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SCIENTIFIC OPINION

Scientific Opinion on the safety assessment of the following processes based on Starlinger Decon technology used to recycle post-consumer PET into food contact materials[1] "Re-PET", "Etimex", "Dannemann","Dentis", "PRT", "Tec-Folien", "Linpac", "Fellinger A flakes","TDX" and "HVZ"

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

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ABSTRACT

This scientific opinion of the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids deals with the safety assessment of the recycling processes Re-PET, Etimex, Dannemann, Dentis, PRT, Tec-Folien, Fellinger A_flakes, Linpac, TDX and HVZ (EU register numbers RECYC031, RECYC032, RECYC045, RECYC046, RECYC048, RECYC049, RECYC059, RECYC077, RECYC100 and RECYC103 respectively) which are all based on the same Starlinger Decon technology. The decontamination efficiency of all these processes was demonstrated using the same challenge test. The input of all the processes is hot caustic washed and dried PET flakes originating from collected post-consumer PET containers, mainly bottles and trays, containing no more than 5 % of PET from non-food consumer applications. Through this technology washed and dried PET flakes are pre-heated before being solid state polymerised (SSP) in a continuous reactor at high temperature under vacuum and gas flow. Having examined the challenge test provided, the Panel concluded that the pre-heating (step 2) and the decontamination in the continuous SSP reactor (step 3) are the critical steps that

1 On request from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, Question No EFSA-Q-2010-00061, the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, Question No EFSA-Q-2010-00062, the Bundesministerium für Gesundheit, Austria, Question No EFSA- Q-2010-00121, the Ministero della Salute, Italy, Question No EFSA-Q-2010-00046, the Bundesministerium für Gesundheit, Austria, Question No EFSA- Q-2010-00025, the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, Question No EFSA-Q-2010-00019, the Bundesministerium für Gesundheit, Austria, Question No EFSA-Q-2010-00122, the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, Question No EFSA-Q-2010- 01064, the Food Standards Agency, United Kingdom, Question No EFSA-Q-2013-00200 and the Ministry of Health, Welfare and Sport, The Netherlands, Question No EFSA-Q-2013-00364, 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 and Constantine Papaspyrides for the preparatory work on this scientific opinion.

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determine the decontamination efficiency of the processes. The operating parameters to control their performance are well defined and are the temperature, the pressure, the residence time and the gas flow for step 2 and 3. Under these conditions it was demonstrated that the recycling processes under evaluation, using the Starlinger Decon technology, are 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 these processes intended to be used at 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.

KEY WORDS

Starlinger Decon; 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 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 processes "Re-PET", "Etimex", "Dannemann", "Dentis", "PRT", "Tec-Folien", "Fellinger A flakes", "Linpac", "TDX" and "HVZ".

The Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, the Bundesministerium für Gesundheit, Austria, the Ministero della Salute, Italy, the Bundesministerium für Gesundheit, Austria, the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, the Bundesministerium für Gesundheit, Austria, the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit Germany , the Food Standards Agency, United Kingdom and the Ministry of Health, Welfare and Sport, The Netherlands requested the evaluation of the recycling processes Re-PET, Etimex, Dannemann, Dentis, PRT, Tec-Folien, Fellinger A flakes, Linpac, TDX and HVZ respectively. The dossiers were submitted on behalf of Re-PET Flaschenrecycling GmbH, Etimex Primary Packaging GmbH, Dannemann Global Extrusion GmbH, Dentis SRL PET Recycling Team GmbH and Tec-Folien-Allgäu GmbH, by Markus Fellinger and on behalf of LINPAC Group Holdings Limited, TDX Ltd and Hordijk Verpakkingsindustrie Zaandam B.V companies. These recycling processes have been allocated the European Union register numbers RECYC031, RECYC032, RECYC045, RECYC046, RECYC048, RECYC049, RECYC059, RECYC077, RECYC100 and RECYC103 respectively. They are deemed to recycle poly(ethylene terephthalate) (PET) flakes from PET containers collected through post-consumer collection systems. The recycled PET is 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 kind of foodstuffs for long term storage at room temperature, with or without hotfill.

