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Safety assessment of the process SML Maschinengesellschaft, based on SML 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 SML Maschinengesellschaft (EU register number RECYC203), which uses the SML 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 heated in an infrared (IR) dryer, then dried with hot air and extruded with vacuum degassing to sheets or pellets. Having examined the challenge test provided, the Panel concluded that the infrared drying (step 2), air drying (step 3) and extrusion (step 4) 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 all steps, air flow rate for step 3 and pressure for step 4. 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 (a) 0.1 μg/kg food, exposure scenario for infants, when such recycled PET is used at up to 50% in mixture with virgin PET and of (b) 0.15 μg/kg food, exposure scenario for toddlers, for contact with all types of foodstuffs except for packaged water at up to 80%, for long-term storage at room temperature, with or without hotfill, and at up to 100% for storage under frozen and refrigerated conditions. 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: SML, SML Maschinengesellschaft mbH, food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling process, safety assessment

Requestor: Austrian Federal Ministry of Labour, Social Affairs, Health and Consumer Protection

Question number: EFSA-Q-2019-00377

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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 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] on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of Regulation (EC) No 1935/2004[2] 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 Austrian Federal Ministry of Labour, Social Affairs, Health and Consumer Protection, an application for evaluation of the recycling process SML Maschinengesellschaft, European Union (EU) register No RECYC203. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2019-00377. The dossier was submitted on behalf of SML Maschinengesellschaft mbH, Austria.

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 SML Maschinengesellschaft 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 dossier following the 'EFSA guidelines for the submission of an application for the safety evaluation of a recycling process to produce recycled plastics intended to be used for the manufacture of materials and articles in contact with food, prior to its authorisation' (EFSA, 2008).

Additional information was sought from the applicant during the assessment process in response to requests from EFSA sent on 20 November 2020 and March 2021 and was subsequently provided (see 'Documentation provided to EFSA').

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

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

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

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

2.2. Methodologies

The principles followed up for the evaluation are described here. 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 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 SML Maschinengesellschaft is intended to recycle food grade PET containers using the SML technology. The recycled PET is intended to be used at up to 50% for the manufacture of materials and articles such as bottles for direct contact with mineral water, beverages and beer for long-term storage at room temperature, with or without hotfill. The recycled PET may also be used at up to 80% for sheets which are thermoformed to make food trays and containers for direct contact with foodstuffs (such as fruits, vegetables, dairy products and desserts) for long-term storage at room temperature, with or without hotfill, or at up to 100% to make trays for direct contact at frozen and refrigerated conditions. The final articles are not intended to be used in microwave and conventional ovens.

3.2. Description of the process

3.2.1. General description[3]

The recycling process SML Maschinengesellschaft 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 four steps below.

Input

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

Decontamination and production of recycled PET material

- In Step 2, the flakes are heated in an infrared dryer.
- In Step 3, the flakes are treated in a drying bin by hot air.
- In step 4, the flakes are extruded under vacuum to produce sheets or pellets.

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

[3] Technical dossier, Section 3.1.1.

The final product of the process (pellets or sheets), are checked against technical requirements, such as intrinsic viscosity, colour and black spots.

3.2.2. Characterisation of the input[4]

According to the applicant, the input material for the recycling process SML Maschinengesellschaft consists of hot washed and dried flakes obtained from PET containers, 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 are provided, such as information on physical properties and on residual contents of moisture, poly(vinyl chloride) (PVC), glue, polyolefins, cellulose and metals (see Appendix A).

3.3. SML technology

3.3.1. Description of the main steps[5]

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

- Infrared drying (step 2): In a continuous process, the flakes are heated and crystallised at high temperature with the use of IR lamps.
- Hot air treatment (step 3): The flakes are dried under a flow of hot air.
- Extrusion (step 4): The flakes are extruded with vacuum degassing to produce sheets or pellets.

[4] Technical dossier, Section 3.2.2.
[5] Technical dossier, Section 3.2.1.

