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Safety assessment of the process Roxane Nord, based on VACUNITE (EREMA basic and Polymetrix SSP V-leaN) 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 Roxane Nord (EU register number RECYC239), which uses the VACUNITE (EREMA basic and Polymetrix SSP V-leaN) technology. The input is hot caustic washed and dried poly(ethylene terephthalate) (PET) flakes mainly 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 and pelletised. The crystallised pellets are then preheated and submitted to solid-state polycondensation (SSP) in a continuous reactor at high temperature under vacuum and gas flow. Having examined the challenge test provided, the Panel concluded that the continuous reactor (step 2), the preheating (step 4) and the SSP reactor (step 5) are critical in determining the decontamination efficiency of the process. The operating parameters to control the performance are temperature and residence time in the continuous reactors of steps 2, 4 and 5, pressure in steps 2 and 5 as well as the gas velocity in steps 4 and 5. 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, 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: VACUNITE (EREMA basic and Polymetrix SSP V-leaN), ROXANE NORD (ROXPET CENTRE), food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

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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. Technical details on recycling step 3 (Section 3.3.1), details of the performed challenge test (Sections 3.3.2 and 3.4) and 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.

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>.

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[†] 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, 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 Competent Authority of France (Ministère de l'Economie, des Finances et de la Relance Bureau 4B Quante des denrees alimentaires), an application for evaluation of the recycling process Roxane Nord, European Union (EU) register No RECYC239. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2021-00167. The dossier was submitted on behalf of ROXANE NORD (ROXPET CENTRE), France.

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 provided by the applicant during the assessment process in response to requests from EFSA sent on 24 November 2021 and 28 February 2022 (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 for the evaluation are described here. 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.

3. Assessment

3.1. General information³

According to the applicant, the recycling process Roxane Nord is intended to recycle food grade PET containers using the VACUNITE (EREMA basic and Polymetrix SSP V-lean) 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 bottles for mineral water, soft drinks, fruit juices and beer for long-term storage at room temperature, with or without hotfill. 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 Roxane Nord produces recycled PET pellets from PET materials originating from post-consumer collection systems (kerbside and deposit collection systems).

The recycling process comprises the five steps below.

Input

- In step 1, the post-consumer PET is sorted and processed into hot caustic washed and dried flakes. This step is performed by third parties.

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 which are then crystallised.
- In step 4, the crystallised pellets are preheated.
- In step 5, the preheated pellets are decontaminated during solid-state polycondensation (SSP) at high temperature, under vacuum and gas flow.

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

Pellets, the final product of the process, are checked against technical requirements, such as intrinsic viscosity, colour and black spots.

³ Technical dossier, Sections 3.1. and 3.1.1.

⁴ Technical dossier, Sections 3.1.1 and 3.2.3.

3.2.2. Characterisation of the input⁵

According to the applicant, the input material for the recycling process Roxane Nord consists of hot washed and dried flakes obtained from PET materials, 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, this proportion will be no more than 5%.

Technical specifications on the hot washed and dried flakes were provided, such as information on physical properties and residual contents of moisture, poly(vinyl chloride) (PVC), polyolefins, glue, PET dust and metals (see Appendix A).

3.3. VACUNITE (EREMA basic and Polymetrix SSP V-lean) technology

3.3.1. Description of the main steps⁶

The general scheme of the VACUNITE (EREMA basic and Polymetrix SSP V-lean) 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 minimum residence time.
- Extrusion of the decontaminated flakes (step 3):
The flakes, continuously introduced from the previous reactor, are molten in the extruder.
The pellets are then crystallised.
- Preheating (step 4): The crystallised pellets are preheated.
- SSP (step 5): The preheated pellets are continuously fed to a countercurrent reactor running under high temperature, vacuum and gas flow for a predefined residence time.

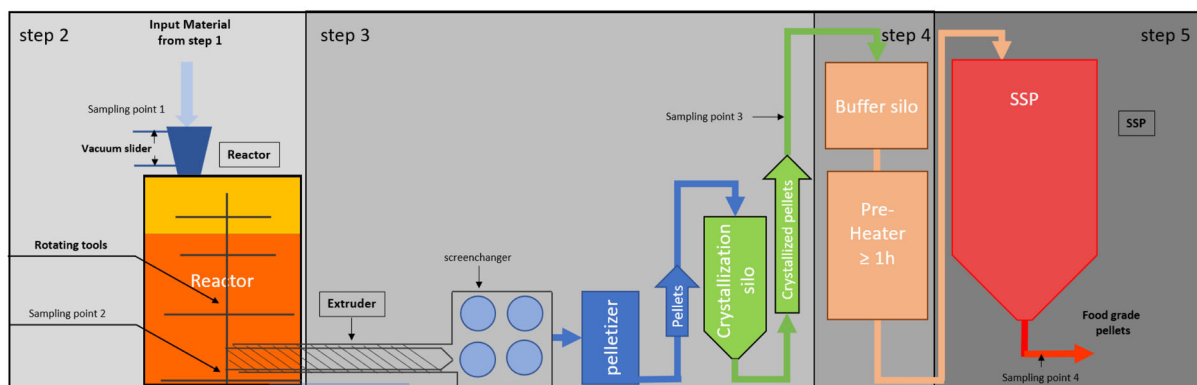


Figure 1: General scheme of the technology (provided by the applicant)

