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SCIENTIFIC OPINION

Scientific Opinion on the safety assessment of the process 'San Miguel Industrias PET' based on Starlinger IV+® 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

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 'San Miguel Industrias' which is based on the Starlinger IV+® technology. The input of the process is hot caustic washed and dried PET flakes originating from collected post-consumer PET containers, containing no more than an average 0.15 % of PET from non-food consumer applications. In this technology, washed and dried PET flakes are dried and crystallised in a reactor, then extruded into pellets which are further crystallised in a second reactor. Crystallised pellets are pre-heated in a third reactor and fed to the Solid State Polycondensation (SSP) reactor. Having examined the challenge test provided, the Panel concluded that the three steps, drying and crystallisation, extrusion and crystallisation and SSP are the critical steps that determine the decontamination efficiency of the process. The operating parameters to control their performance are the temperature, the gas flow and the residence time for the drying and crystallisation step, the temperature, the pressure and the residence time for extrusion and crystallisation and SSP steps. Under these conditions and using the reference contamination level of 3 mg/kg PET, it was demonstrated that the 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 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. Trays made of this recycled PET are not intended to be used, and should not be used in microwave and conventional ovens.

KEY WORDS

Starlinger IV+, San Miguel, food contact materials, plastic, poly(ethylene terephthalate) (PET), recycling, process, safety evaluation

[1] On request from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, Question No EFSA-Q-2014-00167, adopted on 8 September 2015.

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SUMMARY

In accordance with Commission Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials intended to come into contact with foods and amending Regulation (EC) No 2023/2006, EFSA is requested to evaluate recycling processes of plastic waste.

In this context, the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, requested the evaluation of the plastic recycling process 'San Miguel Industrias PET' submitted on behalf of San Miguel Industrias PET S.A. The recycling process has been allocated the European Commission register number RECYC0110. It is deemed to recycle poly(ethylene terephthalate) (PET) materials and articles to produce recycled PET pellets. The recycled pellets are intended to be used 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 kinds of foodstuffs for long term storage at room temperature with or without hotfill. Trays made of this recycled PET are not intended to be used either in microwave or in conventional oven.

The recycling process has four production steps. In step 1, PET containers are processed by sorting-grinding-milling-washing-drying to provide flakes. In step 2, PET flakes are dried and crystallised at high temperature under desiccant air flow. In step 3, flakes are extruded into pellets at high temperature under vacuum degassing then re-crystallised. The fourth step involves a solid state polycondensation (SSP) process under vacuum at high temperature and long residence time to increase the molecular weight and the viscosity, obtaining pellets of recycled PET that are the final product.

Detailed specifications for the input materials are provided for the submitted recycling process. The amount of non-food containers is reported to be average 0.15 % in the bales of PET bottles received from suppliers.

A challenge test was conducted with surrogate contaminants in a pilot plant on the process steps from 2 to 4 to measure the decontamination efficiency.

Although the fourth step is expected to be the most critical step for the decontamination, drying and crystallisation (step 2) and extrusion and crystallisation (step 3) are considered relevant too.

The decontamination efficiencies obtained for each surrogate contaminant from the challenge test, ranging from 90.9 % to more than 99.9 %, 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 intended to be used for manufacture of materials and articles in contact with food' (EFSA CEF Panel, 2011). The CEF Panel noted that the input of the process originates from Peru, South America and, in the absence of data on misuse contamination on this input, used the reference contamination of 3 mg/kg PET (EFSA CEF Panel, 2011) which was derived from experimental data on severity and frequency of contamination of washed and dried flakes reported in an EU survey. According to these criteria, the recycling process under evaluation using a Starlinger IV+® technology are 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 pellets are identified. Having examined the challenge test provided, the Panel concluded that the three steps, drying and crystallisation, extrusion and crystallisation and SSP are the critical steps for the decontamination efficiency of the process. The operating parameters to control their performance are the temperature, the gas flow and the residence time for the drying and crystallisation (step 2) and the temperature, the pressure and the residence time for both the extrusion and crystallisation (step 3) and for the SSP (step 4). Therefore, the Panel considered that the recycling process San Miguel Industrias using the Starlinger IV+® technology is able to reduce any

foreseeable accidental contamination of the post-consumer food contact PET to a concentration that does not give rise to concern for a risk to human health if:

i) the input of the process is not contaminated through misuse at severity and frequency that brings to a reference contamination level higher than 3 mg/kg PET,

ii) 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,

iii) 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 average 5 % of PET from non-food consumer applications.

