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SCIENTIFIC OPINION

Scientific Opinion on the safety assessment of the process SOREPET, based on Buhler B technology, 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

This scientific opinion, published on 26 September 2018, replaces the earlier version published on 18 July 2014*

ABSTRACT

This scientific opinion of the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids deals with the safety assessment of the recycling process SOREPET (EU register No RECYC072). The input to the process is hot caustic washed and dried PET flakes originating from collected post-consumer PET containers, mainly bottles, containing no more than 5 % PET from non-food consumer applications. In this process, washed and dried PET flakes are heated to the decontamination temperature and subsequently are further decontaminated in a continuous countercurrent reactor under high temperature and inter gas flow. Having examined the challenge test provided, the Panel concluded that the third step, the decontamination in continuous countercurrent reactor for solid state polymerisation (SSP), is the critical step that determines the decontamination efficiency of the process. The operating parameters to control its performance are the temperature, the inert gas flow and the residence time. The operating parameters of this step 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 the modelled migration of 0.1 µg/kg food. The Panel concluded that recycled PET obtained from the process, intended to be used up to 100 % for manufacture of materials and articles for contact with all type of foodstuffs for long term storage at room temperature, with or without hot fill, is not considered of safety concern.

[1] On request from Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes, France, Question No EFSA-Q-2010-00869, 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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* The Summary, Discussion and Conclusions sections were updated to clarify the critical step that determines the decontamination efficiency of the process.

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KEY WORDS

Buhler, food contact material, plastic, poly(ethylene terephthalate) (PET), recycling process, SOREPET, safety assessment

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 process in which of plastic waste is recycled. In this context, the CEF Panel evaluated the process "SOREPET".

The Direction Generale De la Concurrence de la Consommation et de la Repression des Fraudes, France, requested the evaluation of the recycling process "SOREPET" submitted by SOREPLA Industry. The recycling process has been allocated the EU register No RECYC072. It is deemed to recycle poly(ethylene terephthalate) (PET) flakes from PET containers, mainly bottles, collected through post-consumer collection systems. The recycled flakes obtained from the process are intended to be used up to 100 % for the manufacture of food contact materials and articles. The recycled material 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 three steps. First the post-consumer collected PET containers are ground and processed into hot caustic washed and dried flakes, which are used as input to the Sorepet process. The flakes are heated to the decontamination temperature (step 2) and then are fed into a continuous countercurrent reactor under high temperature and inert gas flow (step 3).

Detailed specifications for the input materials are provided for the submitted recycling process and the proportion of non-food containers is reported to be below 5 %.

In order to measure the decontamination efficiency, a challenge test was conducted in a unique reactor with surrogate contaminants in a batch mode on the process steps 2 (heating) and 3 (SSP). Step 3 was considered by the Panel as the critical step for the removal of possible contaminants and should be kept under control to guarantee the performance of the decontamination of this process. The operating parameters to control its performance are the temperature, the inert gas flow and the residence time.

The decontamination efficiencies obtained for each surrogate contaminant from the challenge test ranging from 98.6 % to 99.9 %, have been used to calculate the residual concentrations of potential unknown contaminants in flakes (*Cres)* 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). According to these criteria, the recycling process under evaluation using the Buhler technology is able to ensure that the level of unknown contaminants in recycled PET is below a calculated concentration (*Cmod*) 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 flakes are identified. Having examined the results of the challenge test provided, the Panel concluded that the continuous countercurrent (SSP) (step 3) is the critical step for the decontamination efficiency of the process. The operating parameters to control its performance are the temperature, the inert gas flow and the residence time. Therefore, the Panel considered that the recycling process SOREPET is able to reduce any 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 obtained from the challenge test used to measure the decontamination efficiency of the process and,

ii) the input to the process is hot caustic washed and dried post-consumer PET flakes originating from materials and articles that have been manufactured in accordance with the European Union legislation on food contact materials and contain no more than 5 % PET from non-food consumer applications.

The Panel concluded the recycled PET obtained from the process SOREPET, 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 trays made from recycled PET are not intended to be used and should not be used in microwaves and ovens.

The Panel recommended that it should be verified periodically, as part of good manufacturing practice (GMP), that as foreseen in Regulation (EC) No 282/2008, art. 4b, the input originates from materials and articles that have been manufactured in accordance with the European Union 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 describing how it will be 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, EFSA´s 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 evaluation. Each application is supported by a technical dossier submitted by the industry following 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).

In this case, EFSA received from the Direction Generale De la Concurrence de la Consommation et de la Repression des Fraudes, France, an application for evaluation of the recycling process SOREPET. This application has been allocated the EU register No RECYC072.

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 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 SOREPET 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 of 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, pp.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 SOREPET which has been allocated the EU register No RECYC072. The request has been registered in the EFSA's register of questions under the number EFSA-Q-2010-00869. The dossier was submitted by SOREPLA Industry, France.

