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Safety assessment of the process Battenfeld-Cincinnati Germany, based on the Battenfeld 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 Battenfeld-Cincinnati Germany (EU register number RECYC303), which uses the Battenfeld technology. The input consists of 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 heated and pre-decontaminated in an [redacted], then further decontaminated by extrusion to sheets [redacted]. Having examined the challenge test provided, the Panel concluded that the [redacted] drying (step 2) and extrusion (step 3) are critical in determining the decontamination efficiency of the process. The operating parameters to control the performance of these critical steps are temperature and residence time for step 2, temperature, throughput and pressure for step 3. The Panel concluded that this recycling process is able to ensure that the level of migration of potential unknown contaminants into food is below the conservatively modelled migration of 0.15 μg/kg food, exposure scenario for toddlers, under the following conditions of use of the recycled PET: (a) 45% in mixtures with virgin PET to produce trays for storage of fruits and vegetables up to 30 days at room temperature or below, (b) 100% to produce cups for storage of soft drinks and beers up to 1 day at room temperature or below, (c) 100% to produce trays for meat storage up to 30 days at 6°C. Hotfill is not included. Therefore, the Panel concluded that the recycled PET produced by this process is not of safety concern when used under the evaluated conditions. 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.

Keywords: BCG, Battenfeld-Cincinnati Germany, Battenfeld-Cincinnati Germany GmbH, food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process

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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, 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 1935/2004[3] 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 Federal Office of Consumer Protection and Food Safety, Germany, an application for evaluation of the recycling process Battenfeld-Cincinnati Germany, European Union (EU) register No RECYC303. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2022-00014. The dossier was submitted on behalf of Battenfeld-Cincinnati Germany GmbH, Grüner Weg 9, 32547 Bad Oeynhausen, Germany (see 'Documentation provided to EFSA').

1.1.2. Terms of Reference

The Federal Office of Consumer Protection and Food Safety, Germany, requested the safety evaluation of the recycling process Battenfeld-Cincinnati Germany, in compliance 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 Battenfeld-Cincinnati Germany 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 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).

[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 18 January 2023 (see 'Documentation provided to EFSA').

In accordance with Art. 38 of the Commission Regulation (EC) No 178/2002[4] 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 the EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[5] the non-confidential version of the dossier is 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 25 July to 15 August 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 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 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.

[4] Commission 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 online: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements

[6] The non-confidential version of the dossier, following EFSA's assessment of the applicant's confidentiality requests, is published on Open.EFSA and is available at the following link: https://open.efsa.europa.eu/dossier/FCM-2021-1890

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

3. Assessment

3.1. General information[8]

According to the applicant, the recycling process Battenfeld-Cincinnati Germany is intended to recycle food grade PET containers using the Battenfeld technology. The recycled PET is intended to be used between 70% and 100% of the total PET for thermoforming trays/containers for food contact applications. According to the applicant, PET articles will be used in contact with specific food types under specific contact times and temperatures (Table 1). The final articles are not intended to be used in microwave or conventional ovens.

Table 1: Intended uses, contact times and temperatures as proposed by the applicant

	Use	Contact time	Contact temperature
1	Trays for fruit and vegetables	Up to 30 days	Room temperature
2	Cups for soft drinks and beer	Up to 1 day	Room temperature
3	Trays for meat	Up to 30 days	6°C

3.2. Description of the process

3.2.1. General description[9]

The recycling process Battenfeld-Cincinnati Germany produces recycled PET pellets and sheets from PET containers (e.g. bottles), coming from post-consumer collection systems (kerbside and deposit systems).

The recycling process comprises the three 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 dried and decontaminated in an [redacted]
- In step 3, the flakes are extruded [redacted] to produce sheets.

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

The extruded sheets are checked against technical requirements, such as intrinsic viscosity, colour and black spots.

3.2.2. Characterisation of the input[10]

According to the applicant, the input material for the recycling process Battenfeld-Cincinnati Germany consists of washed and dried flakes obtained from PET containers previously used for food packaging, from post-consumer collection systems (kerbside and deposit systems). A small fraction may originate from non-food applications. 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 on the hot washed and dried flakes are provided, such as physical properties and residual contents of moisture, poly(vinyl chloride) (PVC), glue, polyolefins, wood and metals (see Appendix A).

[8] Technical dossier, section 'Recycling process'.
[9] Technical dossier, sections 'Recycling process', 'Characterisation of the input' and 'Characterisation of the recycled plastic'.
[10] Technical dossier, section 'Characterisation of the input'.

