PET materials and articles in which the recycled plastic is used behind a **Functional Barrier**.

Detailed information required by Article 32 of Regulation (EU) 2022/1616.

5 April 2023.

Contents

Forewords: Description of the Consortium, scope, participants

Through regulation EU 2022/1616 on recycled plastic materials and articles intended to come in contact with food of 15th of September 2022, the European Commission sets new obligations for the recyclers using the functional barrier principles in its article 32.2.

A consortium has been established by PETCORE Europe AISBL ("**PETCORE**") and EUPC AISBL ("**EUPC**") to assist their members using the functional barrier principles for the manufacture of PET thermoformed packaging food contact applications in complying with the above-mentioned regulation.

Participants to the consortium have provided information and data to support the establishment of this notification document.

More than 50 companies, representing more than 200 production lines through Europe have joined this consortium and it is assumed they represent more than 70% of the European production capacities of Thermoforms using the functional barrier principles.

A list of the members of the consortium Members is provided in Annex 4.

General information

- Recycled Polyethylene Terephthalate (rPET) is largely used in direct contact with food when it is produced with processes that are capable to decontaminate the polymer recovered from waste streams to a level which makes it in compliance with article 3 of Regulation (EC) 1935/2004 [1]. These processes include several treatments, comprising a combination of temperature, melt filtration and removal of volatiles by vacuum or flow of air or other gases. These treatments are carried in order to remove the contaminants.
- To secure the achievement of the appropriate level of protection, the product is processed behind what is called "functional barrier ".
- This technology has been used for more than 20 years, and a large number of tests have been carried out by independent laboratories during this period to ensure compliance and health safety.

A definition of functional barrier can be found in art. 3(15) of Regulation (EU) 10/2011[2]. The functional barrier must be able to reduce the migration of contaminants below migration limits specified for genotoxic substances, as these limits represent the worst case since, they assume that all contaminant substances are genotoxic substances.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R1935&from=EN

[2] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (europa.eu): "'*functional barrier' means a barrier consisting of one or more layers of any type of material which ensures that the final material or article complies with Article 3 of Regulation (EC) No 1935/2004 and with the provisions of this Regulation*".

Starting from a maximum tolerable daily intake for genotoxic substances equal to 0.0025 µg/kg body weight per day, EFSA[3] considers that a maximum migratable amount of 0.017 µg/kg for infants, 0.028 µg/kg for toddlers and 0.15 µg/kg for adults represent a threshold below which there is no safety concern for human health.

An EFSA Opinion[4] published in 2011 sets a reference contamination level for post-consumer PET conservatively to 3 mg/kg PET for a contaminant resulting from possible misuse. Within this scenario, for the assessment of mechanically recycled PET intended for general use, EFSA applies a migration modelling which contains overestimation factors. To compensate the overestimation, EFSA set limits of migration at 0.1 µg/kg food for infants, 0.15 µg/kg food for toddlers and 0.75 µg/kg for adults. In this scenario it is assumed that all possible contaminants are genotoxic substances.

Description of the structures containing the functional barrier

rPET is used in food contact materials for two main applications: direct contact with food and indirect contact with food. For direct contact with food, the original PET is decontaminated in super-clean processes, and the resulting rPET is used for producing new containers. For indirect contact with food, the original PET is mildly decontaminated, and subsequently embossed between two layers of virgin PET, or PET originating from super-clean processes. In this case, the layer in contact with food acts as "functional barrier", preventing any possible contaminants in the rPET to be transferred to food in a quantity that endangers human health and, therefore, making the final structure compliant with Regulation (EC)1935/2044, in particular with art 3 thereof.

This dossier deals exclusively with the PET containers which include the functional barrier, where the rPET is not in direct contact with food.

These structures containing rPET consist of three-layer sheets having the formula A/B/A, where B consists of either 100% of rPET, or a blend between rPET and virgin PET in various proportions. The A layer is expected to exert the functional barrier properties; this layer consists of virgin PET, or food-grade rPET (i.e. that originates from a recycling process that applies the suitable mechanical PET recycling technology and for which the super-clean recycling process is assessed by EFSA) or a blend of the two. The thickness of the sheets ranges from a minimum of 100µm to a maximum of 1400 µm. The most common proportion of the three layers (in weight percent) in the A/B/A structure corresponds typically to 5%/90%/5% and 10%/80%/10% for structures with total thickness up to about 500-600 µm, but it can be 2%/96%/2% weight percent for structures with total thickness up to 1400 µm . Table 1 lists the thickness of the different layers in A/B/A structures that have a total thickness between 100 µm and 1400 µm for different proportions of the three layers (in weight percent).

[3] EFSA (2016). EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), (2016). Recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials. EFSA Journal, 14, 1-28. https://doi.org/10.2903/j.efsa.2016.4357

[4] 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 (europa.eu)

Table 1: correspondence between layers percentage and layers thickness

	Total thickness				
% layers	100 µm	150 µm	300 µm	500 µm	1400 µm
5%/90%/5%	5µm/90µm/5µm	7.5µm/135µm/7.5µm	15µm/270µm/15µm	25µm/450µm/25µm	70µm/1260µm/70µm
10%/80%/10%	10µm/80µm/10µm	15µm/120µm/15µm	30µm/240µm/30µm	50µm/400µm/50µm	140µm/1120µm/140µm
15%/70%/15	15µm/70µm/15µm	22.5µm/105µm/22.5µm	45µm/210µm/45µm	75µm/350µm/75µm	210µm/980µm/210µm

Typical examples of trays produced by the thermoforming of the above mentioned sheets are shown in Figure 1.

Figure 1: trays produced by thermoforming A/B/A sheets containing rPET in the B layer

The actual thickness of the A layer, expressed in micron, ranges from 5 to 210 µm; the minimum thickness of the A layer is <20 µ for about 23% of the notified structures, and < 70 µ for about 85% of the notified structures.

With very few exceptions, the A/B/A structures are symmetrical.

When the sheet is converted into a tray, the thickness is reduced, and the final thickness of the layers in the tray will depend on the draw ratio[5] used in the thermoforming process. Such draw ratio can

[5] The draw ratio is defined as the area subjected to the thermoforming stress and the depth of the final tray

considerably vary from a low value of 1.1-1.3, applied to obtain very shallow trays, up to a value of 2.5-3.0 for deep drawn trays, which means that the thickness of the functional barrier may be reduced by a factor of 2.5-3.0.

Obviously, sheets with lower thickness are subject to low draw ratio, and only sheets with a high thickness can be thermoformed with a higher draw ratio. The highest draw ratio is usually applied to produce trays that are intended to come in contact with food such as fruits and vegetables, where migration is expected to be very low, so that it can compensate the highest decrease of the barrier layer caused by deeper thermoforming.

Figures 2(a) and (b) show examples of the most common distribution of draw ratios applied to produce thermoforms for protein and bakery products, and for fruits and vegetables, respectively.

Figure 2 (a)

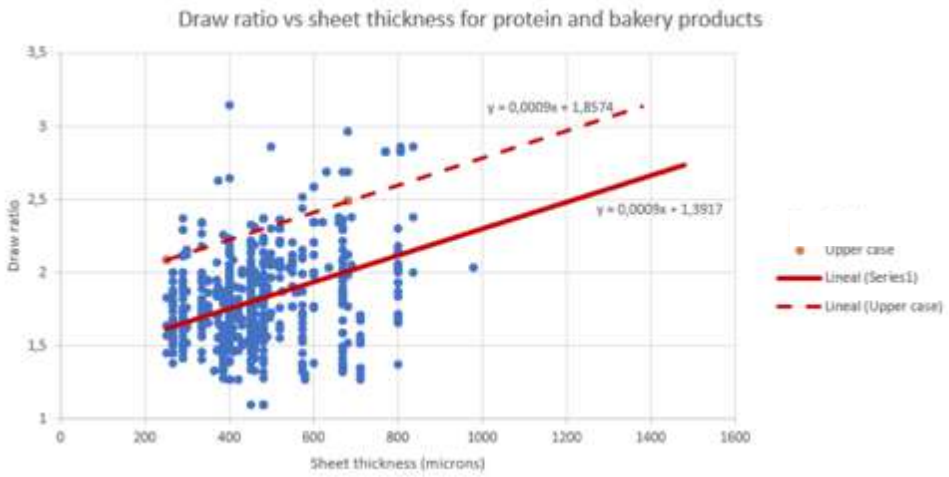
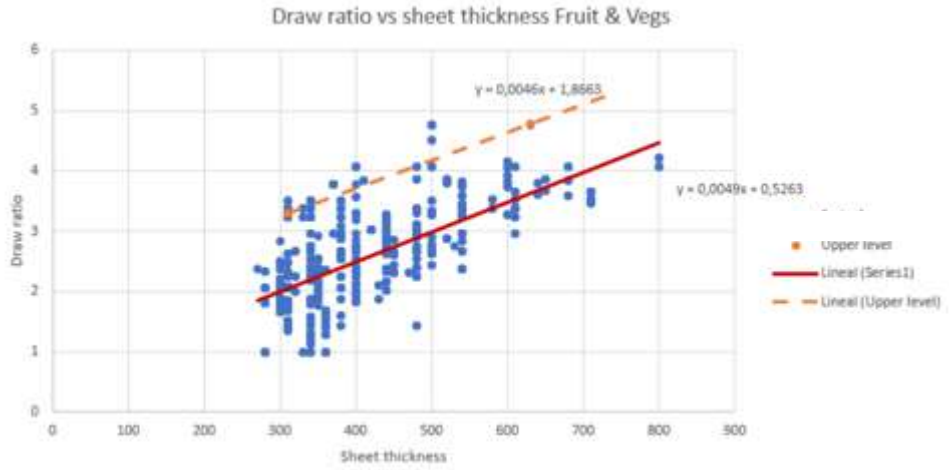


Figure 2(b)



A survey carried out on 231 commercial structures shows that the Surface-to-Volume (S/V) ratio corresponds on average to 6.4 dm2/kg. In this dossier, all calculations have been made with a 6 dm2/kg food, which is the conventional S/V value used in Europe.

Description of the collection system

The PET used in recycling processes may be obtained from two main sources:

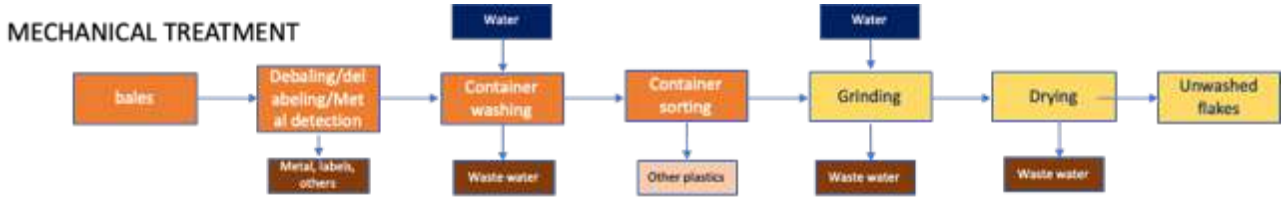
- deposit systems – PET only: PET containers are collected and stored separately from other waste, such as aluminium cans or other plastic containers, like HDPE milk containers.
- curb side collection – different plastics: After the collection of post-consumer plastic waste, the PET containers are sorted out of the waste stream. They are separated from non-PET waste, such as other plastics, either by automatic sorting machines or by manual sorting. Bigger metal parts (ferrous material and non-ferrous material) are sorted out by electrostatic or electromagnetic metal detection. Only PET containers including labels and PE or PP closures are transferred to further process steps.

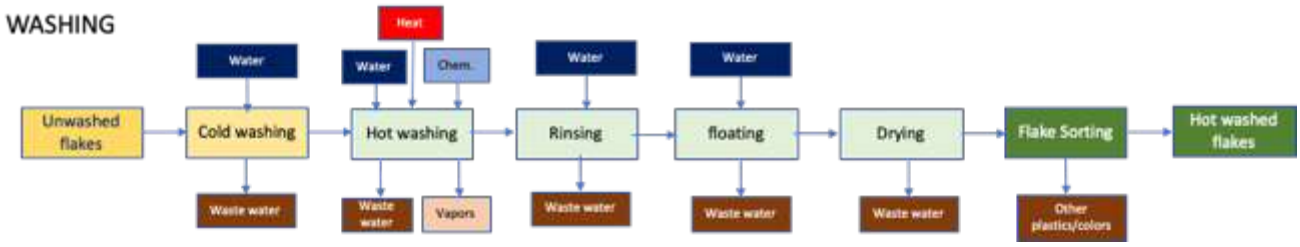
The containers are sorted, shredded in to flakes and are cleaned with water and detergents (see detailed description below). These clean flakes are then used for obtaining the B layer of the A/B/A PET trays for food contact applications.

Description of the recycling processes

Processes leading to the structures introduced in the market include a pre-processing phase.

After the collection, the PET containers are shipped to PET washing plants in pressed bales with a weight between 200 to 1000 kg/bale. The foreign materials in the bales are typically labels, which can be made of paper or other plastics such as PS or PP, and PVC shrink sleeves. Other foreign contamination is coming from the caps, which are made from PP or PE, and other materials, such as metal cans, stones, plastic film, wood, etc.
Washing may be made in a variety of plants, which include grinding, elutriation and sifting to remove light films. The resulting flakes are separated in sink floating tanks and subsequently washed. Washing technologies e.g., hot water and/or caustic soda and other washing detergents are used to remove organic load and other contaminants like glues, paper, wood etc. Finally, the flakes are rinsed to remove the caustic soda with water and dried to a surface moisture of less than 1.5%.





The flakes are delivered to recycling plants after quality control.

Periodical analysis, such as gas chromatography or other suitable test can serve as additional quality check.

The present notification, however, does not cover the washing phase. Nevertheless, control of the input material is key and raw materials are sourced as per specification for post-consumer packaging PET flakes reported in Annex 1.

An example of these specifications is reported in Table 2 below[6]:

Table 2: typical specifications for input flakes

Parameter	Value
Moisture max.	1.0%
Moisture variation	± 0.1% h^{-1}
Bulk density	325 kg m^{-3}
Bulk density variation	± 50 kg m^{-3} h^{-1}
Material temperature	15–50°C
Material temp. variation	± 5°C h^{-1}
PVC max.	500 ppm
Glue max.	50 ppm
Other plastics max.	1,000 ppm
Cellulose (paper, wood) max	5%
Metals max.	1,000 ppm

The manufacturing of A/B/A structures include a combination of some of the following processes:

- A drying and crystallization phase of the washed flakes, which is operated usually under stirring and air flow, at temperature of 140-160°C, generated by friction or IR, for a residence time up to 6 hours.
- An extrusion phase, where flakes are melted to produce the rPET B layer with or without application of vacuum. The temperature profile is usually 270-290°C. When vacuum is applied, the vacuum conditions are typically below 100 mbar.
- The coextrusion step, in which the A layers are applied in a die[7]. In this case the rPET of the future B layer comes in contact with the virgin PET (or mixture between virgin and EFSA assessed PET) of the future A layers, at a temperature of typically 275-290°C. A 3-layer sheet (A/B/A) comes out from the coextrusion process and it is cooled down in a rolled stack press.

[6] Safety assessment of the process 'Linpac', based on Linpac super clean technology, used to recycle post-consumer PET into food contact materials | EFSA (europa.eu)

[7] Kostic, Milivoje & Reifschneider, Louis. (2006). Design of Extrusion Dies. Encyclopaedia of Chemical Processing. (PDF) Design of Extrusion Dies (researchgate.net)

- The final thermoforming phase, in which the sheet is converted into trays. The sheet is heated in an oven to a temperature of 120-130°C, and the tray is formed through the application of pressure and vacuum in a mould. The total cycle takes 2-3 seconds. The tray is then immediately cooled down to an average temperature of around 30°C.

Description of the different equipment configurations

This paragraph provides a description of the different configurations of equipment used by members of the Consortium that are part of this notification (Table 3).

Table 3: configurations of the equipment covered by the notification.

Configurations	Crystallizing/drying	**Extrusion**	**Degassing**	**N of installations**
X1	yes	Single Screw	No	**32**
X2	yes	Single Screw	Yes	**18**
Y1	yes	Twin Screw Co-Rotating	Yes	**17**
Y2	no	Twin Screw Co-Rotating	Yes	**109**
W	no	Single screw and satellitar	Yes	**1**

Figures 3-7 show the flow sheets of the configurations reported above, along with the relevant process parameters

Figure 3: configuration X1- single screw extruder with crystallization and drying

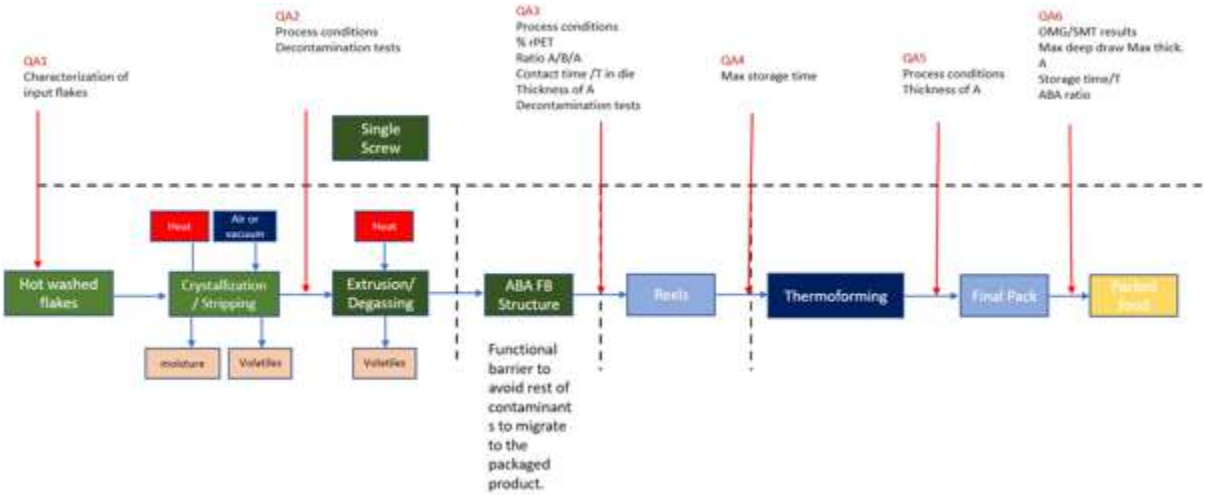


Figure 4: configuration X2 – single screw extruder with degassing, and crystallization/drying

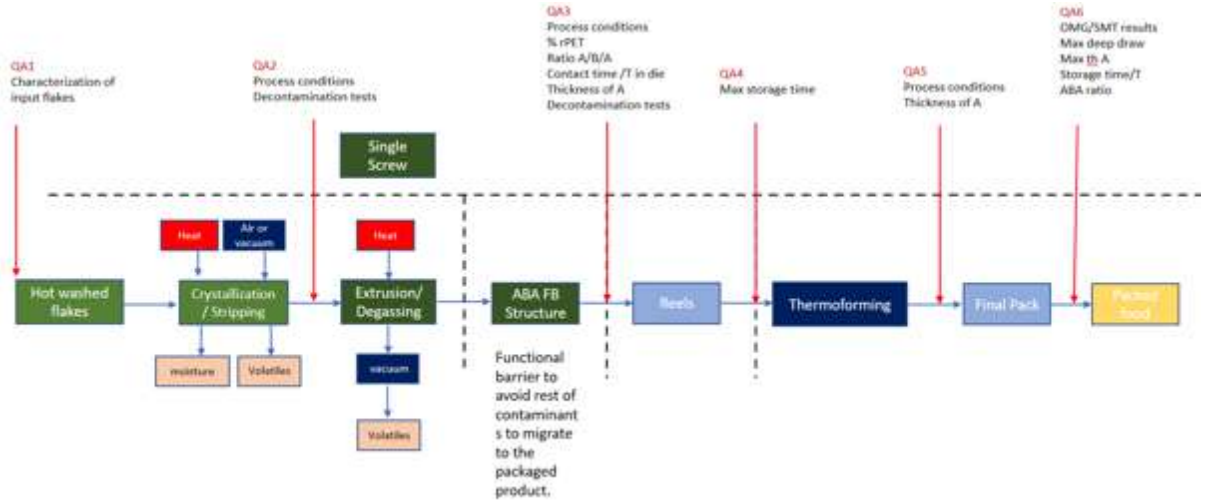


Figure 5: configuration Y1 - twin screw extruder with degassing, and crystallization/drying

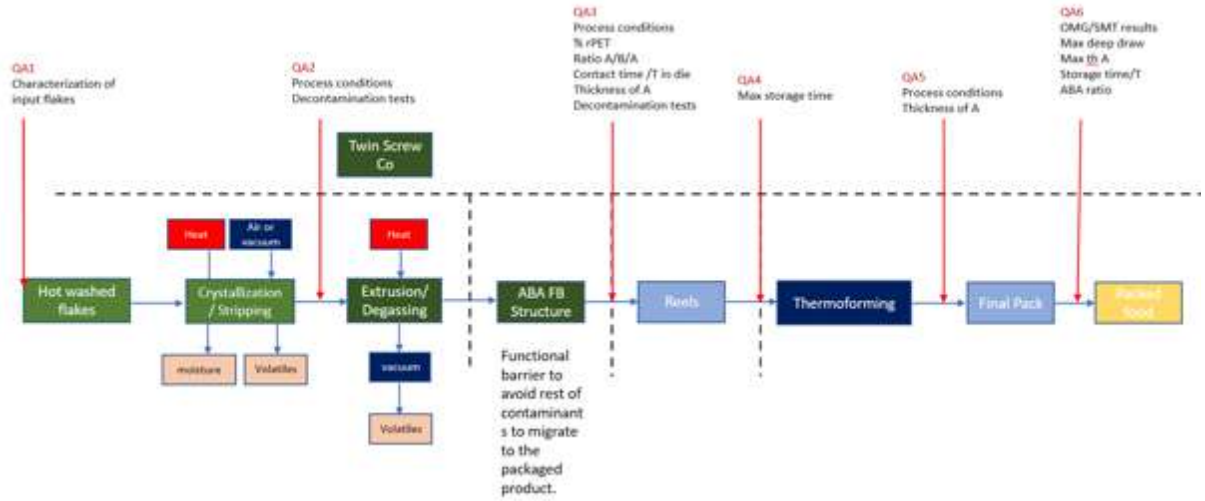


Figure 6: configuration Y2 – twin screw extruder with degassing

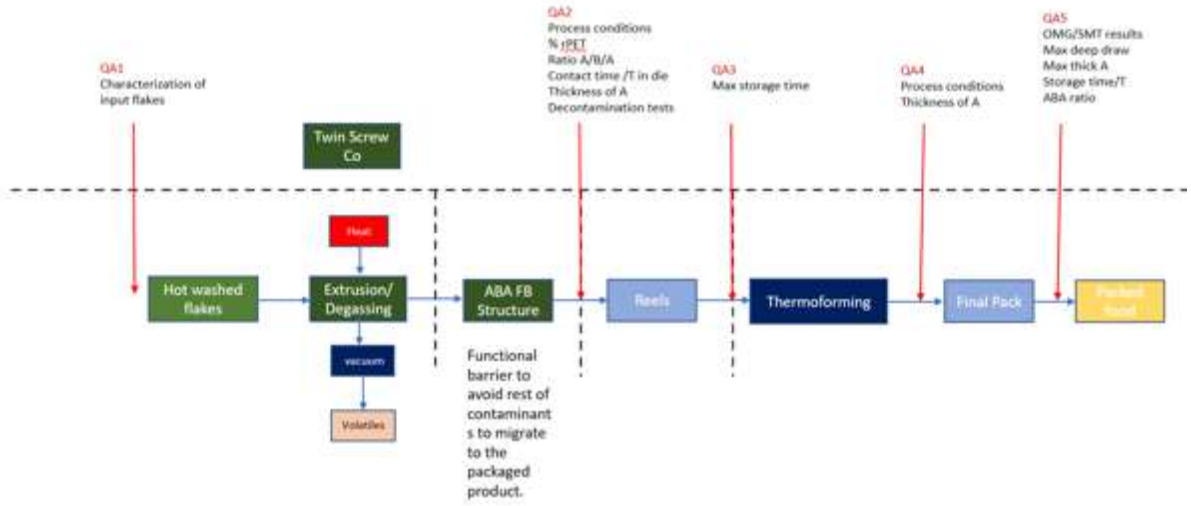
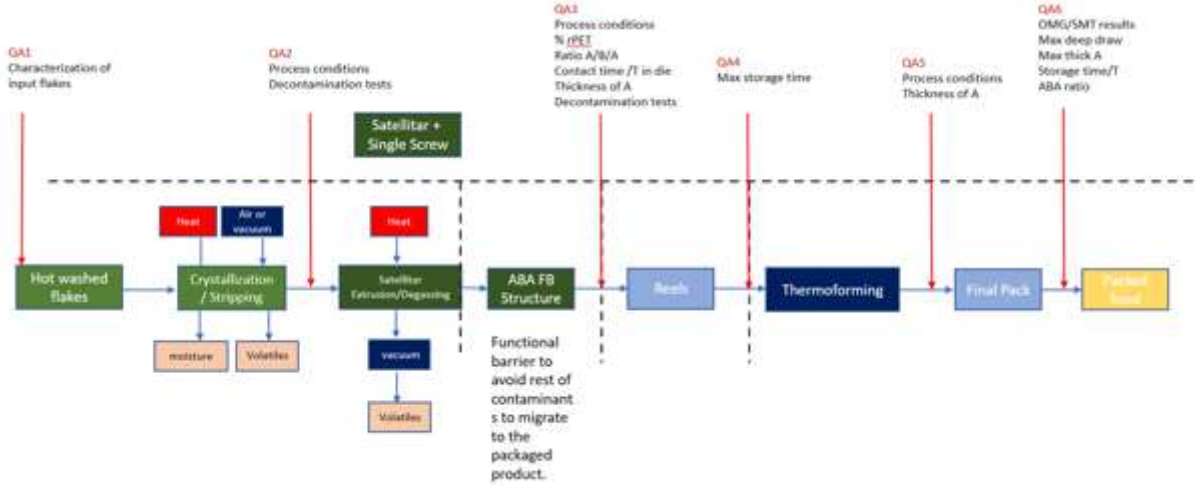


