EFSA Journal 2013;11(2):3094

SCIENTIFIC OPINION

Scientific Opinion on the safety evaluation of the process "MOPET ®" used to recycle post-consumer PET into food contact materials[1]

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

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

This scientific opinion of the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids deals with the safety evaluation of the recycling process MOPET ®, EC register number RECYC001. The input of the process is hot caustic washed and dried PET flakes originating from collected post-consumer PET articles mainly bottles containing no more than 5 % of PET from non-food consumer applications. Through this process, washed and dried PET flakes are extruded in a twin-screw extruder to amorphous pellets before being crystallised and solid state polymerised in a batch reactor. After having examined the challenge tests provided, the Panel concluded that, although the extrusion (step 2) contributes significantly to the overall decontamination efficiency, the decontamination in the batch SSP reactor (step 3) is the critical step that determine the decontamination efficiency of the process. The operating parameters to control its performance are well defined and are the temperature, the pressure, the residence time and the inert gas flow. 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 a conservatively modelled migration of 0.1 μg/kg food. Therefore the Panel concluded that the recycled PET obtained from this process intended for the manufacture of materials and articles for contact with all types of foodstuffs for long term storage at room temperature, with or without hotfill is not considered of safety concern.

KEY WORDS

MOPET ®; Food contact materials; Plastic; Poly(ethylene terephthalate) PET; Recycling; Process; Safety evaluation.

[1] On request from the Ministry of Health, Welfare and Sport, The Netherlands, Question No EFSA-Q-2009-00757, adopted on 29 January 2013.

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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, Constantine Papaspyrides and Karla Pfaff for the preparatory work on this scientific opinion.

Suggested citation: EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on the safety evaluation of the process "MOPET ®" used to recycle post-consumer PET into food contact materials. EFSA Journal 2013;11(2):3094. [15 pp.] doi:10.2903/j.efsa.2013.3094. Available online: www.efsa.europa.eu/efsajournal

SUMMARY

According to the Commission Regulation (EC) No 282/2008[4] of 27 March 2008 on recycled plastic materials intended to come into contact with foods and amending Regulation (EC) No 2023/2006[5], EFSA is requested to evaluate recycling processes of plastic waste. In this context, the CEF Panel evaluated the process MOPET ®.

The Ministry of Health, Welfare and Sport, The Netherlands, requested the evaluation of the recycling process MOPET ® submitted on behalf of Morssinkhof Plastics Zeewolde BV. The recycling process has been allocated the European Commission register number RECYC001. It is deemed to recycle poly(ethylene terephthalate) (PET) pellets from PET articles, mainly bottles and possibly trays, collected through post-consumer collection systems. The recycled pellets are intended to be used at up to 100 % for the manufacture of food contact materials and articles. These recycled materials and articles are intended to be used in direct contact with all kinds of foodstuffs for long term storage at room temperature, with or without hotfill.

The process is composed of three steps. First post-consumer PET articles, mainly bottles and possibly trays, are processed into hot caustic washed and dried flakes which are used as input of the MOPET ® process. Washed flakes are further extruded in the step 2 then crystallised and solid-state polymerised (SSP) in the step 3.

Detailed specifications for the input materials are provided and the amount of non-food use containers is reported to be below 5 %.

Four challenge tests were conducted at the production plant on the process extrusion (step 2) and batch SSP (step 3) to measure the decontamination efficiency. From the two challenge tests carried out with only contaminated materials, one on the extrusion (step 2) and one on the SSP (step 3), the decontamination could be calculated for the two steps respectively.

Although the extrusion (step 2) contributes significantly to the overall decontamination efficiency, the decontamination efficiencies obtained from the challenge test performed on the step 3 and for each surrogate contaminant, ranging from more than 99.4 % 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 Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), 2011). According to these criteria, the recycling processes 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 pellets are identified. After having examined the challenge tests provided, the Panel concluded that the batch SSP reactor (step 3) is the critical step for the decontamination efficiency of the process. The operating parameters to control its performance are the temperature, pressure, residence time and inert gas flow. Therefore, the Panel considered that the recycling process MOPET ® 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:

[4] 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.

