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Safety assessment of the process 'Gneuss 2', based on Gneuss technology, used to recycle post-consumer PET into food contact materials

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Abstract

This scientific opinion of the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids deals with the safety evaluation of the recycling process Gneuss 2 (EU register No RECYC0144). The input is washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, containing no more than 5% of PET from non-food applications. They are extruded under vacuum into pellets or sheets. Having examined the challenge test provided, the Panel concluded that the decontamination in the extruder under vacuum degassing is the critical step for the decontamination efficiency of the process. The operating parameters to control its performance are well defined and are temperature, pressure, residence time, throughput rate, the rotor speed and the satellite screws speed. The operating parameters of this step are at least as severe as those obtained from the challenge test. It was demonstrated that this recycling process is able to ensure that the level of migration of potential unknown contaminants into food is below a conservatively modelled migration of 0.1 µg/kg food. Therefore, the recycled PET obtained from the process Gneuss 2 intended for the manufacture of articles made with up to 90% recycled post-consumer PET and intended for contact for long-term storage at room temperature with all types of foodstuffs is not considered of safety concern. Trays made of this recycled PET are not intended to be used, and should not be used, in microwave and conventional ovens.

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Keywords: Gneuss 2, food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

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Note: The full opinion will be published in accordance with Article 10(6) of Regulation (EC) No 1935/2004 once the decision on confidentiality, in line with Article 20(3) of the Regulation, will be received from the European Commission. 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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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 they contain recycled plastic obtained from an authorised recycling process. Before a recycling process is authorised, EFSA's opinion on its safety is required. This procedure has been established in Article 5 of Regulation (EC) No 282/2008¹ of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of Regulation (EC) No 1935/2004² of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the Member States Competent Authorities which transmit the applications to the European Food Safety Authority (EFSA) for evaluation.

In this case, EFSA received, from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, an application for evaluation of the recycling process Gneuss 2 (Gneuss technology), EU register No RECYC0144. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2016-00706. The dossier was submitted on behalf of Gneuss Kunststofftechnik GmbH, Germany.

According to Article 5 of Regulation (EC) No 282/2008 of the Commission of 27 March 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 Gneuss 2 (Gneuss technology) is able to reduce any contamination of the plastic input to a concentration that does not pose a risk to human health. The poly(ethylene terephthalate) (PET) materials and articles used as input of the process as well as the conditions of use of the recycled PET make part of this evaluation.

2. Data and methodologies

2.1. Data

The applicant has submitted a dossier following the 'EFSA guidelines for the submission of an application for the safety evaluation of a recycling process to produce recycled plastics intended to be used for the manufacture of materials and articles in contact with food, prior to its authorisation' (EFSA, 2008). Applications shall be submitted in accordance with Article 5 of the Regulation (EC) No 282/2008.

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

² Regulation (EC) No 1935/2004 of the European parliament and of the council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4–17.

2.2. Methodologies

The principles followed up for the evaluation are described here. The risks associated to 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 (see guidelines on recycling plastics; 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 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 information

According to the applicant, the recycling process Gneuss 2 (Gneuss technology) is intended to recycle food grade PET containers to produce recycled PET pellets or sheets. According to the applicant, it is intended to use up to 80% recycled PET to manufacture new food packaging articles, i.e. PET sheets for thermoformed trays and containers or PET bottles. These final materials and articles are intended to be used in 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 oven applications. The applicant is the manufacturer of the recycling equipment providing the technology for the Gneuss 2 process, and not a producer of recycled PET.

3.2. Description of the process

3.2.1. General description

The recycling process Gneuss 2 (Gneuss technology) produces recycled PET pellets or sheets from PET containers, coming from post-consumer collection systems (kerbside and deposit collection systems). The recycling process is composed of the two steps below. The first step is performed by third parties.

Input

- In step 1, materials and articles of post-consumer PET containers are processed into washed and dried flakes.

Decontamination and production of recycled PET sheets

- In step 2, the flakes are decontaminated by extrusion including a degassing system and production of sheets or pellets.