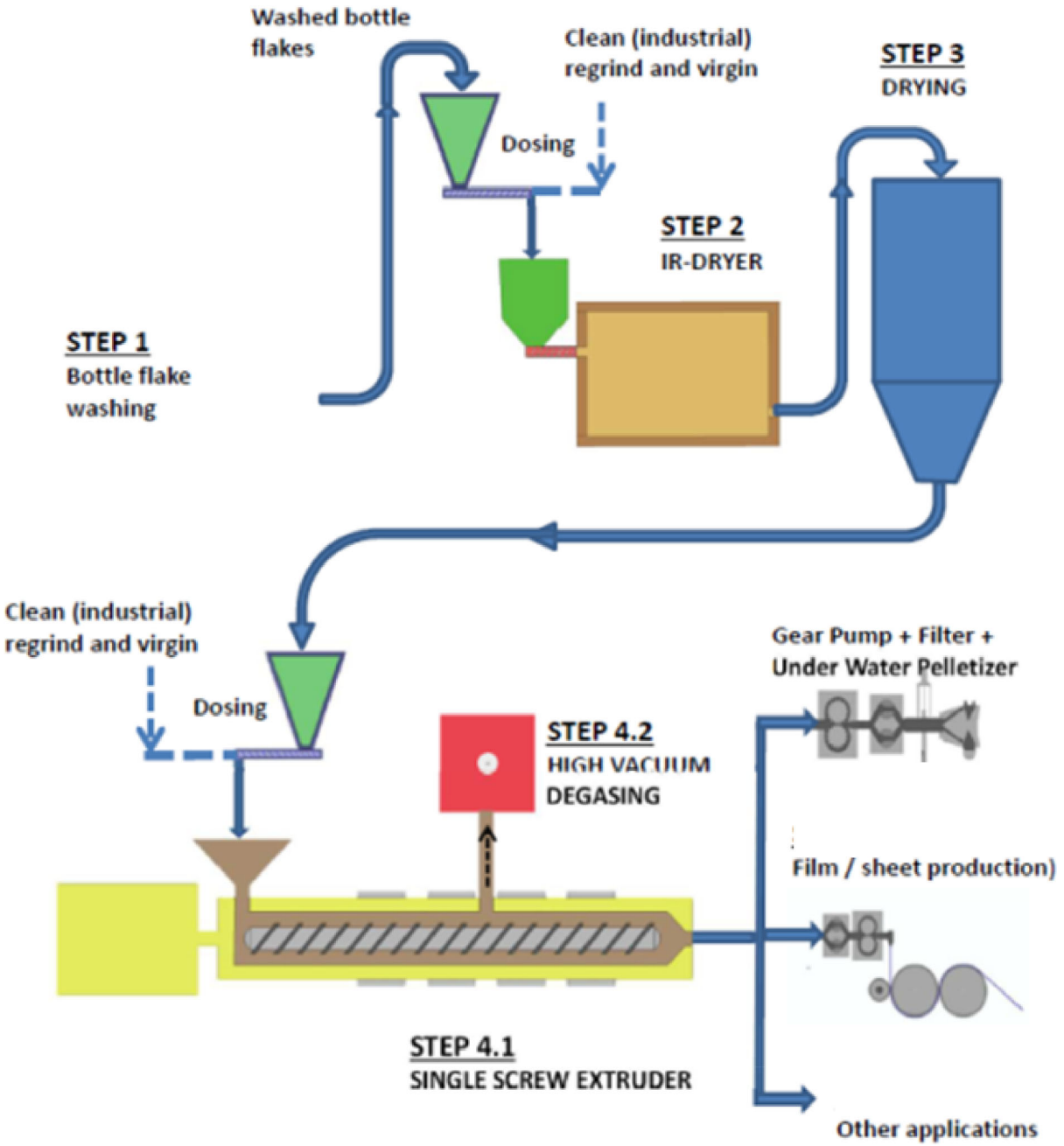

Figure 1: General scheme of the **SML** technology (provided by the applicant)

The process is run under defined operating parameters[6] of temperature, pressure, air flow rate and residence time.

3.3.2. Decontamination efficiency of the recycling process[7]

To demonstrate the decontamination efficiency of the recycling process SML Maschinengesellschaft, a challenge test performed at industrial scale 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

[6] 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).
[7] Technical dossier, Section 3.2.3 and Appendix F.

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).

Conventionally recycled[8] post-consumer PET flakes were soaked in a mixture of surrogates and stored for 7 days at 50°C with periodical agitation. Then, they were washed. The concentration of surrogates in these flakes was determined.

