

ADOPTED: 17 May 2022

doi: 10.2903/j.efsa.2022.7360

Safety assessment of the process Bangladesh Petrochemical Company, based on the Vacurema Prime 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 Panel) assessed the safety of the recycling process Bangladesh Petrochemical Company (EU register number RECYC246), which uses the Vacurema Prime technology. The input material is hot caustic washed and dried poly (ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, including no more than 5% PET from non-food applications. The flakes are heated in a batch reactor (step 2) [REDACTED] and then heated in a continuous reactor (step 3) [REDACTED] before being extruded into pellets. Having examined the challenge test provided, the Panel concluded that step 2 and step 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. The Panel concluded 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 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 for long-term storage at room temperature, with or without hotfill. The final articles made of this recycled PET are not intended to be used in microwave and conventional ovens and such uses are not covered by this evaluation.

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Keywords: vacurema prime, Bangladesh Petrochemical Company, food contact materials, plastic, poly (ethylene terephthalate) (PET), recycling process, safety assessment

Requestor: German Competent Authority (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, BVL)

Question number: EFSA-Q-2021-00119

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Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at <https://ess.efsa.europa.eu/doi/doiweb/doisearch>.

Note: The full opinion will be published in accordance with Article 10(6) of Regulation (EC) No 1935/2004 once the decision on confidentiality, in line with Article 20(3) of the Regulation, will be received from the European Commission. The text and table on the operational parameters (Appendix C) have been provided under confidentiality and they are redacted awaiting the decision of the Commission.

Suggested citation: EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids), Lambré C, Barat Baviera JM, Bolognesi C, Chesson A, Cocconcelli PS, Crebelli R, Gott DM, Grob K, Mengelers M, Mortensen A, Rivière G, Steffensen I-L, Tlustos C, Van Loveren H, Vernis L, Zorn H, Dudler V, Milana MR, Papaspyrides C, Tavares Poças MF, Lioupis A, Tsochatzis E and Lampi E, 2022. Scientific opinion on the safety assessment of the process Bangladesh Petrochemical Company, based on the Vacurema Prime technology, used to recycle post-consumer PET into food contact materials. *EFSA Journal* 2022;20(6):7360, 14 pp. <https://doi.org/10.2903/j.efsa.2022.7360>

ISSN: 1831-4732

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The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.



† Deceased.

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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 282/2008¹ on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of Regulation (EC) No 1935/2004² on materials and articles intended to come into contact with food.

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

In this case, EFSA received from the German Competent Authority (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, BVL), an application for evaluation of the recycling process Bangladesh Petrochemical Company, European Union (EU) register No RECYC246. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2021-00119. The dossier was submitted on behalf of Bangladesh Petrochemical Company.

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 make 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).

Additional information was sought from the applicant during the assessment process in response to requests from EFSA sent on 16 November 2021, 25 January 2022 and 4 April 2022 and was subsequently provided (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.

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 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.

2.2. Methodologies

The principles followed up for the evaluation are described here. The risks associated to 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.

3. Assessment

3.1. General information³

According to the applicant, the recycling process Bangladesh Petrochemical Company 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 for long-term storage at room temperature, with or without hotfill, such as bottles for mineral water, soft drinks and other beverages. The final articles are not intended to be used in microwave and conventional ovens.

3.2. Description of the process

3.2.1. General description⁴

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

The recycling process comprises the four steps below.

Input

- In step 1, 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 pellets

- In step 2, the flakes are crystallised and decontaminated under high temperature [REDACTED] in a batch reactor.
- In step 3, flakes are further treated in a continuous reactor under high temperature [REDACTED].
- In step 4, the material is extruded and pellets of recycled PET are produced.

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

³ Technical dossier, Sections 3.1.1 and 3.2.5.

⁴ Technical dossier, Section 3.2.1.

Recycled pellets, the final product of the process, are checked against technical requirements, such as intrinsic viscosity, black spots, colour, size, bulk density and moisture.

3.2.2. Characterisation of the input⁵

According to the applicant, the input material for the recycling process Bangladesh Petrochemical Company consists of hot caustic washed and dried flakes obtained from PET containers, previously used for food packaging, from post-consumer collection systems (kerbside and deposit systems). A small fraction may originate from non-food applications, such as bottles used for soap, mouth wash or kitchen hygiene agents. According to the applicant, the proportion will be below 5%.

