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Safety assessment of the process EcoBlue, based on PET direct iV+ 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 EcoBlue (EU register number RECYC266, which uses the Starlinger PET direct iV+ technology). The input is hot caustic washed and dried poly(ethylene terephthalate) (PET) flakes mainly originating from collected post-consumer PET containers, with no more than 5% PET from non-food consumer applications. The flakes are extruded to pellets, which are then crystallised, preheated and treated in a solid-state polycondensation (SSP) reactor. Having examined the challenge test provided, the Panel concluded that the three steps, extrusion, crystallisation and SSP, are critical in determining the decontamination efficiency of the process. The operating parameters to control the performance of these critical steps are temperature, gas/PET ratio, pressure and residence time. The challenge test 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 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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Keywords: PET direct iV+, EcoBlue limited, food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

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[†] Deceased.

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1. Introduction

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

1.1.1. Background

Recycled plastic materials and articles shall only be placed on the market if the recycled plastic is from an authorised recycling process. Before a recycling process is authorised, 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 the European Food Safety Authority (EFSA) for evaluation.

In this case, EFSA received from the Spanish Agency of Food Safety and Nutrition, an application for evaluation of the recycling process EcoBlue, European Union (EU) register No RECYC266. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2021-00686. The dossier was submitted on behalf of EcoBlue Limited, Siam Eastern Park, 60/91 Moo 3 Tambol Mabyangporn 21,140/Rayong Amphur Pluakdaeng, Thailand (see '[Documentation provided to EFSA](#)').

1.1.2. Terms of Reference

The Spanish Agency of Food Safety and Nutrition requested the safety evaluation of the recycling process EcoBlue, in accordance with Article 5 of Regulation (EC) No 282/2008.

1.2. Interpretation of the Terms of Reference

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

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

2. Data and methodologies

2.1. Data

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

In accordance with Art. 38 of the Commission Regulation (EC) No 178/2002³ 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 EFSA's Executive Director laying down practical

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, pp. 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, pp. 4–17.

³ 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, pp. 1–48.

arrangements concerning transparency and confidentiality,⁴ the non-confidential version of the dossier is published on Open.EFSA.⁵

According to Article 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 consultations⁴, EFSA carried out a public consultation on the non-confidential version of the application from 15 September to 06 October 2022 for which no comments were received.

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

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

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 $\mu\text{g}/\text{kg}$ 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 information⁶

According to the applicant, the recycling process EcoBlue is intended to recycle food grade PET containers using the Starlinger PET direct iV+ technology. The recycled PET is intended to be used at

⁴ Decision available at <https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements>

⁵ The non-confidential version of the dossier is published on Open.EFSA and is available at the following link: <https://open.efsa.europa.eu/dossier/FCM-2021-1874>

⁶ Technical dossier, sections 'Recycling process' and 'Intended application in contact with food'.

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. The final articles are not intended to be used in microwave and conventional ovens.

3.2. Description of the process

3.2.1. General description⁷

The recycling process EcoBlue produces recycled PET pellets from PET materials originating from post-consumer collection systems (deposit, kerbside and mixed waste collection systems).

The recycling process comprises the four 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 the applicant or by a third party.

Decontamination and production of recycled PET material

- In step 2, the flakes are extruded into pellets [REDACTED].
- In step 3, the PET is crystallised [REDACTED] with an inert gas flow, then further heated before introduction into step 4.
- In step 4, the pellets are processed in the solid-state polycondensation (SSP) reactor [REDACTED] and under vacuum.

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 and bulk density.

3.2.2. Characterisation of the input⁸

According to the applicant, the input material for the recycling process EcoBlue consists of hot caustic washed and dried flakes obtained from PET materials (e.g. bottles and trays) previously used for food packaging, from post-consumer collection systems (kerbside and deposit systems as well as mixed waste collection). A small fraction may originate from non-food applications. According to the applicant, the proportion of this non-food container fraction depends on the collection system and will be no more than 5%.

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

3.3. Starlinger PET direct iV+ technology

3.3.1. Description of the main steps⁹

The general scheme of the Starlinger PET direct iV+ technology, as provided by the applicant, is reported in Figure 1. The steps are:

- Extrusion (step 2): The flakes are transformed into pellets in an extruder.
- Crystallisation (step 3): The extruded pellets are crystallised [REDACTED] in a continuous reactor with inert gas flow [REDACTED] for a predefined residence time, then further heated before introduction into step 4.
- SSP (step 4): The crystallised pellets are introduced semi-continuously into the SSP reactor running under vacuum [REDACTED] and for a predefined residence time.

⁷ Technical dossier, sections 'Recycling process', 'Characterisation of the input' and 'Characterisation of the recycled plastic'.

⁸ Technical dossier, section 'Characterisation of the input'.

⁹ Technical dossier, sections 'Recycling process' and 'Determination of the decontamination efficiency of the recycling process'.