[5] Regulation (EC) No 2023/2006 of the European parliament and of the council of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food. OJ L 384, 29.12.2006, p.75- 78.

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 processes and,

ii. the input of the process is washed and dried post-consumer PET flakes originating from materials and articles that have been manufactured in accordance with the Community legislation on food contact materials containing no more than 5 % of PET from non-food consumer applications.

The Panel concluded that the recycled PET obtained from the process MOPET ® intended for the manufacture of materials and articles for contact with all types of foodstuffs for long term storage at room temperature, with or without hotfill is not considered of safety concern.

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

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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. Before a recycling process is authorized, EFSA opinion on its safety is required. This procedure has been established in Article 5 of the Regulation (EC) No 282/2008 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 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 authorization (EFSA, 2008).

In this case, EFSA received an application for evaluation of the recycling process MOPET ®, EC register number RECYC001, from the Ministry of Health, Welfare and Sport, The Netherlands.

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 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 (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 MOPET ® 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.

[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 Ministry of Health, Welfare and Sport, The Netherlands, to evaluate the safety of the process MOPET ® with EC register number RECYC001. The request has been registered in the EFSA register of questions under the number EFSA-Q-2009-00757. The dossier was submitted on behalf of Morssinkhof Plastics Zeewolde BV.

The dossier submitted for evaluation followed the EFSA Guidelines for the submission of an application for safety evaluation by the EFSA of a recycling process to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food, prior to its authorisation (EFSA, 2008).

2. General Information

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

3. Description of the process

3.1. General description

The recycling process MOPET ® produces recycled PET pellets from mainly bottles and possibly trays, coming from post-consumer collection systems (curbside and deposit collection systems). The recycling process is composed of the three steps below.

<u>Input</u>

- In Step 1, post-consumer PET bottles and possibly trays are processed into hot caustic washed and dried flakes which are used as input of the next steps. Flakes may be either processed in house or bought from the market by approved suppliers.

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

- In Step 2, the flakes are extruded into pellets at high temperature with multiple degassing.

- In Step 3, the pellets are crystallised and solid state polymerised in a unique batch reactor at high temperature under vacuum and inert gas flow.

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 and beer. The recycled pellets may also be used for sheets which are thermoformed to make food trays. The trays are not intended to be used in microwaves and ovens.

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

3.2. Characterisation of the input

According to the applicant, the input for the recycling process MOPET ® is hot caustic washed and dried flakes obtained from PET, mainly bottles and possibly trays, previously used for food packaging, from post-consumer collection systems (curbside and deposit 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, sorting procedures keep this fraction under control and below 5 %.

Technical data for the hot caustic washed and dried flakes are provided such as information on residual content of poly(vinyl chloride) (PVC), polyolefins, paper, metals, polyamide and physical properties (see Annex A).

