SCIENTIFIC OPINION

Scientific Opinion on the safety assessment of the process "Equipolymers Melt-in", 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 Equipolymers Melt-in (EU register number RECYC007). The input of the process is hot caustic washed and dried PET flakes originating from collected post-consumer PET bottles containing no more than 5 % of PET from non-food consumer applications. Through this process, washed and dried PET flakes are infrared dried and extruded. The extruded melt is fed up to 50 % into the main polymer stream of a continuous condensation process for the manufacture of virgin PET in which the melt of virgin and recycled PET is filtered and pellets are produced. The pellets are then crystallised, heated and solid state polymerised in separate reactors. Having examined the challenge test provided, the Panel concluded that crystallisation, heating and solid state polymerisation (step 3) and the addition of 50 % virgin PET melt are critical for the decontamination efficiency of the process. The operating parameters to control its performance are the temperature, the gas flow and the residence time and the addition of 50 % virgin PET melt. 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. The Panel concluded that the recycled PET obtained from the process Equipolymers Melt-in intended for the manufacture of materials and articles made with up to 50 % recycled post-consumer PET for contact with all types of foodstuffs for hotfill and/or long term storage at room temperature is not considered of safety concern.

[1] On request from the Bundesamt für Verbraucherschutz, Germany, Question No EFSA-Q-2009-00772, adopted on 26 September 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 (until March 2013) for the preparatory work on this scientific opinion.

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KEY WORDS

equipolymers Melt-in; Food contact materials; Plastic; Poly(ethylene terephthalate) (PET); Recycling; Process; Safety assessment

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 which plastic waste is recycled pursuant to the definition of recycling in point 7 of Article 3 of Directive 94/62/EC on packaging and packaging waste. In this context, the CEF Panel evaluated the following process "Equipolymers Melt-in".

The Bundesamt für Verbraucherschutz, Germany, requested the evaluation of the recycling process "Equipolymers Melt-in" submitted on behalf of Equipolymers GmbH. The recycling process has been allocated the European Union register number RECYC007. It recycles poly(ethylene terephthalate) (PET) pellets from PET bottles collected though post-consumer collection systems.

The recycled pellets, made up with up to 50 % post consumer PET, are intended to be used for the manufacture of materials and articles destined to be in direct contact with all kind of foodstuffs for long term storage at room temperature, with or without hotfill.

The process is composed of three steps. First post-consumer PET bottles are ground into flakes followed by an intensive hot caustic washing and drying which are used as input of the Equipolymers Melt-in technology. In the step 2, the flakes are infrared dried and extruded. The extruded melt is fed up to 50 % into the main polymer stream of a continuous condensation process for the manufacture of virgin PET in which the melt of virgin and recycled PET is filtered and pellets are produced. In the step 3, the pellets are crystallised, pre-heated and solid state polymerised (SSP) in separate reactors.

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

To measure the decontamination efficiency of the process a challenge test was conducted at laboratory scale with 100 % contaminated flakes on the process steps 2 (drying and extrusion of the flakes into pellets) and 3 (crystallisation, heating and solid state polymerisation). The decontamination efficiency was calculated for the step 3, which is considered to be the most critical step for the elimination of contaminants.

The decontamination efficiencies obtained for each surrogate contaminant from the challenge test, ranging from 94.1 % to 99.8 %, have been used to calculate the residual concentrations of potential unknown contaminants in recycled PET pellets made of 50 % of post-consumer PET mixed with 50 % of virgin PET (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). According to these criteria, the Equipolymers Melt-in recycling process is able to reduce the level of unknown contaminants in recycled PET 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 crystallisation, heating and solid state polymerisation (step 3) and the addition of 50 % virgin PET melt are critical for the decontamination efficiency of the process. The operating parameters to control their performance are the temperature, the gas flow and the residence

[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.

time for step 3 and the addition of 50 % virgin PET melt. Therefore, the Panel considered that the recycling process Equipolymers Melt-in 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,

ii) the input of the process is washed and dried post-consumer PET flakes originating from materials and articles that has 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 and,

iii) the final recycled articles manufactured with pellets recycled with the Equipolymers Melt-in technology, do not contain more than 50 % recycled post-consumer PET.

The Panel concluded that the recycled PET obtained from the Equipolymers Melt-in process, intended for the manufacture of materials and articles made with up to 50 % recycled post-consumer PET for contact with all types of foodstuffs for hotfill and/or long term storage at room temperature is not considered of safety concern.

