SCIENTIFIC OPINION

Scientific Opinion on the safety assessment of the process SOREPET GR based on EREMA Basic 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]

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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 assessment of the recycling process SOREPET GR (EU register No RECYC073) which is based on the EREMA Basic technology. The input to the process is hot caustic washed and dried poly(ethylene terephthalate) (PET) flakes originating from collected post-consumer PET containers, mainly bottles and containing no more than 5 % PET from non-food consumer applications. In this process, washed and dried PET flakes are heated in a continuous reactor under vacuum before being extruded. Having examined the results of the challenge test provided, the Panel concluded that the continuous reactor is the critical step that determines the decontamination efficiency of the process. The operating parameters to control its performance are well defined and are temperature, pressure and residence time. 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 derived from the exposure scenario for infants and 0.15 μg/kg food derived from the exposure scenario for toddlers. The Panel concluded that recycled PET obtained from the process is not of safety concern when used to manufacture articles intended for food contact materials applications in compliance with the conditions as specified in the conclusion of the opinion.

[1] On request from the Direction Générale De la Concurrence, de la Consommation et de la Répression des Fraudes, France, Question No EFSA-Q-2010-01537, 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.

† Deceased.

* Minor changes of an editorial nature were made. The changes do not affect the contents of this report. To avoid confusion, the original version of the opinion has been removed from the website, but is available on request, as a version showing all the changes made.

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KEY WORDS

food contact material, plastic, poly(ethylene terephthalate)(PET), recycling process, EREMA Basic, SOREPET GR, 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 plastic waste is recycled. In this context, the CEF Panel evaluated the process "SOREPET GR".

The Direction Generale De la Concurrence, de la Consommation et de la Repression des Fraudes, France, requested the evaluation of the recycling process "SOREPET GR" submitted on behalf of SOREPLA Industry, France. The recycling process has been allocated the European Union register number RECYC073. It is deemed to recycle poly(ethylene terephthalate) (PET) flakes from PET containers, mainly bottles collected through post-consumer collection systems. According to the applicant, the recycled PET obtained from the process is 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 comprises three steps. First the post-consumer collected PET containers are processed into hot caustic washed, dried and regrinded flakes, which are used as input to the EREMA Basic decontamination technology. Dried flakes are heated in a continuous reactor under vacuum (step 2) before being extruded (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 %.

A challenge test was conducted with surrogate contaminants in an industrial scale plant on the process step 2 (continuous reactor) to measure the decontamination efficiency. Since a mixture of flakes not contaminated with surrogates (white) and contaminated flakes (green, spiked with surrogates) was used for this challenge test, the Panel calculated the decontamination efficiencies taking into account also the amount possibly transferred to the white flakes due to cross-contamination phenomenon during the challenge test.

Step 2 was considered by the Panel to be the critical step for the removal of possible contaminants and should be kept under control to guarantee the performance of the decontamination by this process.

The decontamination efficiencies obtained for each surrogate contaminant from the challenge test, ranging from 92.4 % to 98.6 %, have been used to calculate the residual concentrations of potential unknown contaminants in pellets (*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 the evaluation principles, the *Cres* should not be higher than a modelled concentration in PET (*Cmod*) corresponding to a migration, after one year at 25 °C, which cannot give rise to a dietary exposure exceeding 0.0025 μg/kg body weight(bw)/day, the exposure threshold below which the risk to human health would be negligible. Because the recycled PET are intended to be used up to 100 % for manufacture of bottles and for manufacture of trays and containers not used to package water (since water could be used to prepare infant formula), both scenarios for infants and for toddlers have been applied. A maximum dietary exposure of 0.0025 μg/kg bw/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. Therefore, the migrations of 0.1 μg/kg and 0.15 μg/kg into food have been used to calculate *Cmod* (EFSA CEF Panel, 2011). If the pellets produced by a recycling process are used up to 100 % to produce new articles and they do not meet these targets, recycled pellets should be mixed with virgin PET to make sure that *Cres* will not be higher than *Cmod*. The Panel established the maximum percentages of recycled PET in final articles for which the risk to human health is demonstrated to be negligible. These percentages differed from the initial request from the applicant.

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 results of the challenge test provided, the Panel concluded that the decontamination in a continuous reactor (step 2) is the critical step for the decontamination efficiency of the process. The operating parameters to control its performance are temperature, pressure and residence time. Therefore, the Panel considered that the recycling process SOREPET GR 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 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 and contain no more than 5 % PET from non-food consumer applications and,

iii) the final bottles manufactured with the recycled pellets do not contain more than 70 % recycled post-consumer PET and,

iv) the final thermoformed trays and containers manufactured with the recycled pellets and not used for packaging water contain 100 % recycled post-consumer PET.

