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SCIENTIFIC OPINION

Safety assessment of the process Novatex, 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 Novatex (EU register number RECYC313), which uses the EREMA Basic technology. The input material is [redacted] washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, including no more 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 95% in mixtures with virgin PET, and of 0.15 μg/kg food, derived from the exposure scenario for toddlers when used at up to 100%. Therefore, the Panel concluded that the recycled PET obtained from this process is not of safety concern when used at up to 95% in mixtures with virgin PET for manufacturing of materials and articles for contact with all types of foodstuffs, including drinking water bottles, and at up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs except drinking water, for long-term storage at room temperature or below, with or without hotfill. 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.

KEYWORDS

EREMA basic, food contact materials, Novatex limited, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

CONTENTS

1 | INTRODUCTION

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

Recycled plastic materials and articles shall only be placed on the market if 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 German competent authority (Federal Office of Consumer Protection and Food Safety), an application for evaluation of the recycling process Novatex, European Union (EU) register No RECYC313. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2022-00267. The dossier was submitted on behalf of Novatex Limited, Ground Floor, G&T Tower, #18 Beamount Road, Civil Lines-10, 75,530 Karachi, Pakistan (see 'Documentation provided to EFSA').

1.2 | Terms of Reference

The German Competent Authority (Federal Office of Consumer Protection and Food Safety) requested the safety evaluation of the recycling process Novatex, in accordance with Article 5 of 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 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

[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.

[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-2022-5232.

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

non-confidential version of the application from 12 October 2023 to 2 November 2023, for which no comments were received.

Additional information was provided by the applicant during the assessment process in response to requests from EFSA sent on 04 April 2023, 19 September 2023 and 15 November 2023 (see 'Documentation provided to EFSA').

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 Novatex 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 bottles for mineral water, soft drinks, juices and beer as well as for thermoformed trays/containers, e.g. for fruits, vegetables, cooked and uncooked meats, dairy products and desserts, for long-term food storage at room temperature or below, with or without hotfill. The final articles are not intended to be used in microwave or conventional ovens.

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

3.2 | Description of the process

3.2.1 | General description[9]

The recycling process Novatex produces recycled PET pellets from PET containers from post-consumer collection systems (kerbside and deposit systems).

It comprises the three steps below.

Input

- In step 1, the post-consumer PET containers are processed into [redacted] washed and dried flakes. This step is performed by [redacted].

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 [redacted].

3.2.2 | Characterisation of the input[10]

According to the applicant, the input material for the recycling process Novatex consists of [redacted] washed and dried flakes obtained from PET containers, e.g. bottles, previously used for food packaging, from post-consumer collection systems (kerbside and deposit systems). A small fraction may originate from non-food applications. According to the applicant, the proportion will be no more than 5%.

Technical data on the [redacted] washed and dried flakes are provided, such as on physical properties and residual contents of moisture, poly(vinyl chloride) (PVC), glues, polyolefins, other thermoplastics, polyamide, cellulose, aluminium and PET dust (see Appendix A).

3.3 | EREMA Basic technology

3.3.1 | Description of the main steps[11]

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

- 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 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. [redacted] or [redacted]) are filtered out of the extruded plastic before the melt is converted to pellets.

[9] Technical dossier, sections 'Recycling process', 'Characterisation of the input' and 'Characterisation of the recycled plastic'.

[10] Technical dossier, section 'Characterisation of the input'.

[11] Technical dossier, sections 'Recycling process' and 'Determination of the decontamination efficiency of the recycling process'.