Therefore, the recycled PET obtained from the process San Miguel Industrias PET 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. Trays made of this recycled PET are not intended to be used, and should not be used in microwave and conventional ovens.

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

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BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE LEGISLATION

Recycled plastic materials and articles shall only be placed on the market for food contact materials if they contain recycled plastic obtained from an authorised recycling process.[4] Before a recycling process is authorised, EFSA opinion on its safety is required. This procedure has been established in Article 5 of the Regulation No (EC) 282/2008 of the Commission of 27 March 2008[5] on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of the Regulation (EU) 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 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 Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, an application for evaluation of the recycling process ‘San Miguel Industrias PET’, European Union register number RECYC0110.

EFSA is required by Article 5 of Regulation (EU) No 282/2008[5] to carry out risk assessments on the risk 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 No (EU) 282/2008[5], EFSA will evaluate whether it has been demonstrated in a challenge test, or by other appropriate scientific evidence, that the recycling process San Miguel Industrias PET is able to reduce any contamination of the plastic input to a concentration that does not pose a risk to human health. The materials and articles used as input to the process as well as the conditions of use of the recycled materials and articles 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 Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, to evaluate the safety of the recycling process San Miguel Industrias PET which was allocated the European Union register number RECYC0110. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2014-00167. The dossier was submitted on behalf of San Miguel Industrias PET S.A., Peru.

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 San Miguel Industrias PET is intended to recycle, in Peru, food grade poly(ethylene terephthalate) (PET) containers, to produce recycled PET pellets using the Starlinger IV+® technology. 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 all kind of foodstuffs for long term storage at room temperature, with or without hotfill. Recycled pellets are intended to be placed on the European market.

3. Description of the process

3.1. General description

According to the applicant, the recycling process San Miguel Industrias PET produces recycled PET pellets from PET containers, coming from post-consumer collection systems (kerbside and deposit collection systems). The recycling process is composed of the four steps below.

<u>Input</u>

- In step 1, post-consumer PET containers are processed into hot caustic washed and dried flakes, which are used as input of the process. The flakes are processed in-house.

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

- In step 2, the flakes are dried and crystallised in a reactor under desiccant air flow at high temperature.

- In step 3, the flakes are extruded under vacuum at high temperature and then crystallised.

- In step 4, the crystallised pellets are pre-heated before being handled over in a continuous running solid state polycondensation reactor at high temperature and vacuum.

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

Recycled pellets, the final product of the process, are checked against technical requirements on intrinsic viscosity, colour, black specks, etc. Recycled pellets are intended to be converted by other companies into recycled articles used for hotfill and/or long-term storage at room temperature such as bottles for mineral water, soft drinks, juices, beer, sauces and condiments. The recycled pellets may also be used for sheets, which are thermoformed to make meat trays. The trays are not intended to be used either in microwave or in conventional oven.

3.2. Characterisation of the input

According to the applicant, the input for the recycling process San Miguel Industrias PET is hot caustic washed and dried flakes obtained from PET containers previously used for food packaging and collected from post-consumer collection systems (kerbside and deposit systems). However, a small fraction may originate from non-food applications such as soap bottles, mouth wash, kitchen hygiene bottles, etc. According to the applicant, the amount of this non-food container fraction depends on the re-collection system and is average 0.15 % in the bales of PET bottles received from suppliers. Further automatic and manual sorting steps aim to eliminate these containers.

According to the applicant, the post-consumer PET containers have been manufactured in accordance with Community legislation on plastic food contact materials and articles.