These processes are grouped into a single opinion as they use the same Starlinger Decon technology and their decontamination efficiency was evaluated on the basis of the same challenge test.

The processes are composed of three steps. First post-consumer PET containers, mainly bottles and trays, are processed into hot caustic washed and dried flakes which are used as input of the Starlinger Decon technology. Washed flakes are pre-heated in the step 2 then solid-state polymerised in the step 3(SSP).

Detailed specifications for the input materials are provided for each of the submitted recycling processes and the amount of non-food containers is reported to be no more than 5 % for all of them.

A challenge test was conducted at pilot plant level on the process steps 2 and 3 (pre-heating and continuous SSP reactor) to measure the decontamination efficiency. The decontamination efficiencies obtained for each surrogate contaminant from the challenge test, ranging from 96.3 % to 99.5 %, have been used to calculate the residual concentrations of potential unknown contaminants in flakes (Cres) according to the evaluation procedure described in the Scientific Opinion on "the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food" (EFSA CEF Panel, 2011). According to these criteria the recycling processes under evaluation using a Starlinger Decon 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.

[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.

The Panel considered that all processes are well characterised and the main steps used to recycle the PET flakes into decontaminated PET flakes are identified. Having examined the challenge test provided, the Panel concluded that pre-heating (step 2) and the decontamination in the continuous SSP reactor (step 3) are the critical step for the decontamination efficiency of the processes. The operating parameters to control their performance are the temperature, the residence time, the pressure, and the gas flow. Therefore, the Panel considered that the recycling processes Re-PET, Etimex, Dannemann, Dentis, PRT, Tec-Folien, Fellinger A flakes, Linpac, TDX and HVZ are 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) they are 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 processes 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.

The Panel concluded that the recycled PET obtained from the processes Re-PET, Etimex, Dannemann, Dentis, PRT, Tec-Folien, Fellinger A flakes, Linpac, TDX and HVZ intended be used at up to 100 % for the manufacture of materials and articles for contact with all types of foodstuffs for long term storage at room temperature, with or without hotfill is not considered of safety concern.

The 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 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 processes 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´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 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).

In this case, EFSA received the following applications for evaluation of PET recycling processes which were grouped in this opinion as they use the same Starlinger Decon technology and their decontamination efficiency was evaluated on the basis of the same challenge test:

A. Re-PET, EU register number RECYC031, from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany,
B. Etimex, EU register number RECYC032, from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany,
C. Dannemann, EU register number RECYC045, from the Bundesministerium für Gesundheit, Austria,
D. Dentis, EU register number RECYC046, from the Ministero della Salute, Italy,
E. PRT, EU register number RECYC048, from the Bundesministerium für Gesundheit, Austria,
F. Tec-Folien, EU register number RECYC049, from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany,
G. Fellinger A flakes, EU register number RECYC059, from the Bundesministerium für Gesundheit, Austria,
H. Linpac, EU register number RECYC077, from the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany,
I. TDX, EU register number RECYC100, from the Food Standards Agency, United Kingdom,
J. HVZ, EU register number RECYC103, 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 risks originating from the migration of substances from recycled food contact plastic materials and articles into food and deliver a scientific opinion on the recycling 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 processes Re-PET, Etimex, Dannemann, Dentis, PRT, Tec-Folien, Fellinger A flakes, Linpac, TDX and HVZ are able to reduce any contamination of the plastic input to a concentration that does not

[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.

pose a risk to human health. The PET materials and articles used as input of the processes as well as the conditions of use of the recycled PET make part of this evaluation.

