] Deceased.

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1. Introduction

1.1. Background and Terms of Reference

1.1.1. Background

Recycled plastic materials and articles shall only be placed on the market if the recycled plastic is from an authorised recycling process. Before a recycling process is authorised, the European Food Safety Authority (EFSA)'s opinion on its safety is required. This procedure has been established in Article 5 of Regulation (EC) No 282/2008^{1,2} on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of Regulation (EC) No 1935/2004³ 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 transmits the applications to EFSA for evaluation.

In this case, EFSA received, from the für Verbraucherschutz und Lebensmittelsicherheit, an application for evaluation of the recycling process Acepolymer, European Union (EU) register No RECYC305. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2022-00528. The dossier was submitted on behalf of Acepolymer Co., Ltd., Paltan-myeon, Hwaseong-si, Gyeonggi-do, 8742-28, Sicheong-ro, Republic of Korea.

1.1.2. Terms of Reference

The Bundesamt für Verbraucherschutz und Lebensmittelsicherheit requested the safety evaluation of the recycling process Acepolymer, in accordance with Regulation (EC) No 282/2008 and Articles 8, 9 and 10 of the Regulation (EC) 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 Acepolymer 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 provided by the applicant during the assessment process in response to requests from EFSA sent on 27 March 2023 and was subsequently provided (see '[Documentation provided to EFSA](#)').

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

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

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

In accordance with Art. 38 of the Regulation (EC) No 178/2002⁴ and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,⁵ the non-confidential version of the dossier has been published on Open.EFSA.⁶

According to Art. 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations,⁵ EFSA carried out a public consultation on the non-confidential version of the application from 03 August to 24 August 2023, for which no comments were received.

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

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

2.2. Methodologies

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

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

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

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

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

⁶ The non-confidential version of the dossier has been published on Open.EFSA and is available at the following link: <https://open.efsa.europa.eu/dossier/FCM-2022-8030>

3. Assessment

3.1. General information⁷

According to the applicant, the recycling process Acepolymer is intended to recycle food grade PET containers using the Vacurema Prime technology. The recycled PET is intended to be used at up to 100% for the manufacture of materials and articles for direct contact with all kinds of foodstuffs, such as drinking water, soft drinks, juices, tea, milk, oil, alcoholic beverages and other food products, for long-term storage at room temperature or below, with or without hot fill. The final articles are not intended to be used in microwave or conventional ovens.

3.2. Description of the process

3.2.1. General description⁸

The recycling process Acepolymer 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 is performed by a third party.

Decontamination and production of recycled PET pellets

- In Step 2, the flakes are crystallised and decontaminated under high temperature and vacuum in a batch reactor.
- In Step 3, flakes are further treated in a continuous reactor under high temperature and vacuum.
- In Step 4, the flakes are extruded into 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, moisture, colour, size, bulk density and black spots.

3.2.2. Characterisation of the input⁹

According to the applicant, the input material for the recycling process Acepolymer 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 on physical properties and residual contents of moisture, poly(vinyl chloride) (PVC), high density polyethylene (HDPE)/polypropylene (PP) and aluminium (see Appendix A).

3.3. Vacurema Prime technology

3.3.1. Description of the main steps¹⁰

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

- Decontamination and crystallisation in twin batch reactors (Step 2): The flakes are introduced into twin batch reactors, where vacuum and heat are applied for a predefined residence time. These reactors alternately feed a continuous reactor (Step 3).

⁷ Technical dossier, sections 'Recycling process' and 'Intended application in contact with food'.

⁸ Technical dossier, sections 'Recycling process', 'Characterisation of the input' and 'Characterisation of the recycled plastic'.

⁹ Technical dossier, section 'Characterisation of the input'.

¹⁰ Technical dossier, sections 'Recycling process' and 'Determination of the decontamination efficiency of the recycling process'.

