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Safety assessment of the process NOVAPET, based on the Polymetrix pellet 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 NOVAPET (EU register number RECYC216), which uses the Polymetrix pellet technology. The input material is hot washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, e.g. bottles, including no more than 5% PET from non-food consumer applications. The flakes are extruded into pellets, crystallised, preheated and subsequently decontaminated in a solid-state polycondensation (SSP) reactor under high temperature and gas flow. Having examined the challenge tests provided, the Panel concluded that the fifth step, the decontamination in the SSP reactor, is critical in determining the decontamination efficiency of the process. The operating parameters to control the performance of this critical step are temperature, gas speed 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. 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 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 or conventional ovens and such uses are not covered by this evaluation.

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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 steps 3 and 4 (Sections 3.2.1, 3.3.1, 3.3.2, 3.4 and 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.

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[†] Deceased.

Table of contents

Abstract.....	1
1. Introduction.....	4
1.1. Background and Terms of Reference as provided by the requestor.....	4
2. Data and methodologies.....	4
2.1. Data.....	4
2.2. Methodologies.....	5
3. Assessment.....	5
3.1. General information.....	5
3.2. Description of the process.....	5
3.2.1. General description.....	5
3.2.2. Characterisation of the input.....	6
3.3. Polymetrix pellet technology.....	6
3.3.1. Description of the main steps.....	6
3.3.2. Decontamination efficiency of the recycling process.....	7
3.4. Discussion.....	8
4. Conclusions.....	9
5. Recommendations.....	10
6. Documentation provided to EFSA.....	10
References.....	10
Abbreviations.....	10
Appendix A – Technical data of the washed flakes as provided by the applicant.....	11
Appendix B – Relationship between the key parameters for the evaluation scheme (EFSA CEF Panel, 2011)....	12
Appendix C – Table of operational parameters (Confidential Information).....	13

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 Ministerio de Sanidad, Consumo y Bienestar Social, Spain, an application for evaluation of the recycling process NOVAPET, European Union (EU) register No RECYC216. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2019-00753. The dossier was submitted on behalf of NOVAPET S.A., Spain.

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).

Additional information was sought from the applicant during the assessment process in response to requests from EFSA sent on 27 January 2021 and 11 October 2021 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 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 a 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 information³

According to the applicant, the recycling process NOVAPET is intended to recycle food grade PET containers using the Polymetrix pellet 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 beer. The recycled pellets may also be used for sheets, which are thermoformed to make food trays. The final articles are not intended to be used in microwave or conventional ovens.

3.2. Description of the process

3.2.1. General description⁴

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

The recycling process comprises the five steps below.

Input

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

Decontamination and production of recycled PET material

- In step 2, the flakes are extruded into pellets.
- In step 3, the pellets are crystallised.
- In step 4, the pellets are preheated and conditioned to the decontamination temperature.
- In step 5, the crystallised pellets are decontaminated during solid-state polycondensation (SSP) in a [REDACTED] reactor under high temperature and inert 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, Section 3.1.

⁴ Technical dossier, Section 3.1.1.

3.2.2. Characterisation of the input⁵

According to the applicant, the input material for the recycling process NOVAPET consists of hot 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 for the hot washed and dried flakes are provided, such as information on physical properties and on residual contents of moisture, PVC, glue, other plastics than PET, wood, paper and metals (see Appendix A).

3.3. Polymetrix pellet technology

3.3.1. Description of the main steps⁶

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

- Extrusion (step 2): The washed and dried flakes are fed into the extruder without venting and under atmospheric pressure. The melt is filtered with a screen changer to remove solid particles (e.g. paper and aluminium).
- Crystallisation (step 3): The extruded pellets are fed to a [REDACTED] reactor in which they are crystallised.
- Preheating and conditioning (step 4): The crystallised pellets are heated up to the temperature of the SSP reactor and conditioned.
- SSP (step 5): The crystallised pellets are [REDACTED] fed to a [REDACTED] reactor running under high temperature and inert gas flow for a predefined residence time. Two different conditions of temperature and residence time (T_1, t_1 and T_2, t_2 where $T_1 < T_2$ and $t_1 > t_2$) may be applied.

