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SCIENTIFIC OPINION

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Safety assessment of the process Reliance Industries, based on the ProTec 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 Reliance Industries (EU register number RECYC315), which uses the ProTec technology. The input material consists of washed and dried poly(ethylene terephthalate) (PET) flakes, mainly originating from collected post-consumer PET containers, e.g. bottles, with no more than 5% PET from non-food consumer applications. The flakes are extruded into pellets (step 1), crystallised (step 2) and treated in a solid-state polycondensation (SSP) reactor (step 3). Having examined the challenge test provided, the Panel concluded that the extrusion and the decontamination in the [redacted] SSP reactor (steps 1 and 3) are critical in determining the decontamination efficiency of the process. The operating parameters to control the performance of these critical 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 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. 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.

KEYWORDS

food contact materials, plastic, poly(ethylene terephthalate) (PET), ProTec, recycling process, Reliance Industries Limited, safety assessment

CONTENTS

1 | INTRODUCTION

1.1 | Background and Terms of Reference

1.1.1 | Background

Recycled plastic materials and articles shall only be placed on the market if the recycled plastic is from an authorised recycling process. Before a recycling process is authorised, the European Food Safety Authority (EFSA)'s opinion on its safety is required. This procedure has been established in Article 5 of Regulation (EC) No 282/2008[1,2] on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of Regulation (EC) No 1935/2004[3] on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the competent authorities of Member States, which transmit the applications to EFSA for evaluation.

In this case, EFSA received an application from the Federal Public Service Health, Food Chain Safety and Environment, Belgium, an application for evaluation of the recycling process Reliance Industries, European Union (EU) register No RECYC315. The request has been registered in EFSA's register of received questions under the number Q-2022-00616. The dossier was submitted on behalf of Reliance Industries Limited, 222 Nariman Point, Mumbai, Maharashtra 400,021, India (see 'Documentation provided to EFSA').

1.1.2 | Terms of Reference

The Federal Public Service Health, Food Chain Safety and Environment, Belgium, requested the safety evaluation of the recycling process Reliance Industries, in compliance with Article 5 of Regulation (EC) No 282/2008.

1.2 | Interpretation of the Terms of Reference

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

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

2 | DATA AND METHODOLOGIES

2.1 | Data

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

Additional information was provided by the applicant during the assessment process in response to a request from EFSA sent on 25 May 2023 (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, p. 9–18.

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

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

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 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 21 November to 12 December 2023 for which no comments were received.

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

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

2.2 | Methodologies

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

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

3 | ASSESSMENT

3.1 | General information[8]

According to the applicant, the recycling process Reliance Industries is intended to recycle food grade PET containers using the ProTec technology.[9] 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 for long-term storage at room temperature or below, with or without hotfill,

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

[5]Decision available at 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-2022-6331

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

[8]Technical dossier, Section 'Recycling process'.

[9]Previously known as OHL technology.

such as bottles for drinking water, carbonated soft drinks, sport drinks, edible oil, alcoholic liquors and juices. 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[10]

The recycling process Reliance Industries produces recycled PET pellets from PET containers (e.g. bottles), coming from post-consumer collection systems (curbside and reverse vending machine collection programs).

The recycling process comprises the three steps below.

Input:

- the post-consumer PET containers are washed and converted into dried flakes. This step is performed by a third party.

Decontamination and production of recycled PET material:

- in step 1, the flakes are extruded under vacuum; the plastic is filtered and pelletised;
- in step 2, the pellets are crystallised [redacted] during a short time;
- in step 3, the crystallised pellets are treated in a solid-state polycondensation (SSP) reactor [redacted].

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

Pellets, the final product of the process, are checked against technical requirements, such as the intrinsic viscosity, colour, melting point, crystallinity and presence of acetaldehyde.

3.2.2 | Characterisation of the input[11]

According to the applicant, the input material for the recycling process Reliance Industries consists of hot washed and dried flakes obtained from PET containers, mainly bottles previously used for food packaging, from post-consumer collection systems (curbside and reverse vending machine collection). A small fraction may originate from non-food applications. According to the applicant, the proportion of this non-food container fraction depends on the collection system and 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, poly(vinyl chloride) (PVC), other plastics, glue, glass and metals (see Appendix A).

3.3 | ProTec technology

3.3.1 | Description of the main steps[12]

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

- Extrusion, filtration and pelletising (step 1): The flakes are fed into an extruder operating under vacuum. The extruded melt is filtered and converted into amorphous pellets.
- Crystallisation (step 2): The pellets are crystallised [redacted] for a predefined residence time.
- SSP (step 3): The crystallised pellets are introduced into a tumble dryer for solid-state polycondensation (SSP) [redacted] for a predefined residence time, [redacted].