Figure 7: configuration W – combination of single screw and satellitar extruders



The typical operating conditions are reported in Table 4 below

Table 4: typical operating conditions for single and twin screw extruders

OPERATING CONDITIONS OF SINGLE SCREW EXTRUDER							
Crystallization temperature (°C)	Crystallization residence time (hours)	Drying temperature (°C)	Drying residence time (hours)	Residence time in the extruder from feeding section to die (min)	Temperature profile in the extruder (°C)	Temperature in the die (°C)	Residence time in the die (sec)
100-120	**0.5-3**	**150-180**	**2-6**	**5-9**	**260-290**	**275-290**	**≤60**

OPERATING CONDITIONS OF TWIN SCREW EXTRUDER							
Crystallization temperature (°C) (If any)	Crystallization residence time (hours) (If any)	Drying temperature (°C) (If any)	Drying residence time (hours) (If any)	Residence time in the extruder from feeding section to die (min)	Temperature profile in the extruder (°C)	Temperature in the die (°C)	Residence time in the die (sec)
100-120	**0.5-1.5**	**60-160**	**2-6**	**5**	**240-290**	**275-290**	**≤60**

Characterization of the input material

Input materials consist of PET flakes produced in pre-processing plants by taking PET bales originated from extended producers' responsibility (EPR) schemes in various EU Countries and non- EU Countries that follow EU food contact regulations. The PET containers are subjected to treatment such as hot washing, removal of contaminants during various stages of the process through automatic (especially optical and magnetic) and/or manual sorting systems, and grinding.

All input materials comply with the requirements of the EU Regulation, i.e. they are supported by documentation ensuring (i) traceability of each batch to the point of its origin, (ii) a minimum content of 95% of PET containers or flakes from food contact applications, and (iii) specification of the quality of the input.

Flakes entering the recycling processes may be clear or coloured.

Assessment of the decontamination performance of the recycling process

Several challenge tests carried out between 2013 and 2023 demonstrated that the decontamination of the processed flakes through extrusion processes provides a mild removal of the contaminants. This level of decontamination allows the final rPET to get in indirect contact with food if it is used behind a suitable functional barrier.

Typical and representative decontamination efficiencies for the different equipment configurations, as defined in table 3 are reported in Table 5. The decontamination efficiencies are taken from the challenge test carried out by different companies referred in to the annexes 2 and 3.

Table 5: representative decontamination efficiency, from challenge test

DECONTAMINATION EFFICIENCY %		
	Configurations X1, X2, W	Configuration Y1, Y2
	Reference annex 2	Reference annex 3
toluene	97.5	94.3
chlorobenzene	97.3	93.1
chloroform	92.7	
methyl salicylate	93.8	95.4
phenyl cyclohexane	94.4	92.1
benzophenone	87.5	65.4
methyl stearate	89.3	70.9

Calculation of migration through a functional barrier

As provided for in article 32(2) of the Regulation (EU) 2022/1616, the large number of structures that are part of this notification are grouped on the basis of technical equivalence of the applied recycling installations (Table 3) and the assessment was done on each of these groups.

Since PET containers that use a functional barrier are not used to pack food for infants, the migration limit of 0.028 µg/kg food, calculated by EFSA for the toddlers' scenario is used. When overestimating modelling is used this limit may be multiplied by 5 to become 0.15 µg/kg food. This applies under the conservative assumption that all migrating substances are genotoxic.

Modelling of migration of surrogate contaminants has been carried out starting from concentration of these contaminants of 3 mg/kg (EFSA assumption). The use of migration models for the estimation of migration is a common practice; these models have been developed in the early 2000's [8] and are currently used in the context of applications for new substances in food contact materials, as well as for evaluation of potential contamination from recycled plastic materials.

The software used for the migration modelling was SML365, developed by AKTS[9] (Sierre-Switzerland). The software is widely recognized and used for migration prediction in the context of food contact plastic materials. The base software was equipped with a statistical analysis module, providing information on the distribution of the outcoming results upon fluctuation of initial parameters, as well as changes in the dimensions of the A/B/A structures, and a module for the evaluation of the set-off effect, which enables the calculation of the equilibrium concentration of the

[8] Full article: Evaluation of migration models that might be used in support of regulations for food-contact plastics (tandfonline.com)
[9] About Us Page - AKTS

surrogate contaminants contained in layer B, through layers A at given temperatures and after a pre-set time.

The starting concentration used for the migration modelling is the concentration of the surrogate contaminants at the end of the decontamination process, prior to entering of the material into the die. These can be calculated using the decontamination efficiencies of the challenge tests. By using the decontamination efficiencies reported in Table 5 above and normalizing the content of the surrogate contaminants to an initial concentration of 300 mg/kg, the results reported in Table 6 are obtained. Using a 100 times higher initial concentration of surrogates than the 3 mg/kg contaminant concentration that EFSA assumes to be present in post-consumer food contact PET waste, allows to use a migration limit of 15 µg/kg instead of 0.15 µg/kg as a benchmark.

Table 6: surrogate contaminants concentrations corrected by using the decontamination efficiencies.

	RESIDUE CONCENTRATION OF SURROGATE CONTAMINANTS mg/kg	
	Configurations X1, X2, W	Configuration Y1, Y2
	Ref: annex 2	Ref: annex 3
toluene	7.5	17.1
chloro benzene	8.1	20.7
chloroform	21.9	
methyl salicylate	18.6	13.8
phenyl cyclohexane	16.8	23.7
benzophenone	37.5	103.8
methyl stearate	32.1	87.3

These numbers correspond to the concentration of surrogates that the functional barrier should prevent to be transferred to the food.

There are numerous experimental examples that show that under the test conditions set forth by Regulation (EU) 10/2011, the A layer after thermoforming, i.e. in the actual trays that are used in real conditions, is capable to reduce the migration of surrogate contaminants to a level that is most of the times not detectable with the most sophisticated analytical techniques (Ref. Aliplast, ILPA, Esperia, Cartonpack, others …); the relevant reports are available under request. The detection limit of these tests usually corresponds to 10 µg/kg food simulant.

The predictive model has therefore been applied to the representative A/B/A structures, as follows, expressed in weight percentage of the 3 layers:

5%/90%/5%

10%/80%/10%

15%/70%/15%

The total thickness of the sheets on which the predictive model has been used were: 150 micron, 300 micron and 1400 micron.

The thickness of the functional barrier in these structures is reported in Table 7
Table 7: Thickness of the functional barrier A

% of A layer in A/B/A structure	Total thickness of the A/B/A sheet		
	150 µm	300 µm	1400 µm
5 %	7.5	15	70
10 %	15	30	140
15%	22.5	45	210

The modelling of migration in the food simulants starts when the layers A and B are coextruded and ends at the end of the shelf life of the packaged food. The thermal history can be summarized as follows:

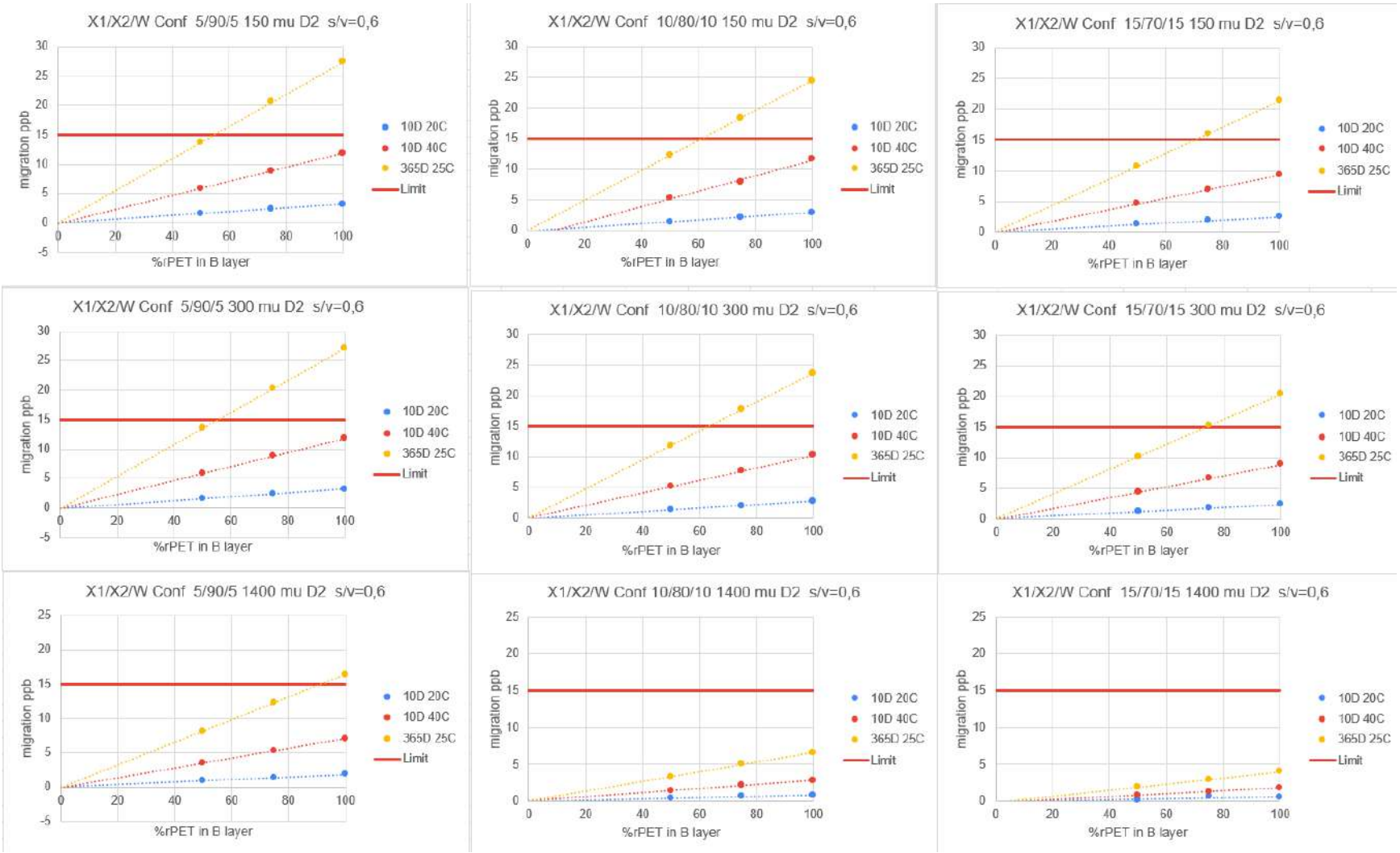
- Initial contact of rPET with virgin PET in the die: 1 minute at 290°C (highest reported conditions)
- storage of the 3-layer sheet at room temperature (25°C) for up to 180 days in reels (storage in the warehouse before thermoforming)
- thermoforming (sheet to tray), at 130°C for 3 seconds
- storage of the final tray before filling with food, up to 180 days at room temperature (25° C)
- In case of form & fill applications, the trays are immediately filled with food after thermoforming.

Under the conditions reported above, the A/B/A tray has reached the equilibrium conditions, in which the concentration of the surrogate contaminants in the layer A have achieved a certain concentration and are ready to migrate into food.
The migration modelling was made by using simulant D2 as a worst case, and took in consideration various rPET percentages in layer B, namely 100%, 75% and 50%.
All other simulants delivered lower migration results; therefore, we are presenting the results relative to simulant D2 only.
The migration modelling was applied to all surrogate contaminants, but the results were reported only for the surrogate which showed higher migration.

Calculation for equipment configurations X1, X2 and W

The results of the modelling for equipment configurations X1, X2 and W (see Table 2) are summarized in the Figure 8 below. It should be noted that the results of the simulation are referred to the final structure after thermoforming.

Figure 8: results of migration modelling for equipment configurations X1, X2 and W



Where X1, X2 and W are the equipment configurations, s/v= 0.6 cm2/cm3 (equal to 6 dm2/kg) refers to the surface to volume ratio, and D2 is the simulant in which the calculation has been done.

The Figure 8 shows that in all structures the calculated migration at 10 days/20°C and 10 days/40°C remains always below the limit of 0.15 ppb. This means that for all applications such as *"frozen and refrigerated temperature for long term storage, and room temperature up to 30 days packaging of all food",* the barrier properties of layer A are confirmed up to a 100% rPET content in layer B.

For other applications entailing shelf life of food at room temperature and below for up to one year, the functional barrier properties are confirmed if the content of rPET in B layer lies between 55% and 75% in the case of structures with total thickness in the low and medium range. When the total thickness of the sheet is increased to 1400 µm, the functional barrier properties are confirmed up to 90% and 100% content of rPET in the B layer.

For applications with a shelf life of up to one year at room temperature and below, Figure 9 shows the migration behaviour of the modelled structures as a function of the total thickness of the sheet, for an rPET content in the B layer of, respectively, 50%, 75% and 100%.

Figure 9: trend of migration as a function of total thickness, for equipment configurations X1, X2 and W, at the conditions 365days /25°C

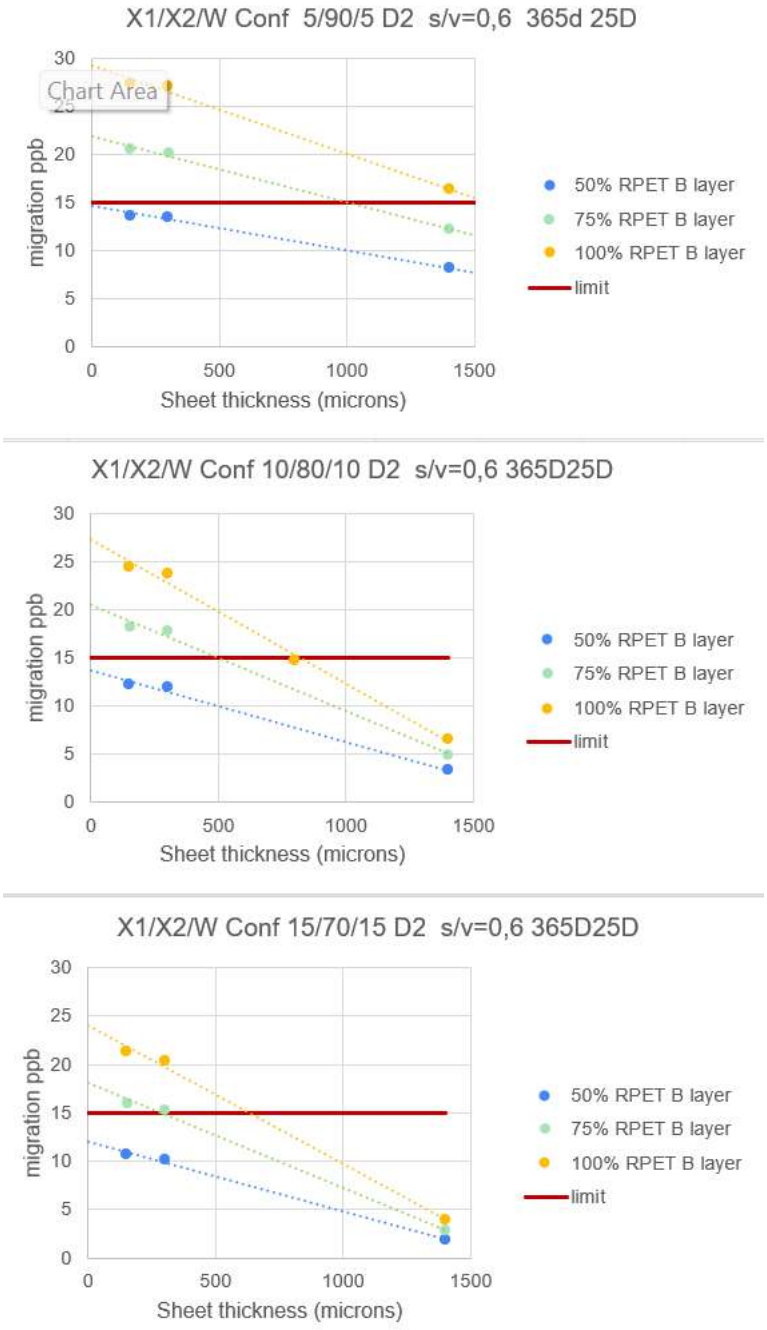


Figure 9 leads to the conclusion that all thicknesses are suitable for such an application, provided that the rPET content does not exceed 50% in the B layer. When the 50% rPET content is exceeded, the total thickness of the sheet defines/determines whether the A layer is a functional barrier or not: for example, with 75% rPET in the B layer, only A/B/A structures thicker than 500 µ are suitable to pack food with shelf life up to one year at room and refrigerated temperature conditions.

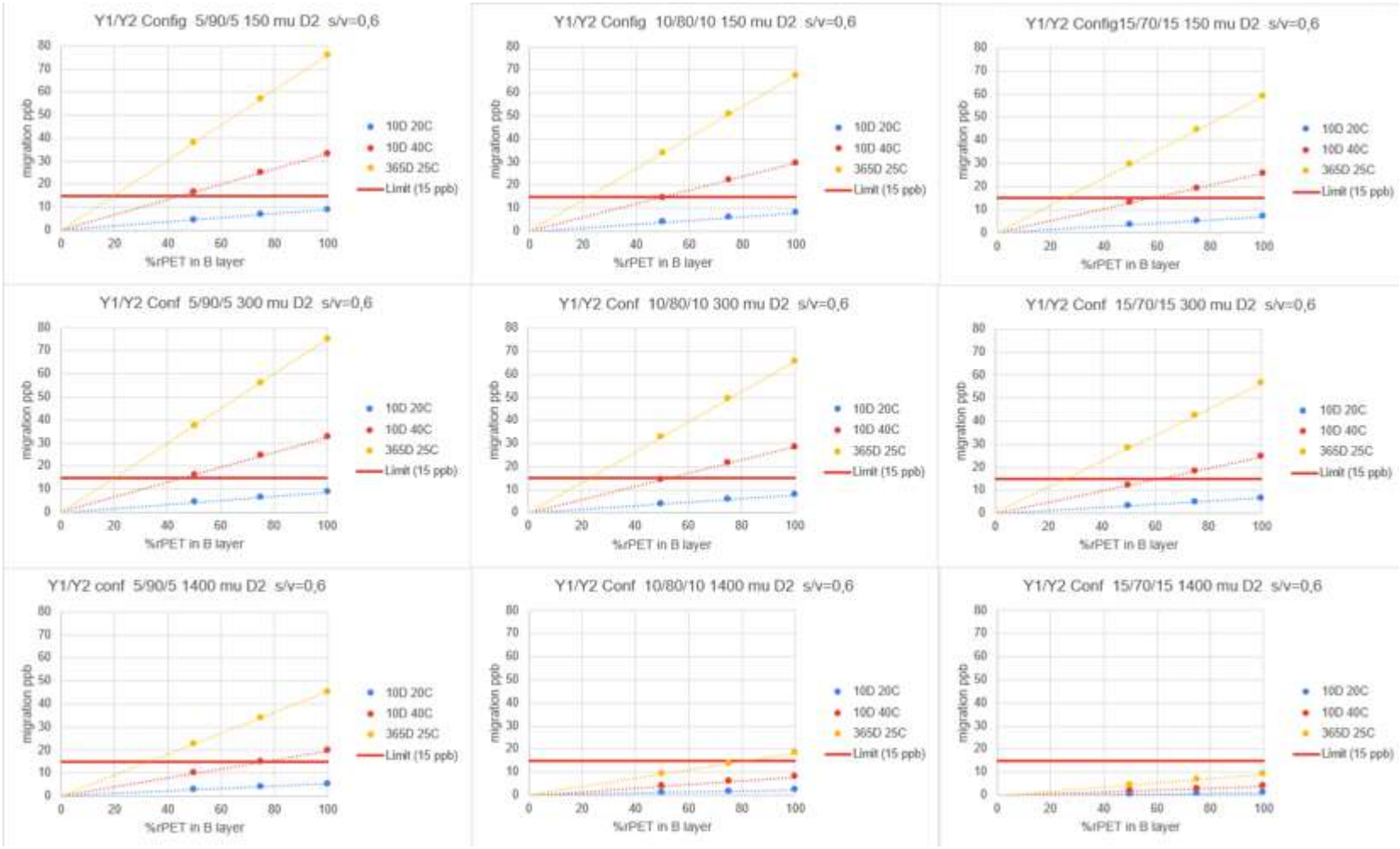
The results of the above analysis for migration conditions 10 days at 20°C are similar to the results obtained by EFSA for such migration conditions in its opinion[10] on the process of which the challenge test results are used in the above analysis. This confirms that the right modelling parameters have been chosen for the above analysis.

Calculation for equipment configurations Y1 and Y2

The results of the modelling for equipment configurations Y1 and Y2 are summarized in the Figure 10 below. It should be noted that the results of the simulation are referred to the final structure after thermoforming.