3.3. Battenfeld technology

3.3.1. Description of the main steps[11]

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

- [redacted] drying (step 2): [redacted], the flakes are continuously heated to and decontaminated [redacted]
- Extrusion (step 3): the flakes are fed to an extruder equipped with [redacted], to produce sheets.

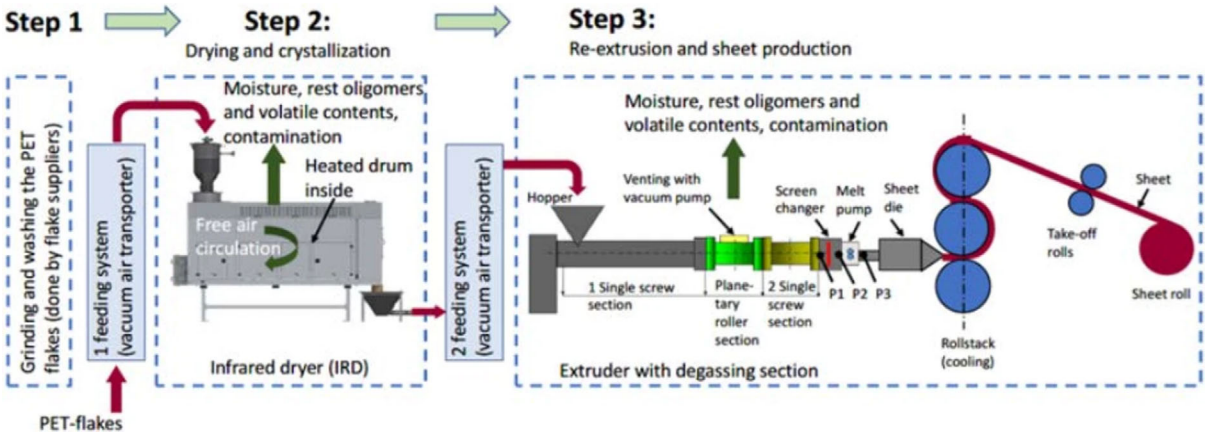

Figure 1: General scheme of the technology (provided by the applicant)

The process is run under defined operating parameters[12] of temperature, pressure, residence time and throughput.

3.3.2. Decontamination efficiency of the recycling process[13]

To demonstrate the decontamination efficiency of the recycling process Battenfeld-Cincinnati Germany, a challenge test performed using an industrial machinery of the same type and size as the one used in the process was submitted to the EFSA.

PET flakes were contaminated with toluene, chlorobenzene, chloroform, methyl salicylate, phenylcyclohexane, 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).

The mixture containing the surrogates was added to conventionally recycled[14] post-consumer PET flakes. The flakes were stored for 7 days at 50°C with periodical agitation, then rinsed with 10% ethanol. The concentration of surrogates in these flakes was determined.

The contaminated flakes were introduced into the [redacted] (step 2) and then extruded (step 3).

[11] Technical dossier, sections 'Recycling process' and 'Determination of the decontamination efficiency of the recycling process'.
[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 includes commonly sorting, grinding, washing and drying steps and produces washed and dried flakes.

The decontamination efficiency of the process was calculated from the concentrations of the surrogates measured before step 2 and after step 3. The results are summarised in Table 2.

Table 2: Efficiency of the decontamination of the Battenfeld technology in the challenge test

Surrogates	Concentration of surrogates before step 2 (mg/kg PET)	Concentration of surrogates after step 3 (mg/kg PET)	Decontamination efficiency (%)
Toluene	161.4	1.9	98.8
Chlorobenzene	350.4	5.9	98.3
Chloroform	121.4	2.2	98.2
Methyl salicylate	597.3	< 0.1[(a)]	> 99.9
Phenylcyclohexane	482.1	26.4	94.5
Benzophenone	717.8	272.8	62.0
Methyl stearate	939.0	135.4	85.6

PET: poly(ethylene terephthalate).
(a): Not detected at the limits of detection given.

As shown in Table 1, the decontamination efficiency ranged from 62.0% for benzophenone to more than 99.9% 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 data, such as physical properties and residual contents of PVC, glue, polyolefins and metals, were provided for the input materials (i.e. washed and dried flakes, step 1). The 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, 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 supplier. According to the applicant, this step is under control. The Battenfeld technology comprises [redacted] drying (step 2) and extrusion (step 3). The operating parameters of temperature, residence time, pressure and throughput have been provided to EFSA.