Technical data for the hot caustic washed and dried 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. Starlinger IV+® technology

4.1. Description of the main steps

To decontaminate post-consumer PET, the recycling process San Miguel Industrias PET uses the Starlinger IV+® technology for which the main steps are described below and for which the general scheme provided by the applicant is summarised in Figure 1.

Drying and crystallisation (step 2): In this step the flakes are dried and crystallised at high temperature in a reactor under desiccant air (dried air) flow, in a continuous process.

Extrusion and crystallisation (step 3): The flakes from the previous step are fed to an extruder under high temperature and vacuum for a predefined residence time. Residual solid particles (e.g. paper, aluminium, etc.) are filtered out before pellets are produced. The extruded pellets are then crystallised at high temperature in a further reactor under atmospheric pressure.

SSP reactor (step 4): The crystallised pellets are continuously pre-heated in a reactor before being introduced in the solid state polycondensation reactor running under vacuum (suction from the right upper side) for a predefined high temperature and residence time.

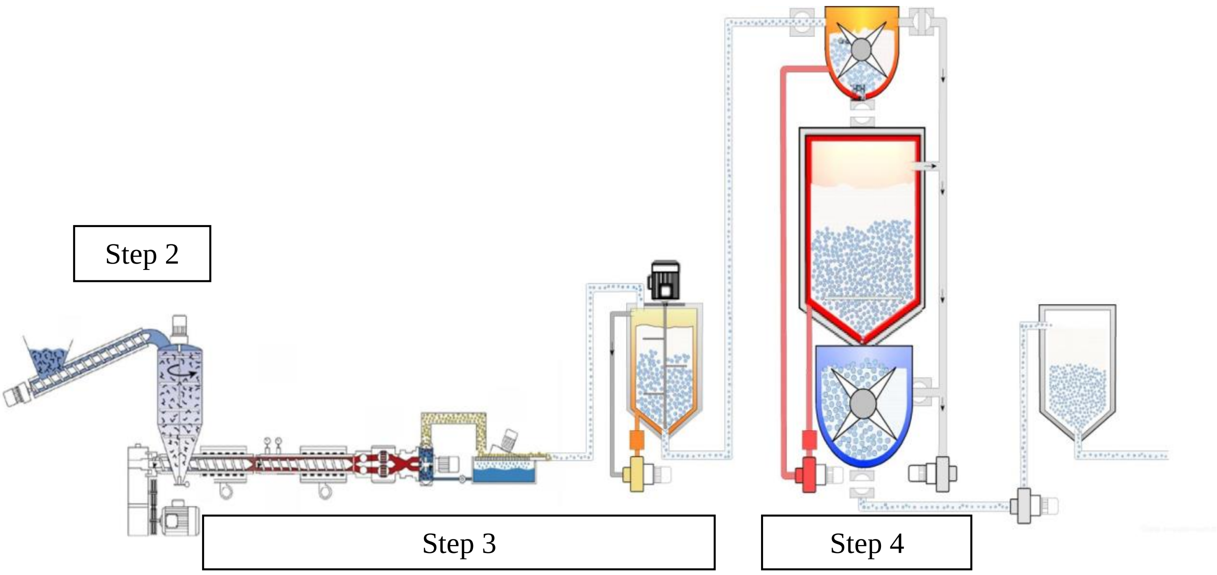


Figure 1: General scheme of the Starlinger IV+® technology

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

4.2. Decontamination efficiency of the recycling process

To demonstrate the decontamination efficiency of the recycling process, a challenge test on the Starlinger IV+® technology was submitted to EFSA.

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

For the preparation of the contaminated PET flakes, conventionally recycled[7] green PET flakes were soaked in a heptane/isopropanol solution containing the surrogates and stored for 14 days at 40 °C. The surrogates solution was decanted and PET flakes were rinsed with water and then air dried. The concentration of surrogates in this material was determined.