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 the 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 SOREPET is intended to recycle post-consumer poly(ethylene terephthalate)(PET) containers, mainly bottles, to produce recycled PET flakes using the Buhler technology. The recycled flakes are intended to be used up to 100 % in the manufacture of new single use PET food contact articles such as bottles and thermoformed trays and containers intended for contact with all types of foodstuffs for long-term storage at room temperature, with or without hotfill.

3. Description of the process

3.1 General description

The recycling process SOREPET produces recycled PET flakes from PET containers, mainly bottles, coming from post-consumer collection systems (kerbside and deposit collection systems). The recycling process comprises the three steps below.

Input

- In Step 1, post-consumer PET containers, mainly bottles, are processed in house into hot caustic washed and dried flakes, which are used as input to the next steps.

Decontamination and production of recycled PET material

- In Step 2, the flakes are heated in a reactor up to the temperature of the next step.
- In Step 3, the flakes are solid state polymerised in a continuous countercurrent reactor under high temperature and inert gas flow.

Recycled PET flakes, the final product of the process, are checked against technical requirements on intrinsic viscosity, colour, black specks, etc. Recycled flakes are intended to be converted in other plants (by other companies) into recycled articles for hotfill and/or long-term storage at room temperature, such as containers, mainly bottles, for mineral water, soft drinks, juices and beer. The recycled flakes may also be used for sheets, which are thermoformed to make food trays. The trays made from recycled PET are not intended to be used in microwaves or in ovens.

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

3.2. Characterisation of the input

According to the applicant, the input to the recycling process SOREPET is hot caustic washed and dried flakes obtained from PET containers, mainly bottles, previously used for food packaging, from

post-consumer collection systems (kerbside and deposit 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, non-food container fraction depends on the re-collection system. On the basis of qualified suppliers and quality control system, the applicant estimates this faction to be below 5 %.

Technical data for the hot caustic washed and dried flakes are provided for the submitted recycling process such as information on the residual content of poly(vinyl chloride) (PVC), metal, wood, labels, colored flakes and physical properties (see Appendix A).

4. Buhler Technology

4.1 Description of the main steps

To decontaminate post-consumer PET, the recycling process SOREPET uses the Buhler B recycling technology, which is described below and for which the general scheme provided by the applicant is reported in figure 1. In step 1 post-consumer PET containers, mainly bottles, are processed into hot caustic washed and dried flakes.

Heating (step 2): The washed and dried flakes are continuously heated up to the temperature of the next SSP reactor step.

Solid state polymerisation (step 3): The flakes are continuously fed to a countercurrent reactor running under high temperature and inert gas flow for a predefined residence time. This step increases the intrinsic viscosity of the material and decontaminated the PET flakes.

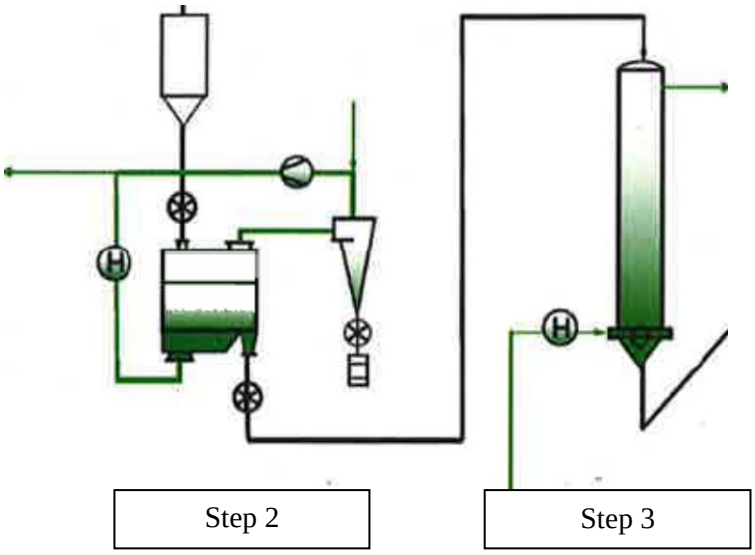


Figure 1: General scheme of the Buhler B technology

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

4.2 Decontamination efficiency of the recycling process

To demonstrate the decontamination efficiency of the recycling process SOREPET, a challenge test on steps 2 and 3 was submitted to EFSA.

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 PET during recycling (EFSA, 2008).

For the preparation of the contaminated PET flakes, conventionally recycled[7] post-consumer PET flakes were soaked in a mixture containing the surrogates and stored for 7 days at 50 °C. The contaminated PET flakes were washed with hot water and detergents, rinsed with water and then air dried. The concentrations of surrogates in this material were determined.