The process is run under defined operating parameters⁷ of temperature, pressure, gas velocity and residence time.

3.3.2. Decontamination efficiency of the recycling process⁸

To demonstrate the decontamination efficiency of the recycling process Roxane Nord, a challenge test on steps 2, 4 and 5 was submitted to the EFSA.

PET flakes were contaminated with toluene, chlorobenzene, chloroform, methyl salicylate, phenyl cyclohexane, benzophenone and methyl stearate, 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

⁵ Technical dossier, Section 3.2.2.

⁶ Technical dossier, Section 3.2.1.

⁷ 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).

⁸ Technical dossier, Section 3.2.3, Appendix E1 and E2.

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 this purpose, 25 mL of each of the liquid surrogates (toluene, chlorobenzene, chloroform, methyl salicylate and phenyl cyclohexane) and 25 g of each of the solid surrogates (benzophenone and methyl stearate) were added to 25 kg of conventionally recycled⁹ post-consumer PET flakes. Eight such batches were produced and stored for 7 days at 50°C with periodical agitation. Afterwards, the contaminated flakes were rinsed with 10% ethanol and the concentrations of the surrogates in this material were determined.

Step 2 of the VACUNITE (EREMA basic and Polymetrix SSP V-leaN) technology was challenged at an industrial-scale plant. The contaminated flakes (200 kg) were fed into the decontamination reactor (step 2) and a sample was taken after step 2. The decontaminated flakes after step 2 were extruded (step 3; not challenged) to produce pellets. One kg of the extruded pellets was used to challenge steps 4 and 5 (i.e. preheating and SSP) at a [REDACTED] scale.

Instead of being operated continuously (as it would be in the industrial process), the step 2 was run in [REDACTED] mode in the challenge test. The Panel considered that the [REDACTED] reactor ran at the same temperature and pressure as is foreseen for the industrial process. In order to prove the representativeness of the residence time of the flakes in the challenge test, an additional challenge test running in continuous mode was provided. In this test, a mixture of green (contaminated) and clear (non-contaminated) flakes was challenged. At different residence times, the ratio of green and clear flakes exiting the reactor was determined. Based on the results, the Panel concluded that the residence time in the challenge test [REDACTED] reactor corresponded to the minimum residence time in the industrial continuous reactor.

The decontamination efficiencies of step 2 (EREMA reactor) and steps 4 and 5 (preheating and SSP reactor) were calculated from the concentration of surrogates before and after each reactor (Tables 1 and 2, respectively).

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

Surrogates	Concentration of surrogates before step 2 (mg/kg PET)	Concentration of surrogates after step 2 (mg/kg PET)	Decontamination efficiency (%)
Toluene	357.0	57.0	84.0
Chloroform	165.6	78.0	52.9
Chlorobenzene	641.1	100.6	84.3
Phenyl cyclohexane	588.2	140.1	76.2
Methyl salicylate	900.6	112.6	87.5
Benzophenone	852.1	171.4	79.9
Methyl stearate	1,279.9	205.2	84.0

PET: poly(ethylene terephthalate).

Table 2: Efficiency of the decontamination by the Polymetrix SSP reactor in the challenge test (steps 4 and 5)

Surrogates	Concentration of surrogates before step 4 (mg/kg PET)	Concentration of surrogates after step 5 (mg/kg PET)	Decontamination efficiency (%)
Toluene	12.6	0.4	96.8
Chloroform	25.1	0.9	96.4
Chlorobenzene	25.2	0.8	96.8
Phenyl cyclohexane	67.5	8.2	87.9
Methyl salicylate	7.9	0.1	98.7
Benzophenone	100.9	9.4	90.7
Methyl stearate	100.4	2.0	98.0

PET: poly(ethylene terephthalate).

⁹ Conventional recycling commonly includes sorting, grinding, washing and drying steps and produces washed and dried flakes.

A combined decontamination efficiency of the process was then calculated from the decontamination efficiencies of step 2 and steps 4 and 5 (Table 3).