The Starlinger IV+® technology was challenged in Starlinger facilities in pilot plant scale. Only contaminated green flakes were introduced directly in the drier (step 2) for producing contaminated pellets (after step 3). Contaminated green pellets were added to the crystalliser that contained some white non-contaminated pellets. Those crystallised pellets were pre-heated under mixing and then added into the SSP reactor (step 4) which was already filled with white non-contaminated pellets (ratio green/white: 1/6). In the SSP reactor, there was no mixing. Cross contamination[8] by diffusion of contaminants from green to white pellets might occur. However, if any cross-contamination were to occur due to mixing in the preheater, it is expected to have a limited impact on the calculation of the final decontamination efficiency.

Green contaminated flakes then pellets were sampled after each step (2-4) of the process. The samples (flakes then pellets) were analysed for their residual concentrations of the applied surrogates. Instead of being processed continuously, the SSP reaction was run in batch mode. In both batch and continuous modes of operation the surrogates diffuse through the pellets to the surface and they are constantly eliminated by the vacuum applied. Therefore continuous working process will result in the same cleaning efficiencies as batch process, as long as the same temperature, pressure conditions and residence time are applied.

The decontamination efficiency of the process was calculated taking into account the concentration of the surrogates detected in washed contaminated flakes before the drying and crystallisation (before step 2) and in contaminated pellets after the SSP (step 4). When not detected, the limit of detection was considered for the calculation of the decontamination efficiency. The results are summarised below in Table 1.

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

[8] 'Cross-contamination', as defined in '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 surrogates from the initially contaminated to the initially non-contaminated flakes (EFSA CEF Panel, 2011).

Table 1: Efficiency of the decontamination of the three steps of the Starlinger IV+® technology

Surrogates	Concentration of surrogates before step 2 (mg/kg PET)	Concentration of surrogates after step 4 (mg/kg PET)	Decontamination efficiency (%)
Toluene	563	< 0.8[(a)]	> 99.9
Chloroform	1 900	< 0.5[(a)]	> 99.9
Phenylcyclohexane	538	< 0.3[(a)]	> 99.9
Benzophenone	694	10.8	98.4
Lindane	373	33.9	90.9

(a): Not detected at the given limits of detection

As shown above, the decontamination efficiency ranged from 90.9 % for lindane to above 99.9 % for toluene, chloroform and phenylcyclohexane.

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 PVC, glue, polyolefins, cellulose, metals, polyamides and physical properties are provided for hot caustic washed and dried flakes (step 1), the input materials of the submitted recycling process. The input material is produced from PET containers previously used for food packaging collected through post-consumer collection systems. However, a small fraction may originate from non-food applications such as soap bottles, mouth wash, kitchen hygiene bottles, etc. According to the applicant, the amount of this non-food container fraction depends on the re-collection system and is average 0.15 % in the bales of PET bottles received from suppliers. Further automatic and manual sorting steps aim to eliminate these containers. The fraction of non-food containers is therefore below the 5 % as recommended by the EFSA CEF Panel in its ‘Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food’ (EFSA Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), 2011). According to the applicant, all usual non-food use PET containers are manufactured from food grade PET material hence should be in compliance with Regulation (EU) No 10/2011.

The process is well described. The production of washed and dried flakes from collected containers (step 1) is conducted by the applicant. According to the applicant, this step is under control. The following steps are those of the Starlinger IV+® technology used to recycle the PET flakes into decontaminated PET pellets: drying and crystallisation (step 2), extrusion and crystallisation (step 3) and solid state polycondensation (step 4). The operating parameters of temperature, pressure, residence time and air flow have been provided to EFSA.

