European Food Safety Authority

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SCIENTIFIC OPINION

Scientific Opinion on the safety assessment of the process "APPE supercycle CP" used to recycle post-consumer PET into food contact materials [1]

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) [2, 3]

European Food Safety Authority (EFSA), Parma, Italy

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 APPE Supercycle CP (EU register No RECYC066). The input of the process is hot caustic washed and dried PET flakes originating from collected post-consumer PET containers, mainly bottles, containing no more than 5 % of PET from non-food consumer applications. Through this process, washed and dried PET flakes are extruded under vacuum and pelletised (step 2). The pellets are crystallised at high temperature under vacuum (step 3) and further decontaminated in a solid state polymerisation reactor (SSP) at high temperature under vacuum. Having examined the challenge test provided, the Panel concluded that the three steps, the extrusion (step 2), the crystallisation (step 3) and the decontamination in the SSP reactor (step 4) are the critical steps for the decontamination efficiency of the process. The operating parameters to control their performance are the temperature, the gas flow, the pressure and the residence time. The operating parameters of these steps in the process are at least as severe as those obtained from the challenge test. Under these conditions, it was demonstrated that the 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 Panel concluded that the recycled PET obtained from this process intended to be used at up to 100 % for the manufacture of materials and articles for contact with all types of foodstuffs for long term storage at room temperature, with or without hotfill is not considered of safety concern.

KEY WORDS

APPE Supercycle CP, RECYC066, Food contact materials, Plastic, Recycling, Process, Safety assessment

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[1] On request from Direction Générale de la Concurrence de la Consommation et de la Répression des Fraudes, France, Question No EFSA-Q-2010-00004, adopted on 26 March 2014.

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[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Recycling processes: Laurence Castle, Vincent Dudler, Nathalie Gontard, Eugenia Lampi, Maria Rosaria Milana, Cristina Nerin and Constantine Papaspyrides for the preparatory work on this scientific opinion.

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SUMMARY

According to Commission Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials intended to come into contact with foods, EFSA is requested to evaluate recycling processes in which plastic waste is recycled. In this context, the CEF Panel evaluated the process "APPE Supercycle CP".

The Direction Générale de la concurrence de la consommation et de la repression des fraudes, requested the evaluation of the recycling process APPE Supercycle CP submitted by Artenius PET recycling. The recycling process has been allocated the EU register No RECYC066. It is deemed to recycle poly(ethylene terephthalate) (PET) pellets from PET containers, mainly bottles collected through post-consumer collection systems. The recycled pellets are intended to be used at up to 100 % for the manufacture of food contact materials and articles. These recycled materials and articles are intended to be used in direct contact with all kind of foodstuffs for long term storage at room temperature, with or without hotfill.

The process is composed of four steps. First the post-consumer collected PET containers, mainly bottles are processed into washed and dried flakes, which are used as input of the APPE Supercycle CP decontamination technology. The dried flakes are extruded under vacuum and pelletised (step 2). The pellets are then crystallised (step 3) before being decontaminated in a solid state polymerisation (SSP) reactor at high temperature under vacuum (step 4).

Detailed specifications for the input materials are provided and the amount of non-food containers is reported to be no more than 2 %.

A challenge test was conducted in the production plant facilities for all steps to measure the decontamination efficiency. The decontamination efficiencies obtained for each surrogate contaminant from the challenge test, ranging from 95.5 to more than 98.4 %, have been used to calculate the residual concentrations of potential unknown contaminants in pellets (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 intended to be used for manufacture of materials and articles in contact with food" (EFSA CEF Panel, 2011). According to these criteria, the recycling process under evaluation 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.

The Panel considered that the process is well characterised and the main steps used to recycle the PET flakes into decontaminated PET pellets are identified. Having examined the challenge test provided, the Panel concluded that the two steps the crystallisation (step 3) and the solid state polymerisation in the SSP reactor (step 4) are the critical steps for the decontamination efficiency of the process. The operating parameters to control their performance are the temperature, the pressure and the residence time for the crystallisation (step 3) and the temperature, the gas flow and the residence time for the SSP (step 4). Therefore, the Panel considered that the recycling process APPE Supercycle CP 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 test used to measure the decontamination efficiency of the process and,

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

The Panel concluded that the recycled PET obtained from the process APPE Supercycle CP intended to be used up to 100 % for the manufacture of materials and articles for contact with all types of foodstuffs for long term storage at room temperature, with or without hotfill is not considered of safety concern.