- Further decontamination in the continuous reactor (Step 3): The flakes from the batch reactors are further treated in a continuous reactor, running under high temperature and vacuum for a predefined residence time.
- Extrusion (Step 4): The flakes continuously coming from the reactor are melted in the extruder and residual solid particles (e.g. paper, aluminium) are filtered out before pellets are produced.

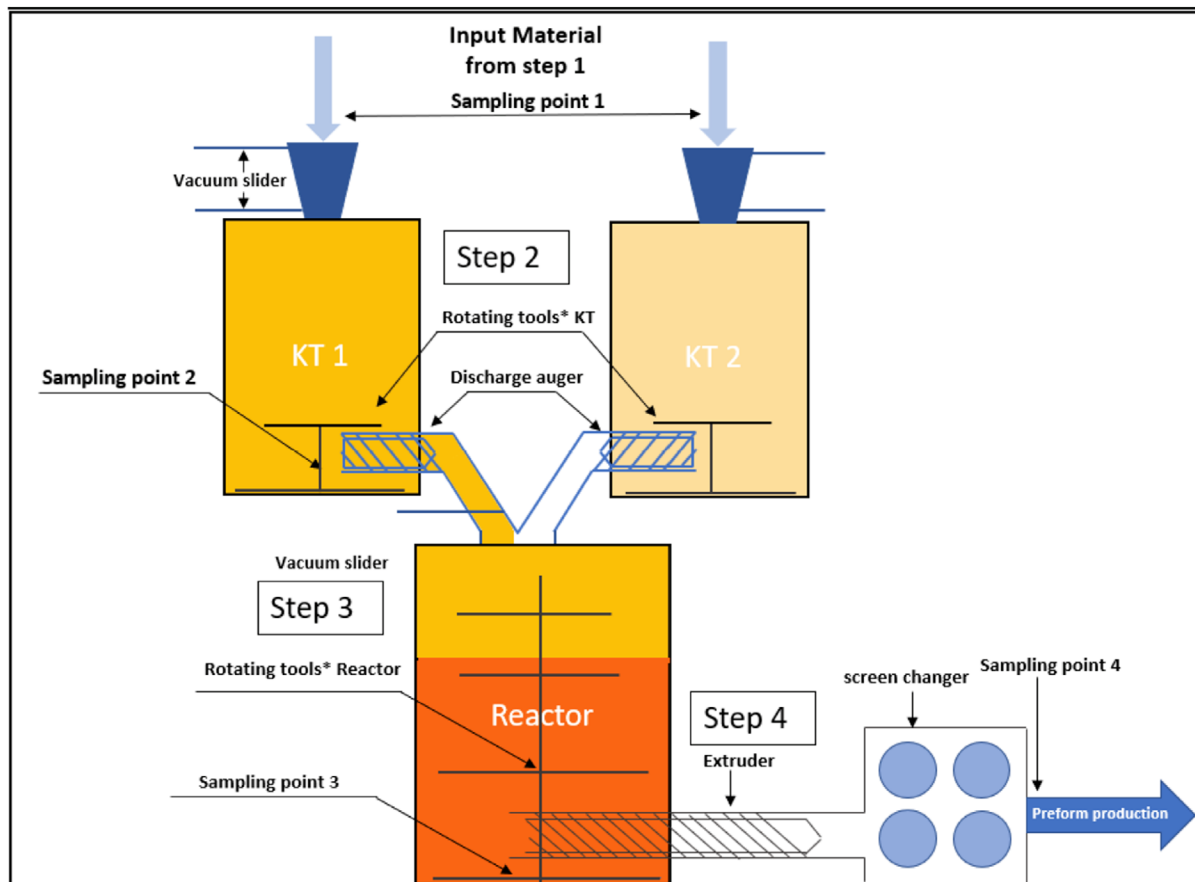


Figure 1: General scheme of the **Vacurema Prime** technology (provided by the applicant)

The process is run under defined operating parameters¹¹ of temperature, pressure and residence time.