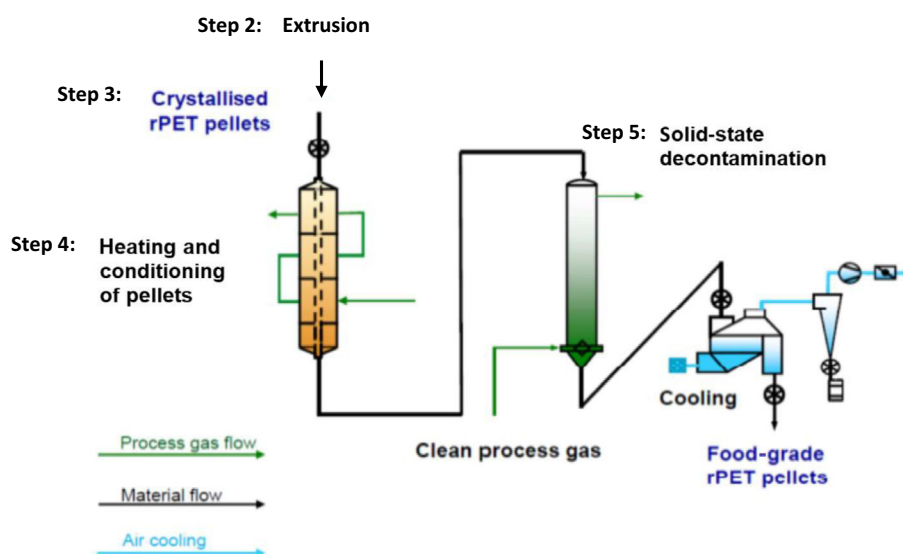


Figure 1: General scheme of the technology (provided by the applicant)

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

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).

3.3.2. Decontamination efficiency of the recycling process⁸

To demonstrate the decontamination efficiency of the recycling process NOVAPET, a challenge test performed at pilot plant scale was submitted to EFSA.

Contaminated PET pellets were produced during extrusion by adding toluene, chlorobenzene, 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).

PET was spiked with a solution containing the surrogates in a pilot plant twin screw extruder without degassing, resulting in a homogenous contamination of the pellets. To prevent possible agglomeration during the challenge test the amorphous pellets were crystallised according to step 3. The concentrations of the surrogates were determined in these crystallised pellets used as starting material for the challenge test.

Three challenge tests were performed on the SSP (step 5) in [redacted] mode at a pilot plant. Three different decontamination temperatures T_a , T_b and T_c ($T_a < T_b < T_c$) were tested for various residence times. For the preferred temperature T_1 selected by the applicant, the residence time t_1 was derived from the three challenge tests performed at three temperatures and various durations. The Panel noted that the process temperature selected by the applicant was not directly tested but derived from the data obtained in the challenge tests run at different temperatures. For the optional operational conditions T_2/t_2 , T_2 is T_b . Instead of being processed [redacted] the SSP reaction was run in [redacted] mode. The Panel considered that, since the reactor in the process works without significant mixing, this [redacted] process will result in a comparable cleaning efficiency as the [redacted] process of the challenge test, provided comparable temperature, inert gas conditions and residence time are applied.

The gas speed was several times higher than in the process to compensate for heat loss, but the Panel accepted the argument that above the gas speed used in production, the diffusion within the pellets is limiting the removal of the contaminants, i.e. that the gas speed no longer influences the decontamination (Huang and Walsh, 1998).