The SML technology was challenged in a production plant scale. The contaminated flakes were washed and introduced into the IR dryer (step 2), then sampled after each step (2–4) to measure the residual concentrations of the applied surrogates.

The decontamination efficiency of the process was calculated from the concentrations of the surrogates measured in the washed contaminated flakes before IR drying (before step 2) and after extrusion to sheets (step 4). The results are summarised below in Table 1.

Table 1: Efficiency of the decontamination by the SML 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	208.5	< 0.1[(a)]	> 99.9
Chlorobenzene	287.8	1.2	99.6
Chloroform	138.4	< 0.1[(a)]	> 99.9
Methyl salicylate	254.4	0.7	99.7
Phenylcyclohexane	246.2	5.2	97.9
Benzophenone	253.7	23.1	90.9
Methyl stearate	228.9	14.4	93.7

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

As shown in Table 1, the decontamination efficiency ranged from 90.9% for benzophenone to more than 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 information on 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). These 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 in the input stream this fraction will be no more than 5%, as recommended by the EFSA CEF Panel in its 'Scientific opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food' (EFSA CEF Panel, 2011).

The process is adequately described. The washing and drying of the flakes from the collected PET containers (step 1) is conducted in different ways depending on the supplier and, according to the applicant, this step is under control. The SML technology comprises IR drying (step 2), hot air treatment (step 3) and extrusion (step 4). The operating parameters of temperature, residence time, pressure and air flow rate have been provided to EFSA.

A challenge test to measure the decontamination efficiency was conducted at production plant 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). The Panel considered that the three steps (IR drying, hot air treatment and extrusion) were critical for the decontamination efficiency of the process. Consequently, the temperature and residence time for steps 2-4, the air flow rate for air drying (step 3) and the air pressure during the extrusion (step 4) should be controlled to guarantee the performance of the decontamination (Appendix C).

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

The decontamination efficiencies obtained for each surrogate, ranging from 90.9% 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, 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 manufacture of bottles, both scenarios for infants and for toddlers have been applied, since 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 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). If the PET produced by a recycling process is used up to 100% to produce new articles and they do not meet these targets, recycled PET should be mixed with virgin PET at a limited percentage to make sure that the C_{res} value does not exceed the C_{mod} value.

The C_{res} values reported in Tables 2–4 were calculated for percentages of incorporated recycled PET for which the risk to human health is demonstrated to be negligible. In Table 2 (scenario for infants), C_{res} is calculated for using 50% recycled PET.

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 50% rPET (mg/kg PET)	C_{mod} (mg/kg PET)
Toluene	> 99.9	< 0.001	0.09
Chlorobenzene	99.6	0.01	0.09
Chloroform	> 99.9	< 0.001	0.10
Methyl salicylate	99.7	0.01	0.13
Phenylcyclohexane	97.9	0.03	0.14
Benzophenone	90.9	0.14	0.16
Methyl stearate	93.7	0.10	0.32

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

In Table 3 (scenario for toddlers), C_{res} is calculated for 80% recycled PET.

Table 3: 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 0.15 μg/kg food after 1 year at 25°C

Surrogates	Decontamination efficiency (%)	C_{res} for 80% rPET (mg/kg PET)	C_{mod} (mg/kg PET)
Toluene	> 99.9	< 0.002	0.13
Chlorobenzene	99.6	0.01	0.15
Chloroform	> 99.9	< 0.002	0.15
Methyl salicylate	99.7	0.01	0.20
Phenylcyclohexane	97.9	0.05	0.21
Benzophenone	90.9	0.22	0.24
Methyl stearate	93.7	0.15	0.47

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

The recycled PET is also intended to be used in the manufacture of PET trays with up to 100% recycled content to be used at frozen and refrigerated conditions, for which standard migration testing for 10 days at 20°C is foreseen by the legislation.[9] For these conditions, the conservative default scenario for toddlers has been applied, the migration of 0.15 μg/kg into food has been used to calculate C_{mod}. The results of these calculations are shown in Table 4.

