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Safety assessment of the process PT Veolia Indonesia, based on the Polymetrix 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 PT Veolia Indonesia (EU register number RECYC289), which uses the Polymetrix 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 to pellets, crystallised 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 fourth 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 velocity 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, 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 or conventional ovens and such uses are not covered by this evaluation.

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† Deceased.

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1. Introduction

1.1. Background and terms of reference

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, the European Food Safety Authority (EFSA)'s opinion on its safety is required. This procedure has been established in Article 5 of Regulation (EC) No 282/2008^{1,2} on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of Regulation (EC) No 1935/2004³ 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 Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, an application for evaluation of the recycling process PT Veolia Indonesia, European Union (EU) register No RECYC289. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2022-00511. The dossier was submitted on behalf of PT Veolia Services Indonesia, Jalan Rembang Industri Raya No.2 PIER, 67152 Rembang, Pasuruan, Jawa Timur, Indonesia.

1.1.2. Terms of Reference

The Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, requested the safety evaluation of the recycling process PT Veolia Indonesia, in compliance with 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 is able to reduce the contamination of the plastic input to a concentration that does not pose a risk to human health. The poly(ethylene terephthalate) (PET) materials and articles used as input of the process as well as the conditions of use of the recycled PET are part of this evaluation.

2. Data and methodologies

2.1. Data

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

¹ Commission Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006. OJ L 86, 28.3.2008, p. 9–18.

² Commission Regulation (EC) No 282/2008 was repealed by Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008 (OJ L 243 20.9.2022, p. 3) which entered into force on 10 October 2022. Applications submitted to EU Member State competent authorities before the date of entry into force of Commission Regulation (EU) 2022/1616 are evaluated by EFSA in accordance with Commission Regulation (EC) No 282/2008.

³ Regulation (EC) No 1935/2004 of the European parliament and of the council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4–17.

Additional information was provided by the applicant during the assessment process in response to a request from EFSA sent on 28 November 2022, (see 'Documentation provided to EFSA').

In accordance with Art. 38 of the Regulation (EC) No 178/2002⁴ 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 arrangements concerning transparency and confidentiality,⁵ the non-confidential version of the dossier has been published on Open.EFSA.⁶

According to Art. 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations,⁷ EFSA carried out a public consultation on the non-confidential version of the application from 17 May to 07 June 2023 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.

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 to be of safety concern for the defined conditions of use (EFSA CEF Panel, 2011).

⁴ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p.1–48.

⁵ Decision available at: <https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements>

⁶ The non-confidential version of the dossier has been published on Open.EFSA and is available at the following link: <https://open.efsa.europa.eu/dossier/FCM-2022-8170>

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

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 information⁸

According to the applicant, the recycling process PT Veolia Indonesia is intended to recycle food grade PET materials and articles using the Polymetrix 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, juices and beer, as well as sheets. The final articles are not intended to be used in microwave or conventional ovens.

3.2. Description of the process

3.2.1. General description⁹

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

The recycling process comprises the four steps below.

Input

- In step 1, the post-consumer PET containers are processed into washed and dried flakes. This step may be performed by a third party or by the applicant.

Decontamination and production of recycled PET material

- In step 2, the flakes are extruded into pellets.
- In step 3, the pellets are crystallised and heated to the decontamination temperature.
- In step 4, the crystallised pellets are decontaminated during solid-state polycondensation (SSP) 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, black spots and selected contaminants.

3.2.2. Characterisation of the input¹⁰

According to the applicant, the input material for the recycling process PT Veolia Indonesia 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 on physical properties and residual contents of moisture, poly(vinyl chloride) (PVC), polyolefins, polyamide, glue, cellulose (wood, paper) and metals (see Appendix A).

3.3. Polymetrix technology

3.3.1. Description of the main steps¹¹

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

- Extrusion (step 2): The washed and dried flakes are extruded to pellets.

⁸ Technical dossier, sections 'Recycling process' and 'Intended application in contact with food'.

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

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

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

- Crystallisation and heating (step 3): The extruded pellets are fed to a [redacted] reactor in which they are crystallised and heated up to the temperature of the SSP reactor.
- SSP (step 4): The crystallised pellets are fed to a continuous [redacted] reactor running under high temperature and countercurrent inert gas flow for a predefined residence time. Two different conditions of temperature (T) and residence time (t) (Ta, ta and Tb, tb where Ta < Tb and ta > tb) may be applied, depending on the desired intrinsic viscosity of the final product.