4. MOPET ® process

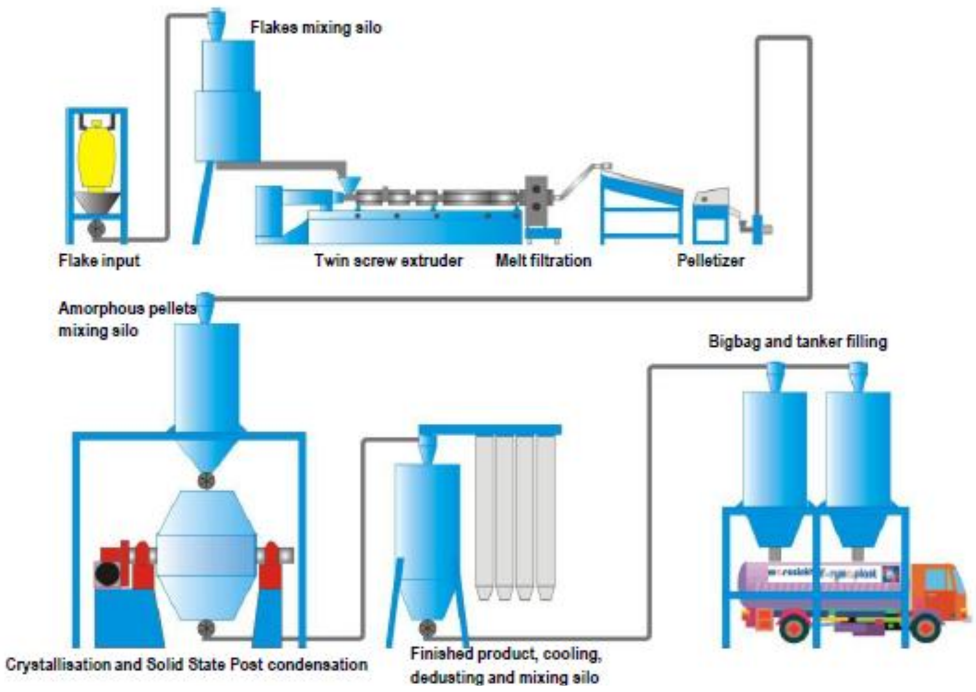
4.1. Description of the main steps

To decontaminate post-consumer PET, the recycling process MOPET ® uses the technology as described below and for which the general scheme provided by the applicant is reported in figure 1.

Extrusion of flakes into pellets (step 2): Flakes are processed on a twin-screw extruder into amorphous pellets with multiple vacuum degassing under high temperature. In the first section flakes are further dried and heated with degassing operating under atmospheric pressure. In the second section the melted material is processed under high temperature and vacuum degassing (two vent zones). In this step, some volatile contaminants are removed and the polymer is melt filtered to remove residual solid particles (e.g. paper, aluminium, etc.).

Crystallisation and solid state polymerisation (SSP) (step 3): The amorphous pellets are loaded into a rotary reactor (also called tumble drier) in which they are first crystallised then solid state polymerised under vacuum, temperature and nitrogen flow to achieve the desired intrinsic viscosity.

Figure 1: General scheme of the MOPET ® technology



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

4.2. Decontamination efficiency of the recycling process

To demonstrate the decontamination efficiency of the process, four challenge tests were submitted to EFSA. One was performed on the extrusion (step 2) and three on the SSP (step 3), all at the industrial plant scale.

PET flakes were contaminated with selected chemicals, toluene, chlorobenzene, phenylcyclohexane, benzophenone, trichloroethane, methylstearate and o-cresol 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] post-consumer PET flakes of green colour were soaked in a hexane solution containing the surrogates and stored for 4 weeks at 35 °C. The surrogates’ solution was decanted and PET flakes were rinsed with water and then air dried. The concentration of surrogates in these flakes was determined and contaminated flakes were used as input for the challenge test on the extrusion. Contaminated pellets coming from the extrusion of the contaminated flakes were used as input of tests on the SSP.

The extrusion step was challenged with only contaminated flakes. On the SSP reactor, one test was carried out at a reduced capacity of the reactor with only contaminated pellets and two were carried out at the full capacity of the reactor using both contaminated and non-contaminated pellets. Contaminated pellets used in these three challenge test on the SSP came from the extrusion. In these last tests, white and green pellets were sampled, separated and both analysed for their residual concentrations of the applied surrogates.

The decontamination efficiencies of the extrusion (step 2) calculated from the challenge test are summarised below in table 1. When not detected, the limit of detection was considered for the calculation of the decontamination efficiency.