ASSESSMENT

1. Introduction

The European Food Safety Authority was asked to evaluate the safety of recycling processes as follows:

A. The Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, requested the EFSA to evaluate the safety of the recycling process Re-PET with the EU register number RECYC031. The request has been registered in the EFSA's register of received questions under the number EFSA-Q-2010-00061. The dossier was submitted on behalf of Re-PET Flaschenrecycling GmbH, Germany,

B. The Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, requested the EFSA to evaluate the the safety of the recycling process Etimex with the EU register number RECYC032. The request has been registered in the EFSA's register of received questions under the number EFSA-Q-2010-00062. The dossier was submitted on behalf of Etimex Primary Packaging GmbH, Germany,

C. The Bundesministerium für Gesundheit, Austria, requested the EFSA to evaluate the safety of the the recycling process Dannemann with the EU register RECYC045. The request has been registered in the EFSA's register of received questions under the number EFSA-Q-2010-00121. The dossier was submitted on behalf of Dannemann Global Extrusion GmbH, Austria,

D. The Ministero della Salute, Italy, requested the EFSA to evaluate the the safety of the recycling process Dentis with the EU register number RECYC046. The request has been registered in the EFSA's register of received questions under the number EFSA-Q-2010-00046. The dossier was submitted on behalf of Dentis SRL, Italy,

E. The Bundesministerium für Gesundheit, Austria, requested the EFSA to evaluate the safety of the recycling process PRT with the EC register number RECYC048. The request has been registered in the EFSA's register of received questions under the number EFSA-Q-2010-00025. The dossier was submitted on behalf of PET Recycling GmbH, Austria,

F. The Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, requested the EFSA to evaluate the safety of the recycling process Tec-Folien with the EU register number RECYC049. The request has been registered in the EFSA's register of received questions under the number EFSA-Q-2010-00019. The dossier was submitted on behalf of Tec-Folien-Allgäu GmbH, Germany,

G. The Bundesministerium für Gesundheit, Austria, requested the EFSA to evaluate the safety of the recycling process Fellinger A flakes with EU register number RECYC059. The request has been registered in the EFSA register of questions under the number EFSA-Q-2010-00122. The dossier was submitted by Markus Fellinger, Austria,

H. The Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany, requested the EFSA to evaluate the safety of the recycling process Linpac with the EU register number RECYC077. The request has been registered in the EFSA's register of received questions under the number EFSA-Q-2010-01064. The dossier was submitted on behalf of LINPAC Group Holdings Limited, United Kingdom,

I. The Food Standards Agency, United Kingdom, requested the EFSA to evaluate the the safety of the recycling process TDX with the EU register number RECYC100. The request has been

registered in the EFSA's register of received questions under the number EFSA-Q-2013-00200. The dossier was submitted on behalf of TDX Ltd, United Kingdom,

J. The Ministry of Health, Welfare and Sport, The Netherlands requested the EFSA to evaluate the the safety of the recycling process HVZ with the EU register number RECYC103. The request has been registered in the EFSA's register of received questions under the number EFSA-Q-2013-00364. The dossier was submitted on behalf of Hordijk Verpakkingsindustrie Zaandam B.V, The Netherlands.

The dossiers submitted for evaluation followed 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 applicants, the recycling processes Re-PET, Etimex, Dannemann, Dentis, PRT, Tec-Folien, Fellinger A flakes, Linpac, TDX and HVZ are intended to recycle food grade polyethylene terephthalate (PET) containers, mainly bottles and trays, to produce recycled PET flakes using the Starlinger Decon technology. The recycled flakes 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.

3. Description of the processes

3.1. General description

The recycling processes Re-PET, Etimex, Dannemann, Dentis, PRT, Tec-Folien, Fellinger A flakes, Linpac, TDX and HVZ produce recycled PET flakes from PET containers, mainly bottles and trays, coming from post-consumer collection systems (curbside, deposit or specific collection systems). The recycling processes are composed of the three steps below. The first step may be performed by a third party or by the applicant.

Input

- In Step 1, post-consumer PET containers, mainly bottles and trays, are processed into hot caustic washed and dried flakes which are used as input of the processes.
  In Dentis, PRT and Fellinger A flakes processes, the flakes may be either bought from the market or processed in-house.
  In Re-PET, Etimex, Dannemann, Tec-Folien, Linpac, TDX and HVZ processes, the flakes are bought from the market.

Decontamination and production of recycled PET material

- In Step 2, the flakes are pre-heated in a batch reactor under vacuum with a flow of hot gas.
- In Step 3, the pre-heated flakes are solid state polymerised in a continuous reactor at high temperature using a combination of vacuum and gas flow.