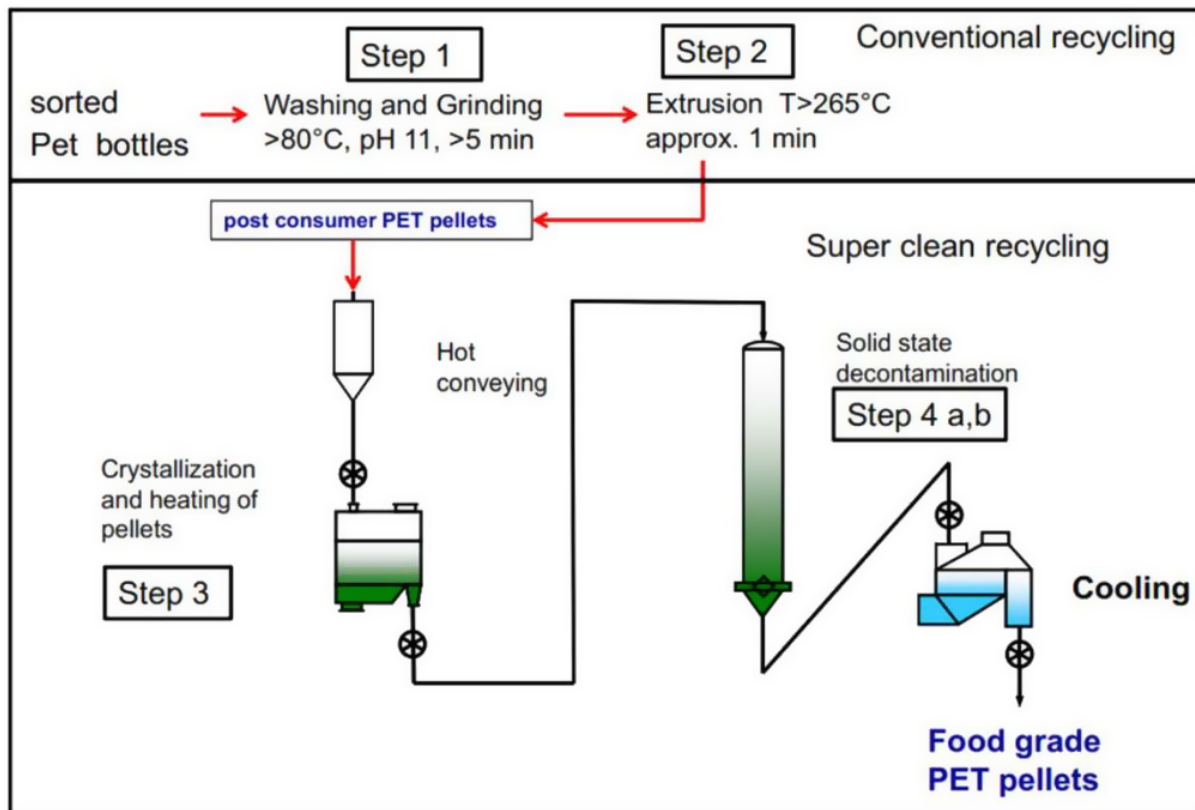


Figure 1: General scheme of the technology (provided by the applicant)

The process is run under defined operating parameters¹² of temperature, pressure, inert gas velocity and residence time.

3.3.2. Decontamination efficiency of the recycling process¹³

To demonstrate the decontamination efficiency of the recycling process PT Veolia Indonesia, challenge tests performed at [redacted] scale were submitted to EFSA.

PET flakes were contaminated with toluene, chlorobenzene, phenylcyclohexane, chloroform, methyl salicylate, benzophenone and methyl stearate, selected as surrogate contaminants in agreement with the EFSA guidelines (EFSA CEF Panel, 2011) and in accordance with the recommendations of the US Food and Drug Administration (FDA, 2006). The surrogates include different molecular masses and polarities to cover possible chemical classes of contaminants of concern and were demonstrated to be suitable to monitor the behaviour of PET during recycling (EFSA, 2008).