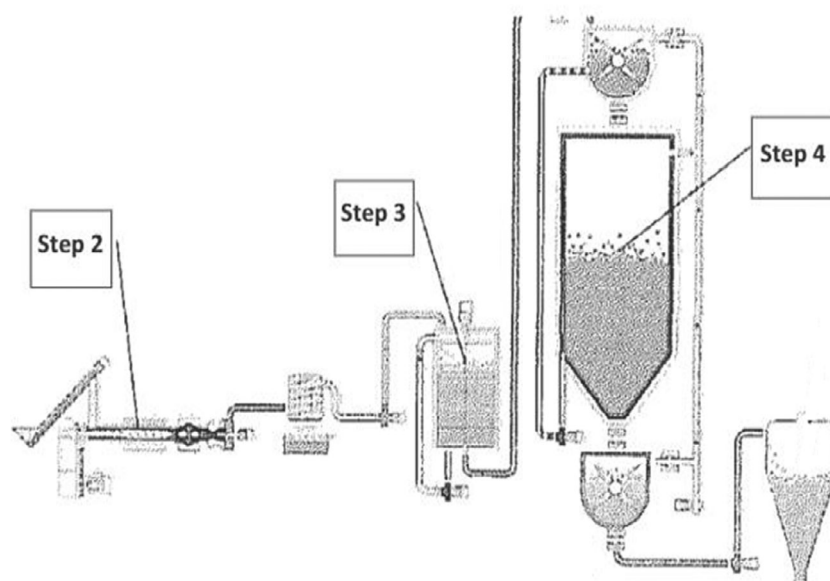


Figure 1: General scheme of the Starlinger PET direct iV+ technology (provided by the applicant)

The process is run under defined operating parameters¹⁰ of temperature, pressure, gas/PET ratio and residence time.

3.3.2. Decontamination efficiency of the recycling process¹¹

To demonstrate the decontamination efficiency of the recycling process EcoBlue, a challenge test was submitted to 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 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 the liquid surrogates (toluene, chlorobenzene, chloroform, methyl salicylate and phenyl cyclohexane). Batches of contaminated PET were stored in a closed steel container for 7 days at 50°C with periodical agitation. The PET flakes were washed and the concentration of the surrogates in this material was determined.

The Starlinger PET direct iV+ technology was challenged at laboratory scale, using only contaminated flakes. The contaminated flakes were extruded into pellets (step 2), crystallised (step 3) and then submitted to an SSP reactor (step 4). The samples (flakes, then pellets) were analysed for the residual concentrations of the applied surrogates. Instead of being processed continuously, the SSP reactor was run in batch mode. However, since the reactor in the process works practically with no mixing, the Panel agreed that the batch reactor in the challenge test provided the same cleaning efficiency when run at the same temperature, pressure and residence time.

The decontamination efficiency of the process was calculated taking into account the amount of the surrogates detected in washed and dried contaminated flakes before extrusion (before step 2) and in pellets after SSP (step 4). When not detected, the limit of detection was considered for the calculation of the decontamination efficiency. The results are summarised in Table 1.

¹⁰ 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).

¹¹ Technical dossier, section 'Determination of the decontamination efficiency of the recycling process'.

Table 1: Efficiency of the decontamination by the Starlinger PET direct iV+ technology in the challenge test

Surrogates	Concentration of surrogates before step 2 (mg/kg PET)	Concentration of surrogates after step 4 (mg/kg PET)	Decontamination efficiency (%)
Toluene	267.8	< 0.2 ^(a)	> 99.9
Chloroform	376.5	< 0.1 ^(a)	> 99.9
Chlorobenzene	467.8	0.7	99.9
Phenyl cyclohexane	572.4	5.7	99.0
Methyl salicylate	410.9	0.4	99.9
Benzophenone	719.4	8.8	98.8
Methyl stearate	505.2	3.2	99.4

PET: poly(ethylene terephthalate).

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

As shown in Table 1, the decontamination efficiency ranged from 98.8% for benzophenone to above 99.9% for toluene and 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, metals and dust, were provided for the input material (i.e. washed and dried flakes, step 1). These consist of PET containers, e.g. bottles and trays, 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 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) are conducted in different ways depending on the plant, by the applicant or by third parties. According to the applicant, this step is under control. The Starlinger PET direct iV+ technology comprises extrusion into pellets (step 2), crystallisation (step 3) and SSP (step 4). The operating parameters of temperature, pressure, residence time and gas/PET ratio have been provided to EFSA.