Table 4: 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 0.15 μg/kg food after 10 days at 20°C

Surrogates	Decontamination efficiency (%)	C_{res} for 100% rPET (mg/kg PET)	C_{mod} (mg/kg PET)
Toluene	> 99.9	< 0.001	1.08
Chlorobenzene	99.6	0.01	1.26
Chloroform	> 99.9	< 0.002	1.32
Methyl salicylate	99.7	0.01	1.67
Phenylcyclohexane	97.9	0.06	1.77
Benzophenone	90.9	0.27	2.04
Methyl stearate	93.7	0.19	4.05

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

The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

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 SML Maschinengesellschaft using the SML technology is able to ensure that the level of migration of unknown contaminants from the recycled PET into food is below the conservatively modelled values of:

- 0.1 μg/kg food at which the risk to human health is considered negligible when the recycled PET is used at up to 50% in mixtures with virgin PET to produce bottles intended for contact with drinking water (scenario of infants) for long term storage at room temperature, with or without hot filling,
- 0.15 μg/kg food at which the risk to human health is considered negligible when the recycled PET is used at up to 80% to produce materials and articles intended for contact with all types of foodstuffs except drinking water (scenario of toddlers) for long term storage at room temperature, with or without hot filling,
- 0.15 μg/kg food at which the risk to human health is considered negligible when the recycled PET is used at up to 100% to produce trays intended for contact with food (scenario of toddlers), at conditions covered by migration testing of 10 days at 20°C.[9]

4. Conclusions

The Panel considered that the SML Maschinengesellschaft recycling process using the SML technology is adequately characterised and that the main steps used to recycle the PET flakes into decontaminated PET sheets or pellets have been identified. Having examined the challenge test provided, the Panel concluded that the three steps (IR drying, air drying and extrusion) are critical for the decontamination efficiency. The operating parameters to control its performance are temperature and residence time for steps 2–4, air flow rate for step 3 and pressure for step 4.

The Panel concluded that the recycling process SML Maschinengesellschaft 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

[9] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food OJ L 12, 15.11.2011, p. 1–89.

on food contact materials containing no more than 5% of PET from non-food consumer applications;

iii) the recycled PET obtained from the process SML Maschinengesellschaft is used at up to:

- 50% in mixtures with virgin PET to produce bottles intended for contact with drinking water, for long-term storage at room temperature, with or without hot filling,
- 80% in mixtures with virgin PET to produce materials and articles intended for contact with all types of foodstuffs except drinking water, for long term storage at room temperature, with or without hot filling,
- 100% to produce trays intended for contact with food at frozen and refrigerated conditions (covered by migration compliance testing of 10 days at 20°C)[9].

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. Recommendation

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 as provided to EFSA

1) Dossier 'SML Maschinengesellschaft'. July 2020. Submitted on behalf of SML Maschinengesellschaft mbH, Austria.
2) Additional information, updated dossier. March 2021. Submitted on behalf of SML Maschinengesellschaft mbH, Austria.
3) Additional information, updated dossier. April 2021. Submitted on behalf of SML Maschinengesellschaft mbH, Austria.

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EFSA (European Food Safety Authority), 2008. Guidelines for the submission of an application for safety evaluation by the EFSA of a recycling process to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food, prior to its authorisation. EFSA Journal 2008,6(7):717, 12 pp. https://doi.org/10.2903/j.efsa.2008.717

EFSA (European Food Safety Authority), 2009. Guidance of the Scientific Committee on transparency in the scientific aspects of risk assessments carried out by EFSA. Part2: General principles. EFSA Journal 2009;7 (5):1051, 22 pp. https://doi.org/10.2903/j.efsa.2009.1051