Table 3: Efficiency of the decontamination by the VACUNITE technology in the challenge test

Surrogates	Decontamination efficiency (%) step 2	Decontamination efficiency (%) steps 4 and 5	Combined decontamination efficiency (%)
Toluene	84.0	96.8	99.5
Chloroform	52.9	96.4	98.3
Chlorobenzene	84.3	96.8	99.5
Phenyl cyclohexane	76.2	87.9	97.1
Methyl salicylate	87.5	98.7	99.8
Benzophenone	79.9	90.7	98.1
Methyl stearate	84.0	98.0	99.7

PET: poly(ethylene terephthalate).

As shown in Table 3, the decontamination efficiency ranged from 97.1% for phenyl cyclohexane to 99.8% for methyl salicylate.

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 specifications, such as information on physical properties and residual contents of moisture, poly(vinyl chloride) (PVC), polyolefins, glue, PET dust and metals, were provided for the input materials (i.e. washed and dried flakes, step 1). 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 (step 1) is conducted by third parties and, according to the applicant, this step is under control. The VACUNITE (EREMA basic and Polymetrix SSP V-leaN) technology comprises the continuous decontamination reactor (step 2), extrusion and crystallisation (step 3), preheating (step 4) and decontamination in the SSP reactor (step 5). The operating parameters of temperature, pressure, residence time and gas velocity have been provided to EFSA.

A challenge test to measure the decontamination efficiency was conducted in a small industrial scale decontamination reactor (step 2), a preheating reactor (step 4) and a ██████████ SSP reactor (step 5). The reactors were operated under pressure, temperature, gas flow and residence time equivalent to those of the commercial process. Since steps 2, 4 and 5 were conducted with only contaminated flakes (step 2) and pellets (steps 4 and 5), cross-contamination could not occur. The Panel considered that this challenge test was performed correctly according to the recommendations of the EFSA guidelines (EFSA, 2008) and that steps 2, 4 and 5 are critical for the decontamination efficiency of the process. Consequently, temperature and residence time of steps 2, 4 and 5, pressure of steps 2 and 5 as well as the gas velocity of steps 4 and 5 of the process should be controlled to guarantee the performance of the decontamination (Appendix C).

The decontamination efficiencies obtained for each surrogate, ranging from 97.1% to 99.8%, have been used to calculate the residual concentrations of potential unknown contaminants in PET (C_{res}) according to the evaluation procedure described in the 'Scientific opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET' (EFSA CEF Panel, 2011; Appendix B). By applying the decontamination percentages to the reference contamination level of 3 mg/kg PET, the C_{res} for the different surrogates was obtained (Table 4).

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, could result in a migration giving rise to a dietary exposure exceeding 0.0025 µg/kg bw per day. Because the recycled PET is intended for manufacture of bottles for mineral water and beverages the scenario for infants has been applied (water could be used to prepare infant formula). A maximum dietary exposure of 0.0025 µg/kg bw/day corresponds to a maximum migration of 0.1 µg/kg of a contaminant substance into the infant's food and has been used to calculate C_{mod} (EFSA CEF Panel, 2011). C_{res} reported in Table 4 is calculated for 100% recycled PET, for which the risk to human health is demonstrated to be negligible. The results of these calculations are shown in Table 4. The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

Table 4: Decontamination efficiencies from the challenge test (overall from steps 2, 4 and 5), residual concentrations of the surrogates in the recycled PET (C_{res}) 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	99.5	0.02	0.09
Chloroform	98.3	0.05	0.10
Chlorobenzene	99.5	0.02	0.09
Phenyl cyclohexane	97.1	0.09	0.14
Methyl salicylate	99.8	0.01	0.13
Benzophenone	98.1	0.06	0.16
Methyl stearate	99.7	0.01	0.32

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

On the basis of the provided data from the challenge test and the applied conservative assumptions, the Panel considered that under the given operating conditions the recycling process using the VACUNITE (EREMA basic and Polymetrix SSP V-lean) technology is able to ensure that the level of migration of unknown contaminants from the recycled PET into food is below the conservatively modelled migration of 0.1 µg/kg food. At this level, the risk to human health is considered negligible when the recycled PET is used at up to 100% to produce materials and articles intended for contact with all types of foodstuffs including drinking water.

4. Conclusions

The Panel considered that the process Roxane Nord, using the VACUNITE (EREMA basic and Polymetrix SSP V-lean) 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 temperature and residence time in the continuous reactors of steps 2, 4 and 5, pressure in steps 2 and 5 as well as the gas velocity in steps 4 and 5 are critical for the decontamination efficiency.

The Panel concluded that the recycling process Roxane Nord 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 contains 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, including drinking water, 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. Recommendation

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 'Roxane Nord'. March 2021. Submitted on behalf of ROXANE NORD (ROXPET CENTRE), France.
- 2) Additional information, January 2022. Submitted on behalf of ROXANE NORD (ROXPET CENTRE), France.
- 3) Additional information, March 2022. Submitted on behalf of ROXANE NORD (ROXPET CENTRE), France.