3.3.2. Decontamination efficiency of the recycling process¹²

To demonstrate the decontamination efficiency of the recycling process Acepolymer, a challenge test 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).

For the preparation of the contaminated PET flakes, ████ kg of conventionally recycled¹³ post-consumer PET flakes of green colour was soaked in a heptane/isopropanol solution containing the surrogates and stored for 14 days at 40°C. The surrogate's solution was decanted and PET flakes were rinsed with water and then air-dried. The concentration of surrogates in this material was determined.

¹¹ In accordance with Art. 9 and 20 of Regulation (EC) No 1935/2004 the parameters were provided to EFSA by the applicant and made available to the Member States and the European Commission (see Appendix C).

¹² Technical dossier, section 'Determination of the decontamination efficiency of the recycling process'.

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

The challenge test was performed in a [REDACTED] of [REDACTED] from Step 2 to Step 4. The batch reactor was filled with washed and dried flakes, both white non-contaminated and green flakes contaminated with surrogates. Green flakes were sampled at regular intervals after each step. After Steps 2 and 3 (before extrusion), green flakes were isolated and analysed for their residual concentrations of the applied surrogates. In the extrusion process (Step 4), contaminated and non-contaminated material were melted together and at the end pellet samples were taken for analysis.

The decontamination efficiency was calculated based on the concentrations of the surrogates in the green contaminated flakes before and after Step 2 operated in batch mode at the residence time as specified in the Table of operating parameters (Appendix C). The results are summarised in Table 1.

Table 1: Efficiency of the decontamination of the technology in the challenge test

Surrogates	Concentration ^(a) of surrogates before Step 2 (mg/kg PET)	Concentration ^(a) of surrogates after Step 2 (mg/kg PET)	Decontamination efficiency (%)
Toluene	1,190	< 0.7 ^(b)	> 99.9
Chloroform	2,078	5.4	99.7
Phenylcyclohexane	113.3	0.9	99.2
Benzophenone	410	3.3	99.2
Lindane	95.2	4.1	95.7

PET: poly(ethylene terephthalate).

(a): Measured in green, contaminated, flakes.

(b): Not detected at the limit of detection given.

As shown in Table 1, the decontamination efficiency over Step 2 ranged from 95.7% for lindane to more than 99.9% 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 PVC, polyolefins (HDPE/PP) and aluminium, 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, such as bottles for soap, mouthwash or kitchen hygiene agents. 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 collected PET containers (Step 1) is conducted by a third party. The Vacurema Prime technology comprises the batch decontamination reactors (Step 2), the continuous reactor (Step 3) and extrusion (Step 4). The operating parameters of temperature, pressure and residence time for Steps 2 and 3 have been provided to EFSA. For Step 4, the operating parameters of temperature and residence time are also provided.

A challenge test was conducted at a [REDACTED] on process Steps 2, 3 and 4. The decontamination efficiency was determined based on Step 2.

Decontamination efficiencies were calculated by determining residual surrogates only in contaminated (green) flakes. Cross-contamination by diffusion of contaminants from green to white flakes may occur, possibly resulting in an overestimation of the decontamination efficiency. However, the Panel considered cross-contamination to be compensated for by the additional decontamination in the subsequent steps. In Step 3 [REDACTED] as in Step 2, but [REDACTED]. Therefore, the decontamination efficiency of Step 3 is at least comparable to that of Step 2. Moreover, the slow discharging of material from Step 2 provides additional residence time to Step 2, and the extrusion (Step 4) further contributes to the overall decontamination. Therefore, the Panel concluded that the decontamination efficiency of the part of Step 2 up to the discharging time, without taking

into account the cross-contamination, can be considered as a conservative estimate of the total decontamination efficiency of the process.