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 European Union legislation on food contact materials and that the proportion of PET from non-food consumer applications is no more than 5 % in the input to be recycled. Critical steps should be monitored and kept under control; supporting documentation 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 authorised, EFSA´s 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 assessment 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 Bundesamt für Verbraucherschutz, Germany, an application for evaluation of the recycling process "Equipolymers Melt-in", EU register number RECYC007.

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 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 Equipolymers Melt-in 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 Bundesamt für Verbraucherschutz, Germany, to evaluate the safety of the process "Equipolymers Melt-in" with EU register number RECYC007. The request has been registered in the EFSA's register of received questions under the number EFSA-Q-2009-00772. The dossier was submitted on behalf of Equipolymers GmbH, Germany.

The dossier submitted for evaluation followed the EFSA Guidelines for the submission of an application for safety assessment 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 "Equipolymers Melt-in" is intended to recycle food grade poly(ethylene terephthalate) (PET) bottles to produce recycled PET pellets. For this purpose post-consumer PET melt is added up to 50 % to production process of virgin PET. The produced recycled pellets, made with up to 50 % recycled PET, are intended to be used for the manufacture of recycled materials and articles for direct contact with all kind of foodstuffs for long term storage at room temperature, with or without hotfill.

3. Description of the process

3.1. General description

The recycling process Equipolymers Melt-in produces recycled PET pellets from PET bottles, coming from post-consumer collection systems (curbside and/or deposit collection systems). The recycling process is composed of the three steps below.

Input

In Step 1, post-consumer PET bottles are processed into hot caustic washed and dried flakes which are bought from the market from approved suppliers based on pre-agreed specifications and which are used as input of the next steps.

Decontamination and production of recycled PET material

In Step 2, the flakes are infrared dried and extruded including high temperature vacuum degassing and filtering before being fed up to 50 % together with virgin PET melt into a continuous condensation process (CPC) before strand granulation.

In Step 3, the pellets are crystallised and pre-heated before being processed in a continuously running solid state polymerisation reactor at high temperature and under nitrogen flow.

The final product is recycled PET pellets containing up to 50 % PET from post-consumer bottles. The recycled pellets are checked against technical requirements on intrinsic viscosity, colour, black specks, etc. Recycled pellets are intended to be converted in other plants (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 either in microwave or in conventional oven.

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 Equipolymers Melt-in is hot caustic washed and dried flakes obtained from post-consumer PET bottles previously used for food packaging and coming from deposit systems as well as from curbside collections. However, a small fraction may originate from non-food applications. According to the applicant, the amount of this non-food container fraction depends on the re-collection system. On the basis of market share data, the applicant estimated this fraction below 5 %.

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), flakes with glue, polyolefins, paper, metals and physical properties (see Annex A).

4. Equipolymers Melt-in technology

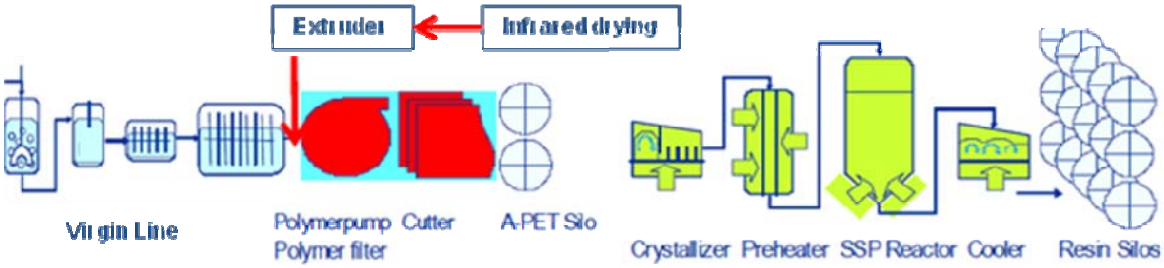
4.1. Description of the main steps

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

Drying and extrusion of the flakes into pellets (step 2): In this step, flakes from step 1 are firstly infrared dried in a reactor then fed to the extruder under high temperature vacuum degassing. The extruded melt is subsequently mixed up to 50 % with virgin melt before being filtered and pelletised. These step conditions favour the vaporisation of possible contaminants of PET flakes.