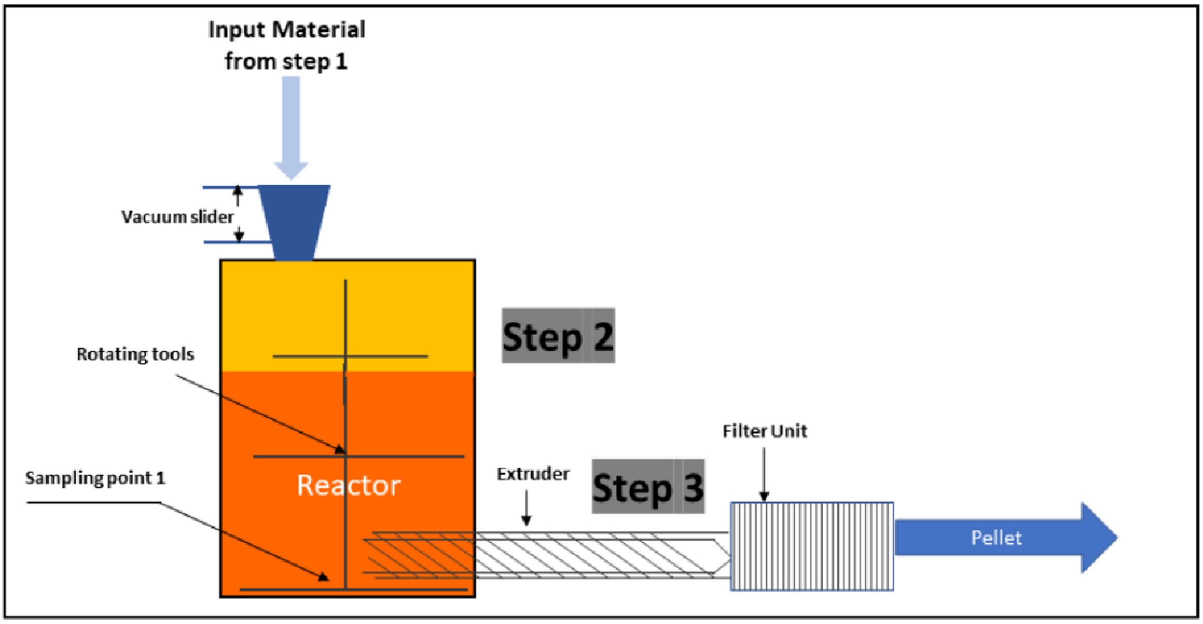

FIGURE 1 General scheme of the EREMA Basic technology (provided by the applicant).

The process is run under defined operating parameters[12] of temperature, pressure and residence time.

3.3.2 | Decontamination efficiency of the recycling process[13]

To demonstrate the decontamination efficiency of the recycling process Novatex, 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) were mixed with liquid surrogates (toluene, chlorobenzene, chloroform, methyl salicylate and phenylcyclohexane) and added to 5 kg of conventionally recycled[14] post-consumer PET flakes. This masterbatch was added to approximately 50 kg PET flakes and stored for 7 days at 50°C with periodical agitation. The contaminated flakes were washed [redacted]. The concentration of surrogates in this material was determined.

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

The Panel noted that decontamination efficiencies, calculated only on the basis of residual surrogates in contaminated (green coloured) flakes, could be overestimated. In fact, cross-contamination[15] by transfer of contaminants from green to white flakes was expected to occur (EFSA CEF Panel, 2011).

Therefore, to take into account cross-contamination, some assumptions and considerations were made by the Panel:

- The mass fraction of green to white flakes at various residence time points was derived from the data provided. A best fitting mass fraction/residence time distribution curve was used to calculate the percentage of green and white flakes at given residence times.

[12]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).

[13]Technical dossier, section 'Determination of the decontamination efficiency of the recycling process'.

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

[15]'Cross-contamination' (partitioning between green and white flakes), as meant in the Scientific Opinion on 'the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food', is the transfer of surrogate contaminants from the initially contaminated to the initially not contaminated material (EFSA CEF Panel, 2011).

- From the residual concentrations of surrogates in the green flakes at different residence times (provided by the applicant), a best fitting curve was derived and used to interpolate the residual concentrations in green flakes at different residence times.
- It was assumed that cross-contamination of surrogates from green to white flakes in the reactor occurred to the extent that the surrogate concentration in the white flakes reached 10% of the residual concentration measured in the green flakes. This percentage reflects the experience gained from previous evaluations.

To take into account the cross-contamination between green and white flakes, the evolution of the total residual surrogate content at the outlet of the continuous reactor (step 2) as a function of residence time was calculated. The amounts transferred into the white flakes (based on the assumption of 10% of the concentration measured in the green flakes) were added to those measured in the green ones, taking into account the mass fraction of green and white flakes. Correspondingly corrected concentrations of the surrogates were compared with their initial concentrations in green flakes at the inlet of the reactor to derive the decontamination efficiencies (see Table 1).

The decontamination efficiencies presented in Table 1 were calculated for the average residence time in the continuous reactor (step 2) in the challenge test.

TABLE 1 Efficiency of the decontamination of the continuous reactor (step 2) in the challenge test.

Surrogates	Concentration[a] of surrogates before step 2 (mg/kg PET)	Concentration[b] of surrogates after step 2 (mg/kg PET)	Decontamination efficiency[c] (%)
Toluene	[redacted]	[redacted]	99.0
Chlorobenzene	[redacted]	[redacted]	98.9
Chloroform	[redacted]	[redacted]	99.1
Methyl salicylate	[redacted]	[redacted]	96.4
Phenylcyclohexane	[redacted]	[redacted]	96.0
Benzophenone	[redacted]	[redacted]	94.6
Methyl stearate	[redacted]	[redacted]	96.9

Abbreviation: PET, poly(ethylene terephthalate).