[10]Technical dossier, Sections 'Recycling process', 'Characterisation of the input' and 'Characterisation of the recycled plastic'.
[11]Technical dossier, Section 'Characterisation of the input'.
[12]Technical dossier, Sections 'Recycling process' and 'Determination of the decontamination efficiency of the recycling process'.

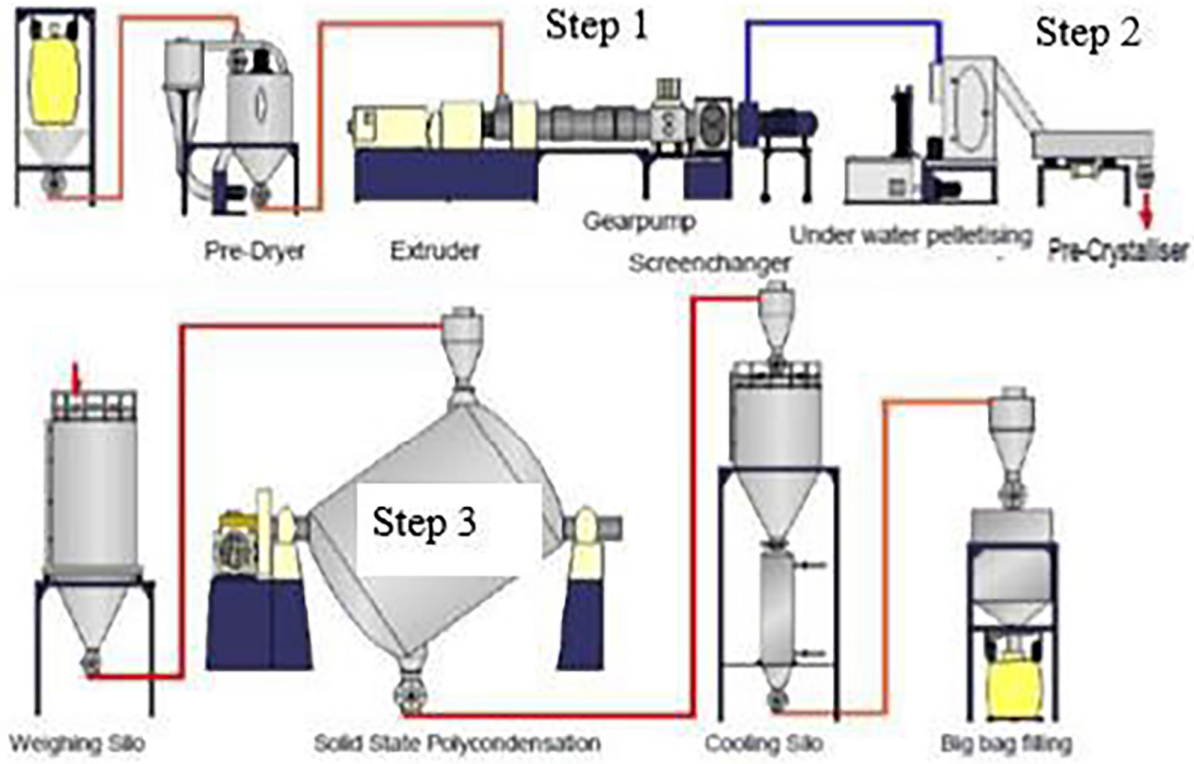

FIGURE 1 General scheme of the Protec technology (provided by the applicant).

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 Reliance Industries, a challenge test performed [redacted] 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).

The mixture containing the surrogates was added to conventionally recycled[15] post-consumer PET flakes and these flakes were stored for 7 days at 50°C under periodical agitation. The PET flakes were rinsed and the concentration of surrogates in these flakes was determined.

The challenge test was performed [redacted] on steps 1, 2 and 3 (extrusion, crystallisation and SSP). In the challenge test, the extruder was fed with only contaminated flakes and the extruded pellets were fed to the tumble dryer. The pellets were sampled before the SSP reactor and at regular intervals after the reactor and analysed for their residual concentrations of the applied surrogates.

The decontamination efficiency of the process was calculated from the concentrations of the surrogates measured in the washed contaminated flakes before extrusion (step 1) and in the pellets after SSP (step 3). The results are summarised below in Table 1.

[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, Section 'Determination of the decontamination efficiency of the recycling process'.

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

TABLE 1 Efficiency of the decontamination by the ProTec technology in the challenge test.