Recycled PET sheets or pellets, the final product of the process, are checked against technical requirements on intrinsic viscosity, colour, black spots, etc. They are intended to be converted in other plants (by other companies) into articles, such as bottles, trays and containers. These final materials and articles are intended to be used in direct contact with all kinds of foodstuffs for long-term storage

at room temperature, with or without hotfill. They are not intended to be used in microwave or conventional ovens.

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

3.2.2. Characterisation of the input

According to the applicant, the input material for the recycling process Gneuss 2 (Gneuss technology) is hot washed and dried flakes obtained from PET containers, mainly bottles, previously used for food packaging, from post-consumer collection systems (kerbside and deposit systems). A small fraction may originate from non-food applications such as soap bottles, mouth wash bottles, kitchen hygiene bottles, etc. According to information from the applicant, the amount of this non-food container fraction depends on the collection system and will be below 5%.

Technical data for the hot washed and dried flakes are provided such as information on residual content of poly(vinyl chloride) (PVC), glue, polyolefins, cellulose, metals, polyamides and physical properties (see Appendix A).

3.3. Gneuss technology

3.3.1. Description of the main steps

The general scheme of the Gneuss technology, as provided by the applicant, is reported in Figure 1. In step 1, post-consumer PET containers are processed into hot washed and dried flakes.

Extrusion (step 2): The washed and dried flakes are continuously fed into the extruder (Gneuss technology). The Gneuss MRS Extruders of two sizes and capacities, MRS70 and MRS110, comprise a degassing section with eight satellite screws, which degasses the melt at high vacuum at predefined temperature and residence time. For each particular extruder geometry, the parameters throughput rate, rotor speed and satellite screws speed highly influence the thickness and surface area of the melt exposed to the vacuum. The residual solid particles (e.g. paper, aluminium) are filtered out before recycled PET is produced.

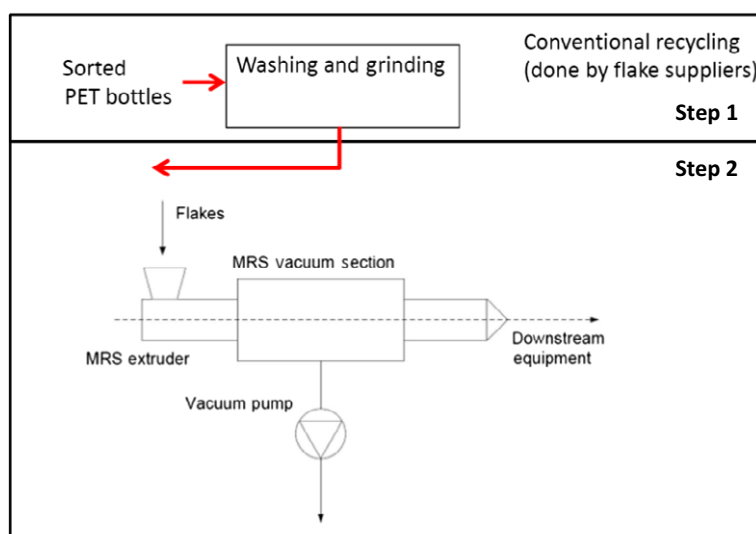


Figure 1: General scheme of the Gneuss technology (provided by the applicant)

The process is operated under defined operating parameters³ of temperature, pressure and residence time.

³ In accordance with Art. 9 and 20 of Regulation (EC) No 1935/2004, the parameters were provided to EFSA and made available to the applicant, the Member States and European Commission (see Appendix C).

3.3.2. Decontamination efficiency of the recycling process

To demonstrate the decontamination efficiency of the recycling process Gneuss 2, a challenge test on the Gneuss technology was submitted to EFSA. According to the applicant, the challenge test was performed in a MRS70 commercial equipment at the Gneuss facilities.

PET flakes were contaminated with selected chemicals, toluene, chlorobenzene, chloroform, methyl salicylate, phenylcyclohexane, benzophenone and methyl stearate, used as surrogate contaminants. The surrogates were chosen in agreement with EFSA guidelines and in accordance with the US-FDA recommendations. The surrogates include different molecular weights and polarities to cover possible chemical classes of contaminants of concern and were demonstrated to be suitable to monitor the behaviour of plastic during recycling (EFSA, 2008).