The Panel recommended that it should be verified periodically, as part of the good manufacturing practice (GMP), that as foreseen in the Regulation (EC) No 282/2008, art. 4b, the input originates from materials and articles that have been manufactured in accordance with the European legislation on food contact materials and that the proportion of PET from non-food consumer applications is no more than 5 % in the input to be recycled. Critical steps should be monitored and kept under control; supporting documentation on how it is ensured that the critical steps are operated under conditions at least as severe as those obtained from the challenge test used to measure the decontamination efficiency of the process should be available.

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BACKGROUND AS PROVIDED BY THE LEGISLATION

Recycled plastic materials and articles shall only be placed on the market if they contain recycled plastic obtained from an authorised recycling process.[4] Before a recycling process is authorized, an EFSA opinion on its safety is required. This procedure has been established in Article 5 of the Regulation (EC) No 282/2008[5] of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of the Regulation (EC) No 1935/2004 [6] 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 EFSA for their evaluation. The application is supported by a technical dossier submitted by the industry following the EFSA guidelines on submission of a dossier 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 (EFSA, 2008).

In this case, EFSA received, from the Direction Generale de la concurrence de la consommation et de la repression des frauds, France, an application for evaluation of the recycling process "APPE Supercycle CP". This application has been allocated the EU register No RECYC066.

TERMS OF REFERENCE AS PROVIDED BY THE LEGISLATION

EFSA is required by 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 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 to deliver a scientific opinion on the recycling processes 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 "APPE Supercycle CP" is able to reduce any contamination of the plastic input to a concentration that does not pose a risk to human health. The PET materials and articles used as input to the process as well as the conditions of use of the recycled PET make part of this evaluation.

[4] Recycling pursuant to the definition in point 7 of Article 3 of European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste. OJ L 365, 31.12.1994, p. 10-23

[5] 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, 28.03.2008, p.9-18

[6] 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

ASSESSMENT

1. Introduction

The European Food Safety Authority was asked by the Direction Generale de la Concurrence de la Consommation et de la Repression des Fraudes, France, to evaluate the safety of the recycling process APPE Supercycle CP which has been allocated the EU register No RECYC066. The request has been registered in the EFSA's register of received questions under the number EFSA-Q-2010-00004. The dossier was submitted on behalf of Artenius PET recycling.

The dossier submitted for evaluation followed the EFSA Guidelines for the submission of an application for safety evaluation by 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, 2008).

2. General Information

According to the applicant, the recycling process APPE Supercycle CP is intended to recycle post-consumer food grade poly(ethylene terephthalate) (PET) articles, mainly bottles, to produce recycled PET pellets. The recycled pellets are intended to be used up to 100 % for the manufacture of recycled materials and articles. These final materials and articles are intended to be used in direct contact with foodstuffs for long term storage at room temperature, with or without hotfill.

3. Description of the process

3.1. General description

The recycling process APPE Supercycle CP produces recycled PET pellets from PET articles, mainly bottles, coming from post-consumer collection systems (kerbside, deposit or specific collection systems). The recycling process is a continuous process and is composed of the four steps below.

Input

- In Step 1, post-consumer PET articles, mainly bottles, are processed into hot caustic washed and dried flakes, which are used as input of the following steps.

Decontamination and production of recycled PET material

- In Step 2, the flakes are extruded into pellets.
- In Step 3, the extruded pellets are crystallised.
- In Step 4, the crystallised pellets are solid-state polymerised (SSP).

Recycled pellets, the final product of the process, are checked against technical requirements on intrinsic viscosity and colour. Recycled pellets are intended to be converted into recycled articles used for hot-fill and/or long-term storage at room temperature, such as bottles for mineral water, soft drinks and juices. The recycled pellets may also be used for sheets, which are thermoformed to make food trays. The trays made of recycled PET are not intended to be used in microwaves and ovens.