Therefore, the recycled PET obtained from the process SOREPET GR, intended to be used for the manufacture of bottles for contact with all types of foodstuffs and for the manufacture of thermoformed trays and containers for contact with all types of foodstuffs except packaged water for long term storage at room temperature, with or without hotfill, is not considered of safety concern when final articles are manufactured with no more than the percentage of recycled post-consumer PET specified above. The trays made of 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 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.

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BACKGROUND AS PROVIDED BY 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 GR. This application has been allocated the EU register No RECYC073.

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 GR 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, 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 SOREPET GR which has been allocated the EU register No RECYC073. The request has been registered in the EFSA's register of questions under the number EFSA-Q-2010-01537. 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 GR is intended to recycle post-consumer poly(ethylene terephthalate)(PET) articles to produce recycled PET pellets using the EREMA Basic technology. According to the applicant, the recycled pellets 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. These final materials and articles are intended to be used for long-term storage at room temperature with or without hot fill.

3. Description of the process

3.1. General description

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

<u>Input</u>

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

<u>Decontamination and production of recycled PET material</u>

- In Step 2, the flakes are continuously crystallised and decontaminated under high temperature and vacuum.

- In Step 3, the decontaminated flakes are extruded to produce pellets.

Recycled pellets, the final product of the process, are checked against technical requirements on intrinsic viscosity, colour, black spots, etc. According to the applicant, recycled pellets are intended to be used (by other companies) up to 100 % to produce recycled articles, such as bottles for mineral water, soft drinks, juices and beer used for hot fill and/or long-term storage at room temperature. According to the applicant, the recycled pellets may also be used up to 100 % 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 to the recycling process SOREPET GR 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 assures this fraction is kept 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), metals, wood, labels and physical properties (see Appendix A).

4. EREMA Basic technology

4.1. Description of the main steps

To decontaminate post-consumer PET, the recycling process SOREPET GR uses the EREMA Basic technology, which is described below and for which the general scheme provided by the applicant is reported in Figure 1. Figure 1 starts at step 2. Step 1 is the washing step performed by the applicant and described above.

Crystallisation and decontamination in a continuous reactor (step 2): In this step the flakes are introduced into a continuous reactor equipped with a bottom-mounted rotating mixing device, in which vacuum and temperature are applied for a predefined residence time. These process conditions favour the vaporisation of possible contaminants and crystallisation of PET flakes.

Re-extrusion of the decontaminated flakes (step 3): The flakes continuously coming from the previous reactor are melted in the extruder. Residual solid particles (e.g. paper, aluminium, etc.) are filtered out of the extruded plastic before the final pellets are produced.

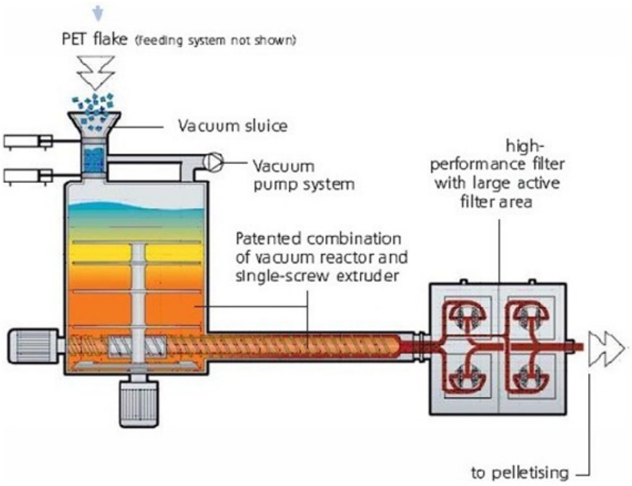


Figure 1: General scheme of the EREMA Basic technology

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

4.2. Decontamination efficiency of the recycling process

To demonstrate the decontamination efficiency of the recycling process a challenge test on step 2 was submitted to the EFSA.

PET flakes were contaminated with selected chemicals, toluene, chloroform, chlorobenzene, phenylcyclohexane, methyl salicylate, benzophenone and methyl stearate, used as surrogate contaminants. The surrogates were chosen in agreement with EFSA guidelines and in accordance with the recommendations of the US Food and Drug Administration (FDA). 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 PET during recycling (EFSA, 2008).

For the preparation of the contaminated PET flakes, conventionally recycled[7] post-consumer PET flakes of green colour were soaked in a mixture containing the surrogates and stored for seven days at 50 to 60 °C, with periodical agitation. The contaminated flakes were washed and rinsed in a batch process on a pilot plant scale. The concentration of surrogates in this material was determined.