Recycled flakes, the final product of the processes, are checked against technical requirements on intrinsic viscosity, colour, black specks, etc. Recycled flakes 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 flakes 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 processes have been provided to EFSA.

3.2. Characterisation of the input

According to the applicants, the input for the recycling processes Re-PET, Etimex, Dannemann, Dentis, PRT, Tec-Folien, Fellinger A flakes, Linpac, TDX and HVZ is hot caustic washed and dried flakes obtained from PET containers, mainly bottles and trays, previously used for food packaging, from post-consumer collection systems (curbside, deposit or specific collection systems). A small fraction may originate from non-food applications such as soap bottles, mouth wash, kitchen hygiene bottles, etc. According to the applicants, the amount of this non-food container fraction depends on the re-collection system. On the basis of market share data, the applicants estimated this fraction below 5 %.

Technical data for the hot caustic washed and dried flakes are provided for each of the submitted recycling processes, such as information on residual content of poly(vinyl chloride) (PVC), cellulose, metals, other plastics, and physical properties (see Annex A).

4. Starlinger Decon technology

4.1. Description of the main steps

To decontaminate post-consumer PET, the recycling processes Re-PET, Etimex, Dannemann, Dentis, PRT, Tec-Folien, Fellinger A flakes, Linpac,TDX and HVZ use the Starlinger Decon technology as described below and for which the general scheme is reported in figure 1. In Step 1, post-consumer PET containers, mainly bottles and trays, are processed into hot caustic washed and dried flakes.

Pre-heating (step 2): the flakes are preheated in a batch reactor, under vacuum with a flow of hot gas up to the temperature of the next step, the SSP reactor. Several pre-heaters can be used alternatively depending on the amount intended to be recycled.

Solid state polymerisation (step 3): the flakes from the batch pre-heater are fed continuously to the SSP reactor running continuously under high temperature and using a combination of gas flow and vacuum for a predefined residence time. In particular, the main reactor remains under varied vacuum conditions due to the feeding mode followed, while gas flow is also provided to facilitate the removal of the contaminants out of the flakes. This step increases the intrinsic viscosity of the material and further decontaminates the PET flakes.

Figure 1: General scheme of the Starlinger Decon technology

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

4.2. Decontamination efficiency of the recycling processes

To demonstrate the decontamination efficiency of the recycling processes Re-PET, Etimex, Dannemann, Dentis, PRT, Tec-Folien, Fellinger A flakes, Linpac, TDX and HVZ, a challenge test on the Starlinger Decon technology was submitted to EFSA.

PET flakes were contaminated with selected chemicals, toluene, chlorobenzene, phenylcyclohexane, chloroform, methyl salicylate, benzophenone and methylstearate 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 were soaked in a solution containing the surrogates and stored for 7 days at 50 °C. The contaminated PET flakes were washed with hot water and detergents then air dried. The concentrations of surrogates in this material were determined.

The challenge test was done at the pilot plant batchwise. The pre-heater reactor was filled with washed and dried contaminated flakes only. Preheated flakes were then fed into the SSP reactor. The flakes were analysed after each step for the residual concentrations of the applied surrogates. In both batch and continuous modes of operation the surrogates diffuse through the flakes to the surface and they are constantly eliminated by the gas flow applied. Therefore in this case, continuous working processes will result in equivalent cleaning efficiencies as batch processes, as long as the same temperature, gas flow, vacuum and residence time are applied.

The decontamination efficiency of the processes was calculated taking into account the amount of the surrogates detected in contaminated flakes before the pre-heating (before step 2) and after the SSP (step 3). 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.

Table 1: Efficiency of the decontamination of the Starlinger Decon technology

Surrogates	Concentration of surrogates before pre-heating step 2 (mg/kg PET)	Concentration of surrogates after SSP step 3 (mg/kg PET)	Decontamination Efficiency (%)
Toluene	206.9	1.1	99.5
Chlorobenzene	393.1	2.1	99.5
Chloroform	120.2	3.4	97.2
Methyl salicylate	369	4.1	98.9
Phenylcyclohexane	404	6.9	98.3
Benzophenone	594.4	22.1	96.3
Methyl stearate	743.4	27.1	96.4

As shown above, the decontamination efficiency ranged from 96.3 % for benzophenone to 99.5 % for toluene and chlorobenzene.