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

3.2. Characterisation of the input

According to the applicant, the input for the recycling process APPE Supercycle CP is hot caustic washed and dried flakes obtained from PET articles, mainly bottles previously used for food

packaging, from post-consumer collection systems (kerbside, deposit or specific collection systems). However, a small fraction may originate from non-food applications such as soap bottles, mouth wash bottles, kitchen cleaning product bottles, etc. According to the applicant, the amount of this non-food container fraction is no more that 2 % during the bottle sorting.

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

4. APPE Supercycle CP Technology

4.1. Description of the main steps

To decontaminate post-consumer PET, the recycling process APPE Supercycle CP uses the technology as described below and for which the general scheme is reported in figure 1. In step 1, post-consumer PET articles, mainly bottles, are processed into hot caustic washed and dried flakes, which are used as input of the following steps.

Extrusion of washed and dried flakes into pellets (step 2): Washed and dried flakes are extruded under vacuum, melt filtered and then processed into pellets.

Crystallisation of extruded pellets (step 3): The extruded pellets are stored in a silo and then crystallised at high temperature under vacuum.

Solid State Polymerisation (step 4): The crystallised pellets are decontaminated under inert gas flow in a continuous solid state polymerisation reactor at high temperature.

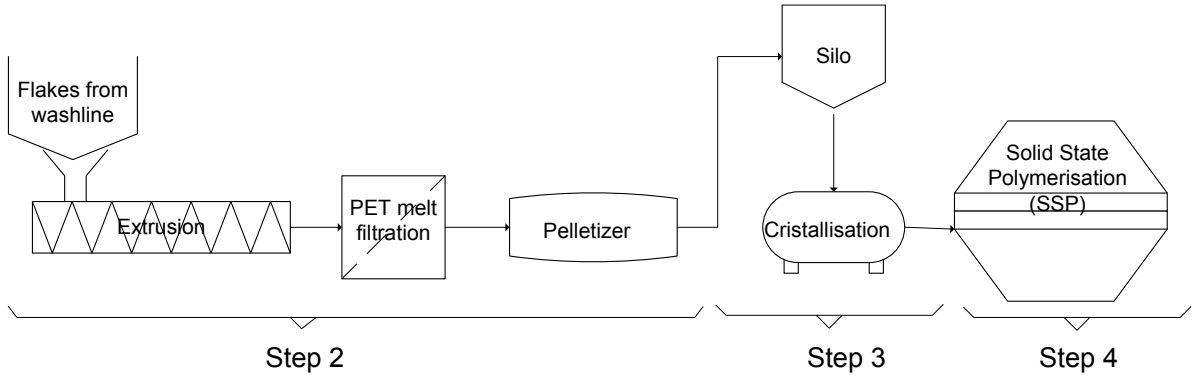


Figure 1: General scheme of the APPE Supercycle CP technology

The process is operated under defined operating parameters of temperature, gas flow, pressure and residence time.

4.2. Decontamination efficiency of the process

To demonstrate the decontamination efficiency of the recycling process, a challenge test performed on the production line was submitted to EFSA.

PET flakes were contaminated with selected chemicals, toluene, phenol, chlorobenzene, limonene and benzophenone, used as surrogate contaminants. The surrogates were chosen in agreement with EFSA guidelines and in accordance with the US-FDA recommendations. The surrogates are of 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, conventionally recycled[7], post-consumer PET flakes were soaked in dichloromethane containing the surrogates in air tight drums and stored for 5 days at room temperature. After eliminating the excess of solvent by drying at 80 °C for 5 h, the master-batch of contaminated flakes was mixed with non-contaminated flakes and surrogates concentrations were determined. The resulting flakes were introduced directly in the extrusion step 2 without prior washing and drying.