The EREMA Basic technology was challenged on the reactor of the step 2 only, using an industrial-scale plant. To process a sufficiently large amount of material compatible with the high capacity of the continuous industrial plant, the reactor was fed initially with non-contaminated (white colour) flakes. After reaching stable process conditions a defined amount of contaminated flakes (coloured green) were introduced into reactor. Samples were taken at the outlet of the reactor at regular intervals. The green flakes were separated from the white flakes and the evolution of the fraction of green flakes with time (residence time distribution curve) was determined by weighing. The green flakes were then analysed for their residual concentrations of the applied surrogates.

The Panel noted that decontamination efficiency, calculated only on the basis of residual surrogates in the contaminated (green coloured) flakes could be overestimated. In fact, cross-contamination by transfer of contaminants from green to white flakes may occur.[8]

Therefore to take into account of the cross-contamination phenomenon and in the absence of specific data provided by the applicant, some assumptions and considerations were made, as follows:

- The mass fraction of green to white flakes at each sampling time, was derived from the data provided. A best fitting residence time distribution curve was derived from the experimental figures and was used to calculate the percentage of green and white flakes at the residence time used in the recycling process.

- The residual concentrations of surrogates in the green flakes after decontamination were derived from the data provided. A best fitting curve was derived from the experimental figures and was used to interpolate the residual concentrations in green flakes at the residence time used in the recycling process.

- The Panel made the assumption that cross-contamination of surrogates from green to white flakes in the reactor occurred to the extent of 10 % of the residual concentration measured in the green flakes. This percentage reflects the experience gained from previous evaluations.

To take into account the cross-contamination between green and white flakes, the evolution of the total residual surrogate content at the outlet of the continuous reactor (step 2) as a function of (residence) time was calculated by adding the residual surrogate amount in green flakes to the residual surrogate amount in white flakes. The residual surrogate amount in green flakes was calculated from the mass fraction of green flakes multiplied by the residual concentration of surrogates in the green flakes. The residual surrogate amount in white flakes was calculated from the mass fraction of white flakes multiplied by the residual concentration of surrogates in the white flakes (assumption of 10 % of the

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

[8] "Cross-contamination", as meant 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", is the transfer of surrogate contaminants from the initially contaminated to the initially not contaminated material (EFSA CEF Panel, 2011).

concentration measured in the green flakes). The calculated total residual surrogate amounts were compared with the initial contamination level of green flakes at the inlet of the reactor to derive the decontamination efficiency (Table 1).

Table 1: Efficiency of the decontamination of the continuous reactor

Surrogates	Concentration [(a)] before decontamination (step 2) (mg/kg PET)	Concentration [(b)] after decontamination (step 2) (mg/kg PET)	Decontamination Efficiency [(c)] (%)
Toluene	202	0.40	98.4
Chloroform	291	0.48	98.6
Chlorobenzene	361	0.76	98.3
Phenylcyclohexane	364	2.31	94.7
Methyl salicylate	143	1.03	94.0
Benzophenone	480	4.37	92.4
Methyl stearate	360	1.93	95.5

(a): Measured in green-coloured contaminated flakes.
(b): Calculated for green-coloured decontaminated flakes
(c): Decontamination efficiency (%) after correction for cross-contamination (see text).

The decontamination efficiencies as presented in Table 1 were calculated at the time of exit from the continuous reactor (step 2) in the challenge test. The overall decontamination efficiency of the process is expected to be higher as further decontamination will occur during the extrusion step 3.

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, metals, wood, labels and physical properties are provided for the input materials, hot-caustic washed flakes (step 1) for the recycling process. The input materials are produced from PET 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, 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 washed and dried flakes from collected containers (step 1) is under control. The following steps are those of the EREMA Basic technology used to recycle the PET flakes into decontaminated PET pellets: continuous decontamination reactor (step 2) and extrusion (step 3). The operating parameters of temperature, pressure and residence time for the critical step 2 have been provided to EFSA.

A challenge test on the process step 2 (continuous decontamination reactor) was carried out in an industrial-scale plant to measure the decontamination efficiency. In the challenge test, the continuous reactor was operated under pressure and temperature conditions equivalent to those of the commercial process. The decontamination efficiency was determined from the continuous reactor data (step 2). The challenge test was performed according to the recommendations in the EFSA guidelines (EFSA, 2008). Since a mixture of flakes not contaminated with surrogates (white) and contaminated flakes (green, spiked with surrogates) was collected at the outlet of the reactor used for this challenge test, the Panel calculated the decontamination efficiencies taking into account also the amount possibly transferred to the white flakes as a result of cross-contamination during the challenge test. The Panel considered that decontamination in a continuous reactor (step 2) is the critical step for the decontamination efficiency of the process. Consequently the temperature, pressure and residence time parameters of the step 2 of the process 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 92.4 % to 98.6 %, have been used to calculate the residual concentrations of potential unknown contaminants in pellets (*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 , 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 and Table 3).