[10] Safety assessment of the process 'Linpac', based on Linpac superclean technology, used to recycle post-consumer PET into food contact materials
https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5323

Figure 10: results of migration modelling for Equipment configurations Y1 and Y2



Where Y1 and Y2 are the equipment configurations, s/v= 0.6 cm2/cm3 (equal to 6 dm2/kg) refers to the surface to volume ratio, and D2 is the simulant in which the calculation has been done.

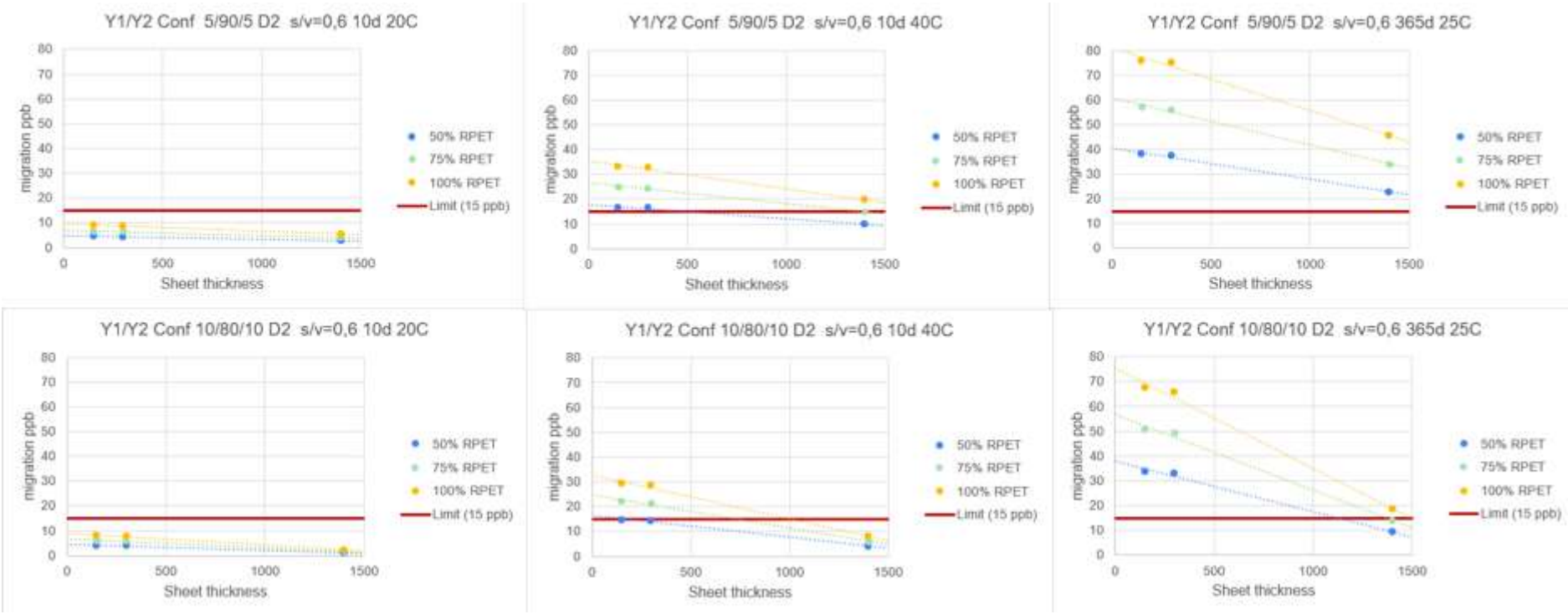
Figure 10 shows that in all structures the calculated migration at 10 days/20°C remains always below the limit of 0.15 ppb. This means that for all applications such as *"frozen temperature packaging of food for long term storage and refrigerated temperature of food up to 30 days"*, the functional barrier properties of layer A are confirmed up to a 100% rPET content in layer B.

However, when using 100% rPET in the B-layer, the calculated migration at 10 days/40°C lies below the limit only for structures with a high thickness and in the A barrier layer of 10% or higher. When it comes to low and medium thickness structures, the calculated migration is below limit only if the rPET content in the B layer is below 50%.
This would lead to the conclusion that, for these equipment configurations Y1 and Y2, only an rPET content in the B layer of 50% or below can be used for A/B/A structures with at total thickness of 300 micron and below.

For shelf lives up to one year at 25°C and below, Figure 10 indicates that the 0.15 µg/kg food limit is fulfilled only if the percentage of rPET in the B layer does not exceed 20% for 5/90/5, 23% for 10/80/10 and 25% for 15/70/15 A/B/A structures with at total thickness of 300 µm, and higher % of rPET for thicker structures.

For configurations Y1 and Y2, Figure 11 allows to identify the minimum total thickness needed for compliance.

Figure 11: minimum total thickness needed for compliance



The figure confirms that A/B/A structures of all thicknesses fulfil the limit for refrigerated and frozen food storage conditions (10 days/20°C), while for room temperature food storage conditions (10 days/40°C) the minimum thickness corresponds to about 200µ with rPET content of 50% and barrier layer 10%, while decreasing the barrier layer and increasing the rPET content leads to an increase of the minimum thickness needed to fulfil the limits.

Further considerations on equipment configurations Y1 and Y2

With particular sight to the processes described in configurations Y1 and Y2, it should be highlighted that the calculation of the migration for all applications has been carried out at 10 days/40°C by using simulant D2. In case the final food contact article only would be used for fruits and vegetables, the appropriate simulant is simulant E (Tenax), as indicated in Regulation (EC) 10/2011, Annex III, Table 2. In particular, for *"fruits, fresh and chilled- unpeeled and uncut"* (food type 04.01-A), compliance can be established by dividing the result of the migration in simulant E by a reduction factor of 10. Therefore, the results of the migration modelling obtained with simulant D2, which is considered worst case as compared to simulant E, can be divided by the same reduction factor of 10 for articles used to pack foods type 04.01-A. In such a case, the limit of 0.15 ppb is met for the condition 10 days/40°C with 100% rPET in the B layer, at all thickness of the barrier A layer.

Use of reduction factors for calculation of rPET in the B layer

Depending on the food that will be packed, also for food simulant D2, regulation (EU) No 10/2011 authorizes the use of D2 reduction factors[11]. For applications in which such reduction factor can be used, it is possible to calculate the amount % of rPET for the different configurations, which allows the calculated migration to lie below the 0.15 ppb threshold. The results of such calculations is reported in the tables of Figure 12.

[11] (EU) No 10/2011, Annex III: "*For food categories where in sub-column D2 or E the cross is followed by an oblique stroke and a figure, the migration test result shall be corrected by dividing the result by this figure. The corrected test result shall then be compared to the migration limit to establish compliance. The test results for substances that shall not migrate in detectable quantities shall not be corrected in this way*."

Figure 12: percentage of rPET in the B layer enabling to meet the migration threshold of 0.15 ppb when applying a reduction factor.

X1/X2/W Configurations.

10d 20C — X1/X2/W Conf. MAX % rPET IN B LAYER FOR 10d 20C

A layer ratio (%)	Sheet Thickness (µm)	REDUCTION FACTOR for D2: 0	2	3	4	5	REDUCTION FACTOR for E: 10
5/90/5	150	100	100	100	100	100	100
	300	100	100	100	100	100	100
	1400	100	100	100	100	100	100
10/80/10	150	100	100	100	100	100	100
	300	100	100	100	100	100	100
	1400	100	100	100	100	100	100
15/70/15	150	100	100	100	100	100	100
	300	100	100	100	100	100	100
	1400	100	100	100	100	100	100

10d 40C — X1/X2/W Conf. MAX % rPET IN B LAYER FOR 10d 40C

A layer ratio (%)	Sheet Thickness (µm)	REDUCTION FACTOR for D2: 0	2	3	4	5	REDUCTION FACTOR for E: 10
5/90/5	150	100	100	100	100	100	100
	300	100	100	100	100	100	100
	1400	100	100	100	100	100	100
10/80/10	150	100	100	100	100	100	100
	300	100	100	100	100	100	100
	1000	100	100	100	100	100	100
	1400	100	100	100	100	100	100
15/70/15	150	100	100	100	100	100	100
	300	100	100	100	100	100	100
	1400	100	100	100	100	100	100

365d 25C — X1/X2/W Conf. MAX % rPET IN B LAYER FOR 365d 25C

A layer ratio (%)	Sheet Thickness (µm)	REDUCTION FACTOR for D2: 0	2	3	4	5	REDUCTION FACTOR for E: 10
5/90/5	150	55	100	100	100	100	100
	300	55	100	100	100	100	100
	1400	90	100	100	100	100	100
10/80/10	150	60	100	100	100	100	100
	300	60	100	100	100	100	100
	820	100	100	100	100	100	100
	1400	100	100	100	100	100	100
15/70/15	150	70	100	100	100	100	100
	300	75	100	100	100	100	100
	633	100	100	100	100	100	100
	1400	100	100	100	100	100	100

Y1/Y2 Configurations.

10d 20C — Y1/Y2 Conf. MAX % rPET IN B LAYER FOR 10d 20C

A layer ratio (%)	Sheet Thickness (µm)	REDUCTION FACTOR for D2: 0	2	3	4	5	REDUCTION FACTOR for E: 10
5/90/5	150	100	100	100	100	100	100
	300	100	100	100	100	100	100
	1400	100	100	100	100	100	100
10/80/10	150	100	100	100	100	100	100
	300	100	100	100	100	100	100
	1400	100	100	100	100	100	100
15/70/15	150	100	100	100	100	100	100
	300	100	100	100	100	100	100
	1400	100	100	100	100	100	100

10d 40C — Y1/Y2 Conf. MAX % rPET IN B LAYER FOR 10d 40C

A layer ratio (%)	Sheet Thickness (µm)	REDUCTION FACTOR for D2: 0	2	3	4	5	REDUCTION FACTOR for E: 10
5/90/5	150	45	90	100	100	100	100
	300	45	90	100	100	100	100
	1400	75	100	100	100	100	100
10/80/10	150	50	100	100	100	100	100
	300	50	100	100	100	100	100
	1000	100	100	100	100	100	100
	1400	100	100	100	100	100	100
15/70/15	150	55	100	100	100	100	100
	300	60	100	100	100	100	100
	780	100	100	100	100	100	100
	1400	100	100	100	100	100	100

365d 25C — Y1/Y2 Conf. MAX % rPET IN B LAYER FOR 365d 25C

A layer ratio (%)	Sheet Thickness (µm)	REDUCTION FACTOR for D2: 0	2	3	4	5	REDUCTION FACTOR for E: 10
5/90/5	150	20	40	60	80	99	100
	300	20	40	60	80	100	100
	1400	30	60	90	100	100	100
10/80/10	150	20	40	60	80	100	100
	300	25	50	75	100	100	100
	1120	50	100	100	100	100	100
	1400	80	100	100	100	100	100
15/70/15	150	25	50	75	100	100	100
	300	30	55	90	100	100	100
	1230	100	100	100	100	100	100
	1400	100	100	100	100	100	100

The minimum total thickness at which 100% rPET can be used to meet the specified limit for all types of food is highlighted in green.

The tables of Figure 12 need to be read in combination with the descriptions of food to which the various reduction factors are applicable; such description can be found in Annex III of Regulation (EC) 10/2011. A summary is reported in Figure 13, for reference.

Figure 13: summary of reduction factors and food to which they are applicable

EC 10/2011; Annex III Table 2; Food category specific assignment of food simulants

02.Cereals
03.Confectionery & chocolates
04.Fruit & Vegs
05.Fats & Oils
06.01.Fish fresh, chilled, processed
06.03 & 04 Meat
07.Milk products
08. Miscellaneous
06.05 Eggs

REDUCTION FACTOR for D2				
none	X/2	X/3	X/4	X/5
04.02 C I	03.02 B I	02.05 A	06.03 A	08.02 A
04.03 C	05.02	02.06 A	06.03 B	08.03 A I
04.05 D I		03.01	08.02 B	08.03 B I
05.01		03.02 A I		08.06 A
06.01 B I		06.01A		08.08 A
06.02 B I		06.04 A		
06.03 C		07.04 B		
07.04 D I		08.05		
08.04 B		08.11 B		
08.15				

REDUCTION FACTOR for E	
none	X/10
02.01	04.01 A
02.02	04.04 A
02.03	
02.04	
02.05 B	
02.06 B	
03.02 A II	
03.03 A	
04.02 A	
04.03 A	
04.03 B	
04.05	
06.05 A	
07.01.B	
07.04 A	
08.03 A II	
08.06 B	
08.08 B	
08.09	
08.11. A	
08.12	
08.13	
08.14	

Conditions of contact with food

The partially decontaminated rPET which comes from the extrusion phase enters in contact with the virgin layer A in the extrusion die, at a temperature of 275-286°C for a short time, for an average time of ab. 60 seconds.

The trays resulting from thermoforming of the A/B/A sheets can be safely used for frozen, refrigerated and room temperature of food for long term, subject to the limitations in the rPET content identified by the simulation.

Examination of relevant published literature

The calculation made in this notification has been done by using the SML365 software under conservative assumptions, in particular the prediction model used upper bound values for estimation of diffusion coefficients in the equation underpinning the migration behavior[12].

This represents an additional overestimation assumption used in the context of migration prediction. In more general terms, the safety limit used by EFSA for assessing processes of production of rPET contains many overestimation factors, which make that limit very conservative. The limit is set by (i) assuming that 1 kg of rPET could potentially contain 3 mg/kg of genotoxic substance, (ii) applying a migration prediction model with parameters that largely overestimate the migration, and (iii) assuming a highly overestimated daily intake for toddlers and adults to calculate the intake of potential contaminants.

More realistic prediction methods have been developed[13]. According to these models and even when maintaining unchanged all others EFSA overestimated assumptions, the conclusions drawn for tray applications are that *"no cleaning efficiency is necessary for substances with molecular weights above of approximately. 220 g/mol (migration limit 0.15 µg/L, 365 d at 25°C) and above of approximately 130 g/mol for meat trays (migration limit 0.15 µg/L, 10 d at 20°C), respectively".*[14]

In a more recent publication[15] , it was evidenced how recycling of PET bottles to produce trays for packaging meat products, and fruits and vegetables need low cleaning efficiency due to short shelf-life and low specific product temperature. The calculated minimum cleaning efficiency required by a recycling process of PET bottle-to-meat tray is shown in Figure 14, taken from the above reference. Such efficiency corresponds to ab. 60% for low molecular weight contaminants, and 20% for high molecular weight contaminants. The conclusions of this paper were: *"recyclate applications in meat and fruit trays do not need supercleaning of the recyclates up to molecular weights of about 200 g/mol, even under the assumption that the whole input of post-consumer substances are genotoxic compounds".*

[12] Hoechstra et al., JRC Technical Reports-Practical guidelines on the application of migration modelling for the estimation of specific migration, 2015

[13]A new method for the prediction of diffusion coefficients in poly(ethylene terephthalate)
Frank Welle, First published: 24 December 2012 https://doi.org/10.1002/app.38885

[14] Franz, R.; Welle, F. Recycling of Post-Consumer Packaging Materials into New Food Packaging Applications—Critical Review of the European Approach and Future Perspectives. Sustainability 2022, 14, 824. https://doi.org/10.3390/su14020824

[15] F. Welle, VerpackungRundschau, Circular Economy- Considerations on PET Recycling, 4/2019

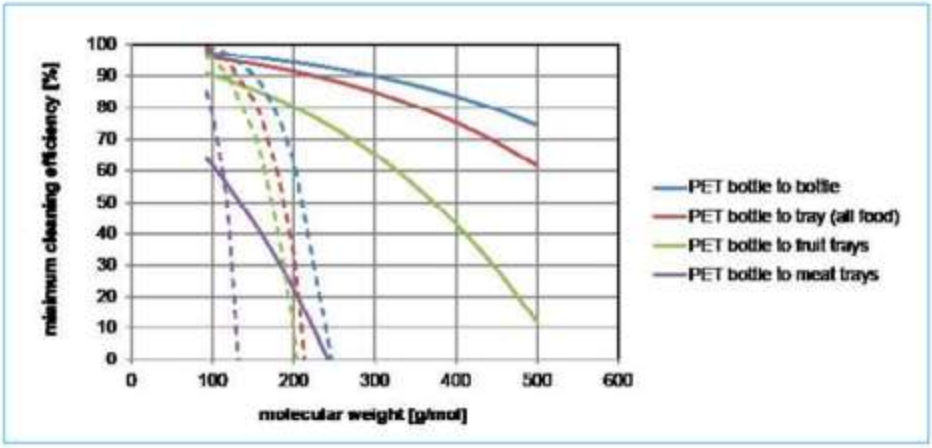


Figure 1: Minimum cleaning efficiencies of the super-clean recycling processes necessary for different applications of the post-consumer recyclate (calculated for 100% recyclate content). Solid lines calculated with the AP model applied by EFSA [2,5]. Dashed lines calculated with realistic diffusion coefficients [6].

Evaluation of migration from A/B/A trays

During the last 15-20 years industry has carried out overall and specific migration test on many A/B/A structures. In no case the migration limits set in Regulation (EC) 10/2011 have been exceeded.

In addition to standard migration tests, analysis of NIAS (non-intentionally added substances) is carried out by most of the Consortium members, although not periodically. A more systematic approach and in line with Article 13 of the regulation EU 2022/1616 will be implemented by the members of the Consortium, which is reported in the paragraph on “quality control”.

Quality Assurance

The quality assurance systems in place at the Consortium members operations ensure amongst others that the specifications for incoming raw materials are fulfilled. This is normally done through certificates received from suppliers. The minimum requirements for incoming flakes are reported in Annex 1

The constant thickness of the A layer is ensured by controlling the ratio between the throughput (kg/hour) of A and B. Periodically, at least twice a year, or after every maintenance intervention, a colorant is added in either layer A or B, and the relative thickness is measured via optical microscopy.

Process parameters are recorded in order to ensure that the process is under control and no variations other than the established operating ranges take place, in particular as regard the critical control parameters. The recorded parameters for both extrusion lines (for A and B) are temperature, vacuum, output in kg/hour, dosing percentage of the raw materials, pressure, speed of melt pump, screen changer delta pressure, die temperature, calendrers temperature, thickness of the final sheet.

The critical control points for the equipment configurations leading to the production of the sheets notified through this paper are reported in Table 8.

Table 8: critical control parameters for the notified equipment configurations

Critical control parameter	Configurations X1, X2, W	Configurations Y1 and Y2
Crystallization temperature	120-170°C	---
Crystallization residence time	>20 min	---
Dryer temperature	165°C	---
Dryer residence time	> 40 min	---
Dryer air flow	> 600 m3/hour	---
Temperature profile in the extruder	---	275-290°C
Vacuum level	---	< 90 mbar

Figure 14. QAS diagram for X1,X2 and W equipment technologies

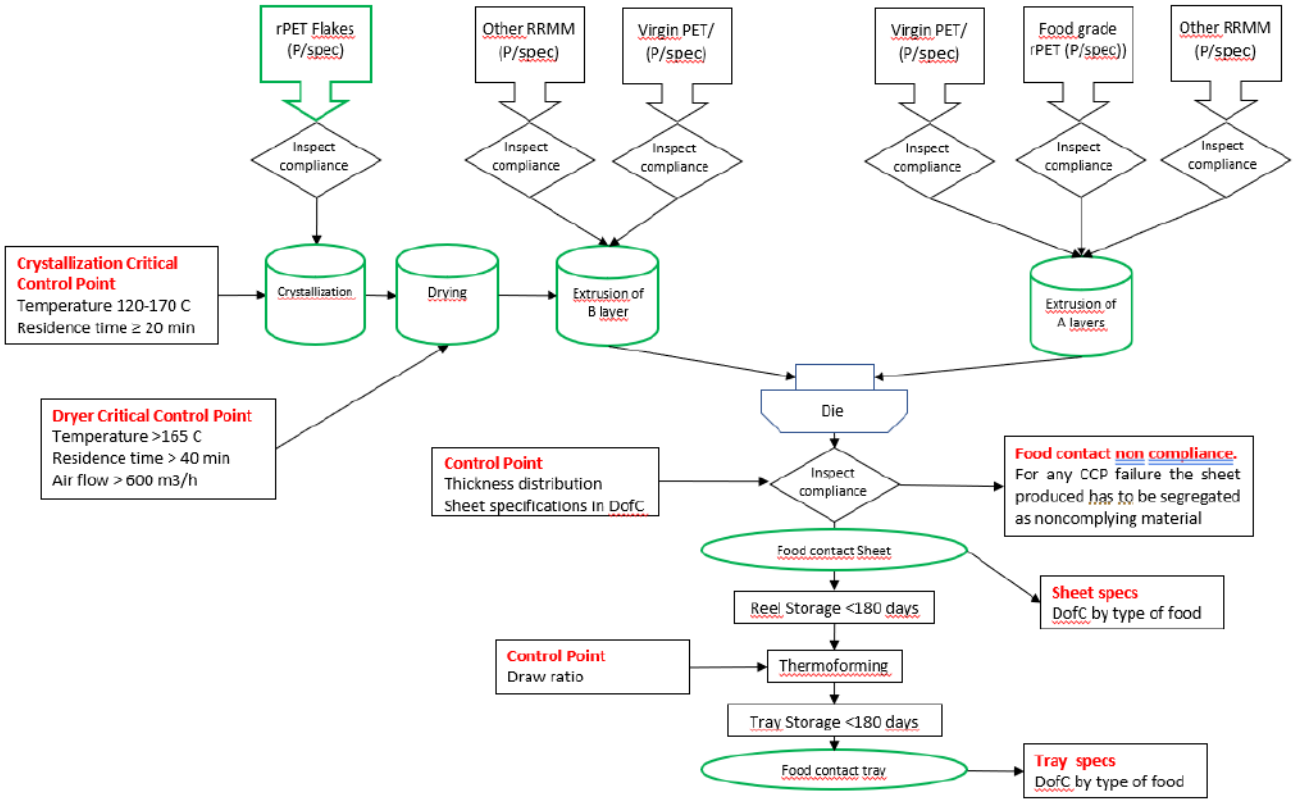
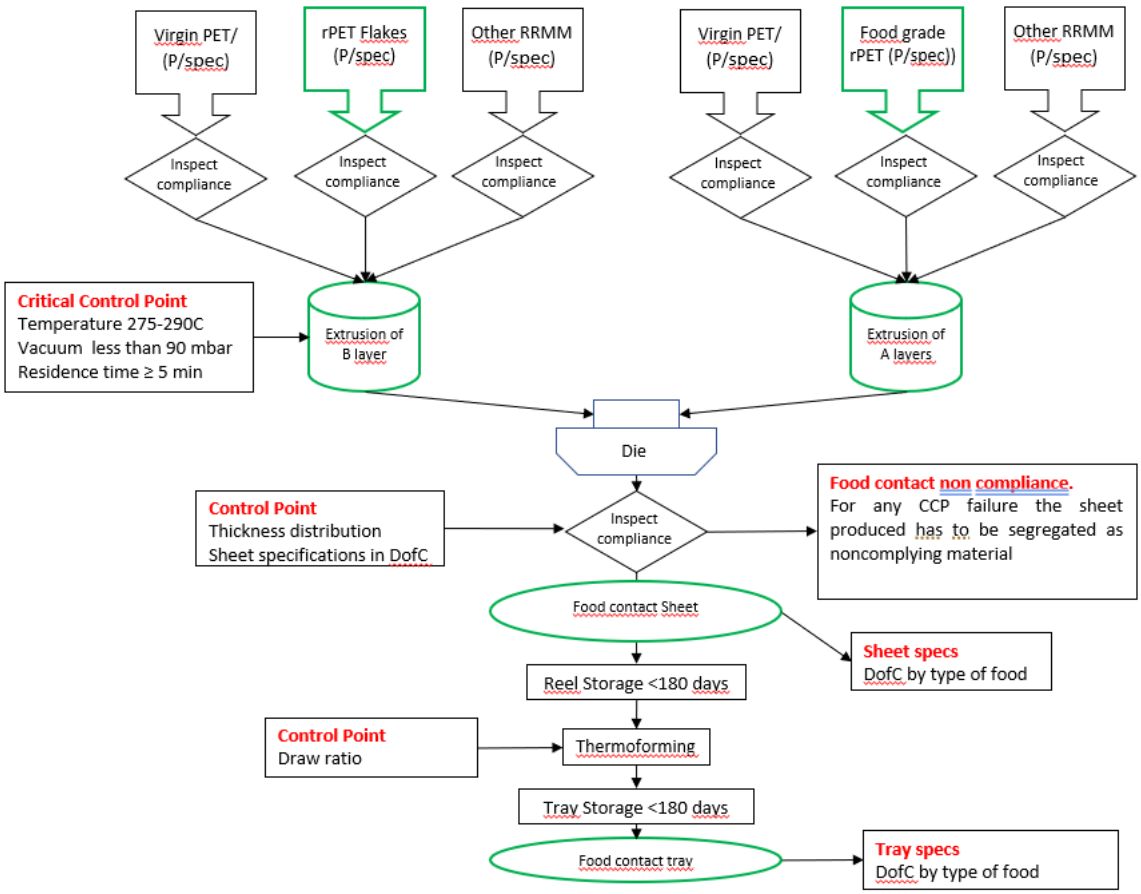