Solid surrogates (benzophenone and methyl stearate) and liquid surrogates (toluene, chlorobenzene, chloroform, methyl salicylate and phenyl cyclohexane) were added to 25 kg of conventionally recycled¹⁴ post-consumer PET flakes. Eight such barrels were prepared and stored for 7 days at 50°C with periodical agitation. Afterwards, the contaminated flakes were rinsed with 10% ethanol.

¹² In accordance with Art. 9 and 20 of Regulation (EC) No 1935/2004, the parameters were provided to EFSA by the applicant and made available to the Member States and the European Commission (see Appendix C).

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

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

The contaminated PET flakes were extruded (step 2), resulting in a homogenous contamination of the obtained pellets. The amorphous pellets were then crystallised (step 3). The concentrations of the surrogates were determined in these crystallised pellets, used as starting material for the decontamination step of the challenge test (step 4), performed in [REDACTED] mode at [REDACTED] scale at two decontamination temperatures, T_a and T_b , for various residence times.

[REDACTED] However, since the reactor in the process works practically with no mixing, the Panel agreed that the [REDACTED] reactor in the challenge test provided the same cleaning efficiency when run at the same temperature and residence time of the industrial process.

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

The decontamination efficiency of the process was calculated from the concentrations of the surrogates measured in the crystallised pellets before and after the SSP (step 4, conditions a and b). The results are summarised in Table 1.

Table 1: Efficiency of the decontamination of the SSP reactor at temperature and residence time conditions (a) and (b), where $T_a < T_b$ and $t_a > t_b$

Surrogates	Concentration of surrogates before step 4 (mg/kg PET)	Concentration of surrogates after step 4 (a) (mg/kg PET)	Concentration of surrogates after step 4 (b) (mg/kg PET)	Decontamination Efficiency (a) (%)	Decontamination Efficiency (b) (%)
Toluene	22.3	< 0.2 ^(a)	< 0.2 ^(a)	> 99.1	> 99.1
Chlorobenzene	42.1	< 0.1 ^(a)	< 0.1 ^(a)	> 99.8	> 99.8
Chloroform	36.6	< 0.5 ^(a)	< 0.5 ^(a)	> 98.6	> 98.6
Methyl salicylate	86.7	< 0.1 ^(a)	< 0.1 ^(a)	> 99.9	> 99.9
Phenylcyclohexane	85.9	3.7	3.3	95.7	96.2
Benzophenone	266.4	8.5	7.2	96.8	97.3
Methyl stearate	259.3	3.7	2.7	98.6	99.0

PET: poly(ethylene terephthalate).

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

As shown in Table 1, the decontamination efficiency was at least 95.7% (phenylcyclohexane) for option (a) and at least 96.2% (phenylcyclohexane) for option (b).

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 moisture, poly(vinyl chloride) (PVC), polyolefins, polyamide, glue, cellulose (wood, paper) and metals, were provided for the input materials (i.e. washed and dried flakes, step 1). These flakes are mainly produced from PET containers, e.g. bottles, previously used for food packaging, collected through post-consumer collection systems. However, a small fraction may originate from non-food applications, such as bottles for soap, mouth wash or kitchen hygiene agents. According to the applicant, the collection system and the process are managed in such a way that this fraction will be no more than 5% in the input stream, as recommended by the EFSA CEF Panel in its 'Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food' (EFSA CEF Panel, 2011).

The process is adequately described. The washing and drying of the flakes from the collected PET articles (step 1) are conducted in different ways depending on the plant and, according to the applicant, this step is under control. The Polymetrix technology comprises the extrusion (step 2), crystallisation and heating (step 3) and continuous SSP (step 4). The operating parameters of temperature and residence time for steps 2 and 3 and temperature, residence time and inert gas velocity for step 4 have been provided to EFSA.

Two challenge tests to measure the decontamination efficiency were conducted at [redacted] scale in [redacted] mode on the process step 4. The surrogate substances were determined in the pellets before and after the SSP reactor. The Panel considered that these challenge tests were performed according to the recommendations of the EFSA guidelines (EFSA, 2008).

The Panel considered that the SSP (step 4) is the critical step for the decontamination efficiency of the process. Consequently, the temperature, the residence time and the inert gas velocity of step 4 should be controlled to guarantee the performance of the decontamination.