Technical data for the hot caustic washed and dried flakes are provided such as information on residual content of moisture, poly(vinyl chloride) (PVC), glue, polyolefins, cellulose, metals and physical properties (see Appendix A).

3.3. Vacurema Prime technology

3.3.1. Description of the main steps⁴

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 [REDACTED] heat are applied for a predefined residence time. These process conditions favour the vaporisation of possible contaminants and crystallisation of PET flakes. The twin reactors alternately feed a continuous reactor. The time for emptying one batch reactor is equal to the processing time in the other.
- Further decontamination in the continuous reactor (step 3): The flakes from each batch reactor are fed to a continuous reactor, running under high temperature [REDACTED] for a predefined residence time. Further decontamination occurs in this reactor.
- 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.

⁵ Technical dossier, Section 3.2.2.

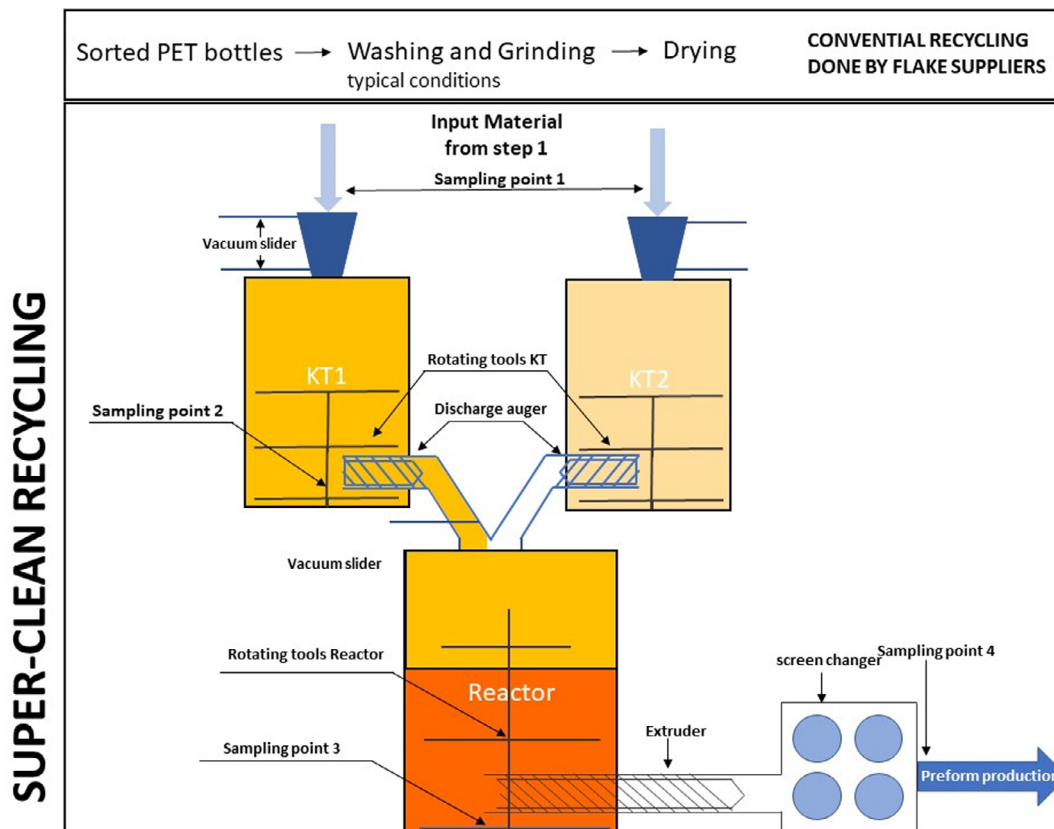


Figure 1: General scheme of the Vacurema Prime technology (provided by the applicant)

The process is run under defined operating parameters⁶ of temperature, pressure and residence time.

3.3.2. Decontamination efficiency of the recycling process⁷

To demonstrate the decontamination efficiency of the recycling process Bangladesh Petrochemical Company, a challenge test was submitted to EFSA.

PET flakes were contaminated with toluene, chloroform, phenylcyclohexane, benzophenone and lindane, selected as surrogates 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, 100 kg of conventionally recycled⁸ 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 surrogates solution was decanted and PET flakes were rinsed with water and then air dried. The concentration of surrogates in this material was determined.