Crystallisation, heating and solid state polymerisation (step 3): The amorphous pellets are introduced in a crystalliser (step 3.1) then pre-heated in a further reactor (step 3.2) before being subjected to a continuous solid state polymerisation (SSP) reactor under high temperature conditions and nitrogen flow for a predefined residence time (step 3.3). Further decontamination occurs in this reactor.

Figure 1: General scheme of "Equipolymers Melt-in" process



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

4.2. Decontamination efficiency of the recycling process

To demonstrate the decontamination efficiency of the process, a challenge test on the steps 2 (without infrared drying and vacuum degassing in the extrusion procedure) and 3 was submitted to EFSA.

PET flakes were contaminated with selected chemicals, toluene, chlorobenzene, chloroform, methylsalicylate, phenylcyclohexane, benzophenone, lindane, and methylstearate 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 were soaked in a solution containing the surrogates for 14 days at 40 °C and stand in an open drum for 24 hours for reduction of excessive solvent. The concentration of surrogates in this material was determined.

The challenge test was performed with only contaminated flakes at laboratory scale on the extruder (step 2, without infrared drying and vacuum degassing during the extrusion) and on the crystallisation, heating and SSP step 3. Instead of using three separate reactors for the crystallisation (step 3.1), pre-heating (step 3.2) and SSP (step 3.3) as in the production plant, the whole step 3 was challenged in a unique reactor. However in this unique reactor, the sequence of steps 3.1, 3.2 and 3.3 was respected and corresponding operating parameters were less severe or based on performance data, equivalent to those operated in the process at the production plant. Samples were taken after the extruder reactor and after the SSP reactor and were analysed for their residual concentrations of the applied surrogates.

Although the contaminated flakes were not washed and dried, the flakes were introduced directly in the extruder and melted (step 2) and therefore this step could have been considered in the calculation of the decontamination efficiency. However, the Panel noted that the step 2 was carried out in the challenge test without degassing and drying and that it did not contribute significantly to the decontamination. Thus, the Panel decided not to use step 2 in the calculation of the overall decontamination efficiency. The decontamination efficiency was calculated based on the concentrations of surrogates in the contaminated pellets before and after step 3 (crystalliser, pre-heater and solid state polymerisation). When not detected, the limit of detection was considered for the calculation of the decontamination efficiency. The results are summarised below in table 1.

Table 1: Efficiency of the decontamination of the step 3 (crystalliser, pre-heater and SSP)

Surrogates	Concentration before crystalliser (mg/kg PET)	Concentration after SSP (mg/kg PET)	Decontamination efficiency (%)**
Toluene	63.9	0.1	99.8
Chloroform	262	0.5	99.8
Chlorobenzene	135	0.4	99.7
Methyl salicylate	64.5	<0.1*	>99.5
Phenylcyclohexane	5.1	0.3	94.1
Benzophenone	97.6	2.6	97.3
Lindane	42.5	2.4	94.4
Methyl stearate	95.7	1.2	98.7

*Not detected at the indicated limit of detection

** The decontamination efficiency determinated with 100 % contaminated flakes

As shown above, the decontamination efficiency of the step 3 ranged from 94.1 % for phenylcyclohexane to 99.8 % for toluene and chloroform.

The decontamination occurring during infrared drying and the application of vacuum degassing in the extrusion procedure, was not taken into account in the calculation. Therefore the overall decontamination efficiency is expected to be higher than calculated.

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

5. Discussion

Considering the high temperatures used during the process, the possibility of contamination by microorganisms can be discounted. Therefore this evaluation focuses on the chemical safety of the final product.

Technical data such as information on residual content of PVC, glue, polyolefins, cellulose, metals, and physical properties are provided for hot caustic washed flakes the input materials (step 1) for the submitted recycling process. The input material is 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 containers,mainly bottles, mouth wash, kitchen hygiene bottles, etc. According to the applicant, the amount of this non-food container fraction depends on the collection system and, on the basis of market share data can be kept below 5 % as recommended by the CEF Panel in its Scientific Opinion on "the criteria to be used for safety assessment 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 washed and dried flakes from post-consumer collected bottles (step 1) are bought from flakes suppliers according to agreed quality specifications. The following steps are those of the Equipolymer Melt-in process used to recycle the PET flakes into decontaminated PET pellets: infrared drying and extrusion of the flakes into pellets (step 2) and crystallisation, heating and solid state polymerisation (step 3). The operating parameters of temperature, vacuum, gas flow and residence time for both step 2 and step 3 have been provided to EFSA.