A challenge test was conducted at a pilot plant scale on the process steps from 2 to 4 (drying, extrusion and crystallisation, and SSP reactors) to measure the decontamination efficiency. The operating parameters of these steps in the process are at least as severe as those operated for the challenge test. The Panel considered that the challenge test was performed correctly according to the EFSA Guidelines (EFSA, 2008). Although the fourth step is expected to be the most critical step for the decontamination, drying and crystallisation (step 2) and extrusion (step 3) are relevant too. Therefore, the Panel considered that the three steps, drying and crystallisation, extrusion and crystallisation, and SSP are the critical steps for the decontamination efficiency of the process. Consequently the temperature, the gas flow and the residence time for the drying and crystallisation (step 2) and the temperature, the pressure and the residence time for both the extrusion and crystallisation (step 3) and for the SSP (step 4) should be controlled to guarantee the performance of the decontamination. These parameters have been provided to EFSA.

The decontamination efficiencies obtained from the challenge test for each surrogate contaminant and ranging from 90.9 % to above 99.9 %, 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 intended to be used for manufacture of materials and articles in contact with food' (Appendix B; EFSA CEF Panel, 2011). 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). The CEF Panel noted that the input of the process originates from Peru, South America and, in the absence of data on misuse contamination on this input, used the reference contamination of 3 mg/kg PET (EFSA CEF Panel, 2011) which was derived from experimental data on severity and frequency of contamination of washed and dried flakes reported in an EU survey.

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.[9] 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 0.1µg/kg into food has been used to calculate Cmod (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.

Table 2: 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 1 year at 25 °C

Surrogates	Decontamination efficiency (%)	Cres (mg/kg PET)	Cmod (mg/kg PET)
Toluene	> 99.9	< 0.003	0.09
Chloroform	> 99.9	< 0.003	0.10
Phenylcyclohexane	> 99.9	< 0.003	0.14
Benzophenone	98.4	0.048	0.16
Lindane	90.9	0.273	0.31

The residual concentrations of all surrogates in PET after the decontamination (Cres) are lower than the corresponding modelled concentrations in PET (Cmod). Therefore, using the reference contamination level of 3 mg/kg PET, the Panel considered that the recycling process San Miguel Industrias PET using a Starlinger IV+® technology 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 CEF 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 three steps, drying and crystallisation, extrusion and crystallisation and SSP are the critical steps for the decontamination efficiency of the process. The operating parameters to control their performance are the temperature, the gas flow and the residence time for the drying and crystallisation (step 2) and the temperature, the pressure and the residence time

[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)(EFSA CEF Panel, 2011).

for both the extrusion and crystallisation (step 3) and for the SSP (step 4). Therefore, the Panel considered that the recycling process San Miguel Industrias PET 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) the input of the process is not contaminated through misuse at severity and frequency that brings to a reference contamination level higher than 3 mg/kg PET,

ii) 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,

iii) 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 San Miguel Industrias PET 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. Trays made of this recycled PET are not intended to be used, and should not be used in microwave and conventional ovens.

Recommendations

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

Documentation provided to EFSA

1. Initial dossier, March 2014. Submitted on behalf of San Miguel Industrias S.A.

2. Revised dossier, August 2014. Submitted on behalf of San Miguel Industrias S.A.

3. Clarifications, December 2014, January and February 2015. Submitted on behalf of San Miguel Industrias S.A.

4. Clarifications in May 2015. Submitted on behalf of San Miguel Industrias S.A.

References

EFSA (European Food Safety Authority), 2008. 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 Journal 2008, 717, 1–12.