The Vacurema Prime technology was challenged using a [redacted] plant [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.

⁶ In accordance with Art. 9 and 20 of Regulation (EC) No 1935/2004 the parameters were provided to EFSA by the applicant and were made available to the Member States and European Commission (see Appendix C).

⁷ Technical dossier, Section 3.2.3.

⁸ Conventional recycling includes commonly sorting, grinding, washing and drying steps and produces washed and dried flakes.

No surrogates were detected in the green flakes after step 3. 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. The results are summarised in Table 1.

Table 1: Efficiency of the decontamination of the batch reactors (Vacurema Prime, step 2) 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. After step 3, none of the surrogates were detected.

3.4. Discussion

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

Technical data, such as information on residual content of moisture, PVC, glue, polyolefins, cellulose, metals and physical properties, were provided for the input materials (i.e. hot caustic washed and dried flakes, step 1). The input materials are produced from PET containers, e.g. bottles, previously used for food packaging collected through post-consumer collection systems. However, a small fraction of the input may originate from non-food applications such as soap bottles, mouth wash bottles, kitchen hygiene bottles, etc. According to the applicant, the proportion of this non-food container fraction depends on the collection system and the process is managed in such a way that in the input stream of the recycling process this amount will be lower 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 the applicant. The VACUREMA Prime technology comprises the batch decontamination reactors (step 2), continuous decontamination 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] plant on process steps 2, 3 and 4 (batch decontamination reactor, continuous decontamination reactor and extrusion, respectively) to measure the decontamination efficiency. The decontamination efficiency was determined in the challenge test from step 2 operated at batch mode, considered to be representative of step 2 in the plant.

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. However, it is considered to be compensated by the additional decontamination in the subsequent steps. In step 3, [REDACTED] the temperature is higher. Therefore, the efficiency of step 3 in decontaminating the flakes is at least comparable to that of step 2. Moreover, the slow discharging of step 2, providing additional residence time to step 2, and the extrusion (step 4) contribute further to the overall decontamination. Therefore, the Panel noted that the decontamination efficiency of the part of step 2 up to the discharging time, challenged by the test, without taking into account the cross contamination, can be considered to cover the decontamination efficiency of the actual process.

The Panel considered that the two steps, the decontamination in batch reactors (step 2) and the decontamination in continuous reactor (step 3) are the critical steps for the decontamination efficiency of the process. Consequently temperature, pressure and residence time parameters of the steps 2 and 3 of the processes 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 for each surrogate contaminant, 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).

Table 2: Decontamination efficiency from challenge test, residual concentration of surrogate contaminants in recycled PET (C_{res}) and calculated concentration of surrogate contaminants in PET (C_{mod}) corresponding to a modelled migration of 0.1 $\mu\text{g}/\text{kg}$ 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	99.7	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).

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 would be negligible.⁹ The C_{res} value should not exceed the modelled concentration in PET (C_{mod}) that could result, after 1 year at 25°C, in a migration giving rise to a dietary exposure exceeding 0.0025 $\mu\text{g}/\text{kg}$ bw per day. Because the recycled PET is intended for the manufacturing of materials and articles (including bottles for drinking water) containing up to 100% recycled PET, the exposure scenario for infants has been applied. A maximum dietary exposure of 0.0025 $\mu\text{g}/\text{kg}$ bw per day corresponds to a maximum migration of 0.1 $\mu\text{g}/\text{kg}$ 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.

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 Bangladesh Petrochemical Company 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.

The Panel noted that the input of the process originates from Bangladesh. 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 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.

4. Conclusions

The Panel considered that the process Bangladesh Petrochemical Company using the Vacurema Prime technology is adequately characterised and that the critical steps to decontaminate the PET

⁹ 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).

have been identified. Having examined the challenge test provided, the Panel concluded that temperature, pressure and residence time in the batch reactors (step 2) and in the continuous reactor (step 3) are critical for the decontamination efficiency of the process.

The Panel considered that the recycling process Bangladesh Petrochemical Company is able to reduce any foreseeable accidental contamination of the 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 tests used to measure the decontamination efficiency of the process;
- ii) the input 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 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, 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.