Table 1: Efficiency of the decontamination of the extrusion (step 2) (performed with 100 % contaminated flakes)

Surrogates	Concentration of surrogates before extrusion (mg/Kg PET)	Concentration of surrogates after extrusion (mg/Kg PET)	Decontamination Efficiency (%)
Toluene	352	17	95.2
Chlorobenzene,	71	5	93.0
Phenylcyclohexane	73	18	75.3
Benzophenone	747	388	48.1
Trichloroethane	28	<0.1*	>99.6
Methyl stearate	667	251	62.4
o-Cresol	1842	378	79.5

*Not detected at the indicated limit of detection

As shown above, the decontamination efficiency of the extrusion ranged from 48.1 % for benzophenone to more than 99.6 % for trichloroethane.

As regards the decontamination efficiency of the SSP (step 3), the Panel could not use the decontamination efficiency obtained from the two tests performed with both contaminated and non-

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

contaminated pellets when considering possible cross-contamination[8] phenomena. Even taking into account the limit of detection as a residual concentration in initially non-contaminated flakes, the decontamination efficiency is mathematically decreased and the results are inconclusive. Therefore the Panel did not use these results and reported the decontamination efficiency of the SSP reactor calculated from the challenge test carried out with only contaminated pellets. The decontamination efficiency was calculated on the concentration of surrogates measured before and after the SSP step. When not detected, the limit of detection was considered for the calculation of the decontamination efficiency. The results are summarised below in table 2.

Table 2: Efficiency of the decontamination of the SSP reactor (step 3) (performed with 100 % contaminated pellets)

Surrogates	Concentration of surrogates before SSP (mg/Kg PET)	Concentration of surrogates after SSP* (mg/Kg PET)	Decontamination Efficiency (%)
Toluene	17.6	<0.023	>99.8
Chlorobenzene	3.9	<0.025	>99.4
Phenylcyclohexane	16	<0.025	>99.8
Benzophenone	416	<0.178	>99.9
Trichloroethane	<0.1	**	**
Methyl stearate	257	<0.102	>99.9
o-Cresol	435	<0.182	>99.9

* Not detected at the indicated limit of detection

** Not determined as it was not detected in pellets before being submitted to the SSP reactor

As shown above, the decontamination efficiency of the SSP ranged from more than 99.4 % for chlorobenzene to more than 99.9 % for benzophenone, methylstearate and o-cresol. The overall decontamination efficiency of the process is expected to be even higher as significant decontamination will occur during the extrusion with multiple degassing.

It must be noted that, although this challenge test was performed at a reduced capacity of the reactor, the Panel considered it representative of the decontamination efficiency at the production scale. The Panel considered that the operating parameters time, temperature and relative gas flow per mass of pellets were the same in the challenge test and at the production scale.

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, polyolefin, paper, metals, polyamide and physical properties are provided for hot caustic washed and dried flakes (step 1), the input materials for the recycling process. The input materials are produced from PET containers, mainly bottles and possibly trays, previously used for food packaging and 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, kitchen hygiene bottles, etc. According to the applicant, sorting procedures keep this non-food container fraction under control and 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

[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 Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), 2011).

articles in contact with food” (EFSA Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), 2011).

The process is well described. According to the applicant, the production of washed and dried flakes from collected PET post-consumer articles comprising largely bottles and possibly trays (step 1) is conducted in different ways depending on their production plant, in line with pre-established procedure. The following steps are those of the MOPET ® process used to recycle the PET flakes into decontaminated PET pellets: extrusion under vacuum (step 2) and batch SSP reactor (step 3). The operating parameters of temperature, pressure and residence time for the extrusion (step 2) and temperature, pressure, nitrogen flow and residence time for the crystallisation and SSP (step 3) have been provided to EFSA.