5. Discussion

Considering the high temperatures used during the processes, 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, other plastics and physical properties are provided for the input materials, hot caustic washed and dried flakes (step 1) for each of the submitted recycling processes. The input materials are produced from PET containers, mainly bottles and trays, previously used for food packaging collected through post-consumer collection systems. However, a small fraction of the input may originate from non-food applications such as soap bottles, mouth wash, kitchen hygiene bottles, etc. According to the applicants, the amount of this non-food container fraction depends on the collection system and, on the basis of market share data it is below 5 % as recommended by the CEF Panel in its Scientific Opinion on "the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food" (EFSA CEF Panel, 2011).

All processes are well described. The production of washed and dried flakes from collected PET containers (step 1) is conducted in different ways depending on the plant. According to the applicants, they are under control. The following steps are those of the Starlinger Decon technology used to recycle the PET flakes into decontaminated PET flakes:batch pre-heating (step 2) and continuous SSP reaction (step 3). The operating parameters of temperature, residence time, pressure and gas flow have been provided to EFSA.

A challenge test was conducted at pilot plant scale batchwise on the steps 2 and 3 (pre-heating and SSP reactor) to measure the decontamination efficiency. The Panel considered that the challenge test was performed correctly according to the recommendations in the EFSA Guidelines (EFSA, 2008) and that the steps 2 and 3 are the critical steps for the decontamination efficiency of the processes. Consequently the temperature, the residence time, the pressure and the gas flow parameters of the steps 2 and 3 of the processes 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 2 and the step 3 for each surrogate contaminant, ranging from 96.3 % to 99.5 %, 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, 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[8]. Because the recycled PET is intended for general use for the manufacturing of articles containing up to 100 % recycled PET, the most conservative default scenario for infants has been applied. Therefore, the migration of 0.1 µg/kg into food has been used to calculate Cmod (EFSA CEF Panel, 2011). The results of 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 of pre-heating (step 2) and continuous SSP reactor (step 3), 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	99.5	0.02	0.09
Chlorobenzene	99.5	0.02	0.10
Chloroform	97.2	0.08	0.10
Methyl salicylate	98.9	0.03	0.13
Phenylcyclohexane	98.3	0.05	0.14
Benzophenone	96.3	0.11	0.16
Methyl stearate	96.4	0.11	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 the recycling processes under evaluation using the Starlinger Decon technology are 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 all processes are well characterised and the main steps used to recycle the PET flakes into decontaminated PET flakes are identified. Having examined the challenge test provided, the Panel concluded that the pre-heating (step 2) and the decontamination in the continuous SSP reactor (step 3) are the critical steps for the decontamination efficiency of the processes. The operating parameters to control their performance are the temperature, the residence time, the pressure and the gas flow. Therefore, the Panel considered that the recycling processes Re-PET, Etimex, Dannemann, Dentis, PRT, Tec-Folien, Fellinger A flakes, Linpac, TDX and HVZ are 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:

[8] 0.0025 µg/kg bw/day is the human exposure threshold value for chemicals with structural alerts raising concern for potential genotoxicity, below which the risk to human health would be negligible (EFSA CEF Panel, 2011).

i) they are 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 processes 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 processes Re-PET, Etimex, Dannemann, Dentis, PRT, Tec-Folien, Fellinger A flakes, Linpac, TDX and HVZ intended to be used at up to 100 % 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 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 processes should be available.