To measure the decontamination efficiency of the process, a challenge test was conducted at laboratory scale on step 2 (without infrared drying and vacuum degassing during the extrusion) and step 3 under conditions of temperature, gas flow and residence time less severe or equivalent to those operated in the process at the production plant. The challenge test was performed according to the recommendations in the EFSA Guidelines (EFSA, 2008). The Panel noted that the step 2 was carried out in the challenge test without degassing and drying and that it did not contribute significantly to the decontamination. Therefore and although the Panel considered that step 2 (infrared drying, melting and extrusion including high temperature and vacuum degassing) will contribute to the overall decontamination in the process, the decontamination efficiency of the challenge test was calculated only for the step 3 (crystallisation, heating and solid state polymerisation). Therefore the Panel considered the step 3 as critical for the decontamination efficiency of the process. Consequently the temperature, the gas flow and the residence time of the step 3 should be kept under control 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 94.1 % to 99.8 % 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; Annex B). By applying the decontamination efficiency percentage to the Reference Contamination level of 3 mg/kg PET and a dilution factor of 2 (the recycled pellets are manufactured with the addition of at least 50 % virgin PET melt), the Cres for the different surrogates is obtained (Table 2).

According to the evaluation principles (EFSA CEF Panel, 2011), the Cres should not be higher than a modelled concentration in PET (Cmod) corresponding to a migration, after 1 year at 25°C, which cannot give rise to a dietary exposure exceeding 0.0025 μg/kg bw/day, the exposure threshold below which the risk to human health would be negligible. Because the recycled PET is intended for general use for the manufacturing of articles, the most conservative default scenario for infants has been applied. Therefore, the migration of 0.1 μg of unknown contaminants into 1 kg 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 Annex B.

Table 2: Decontamination efficiency from challenge test, residual concentration of surrogate contaminants in recycled PET (Cres) calculated for 50 % addition of contaminated flakes to virgin PET melt and calculated concentration of surrogate contaminants in PET (Cmod) corresponding to a modeled 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	99.8	0.005	0.09
Chloroform	99.8	0.005	0.10
Chlorobenzene	99.7	0.005	0.09
Methyl salicylate	>99.5	<0.010	0.13
Phenylcyclohexane	94.1	0.090	0.14
Benzophenone	97.3	0.040	0.16
Lindane	94.4	0.090	0.31
Methyl stearate	98.7	0.020	0.32

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 that the recycling process under evaluation is able to ensure that the level of migration of unknown contaminants from the recycled PET into food is below the conservatively modelled migration of 0.1 µg/kg food at which the risk to human health would be negligible.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The Panel considered that the process is well characterised and the main steps used to recycle the PET flakes into decontaminated PET pellets are identified. Having examined the challenge test provided, the Panel concluded that the crystallisation, heating and solid state polymerisation (step 3) and the addition of 50 % virgin PET melt are critical for the decontamination efficiency of the process. The operating parameters to control their performance are the temperature, the gas flow and the residence time. Therefore, the Panel considered that the recycling process Equipolymers Melt-in 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,

ii) the input of the process is washed and dried post-consumer PET flakes originating from materials and articles that has 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 and,

iii) the final recycled articles manufactured with pellets recycled with the Equipolymers Melt-in technology, do not contain more than 50 % recycled post-consumer PET.

Therefore, the recycled PET obtained from the Equipolymers Melt-in process, intended for the manufacture of materials and articles made with up to 50 % recycled post-consumer PET 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 European Union legislation on food contact materials and that the proportion of PET from non-food consumer applications is no more than 5 % in the input to be recycled. Critical steps should be monitored and kept under control; supporting documentation 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 "Equipolymers Melt-in". July 2009. Submitted on behalf of Equipolymers GmbH.