Surrogates	Concentration of surrogates before step 1 (mg/kg PET)	Concentration of surrogates after step 3 (mg/kg PET)	Decontamination efficiency (%)
Toluene	212.7	0.2	99.9%
Chloroform	393.8	0.4	99.9%
Chlorobenzene	309.4	1.1	99.6%
Phenylcyclohexane	293.4	6.8	97.7%
Methyl salicylate	236.5	0.4	99.8%
Benzophenone	310.5	10.9	96.5%
Methyl stearate	129.5	2.4	98.1%

Abbreviations: PET, poly(ethylene terephthalate).

As shown in Table 1, the decontamination efficiency ranged from 96.5% for benzophenone to 99.9% for toluene and chloroform.

3.4 | Discussion

Considering [redacted] 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 on residual contents of moisture, poly(vinyl chloride) (PVC), other plastics, glue, glass and metals were provided for the input materials (i.e. washed and dried flakes). These are produced from PET containers, e.g. bottles, previously used for food packaging collected through post-consumer collection systems. However, a small fraction may originate from non-food applications such as bottles for soap, mouthwash or kitchen hygiene agents. According to the applicant, the collection system and the 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 containers is conducted by third parties and, according to the applicant, this step is under control. The ProTec technology comprises extrusion, filtration and pelletisation (step 1), crystallisation (step 2) and SSP (step 3). The operating parameters of temperature, residence time and pressure have been provided to EFSA.

A challenge test to measure the decontamination efficiency was conducted [redacted] on process steps 1, 2 and 3. The Panel considered that this challenge test was performed correctly according to the recommendations in the EFSA guidelines (EFSA, 2008). The Panel considered that steps 1 (extrusion) and 3 (SSP) are critical for the decontamination efficiency of the process. Consequently, the temperature, the pressure and the residence time for extrusion (step 1) and SSP (step 3) should be controlled to guarantee the performance of the decontamination (Appendix C).

The decontamination efficiencies obtained for each surrogate, ranging from 96.5% 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 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 (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)
Toluene	99.9%	0.003	0.09
Chloroform	99.9%	0.003	0.10
Chlorobenzene	99.6%	0.01	0.09
Phenylcyclohexane	97.7%	0.07	0.14
Methyl salicylate	99.8%	0.01	0.13
Benzophenone	96.5%	0.11	0.16
Methyl stearate	98.1%	0.06	0.32

Abbreviation: PET, poly(ethylene terephthalate).

On the basis of the provided data from the challenge test and the applied conservative assumptions, the Panel concluded that, under the given operating conditions, the recycling process Reliance Industries, using the ProTec technology, is able to ensure that the level of migration of unknown contaminants from the recycled PET into food is below the conservatively modelled migrations of 0.10 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.

The Panel noted that the input of the process originates from India. 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 ProTec 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 Reliance Industries using the ProTec 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 two steps 1 and 3 (extrusion and SSP) are critical for the decontamination efficiency. The operating parameters to control its performance are temperature, pressure and residence time for these steps.

The Panel concluded that the recycling process Reliance Industries 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 containing no more than 5% of PET from non-food consumer applications;
(iii) the recycled PET obtained from the process Reliance Industries 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 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 | RECOMMENDATIONS

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 'Reliance Industries', February 2023. Submitted on behalf of Reliance Industries Limited, India.
2. Additional information, August 2023. Submitted on behalf of Reliance Industries Limited, India.

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
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)
rPET	recycled poly(ethylene terephthalate)

ACKNOWLEDGEMENTS

The Panel wishes to thank Elisa Savini for the support provided to this scientific output.

CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

Agencia Española de Seguridad Alimentaria y Nutrición

QUESTION NUMBER

Q-2022-00616

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APPENDIX A

Technical data of the washed flakes as provided by the applicant.[16]