DOCUMENTATION PROVIDED TO EFSA

1. Dossier "Re-PET". December 2009. Submitted on behalf of Re-PET Flaschenrecycling GmbH.
2. Additional data for Dossier "Re-PET". February 2012. Submitted on behalf of Re-PET Flaschenrecycling GmbH.
3. Additional data for Dossier "Re-PET". January 2013. Submitted on behalf of Re-PET Flaschenrecycling GmbH.
4. Additional data for Dossier "Re-PET". May 2013. Submitted on behalf of Re-PET Flaschenrecycling GmbH.
5. Dossier "Etimex". December 2009. Submitted on behalf of Etimex Primary Packaging GmbH.
6. Additional data for Dossier "Etimex". August 2011. Submitted on behalf of Re Etimex Primary Packaging GmbH.
7. Additional data for Dossier "Etimex". March 2012. Submitted on behalf of Etimex Primary Packaging GmbH.
8. Additional data for Dossier "Etimex". January 2013. Submitted on behalf of Etimex Primary Packaging GmbH.
9. Additional data for Dossier "Etimex". May 2013. Submitted on behalf of Etimex Primary Packaging GmbH.
10. Dossier "Dannemann". December 2009. Submitted on behalf of Dannemann Global Extrusion GmbH.

11. Additional data for Dossier “Dannemann”. March 2011. Submitted on behalf of Dannemann Global Extrusion GmbH.

12. Additional data for Dossier “Dannemann”. July 2011. Submitted on behalf of Dannemann Global Extrusion GmbH.

13. Additional data for Dossier “Dannemann”. January 2013. Submitted on behalf of Dannemann Global Extrusion GmbH.

14. Additional data for Dossier “Dannemann”. May 2013. Submitted on behalf of Dannemann Global Extrusion GmbH.

15. Dossier“Dentis”. December 2009. Submitted on behalf of Dentis SRL.

16. Additional data for Dossier “Dentis”. July 2011. Submitted on behalf of Dentis SRL.

17. Additional data for Dossier “Dentis”. March 2012. Submitted on behalf of Dentis SRL.

18. Additional data for Dossier “Dentis”. January 2013. Submitted on behalf of Dentis SRL.

19. Additional data for Dossier “Dentis”. May 2013. Submitted on behalf of Dentis SRL.

20. Dossier “PRT”. December 2009. Submitted on behalf of PET Recycling Team GmbH.

21. Additional data for Dossier “PRT”. January 2013. Submitted on behalf of PET Recycling Team GmbH.

22. Additional data for Dossier “PRT”. May 2013. Submitted on behalf of PET Recycling Team GmbH.

23. Dossier “Tec-Folien”. December 2009. Submitted on behalf of Tec-Folien-Allgäu GmbH.

24. Additional data for Dossier “Tec-Folien”. March 2012. Submitted on behalf of Tec-Folien-Allgäu GmbH.

25. Additional data for Dossier “Tec-Folien”. January 2013. Submitted on behalf of Tec-Folien-Allgäu GmbH.

26. Additional data for Dossier “Tec-Folien”. May 2013. Submitted on behalf of Tec-Folien-Allgäu GmbH.

27. Dossier “Fellinger A_ flakes”. December 2009. Submitted by Markus Fellinger

28. Additional data for Dossier “Fellinger A flakes”. May 2012. Submitted by Markus Fellinger.

29. Additional data for Dossier “Fellinger A flakes”. December 2012. Submitted by Markus Fellinger.

30. Additional data for Dossier “Fellinger A flakes”. May 2013. Submitted by Markus Fellinger.

31. Dossier “Linpac”. September 2011. Submitted on behalf of LINPAC Group Holdings Limited.

32. Additional data for Dossier “Linpac”. July 2012. Submitted on behalf of LINPAC Group Holdings Limited.

33. Additional data for Dossier "Linpac". January 2013. Submitted on behalf of LINPAC Group Holdings Limited.

34. Additional data for Dossier "Linpac". May 2013. Submitted on behalf of LINPAC Group Holdings Limited.

35. Dossier "TDX". February 2013. Submitted on behalf of TDX Ltd.

36. Additional data for Dossier "TDX". May 2013. Submitted on behalf of TDX Ltd.

37. Dossier "HVZ". April 2013. Submitted on behalf of Hordijk Verpakkingsindustrie Zaandam B.V.

REFERENCES

EFSA (European Food Safety Authority), 2008. Guidelines for the submission of an application for safety evaluation by the EFSA of a recycling process to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food, prior to its authorisation. The EFSA Journal 2008, 717, 2-12.