The three steps of the APPE Supercycle CP technology, extrusion (step 2), crystallisation (step 3), and SSP (step 4), were challenged using the commercial production line. Concentrations of surrogates were determined in flakes or pellets after each step. Owing to the presence of the added surrogates on the surface of the unwashed flakes, the decontamination efficiency evaluated from unwashed flakes is expected to be overestimated and thus not applicable for comparison with the reference contamination level (EFSA CEF Panel, 2011). Therefore the Panel decided not to use step 2 in the calculation of the overall decontamination efficiency.

The decontamination efficiency was calculated using the concentration of surrogates measured in the extruded pellets before crystallisation (step 3) and after the solid state polymerized pellets (step 4). When a particular surrogate could not be detected, the limit of detection for that surrogate was considered for the calculation of the decontamination efficiency. The results are summarised in table 1.

Table 1: Efficiency of the decontamination of the crystallisation (step 3) and the solid state polymerisation (step 4)

Surrogates	Concentration of surrogates in contaminated pellets before crystallisation (step 3) (mg/kg PET)	Concentration of surrogates in contaminated pellets after SSP (step 4) (mg/kg PET)	Decontamination Efficiency * (%)
Toluene	55	<2.5*	>95.5**
Phenol	459	<5*	>98.3**
Chlorobenzene	76	<2.5*	>96.7**
Limonene	155	<2.5*	>98.4
Benzophenone	339	7.2	97.9

* Not detected at the indicated limit of detection
** Calculated based on the limit of detection

As shown above, the decontamination efficiency calculated ranged from more than 95.5 % for toluene to more than 98.4 % for limonene. The overall decontamination efficiency of the process is expected to be higher as further decontamination will occur during the extrusion under vacuum (step 2).

5. 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 residual content of poly(vinyl chloride) (PVC), glue, polyolefins, cellulose, metals, polyamides and physical properties are provided for the hot caustic washed and dried flakes (step 1), the input materials for the recycling process. The input materials are produced from PET articles, mainly bottles previously used for food packaging collected through post-

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

consumer collection systems. However, a small fraction of the input may originate from non-food applications such as soap bottles, mouth wash bottles, kitchen cleaning product bottles, etc. According to the applicant, the fraction of non-food containers is reduced during material sorting to no more than 5 % as recommended by the 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 washed and dried flakes from collected containers (step 1) is kept under control according to the applicant. The following steps are used to recycle the PET flakes into decontaminated PET pellets: extrusion (step 2), crystallisation (step 3) and solid state polymerisation (step 4). The operating parameters of temperature, pressure, gas flow and residence time for the steps 2 to 4 have been provided to EFSA.

A challenge test was conducted in the commercial production plant on the process steps 2, 3 and 4 (extrusion, crystallisation and solid state polymerisation respectively) to measure the decontamination efficiency. In the challenge test performed according to the recommendations in the EFSA Guidelines (EFSA, 2008), all steps were operated under pressure, temperature, gas flow and residence time conditions equivalent or less severe than those of the process. Taking into account that the contaminated flakes were directly subject to step 2 of the process without prior washing and drying, the decontamination efficiency calculated including step 2 is expected to be overestimated. Although the Panel considered that step 2 (extrusion) will contribute to the overall decontamination, the decontamination efficiency was calculated from step 3 (crystallisation) and step 4 (SSP) which are therefore considered to be the critical steps for the decontamination efficiency of the process. Consequently temperature, pressure and residence time for crystallisation (step 3) and temperature, gas flow and residence time for SSP (step 4) should be controlled to guarantee the performance of the decontamination. These parameters have been provided to EFSA.

The decontamination efficiencies of the step 3 (crystallisation) and step 4 (SSP) obtained for each surrogate contaminant from the challenge test, ranging from more than 95.5 % to more than 98.4 % have been used to calculate the residual concentrations of potential unknown contaminants in pellets (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 *Cres* for the different surrogates is obtained (Table 2).

According to the evaluation principles (EFSA CEF Panel, 2011), the *Cres* should not be higher than a modelled concentration in PET (*Cmod*) corresponding to a migration, after 1 year at 25 °C, which cannot give rise to a dietary exposure exceeding 0.0025 µg/kg bw/day, the exposure threshold below which the risk to human health would be negligible[8]. Because the recycled PET is intended for general use for the manufacturing of articles containing up to 100 % recycled PET, the most conservative default scenario for infants has been applied. 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. The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

[8] 0.0025 µg/kg bw/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 Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), 2011).