[a]Initial concentration in the contaminated PET flakes.

[b]Residual concentration derived for green flakes after decontamination.

[c]Decontamination efficiency of step 2 in the challenge test after correction for cross-contamination (see text).

The decontamination efficiency ranged from 94.6% for benzophenone up to 99.1% for chloroform.

3.4 | Discussion

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

Technical data, such as on physical properties and residual contents of PVC, glue, polyolefins and metals, were provided for the input materials (i.e. [redacted] 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 no more 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 [redacted] 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. Since a mixture of non-contaminated (white) and contaminated (green) flakes was collected at the outlet of the reactor, the Panel calculated the decontamination efficiencies taking into account also the amount of surrogates possibly transferred to the white flakes due to cross-contamination. 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 94.6% to 99.1%, 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. A maximum dietary exposure of 0.0025 μg/kg bw per day corresponds to a maximum migration of 0.10 μg/kg of the contaminant into the infant's food and of 0.15 μg/kg of the contaminant into the toddler's food, and has been used to calculate C_{mod} (EFSA CEF Panel, 2011).

If the PET produced by a recycling process does not meet the targets, it should be mixed with virgin PET to make sure that the C_{res} value does not exceed the C_{mod} value. The calculated percentages are reported in Tables 2 and 3. C_{res} reported in Table 2 (scenario for infants) is calculated for 95% recycled PET, for which the risk to human health is demonstrated to be negligible. Similarly, C_{res} reported in Table 3 (scenario for toddlers) is calculated for 100% recycled PET. 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 0.10 μg/kg food after 1 year at 25°C.

Surrogates	Decontamination efficiency (%)	C_{res} for 95% rPET (mg/kg PET)	C_{mod} (mg/kg PET); infant scenario
Toluene	99.0	0.03	0.09
Chlorobenzene	98.9	0.03	0.09
Chloroform	99.1	0.03	0.10
Methyl salicylate	96.4	0.10	0.13
Phenylcyclohexane	96.0	0.12	0.14
Benzophenone	94.6	0.16	0.16
Methyl stearate	96.9	0.09	0.32

Abbreviations: PET, poly(ethylene terephthalate; rPET, recycled poly(ethylene terephthalate).

TABLE 3 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 modelled migrations of 0.15 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); toddler scenario
Toluene	99.0	0.03	0.13
Chlorobenzene	98.9	0.03	0.15
Chloroform	99.1	0.03	0.15
Methyl salicylate	96.4	0.11	0.20
Phenylcyclohexane	96.0	0.12	0.21
Benzophenone	94.6	0.16	0.24
Methyl stearate	96.9	0.09	0.47

Abbreviations: 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 Novatex 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 migrations of:

- 0.1 μg/kg food at which the risk to human health is considered negligible when the recycled PET is used at up to 95% in mixtures with virgin PET to produce materials and articles intended for contact with all types of foodstuffs, including drinking water bottles, (scenario of infants) for long-term storage at room temperature or below, with or without hotfill.
- 0.15 μg/kg food at which 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 except drinking water (scenario of toddlers), for long-term storage at room temperature or below, with or without hotfill.

The Panel noted that the input of the process originates from Pakistan. 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 the EREMA Basic technology is able to ensure that the level of unknown contaminants in recycled PET is below a calculated concentration (C_{mod}) corresponding to modelled migrations of 0.10 and 0.15 μg/kg food when the recycled PET is used in the proportions described above.

4 | CONCLUSIONS

The Panel considered that the Novatex 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 Novatex 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 is used at up to 95% in mixtures with virgin PET for the manufacture of materials and articles intended for contact with all types of foodstuffs, including drinking water bottles, for long-term storage at room temperature, with or without hotfill;
(iv) the recycled PET is used at up to 100% for the manufacture materials and articles not used for drinking water, for long-term storage at room temperature or below, with or without hotfill.

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 PROVIDED TO EFSA

Dossier 'Novatex'. November 2022. Submitted on behalf of Novatex Limited, Pakistan.

Additional information, June 2023. Submitted on behalf of Novatex Limited, Pakistan.

Additional information, October 2023. Submitted on behalf of Novatex Limited, Pakistan.

Additional information, November 2023. Submitted on behalf of Novatex Limited, Pakistan.