A challenge test was performed with only contaminated flakes on the process steps 2 and 3 (heating and solid state polymerisation) in batch mode at laboratory scale. Instead of using two separated reactors for the heating (step 2) and solid state polymerisation (step 3) as in the production plant, the step 2 and 3 were challenges in a single reactor. In both batch and continuous modes of operation the surrogates diffuse through the flakes to the surface and they are constantly eliminated by the applied gas flow. Once a minimum gas velocity is exceeded, it is the diffusion of the contaminants to the surface that is the limiting step in the decontamination process. Therefore continuous processes will result in the same cleaning efficiencies as batch processes, as long as the temperature and residence time applied are at least as severe and if the gas velocity is sufficient to purge the contaminants. In the challenge test using the single reactor, the sequence of steps 2 and 3 was respected, the operating parameters of residence time and temperature were less severe than those used at the production plant, and the minimum gas velocity was exceeded in both the challenge test and in the production plant. Therefore the results of the challenge test were considered sufficiently representative of the decontamination efficiency to be expected in the production plant.

The decontamination efficiency was calculated based on the concentration of the surrogates detected in contaminated flakes before the heating and after the SSP reactor. When a surrogate could not be detected in the flakes, 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 steps 2 and 3

Surrogates	Concentration before heating (step 2) (mg/kg PET)	Concentration after SSP (step 3) (mg/kg PET)	Decontamination Efficiency (%)
Toluene	203.9	<0.1*	>99.9
Chlorobenzene	373.1	0.5	99.9
Chloroform	128.8	0.7	99.5
Methyl salicylate	366.0	1.5	99.6
Phenylcyclohexane	311.8	4.2	98.6
Benzophenone	445.6	6.0	98.6
Methyl stearate	481.7	5.0	98.9

*Not detected at the limit of detection given

As shown above, the decontamination efficiency ranged from 98.6 % for phenylcyclohexane to above 99.9 % for toluene.

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

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 the residual content of PVC, metal, wood, labels, coloured flakes and physical properties are provided for the hot-caustic washed flakes input material (step 1) for the submitted recycling process. The input material is produced from PET containers, mainly bottles, 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 cleaning products bottles, etc. According to the applicant, the amount of this non-food container fraction depends on the collection system and, on the basis of qualified suppliers and quality control system, it is below 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 hot caustic washed and dried flakes from collected containers, mainly bottles (step 1) is conducted by the applicant. The following steps are those of the Buhler technology used to recycle the PET flakes into decontaminated PET flakes: continuously heating (step 2) and continuous countercurrent reactor for solid state polymerisation (step 3). The operating parameters of temperature and residence time for the step 2 and the temperature, residence time and inert gas flow for the step 3 are provided to EFSA.

A challenge test was conducted with only contaminated flakes at laboratory scale, in a unique reactor, on the process steps 2 and 3 in batch mode, to measure the decontamination efficiency. The decontamination efficiency was determined from the contaminated flakes before and after the reactor. The challenge test was performed according to the recommendations in the EFSA Guidelines (EFSA, 2008). The Panel noted that step 3 is the critical step for the decontamination efficiency of the process. The parameters operated in the challenge test in step 3 have been provided to EFSA.

The decontamination efficiencies obtained for each surrogate contaminant from the challenge test ranging from 98.6 % to above 99.9 %, have been used to calculate the residual concentrations of potential unknown contaminants in flakes (*Cres)*, 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 in the challenge test are 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 *Cmod* (EFSA CEF Panel, 2011). The results of the calculations are shown in table 2. The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

Table 2: Decontamination efficiency from challenge test, 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

[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 CEF Panel, 2011)

Surrogates	Decontamination efficiency (%)	C*res* (mg/kg PET)	C*mod* (mg/kg PET)
Toluene	>99.9	<0.003	0.09
Chlorobenzene	99.9	0.003	0.10
Chloroform	99.5	0.015	0.10
Methyl salicylate	99.6	0.012	0.13
Phenylcyclohexane	98.6	0.039	0.14
Benzophenone	98.6	0.039	0.16
Methyl stearate	98.9	0.033	0.32

The residual concentrations of all surrogates in PET after the decontamination (C*res*) are lower than the corresponding modelled concentrations in PET (C*mod*). 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.

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 flakes are identified. Having examined the challenge test provided, the Panel concluded that step 3, the decontamination in the continuous countercurrent SSP reactor, is the critical step for the decontamination efficiency of the process. The operating parameters to control its performance are the temperature, the inert gas flow and the residence time. Therefore, the Panel considered that the recycling process SOREPET 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 Union 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 SOREPET 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 trays made of the 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 good manufacturing practice (GMP), that as foreseen in 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 describing how it will be 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 "SOREPET". December 2009. Submitted on behalf of SOREPLA Industrie.
2. Additional data for Dossier "SOREPET". October 2010. Submitted on behalf of SOREPLA Industrie.
3. Additional data for Dossier "SOREPET". November 2013. Submitted on behalf of SOREPLA Industrie.