For the preparation of the contaminated PET flakes, 60 kg washed and dried conventionally recycled green PET flakes were mixed with the surrogates and stored for 7 days at 50°C under periodical agitation. The contaminated flakes were rinsed with 10% ethanol. The concentration of surrogates in this material was determined. After rinsing, the flakes were introduced into the extruder without further washing and drying.

The Gneuss 2 process was challenged using the extruder MRS70. The process was running with non-contaminated transparent flakes for around 1 h. Subsequently, 30 kg of the contaminated green flakes were introduced into the hopper (feeder). The extruder run with 100% green contaminated flakes before the challenge test samples were drawn. There was no dilution with non-contaminated clear flakes.

The decontamination efficiency was calculated based on the concentration of surrogates in PET material before (flakes) and after (pellets) the extrusion. The results are summarised below in Table 1.

Table 1: Efficiency of the decontamination of the Gneuss 2 process in the challenge test

Surrogates	Concentration of surrogates before step 2 (mg/kg PET)	Concentration of surrogates after step 2 (mg/kg PET)	Decontamination efficiency (%)
Toluene	256	< 0.2	> 99.9
Chloroform	311	1.1	99.7
Chlorobenzene	537	3.6	99.3
Phenylcyclohexane	411	12.3	97.0
Methyl salicylate	736	< 0.1	> 99.9
Benzophenone	762	43.1	94.3
Methyl stearate	966	27.1	97.2

PET: poly(ethylene terephthalate).

As shown above, the decontamination efficiency ranged from 94.3% for benzophenone to above 99.9% for toluene and methyl salicylate.

3.4. Discussion

Considering the high temperatures used during the extrusion, 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 residual content of PVC, glue, polyolefins, cellulose, metals, polyamides and physical properties, are provided for the input materials (washed and dried flakes (step 1)) for the submitted recycling process. The input materials are produced from PET containers, previously used for food packaging collected through post-consumer collection systems. However, a small fraction of the input may originate from non-food applications such as soap bottles, mouth wash bottles, kitchen hygiene bottles, etc. According to the applicant, the amount of this non-food container fraction depends on the collection system and the process is managed in such a way that in the input stream of the recycling process this amount will be lower 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 well described. The production of hot washed and dried flakes from collected containers, mainly bottles (step 1) is conducted by third parties. According to the applicant, the

defined specifications (Annex 1) for the supplied flakes are checked on a regular basis. The Gneuss technology used an extrusion with multiple degassing (step 2) to recycle the PET flakes into decontaminated product (pellets or sheets). Two different extruders corresponding to different sizes and capacities are used, the MRS70 and MRS110. The operating parameters of temperature, residence time, pressure, throughput rate, rotor speed and satellite screws speed have been provided to EFSA.

To measure the decontamination efficiency of the process, a challenge test with contaminated flakes was conducted on step 2 (vacuum extrusion) at the commercial equipment MRS70. Based on data provided by the applicant, the Panel considered it representative also of the alternative equipment MRS110. The challenge test was performed according to the recommendations in the EFSA Guidelines (EFSA, 2008). The contaminated flakes were rinsed before being subjected to step 2.

The Panel noted that step 2 (vacuum extrusion) is the critical step for the decontamination efficiency of the process. It considered that critical parameters for the decontamination of the melt, for each specific extruder geometry, are the surface and the thickness of the melt exposed to the vacuum, which are critically affected by the throughput rate, the rotor speed and the satellite screws speed. Consequently, the temperature, pressure, residence time, throughput rate, rotor speed and satellite screws speed parameters of the extrusion should be controlled to guarantee the performance of the decontamination. These parameters have been provided to EFSA.

The decontamination efficiencies obtained for each surrogate contaminant from the challenge test, ranging from 94.3% to above 99.9%, have been used to calculate the residual concentrations of potential unknown contaminants in sheets (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; Annex II). By applying the decontamination efficiency percentage to the Reference Contamination level of 3 mg/kg PET the C_{res} for the different surrogates in recycled sheets is obtained (Table 2).