According to the evaluation principles (EFSA CEF Panel, 2011), *Cres* should not be higher than a modelled concentration in PET (*Cmod*) corresponding to a migration, after one 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.[9] Because the recycled PET are intended to be used up to 100 % for manufacture of bottles and up to 100 %, for manufacture of trays and containers not used to package water (since water could be used to prepare infant formula), both scenarios for infants and for toddlers have been applied. A maximum dietary exposure of 0.0025 µg/kg bw/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. Therefore, the corresponding migration of 0.1 µg/kg (scenario of infants) and 0.15 µg/kg (scenario of toddlers) into food have been used to calculate *Cmod* (EFSA CEF Panel, 2011). If the pellets produced by a recycling process are used up to 100 % to produce new articles and they do not meet these targets, recycled pellets should be mixed with virgin PET to make sure that C*res* will not be higher than C*mod*. This has been done for the residence time requested by the applicant. C*res* reported in Table 2 (scenario for infants) is calculated for 70 % recycled PET, for which the risk to human health is demonstrated to be negligible and differ from the initial request from the applicant. C*res* reported in Table 3 (scenario for toddlers) is calculated for 100 % recycled PET, for which the risk to human health is demonstrated to be negligible.

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

Table 2: Scenario for infants for 70 % recycled PET: Decontamination efficiency from 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 one year at 25 °C.

Surrogates	Decontamination efficiency (%)	Cres (mg/kg PET)	Cmod (mg/kg PET)
Toluene	98.4	0.03	0.09
Chloroform	98.6	0.03	0.10
Chlorobenzene	98.3	0.04	0.09
Phenylcyclohexane	94.7	0.11	0.14
Methyl salicylate	94.0	0.13	0.13
Benzophenone	92.4	0.16	0.16
Methyl stearate	95.5	0.09	0.32

[9] 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).

Table 3: Scenario for toddlers for 100 % recycled PET: Decontamination efficiency from 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 0.15 µg/kg food after one year at 25 °C.

Surrogates	Decontamination efficiency (%)	Cres (mg/kg PET)	Cmod (mg/kg PET)
Toluene	98.4	0.05	0.13
Chloroform	98.6	0.04	0.15
Chlorobenzene	98.3	0.05	0.15
Phenylcyclohexane	94.7	0.16	0.21
Methyl salicylate	94.0	0.18	0.20
Benzophenone	92.4	0.23	0.24
Methyl stearate	95.5	0.13	0.47

On the basis of the data provided from challenge test and the applied conservative assumptions, 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 conservative modelled migration of:

- 0.1 µg/kg food at which the risk to human health would be negligible when the recycled pellets are used up to 70 % in mixtures with virgin PET to produce recycled bottles intended for contact with all types of foodstuffs (scenario of infants),
- 0.15 µg/kg food at which the risk to human health would be negligible when the recycled pellets are used up to 100 % to produce recycled trays and containers intended for contact with all types of foodstuffs except packaged water (scenario of toddlers).

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 test provided, the Panel concluded that the decontamination in a continuous reactor (step 2) is the critical step for the decontamination efficiency of the process. The operating parameters to control its performance are temperature, pressure and residence time. Therefore, the Panel considered that the recycling process SOREPET GR 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 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 and contain no more than 5 % PET from non-food consumer applications and,

iii) the final bottles manufactured with the recycled pellets do not contain more than 70 % recycled post-consumer PET and,

iv) the final thermoformed trays and containers manufactured with the recycled pellets and not used for packaging water do contain up to 100 % recycled post-consumer PET.

Therefore, the recycled PET obtained from the process SOREPET GR intended to be used for the manufacture of bottles for contact with all types of foodstuffs and for the manufacture of thermoformed trays and containers for contact with all types of foodstuffs except packaged water for long term storage at room temperature with or without hotfill, is not considered of safety concern when final articles are manufactured with no more than the percentage of recycled post-consumer PET specified above. 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 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 GR". May 2010. Submitted on behalf of SOREPLA Industrie.
2. Additional data for Dossier "SOREPET GR". November 2010. Submitted on behalf of SOREPLA Industrie.
3. Additional data for Dossier "SOREPET GR". December 2013. Submitted on behalf of SOREPLA Industrie.