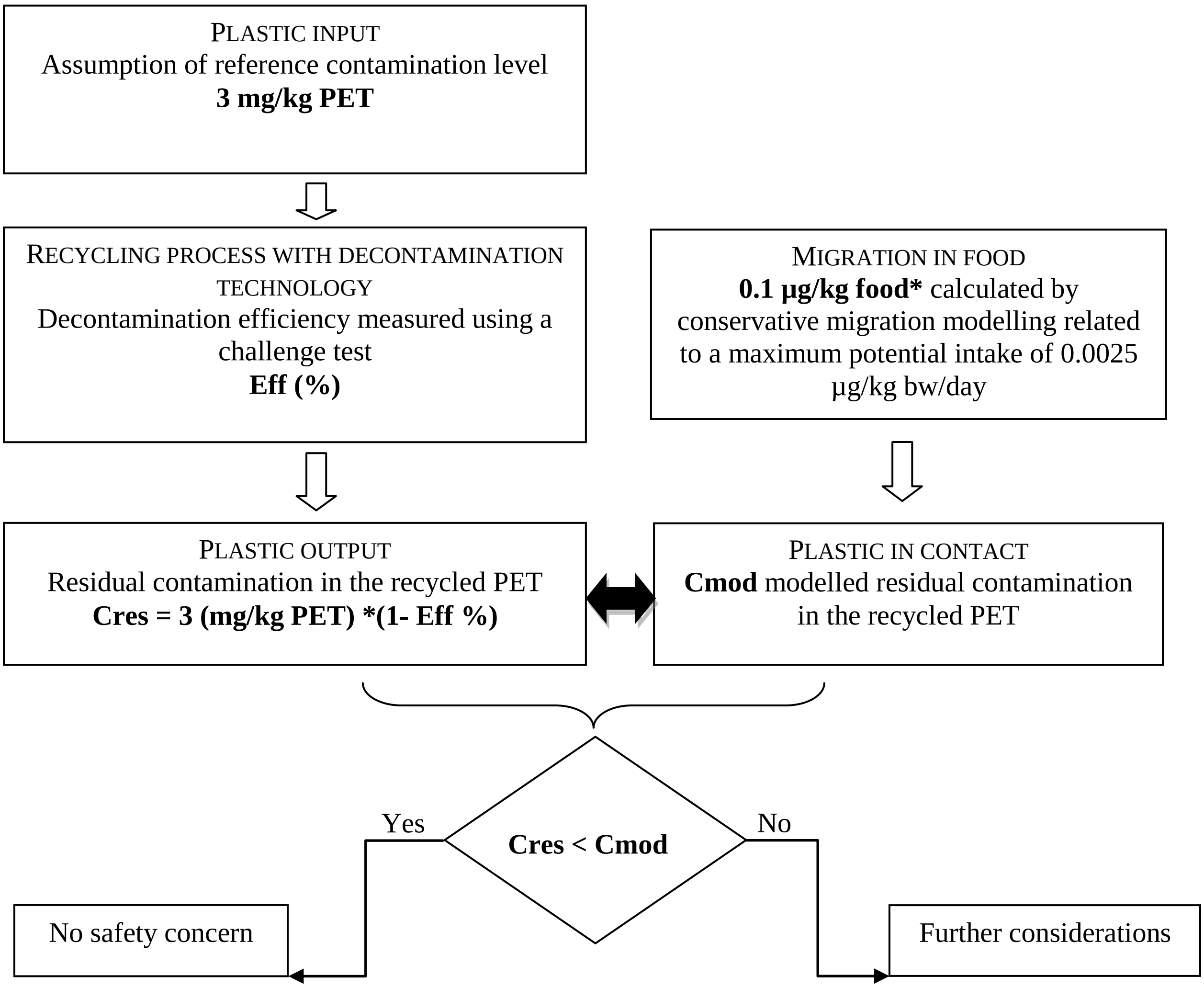
EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), 2011. Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food. EFSA Journal 2011;9(7):2184, 25 pp.

APPENDICES

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

Parameter	Value
Moisture max.	0.4 to 0.6 %
Moisture variation	± 0.3 % h^{-1}
Bulk density	300 $kg.m^{-3}$
Bulk density variation	± 100 $kg.m^{-3}.h^{-1}$
Material temperature	10 – 60 °C
PVC max.	50 ppm
Glue max. (exclusive of flake)	100 ppm
Polyolefins max.	20 ppm
Cellulose (paper, wood)	10 ppm
Metals max.	20 ppm
Polyamide max.	50 ppm

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

bw	body weight
CEF	Food contact materials, enzymes, flavourings and processing aids
Cmod	modelled concentration in PET
Cres	residual concentrations in PET
EC	European Commission
EU	European Union
GMP	Good manufacturing practice
PET	poly(ethylene terephthalate)
PVC	poly(vinylchloride)