Figure 15. QAS diagram for Y1 and Y2 equipment technologies



Functional Barrier Task Force represented by PETCORE Europe

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Annex 1: Flakes specifications example

Name of product:			
Supplier:			
Chemical definition:			
Source of material:	bottle nonreturnable	bottle returnable	trays

GENERAL STATEMENTS			
Requirement	**Yes**	**No**	**Comments**
Hot washed flakes, washed with caustic soda			
Certified quality assurance system including traceability (article 6 of Regulation (EU) 2022/1616 – mandatory from 10 October 2024 (please provide certificate)			
RecyClass or EuCertPlast certifications – mandatory for recycled content certification (please provide certificate)			
Other certifications (please provide certificate and accreditation), according to UN15343			
Compliance with Regulation (EC) No 1907/2006 – REACH • SVHC substances >0,1%, candidate list in its actual version http://echa.europa.eu/de/candidate-list-table • comply with article 2 (7), d (input material registered, EU origin)			
Input material (bottles or trays) complies with Framework Regulation (EC) No 1935/2004 • on materials and articles intended to come into contact with food			
Input material (bottles or trays) complies with Regulation (EU) No 10/2011 • on plastics materials in contact with foodstuffs			
In compliance with Regulation (EC) No 2023/2006 (GMP) ○ Good manufacturing practice, GMP ○ Traceability ○ Quality managements system			
sorting purity of > 95% from food contact applications (< 5% from non-food contact applications)			
In compliance with Recycling Regulation (EU) 2022/1616 Use of a decontamination process according EFSA criteria EFSA registered process EFSA positively evaluated process European Commission authorised process			EFSA Question Number: Recycling authorisation number (RAN) Recycling installation number (RIN)
In compliance with Directive 94/62/EC incl. all effective amendments Heavy metal content < 100 ppm			
No restricted substances (like phthalates) are used or intentionally added			

Contamination	**comments**	**A-quality**	**OK,√**	**B-quality**	**OK,√**	**Unit**	**Comments**	**COA**
PET blue		< 5		<10		%		YES -
PET other colour		< 0,1		< 0,2		%		YES
Other plastics	e.g. PA, PS, etc.	< 50		< 100		ppm		YES
PO labels and cups		< 25		< 45		ppm		YES
Metal		< 5		< 10		ppm		YES
Paper		< 5		< 10		ppm		NO
Other parts	e.g. wood, stone, rubber, etc.	< 25		< 45		ppm		NO
after roasting test (Röstprobe)								
PVC	black	< 20		< 50		ppm		YES
Flakes discoloured	Brown and black	< 5000		< 7000		ppm		YES
Multilayer / PA		< 100		< 200		ppm		NO
Oxygen scavenger	Monolayer	< 15.000		< 25.000		ppm		NO
Bulk weight		> 400		> 250		kg/m³		YES
Residual moisture		< 0,8		< 1		%		YES
Flakes	>10mm	< 1		< 2		%		YES
Fines	< 1 mm	< 0,5		< 1		%		YES

Remarks	1) check at least the mixture of 3 Big Bags, 1 kg / Big Bag, test compound 300 g 2) counting after roasting test (Röstprobe), 300 g sample, conditions 2h, 200°C		
Comments	Supplied material should not be older than ½ year.		
Other	By shipment of material appropriate to the purchase order, the supplier continues to guarantee that the material is manufactured acc. our specification requirements. We must be notified in writing and has to approve if a significant change of the raw material components, formulation, equipment / facility and /or manufacturing process prior to implementation.		
COA	*COAs for every delivery together with shipping documents* *Should mention: batchnumber, number of delivery note, production date, quality level and the above indicated parameters*	*every Batch*	*Yes*

Date: Producer:
Signature: Name: Position:

Annex 2: Challenge test for equipment configurations X1, X2, W

Fraunhofer
IVV

3. Technical Dossier

updated according to question in EFSA letter from 28.10.2016

Recycled Poly(ethylene terephthalate) for Direct Food Contact Application

Petitioner:

Linpac Packaging GmbH
Deltastraße 1
27721 Ritterhude
Germany

Representative Laboratory:

Fraunhofer-Institute for Process Engineering and Packaging IVV
Giggenhauser Straße 35
85354 Freising
Germany

Super-clean technology: Linpac

Contains Confidential Information

(in Section 3.2.1)

This updated version refers to EFSA-Q-2016-00550 request for more data from 28.10.2016.

All changes made in the updated petition are highlighted in grey.

Text for the register:

The company Linpac is running a recycling facility for the recycling of post-consumer PET with a total capacity of 18000 t per year maximum output. Linpac has developed an own super-clean recycling technology for the production of PET trays. The input material for the recycling process is conventionally recycled post-consumer poly(ethylene terephthalate) (PET) containers of original food grade quality.

The Linpac recycling process technology includes basically the following steps:

- Step 1: Grinding of re-collected post-consumer PET containers into flakes followed by an intensive wash process and drying (done by flake suppliers)
- Step 2: Treatment of flakes by means of IR dryer
- Step 3: Treatment of flakes by means of 1800 l dryer 1
- Step 4: Re-extrusion of the decontaminated flakes from step 3 and flat sheet production

The Linpac recyclate will be used to produce new single use PET trays for fresh food (e.g. meat) with maximum storage conditions of 30 d at 6 °C articles with up to about 100% recyclate content.

Table of Contents

3.1 General information

The company SP group with its subsidiary Linpac is running a recycling facility for the recycling of post-consumer PET. Linpac has developed an own super-clean recycling technology for the production of PET trays. The input material for the recycling process is conventionally recycled post-consumer poly(ethylene terephthalate) (PET) containers of original food grade quality.

Linpsc and the Fraunhofer-Institute for Process Engineering and Packaging (Freising, Germany) have been working together on the evaluation of the cleaning efficiency of their super-clean recycling process (for definitions see Glossary in Chapter 3.4). The cleaning efficiencies were examined by carrying out a challenge test according to the principles recommended by European Guidelines and US FDA[1,2,3,4] in order to investigate whether the output material is suitable for being re-used in packaging materials for direct food contact.

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[1] *Recycling of Plastics for Food Contact Use*, Guidelines prepared under the responsibility of the International Life Sciences Institute (ILSI) - European Packaging Task Force, 83 Avenue E. Mounier, B-1200 Brussels, Belgium, May 1998

[2] R. Franz, F. Bayer, F. Welle, Guidance and Criteria for Safe Recycling of Post Consumer Polyethylene Terephthalate (PET) into New Food Packaging Applications, EU Report 21155, ISBN 92-894-6776-2, Luxembourg 2004.

[3] Opinion of the French Food Safety Agency (AFSSA) on the assessment of health risks associated with the use of materials made from recycled poly(ethylene terephthalate) intended for or placed in contact with foodstuffs and drinking water, November 2006.

[4] *Points to Consider for the Use of Recycled Plastics in Food Packaging: Chemistry Considerations*, US Food and Drug Administration, Center for Food Safety and Applied Nutrition, (HFF-410), May 1992, 200 C Street SW, Washington, DC 20204; internet: URL: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm120762.htm [March 2014]

3.1.1 General description

The Linpac super-clean recycling process uses re-collected post-consumer poly(ethylene terephthalate (PET) containers of original food grade quality as input material. The input material originates from collections systems such as curbside and deposit collections. During the process this material is washed, processed and cleaned up in such a way that the output material, the recycled PET flakes, can be used again for the production of new articles for direct contact with foodstuffs.

The Linpac recycling process technology includes basically the following steps:

- Step 1: Step 1: Grinding of re-collected post-consumer PET containers into flakes followed by an intensive wash process and drying (done by flake suppliers)
- Step 2: Treatment of flakes by means of IR dryer
- Step 3: Treatment of flakes by means of 1800 l dryer 1
- Step 4: Re-extrusion of the decontaminated flakes from step 3 and flat sheet production

The Linpac recyclate will be used to produce new single use PET trays for fresh food (e.g. meat) with maximum storage conditions of 30 d at 6 °C articles with up to about 100% recyclate content. Thermoforming trays are in general for single use only. PET trays for microwave applications are excluded.

3.1.2 Existing authorisations

The applied recycling technology has no authorisations and other evaluations

The Linpac recycling process is currently running in Ritterhude, Germany, at a total capacity of about 18000 t super-clean recyclate per year.

3.2 Specific information

3.2.1 Recycling process

CONFIDENTIAL INFORMATION

This chapter contains information about process steps and process parameters. The process parameters are fundamental to decontamination efficiency. The process parameters form part of the intellectual property of the technology manufacturer of the recycling process. Therefore the process parameters should be kept confidential.

The Linpac super-clean recycling process comprises the following main decontamination process steps:

- Step 1: hot washing of the post-consumer PET flakes with caustic soda and surfactants followed by surface drying (remark: step 1 is made by the flake suppliers)

- Step 2: Treatment of flakes by means of IR dryer (temperature zone 1: 110 °C, zone 2: 140 °C, zone 3: 170 °C). Output 1600 kg/h, residence time >20 min
- Step 3: Treatment of flakes by means of 1800 l dryer 1 (temperature >165 °C), residence time >14 min
- Step 4: Extrusion of flakes into sheets by means of the Linpac extrusion line with degassing under high vacuum (<0.2 bar). Output 1600 kg/h (remark: not challenged)

Description of the Linpac recycling process:

Linpac is buying washed flakes from the market. The flake suppliers are using state of the art washing process parameters. In the first step, the bottles, labels and closures are cut into flakes. Subsequently, the non-PET materials (closures, labels) were separated. The PET flakes are further washed with hot washing processes. During such hot washing processes, typically temperatures between 70 °C and 90 °C are used. To the washing solution, caustic soda at a concentration of about 1% to 3% is added as well as surfactants. The overall residence time of the flakes in the washing line is typically about 20 min. The hot washing process is followed by a rinsing with water and surface drying of the PET flakes.

In the second step, the washed flakes are continuously feed into the IR drier. The material is heated up to 170 °C in the final zone of the IR drier. The residence time is >20 min (exhaust air 2750 m^3/h). Subsequently the material is transferred into drier 1. The material is kept at a decontamination temperature of 165 °C for >14 min under dried air with air flush (600 m^3/h).

In the last step of the Linpac process, the decontaminated material is re-extruded (extruder temperature >255 °C, maximum temperature 290 °C) with vacuum degassing (<0.2 bar). After the extruders there is a range of downstream equipment that produced flat sheet. The manufactured sheet containing recyclate is made in a thickness, ranging from 120 µm to 950 µm, depending on the requirements of the food contact tray.

A flow chart of the investigated super-clean recycling process is shown in Figure 1.

The challenge test was performed with contaminated PET flakes. The contaminated flakes were introduced into the Linpac recycling process after washing process. 200 kg of the contaminated and washed flakes were feed into the industrial scale super-clean recycling line at the Linpac facilities in Ritterhude. The throughput of the super-clean recycling process during the challenge test was about 1600 kg h^{-1}. Due to the fact, that the challenge test was performed on the industrial scale line, the process parameters within the challenge test are the same as give above.

A Fraunhofer report (see Appendix E: Report: PA/4859a/15) is available containing all surrogate concentrations of the investigated samples. All these data are given in Chapter 3.2.3.7.

Comparison of the critical parameters:

Challenge Test:

Step 2: temperature: 110 °C, zone 2: 140 °C, zone 3: 170 °C). Output 1600 kg/h, residence time 20 min
Step 3: temperature 165 °C), residence time 14 min
Step 4: Extrusion: not challenged

Industrial process:

Step 2: temperature: 110 °C, zone 2: 140 °C, zone 3: >170 °C). Output 1600 kg/h, residence time >20 min
Step 3: temperature >165 °C), residence time >14 min
Step 4: Extrusion: (a) time: approx. 3-4 min, (b) pressure: <0.2 bar, (c) temperature: >255 °C

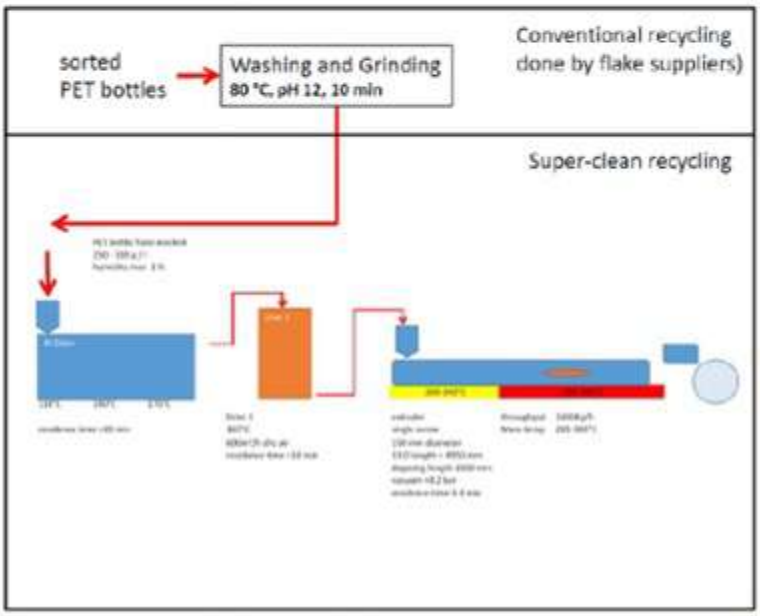

Figure 1: Flow chart of the investigated super-clean recycling process.

END OF CONFIDENTIAL INFORMATION

3.2.2 Characterisation of the input

The investigated super-clean recycling process uses as a raw material source post-consumer PET container materials. This input material originates from deposit systems as well from curbside collections. In the large majority the recollected PET containers have been previously used food packing. However, a small fraction originates from non-food applications such as e.g. soap bottles, mouth wash, kitchen hygiene bottles etc. According to information from Linpac the amount of the non-food container fraction depends on the re-collection system and will be between (nearly) 0% and 5%.

As far as we know, all usual non-food application PET containers are manufactured from food grade PET material as used also for food packaging purposes and should therefore, before first use, be in compliance with EU Regulation 10/2011. The

diffusion behaviour of PET from non-food packaging containers the same as for PET from food containers[5].

Table 1 contains data about the quality of the input material before super-clean recycling without significant attention on quality of the final product (flakes). It should be noted here, that for PET super-clean recycling the quality or the impurities of the washed flakes before super-clean recycling is important. The impurities in the re-collected PET containers e.g. polyolefins, metals, dust etc. are not so critical, because the washing process includes separation steps for metals and polyolefins.

Table 1: Data about the quality of the input material of the super-clean recycling process (washed flakes before super-cleaning)

Parameter	Value
Moisture max.	2 ~~1.0~~%
Moisture variation	±0.1% h^{-1}
Bulk density	325 ~~350 – 850~~ kg m^{-3}
Bulk density variation	±50 kg m^{-3} h^{-1}
Material temperature	15 – 50 °C
Material Temp. variation	±5 °C h^{-1}
PVC max.	500 ~~25~~ ppm
Glue max.	50 ppm
other plastics ~~Polyolefins~~ max.	1000 ~~25~~ ppm
cellulose (paper, wood) max.	5% ~~50 ppm~~
metals max.	1000 ~~2~~ ppm
~~polyamide max.~~	~~5 ppm~~

3.2.3 Determination of the decontamination efficiency of the recycling process

3.2.3.1 Selection of the surrogates

The cleaning efficiency of the recycling process was determined by introducing purposefully highly contaminated post-consumer PET flakes into the Linpac recycling process. The surrogates were chosen in accordance with EU relevant criteria and US FDA recommendations[1,2,3,4] such that they covered the whole spectrum of physical properties.

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[5] T. H. Begley, T. P. McNeal, J. E. Biles, K. E. Paquette, Evaluating the potential for recycling all PET bottles into new food packaging, Food Additives and Contaminants, 2002, Vol. 19, Supplement, 135-143

The surrogates correspond with the following four categories of organic compounds:

- high volatile and polar
- high volatile and non-polar
- low volatile and polar
- low volatile and non-polar

In addition, the surrogates used in the challenge test represent a variety of functional groups in order to reflect the different chemical and physical properties of real-life contaminants e.g. aliphatic and aromatic hydrocarbons, chlorinated hydrocarbons and carbonyl functional groups. From migration theoretical considerations, the molecular weight represents the major parameter important for the selection of the surrogates. It is well established that chemicals with a molecular weight up to approximately 300 g mol^{-1} are the most relevant ones for migration from PET. Substances with a molecular weight >300 g mol^{-1} have an extremely low migration potential due to their low diffusivity in PET[6].

Migration from PET can be considered as predominantly controlled by the diffusion process in the polymer. In this initial phase of a migration curve (which is typical for PET) the migration values are almost independent of the partition coefficient between polymer and foodstuff. The consequence is that the potential requirement of "water solubility" for a surrogate can be neglected. This is in particular the case when food simulants such as 50% ethanol are used or when migration modelling assumes good solubility (uses $K_{polymer / food} = 1$) for the surrogate in food.

Finally, our selection of surrogates also included the aspect of chemical stability under high temperature conditions as applied in PET extrusion. From our experience, from limited measurements in our laboratory and from chemical considerations surrogates such as e.g. limonene and phenol proposed by Lit.[3] are or can be instable and decompose during the PET extrusion conditions. Limonene for example might be oxidized. A stable surrogate for limonene is phenyl cyclohexane. The other example, phenol will be bound to the polyester backbone during re-extrusion due to transesterification reaction in the polyester melt. As a consequence, there is potential to obtain false-negative values with regards to the cleaning efficiency when using unstable or reactive surrogates.

Table 2 gives an overview of the chemical substances, which were selected and used as model contaminants (surrogates) for spiking of PET flakes.

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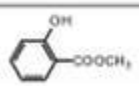
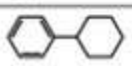
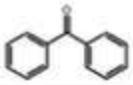
[6] J. Ewender, F. Welle, Determination of the activation energies of diffusion of organic molecules in poly(ethylene terephthalate), *Journal of Applied Polymer Science*, 2013, *128(6)*, 3885-3892

Table 2: Model contaminants ("surrogates") selected for the challenge test

Chemical name, formula	M_W[a]	Structure	Functional Group	Physical properties
Toluene	92.1		aromatic hydrocarbon	volatile, non-polar
Chlorobenzene	112.6	C_6H_5Cl	halogenated aromatic hydrocarbon	volatile, medium-polar, aggressive to PET
Chloroform		$CHCl_3$	halogenated aromatic hydrocarbon	volatile, medium-polar, aggressive to PET
Methyl salicylate	152.1		aromatic ester	medium-volatile, polar
Phenyl cyclo-hexane	160.3		aromatic hydrocarbon	non-volatile, non-polar
Benzophenone	182.2		aromatic ketone	non-volatile, polar
Methyl stearate	298.5	$CH_3(CH_2)_{16}COOCH_3$	aliphatic ester	non-volatile, polar

[a]Molecular weight in g mol^{-1}

3.2.3.2 Contamination procedure

In the real life, PET bottles would be occasionally contaminated by so-called misuse events, which may be, for instance, that the consumer would store aggressive chemicals in a bottle. The contaminated materials would therefore be PET bottles which are ground into flakes. In our challenge test we use PET flakes for contamination with surrogates to achieve a more efficient contamination effect, e.g. the contamination on flakes is on both sides of the flake material not only on the inner surface of the PET bottle. The preparation of the contaminated PET flakes was carried out using the following procedure:

200 kg of post-consumer PET flakes were contaminated in six batches of 33-34 kg. For this purpose, 34 ml each of the liquid surrogates toluene, chlorobenzene, chloroform, methyl salicylate and phenyl cyclohexane were mixed. To this mixture 34 g of the solid surrogates benzophenone and methyl stearate were given and stirred in order to give a homogenous solution. The batches were stored in a closed steel container for 7 d at 50 °C with periodical agitation. Subsequently the contaminated flakes were rinsed with 10% ethanol and shipped in a sealed steel container to the washing plant.

The contaminated flakes were washed using a 0.6% NaOH solution for 5 min at 85 °C with 0.2% detergents. Subsequently the flakes were rinsed with cold water and air dried at 130 °C for 30 s.

The concentration levels of the surrogates obtained after washing were determined analytically as described in Appendix A. The concentration levels in the contaminated flakes before recycling are called below "initial concentrations".

3.2.3.3 Super-clean recycling process

The recycling of the contaminated PET flakes during the challenge-test was performed with the Linpac process in production plant scale (see Chapter 3.2.1). All relevant process parameters were documented by Linpac. The residence time, temperature and vacuum profiles were close to the Linpac industrial process.

3.2.3.4 Samples from the challenge test

Table 3 gives an overview on type and number of PET samples introduced into and taken from the challenge test. These samples were analysed for the content of surrogates.

Table 3: Overview of PET samples drawn during of the challenge tests

Code	Description	Amount of samples
F	contaminated flakes	18 samples
W	flakes after washing	5 samples
D	flakes after IR dryer	1 sample
D1	flakes after dryer 1	1 sample

3.2.3.5 Determination of surrogate concentrations in PET samples

The surrogate concentrations were determined using an solvent (*iso*-propanol) extraction method which includes swelling of the polymer matrix using 1,1,1,3,3,3-hexafluoro-*iso*-propanol, which is a well-known very aggressive substance for PET. The extracts were analysed using gas chromatography with FID or ECD detection. Each PET sample was analysed in triplicate. The determined concentrations of the surrogates in the PET challenge test samples are reported in Table 4. A more detailed method description including analytical precision data is provided in Annex A and B.

3.2.3.6 Calculation of cleaning efficiencies

The cleaning efficiency of the process for each of the applied surrogates after a given cleaning step, respectively the full recycling process was calculated according to Equation 1.