According to the evaluation principles (EFSA CEF Panel, 2011), the C_{res} should not be higher than a modelled concentration in PET (C_{mod}) corresponding to a migration, after 1 year at 25°C, which cannot give rise to a dietary exposure exceeding 0.0025 µg/kg bw per day, the exposure threshold below which the risk to human health would be negligible.⁴ The results of these calculations are shown in Table 2 for 100% input of contaminated PET. The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

Table 2: Decontamination efficiency from challenge test obtained with 100% contaminated PET as input material, residual concentration of surrogate contaminants in recycled PET (C_{res}) and calculated concentration of surrogate contaminants 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} (mg/kg PET)	C_{mod} (mg/kg PET)
Toluene	> 99.9	0.002 (0.002)*	0.09
Chloroform	99.7	0.011 (0.010)*	0.10
Chlorobenzene	99.4	0.017 (0.018)*	0.10
Phenylcyclohexane	97.0	0.090 (0.080)*	0.14
Methylsalicylate	> 99.9	0.0004 (0.0004)*	0.13
Benzophenone	94.3	0.17 (0.153)*	0.16
Methyl stearate	97.2	0.084 (0.076)*	0.32

PET: poly(ethylene terephthalate).

*: For 90% use of recycle.

Therefore, the Panel considered the recycling process under evaluation 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.

4. Conclusions

The Panel considered that the process Gneuss 2 (Gneuss technology) is well characterised and the main steps used to recycle the PET flakes into decontaminated PET products are identified. Having

⁴ 0.0025 µg/kg bw per day is the human exposure threshold value for chemicals with structural alerts raising concern for potential genotoxicity, below which the risk to human health would be negligible (EFSA CEF Panel (2011)).

examined the challenge tests provided, the Panel concluded that the step 2 (extrusion with vacuum degassing, using either the MRS70 or the MRS110 extruders) is critical for the decontamination efficiency. The operating parameters to control its performance are temperature, pressure, residence time, throughput rate, rotor speed and the satellite screws speed. Therefore, the Panel considered that the recycling process Gneuss 2 (Gneuss technology) is able to reduce any foreseeable accidental contamination of the 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 obtained from the challenge tests used to measure the decontamination efficiency of the process;
- ii) the input 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.

Therefore, the recycled PET obtained from the process Gneuss 2 (Gneuss technology), if used up to 90 % for the manufacture of materials and articles for contact with all types of foodstuffs for long term storage at room temperature, is not considered of safety concern. Trays made of this recycled PET are not intended to be used, and should not be used in microwave and conventional ovens.

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.

Documentation provided to EFSA

- 1) Dossier "Super-clean technology: Gneuss 2 process". October 2016. Submitted on behalf of Gneuss Kunststofftechnik GmbH, Germany.
- 2) Additional information for the dossier "Super-clean technology: Gneuss 2 process". September 2017. Submitted on behalf of Gneuss Kunststofftechnik GmbH, Germany.
- 3) Additional information for the dossier "Super-clean technology: Gneuss 2 process". April 2018. Submitted on behalf of Gneuss Kunststofftechnik GmbH, Germany.

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- EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), 2011. 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 Journal 2011;9(7):2184, 25 pp. <https://doi.org/10.2903/j.efsa.2011.2184>