A challenge test to measure the decontamination efficiency was conducted on steps 2 and 3 using an industrial machinery of the same type and size as the one used in the process. The Panel considered that it was performed correctly according to the recommendations in the EFSA guidelines (EFSA, 2008). It also considered that the two steps ([redacted] drying and extrusion) were critical for the decontamination efficiency of the process. Consequently, temperature and residence time for step 2 and temperature, pressure and throughput during the extrusion (step 3) should be controlled to guarantee the performance of the decontamination (Appendix C).

The decontamination efficiencies obtained for each surrogate, ranging from 62.0% 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. A maximum dietary exposure of 0.0025 μg/kg bw per day corresponds to a maximum migration of 0.15 μg/kg of the contaminant into the toddler's food and these parameters have been used to calculate C_{mod}

(EFSA CEF Panel, 2011). The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

If new articles produced with 100% recycled PET do not fulfil these requirements, the recycled PET should be mixed with virgin PET to ensure that the C_{res} value does not exceed the C_{mod} value. The relationship between the key parameters for the evaluation scheme is reported in Appendix D.

The Panel noted that the applicant requested three specific uses, not including contact with drinking water, and proposed their related C_{mod} using the conditions reported in Table 1. However, migration time and temperature conditions should be selected according to the Regulation (EU) 10/2011, as specified by the EFSA CEF Panel (EFSA CEF Panel, 2011). Therefore, the Panel selected the migration conditions from Regulation (EU) 10/2011, based on the specific uses proposed by the applicant (Appendix D). Then, the Panel determined C_{mod} by using currently validated migration models (Simoneau et al., 2015).

Tables 3–5 report C_{mod} and C_{res} values calculated by the Panel for the scenario of toddlers for the three specific uses. For each one, C_{res} was calculated for a given percentage of recycled PET, for which the risk to human health was demonstrated to be negligible ($C_{res} < C_{mod}$).

Table 3: Decontamination efficiencies from the challenge test, 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 0.15 μg/kg food (scenario for toddlers) after 10 days at 40°C

Surrogates	Decontamination efficiency (%)	C_{res} for 45% rPET (mg/kg PET)	C_{mod} (mg/kg PET)
Toluene	98.8	0.02	0.28
Chlorobenzene	98.3	0.02	0.33
Chloroform	98.2	0.02	0.35
Methyl salicylate	> 99.9	< 0.01	0.44
Phenylcyclohexane	94.5	0.07	0.47
Benzophenone	62.0	0.51	0.54
Methyl stearate	85.6	0.19	1.06

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

Table 4: Decontamination efficiencies from the challenge test, 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 0.15 μg/kg food (scenario for toddlers) after 1 day at 40°C

Surrogates	Decontamination efficiency (%)	C_{res} for 100% rPET (mg/kg PET)	C_{mod} (mg/kg PET)
Toluene	98.8	0.04	0.88
Chlorobenzene	98.3	0.05	1.04
Chloroform	98.2	0.05	1.10
Methyl salicylate	> 99.9	< 0.01	1.40
Phenylcyclohexane	94.5	0.16	1.48
Benzophenone	62.0	1.14	1.71
Methyl stearate	85.6	0.43	3.34

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

Table 5: Decontamination efficiencies from the challenge test, 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 0.15 μg/kg food (scenario for toddlers) after 10 days at 20°C

Surrogates	Decontamination efficiency (%)	C_{res} for 100% rPET (mg/kg PET)	C_{mod} (mg/kg PET)
Toluene	98.8	0.04	1.04
Chlorobenzene	98.3	0.05	1.22
Chloroform	98.2	0.05	1.29
Methyl salicylate	> 99.9	< 0.01	1.64
Phenylcyclohexane	94.5	0.16	1.73
Benzophenone	62.0	1.14	2.00
Methyl stearate	85.6	0.43	3.19

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

Based on the provided data from the challenge test and the applied conservative assumptions, the Panel considered that, under the given operating conditions, the recycling process Battenfeld-Cincinnati Germany using the Battenfeld 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 0.15 μg/kg food, when the recycled PET is used to produce materials and articles at up to:

- 45% in virgin PET for contact with fruits and vegetables, up to 30 days at room temperature or below,
- 100% for contact with soft drinks and beer up to 1 day at room temperature or below,
- 100% for contact with meat up to 30 days at 6°C.