Eq. 1: $$Cleaning\ efficiency = (1 - \frac{surrogate\ concentration\ after\ recycling}{surrogate\ concentration\ before\ recycling}) 100\%$$

3.2.3.7 Results of the challenge test with regard to PET material cleaning efficiencies

The concentrations of the surrogates established in the PET flakes by the contamination procedure are given in Table 4. One can note a certain scatter of the data which is due to a certain inhomogeneity of flakes and chemicals within the used steel containers. This however is of no relevance because the whole amount of flakes is then introduced into the washing process. The residual concentrations after washing are given in Table 5. As recommended by EFSA, the concentrations of the surrogates after washing were used as the basis for the evaluation of the cleaning efficiencies. The residual concentrations in the challenge test samples are given in Table 5.

Table 4: Concentrations of the surrogates in the challenge test samples

Sample	Concentration [mg/kg]						
	Toluene	Chloroform	Chloro-benzene	Methyl salicylate	Phenyl cyclohexane	Benzophenone	Methyl stearate
contaminated flakes 1.1	330.8 ±1.2	141.0 ±0.5	709.8 ±0.9	912.9 ±3.4	698.7 ±3.1	795.8 ±1.7	952.9 ±3.0
contaminated flakes 1.2	253.5 ±3.0	136.3 ±0.2	590.7 ±3.4	774.1 ±2.8	577.5 ±2.8	677.5 ±2.4	770.1 ±2.4
contaminated flakes 1.3	277.6 ±1.8	138.5 ±0.3	622.2 ±1.9	686.5 ±3.6	522.4 ±2.6	594.8 ±2.7	670.8 ±4.3
contaminated flakes 2.1	230.7 ±2.3	135.5 ±0.2	548.8 ±0.9	575.1 ±0.9	456.6 ±1.3	467.4 ±0.6	547.6 ±0.6
contaminated flakes 2.2	286.6 ±6.0	138.0 ±0.3	627.2 ±3.7	729.8 ±2.1	580.6 ±1.3	621.5 ±1.9	748.4 ±3.5
contaminated flakes 2.3	314.4 ±0.4	140.8 ±0.2	664.8 ±0.2	856.4 ±3.4	655.7 ±0.9	771.6 ±3.1	782.5 ±5.1
contaminated flakes 3.1	363.7 ±1.6	142.7 ±0.2	743.1 ±0.4	896.0 ±3.5	714.3 ±3.0	848.1 ±4.2	795.3 ±5.9
contaminated flakes 3.2	331.7 ±2.7	140.6 ±0.2	697.2 ±1.0	853.7 ±2.4	685.8 ±2.2	784.1 ±2.6	842.6 ±2.6
contaminated flakes 3.3	326.7 ±2.9	140.7 ±0.2	683.6 ±1.0	820.5 ±3.2	628.5 ±2.4	729.5 ±3.3	771.8 ±2.3
contaminated flakes 4.1	320.4 ±4.5	141.1 ±0.2	661.3 ±4.3	853.9 ±7.0	702.7 ±5.5	762.7 ±5.1	785.3 ±5.0
contaminated flakes 4.2	351.8 ±3.3	143.8 ±0.2	714.9 ±0.8	895.9 ±1.1	720.5 ±3.2	789.6 ±2.3	861.3 ±2.5
contaminated flakes 4.3	308.7 ±3.8	140.9 ±0.2	645.8 ±3.8	783.9 ±5.3	615.5 ±4.1	684.2 ±5.4	718.1 ±4.4
contaminated flakes 5.1	365.8 ±5.4	144.3 ±0.2	729.4 ±3.2	987.7 ±7.0	779.4 ±3.5	895.3 ±3.9	940.9 ±2.0
contaminated flakes 5.2	382.5 ±2.5	144.6 ±0.1	765.2 ±4.2	1063.1 ±2.8	863.5 ±3.4	1002.6 ±4.9	1097.4 ±3.9
contaminated flakes 5.3	359.0 ±6.7	143.1 ±0.3	724.8 ±7.4	1001.9 ±13.4	820.4 ±7.7	956.3 ±10.3	1037.6 ±9.0
contaminated flakes 6.1	335.0 ±4.2	141.1 ±0.4	679.7 ±5.3	967.4 ±6.0	843.4 ±5.5	882.8 ±4.6	979.7 ±5.1
contaminated flakes 6.2	364.7 ±1.5	144.1 ±0.2	718.9 ±1.1	998.6 ±2.3	793.7 ±3.4	901.0 ±1.1	960.9 ±2.0
contaminated flakes 6.3	335.7 ±0.9	142.8 ±0.1	683.6 ±0.2	924.6 ±1.1	745.6 ±1.3	822.6 ±1.4	909.6 ±3.1
mean (contaminated flakes)	**324.4 ±40.8**	**141.1 ±2.7**	**678.4 ±55.7**	**865.7 ±123.8**	**689.2 ±111.7**	**777.1 ±134.1**	**842.9 ±137.8**

Table 5: Concentrations of the surrogates in the contaminated after washing (input concentration) and the challenge test samples

Sample (cleaning efficiency)	Concentration [mg/kg]						
	Toluene	Chloroform	Chloro-benzene	Methyl salicylate	Phenyl cyclohexane	Benzophenone	Methyl stearate
washed flake 1	201.6 ±0.9	124.9 ±0.3	326.5 ±0.2	270.0 ±0.9	421.2 ±1.3	464.8 ±1.5	198.9 ±0.5
washed flake 2	184.3 ±1.0	124.1 ±0.5	300.6 ±1.0	206.8 ±1.3	336.6 ±2.2	376.5 ±0.5	171.7 ±0.5
washed flake 3	236.5 ±1.0	130.9 ±0.5	382.6 ±0.5	282.5 ±1.2	443.5 ±1.6	499.0 ±2.9	226.9 ±1.1
washed flake 4	193.1 ±1.0	83.1 ±0.1	310.9 ±1.4	261.5 ±2.3	415.3 ±4.0	475.2 ±4.7	213.9 ±1.6
washed flake 5	202.7 ±0.7	84.6 ±0.1	328.7 ±0.2	252.8 ±0.7	455.2 ±1.5	507.4 ±1.5	225.1 ±0.5
mean (washed flakes)	**203.6 ±19.8**	**109.5 ±23.6**	**329.9 ±31.7**	**254.7 ±28.9**	**414.4 ±46.4**	**464.6 ±52.2**	**207.3 ±22.8**
after IR drier	12.8 ±0.1 (93.7%)	20.9 ±0.1 (80.9%)	27.1 ±0.2 (91.8%)	54.6 ±0.1 (78.6%)	53.5 ±0.1 (87.1%)	225.8 ±0.4 (51.4%)	85.1 ±0.3 (58.9%)
after drier 1	5.0 ±0.1 (97.5%)	8.0 ±0.1 (92.7%)	9.0 ±0.1 (97.3%)	15.8 ±0.1 (93.8%)	23.3 ±0.2 (94.4%)	58.3 ±0.3 (87.5%)	22.1 ±0.1 (89.3%)

3.2.3.8 Cross Contamination

The challenge test was performed with contaminated flakes only. Cross-contamination cannot occur.

3.2.3.9 Results of the challenge test with regard to migration from cleaned PET material obtained in the challenge test

According to the EFSA Scientific opinion "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[7], the maximum migration of compounds from the post-consumer materials should be below of 0.1 µg per kg foodstuff for infants, 0.15 µg/kg for toddlers and 0.75 µg/kg for adults . In addition, the EFSA has defined the maximum contamination level of post-consumer recycles to 3 ppm. Using migration models, the maximum amount of substances of different molecular weights can be calculated using $A_D' = 3.1$ and $\tau = 1577$ K[8]. The maximum concentrations C_{mod} of the applied surrogates were calculated for a food package with 1 l volume and 600 cm^2 surface area ("EU cube") which would correspond to the EFSA migration limit of 0.1 µg/kg (ppb) in the food. The calculation was done for a food with high solubility for the surrogates (partition coefficient $K_{Polymer/food} = 1$).

In the EFSA Opinion[7] the storage conditions was 365 d at 25 °C which was assumed for mineral water applications. In the case of meat trays, however, typical storage conditions are 21 d at 4 °C. The calculations in this study were performed at conditions 30 d at 6 °C. It should be mentioned here, that only the storage conditions were changed compared to the EFSA opinion[7], which means that the exposure scenario is still the same. This means, that an infant of 5 kg body weight consumes 750 g meat.

The applied modeling parameters can be considered as conservative, which overestimates the migration into food. In a recent publication[9] it could be shown from experimental migration kinetics into beverages, that - under non-swelling conditions - the applied $A_D' = 3.1$ is still overestimating the migration. Only for high ethanolic food simulants (e.g. 95% ethanol), $A_D' = 4$ is simulating the migration actually occurring for 95% ethanol. In this case, the ethanolic food simulants is swelling the PET material, which results in a non-linear correlation of the migration versus square root of time because of increasing diffusion coefficients with increasing storage time.

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[7]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 pages)

[8]C. Simoneau (editor). Applicability of generally recognised diffusion models for the estimation of specific migration in support of EU Directive 2002/72/EC. EU report 24514 EN. 2010. ISBN 978-92-79-16586-3.

[9]R. Franz, F. Welle, Migration measurement and modelling from poly(ethylene terephthalate) (PET) into softdrinks and fruit juices in comparison with food simulants, Food Additives and Contaminants, 2008, *25(8)*, 1033-1046

In conclusion, the maximum concentration levels C_{mod} can serve as a reliable indication whether residual contents of surrogates will lead to migration exceeding the 0.1 µg/kg (infants), 0.15 µg/kg (toddlers) or 0.75 µg/kg (adults) criterion or not. In addition, from the calculated residual concentrations in the PET (c_{mod}) the minimum cleaning efficiency can be calculated. The results are visualized in Figure 2 and Figure 3.

As a result the cleaning efficiencies of the Linpac process meet these evaluation criteria up to a recyclate content of the meat trays of 100%.

It should be mentioned here, that the sheet production process has not been challenged within this study. The cleaning efficiency of the sheet production with vacuum degasing has therefore not taken into account. The cleaning efficiency will give an additional safety factor within the evaluation.

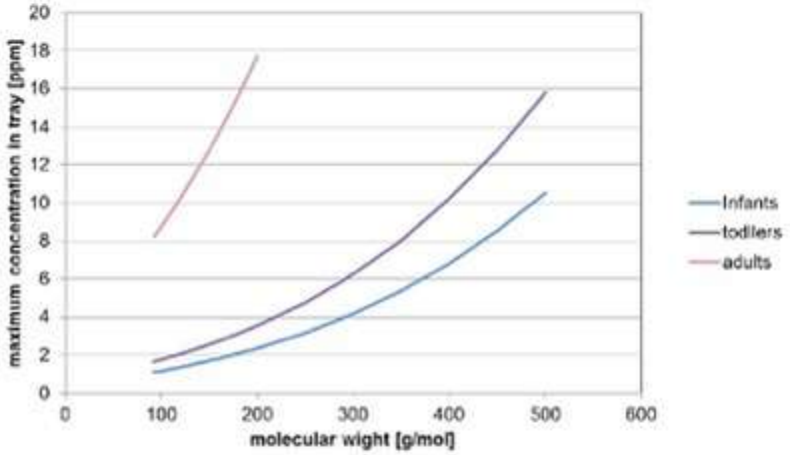

Figure 2: Residual concentrations corresponding to a migration of 0.1 µg/kg of surrogates adjusted to 3 ppm initial concentration, line: maximum concentrations, blue dots: experimental data (C_{res})

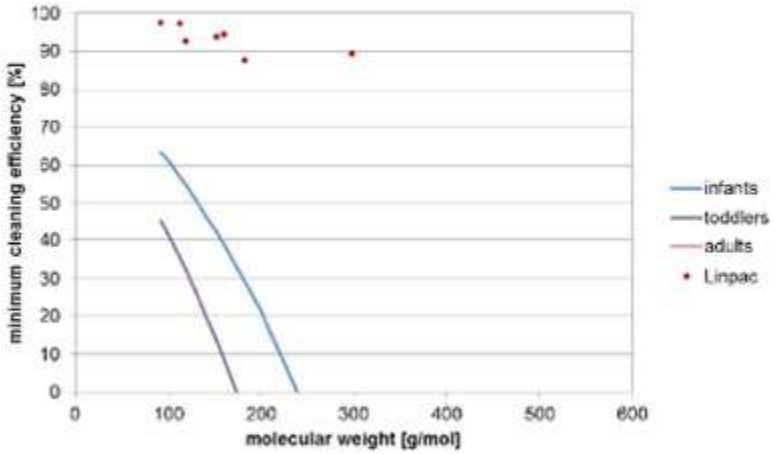

Figure 3: Cleaning efficiencies of surrogates in the challenge test with 100% recyclate (Figure 2), lines: Minimum cleaning efficiency, blue dots: experimental data

Table 6: Maximum residual concentrations $C_{f,0}$ corresponding to a migration limit equal to or smaller than 0.1 ppb estimated from diffusion models (calculated with A_c^{-1} = 3.1), contact conditions: K = 1, sheet wall thickness 300 µm, volume 1 l, surface area 600 cm^2)

Surrogate	molecular weight [g mol^{-1}]	Initial concentration in the challenge test [ppm][a]	Experimental concentrations c_0 [ppm][b] (challenge test)	Cleaning efficiency (exp.)	adjusted final concentration [ppm] to an input concentration of 3 ppm (c_{rel})	modelled concentration [ppm] to a migration of 0.1 ppb (c_{max})[c]	minimum cleaning efficiency (calc.)
Toluene	92	203.6 ±19.8	5.0 ±0.1	97.5%	0.074	1.100	97.34%
Chlorobenzene	113	329.9 ±31.7	9.0 ±0.1	97.3%	0.082	1.300	96.85%
Chloroform	119	109.5 ±23.6	8.0 ±0.1	92.7%	0.219	1.360	96.70%
Methyl salicylate	152	254.7 ±28.9	15.8 ±0.1	93.8%	0.186	1.730	95.81%
Phenyl cyclohexane	160	414.4 ±46.4	23.3 ±0.2	94.4%	0.167	1.830	95.57%
Benzophenone	182	464.6 ±52.2	58.3 ±0.3	87.5%	0.376	2.120	94.87%
Methyl stearate	291	207.3 ±22.8	22.1 ±0.1	89.3%	0.320	3.980	90.33%
fictive substance	400	/	/	/	/	6.810	83.51%
fictive substance	500	/	/	/	/	10.560	74.33%

[a] washed flakes, [b] flake after dryer 1, calculated for a maximum storage time of 30 d at 6 °C

3.2.4 Characterisation of the recycled plastic

The final product of the recycling process was tested typically for the intrinsic viscosity, for black spots and for the colour. These parameters have no direct influence on the suitability of the recycled plastics for direct food contact. However, the intrinsic viscosity due to the fact, that the increase in the intrinsic viscosity is correlation with the decontamination of the post-consumer PET. In addition most of the recyclers are using headspace gas chromatography in order to controlled each batch for volatile organic contaminants. The headspace gas chromatographic method is described in Lit.[10].

3.2.5 Intended application in contact with food

The Linpac recyclate will be used to produce new single use PET trays for fresh food (e.g. meat) with maximum storage conditions of 30 d at 6 °C articles with up to about 100% recyclate content. Thermoforming trays are in general for single use only. PET trays for microwave applications are excluded.

3.2.6 Compliance with the relevant provisions on food contact materials and articles

According to Table 4 the input concentrations for the applied surrogates in the contaminated flakes entering the challenge test were established at concentration levels between 140 ppm and 840 ppm. 200 kg of contaminated material is introduced at the same time into the super-clean recycling process. Such high contamination levels cannot be achieved on a big scale in recollection systems but, if at all, in individual bottles only after misuse by a consumer or, as a worst case, in small population of recollected bottles. From statistical considerations regarding the frequency of return of highly contaminated bottles and the inherent high dilution effect[2] average contamination levels which might be present in the PET feedstream entering the recycling technology must be extremely lower. This was confirmed in a European project FAIR-CT98-4318 "Recyclability"[10] in which we have studied concentration levels occurring in recollected post-consumer PET which was conventionally recycled and which can be typically used for super-clean recycling into new food applications. Typical contamination levels in these recollected PET materials were found to range up to 2.7 ppm for misuse chemicals such as solvents. Only for limonene, a soft drink constituent, higher "contamination" levels up to 20 ppm were found.

Against these findings, when starting with the above mentioned high contamination levels in the input material for the challenge test, the final contamination levels achieved by the Linpac super-clean recycling technology ranged in the 2.2 ppm to 15.2 ppm concentration range. According to Table 4 the cleaning efficiencies meet

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[10] R. Franz, A. Mauer, F. Welle, European Survey on Post-Consumer Poly(ethylene terephthalate) Materials to Determine Contamination Levels and Maximum Consumer Exposure from Food Packages Made from Recycled PET, Food Additives and Contaminants, 2004, *21(3)*, 265-286

the requirements of EFSA criteria[11] assuming a maximum storage time of 30 d at 6 °C.

From the data provided in this dossier we come to the following conclusions:

- The investigated super-clean recycling process is in a position to produce recyclates which are in compliance with Article 3 of the EU Framework Regulation 1935/2004.
- The produced PET recyclate fulfils the requirements for overall migration and specific migration of PET monomers according to EU Directive 2002/72/EC.
- The produced PET recyclate fulfils the requirements of Article 4 of the EU Regulation 282/2008.
- Referring to the attached description of the petitioners quality assurance system (QAS) we conclude also that the investigated super-clean recycling process is in a position to fulfil the requirements of the GMP Regulation (EC) 2023/2006.

3.2.7 Process analysis and evaluation

The crucial parameters of the recycling process are the initial concentration of potential contaminants in the washed flakes before super-clean recycling. In addition residence times of the decontamination reaction, decontamination temperatures as well as the applied vacuum are important for the decontamination process.

The control of possible contamination in the input feedstream and the decontamination during the process includes several steps:

- The first important step is achieved with the recollection system and the characterisation of the input material (see Chapter 3.2.2).
- The two key steps of the recycling process technology which are essential for the decontamination efficiency of the recycling process technology follow. In step 1 efficient surface washing occurs followed by volatilisation effects due to the applied drying conditions.
- Under the temperature (step 2 and 3) and under vacuum (step 4) conditions during the decontamination ~~steps 2 and 3~~ potential contaminants are efficiently removed as long as they are volatile enough. The volatility of potential contaminants corresponds in general with the molecular size. For PET, this leads to an advantageous situation, because PET has a very low diffusivity. Potential contaminants exactly those contaminants which have a potential to enter the PET matrix can be removed again.
- The applied residence times, temperatures and vacuum conditions are essential for the cleaning efficiency. Therefore these parameters are controlled and locked by a data locking system. In the case of failure, the recyclates are not used for direct food contact applications.
- Finally, the increase in the intrinsic viscosity correlates with the decontamination efficiency. Therefore final recyclates would not meet the technically needed intrinsic viscosity (iV) and would not be suitable for being processed into new sheet.

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[11] EFSA 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 pages).

Remark: a correlation between the cleaning efficiency and the intrinsic viscosity during a challenge test is, in principle, not possible because high concentrations of the surrogates influence the intrinsic viscosity of challenge test samples. A proper determined of the intrinsic viscosity is therefore only possible for non-contaminated samples. A literature study shows the general correlation between the temperature, the catalyst concentration and the heating time[12].

[12] Duh B. Effect of antimony catalysts on solid-state polycondensation of poly(ethylene terephthalate), Polymer, 2002, 43, 3147-3154

3.3 Signatures

Fraunhofer Institute
for Process Engineering and Packaging (IVV)

Freising, 12.08.2016

Dr. Roland Franz
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3.4 Glossary

Adventitious contaminants: Any unwanted substance that deliberately or inadvertently comes into contact with the packaging material before it is collected for recycling and that therefore may contaminate the plastic and negatively influence the quality of the product filled by a recycled packaging material.

Challenge test: A test of the effectiveness of a recycling process to remove chemical contamination from materials or articles. The test involves introduction of exaggerated levels of surrogates.

Conventional PET recycling: A recycling procedure using the process steps grinding, washing and surface-drying of re-collected PET containers. The output material of conventional recycling processes are PET materials customary used for non-food or for the core layer of multi-layer applications or for fibers. Conventional recycled PET is usually used as input material for so-called "super-clean" recycling processes.

Extraction: Quantitative dissolution of constituents from a plastic into a solvent based on a strong interaction between plastic and solvent.

Migration: Diffusion-controlled mass transfer from a packaging material or article to food or simulant.

Migrations limits: Food regulatory maximum concentrations of migrants in foodstuffs resulting from a migration process. With respect to the sensitive area of recycled food packaging materials and articles, the legally prescribed overall migration are of much lower relevance and importance than specific migration limits as for instance defined also by a threshold of no concern.

Solid state post-condensation: Heating the PET polymer at temperatures up to about 230 °C under vacuum or inter atmosphere. During heating acid, hydroxyl as well as ester end groups react under elimination of water or low molecular weight alcohols leading to a higher molecular weight polymer. The solid state post-condensation reaction starts at temperatures >180 °C. The intrisic viscosity of the polymer melt (iV) is typically used as the target value of the solid state post condensation reaction.

Super-clean PET recycling: The process uses as a source the output material from conventional recycling, for example washed and surface-dried PET Flakes, and includes one or more additional cleaning steps. The output of "super-clean" processes can be used for packaging applications in direct contact to the foodstuff.

Surrogates: Organic compounds (also known as "model contaminants") of a wide range of chemical types and physical properties representing exaggerated contamination to challenge the safety of recycled materials and articles. Possible application may be as individuals or a test mixture.

Threshold of no concern: A concentration of a migrant in a foodstuff which, from a toxicological point of view, is considered to pose no health risk to the consumer even in case that the chemical structure of the migrant is unknown. As an example the US-

FDA threshold-of-regulation may serve where the threshold, understood as the daily dietary intake, is set at 0.5 ppb (μg kg^{-1} food).

3.5 Appendix A: Experimental details of the Challenge Test

3.5.1 HFIP-extraction of the PET material

Each PET material sample was analysed in the following way: 1.0 g of each PET sample was placed in a 5 ml glass vial. 1.0 ml 1,1,1,3,3,3-hexafluoro-*iso*-propanol (HFIP) was given to the PET material and stored for 1 d at 60 °C in order to swell the PET matrix. Subsequently 3.0 ml *iso*-propanol was added for 1 d at 60 °C to extract the swollen matrix. The extract was decanted from the polymer and stored for 8 h at 4 °C. Then it was decanted again from the precipitate and analyzed by GC/FID and GC/ECD.

3.5.2 GC/FID analysis

The extracts were analysed by gas chromatography with a flame ionisation detector (FID). Quantification was achieved by external calibration using the standard addition method. Parts of a standard solution of the surrogates in *iso*-propanol were added to uncontaminated PET Flakes and were analysed together with the PET samples of the contamination experiments. Gas chromatograph: HP 5890II, column: SE 10 - 30 m - 0.32 mm i.d. - 0.32 µm film thickness, temperature program: 40 °C (5 min), rate 15 °C min^{-1}, 240 °C (15 min), pressure: 50 kPa hydrogen, split: 10 ml min^{-1}. Except chloroform all surrogates were quantified by FID. Only chloroform was quantified using ECD detector. The detection limits of the surrogates are given in Table 7. Calibration curves for low concentrations and high concentrations are given in the Appendix B.

3.5.3 Detection limits

The detection limits of the applied methods are summarized in Table 7. The detection limits were determined according to DIN 32645.

Table 7: Detection limits for the surrogates in the PET material

surrogate	detection limit [mg/kg]
toluene	0.3
chloroform	0.2
chlorobenzene	0.1
phenyl cyclohexane	0.1
benzophenone	0.1
methyl stearate	0.1

3.5.4 Recovery rates

The recovery rates were determined by spiking the non-contaminated reference samples with standard solutions of the applied surrogates before extraction. The results are given in Table 8 to Table 12. The recovery rates are not considered in the experimental data given in Table 4.