A challenge test to measure the decontamination efficiency was conducted at laboratory scale on process steps 2–4. The Panel considered that this challenge test was performed correctly according to the recommendations in the EFSA guidelines (EFSA, 2008). Although the fourth step is expected to be most critical for the decontamination, steps 2 and 3 may also be relevant. Therefore, the Panel considered that all three steps are critical for the decontamination efficiency of the process. Consequently, the temperature for extrusion (step 2), the temperature, the gas/PET ratio and the residence time for crystallisation (step 3) and the temperature, the pressure and the residence time for SSP (step 4) should be controlled to guarantee the performance of the decontamination (Appendix C).

The decontamination efficiencies obtained for each surrogate, ranging from 98.8% to > 99.9%, have been used to calculate the residual concentrations of potential unknown contaminants in PET (C_{res}) according to the evaluation procedure described in the 'Scientific opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET' (EFSA CEF Panel, 2011; Appendix B). By applying the decontamination percentages to the reference contamination level of 3 mg/kg PET, the C_{res} for the different surrogates was obtained (Table 2).

According to the evaluation principles (EFSA CEF Panel, 2011), the dietary exposure must not exceed 0.0025 µg/kg bw per day, below which the risk to human health is considered negligible. The C_{res} value should not exceed the modelled concentration in PET (C_{mod}) that, after 1 year at 25°C, results in a migration giving rise to a dietary exposure of 0.0025 µg/kg bw per day. Because the

recycled PET is intended for the manufacturing of articles (e.g. bottles) to be used in direct contact with drinking water, the exposure scenario for infants has been applied (water could be used to prepare infant formula). A maximum dietary exposure of 0.0025 µg/kg bw per day corresponds to a maximum migration of 0.1 µg/kg of a contaminant substance into the infant's food and has been used to calculate C_{mod} (EFSA CEF Panel, 2011). The results of these calculations are shown in Table 2. The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

Table 2: Decontamination efficiencies from the challenge test, 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	> 99.9	< 0.003	0.09
Chloroform	> 99.9	< 0.024	0.10
Chlorobenzene	99.9	0.003	0.10
Phenyl cyclohexane	99.0	0.030	0.14
Methyl salicylate	99.9	0.003	0.13
Benzophenone	98.8	0.006	0.16
Methyl stearate	99.4	0.018	0.32

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

As C_{res} values are lower than the corresponding modelled concentrations in PET (C_{mod}), the Panel considered that under the given operating conditions, the recycling process EcoBlue using the Starlinger PET direct IV+ technology is able to ensure that the level of migration of unknown contaminants from the recycled PET into food is below the conservatively modelled value 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 for long-term storage at room temperature, with or without hotfill.

The Panel noted that the input of the process originates from Thailand. 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 Starlinger PET direct IV+ technology is able to ensure that the level of unknown contaminants in recycled PET is below a calculated concentration (C_{mod}) corresponding to a modelled migration of 0.1 µg/kg food.

4. Conclusions

The Panel considered that the process EcoBlue, using the Starlinger PET direct IV+ 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 three steps, extrusion, crystallisation and SSP, are critical for the decontamination efficiency. The operating parameters to control their performance are the temperature for the extrusion (step 2), the temperature, the gas/PET ratio and residence time for the crystallisation (step 3) and the temperature, the pressure and the residence time for the SSP (step 4).

The Panel concluded that the recycling process EcoBlue 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 obtained from the process EcoBlue 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 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 'EcoBlue'. February 2022. Submitted on behalf of EcoBlue Limited, Thailand.