Abbreviations

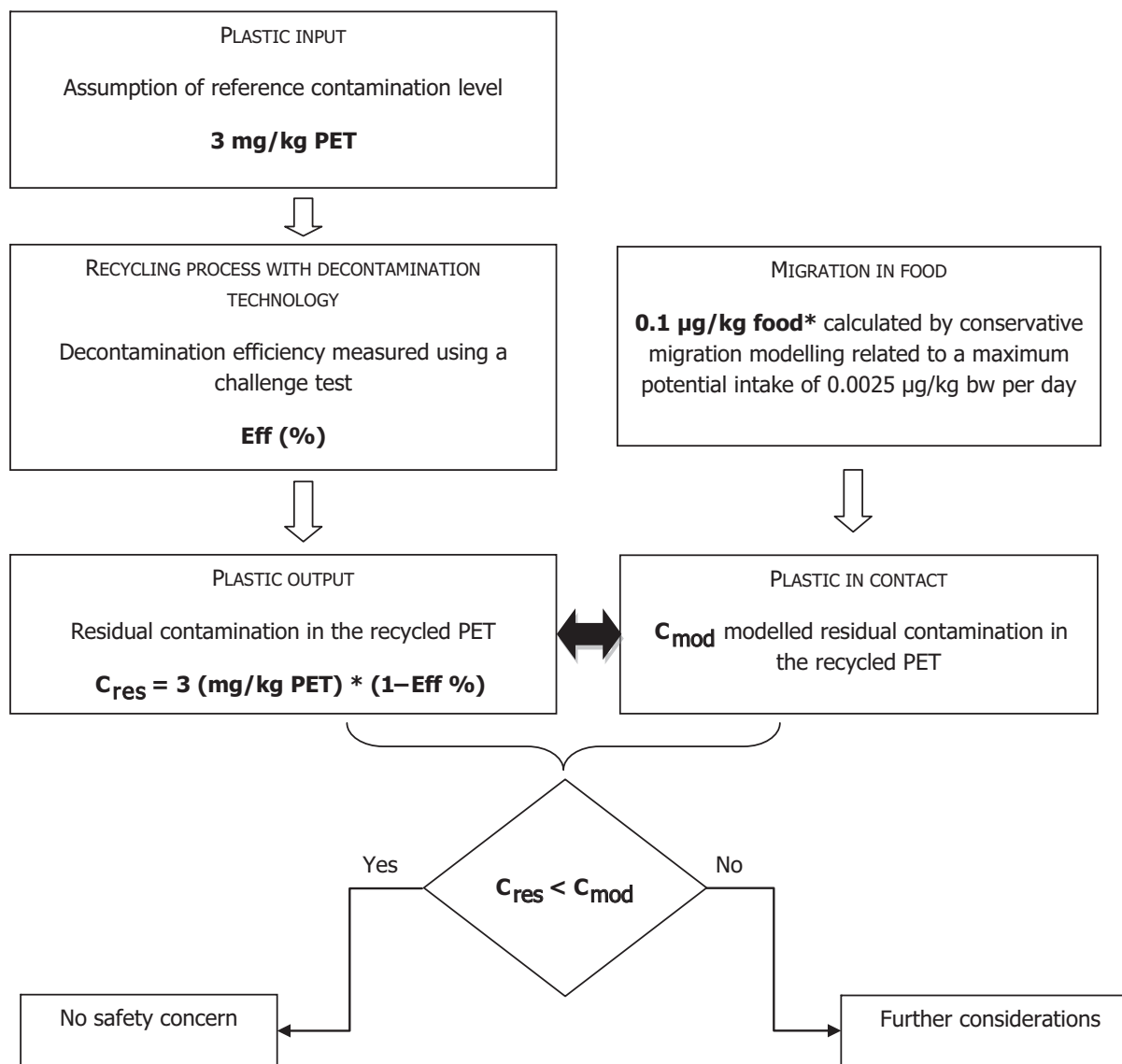
bw	body weight
CEF	Food Contact Materials, Enzymes, Flavourings and Processing Aids
C _{mod}	modelled concentration in PET
C _{res}	residual concentrations in PET
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)

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

Parameter	Value
Moisture max.	1.0%
Moisture variation	$\pm 0.3\% \text{ h}^{-1}$
Bulk density	200–850 kg/m ³
Bulk density variation	$\pm 150 \text{ kg}/(\text{m}^3\text{h})$
Material temperature	10–120°C
Material temp. variation	$\pm 10^\circ\text{C}/\text{h}$
PVC max.	200 ppm
Glue max.	100 ppm
Polyolefins max.	300 ppm
Cellulose (paper, wood)	100 ppm
Metal max.	100 ppm
Polyamide max.	100 ppm

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.

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