For each challenge test, the contaminated PET pellets, which were clear (without added colour) were mixed with a many times larger amount of blue, non-contaminated pellets in order to provide the quantity of material needed for the pilot plant. From the samples drawn after the SSP (step 5), only the clear contaminated pellets were analysed for their residual concentrations of the applied surrogates. The applicant provided data on a challenge test with only contaminated pellets run at conditions corresponding to one of the challenge tests described above. Data were similar, indicating negligible effect by cross-contamination⁹.

When not detected, the limit of detection was considered for the calculation of the decontamination efficiency. The most relevant results are summarised in Tables 1–3.

Table 1: Efficiency of the decontamination of the SSP reactor at decontamination temperature T_a and residence time t_2

Surrogates	Concentration of surrogates before step 5 (mg/kg PET)	Concentration of surrogates after step 5 (mg/kg PET)	Decontamination efficiency (%)
Toluene	8.8	< 0.1 ^(a)	> 98.8
Chlorobenzene	71.5	1.3	98.2
Phenylcyclohexane	614.6	58.2	90.5
Benzophenone	565.0	38.2	93.2
Methyl stearate	623.1	26.0	95.8

PET: poly(ethylene terephthalate); SSP: solid-state polymerisation.

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

⁸ Technical dossier, Section 3.2.3 and Appendix E.

⁹ 'Cross-contamination' (partitioning between clear and blue 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).

Table 2: Efficiency of the decontamination of the SSP reactor at decontamination temperature T_b and residence time t_2

Surrogates	Concentration of surrogates before step 5 (mg/kg PET)	Concentration of surrogates after step 5 (mg/kg PET)	Decontamination efficiency (%)
Toluene	10.2	< 0.1 ^(a)	> 99.0
Chlorobenzene	81.3	1.2	98.5
Phenylcyclohexane	630.4	26.0	95.9
Benzophenone	574.9	14.7	97.4
Methyl stearate	627.9	7.8	98.8

PET: poly(ethylene terephthalate); SSP: solid-state polymerisation.

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

Table 3: Efficiency of the decontamination of the SSP reactor at decontamination temperature T_c and residence time t_2

Surrogates	Concentration of surrogates before step 5 (mg/kg PET)	Concentration of surrogates after step 5 (mg/kg PET)	Decontamination efficiency (%)
Toluene	18.6	< 0.1 ^(a)	> 99.5
Chlorobenzene	127.3	1.2	99.1
Phenylcyclohexane	580.1	3.7	99.4
Benzophenone	505.0	1.7	99.7
Methyl stearate	554.2	0.3	99.9

PET: poly(ethylene terephthalate); SSP: solid-state polymerisation.

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

In Tables 1–3, the decontamination efficiency depended on the temperature applied in the challenge tests and ranged from 90.5% for phenylcyclohexane up to 99.9% for methyl stearate. The Panel noted that the values of Tables 1 and 3 do not correspond to the critical parameters of the process and were only used to derive the t_1 value for the T1 selected by the applicant.

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 physical properties and residual contents of PVC, glues, plastics other than PET, wood, paper and metals, were provided for the input materials (i.e. washed and dried flakes, step 1). These 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 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) are conducted in different ways depending on the plant and, according to the applicant, this step is under control. The Polymetrix pellet technology comprises the extrusion (step 2), crystallisation (step 3), preheating and conditioning (step 4) and SSP (step 5). The operating parameters of temperature and residence time for steps 2–4, inert gas speed for step 4 and temperature, inert gas speed and residence time for step 5 have been provided to EFSA.

Three challenge tests to measure the decontamination efficiency were conducted in a pilot plant (mode) on the process step 5 (reactor for SSP, which is the main decontamination reactor). The decontamination efficiency was determined from the contaminated pellets before and after the SSP reactor. The Panel considered that this challenge tests were performed according to the recommendations of the EFSA guidelines (EFSA, 2008). Potential cross-contamination between clear

contaminated and blue non-contaminated pellets was shown to have had negligible impact on the final decontamination efficiency calculated.