EFSA 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 APPLICANTS

Washed and dried flakes used for the Re-PET recycling process

Parameter	Value
Moisture max.	1.0%
Moisture variation	±0.3% h^{-1}
Bulk density	240 – 330 kg m^{-3}
Material temperature	10 – 60 °C
PVC max.	20 ppm
Glue max.	50 ppm
Polyolefins max.	20 ppm
Cellulose (paper, wood)	20 ppm
Metals max.	20 ppm
Other impurities max.	20 ppm

Washed and dried flakes used for the Etimex recycling process

Parameter	Value
Moisture max.	1.5%
Moisture variation	±0.3% h^{-1}
Bulk density	200 – 500 kg m^{-3}
Material temperature	10 – 60 °C
PVC max.	50 ppm
Glue max.	50 ppm
Polyolefins max.	50 ppm
Cellulose (paper, wood)	50 ppm
Metals max.	50 ppm

Washed and dried flakes used for the Dannemann recycling process

Parameter	Value
Moisture max.	1.5%
Moisture variation	±0.3% h^{-1}
Bulk density	200 – 500 kg m^{-3}
Material temperature	10 – 60 °C
PVC max.	50 ppm
Glue max.	50 ppm
Polyolefins max.	50 ppm
Cellulose (paper, wood)	50 ppm
Metals max.	50 ppm
Polyamide max.	2000 ppm

Washed and dried flakes used for the Dentis recycling process

Parameter	Value
Moisture max.	0.7%
Moisture variation	±0.3% h^{-1}
Bulk density	300 – 500 kg m^{-3}
Material temperature	20 – 70 °C
PVC max.	20 ppm
Glue max.	50 ppm
Polyolefins max.	10 ppm
Cellulose (paper, wood)	5 ppm
Metals max.	10 ppm
Polyamide max.	100 ppm

Washed and dried flakes used for the PRT recycling process

Parameter	Value
Moisture max.	1.0 %
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.	20 ppm
Glue max.	50 ppm
Polyolefins max.	50 ppm
Cellulose (paper, wood)	50 ppm
Metals max.	20 ppm

Washed and dried flakes used for the Tec-Folien recycling process

Parameter	Value
Moisture max.	1.5 %
Moisture variation	±0.3 % h^{-1}
Bulk density	200 – 500 kg m^{-3}
Material temperature	10 – 60 °C
PVC max.	50 ppm
Glue max.	50 ppm
Polyolefins max.	50 ppm
Cellulose (paper, wood)	50 ppm
Metals max.	50 ppm
Polyamide max.	2000 ppm

Washed and dried flakes used for the Fellinger A flakes recycling process

Parameter	Value
Moisture	< 0.5 %
PVC content	< 100 ppm
Other plastics	< 500 ppm
Flakes with glue content	< 4000 ppm
PET dust:	< 1 %
Metal content	< 500 ppm
Cellulose (paper, wood)	< 100 ppm
iV	0.7-1.2 dl/g
Bulk density	250-750 kg m^{-3}
Flakes size	1-15mm
Flakes thickness	50-1200 µm

Washed and dried flakes used for the Linpac recycling process

Parameter	Value
Moisture max.	1.5 %
Moisture variation	±0.3 % h^{-1}
Bulk density	230 – 850 kg m^{-3}
Bulk density variation	±150 kg m^{-3} h^{-1}
Material temperature	10 – 60 °C
Material Temp. variation	±10 °C h^{-1}
PVC max.	50 ppm
Glue max.	100 ppm
Polyolefins max.	100 ppm
Cellulose (paper, wood)	50 ppm
Metals max.	40 ppm
Polyamide max.	100 ppm