Table 8: Recovery rates for the surrogate toluene

sample	spiking level [ppm]	determined concentration [ppm][a]	recovery rate
washed flakes	105.8	97.1 ±5.2	91.8 ±4.9%
washed flakes	105.8	109.5 ±6.2	103.5 ±5.9%
washed flakes	10.6	7.7 ±0.1	72.6 ±0.9%
washed flakes	10.6	6.9 ±0.1	65.1 ±0.9%
super-clean pellets	105.8	109.1 ±0.8	103.1 ±0.8%
super-clean pellets	105.8	104.2 ±4.7	98.5 ±4.4%
super-clean pellets	10.6	7.2 ±0.1	67.9 ±0.9%
super-clean pellets	10.6	6.6 ±0.3	62.3 ±2.8%

[a]mean value and standard deviation from three injections

Table 9: Recovery rates for the surrogate chlorobenzene

sample	spiking level [ppm]	determined concentration [ppm][a]	recovery rate
washed flakes	99.0	91.5 ±5.6	91.6 ±5.6%
washed flakes	99.0	103.0 ±5.9	103.1 ±5.9%
washed flakes	9.9	9.8 ±0.3	98.9 ±3.0%
washed flakes	9.9	9.6 ±1.7	97.0 ±17%
super-clean pellets	99.0	105.5 ±0.8	105.6 ±8.1%
super-clean pellets	99.0	101.4 ±4.6	101.5 ±4.6%
super-clean pellets	9.9	8.8 ±0.1	88.9 ±1.0%
super-clean pellets	9.9	7.5 ±0.8	75.8 ±8.1%

[a]mean value and standard deviation from three injections

Table 10: Recovery rates for the surrogate phenyl cyclohexane

sample	spiking level [ppm]	determined concentration [ppm][a]	recovery rate
washed flakes	101.6	86.7 ±5.5	85.3 ±5.4%
washed flakes	101.6	100.6 ±6.6	99.0 ±6.5%
washed flakes	10.2	9.5 ±0.2	93.1 ±2.0%
washed flakes	10.2	8.9 ±0.4	87.3 ±3.9%
super-clean pellets	101.6	97.0 ±0.9	95.5 ±0.9%
super-clean pellets	101.6	93.5 ±6.2	92.0 ±6.1%
super-clean pellets	10.2	7.9 ±0.1	77.5 ±1.0%
super-clean pellets	10.2	7.1 ±0.6	69.6 ±5.9%

[a]mean value and standard deviation from three injections

Table 11: Recovery rates for the surrogate benzophenone

sample	spiking level [ppm]	determined concentration [ppm][a]	recovery rate
washed flakes	100.2	71.9 ±5.2	71.9 ±5.2%
washed flakes	100.2	86.7 ±5.2	86.7 ±5.2%
washed flakes	10.0	9.1 ±0.2	91.0 ±2.0%
washed flakes	10.0	8.3 ±0.4	83.0 ±4.0%
super-clean pellets	100.2	74.1 ±0.8	74.1 ±0.8%
super-clean pellets	100.2	70.3 ±4.6	70.3 ±4.6%
super-clean pellets	10.0	6.7 ±0.1	67.0 ±1.0%
super-clean pellets	10.0	5.9 ±0.5	59.0 ±5.0%

[a]mean value and standard deviation from three injections

Table 12: Recovery rates for the surrogate methyl stearate

sample	spiking level [ppm]	determined concentration [ppm][x]	recovery rate
washed flakes	99.4	76.2 ±6.0	76.7 ±6.0%
washed flakes	99.4	90.8 ±4.9	91.3 ±4.9
washed flakes	9.9	7.7 ±0.1	77.8 ±1.0%
washed flakes	9.9	8.3 ±0.3	83.8 ±3.0%
super-clean pellets	99.4	70.9 ±1.2	71.3 ±1.2%
super-clean pellets	99.4	69.6 ±1.9	70.0 ±1.9%
super-clean pellets	9.9	5.4 ±0.1	54.5 ±1.0%
super-clean pellets	9.9	5.0 ±0.3	50.5 ±3.0%

[x]mean value and standard deviation from three injections

3.5.5 Migration modelling

In addition to the experimental migration test, a migration model based on diffusion coefficient estimation of organic chemical substances in polymers has been used. The calculation was performed using the MIGRATEST© Lite 2001 (Fabes GmbH, Munich, Germany).

3.6 Appendix B: Calibration curves and gas chromatograms (examples)

3.6.1 Calibration curves and validation data

1) Raw data for calibration curve: Toluene
2) Raw data for calibration curve: Chloroform
3) Raw data for calibration curve: Chlorobenzene for low concentrations
4) Raw data for calibration curve: Chlorobenzene for high concentrations
5) Raw data for calibration curves: Phenyl cyclohexane for low concentrations
6) Raw data for calibration curves: Phenyl cyclohexane for high concentrations
7 Raw data for calibration curves: Methyl salicylate for low concentrations
8) Raw data for calibration curves: Methyl salicylate for high concentrations
9) Raw data for calibration curves: Benzophenone for low concentrations
10) Raw data for calibration curves: Benzophenone for high concentrations
11) Raw data for calibration curves: Methyl stearate for low concentrations
12) Raw data for calibration curves: Methyl stearate for high concentrations

3.6.2 Gas chromatograms of the investigated samples (examples)

13) Gas chromatogram of contaminated flakes (#F6), Detector FID
14) Gas chromatogram of contaminated flakes (#F6), Detector ECD
15) Gas chromatogram of washed flakes (#W3), Detector FID
16) Gas chromatogram of washed flakes (#W3), Detector ECD
17) Gas chromatogram of decontaminated flakes (#D), Detector FID
18) Gas chromatogram of decontaminated flakes (#D), Detector ECD
19) Gas chromatogram of decontaminated flakes (#D1), Detector FID
20) Gas chromatogram of decontaminated flakes (#D1), Detector ECD
21) Gas chromatogram of standard: 0.5 ppm, Detector FID
22) Gas chromatogram of standard: 0.5 ppm, Detector ECD
23) Gas chromatogram of standard: 5 ppm, Detector FID
24) Gas chromatogram of standard: 5 ppm, Detector ECD
25) Gas chromatogram of standard: 50 ppm, Detector FID
26) Gas chromatogram of standard: 50 ppm, Detector ECD
27) Gas chromatogram of standard: 500 ppm, Detector FID
28) Gas chromatogram of standard: 500 ppm, Detector ECD

Annex 3: Challenge test for equipment configurations Y1 and Y2

Estudio de las propiedades del PET reciclado descontaminado y resultados challenge test

Proyecto CIEN CEUS

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20/03/2023

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Contenidos

1. Introducción

El ensayo challenge test tiene como objetivo la demostración de la eficacia de descontaminación de un proceso de reciclado. Básicamente consiste en dopar material con un cóctel de contaminantes representativos de los distintos tipos de sustancias químicas que pueden estar presentes en el input, a una concentración conocida. Posteriormente, se somete el material contaminado al proceso de descontaminación y, por último, se determina la eficacia de descontaminación del mismo, mediante la comparación de la concentración de contaminantes antes y tras el proceso de descontaminación.
Para diseñar el challenge test se dispone de recomendaciones emitidas por los organismos de evaluación de riesgos oficiales en Estados Unidos (FDA)[1], Europa (EFSA)[2] y también se cuenta con un documento emitido por la autoridad francesa AFSSA[3].

El challenge test se plantea de tal forma que simula los niveles máximos de contaminación que cabe esperar del insumo procedente de RSU, es decir, el caso más desfavorable definido. Los challenge test se componen, básicamente, de las siguientes etapas:

- Contaminación (dopado) de PET virgen con un mix de contaminantes conocido
- Sometimiento del material contaminado al proceso de descontaminación
- Evaluación de la capacidad del proceso de descontaminación mediante cuantificación mediante técnicas cromatográficas de los contaminantes conocidos

El objetivo del presente informe es describir la metodología aplicada y los resultados obtenidos en lo relativo a la ejecución de un challenge test a fin de evaluar la eficacia del proceso de descontaminación de la empresa LINPAC para PET reciclado.

2. Metodología

2.1. Materiales

Selección de contaminantes

En primer lugar, si nos apoyamos en la Guía de la FDA para plásticos reciclados, se recomienda seleccionar los contaminantes de la lista mostrada en la Tabla 1, tomando un contaminante de cada categoría.

Tabla 1. Compuestos indicados por la FDA para la contaminación de PET en lo relativo al challenge test.

Volatile Polar Chloroform Chlorobenzene 1,1,1-Trichloroethane Diethyl ketone **Heavy Metal** Copper(II) 2-ethylhexanoate	**Volatile Non-Polar** Toluene **Non-Volatile Polar** Benzophenone Methyl salicylate	**Non-Volatile Non-Polar** Tetracosane Lindane Methyl stearate Phenylcyclohexane 1-Phenyldecane 2,4,6-Trichloroanisole

[1] FDA, Food and Drug Administration, 2021: Use of Recycled Plastics in Food Packaging: Chemistry Considerations, Division of Food Contact Notifications HFS-275, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740

[2] EFSA, 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.

[3] AFSSA, 2006. Evaluation sanitaire des "matériaux en poly(éthylène téréphtalate) recyclés [...]».

Por otro lado, en Europa, la EFSA especifica que los contaminantes han de abarcar distintos pesos moleculares y polaridades representativos de los contaminantes preocupantes típicos que pueden encontrarse en el PET posconsumo. En cuanto a la elección de tales sustancias, no propone ningún tipo de cóctel en particular, sino que cita la guía de plásticos reciclados de la FDA y un artículo científico.

A modo de ejemplo, se muestran algunas imágenes (**Erreur ! Source du renvoi introuvable.**, Figura 2 y Figura 3) que son extractos de opiniones científicas emitidas por la EFSA, relativas a tablas de resultados de eficacia de descontaminación de diferentes procesos de reciclado mecánico de PET basados en las tecnologías Starlinger iV+[4], EREMA[5] y SUPER CLEAN[6]. Dichas imágenes muestran cócteles típicos de contaminantes utilizados por distintas empresas que han llevado a cabo ensayos de challenge para la tramitación de las correspondientes solicitudes de evaluación de los procesos de reciclado mecánico de PET con los que trabajan.

Decontamination efficiency from the challenge test, residual concentrations of the surrogates in the recycled PET (C_{res}) and calculated concentrations of the surrogates in PET (C_{mod}) corresponding to a modelled migration of 0.1 µg/kg food after 1 year at 25°C

Surrogates	Decontamination efficiency (%)	C_{res} for 100% rPET (mg/kg PET)	C_{mod} (mg/kg PET)
Toluene	> 99.9	< 0.003	0.09
Chloroform	> 99.9	< 0.003	0.10
Phenylcyclohexane	> 99.9	< 0.003	0.14
Benzophenone	98.4	0.048	0.16
Lindane	90.9	0.273	0.31

PET: poly(ethylene terephthalate); rPET: recycled poly(ethylene terephthalate).

Figura 1. Imagen extracto de una opinión científica emitida por la EFSA relativa a la tabla de resultados de eficacia de descontaminación de un proceso de reciclado mecánico de PET basado en la tecnología Starlinger iV+.

SC = Initial concentration (mg/kg) in the contaminated PET
DC = Residual concentration in green flakes (mg/kg) after decontamination, for the residence time (t) indicated.
DE = Decontamination efficiency (%) of the step 2 reactor in the challenge test for the residence time indicated and after correction for cross-contamination (see text).

Surrogates	SC	DC t1*	DE %	DC t2*	DE %	DC t3*	DE %	DC t4*	DE %	DC t5*	DE %	DC t6*	DE %	DC t7*	DE %
Toluene	202	0.87	97.3	0.62	97.7	0.12	98.1	0.40	98.4	0.31	98.6	0.24	98.8	0.14	99.2
Chlorobenzene	561	1.60	97.7	1.25	97.8	0.97	98.0	0.76	98.3	0.59	98.5	0.47	98.7	0.29	99.1
Chloroform	293	0.99	97.8	0.78	98.1	0.61	98.4	0.48	98.6	0.38	98.8	0.30	99.0	0.19	99.2
Methyl salicylate	143	2.24	90.0	1.73	91.0	1.33	92.0	1.03	94.0	0.79	95.0	0.63	95.7	0.37	98.9
Phenylcyclohexane	564	3.96	93.1	3.51	93.7	2.77	94.3	2.31	94.7	1.93	95.2	1.64	97.8	1.15	98.3
Benzophenone	480	7.96	89.4	6.52	90.3	5.34	91.0	4.37	92.4	3.58	93.2	2.99	93.8	2.03	95.1
Methyl stearate	160	3.63	91.4	2.84	94.1	2.30	93.0	1.93	95.0	1.37	96.0	1.30	96.1	0.81	97.2

(*): t1= t2 + t3 + t4 + t5 + t6 + t7

Figura 2. Imagen extracto de una opinión científica emitida por la EFSA relativa a la tabla de resultados de eficacia de descontaminación de un proceso de reciclado mecánico de PET basado en la tecnología EREMA.

[4] Safety assessment of the process Estremadura Torrepet, based on the Starlinger iV+ technology, used to recycle post-consumer PET into Food contact materials; *EFSA Journal* 2022; 20(7): 7388

[5] Scientific Opinion on the safety evaluation of the following processes based on EREMA Basic technology used to recycle post-consumer PET into food contact materials "Octal", "Pregis", "Saberf", "Linpac", "ExtruPET", "Evertis", "Holdfeld", "Huhtamaki", "Sneicore", and "Re-PET". *EFSA Journal 2013*; 11(11): 3462

[6] Safety assessment of the process "Linpac", based on Linpac super clean technology, used to recycled post-consumer PET into food contact materials. *EFSA Journal. 2018*; 16(7): 5323

Surrogates	Concentration of surrogates before step 2 (mg/kg PET)	Concentration of surrogates after step 3 (mg/kg PET)	Decontamination efficiency (%)
Toluene	203.6 ± 19.8	5.0 ± 0.1	97.5
Chlorobenzene	329.9 ± 31.7	9.0 ± 0.1	97.3
Chloroform	109.5 ± 23.6	8.0 ± 0.1	92.7
Methyl salicylate	254.7 ± 28.9	15.8 ± 0.1	93.8
Phenylcyclohexane	414.4 ± 46.4	23.3 ± 0.2	94.4
Benzophenone	464.6 ± 52.2	58.3 ± 0.3	87.5
Methyl stearate	207.3 ± 22.8	22.1 ± 0.1	89.3

PET: poly(ethylene terephthalate).

Figura 3. Imagen extracto de una opinión científica emitida por la EFSA relativa a la tabla de resultados de eficacia de descontaminación de un proceso de reciclado mecánico de PET basado en la tecnología SUPER CLEAN.

Basándonos en la información analizada y expuesta más arriba, se seleccionó el siguiente cóctel de contaminantes, que recoge al menos un compuesto de cada categoría (según volatilidad y polaridad) de los indicados por la FDA (Tabla 2).

Tabla 2. Compuestos seleccionados para la contaminación del PET: V NP (volátil no polar), V P (volátil polar), NV NP (no volátil no polar), NV P (no volátil polar).

Compuesto	Categoría	PM (g/mol)
Tolueno	V NP	92
Clorobenceno	V P	112,56
Cloroformo	V P	119,38
Metilsalicilato	NV P	152,15
Fenilciclohexano	NV NP	160
Benzofenona	NV P	182
Metil estearato	NV NP	298,51

En cuanto a la concentración de cada contaminante, se estableció un valor objetivo de 500 mg contaminante/kg PET para, de esta manera, poder estar en el rango de 250 – 1000 mg/kg conforme con lo dispuesto en la guía de referencia publicada por la EFSA[2].

En cuanto a la cantidad de material a contaminar, de acuerdo con la bibliografía consultada, para evaluar la eficacia de procesos industriales se puede diluir el material dopado con material virgen en una ratio 1:20 aproximadamente. De este modo, para aquellos procesos que requieran un mínimo de 1.000 kg de material (siendo el caso de LINPAC), sería necesario dopar 50 kg de material.

2.2. Experimental

2.2.1. Contaminación de escamas

Una vez identificadas las condiciones de contaminación más favorables, se procedió a la puesta a punto del proceso de contaminación a escala piloto. Para ello, se introdujo un total de 5kg de escamas dentro de un reactor de vidrio Radleys con camisa de 10L de capacidad. Seguidamente se introducen los distintos contaminantes partiendo de las condiciones de dopado 3, se añaden unos 8,3L de heptano y se deja con agitación mecánica continua 1 día a 70 °C. Transcurridas 24 horas las escamas se lavan con etanol al 10 % (v/v) para retirar la contaminación superficial y se determina el contenido de los distintos contaminantes.

Dado que se requería un total de 50 kg de escamas contaminadas, se contaminaron lotes de aproximadamente 5 kg de escamas hasta llegar a la cantidad especificada. Cada lote de escamas contaminadas fue envasado en vacío y almacenado en congelación hasta que tuvo lugar el envío. En paralelo, se tomó muestra de cada uno de los lotes, nada más obtenidos, para verificar que el nivel de contaminantes alcanzado era conforme al objetivo, alrededor de los 500 mg/kg.

Una vez contaminados los 50 kg de escamas, estas fueron mezcladas, envasadas a vacío en dos sacos alta barrera e introducidas en dos bidones metálicos respectivamente. Se tomó muestra de las escamas en este momento para verificar el nivel de contaminantes tras homogeneizar todos los lotes y previo a la expedición. Además, se tomaron muestras que fueron envasadas a vacío en alta barrera y guardadas en ITENE en condiciones que simulan el transporte hasta las instalaciones de LINPAC.

Seguidamente, los dos bidones conteniendo en suma 50 kg de escamas fueron enviados a las instalaciones de LINPAC mediante transporte urgente refrigerado.

Una vez en las instalaciones de LINPAC, justo antes de someter las escamas al proceso de descontaminación, se informó a ITENE para analizar la concentración de contaminantes presente en las escamas. Esta concentración fue tomada como punto cero, para realizar el cálculo de la eficacia de descontaminación.

2.2.2. Descontaminación de escamas

Para descontaminar las escamas se ha utilizado un proceso de extrusión de doble husillo co-rotante de la casa Bandera con bombas de vacío según el siguiente esquema de temperaturas y con dos zonas de vacío, dosificando el material contaminado en una proporción del 25%:

Tabla 3. Condiciones de temperatura y vacío del proceso de descontaminación.

Zona	1	2	3	4	5	6	7
Vacío			92mbar	101mbar			
Temperatura	280°C	270°C	265°C	265°C	265°C	270°C	270°C

El tiempo medio de residencia del material en el husillo calefactado es de 7 minutos.

Tras el proceso de descontaminación se obtuvieron láminas con el material rPET descontaminado con un espesor de 500 micras. Estas muestras se identificaron como M2.

2.2.3. Cuantificación de contaminantes en los materiales

El contenido de contaminantes en las muestras (tanto escamas como en las láminas) se llevó a cabo mediante extracción con solventes. Para ello se pesaron aproximadamente 30 gramos de material y se sometieron a extracción Soxhlet durante 15 horas a 85 – 100°C, utilizando 200 ml de diclorometano como disolvente de extracción. Una vez finalizada la extracción, se tomó 1 ml de extracto, se filtró mediante filtro de 0,22 µm y se analizó mediante cromatografía gaseosa con detector masas marca Agilent (GC modelo 7890B y detector MS modelo 5977B MSD) equipado con columna HP-5MS 30 m x 0,25 mm x 0,25 µm. Cada uno de los contaminantes fue cuantificado mediante calibrado externo.

2.2.4. Evaluación de la eficacia de la descontaminación

El cálculo de la eficacia de descontaminación se realizó mediante comparación de la concentración de contaminante en el material contaminado, que se dosificó en una proporción del 25%, antes y después de pasar por el proceso de descontaminación. En este sentido, como punto de partida se tomó la concentración de contaminante justo antes de que el material contaminado fuera sometido al proceso de descontaminación. El punto final fue tomado una vez obtenida la lámina, fabricada a partir del material descontaminado.

En el cálculo se consideró únicamente a la muestra M2, dado que consiste en un 100% de material reciclado (y descontaminado), mientras que la muestra M1 contiene un 20% de material virgen sin contaminar, lo cual tiene un efecto de dilución y podría llevar a la sobreestimación de la eficacia de descontaminación.

Adicionalmente, se realizaron ensayos de migración específica de contaminantes desde las láminas hacia los simulantes alimentarios que cubren el contacto con todo tipo de alimentos, A (etanol 10% (v/v)), B (ácido acético 3 % (p/v)) y D2 (se han empleado los simulantes alternativos grasos etanol 95 % (v/v) e isooctano).

Las condiciones de ensayo seleccionadas fueron 10 días a 60 °C, que cubren el almacenamiento durante más 6 meses a temperatura ambiente e inferior, incluidas las condiciones de llenado en caliente o el calentamiento hasta 70 °C ≤ T ≤ 100 °C durante un máximo de t = 120/2 ^ [(T – 70) /10] minutos.

El ensayo tuvo lugar mediante celda, donde únicamente la cara de contacto con el alimento fue expuesta al simulante.

La superficie de material expuesta al simulante fue de 0,5 dm^2 y el volumen de simulante empleado fue de 83 ml.

Una vez finalizada la etapa de contacto material – simulante en las condiciones tiempo - temperatura fijadas, el extracto de migración fue recogido y se determinó la concentración de cada uno de los contaminantes añadidos a las escamas durante la etapa de contaminación del challenge test mediante la metodología de análisis descrita en párrafos anteriores.

3. Resultados

3.1. Contaminación

La concentración de cada uno de los contaminantes optimizada en el cóctel tras la realización de diferentes pruebas de contaminación se presenta en la Tabla 4.

Tabla 4. Concentración optimizada para cada contaminante en el cóctel.

Compuesto	Categoría	mg/kg PET
Tolueno	V NP	30.000
Clorobenceno	V P	17.000
Metilsalicilato	NV P	7.000
Fenilciclohexano	NV NP	20.000
Benzofenona	NV P	6000
Metil estearato	NV NP	1.500

Los resultados obtenidos en la contaminación de los distintos lotes de 5kg se presenta en la siguiente figura en forma de promedio, observándose, en todos los casos, valores dentro de los límites recomendados por la EFSA.

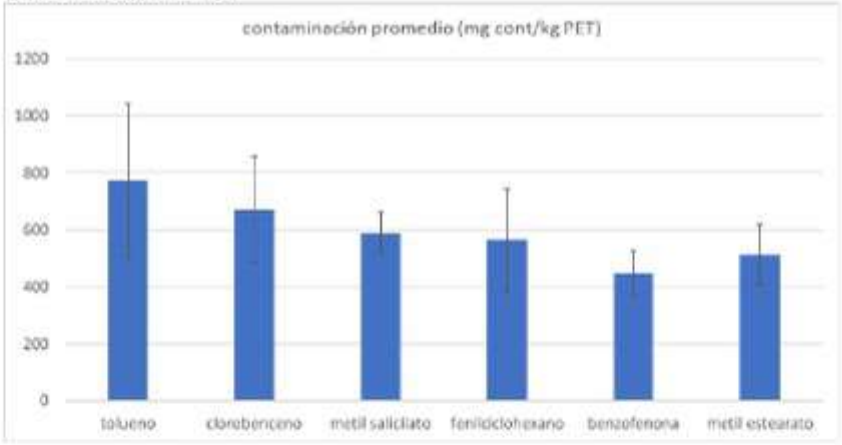

Figura 4. Contaminación promedio de los distintos compuestos presentes en los 50kg de escamas de rPET contaminadas.