Table 2: Decontamination efficiency of the step 3 (crystallisation) and step 4 (SSP) from the challenge test, residual concentration of surrogate contaminants in recycled PET (*Cres*) and calculated concentration of surrogate contaminants in PET (*Cmod*) 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	>95.5	<0.135	0.09
Phenol	>98.3	<0.051	0.09
Chlorobenzene	>96.7	<0.099	0.10
Limonene	>98.4	<0.048	0.13
Benzophenone	97.9	0.063	0.16

The residual concentrations of all surrogates in PET after the decontamination (C*res*) are lower than the corresponding modelled concentrations in PET (C*mod*) except for toluene, where, based on data calculated from the detection limit the C*res* (< 0.135 mg/kg PET) is not lower than the C*mod* (0.09 mg/kg PET.)

The Panel noted that the figure for C*res*, calculated from the decontamination percentage obtained from the challenge test is the mathematical consequence of the low initial toluene concentration combined with the high limit of detection. Taking into account that the decontamination efficiency demonstrated for the most critical surrogates (ie benzophenone) is sufficient, it is expected that also for toluene (highly volatile) the C*res* would be lower than the C*mod*. Therefore, the Panel considered that 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.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The Panel considered that the process is well characterised and the main steps used to recycle the PET flakes into decontaminated PET pellets are identified. Having examined the challenge tests provided, the Panel concluded that the two steps: the crystallisation (step 3) and the continuous SSP solid state polymerisation (step 4) are the critical steps for the decontamination efficiency of the process. The operating parameters to control the performance of these critical steps are the temperature, the pressure and the residence time for the crystallisation (step 3) and the temperature, the gas flow and the residence time for the SSP (step 4). Therefore, the Panel considered that the recycling process APPE Supercycle CP 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 test used to measure the decontamination efficiency of the process and,

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 Community 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 APPE Supercycle CP intended to be used up to 100 % for the manufacture of materials and articles for contact with all types of foodstuffs for hotfill and/or long term storage at room temperature is not considered of safety concern. The trays made of recycled PET are not intended to be used and should not be used in microwaves and ovens.

RECOMMENDATIONS

The Panel recommends that it should be verified periodically, as part of the good manufacturing practice (GMP), that as foreseen in the Regulation (EC) No 282/2008, art. 4b, the input originates from materials and articles that have been manufactured in accordance with the Community legislation on food contact materials and that the proportion of PET from non-food consumer applications is no more than 5 % in the input to be recycled. Critical steps should be monitored and kept under control; supporting documentation on how it is ensured that the critical steps are operated under conditions at least as severe as those obtained from the challenge test used to measure the decontamination efficiency of the process should be available.

DOCUMENTATION PROVIDED TO EFSA

1. Dossier "supercycle". December 2010. Submitted on behalf of Artenius PET recycling France SAS.

2. Dossier "supercycle". April 2013. Submitted on behalf of Artenius PET recycling France SAS.

REFERENCES

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. The EFSA Journal 2008, 717, 2-12.

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. doi:10.2903/j.efsa.2011.2184