5. Recommendations

The Panel recommended periodic verification that the input 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 "Bangladesh Petrochemical Company". September 2021. Submitted on behalf of Bangladesh Petrochemical Company, Bangladesh.
- 2) Dossier "Bangladesh Petrochemical Company". November 2021. Submitted on behalf of Bangladesh Petrochemical Company, Bangladesh.
- 3) Dossier "Bangladesh Petrochemical Company". January 2022. Submitted on behalf of Bangladesh Petrochemical Company, Bangladesh.
- 4) Dossier "Bangladesh Petrochemical Company". April 2022. Submitted on behalf of Bangladesh Petrochemical Company, Bangladesh.

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- FDA (Food and Drug Administration), 2006. Guidance for industry: use of recycled plastics in food packaging: chemistry considerations. Available online: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-use-recycled-plastics-food-packaging-chemistry-considerations>

Abbreviations

- bw body weight
CEF Food Contact Materials, Enzymes, Flavourings and Processing Aids

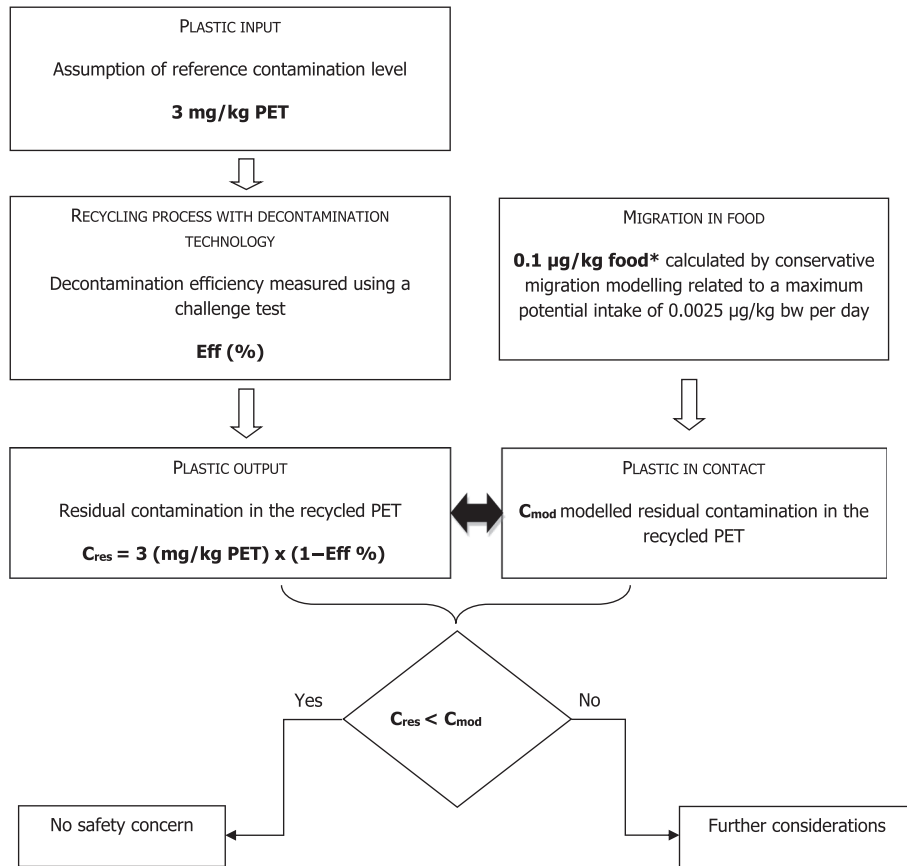
CEP Food Contact Materials, Enzymes and Processing Aids
 C_{mod} modelled concentration in PET
 C_{res} residual concentrations in PET
PET poly(ethylene terephthalate)
PVC poly(vinyl chloride)

Appendix A – Technical data of the washed flakes as provided by the applicant⁵

Parameter	Value
Moisture max.	0.9%
Moisture variation	± 0.2%/h
Bulk density	270 kg/m ³
Bulk density variation	± 25 kg/(h*m ³)
Material temperature	30–60°C
PVC max.	30 mg/kg
Glue max.	20 mg/kg
Polyolefins max.	10 mg/kg
Cellulose (paper, wood)	50 mg/kg
Metal max.	25 mg/kg

PVC: poly(vinyl chloride).

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 on Operational parameters (Confidential Information)¹⁰

[Redacted content]

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

[Redacted content]

¹⁰ Technical dossier, Section 3.2.3 and Appendix F (Challenge Test report).