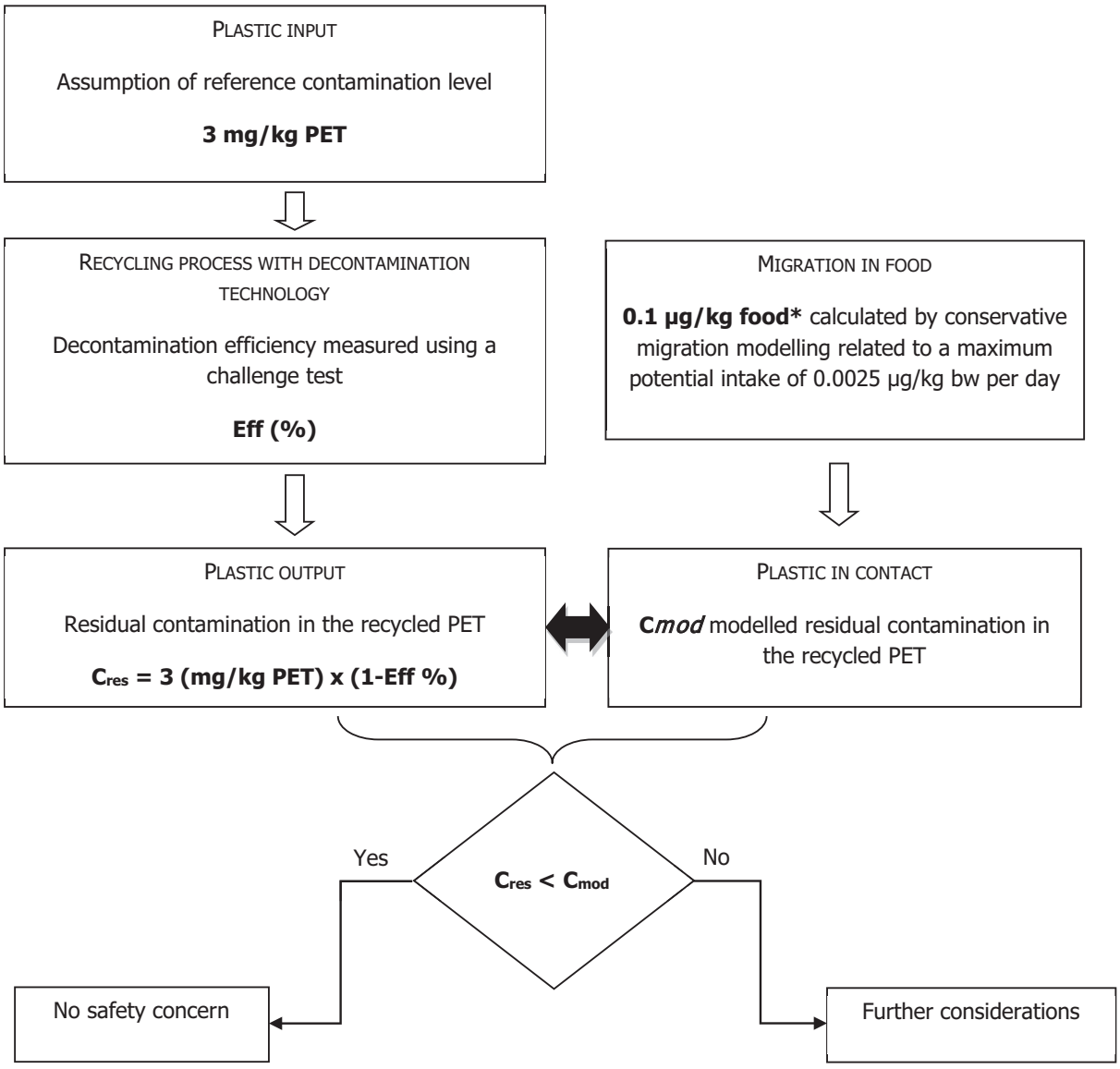
Parameter	Value
Flowability	Free flowing
Intrinsic viscosity	0.68 (dL/g)
Moisture content	< 0.7%
Colour	Clear
L*	> 65 (CIE)
b*	< 3 (CIE)
Bulk density	250–400 kg/m^3
Particle size distribution	10–14 mm
Fines (< 0.5 mm)	< 0.3%
pH	7 ± 0.5
Chemical wash residuals	< 2 ppm
Floatable contamination	< 10 ppm
PVC contamination	< 30 ppm
Other Plastics contamination	< 20 ppm
Glue contamination	< 10 ppm
Metal contamination	< 5 ppm
Light blue colour contamination	< 100 ppm
Yellow colour contamination	< 100 ppm
Mix Coloured contamination	< 50 ppm
Black PET etc.	< 5 ppm
Glass contamination	NIL
OTHERS (Rubber, Cloth, Stone)	NIL

Abbreviation: PVC, poly(vinyl chloride).

[16]Technical dossier, Section 'Characterisation of the input'.

APPENDIX B

Relationship between the key parameters for the evaluation scheme (EFSA CEF Panel, 2011).



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

APPENDIX C

Table of operational parameters[17]

[redacted]

Process Reliance Industries (RECYC315) based on the ProTec technology									
	Step 1			Step 2			Step 3		
	Extrusion			Crystallisation			Solid-State Polymerisation		
	t	P	T	t	P	T	t	P	T
Parameters	(min)	(mbar)	(°C)	(min)	(mbar)	(°C)	(h)	(mbar)	(°C)
Challenge test ([redacted] PA/4300/08)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Process	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[17]Technical report, Section 'Table of operating Parameters'.