3.2. Descontaminación

En primer lugar, en la Tabla 5, se muestran los datos de contenido de contaminantes en las escamas de PET tras ser homogeneizadas y justo antes de enviarlas a las instalaciones de LINPAC, y en el punto cero, es decir, en el momento previo a ser incorporadas al proceso de descontaminación.

Tabla 5. Concentración de contaminantes en las escamas, justo antes de la expedición y en el momento previo a la descontaminación, en mg/kg PET. Valores promedio y desviación estándar.

Contaminante	Previo a la expedición (mg/kg PET)	Previo a la descontaminación (punto cero) (mg/kg PET)
tolueno	602,1 ± 12,5	579,2 ± 42,9
clorobenceno	583,4 ± 5,9	562,9 ± 41,2
metil salicilato	592,5 ± 9,4	585,8 ± 27,7
fenilciclohexano	457,5 ± 6,3	436,5 ± 17,3
benzofenona	449,6 ± 3,4	420,3 ± 22,3
metil estearato	469,8 ± 20,5	422,7 ± 38,1

La Tabla 6 muestra las concentraciones de cada uno de los contaminantes en las láminas fabricadas a partir de las escamas descontaminadas.

Tabla 6. Concentración de contaminantes en las láminas M2 en mg/kg PET. Valores promedio y desviación estándar.

Contaminante	M2 (mg/kg PET)
tolueno	8,3 ± 0,2
clorobenceno	9,7 ± 0,2
metil salicilato	6,7*
fenilciclohexano	8,6 ± 0,3
benzofenona	36,4 ± 2,4
metil estearato	30,7 ± 0,6

*LOQ= 6,7 mg/kg

La Tabla 7 presenta el resultado de la eficacia de descontaminación del proceso de reciclado, basado en la concentración de contaminantes medida antes y después de someter las muestras a dicho proceso.

Tabla 7. Eficacia de descontaminación del proceso, expresado como porcentaje.

Contaminante	Eficacia descontaminación (%)
tolueno	94,3%
clorobenceno	93,1%
metil salicilato	95,4%
fenilciclohexano	92,1%
benzofenona	65,4%
metil estearato	70,9%

En cuanto a los ensayos de migración específica, los resultados del ensayo se muestran en la Tabla 8. Como se puede observar, en todos los casos, excepto en el clorobenceno en etanol 95% (v/v), la migración de los contaminantes es inferior al límite de cuantificación de la técnica.

Tabla 8. Migración específica de los contaminantes en distintos simulantes alimentarios para las muestras de láminas M2 (mg sustancia/kg simulante).

Contaminante	Simulante A (mg/kg)	Simulante B (mg/kg)	Etanol 95 % (v/v) (Simulante D2) (mg/kg)	Isooctano (Simulante D2) (mg/kg)
tolueno	< 0,05	< 0,5	< 0,05	< 0,5
clorobenceno	< 0,01	< 0,05	1,3 ± 0,3	< 0,01
metil salicilato	< 0,5	< 0,01	< 0,01	< 0,01
fenilciclohexano	< 0,05	< 0,1	< 0,01	< 0,01
benzofenona	< 0,5	< 0,5	< 0,1	< 0,05
metil estearato	< 0,5	< 0,5	< 0,1	< 0,1

4. Conclusiones

En este paquete de trabajo se han llevado a cabo un ensayo de desafío o challenge test. A continuación, se resumen las tareas específicas llevadas a cabo y las principales conclusiones alcanzadas:

- Puesta a punto de la metodología de contaminación de escamas de PET:
  - Se ha llevado a cabo la selección de un cóctel de contaminantes representativos de distintos pesos moleculares y polaridades, y utilizados con frecuencia en los ensayos de challenge presentados en las solicitudes a la EFSA: tolueno, clorobenceno, metil salicilato, fenilciclohexano, benzofenona y metil estearato.
  - Se ha seleccionado la concentración de cada uno de los contaminantes en el cóctel a fin de conseguir valores dentro de los recomendados por la EFSA (250-1000 mg/kg PET).
  - Se han seleccionado las condiciones de contaminación (tiempo – temperatura): 24 horas a 70 °C.

- Contaminación de escamas de PET por lotes, hasta alcanzar los 50 kg requeridos para el proceso de descontaminación en las instalaciones de LINPAC.
- Descontaminación de las escamas de PET contaminadas artificialmente en las instalaciones de LINPAC.
- Determinación de la eficacia de descontaminación de las escamas, donde se observó una elevada eficacia de descontaminación, que va desde un 95,4% de eficacia obtenida para el metil salicilato, hasta un 65,4% obtenida para la benzofenona.

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Annex 4: List of consortium members

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SODE S.A.	SODE S.A.	Pol. Ind. Asteasu Zona a NP10	20159	Asteasu	Spain	Roberto Mendizabal	rmendizabal@sodesa.es	FUNCTIONAL BARRIER	3
SZP Advanced Packaging Products Ltd	Ismail	N'yam 1	2280600	Shoam Zion,	Ismail	David Tesicher	david@szp.co.il	FUNCTIONAL BARRIER	2
Thermodynamix Thermoforming Specialist Services Limited t/a "TDX" t/a AMB Packaging	Unit 3	3 Princes Park, Princeway North, Gateshead, Tyne & Wear, NE11 0NF	NE11 0NF	Gateshead	United Kingdom	Mark Prinn	markprinn@ambpackaging.com	FUNCTIONAL BARRIER	3
Thermodynamix Thermoforming Specialist Services Limited t/a "TDX" t/a AMB Packaging	Unit 10	10 Princes Park Team Valley Trading Estate, Gateshead, Tyne & Wear,NE11 0TY	NE11 0TY	Gateshead	United Kingdom	Mark Prinn	markprinn@ambpackaging.com	FUNCTIONAL BARRIER	3
Viplast AD	Facility 1	Yagodinovo shose	4113	Yagodovo	Bulgaria	Rosen Petrov	r.petrov@viplast.bg	FUNCTIONAL BARRIER	2
Drava International	Brijest	Zapadno predgrađe 21	31000	Osijek	Croatia	Vanja Biro	vanja.biro@drava-international.hr	FUNCTIONAL BARRIER	6
ECOLOGIA, RECICLAJE Y MEDIOAMBIENTE, S.A.		Barrio Sorabilla S/N	20140	Andoain	Spain	Mikel Urain	urain@ekorec.net	FUNCTIONAL BARRIER	2
ELİTPAK AMBALAJ VE URETİM SANAYİ VE TİC LTD STİ	GEBZE	İÇNÜ MAH.BALCIK YOLU UZERİ GEBZE PASTACILER OSB GAPOSB 2. CADDE 11 SOKAK NO 10 GEBZE	41400	Kocaeli	Turkey	Mehmet Ali Sahin	mas@elitpakambalaj.com	FUNCTIONAL BARRIER	1
ENVALIA 2001,S.L.U	ENVALIA 2001,S.L.U	c/Sabadell nº7	08503	GURB	SPAIN	Jordi Monera	jmonera@casatarradella.es	FUNCTIONAL BARRIER	1
ENVAPLASTER S.A.	VIANA	P.I. LA ALBERGUERIA, STREET JAVIER INDAVE 3	31230	VIANA	SPAIN	JORGE SAN JUAN	jorge.sanjuan@envaplaster.com;	FUNCTIONAL BARRIER	3
FABTOM Sp. z o. o.	Production facility 2: PET film manufacturing plant	ul. Sportowa 5	26-700	Zwoleń	POLAND	Marta Drab	marta.drab@fabtom.eu	FUNCTIONAL BARRIER	4
Folienwerk Wolfen GmbH		Guardianstrasse 4	06766	Bitterfeld-Wolfen	Germany	Thomas Olszowy	thomas.olszowy@folienwerk-wolfen.de	FUNCTIONAL BARRIER	6
ITALEXTRUSION SRL	LOCATION OR SUBSIDIARY 2	VIA BELLINGHIERA 52	35019	TOMBOLO	ITALY	ALICE ANTONELLO	quality2@hotform.it	FUNCTIONAL BARRIER	2
Jaun Neoform GmbH		Gutenbergstrasse 2	72810	Gomaringen	Germany	EP Jaun	kp.jaun@jaun-neoform.de	FUNCTIONAL BARRIER	1
krumbeck Kunstoffverarbeitung GmbH		Von-Ardenne-Str 44	48703	Stadtlohn	Germany	Thomas Krumbeck	t.krumbeck@krumbeck-kunstoff.de	FUNCTIONAL BARRIER	6
New Packaging Group	Meulendijks verpakkingen	Lagedijk 33	5705 BK	Helmond	Netherlands	Ad Ooms	a.ooms@nedupack.nl	FUNCTIONAL BARRIER	1
PAL PACKAGING PALAMIDIS SA	KIFISIA GREECE	9 IGOSON STR 14564 KIFISIA GREECE	14564	KIFISIA	GREECE	MARY KRAFA	mkrafa@pal.gr	FUNCTIONAL BARRIER	1
Plastsavio S.p.A.	Plastsavio S.p.A.	Via della liberazione, 36	47025	Mercato Saraceno	Italia	Maria Chiara Abbondanza	mariachiara.abbondanza@plastsavio.it	FUNCTIONAL BARRIER	2
POLISUR 2000 SL		Finca las Majadillas Cno N444, Km 2,95	21840	Lepe (Huelva)	Spain	Armenio Guerrero,Jose Antonio Ramirez	armenio@polisur.es	FUNCTIONAL BARRIER	2
PRAGMAGEST SPA	PRAGMAGEST SPA	VIA NEWTON, 21	47025	MERCATO SARACENO	ITALY	SONIA CORTESI	s.cortesi@pragmagest.it	FUNCTIONAL BARRIER	1
Roboplast Srl		Via I Maggio, 7	12010	Vignolo	Italia	Paolo Clot	paolo.clot@roboplast.com	FUNCTIONAL BARRIER	3
twin pack spa	Ragusa	Zona Industriale 3 fase Viale 21 n.1	97100	Ragusa	Italy	Giovanna Amore	twinpackspa@gmail.com	FUNCTIONAL BARRIER	2

Annex 5: Examples of migration tests

CHELAB S.R.L.

TEST REPORT N. 21/000393703

date of issue 25/08/2021

Customer ID [redacted]

Messrs [redacted]

Sample information

Acceptance number 21.520614.0001

Delivered by [redacted]

Receiving Date 14/06/2021

Place of origin [redacted]

Sample Description [redacted]

Sampling information

Sampled by Customer

CHELAB S.r.l. Socio Unico, Company subject to the direction and coordination of Mérieux NutriSciences Corporation

Head office: Via Fratta 25 31023 Resana, Italy Phone. + 39 0423.7177 / Fax + 39 0423.715058 www.merieuxnutrisciences.it

VAT nr. 01500900269, R.E.A Treviso n. 156079 Fully paid up € 103.480,00.

ANALYTICAL RESULTS

	Value/ Uncertainty	Unit of measure	LoQ	LoD	Start/end date of analysis	Op. units	Row
ON SAMPLE AS IT IS							1
SEMIVOLATILE AND VOLATILE ORGANIC COMPOUNDS Met.: AR 2012/075/A-CAP.1	see attachment 1				14/06/2021--04/08/2021	02	2
EXTRACTIVE WASHING APPROACH							3
SEMIVOLATILE AND NOT VOLATILE ORGANIC COMPOUNDS Met.: AR 2011/216/A-CAP.3	see attachment 1				24/06/2021--04/08/2021	02	4
NOT VOLATILE ORGANIC COMPOUNDS Met.: AR 2016/235/B-CAP.5	see attachment 1				24/06/2021--04/08/2021	02	5

Operative units

Unit 02 : Via Castellana Resana (TV)

Additional information.

Information provided by the client

Sampled by: Customer
Place of origin: [redacted]
Description: [redacted]

Chemical responsible

Dott. Enrico Nieddu

Chimico
Ordine dei Chimici e dei Fisici- Provincia di Treviso
Iscrizione n. A339

Num. certificato 21005119 emesso dall'ente certificatore ArubaPEC S.p.A. NG CA 3, ArubaPEC S.p.A., IT

Chemical responsible

Dott.ssa Barbara Scantamburlo

Chimico
Ordine dei Chimici e dei Fisici - Provincia di Treviso
Iscrizione n. A351

Num. certificato 21005078 emesso dall'ente certificatore ArubaPEC S.p.A. NG CA 3, ArubaPEC S.p.A., IT

- If not otherwise specified, the uncertainty is extended and has been calculated with a coverage factor k=2 corresponding to a probability interval of about 95%. - LoD is the detection limit and identifies a confidence interval of zero with a probabilty interval of about 99%. - LoQ is the limit of quantification."n.d" is not detected and indicates a value inferior to the LoD. "traces (X)" means a value between LoD and LoQ, this value is indicative. "<x" or ">x" indicate inferior or superior to the measurement field of the test. - If not differently specified, the sums are calculated by lower bound criteria (L.B.). - In case of alteration of the sample the laboratory declines any responsibility on the results that can be influenced by the deviation in case the customer asks for the execution of the test anyway. - If the sampling is not carried out by the laboratory staff, the results obtained are considered referring to the sample as received and the laboratory declines its responsibility for the results calculated considering the sampling data provided by the Customer. The name and contact information of the Customer are always provided by the Customer. - If there is a specification (customer specifications, law limits) which has been compared to the analytical results, the values shown in bold indicate a result which is out of the specification. - If not differently specified the judgments of compliance /non-compliance eventually reported are referred to analysed parameters and are based on the comparison of the value with the reference values without considering the confidence interval of measure.

END OF TEST REPORT

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CHELAB S.R.L.

REPORT NO. 1 ANNEX TO TEST REPORT 21/000393703

SCREENING OF VOLATILE, SEMI-VOLATILE AND NON-VOLATILE ORGANIC COMPOUNDS IN FOOD CONTACT MATERIALS

Sample Information:

ID Sample: 21.520614.0001

Sample Description: [redacted]

Picture

TABLE OF CONTENTS

1. AIM OF THE SCREENING TEST

Screening tests allow the identification of potential substances which can migrate into the food product as Intentionally Added (IAS) and Not Intentionally Added (NIAS) molecules.

In this context, the best mass spectrometry tools available are employed, along with different chromatography techniques.

The study is divided into three levels:

A. Determination of volatile and semi-volatile organic compounds on sample as it is: dynamic headspace gas chromatography (SPME-HS-GC/MS) – method AR 2012/075/A

This test evaluates the presence of volatile and semi-volatiles organic compounds in the material which could migrate and/or cause sensory changes in the food contained in the packaging. The identification is carried out through instrumental sets, while the semi-quantification is performed using the reaction factor of the internal standard used.

B. Determination of semi-volatile and non-volatile organic compounds on the extraction liquid from the side intended to come into contact with food: gas chromatography with mass detector (GC/MS) – method AR 2011/216/A-CAP.3

This analysis evaluates the presence of semi-volatile and non-volatile organic compounds which could migrate into the food product. The identification is carried out through instrumental libraries, while the semi-quantification is performed using the response factor of the internal standard used.

C. Determination of non-volatile organic compounds: multi-item screening by liquid chromatography equipped with high-resolution mass detector (UHPLC ESI-MS/HRMS) – method AR 2016/235/B-CAP.1

This analysis evaluates the presence of a wide range of non-volatile organic compounds in the package, which could migrate into the food product through:

GROUP 1: Quantitative Target Screening (the organic compounds are identified and quantified by comparing them with certified standard solutions).

GROUP 2: Semi-quantitative Target Screening (by comparison with an instrument library containing more than one thousand additives commonly used in the packaging industry).

2. RESULTS AND EVALUATION

For each analysis category, the results obtained are compared with any legal limits, and coded based on their severity. A different code is assigned according to evaluation.

A *green code* is assigned to the following organic compounds:

- for which a legal limit exists (SML) and whose semi-quantitative analysis value is significantly lower than specific migration limit;
- present in positive list of Reg. 10/2011, but without a specific migration limit (if the value of the semi-quantitative analysis is significantly lower than 60 mg/kg).

A *red code* is assigned to those substances for which a legal limit exists, and whose semi-quantitative analysis value exceeds the specific migration limit.

A *yellow code* is assigned to all semi-quantified substances not belonging to the two categories above and require further assessment (e.g. compounds not included in the positive list). To evaluate the compliance with the legislation further investigation could be necessary, as bibliographic research, possible severity assessment by ToxTree software and quantitative target test, with certified standards, on specific migration with food simulants.

2.1 VOLATILE AND SEMI-VOLATILE ORGANIC COMPOUNDS

INSTRUMENT		
	Gas Chromatograph	Shimadzu
	Mass Spectrometer	Shimadzu
	Chromatographic Column	HP-5ms
	Extraction	SPME-HS
TEST CONDITIONS		
	Range of mass acquisition	m/z 35÷400
	Internal Standard	1,4-bromofluorobenzene
PERFORMANCES		
	Sensibility	0.2 µg/dm^2
IDENTIFICATION OF COMPOUNDS		
	Library	NIST/EPA/NIH Mass Spectral Library
IDENTIFICATION CRITERIA		
	Match Quality > 90	Good
	Match Quality tra 80-90	Acceptable
	Match Quality < 80	Unknown

Table 1 – Semi-quantitative distribution of volatile and semi-volatile organic compounds

Retention time	CAS	compound	Match quality	Concentration with reference to internal standard	Potential specific migration[1]	SML Reg. 10/2011	Evaluation
min				µg/dm²	mg/kg food	mg/kg food	
13.98	124-19-6	Nonanal	98	0.249	0.001	Not listed	
19.87	112-31-2	Decanal	97	0.522	0.003	Not listed	

Potential odour impact:

No significant concentration of sensorial active volatiles and semi-volatiles organic compounds has been detected.

[1] **mg/kg** $_{food}$ have been obtained considering the conventional ratio 6 dm^2/1 kg_{food}

2.2 SEMI-VOLATILE AND NON-VOLATILE ORGANIC COMPOUNDS

INSTRUMENT		
	Gas Chromatograph	Agilent
	Mass Spectrometer	Agilent
	Chromatographic Column	HP5-MS
TEST CONDITIONS		
	Range of mass acquisition	m/z 50÷1000
	Internal Standard 1 (quantification)	4,4-difluorbiphenyl
	Internal Standard 2 (LoQ)	Methylmargarate
EXTRACTION CONDITIONS		
	Extraction Solvent	Hexane/Ethanol 3/1
	Type of contact	Cell
	Contact surface	1.02 dm^2
	Contact Volume	50 mL
	Time and temperature of contact	8 hours at 20°C
PERFORMANCES		
	Sensibility	0.010 mg/kg
IDENTIFICATION OF COMPOUNDS		
	Library	NIST/EPA/NIH Mass Spectral Library
IDENTIFICATION CRITERIA		
	Match Quality > 90	Good
	Match Quality tra 80-90	Acceptable
	Match Quality < 80	Unknown

Table 2 – Semi-quantitative distribution of semi-volatile and non-volatile organic compounds

Retention time	CAS	Compound	Match quality	Concentration with reference to internal standard	Potential specific migration[2]	SML Reg. 10/2011	Evaluation
min				µg/dm^2	mg/kg $_{food}$	mg/kg $_{food}$	
14.80	124-19-6	Nonanal	99	11.6	0.070	Not listed	
18.00	112-05-0	Nonanoic acid	97	5.70	0.034	Not listed	

[2] **mg/kg$_{food}$** have been obtained considering the conventional ratio 6 dm^2/1 kg$_{food}$

2.3 NON VOLATILE ORGANIC COMPOUNDS

INSTRUMENT

UHPLC ESI-MS/HRMS	Thermo
Mass Spectrometer	Thermo
Chromatographic column	C18

TEST CONDITIONS

Range of mass acquisition	m/z 70÷1000
Polarity	Positive and negative
POS Internal Standard	Benzyl butyl phthalate-d4
NEG Internal Standard	Nimesulide

EXTRACTION CONDITIONS

Extraction Solvent	Hexane/Ethanol 3/1
Type of contact	Cell
Contact surface	1.02 dm^2
Contact Volume	50 mL
Time and temperature of contact	8 hours at 20°C

PERFORMANCES

Sensibility (group 1)	0.010 mg/kg $_{extract}$
Sensibility (group 2)	0.010 mg/kg $_{food}$

2.3.1 Target Quantitative Screening GROUP 1

Organic compounds are identified and quantified by comparing them with certified standard solutions at target screening level on extraction solvent. The concentration of standard solutions corresponds to the sensibility for single compound in the test conditions.

If the values are inferior to the concentration of the standard solutions the results confirm the absence of the substance; if the values are superior to the limit of quantification the presence of the compound is certain.

All the substances listed in Annex II have been investigated. None is greater than the limit of quantification.

Semi-quantitative Target Screening GROUP 2 (Qualitative Tests and conventionally expressed as Benzyl butyl phthalate (BBP-d4) or Nimesulide)

Compounds are identified by suitably comparing them – at quantitative level – with an internal DATABASE/library containing over 1000 molecules, reaction and degradation products belonging to the following use classes: initiators/accelerators/catalysts, antidegradants/anti-oxidants, coupling agents, flame retardants, plasticizers, additives. The quantification is done by internal standard.

The analysis conducted did not detect the presence of non-volatile substances in concentrations above 10 µg/kg (as benzyl butyl phthalate-d4 and nimesulide).

3. CONCLUSIONS

Results obtained from the adopted operative and instrumental conditions highlight the presence of identified substances not found in the positive list of Reg. 10/2011 (marked with ❑) for which, however, the potential specific migration is less than 90 µg/kg (limit for the Cramer Class III corresponding to a high toxicity assuming that in 1 day a person of 60 kg takes 1 kg of substance).

This analytical protocol is a useful support for the risk assessment of food contact materials, focused on NIAS investigation.

The complete raw data (chromatograms and spectra) are preserved in Mèrieux NutriSciences for necessary future investigations.

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ANNEX I - BLANK DETERMINATION AND RULES TO CORRECTLY CONSTRUE EXPERIMENTAL DATA

BLANK DETERMINATION

An integral part of the process employed to detect and quantify the extractable organic compounds - as detailed above - is the blank determination.

The assessment of the organic compounds which can be determined in the blank, under the method operative conditions, is essential to prevent the attribution of organic compounds related to environmental contamination or solvents/reagents and glassware used to the sample extractable part.

RULES FOR A CORRECT INTERPRETATION OF EXPERIMENTAL DATA ON VOLATILE, SEMI-VOLATILE AND NON-VOLATILE ORGANIC COMPOUNDS (SPME-HS-GC/MS AND GC/MS ANALYSIS).

In order to correctly interpret the results obtained, we must take the following observations into consideration:

1. The identification of organic compounds is carried out by comparing the ionic profile of the substance fragmented section experimentally compared with the profiles of the molecules present in the tool sets.
2. The organic compound quantification is carried out by assuming that they have the same response factor as the internal standard.
3. The detection limit estimate is based on the internal standard response factor under the testing conditions.

RULES FOR A CORRECT INTERPRETATION OF EXPERIMENTAL DATA ON NON-VOLATILE ORGANIC COMPOUNDS (GROUP 1)

In order to correctly interpret the results obtained, we must take the following observations into consideration:

1. The identification of organic compounds is carried out by comparing the ionic profile of the substance fragmented section experimentally compared with the profiles of the molecules present in the related certified standards;
2. The organic compound quantification is carried out by comparison with the related certified standard;
3. The estimate quantification limit for each item is based on the matrix response of the related certified standard.
4. The identification and quantification are guaranteed by comparison with certified standard solutions.