2. Additional data for Dossier "Equipolymers Melt-in". August 2011. Submitted on behalf of Equipolymers GmbH.

3. Additional data for Dossier "Equipolymers Melt-in". December 2011. Submitted on behalf of Equipolymers GmbH.

4. Additional data for Dossier "Equipolymers Melt-in". April 2013. Submitted via e-mail by Equipolymers GmbH.

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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. The EFSA Journal 2008, 717, 1-12. 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

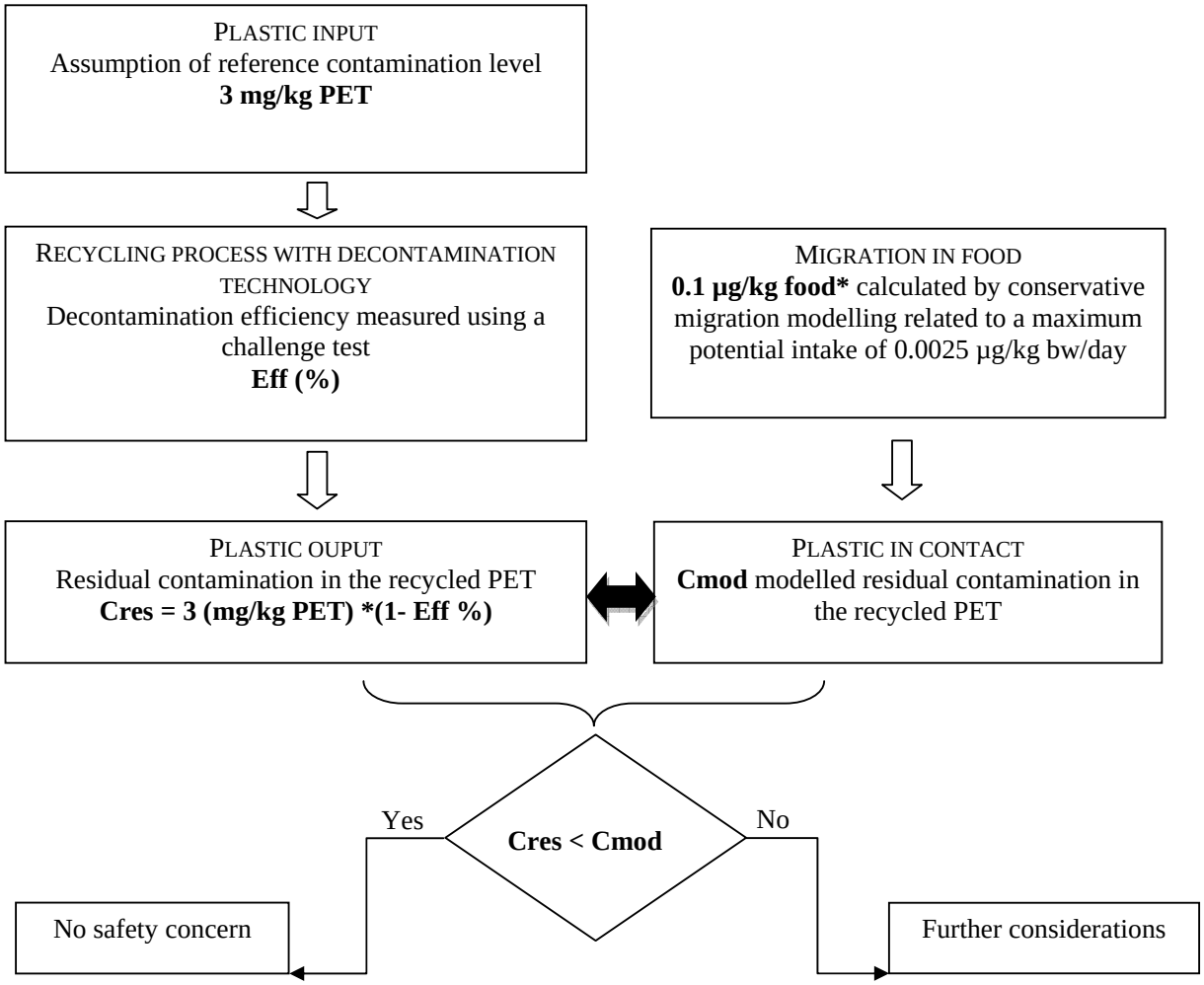
ANNEXES

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

Washed and dried flakes used for the Equipolymers Melt-in recycling process

Parameter	Value
Impurities	<100 ppm
Metals	<10 ppm
Paper	<50 ppm
Polyolefines	<50 ppm
Poly(vinylchloride) (PVC)	<10 ppm
Colored flakes	<1500 ppm
Flakes containing glue	< 400 ppm
Limonene content	< 10 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 polymerisation
US-FDA	United States Food and Drug Administration