The Panel considered that the SSP reactor (step 5), is the critical step for the decontamination efficiency of the process. Consequently, the temperature, the inert gas speed and the residence time parameters of step 5 of the process should be controlled to guarantee the performance of the decontamination. These parameters have been provided to EFSA.

The decontamination efficiencies obtained for each surrogate 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 efficiency percentage to the reference contamination level of 3 mg/kg PET, the C_{res} for the different surrogates in the three challenge tests were obtained. For conditions T2/t2, Table 4 applies.

Table 4: Decontamination efficiency from the challenge test at temperature T_b , 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 $\mu\text{g}/\text{kg}$ food after 1 year at 25°C

Surrogates	Decontamination efficiency (%)	C_{res} for 100% rPET (mg/kg PET)	C_{mod} (mg/kg PET)
Toluene	> 99.0	< 0.03	0.09
Chlorobenzene	98.5	0.04	0.09
Phenylcyclohexane	95.9	0.12	0.14
Benzophenone	97.4	0.08	0.16
Methyl stearate	98.8	0.04	0.32

According to the evaluation principles (EFSA CEF Panel, 2011), the dietary exposure must not exceed 0.0025 $\mu\text{g}/\text{kg}$ bw per day, below which the risk to human health is considered negligible. 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 $\mu\text{g}/\text{kg}$ bw per day. Because the recycled PET is intended for the manufacture of bottles at up to 100% recycled PET, the scenario for infants has been applied (water could be used to prepare infant formula). Therefore, the migration of 0.1 $\mu\text{g}/\text{kg}$ into food has been used to calculate C_{mod} (EFSA CEF Panel, 2011). 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.

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

The applicant states that for the industrial process, the [redacted] reactor for SSP (step 5) is run either at a temperature higher than T_a and lower than T_b (main option, T1), or at temperature T2 equal to T_b . Data were provided for derivation of the minimum residence time t1 for the selected temperature T1 at which the process should be run in order to bring the residual concentrations of the surrogates in PET after the decontamination (C_{res}) to values lower than the corresponding modelled concentrations in PET (C_{mod}).

The Panel considered that under the given operating conditions the recycling process NOVAPET using the Polymetrix pellet 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 which the risk to human health would be negligible.

4. Conclusions

The Panel considered that the process NOVAPET using the Polymetrix pellet 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 decontamination in the [redacted] SSP reactor (step 5) is critical for the decontamination efficiency. The operating parameters to control its performance are temperature, residence time, and inert gas speed.

The Panel concluded that the recycling process NOVAPET 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 derived from the challenge tests used to measure the decontamination efficiency of the process;
- ii) the input material of the process is washed and dried post-consumer PET flakes originating from materials and articles that have been manufactured in accordance with the EU legislation on food contact materials and contain no more than 5% of PET from non-food consumer applications;
- iii) the recycled PET obtained from the process NOVAPET 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 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

Dossier 'NOVAPET'. Month Year. Submitted on behalf of NOVAPET S.A., Spain.
 Additional information, August 2021. Submitted on behalf of NOVAPET S.A., Spain.
 Additional information, October 2021. Submitted on behalf of NOVAPET S.A., Spain.