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 surrogates in the two challenge tests (a, b) were 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, 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 the manufacture 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). Therefore, the migration of 0.1 µg/kg into food has been used to calculate C_{mod} (EFSA CEF Panel, 2011). The results of these calculations are shown in Table 2, for temperature and residence time conditions (a) and (b). The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

Table 2: Decontamination efficiencies from the challenge tests, residual concentrations of the surrogates (C_{res}) related to the reference contamination level and calculated concentrations of the surrogates in PET (C_{mod}) corresponding to a modelled migration of 0.1 µg/kg food after 1 year at 25°C, at temperature and residence time conditions (a) and (b). ($T_a < T_b$, $t_a > t_b$)

Surrogates	Decontamination efficiency (a) (%)	Decontamination efficiency (b) (%)	C_{res} for 100% rPET (a) (mg/kg PET)	C_{res} for 100% rPET (b) (mg/kg PET)	C_{mod} (mg/kg PET)
Toluene	> 99.1	> 99.1	< 0.03	< 0.03	0.09
Chlorobenzene	> 99.8	> 99.8	< 0.01	< 0.01	0.09
Chloroform	> 98.6	> 98.6	< 0.04	< 0.04	0.10
Methyl salicylate	> 99.9	> 99.9	< 0.01	< 0.01	0.13
Phenylcyclohexane	95.7	96.2	0.13	0.12	0.14
Benzophenone	96.8	97.3	0.10	0.08	0.16
Methyl stearate	98.6	99.0	0.04	0.03	0.32

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

The Panel considered that under the given operating conditions, the recycling process PT Veolia Indonesia using the Polymetrix 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 which the risk to human health would be negligible. 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 Indonesia. In the absence of data on contamination by misuse 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 Polymetrix 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 PT Veolia Indonesia using the Polymetrix 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 continuous SSP reactor (step 4) is critical for the decontamination efficiency. The operating parameters to control its performance are temperature, residence time and inert gas velocity.

The Panel concluded that the recycling process PT Veolia Indonesia 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 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 PT Veolia Indonesia 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 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 'PT Veolia Indonesia'. August 2022. Submitted on behalf of PT Veolia Services Indonesia, Indonesia.

Additional information, February 2023. Submitted on behalf of PT Veolia Services Indonesia, Indonesia.

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Abbreviations

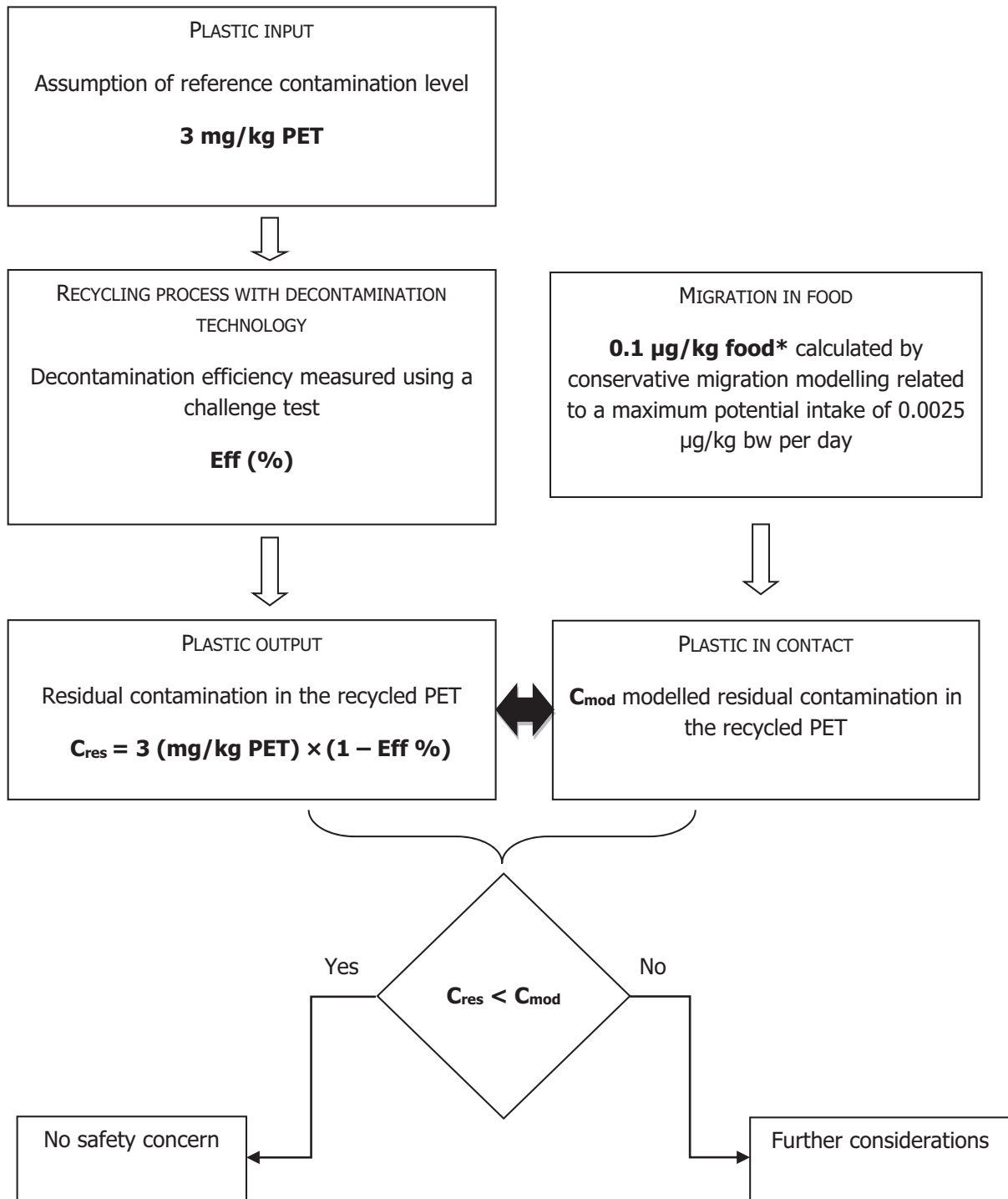
bw	body weight
CEF Panel	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP Panel	Panel on Food Contact Materials, Enzymes and Processing Aids
C_{mod}	modelled concentration in PET
C_{res}	residual concentrations in PET
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)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