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Abbreviations

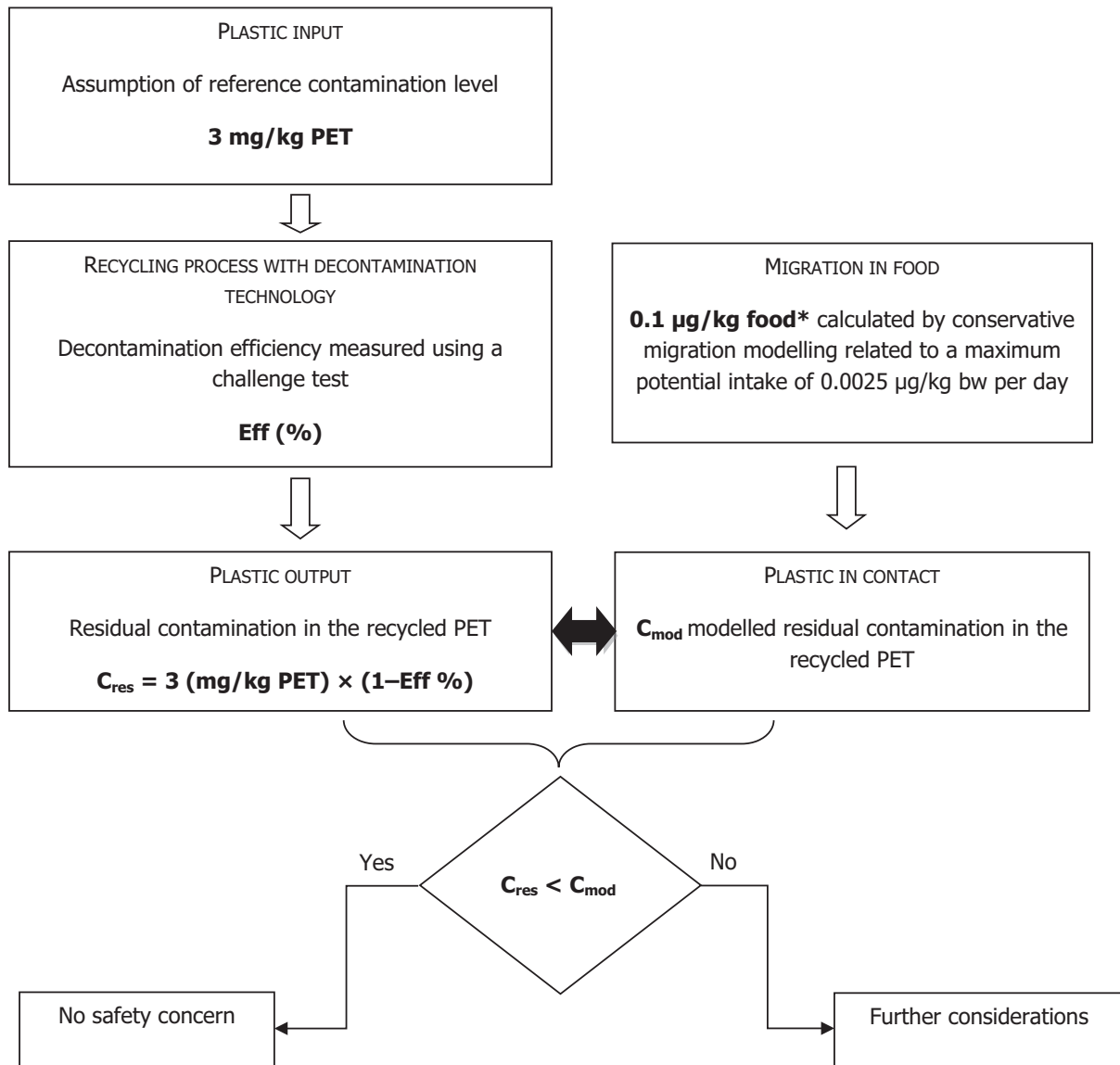
bw	body weight
CEF	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP	Panel on Food Contact Materials, Enzymes and Processing Aids
C_{mod}	modelled concentration in PET
C_{res}	residual concentration in PET
iV	intrinsic viscosity
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)
SSP	solid-state polycondensation

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

Parameter	Value
Moisture max.	< 1.5%
Moisture variation	0.3%
Bulk density	250–350 kg/m ³
PVC max.	< 25 mg/kg
Glue max.	< 20 mg/kg
Polyolefins max.	< 30 mg/kg
Metals max.	< 25 mg/kg
PET dust max.	< 0.4%

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.