The Panel considered that this challenge test was performed correctly according to the recommendations of the EFSA guidelines (EFSA, 2008) and concluded that the two steps, the decontamination in batch reactors (Step 2) and the decontamination in the continuous reactor (Step 3) are critical for the decontamination efficiency of the process. Consequently temperature, pressure and residence time of the Steps 2 and 3 of the process should be controlled to guarantee the performance of the decontamination. These parameters have been provided to EFSA.

The decontamination efficiencies obtained from the challenge test data on Step 2, ranging from 95.7% to > 99.9%, have been used to calculate the residual concentrations of potential unknown contaminants in PET (C_{res}) in accordance with the evaluation procedure described in the 'Scientific opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET' (EFSA CEF Panel, 2011; Appendix B). By applying the decontamination efficiency percentage to the reference contamination level of 3 mg/kg PET, C_{res} for the different surrogates is obtained (Table 2).

According to the evaluation principles (EFSA CEF Panel, 2011), the dietary exposure must not exceed 0.0025 $\mu\text{g}/\text{kg}$ bw per day, below which the risk to human health is considered negligible.¹⁴ 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 $\mu\text{g}/\text{kg}$ 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 $\mu\text{g}/\text{kg}$ bw per day corresponds to a maximum migration of 0.1 $\mu\text{g}/\text{kg}$ 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 concentration of the surrogates in then recycled PET (C_{res}) and calculated concentrations of the surrogates in PET corresponding to modelled migrations of 0.10 $\mu\text{g}/\text{kg}$ food after 1 year at 25°C (C_{mod})

Surrogates	Decontamination efficiency (%)	C_{res} for 100% rPET (mg/kg PET)	C_{mod} (mg/kg PET)
Toluene	> 99.9	< 0.003	0.09
Chloroform	99.7	0.009	0.10
Phenylcyclohexane	99.2	0.024	0.14
Benzophenone	99.2	0.024	0.16
Lindane	95.7	0.129	0.31

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 Acepolymer using the Vacurema Prime 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 $\mu\text{g}/\text{kg}$ 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 for long-term storage at room temperature or below, with or without hot fill.

The Panel noted that the input of the process originates from Republic of Korea. 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 Vacurema Prime 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 $\mu\text{g}/\text{kg}$ food.

¹⁴ 0.0025 $\mu\text{g}/\text{kg}$ 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 process Acepolymer using the Vacurema Prime 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 temperature, the pressure and the residence time in the batch reactors (Step 2) and in the continuous reactor (Step 3) 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 Acepolymer 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 Vacurema Prime is used at up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs for long-term storage at room temperature or below, with or without hot fill.

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.

Documentation as provided to EFSA

Dossier 'Vacurema Prime'. January 2023. Submitted on behalf of Acepolymer Co., Ltd., Republic of Korea.

Additional information, May 2023. Submitted on behalf of Acepolymer Co., Ltd., Republic of Korea.