Four challenges tests were conducted at production plant on the process extrusion step 2 and batch SSP step 3 to measure the decontamination efficiency. The challenge tests were performed according to the recommendations in the EFSA Guidelines (EFSA, 2008). From the two challenge tests carried out with only contaminated materials, one on the extrusion (step 2) and one on the SSP (step 3), the decontamination could be calculated for the two steps respectively. The two steps, the extrusion under vacuum (step 2) and the SSP batch reactor (step 3) were shown to contribute to the decontamination efficiency of the process. However the Panel considered that the SSP batch reactor (step 3) is the critical step for the decontamination efficiency of the process. Consequently temperature, pressure, residence time and inert gas flow for the SSP of the process 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 performed on the step 3 and for each surrogate contaminant, ranging from more than 99.4 % 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” (EFSA Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), 2011; Annex B). By applying the decontamination efficiency percentage to the Reference Contamination level of 3 mg/kg PET, the Cres for the different surrogates is obtained (Table 2).

According to the evaluation principles (EFSA Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), 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 negligible9. 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 Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), 2011). The results of these calculations are shown in Table 3. The relationship between the key parameters for the evaluation scheme is reported in Annex B.

[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 Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), 2011).

Table 3: Decontamination efficiency from challenge test on the SSP, 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	<0.004	0.09
Chlorobenzene	>99.4	<0.019	0.09
Phenylcyclohexane	>99.8	<0.005	0.14
Benzophenone	>99.9	<0.001	0.16
Methyl stearate	>99.9	<0.001	0.32
o-Cresol	>99.9	<0.001	0.09

The residual concentrations of all surrogates in PET after the decontamination (Cres) are lower than the corresponding modelled concentrations in PET (Cmod). 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 pellets are identified. After having examined the challenge tests provided, the Panel concluded that the batch SSP reactor (step 3) is the critical step for the decontamination efficiency of the process. The operating parameters to control its performance are the temperature, pressure, residence time and inert gas flow. Therefore, the Panel considered that the recycling process MOPET ® is able to reduce any foreseeable accidental contamination of the post-consumer food contact PET to a concentration that does not give rise to concern for a risk to human health if:

i. it is operated under conditions that are at least as severe as those obtained from the challenge test used to measure the decontamination efficiency of the process and,

ii. the input of the process is washed and dried post-consumer PET flakes originating from materials and articles that have been manufactured in accordance with the Community legislation on food contact materials containing no more than 5 % of PET from non-food consumer applications.

Therefore, the recycled PET obtained from the process MOPET ® intended for the manufacture of materials and articles for contact with all types of foodstuffs for hotfill and/or long term storage at room temperature is not considered of safety concern.

Recommendations

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

DOCUMENTATION PROVIDED TO EFSA

1. Dossier “MOPET ®”. Dated April 2009.Submitted on behalf of Morssinkhof Plastics Zeewolde BV.

2. Additional data for Dossier “MOPET ®”. Dated February 2011. Submitted on behalf of Morssinkhof Plastics Zeewolde BV.

3. Additional data for Dossier “MOPET ®”. Dated July 2012. Submitted by Morssinkhof Plastics Zeewolde BV.

4. Additional information for Dossier “MOPET ®”. Dated December 2012. Submitted by Morssinkhof Plastics Zeewolde BV.

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. doi:10.2903/j.efsa.2008.717

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), 2011. Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food. EFSA Journal 2011;9(7):2184, 25 pp. doi:10.2903/j.efsa.2011.2184