Appendix A – Technical data of the washed flakes as provided by the applicant¹⁰

Parameter	Value
Moisture max.	1.5%
Moisture variation	$\pm 0.3\% \text{ h}^{-1}$
Bulk density	200–500 kg/m ³
Material temperature	10–60°C
PVC max.	50 mg/kg
Glue	50 mg/kg
Polyolefins max.	50 mg/kg
Cellulose (paper, wood)	50 mg/kg
Metals max.	50 mg/kg
Polyamide max.	2000 mg/kg

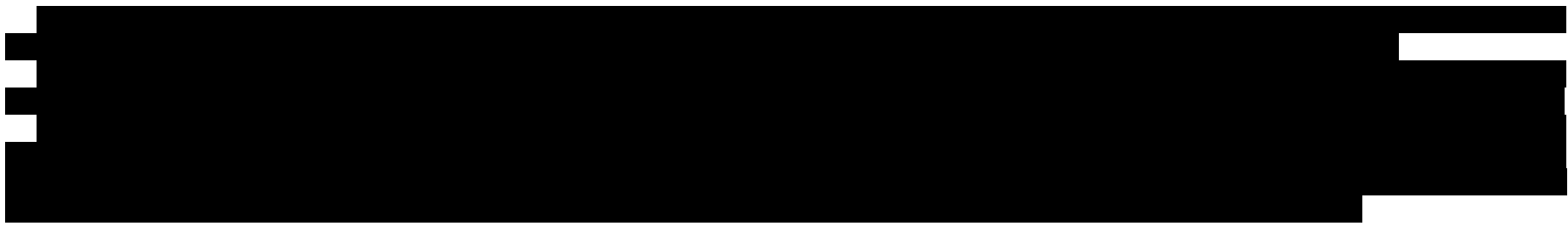
PVC: poly(vinyl chloride).

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 parameters¹⁵



Process PT Veolia Indonesia (RECYC289) based on the Polymetrix technology

Parameters	Step 2 Extrusion			Step 3 Crystallisation and heating			Step 4 SSP			
	T (°C)	t (min)	P (mbar)	T (°C)	t (min)	P (mbar)	t* (h)	Gas velocity (m/s) ^{***}	P (mbar)	T* (°C)
Challenge test (batch)	Not tested			Not tested						
Process (continuous)										
Option (a)										
Option (b)										



¹⁵ Technical dossier, Section 'Table of operating parameters'.