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Abbreviations

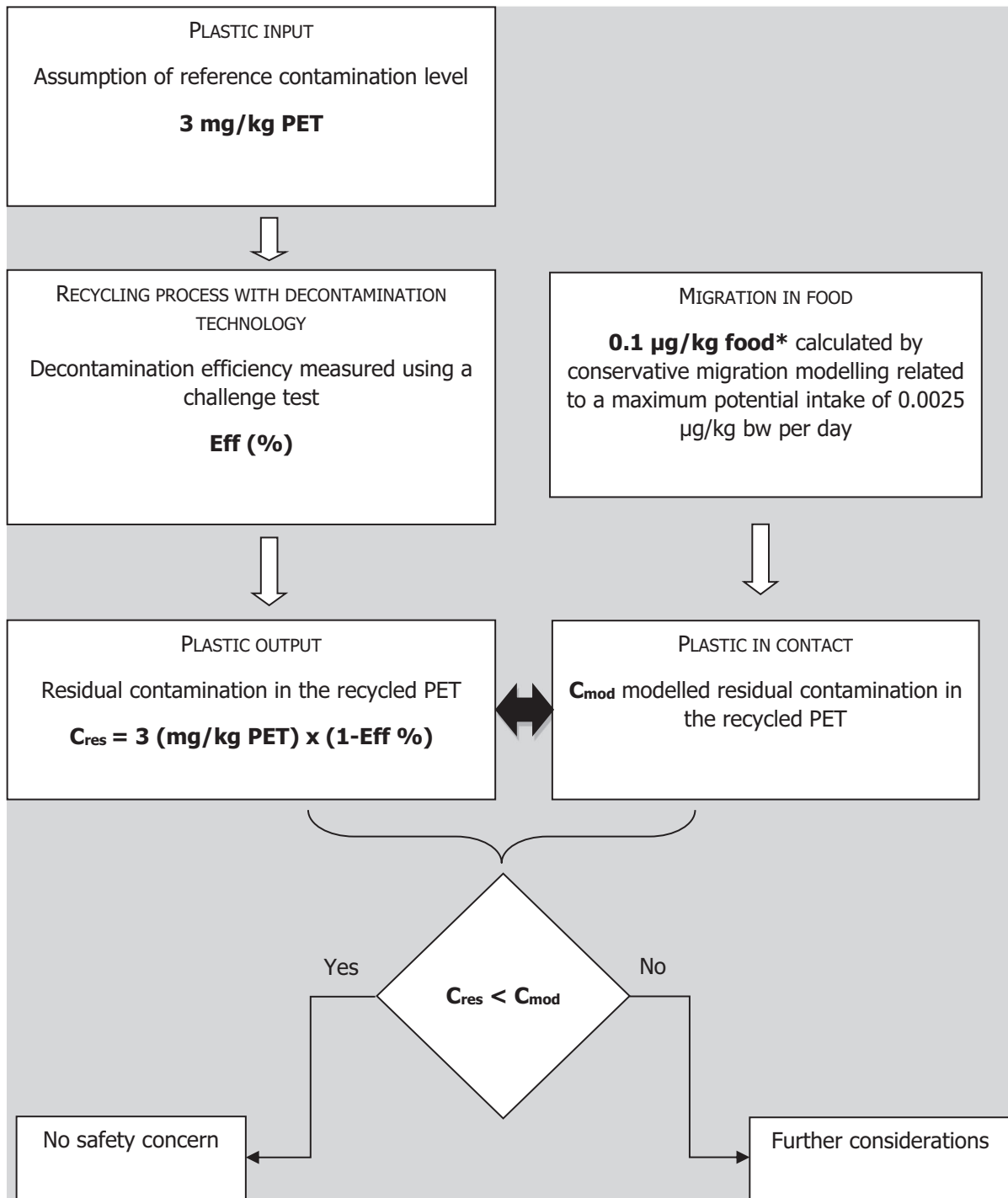
bw	body weight
CEF Panel	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP Panel	Panel on Food Contact Materials, Enzymes and Processing Aids
C_{mod}	modelled concentration in PET
C_{res}	residual concentrations in PET
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)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

Appendix A – Technical data of the washed flakes as provided by the applicant⁹

Parameter	Value
Bulk density	250–380 kg/m ³
Intrinsic viscosity	0.70–0.73 dL/g
Moisture	< 1.0%
PVC content	< 50 mg/kg
HDPE/PP	< 15 mg/kg
Aluminium	< 20 mg/kg

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 (Confidential Information)¹⁵

[Redacted text block]

Process Acepolymer (RECYC305) based on the Vacurema Prime technology

[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]

[Redacted text block]

¹⁵ Technical dossier, section 'Table of operating parameters'.

¹⁶ Please note that the operational parameters applied in the Challenge Test (CT) were not usable as such for the process (see explanation in the opinion) and therefore, the critical parameters to be controlled indicated in the table are those derived from the CT.