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Abbreviations

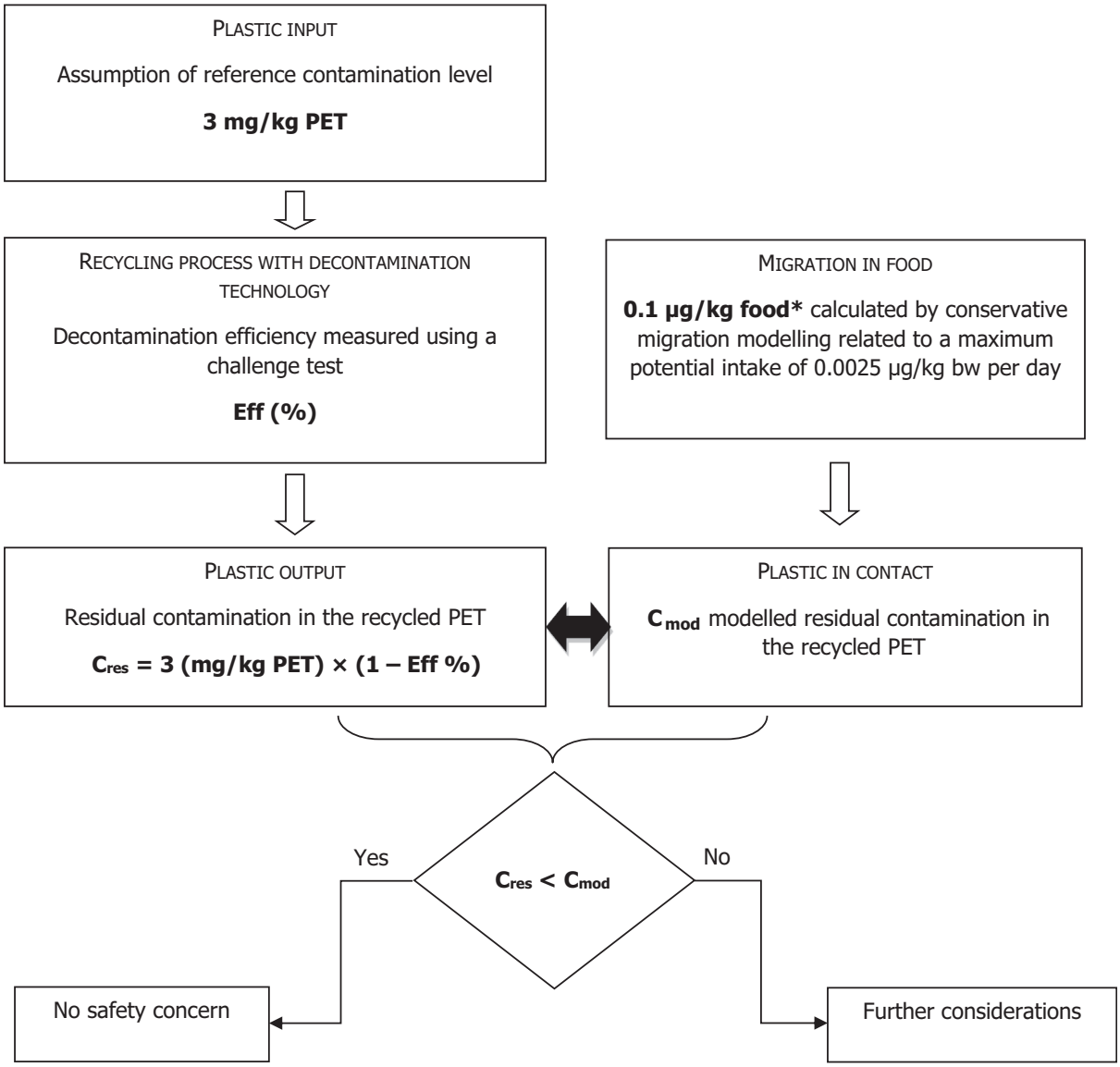
bw	body weight
CEF	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP	Panel on Food Contact Materials, Enzymes and Processing Aids
C_{mod}	modelled concentration in PET
C_{res}	residual concentration in PET
iV	intrinsic viscosity
IR	infrared
PET	poly(ethylene terephthalate)
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	± 0.3%/h
Bulk density	230–850 kg/m^3
Bulk density variation	± 50 kg/(m^3h)
Material temperature	5–40°C
Material temp. variation	± 10°C/h
PVC max.	100 mg/kg
Glue max.	100 mg/kg
Polyolefins max.	100 mg/kg
Cellulose (paper, wood)	100 mg/kg
Metals max.	100 mg/kg

PVC: poly(vinyl chloride).

Appendix B – Relationship between the key parameters for the evaluation scheme (EFSA CEF Panel, 2011)



*: Default scenario (infant). For adults and toddlers, the migration criterion will be 0.75 and 0.15 µg/kg food, respectively. The figures are derived from the application of the human exposure threshold value of 0.0025 µg/kg bw per day applying a factor of 5 related to the overestimation of modelling.

Appendix C – Table of operational parameters (confidential information)