At the above conditions, the risk to human health is considered negligible.

4. Conclusions

The Panel considered that the Battenfeld-Cincinnati Germany recycling process using the Battenfeld technology is adequately characterised and that the main steps used to recycle the PET flakes into decontaminated PET sheets have been identified.

Having examined the challenge test provided, the Panel concluded that the two steps ([redacted] drying and extrusion) are critical for the decontamination efficiency. The operating parameters to control its performance are temperature and residence time for step 2 and temperature, pressure and throughput for step 3.

The Panel concluded that the recycling process Battenfeld-Cincinnati Germany 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 containing no more than 5% of PET from non-food consumer applications;
iii) the recycled PET obtained from the process Battenfeld-Cincinnati Germany is used at up to:

- 45% in mixtures with virgin PET to produce trays for storage of fruits and vegetables up to 30 days at room temperature or below,
- 100% to produce cups for storage of soft drinks and beers up to 1 day at room temperature or below,
- 100% to produce trays for meat storage up to 30 days at 6°C.

The hotfill is not included in the above conditions. The final articles made of this recycled PET are not intended to be used in microwave and conventional ovens and such uses are not covered by this evaluation.

5. Recommendations

The Panel recommended periodic verification that the input 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

1) Dossier 'Battenfeld-Cincinnati Germany', October 2022. Submitted on behalf of Battenfeld-Cincinnati Germany GmbH, Germany.
2) Additional information, updated dossier, April 2023. Submitted on behalf of Battenfeld-Cincinnati Germany GmbH, Germany.

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Abbreviations

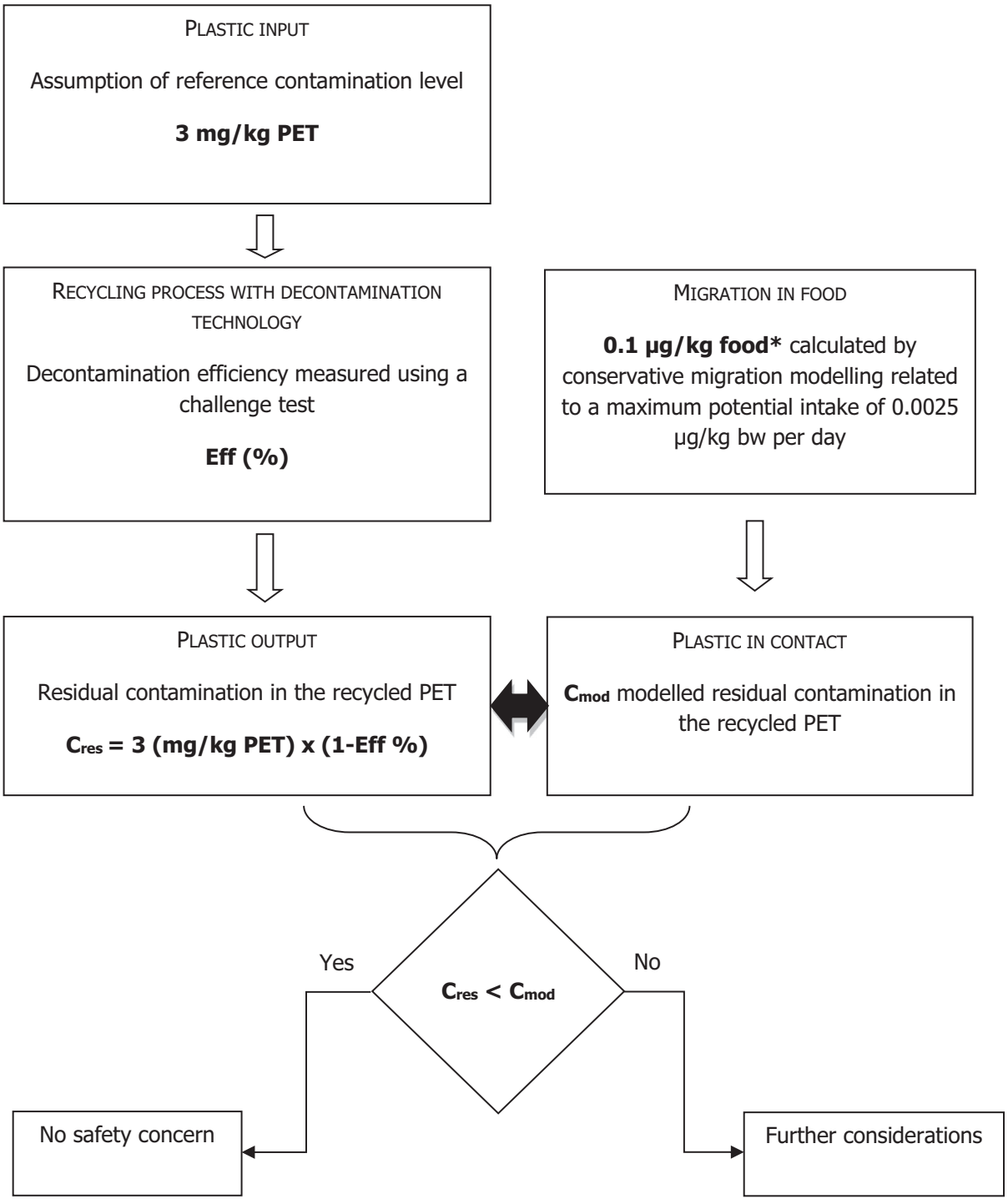
bw	body weight
CEF Panel	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP Panel	Panel on Food Contact Materials, Enzymes and Processing Aids
C_{mod}	modelled concentration in PET
C_{res}	residual concentrations in PET
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)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