REFERENCES

EFSA (European Food Safety Authority), 2008. Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and materials in contact with food (AFC) on 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.

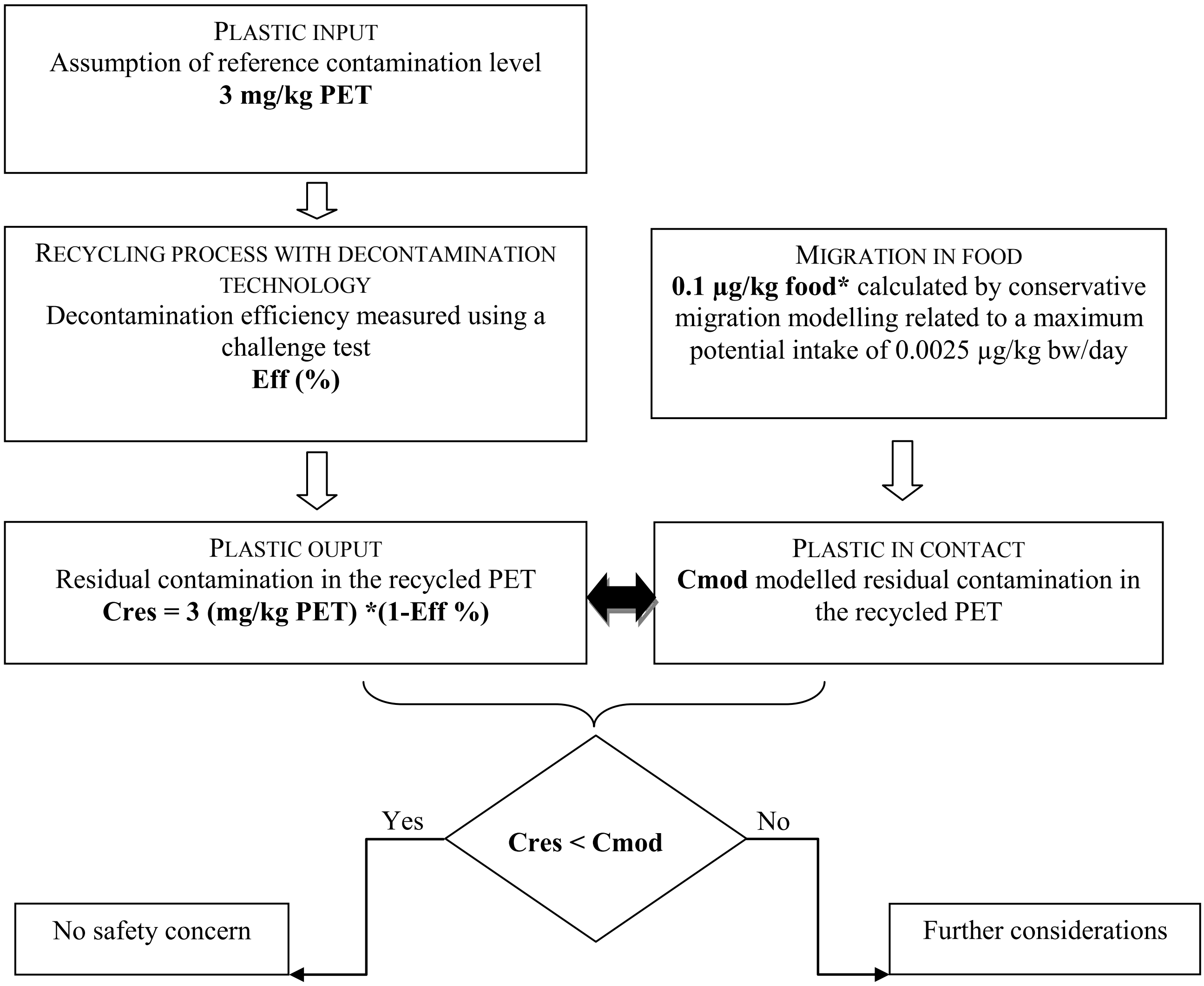
EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2011. Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact 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
Caps	< 5 ppm
PVC	< 15 ppm
Metal	< 5 ppm
Wood	< 10 ppm
Labels	< 5 ppm
Other	< 10 ppm
Coloured flakes	< 50 ppm
Bulk density	290 – 400 kg/m3
Moisture	Max 1 %
Colour	Cristal, 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
FDA	Food and Drug Administration
GMP	good manufacturing practice
PET	poly(ethylene terephthalate)
PVC	poly(vinyl chloride)