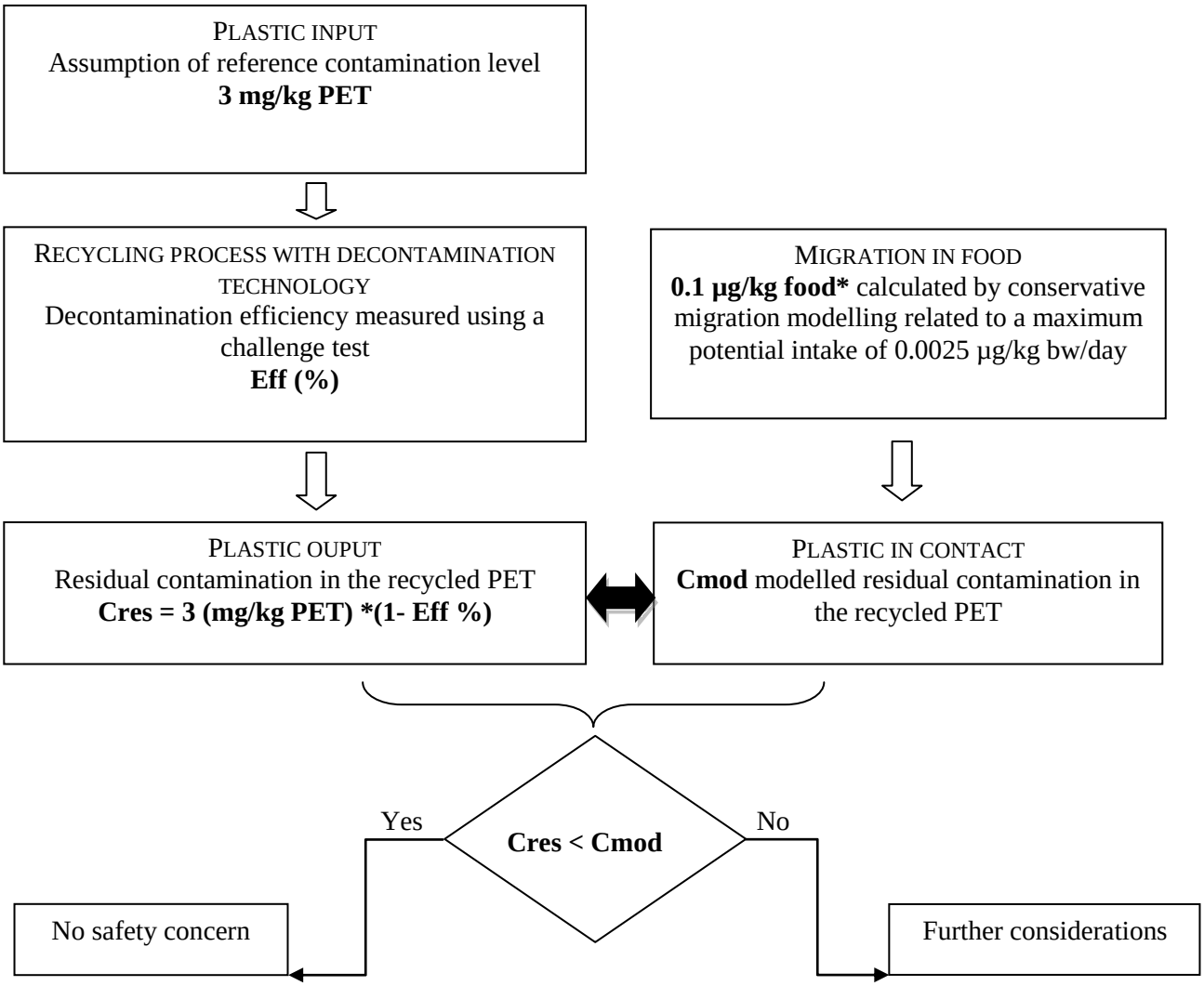
Washed and dried flakes used for the TDX recycling process

Parameter	Value
Moisture max.	1.5 %
Moisture variation	±0.3 % h^{-1}
Bulk density	200 – 500 kg m^{-3}
Material temperature	10 – 60 °C
PVC max.	50 ppm
Glue max.	50 ppm
Polyolefins max.	50 ppm
Cellulose (paper, wood)	50 ppm
Metals max.	50 ppm
Polyamide max.	2000 ppm

Washed and dried flakes used for the HVZ recycling process

Parameter	Value
Moisture max.	1.5%
Moisture variation	±0.3% h^{-1}
Bulk density	200 – 500 kg m^{-3}
Material temperature	10 – 60 °C
PVC max.	50 ppm
Glue max.	50 ppm
Polyolefins max.	50 ppm
cellulose (paper, wood)	50 ppm
metals max.	50 ppm
polyamide max.	2000 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