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Abbreviations

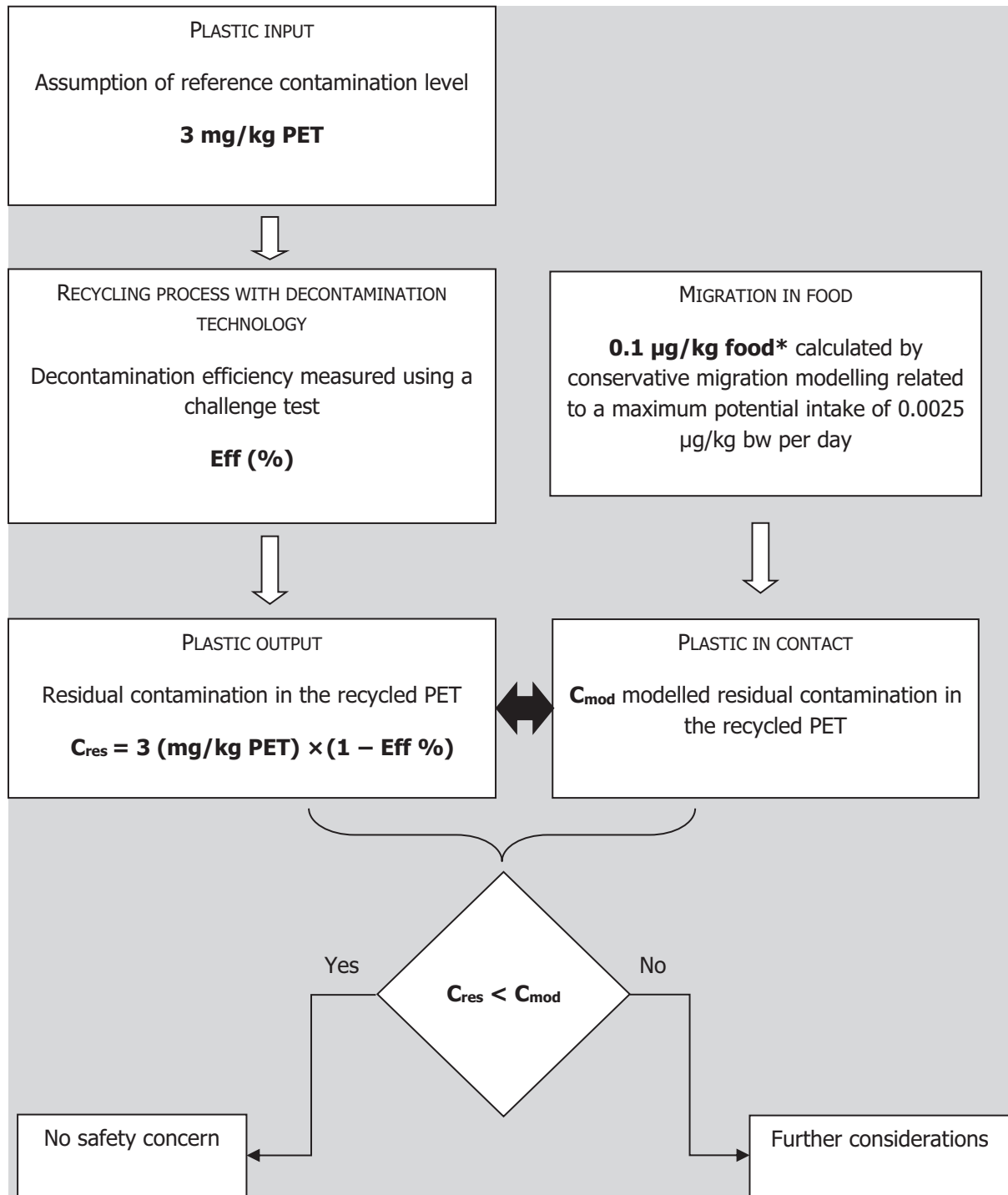
bw	body weight
CEF Panel	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP Panel	Panel on Food Contact Materials, Enzymes and Processing Aids
C_{mod}	modelled concentration in PET
C_{res}	residual concentrations in PET
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)
rPET	recycled poly(ethylene terephthalate)
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	200–500 kg/m ³
Material temperature	10–60°C
PVC max.	50 mg/kg
Glue	50 mg/kg
Polyolefins max.	200 mg/kg
Cellulose (paper, wood)	50 mg/kg
Metals max.	50 mg/kg
Polyamide max.	500 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 of operational parameters (Confidential Information)¹⁰

[Redacted content]

[Redacted]													
[Redacted]	[Redacted]			[Redacted]			[Redacted]			[Redacted]			
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¹⁰ Technical dossier, Sections 3.2.1. and 3.10.

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