Appendix A – Technical data of the washed flakes as provided by the applicant[10]

Parameter	Value
Moisture max.	0.5–0.7%
Moisture variation	± 0.3%/h
Bulk density	230–350 kg/m^3
PVC	0–50 mg/kg
Glue	0–40 flakes per 1 kg sample
Polyolefins	0–20 mg/kg
Wood	0–10 mg/kg
Metals	0–20 mg/kg

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.

Appendix C – Table of operational parameters[15]

Although the operational parameters are reported for all the process steps, the critical steps and the corresponding parameters of the challenge test/process, considered for the evaluation of the process and for which it has been concluded that the process is safe, are highlighted in green.

The process should be operated at conditions at least as severe as the ones indicated in green in the table (e.g. lower pressures are more severe than higher, higher temperatures are more severe than lower, longer times are more severe than shorter, higher gas flows generally are more severe than lower).

The official enforcement control shall verify that the recycling plant is operating in a way that complies with its authorisation. Depending on the technology, some of the parameters are inter-related and changing one parameter to a more severe value may impact another parameter into a less severe value. Therefore, eventual deviations from the values of the parameters indicated as critical (marked in green in the table) should be demonstrated not impacting significantly on the safety assessment. The table does not necessarily report all the tolerances for the operational parameters.

Process Battenfeld-Cincinnati Germany (RECYC303) based on the Battenfeld technology

	Step 2 [redacted] Drying			Step 3 Extrusion		
Parameters	**t (min)**	**P (mbar)**	**T (°C)**	**Throughput (kg/h)**	**P (mbar)**	**T (°C)**
Challenge test (PA/4838/20)	[redacted] continuous	Atmospheric	[redacted]	[redacted] continuous	[redacted]	[redacted]
Process*	[redacted] continuous	Atmospheric	[redacted]	[redacted] continuous	[redacted]	[redacted]

*: The challenge test was conducted on an industrial machinery. The process should be performed at the same size of the industrial machinery as used in the challenge test.

[15] Technical report, section 'Table of operating Parameters'.

Appendix D – Modelling parameters used by the Panel to calculate concentrations in PET(C_{mod}) corresponding to a migration of 0.15 μg/kg food

Contact times and temperatures were taken from Reg. (EU) 10/2011, selecting the migration conditions corresponding to the specific uses intended by the applicant:

	Intended use	Intended conditions of use	Corresponding conditions in Reg (EU) 10/2011
1	Trays for fruit and vegetables	Up to 30 days 25°C	10 days at 40°C
2	Cups for soft drinks and beer	Up to 1 day 25°C	1 day at 40°C
3	Trays for meat	Up to 30 days 6°C	10 days at 20°C

Other relevant parameters are the following:

- Good solubility of the migrant in food simulant is assumed ($K_{P/F}$ = 1).
- A food contact material or article made entirely with 100% recycled PET.
- A surface area to volume ratio of 6 dm^2 PET to 1 kg food/drink.
- A material thickness of 300 μm is assumed.
- Modelling parameters Ap' = 3.1 and τ = 1577 are used to estimate the diffusion coefficient in PET (Simoneau et al., 2015).
- Density of PET is 1.375 g/cm^3