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)

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

German Competent Authority (Federal Office of Consumer Protection and Food Safety)

QUESTION NUMBER
EFSA-Q-2022-00267

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APPENDIX A

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

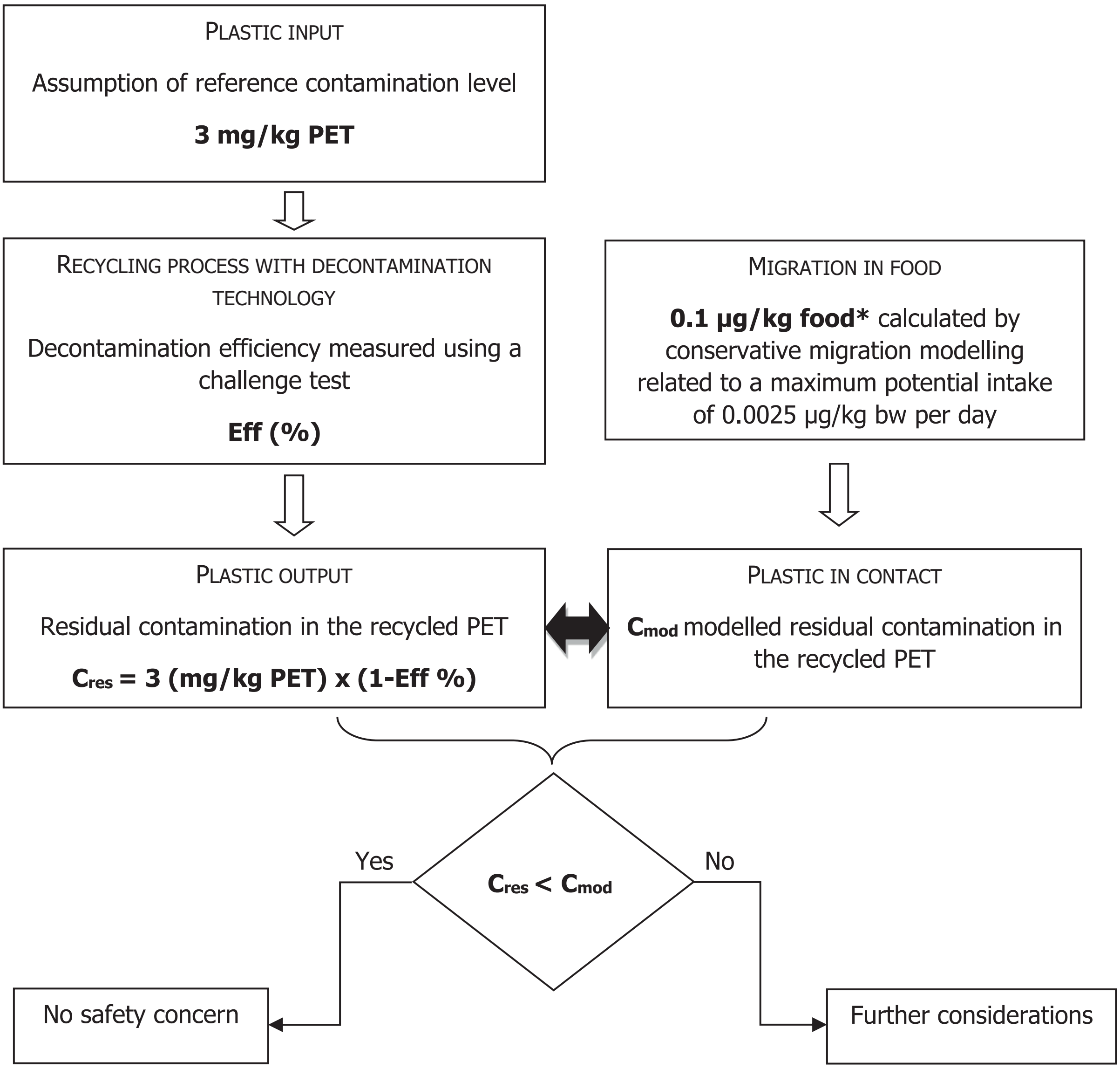
Parameter	Value
Moisture max.	1.5%
Moisture variation	± 0.3
Bulk density	250–500 kg/m^3
Bulk density variation	± 150
Material temperature	10–60°C
PVC max.	100 mg/kg
Glue max.	500 mg/kg
Polyolefins max.	500 mg/kg
Other thermoplastics	300 mg/kg
Polyamide	10 mg/kg
Cellulose (paper, wood)	500 mg/kg
Aluminium max.	400 mg/kg
PET dust	1%

Abbreviations: PET, poly(ethylene terephthalate); 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]

[redacted]

[redacted]

Process Novatex (RECYC313) based on the EREMA basic 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]

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