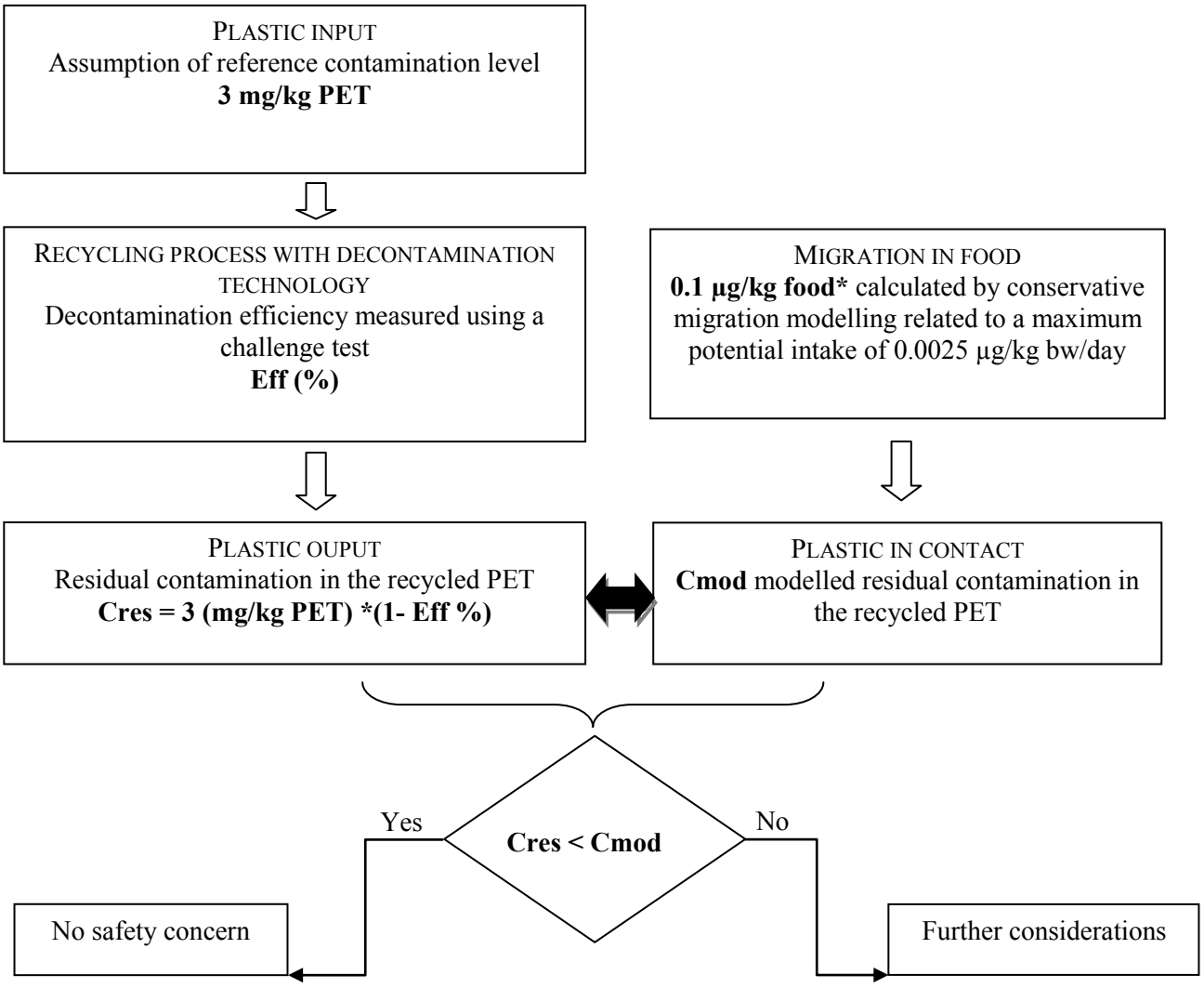
APPENDICES

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

Washed and dried flakes used for the APPE Supercycle CP recycling process

Parameter	Value
Moisture max.	1.5%
Moisture variation	±0.3% h^{-1}
Bulk density	200 – 500 kg m^{-3}
Material temperature	10 – 60 °C
PVC max.	50 ppm
Glue max.	50 ppm
Polyolefins max.	50 ppm
cellulose (paper, wood)	50 ppm
metals max.	50 ppm
polyamide max.	2000 ppm

Appendix B. Relationship between the key parameters for the evaluation scheme (EFSA Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), 2011)



*: *Default scenario (Infant). For adults and toddlers, the migration criterion will be 0.75 and 0.15 µg/kg food respectively.*

GLOSSARY

CEF	Food Contact Materials, Enzymes, Flavourings and Processing Aids
Cmod	Modelled concentration in PET
Cres	Residual concentrations in PET
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
GMP	Good manufacturing practice
PET	Poly(ethylene terephthalate)
PVC	Poly(vinyl chloride)
SSP	Solid state polymerisation
US-FDA	United States-Food and Drug Administration