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Abbreviation

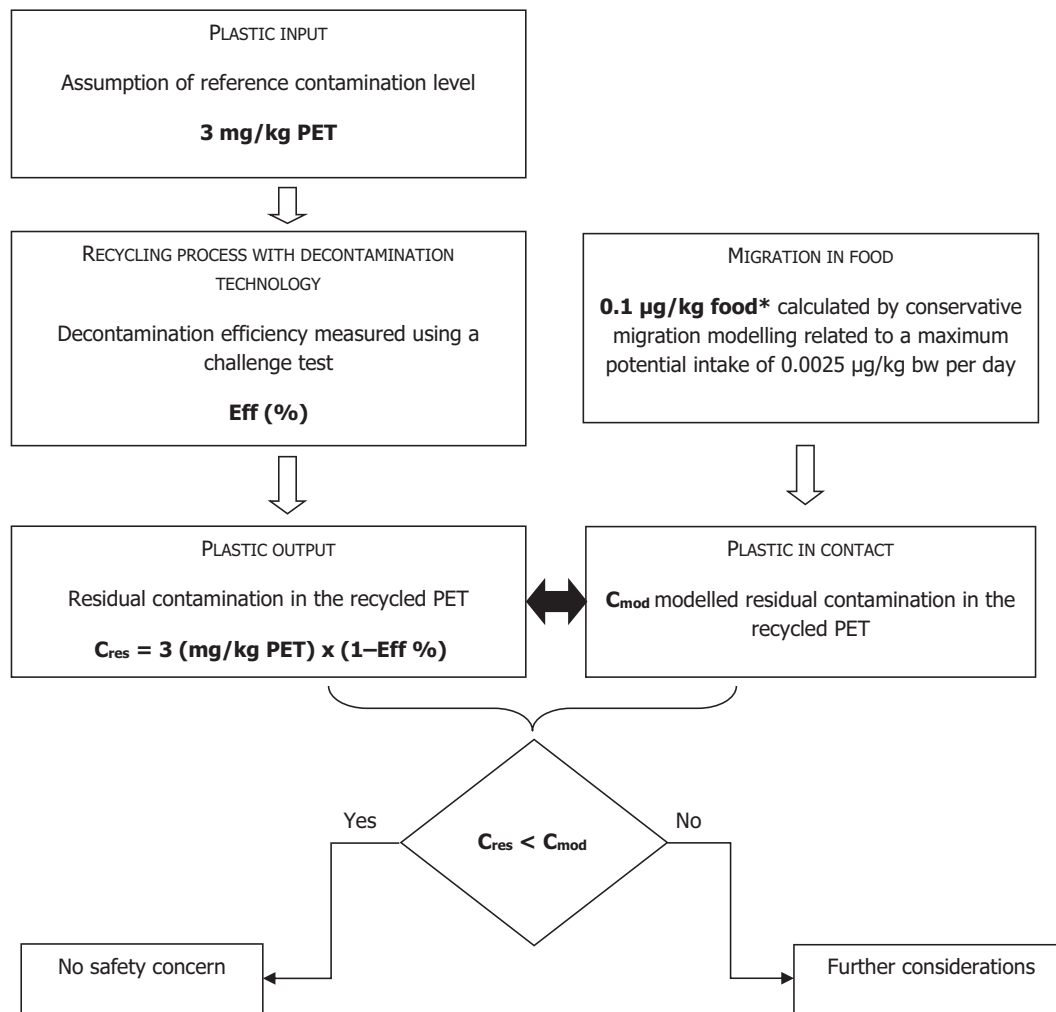
bw	body weight
CEF	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP	Panel on Food Contact Materials, Enzymes and Processing Aids
C_{mod}	modelled concentration in PET
C_{res}	residual concentration in PET
iV	intrinsic viscosity
PET	poly(ethylene terephthalate)
PVC	poly(vinyl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

Appendix A – Technical data of the washed flakes as provided by the applicant⁸

Parameter	Value
Moisture max.	< 2.5%
Bulk density	200–600 kg/m ³
PVC	< 200 mg/kg
Polyolefins	< 100 mg/kg
Other plastics	< 200 mg/kg
Metals	< 200 mg/kg
Dust	< 1.5%
Amount of non-food application PET	< 5%

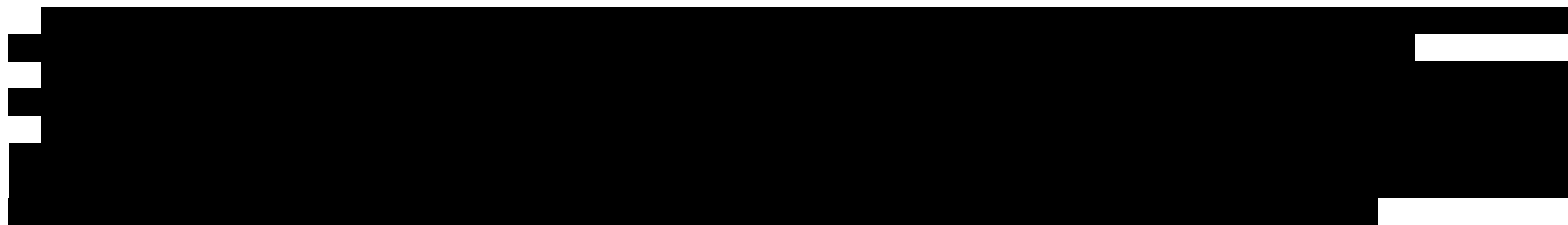
PVC: poly(vinyl chloride).

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 parameters¹²



Process EcoBlue (REC number RECYC266) based on the Starlinger PET direct IV+ technology

Parameters	Step 2 Extrusion			Step 3 Crystallisation of pellets			Step 4 SSP		
	t (min)	P (mbar)	T (°C)	t (min)	Gas/PET ratio (m ³ /kg)	T(°C)	t (h)	P (mbar)	T (°C)
Challenge test (Report No. PA/4255/08)	Not measured	atm	■	■	Inert gas ■	■	■	■	■
	Continuous	■		Batch			Batch		
Process	Not measured	atm	≥ ■	≥ ■	Inert gas* ≥ ■	≥ ■	≥ ■	≤ ■	≥ ■
	Continuous			Continuous			Semi-continuous**		

*: ■

** : Reactor first in/first out.

¹² Technical dossier, section "Table of operating parameters".