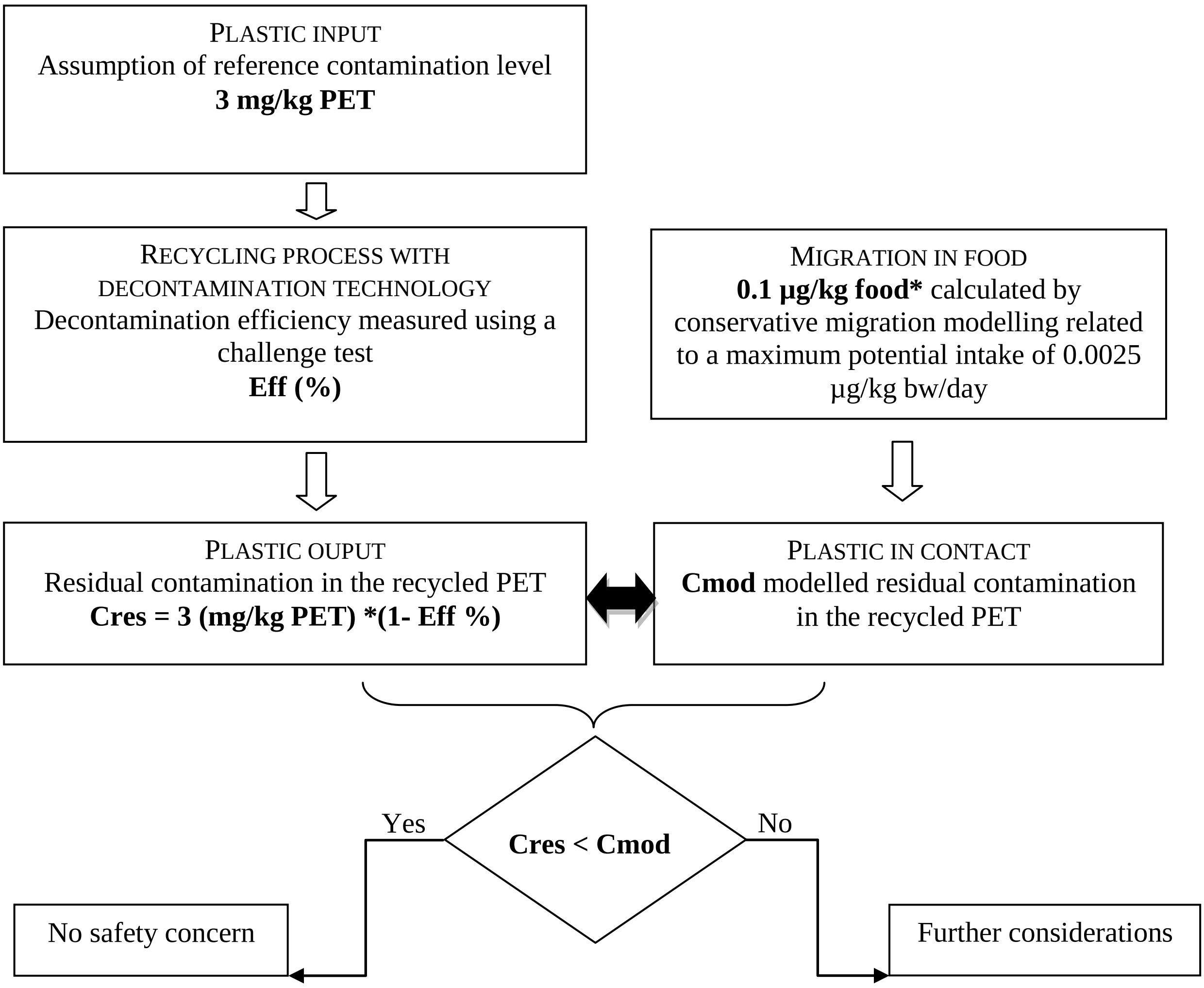
ANNEXES

A. TECHNICAL DATA OF THE WASHED FLAKES AS PROVIDED BY THE APPLICANT

Washed and dried flakes used for the MOPET ® recycling process

Parameter	Value	Unit
Humidity	< 1,5	%
Bulk density	0.25 – 0.60 (90 %)	kg/dm^3
Light blue coloured Flakes (average)	35 Max	%
Other coloured Flakes (average)	10 Max	%
Particle size (average)	5 – 25 (75 %)	mm
Melting point	> 240	^{o}C
PVC	< 100	ppm
Metals	< 50	ppm
Polyolefine (PE/PP)	< 100	ppm
Paper	< 100	ppm
Polyamide	< 200	ppm
Others (lime, salt, etc.)	< 100	ppm

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



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

ABBREVIATIONS

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