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.

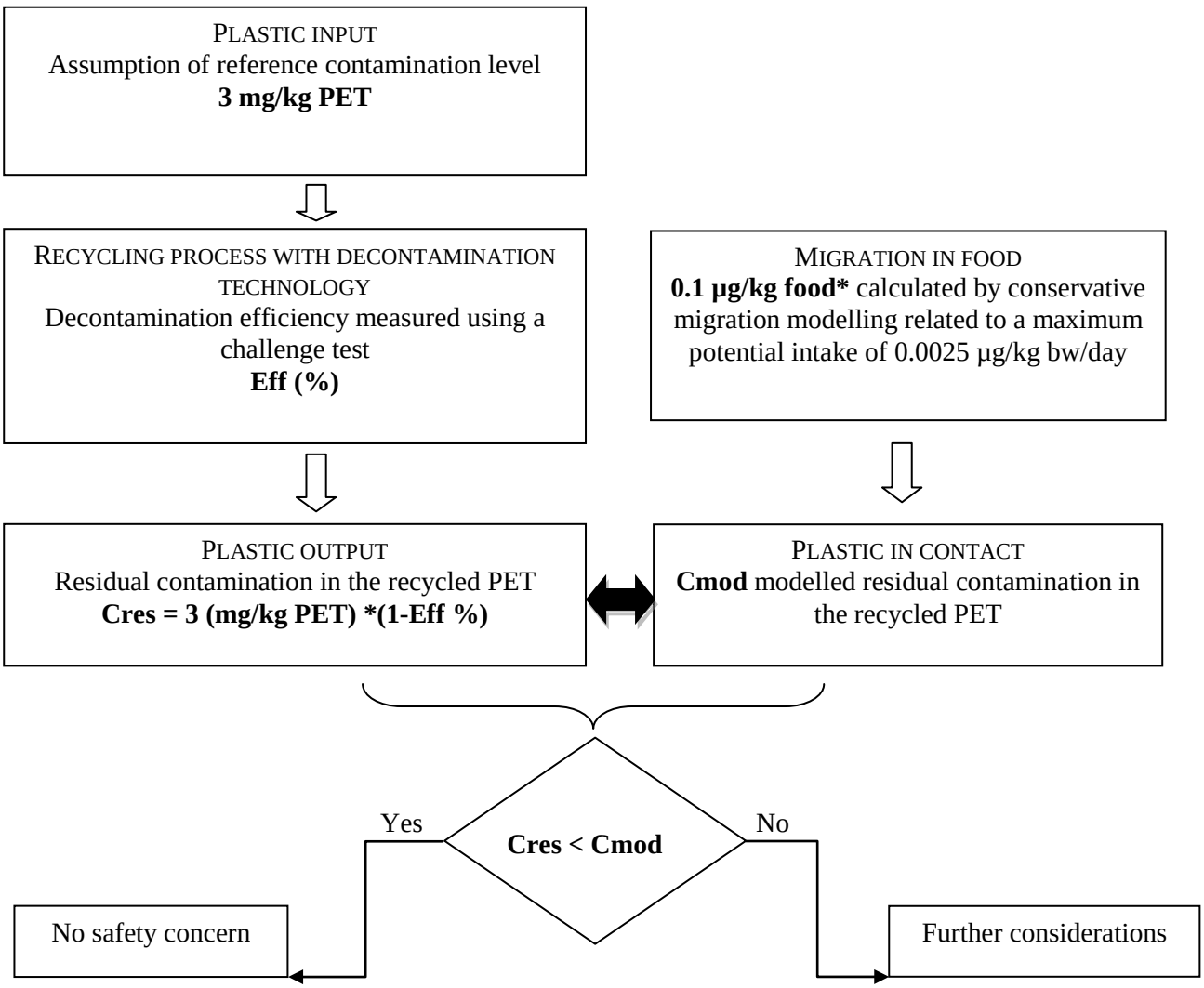
EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2011. Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact 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

Parameter	Value
Bouchon/cap	< 5 ppm
PVC	< 15 ppm
Metal	< 5 ppm
Wood	< 10 ppm
Labels	< 5 ppm
Other	< 10 ppm
Colored flakes	< 50 ppm
Bulk density	< 290-400 > kg/m^3
Moisture	1 % max.
Color	Crystal light blue-green
Type	Flakes 8 mm

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.*

ABBREVIATIONS

CEF	Food Contact Materials, Enzymes, Flavourings and Processing Aids
C*mod*	Modelled concentration in PET
C*res*	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