RULES FOR A CORRECT INTERPRETATION OF EXPERIMENTAL DATA ON NON-VOLATILE ORGANIC COMPOUNDS (GROUP 2)

In order to correctly interpret the results obtained, we must take the following observations into consideration:

1. The identification of organic compounds belonging to group 2 is performed by comparing the accurate mass and the isotopic pattern of the substance found experimentally with the theoretical values calculated by the software on the basis of the molecular formula inserted in the database and associated with one or more analytes.
2. The organic compound quantification is carried out by assuming that they have the same response factor as the internal standard.
3. The detection limit estimate is based on the internal standard response factor under the testing conditions.

ANNEX II – LIST OF SUBSTANCES RESEARCHED IN THE TARGET SCREENING OF NON-VOLATILE ORGANIC COMPOUNDS NON VOLATILI (GROUP 1)

CAS	Compound	SML Reg. 10/2011
		mg/kg food
166412-78-8	1,2-Cyclohexanedicarboxylicaciddiisononylester (DINCH)	SML(T) : 60
0002855-13-2	1-Amino-3-(aminomethyl)-3,5,5-trimethylcyclohexane (Isophorone diamine)	6,0
085209-91-2	Sodium 2,2'-methylene-bis-(4,6-di-tert-butylphenyl)phosphate	5,0
0110553-27-0	2,4-bis-(ottil-tiometil)-metilfenolo	SML(T) : 5
007128-64-5	2,5 Bis(5-tert-butyl-2-benzoxazolyl)thiophene (BBOT)	0,6
023676-09-7	4-Ethoxy ethylbenzoate	3,6
000105-99-7	Dibutyl adipate	Not listed
000141-04-8	Diisobutyl adipate	Not listed
000141-28-6	Diethyl adipate	Not listed
000103-23-1	Bis(2-ethylhexyl) adipate (DEHA)	18,0
0027676-62-6	1,3,5-Tris[4-hydroxy-3,5-bis(2-méthyl-2-propanyl)benzyl]-1,3,5-triazinane-2,4,6-trione (IRGANOX 3114)	5,0
0040601-76-1	1,3,5-Tris[3-hydroxy-2,6-dimethyl-4-(2-methyl-2-propanyl)benzyl]-1,3,5-triazinane-2,4,6-trione (IRGANOX 1790)	6,0
001675-54-3	BADGE	SML(T) : 9*
076002-91-0	BADGExH2O	SML(T) : 9*
005581-32-8	BADGEx2H2O	SML(T) : 9*
227947-06-0	BADGExH2OxHCl	SML(T) : 1*
013836-48-1	BADGExHCl	SML(T) : 1*
004809-35-2	BADGEx2HCl	SML(T) : 1*
2095-03-6	BFDGE	n.d. *
72406-26-9	BFDGEx2H2O	n.d. *
374772-79-9	BFDGEx2HCl	n.d. *
1724-08-9	Bicyclo[2.2.1]heptane-2,3-dicarboxylic acid	5,0
000105-60-2	Caprolactam	SML(T) : 15
000947-04-6	Laurolactam	5,0
000108-78-1	1,3,5-Triazine-2,4,6-triamine	2,5
108-80-5	Cyanuric acid	Not listed
123-94-4	Monostearine	No SML
71786-60-2	N,N-bis(2-hydroxyethyl)alkyl(C8-C18)amine	SML(T) :1,2
-	3-Ring NOGE (Novolac glycidyl ether) mix of isomers (chain like/branched)	n.d. *
-	4-Ring NOGE (Novolac glycidyl ether) mix of isomers (chain like/branched)	n.d. *
-	5-Ring NOGE (Novolac glycidyl ether) mix of isomers (chain like/branched)	n.d. *
-	6-Ring NOGE (Novolac glycidyl ether) mix of isomers (chain like/branched)	n.d. *
134-84-9	4-methylbenzophenone	Not listed
00119-61-9	Benzophenone	0,6
5495-84-1	2-Isopropylthioxantone (ITX)	Not listed
21245-02-3	2-Ethylhexyl 4-dimethylaminobenzoate	Not listed
947-19-3	1-Hydroxycyclohexyl Phenyl Ketone	Not listed

24650-42-8	2,2-Dimethoxy-2-phenylacetophenone	Not listed
71868-10-5	2-Methyl-4'-(methylthio)-2-morpholinopropiophenone	Not listed
82799-44-8	2,4-Diethyl-9H-thioxanthen-9-one	Not listed
1137-42-4	4-Hydroxybenzophenone	Not listed
80-39-7(para-)	N-Ethyl-toluenesulfonamide	Not listed
90-94-8	4,4'-Bis(dimethylamino)benzophenone	Not listed
90-93-7	4,4'-bis(Diethylamino)benzophenone	Not listed
117-81-7	Bis(2-ethylhexyl) phthalate	1,5 SML(T) : 60
85-68-7	Benzyl butyl phthalate	30 SML(T) : 60
84-61-7	Dicyclohexyl phthalate	Not listed
84-66-2	Diethyl phthalate	Not listed
84-69-5	Diisobutyl phthalate	Not listed
068515-49-1 026761-40-0	Di-isodecyl phthalate (DIDP)	SML(T) : 9 e 60
068515-48-0 028553-12-0	Diisononylphthalate (DINP)	SML(T) : 9 e 60
27554-26-3	Di-iso-octyl phthalate	Not listed
131-11-3	Dimethyl phthalate	Not listed
131-18-0	Di-n-Amyl phthalate	Not listed
84-74-2	Dibutyl phthalate	0,3
117-84-0	Di-n-octyl Phthalate	Not listed
6362-79-4	5-Sulfoisophthalic acid	5,0
88-99-3	ortho-phthalic acid	SML(T) : 7.5
000121-91-5	Isophthalic acid	SML(T) : 5
000100-21-0	Terephthalic acid	SML(T) : 7.5
000109-43-3	Dibutyl sebacate	SML(T) : 60
000112-84-5	Erucamide	No SML
000301-02-0	Oleamide	No SML
0036443-68-2	Triethylene glycol bis-3-(3-tert-butyl-4-hydroxy-5-methylplenyl)propionate	9,0
0000122-20-3	Triisopropanolamine	5,0
000077-90-7	Tributyl acetylcitrate (ATBC)	SML(T) : 60
117-82-8	Bis(2-methoxyethyl)phthalate	Not listed
87-86-5	Pentachlorophenol (PCP)	Not listed
115-86-6	Triphenylphosphate	Not listed
605-50-5	diisopentyl phthalate	Not listed
1241-94-7	2-Ethylhexyl diphenyl phosphate	SML: 2.4
41451-28-9	Diisoheptyl phthalate	Not listed
3648-21-3	Di-n-heptyl phthalate	Not listed
2208-05-1	2-(dimethylamino)ethyl benzoate	Not listed
131-58-8	2-methylbenzophenone	Not listed
954-16-5	2,4,6-Trimethylbenzophenone	Not listed
75980-60-8	Diphenyl(2,4,6-trimethykbenzoyl) phosphine oxide	Not listed
91-76-9	2,4-Diamino-6-fenil-1,3,5-triazina (Benzoguanamine)	SML: 5
182121-12-6	9,9-bis(methoxymethyl)fluorene	SML: 0.05
2682-20-4	2-Methyl-4-isothiazolin-3-one (MIT)	SML: 0.5
26172-55-4	5-Chloro-2-methyl-4-isothiazolin-3-one (CMIT)	Not listed
000119-47-1	2,2'-methylenebis(4-methyl-6-tert-butylphenol) (Antioxidant 2246)	SML (T): 1.5

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Nome cliente *Applicant's name*	[redacted]
Indirizzo *Address*	[redacted]
Specifiche di prova: *Test specification:*	Guarda / *See* § 2
Norme di riferimento *Standard*	Reg. (EU) n.10/2011 GUUE L12 del 15/01/2011 e successivi aggiornamenti / *and amendments*
Descrizione campioni ricevuti *Test item description*	Materiale con contatto alimentare / *Material with food contact*
Data ricevimento campione *Date of samples receiving*	04/03/2021
Campioni selezionati da *Samples selected by*	Il campionamento è effettuato dal cliente / *Sampling performed by applicant*
Data di inizio e fine prove *Date of start and finish of tests*	09/03/2021 – 21/05/2021
Nome commerciale (se applicabile) *Trade Mark (if applicable)*	N/A
Modello *Model/Type reference*	Guarda / *See* § 2
Risultati test *Test results*	Guarda / *See* § 2

X

Andrea Castiglione
Chemical Laboratory Manager
Signed by: Andrea Castiglione

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1. Lista dei Materiali / List of Materials

Codice interno / *Internal code*	**Identificazione del campione /** *Sample identification*	**Materiale /** *Material*	**Risultati /** *Result*
A003010111 011	CONTENITORE IN PET ABA [10 % VERGINE (A)- 80 % R-PET (B)-10 %VERGINE (A)] / PUNNET IN PET ABA [10 % VIRGIN (A)- 80 % R-PET (B)-10 %VIRGIN (A)]	PET	Pass

2.Risultati / Results

2.1 Migrazione globale in simulanti acquosi (Immersione)
Overall migration into aqueous simulants (Total Immersion)

Metodo *Test method*	EN 1186-1:2002 + EN 1186-3:2002 (Immersione totale – Metodo A / Total immersion – Method A)
Limite *Limit*	Reg. (EU) n.10/2011 GUUE L12 del 15/01/2011 e successivi aggiornamenti *Reg. (EU) n.10/2011 GUUE L12 of 15/01/2011 and amendments*

Simulante ***Food simulant***	**Durata test / Temperatura** ***Test duration / Temperature***
Simulante A – Etanolo 10% Simulant A – Ethanol 10%	10 giorni / 40°C + 2 ore / 100°C *10 day(s) / 40°C* + 2 hour(s) / 100°C
Simulante B – Acido acetico 3% Simulant B – Acetic acid 3%	10 giorni / 40°C + 2 ore / 100°C *10 day(s) / 40°C* + 2 hour(s) / 100°C

Test	001				
Campione Sample	A003010111 011				
Rapporto migrazione *Migration ratio*	100 ml / 1 dm^2				
Parametro ***Parameter***	**Unità** ***Unit***	**Risultato delle singole prove** ***Individual test result***	**Media** ***Average***	**Incertezza** ***Uncertainty***	**Limite** ***Limit***
A	mg/dm^2	1,2	1,3	1,1	10
	mg/dm^2	1,4			
	mg/dm^2	1,3			
B	mg/dm^2	2,2	2,3	1,2	10
	mg/dm^2	2,4			
	mg/dm^2	2,3			

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Abbreviazioni / *Abbreviations*:

mg/dm^2 = milligrammi per decimetro quadrato / *milligram per square decimeter*

< = inferiore a / *less than*

Strumento / *Instrument*: Bilancia Analitica / *Analitical scale* (2782530); Stufa / *Oven* (2782519)

2.2 Migrazione globale in simulante olio di oliva (Immersione)
Overall migration into olive oil simulant (Immersion)

Metodo / *Test method*: EN 1186-2:2002

Limite / *Limit*: Reg. (EU) n.10/2011 GUUE L12 del 15/01/2011 e successivi aggiornamenti / *Reg. (EU) n.10/2011 GUUE L12 of 15/01/2011 and amendments*

Simulante ***Food simulant***	**Durata test / Temperatura** ***Test duration / Temperature***
Simulante D2 – Olio di oliva Food Simulant D2 – olive oil	10 giorni / 40°C + 2 ore / 100°C *10 day(s) / 40°C* + 2 hour(s) / 100°C

Test	002				
Campione *Sample*	A003010111 011				
Rapporto migrazione *Migration ratio*	100 ml / 1 dm^2				
Parametro ***Parameter***	**Unità** ***Unit***	**Risultato delle singole prove** ***Single Result***	**Media** ***Average***	**Incertezza** ***Uncertainty***	**Limite** ***Limit***
D2	mg/dm^2	< 2	< 2	-	10
	mg/dm^2	< 2			
	mg/dm^2	< 2			

Aggiustamento apportato per perdita di sostanza volatile / *Adjustment made for loss volatile substance: 0,2 mg/dm^2*

Determinazione della necessità di condizionamento dei campioni in accordo a Appendice B / *Determination of the need for sample conditioning according to Annex B*

Abbreviazioni / *Abbreviations*:

mg/dm^2 = milligrammi per decimetro quadrato / *milligram per square decimeter*

< = inferiore a / *less than*

Strumento / *Instrument*: Bilancia Analitica / *Analitical scale* (2782530); GC-MS (2782503-2782504); Stufa / *Oven* (2782519)

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2.3 Migrazione specifica di ammine aromatiche primarie/ *Specific migration of primary aromatic amines*

Metodo / *Method*: LMBG § 35 L 00.00-6:1995/Cor:2002

Limite / *Limit*: *Reg. (EU) n.10/2011 GUUE L12 del 15/01/2011 e successivi aggiornamenti / and amendments*

Simulante ***Food simulant***	**Durata test / Temperatura** ***Test duration / Temperature***
Simulante B – Acido acetico 3% *Simulant B – 3% Acetic acid*	10 giorni / 60 °C + 2 ore / 100°C *10 day(s) / 60 °C + 2 hour(s) / 100°C*

Test:	003		
Campione *Sample*	A003010111 011		
Rapporto migrazione *Migration ratio*	100 ml / 1 dm^2		
Parametro ***Parameter***	**Risultato*** ***Result**** **(mg/kg)**	**Incertezza** **Uncertainty** **(mg/kg)**	**Limite** ***Limit*** ***(mg/kg)***
Ammine primarie aromatiche *Primary aromatic amines*	0,003	0,001	<0,01

*Il valore è espresso come anilina / the value is given as aniline

Abbreviazioni / Abbreviations:

mg/kg = Milligrammi per chilogrammo / *Milligram per kilogram*

< = inferiore a / less than

Strumento / *Instrument*: Spettrometro UV / UV spectrometer (2782514)

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2.4 Migrazione specifica dei metalli Annex 2 Reg. (UE) n.10/2011 (Laboratorio 2)
Specific migration of metal Annex 2 Reg. (EU) n.10/2011 (Laboratory 2)

Metodo
Test method

La migrazione è condotta in accordo al Capo V, Articlo 18 del Regolamento Europeo 10/2011 e successivi aggiornamenti. Quantificazione mediante ICP-OES in accordo alla norma DIN EN ISO 11885 e ICP-MS in accordo alla norma DIN EN ISO 17294-2. / *The migratory behaviour is examined with reference to Chapter V, Article 18 of Commission Regulation 10/2011 and its amendments. Quantification by ICP-OES according to DIN EN ISO 11885 and ICP-MS according to DIN EN ISO 17294-2.*

Limite
Limit

Reg. (EU) n.10/2011 GUUE L12 del 15/01/2011 ANNEX II e successivi aggiornamenti
Reg. (EU) n.10/2011 GUUE L12 of 15/01/2011 ANNEX II and amendments

Simulante ***Food simulant***	**Durata test / Temperatura** ***Test duration / Temperature***
Simulante B – Acido acetico 3% *Food Simulant B – Acetic acid 3%*	10 giorni / 60 °C + 2 ore / 100°C *10 day(s) / 60 °C + 2 hour(s) / 100°C*

Test:	004	
Campione / *Sample*:	A003010111 011	
Rapporto migrazione *Migration ratio*	100 ml / 1 dm^2	
Parametro ***Parameter***	**Migrazione specifica** ***Specific migration*** ***(mg/kg)***	**Limite** ***Limit*** **(mg/kg)**
Bario / *Barium*	< 0,3	1
Cobalto / *Cobalt*	< 0,01	0,05
Rame / *Copper*	< 1	5
Ferro / *Iron*	< 5	48
Litio / *Lithium*	< 0,05	0,6
Manganese / *Manganese*	< 0,05	0,6
Zinco / *Zinc*	< 1	5
Alluminio *Aluminum*	< 0,2	1
Nichel / *Nickel*	< 0,01	0,02

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Parametro ***Parameter***	**Migrazione specifica** ***Specific migration*** ***(mg/kg)***	**Limite** ***Limit*** **(mg/kg)**
Antimonio / *Antimony*	< 0,02	0,04
Arsenico / *Arsenic*	< 0,005	ND
Cadmio / *Cadmium*	< 0,001	ND (LOD 0,002)
Cromo / *Chromium*	<0,01	ND
Europium / *Europium*	<0,01	0,05 (somma / *sum)*
Gadolinio / *Gadolinium*	<0,01	
Lantanio / *Lanthanum*	<0,01	
Piombo / *Lead*	<0,005	ND
Mercurio / *Mercury*	<0,005	ND
Terbio / *Terbium*	<0,01	0,05

Abbreviazioni / *Abbreviations*:

mg/kg = milligrammi per chilogrammo di simulante alimentare / *Milligram per kilogram of food simulant*

< = inferiore a / *less than*

ND = non rilevabile / *not detectable*

Test report N 0001086070/10 AZ 408590

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2.5 Migrazione specifica di ammine aromatiche primarie (Laboratorio 2) / *Specific migration of primary aromatic amines (Laboratory 2)*

Metodo *Test Method*	La migrazione è condotta in accordo al Capo V, Articlo 18 del Regolamento Europeo 10/2011 e successivi aggiornamenti. Quantificazione mediante HPLC-MS/MS (metodo interno) / *The migratory behaviour is examined with reference to Chapter V, Article 18 of Commission Regulation 10/2011 and its amendments. Quantification by HPLC-MS/MS (In-house method)*
Limite *Limit*	*Reg. (EU) n.10/2011 GUUE L12 del 15/01/2011 e successivi aggiornamenti / and amendments*

Simulante ***Food simulant***	**Durata test / Temperatura** ***Test duration / Temperature***
Simulante B – Acido acetico 3% *Food Simulant B – Acetic acid 3%*	10 giorni / 60 °C + 2 ore / 100°C *10 day(s) / 60 °C + 2 hour(s) / 100°C*

Test:	005	
Campione/ *Sample*	A003010111 011	
Rapporto migrazione *Migration ratio*	100 ml / 1 dm^2	
Parametro ***Parameter***	**Risultato** ***Result*** **(mg/kg)**	**Limite** ***Limit*** ***(mg/kg)***
2,4-Dimethylaniline *	<0,002	<0,01
4,4´-Diaminodiphenylmethane (4,4-MDA) *	<0,002	
4,4´-MCDA	<0,01	
Aniline	<0,002	
Benzidine *	<0,002	
Benzoguanamine	<0,01	
m-Anisidine	<0,01	
m-Toluidine	<0,01	
o-Aminoazotoluene *	<0,002	
o-Anisidine *	<0,002	
o-Phenylenediamine	<0,002	
o-Toluidine *	<0,002	
p-Chloraniline *	<0,002	
p-Cresidine *	<0,002	
p-Phenylenediamine	<0,01	
m-Phenylenediamine	<0,01	

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Parametro ***Parameter***	**Risultato** ***Result*** **(mg/kg)**	**Limite** ***Limit*** ***(mg/kg)***
p-Toluidine	<0,002	<0,01
1,5-Diaminonaphthalene	<0,002	
2-Naphthylamine *	<0,002	
2,4-Diaminoanisole *	<0,002	
2,4-Toluylendiamine *	<0,002	
2,4,5-Trimethylaniline *	<0,002	
2,6-Dimethylaniline *	<0,002	
2,6-Toluylendiamine	<0,01	
3,3´-Dichlorobenzidine *	<0,002	
3,3´-Dimethoxybenzidine	<0,002	
3,3´-Dimethylbenzidine *	<0,002	
3,3-Dimethyl-4,4-diaminodiphenylmethane *	<0,002	
4-Aminoazobenzene *	<0,002	
4-Aminobiphenyl *	<0,002	
4-Chloro-o-toluidine *	<0,002	
4,4´-Methylen-bis-(2-chloroaniline) *	<0,002	
4,4´-Oxydianiline *	<0,002	
4,4´-Thiodianiline *	<0,002	
5-Nitro-o-toluidine *	<0,002	
Dimethyl-2-aminoterephthalate	<0,01	
3-Amino-4-methylbenzamide	<0,01	
3-Amino-4-methoxybenzanilide	<0,01	
3-Chloroaniline	<0,01	
2-Chloroaniline	<0,01	
4-Ethoxyaniline	<0,01	
2-Ethoxyaniline	<0,01	
4-Aminobenzamide	<0,01	
5-Chloro-2-methylaniline	<0,002	
4-Chloro-2,5-dimethoxyaniline	<0,01	
5-Chloro-2-anisidine	<0,01	
2-Nitroaniline	<0,01	
2-Methoxy-4-nitroaniline	<0,01	

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Parametro ***Parameter***	**Risultato** ***Result*** **(mg/kg)**	**Limite** ***Limit*** ***(mg/kg)***
5-Amino-6-methyl benzimidiazolone	<0,01	<0,01
1,3-Diiminoisoindolen	<0,01	
2,5-Dichloraniline	<0,01	
2-Chlor-4-nitroaniline	<0,01	
2,4,5-Trichloraniline	<0,01	
4-Chlor-3-methoxyaniline	<0,01	
4-Aminotoluene-3-sulfonic acid	<0,01	
2-Amino-1-naphtalenesulfonic acid	<0,01	
2-Aminobiphenyl	<0,002	
4-Nitro-o-toluidine	<0,002	

Abbreviazioni / *Abbreviations*:

mg/kg = Milligrammi per chilogrammo / *Milligram per kilogram*

< = inferiore a / *less than*

4,4´-MCDA = 4,4´-Methylenebis-(3-chloro-2,6-diethylaniline)

Nota / *remark*: le sostanze contrassegnate con ***** hanno limite di migrazione specifica singolo di 0,002 mg/kg / *substances marked with * have a single specific migration limit of 0,002 mg/kg.*

Test report N 0001086070/10 AZ 408590

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2.6 Determinazione del contenuto residuo di acetaldeide(CAS 75-07-0) / *Determination of residual content of acetaldehyde (CAS 75-07-0)*

Metodo *Method*	Analisi / Analysis: GC-HS
Limite *Limit*	*Reg. (EU) n.10/2011 GUUE L12 del 15/01/2011 e successivi aggiornamenti / and amendments*

Test:	006		
Campione *Sample*:	A003010111 011		
Parametro ***Parameter***	**Risultato** **Result** ***(mg/kg)***	**Migrazione massima teorica*** ***Theoretical specific migration**** **(mg/kg)**	**Limite** ***Limit*** **(mg/kg)**
Acetaldehyde	36	0,45	6

Grammatura/weight: 2,1 g/dm^2

* Calcolata considerando il fattore 6 dm^2/kg / *Calculated considering the 6 dm^2/kg factor*

Abbreviazioni / *Abbreviations*:

mg/kg = Milligrammi per chilogrammo / *Milligram per kilogram*

< = inferiore a / less than

Strumento / *Instrument*: GC-HS (2782508 - 2782509)

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2.7 Determinazione del contenuto residuo di etilen glicole (CAS 107-21-1) e dietilen glicole (CAS 111-46-6) / *Determination of residual content of Ethylene glycol (CAS 107-21-1) and Diethylene glycol (CAS 111-46-6)*

Metodo *Method*	Estrazione / Extraction: n-Esano/n-Hexane Analisi / Analysis: GC-MS
Limite *Limit*	*Reg. (EU) n.10/2011 GUUE L12 del 15/01/2011 e successivi aggiornamenti / and amendments*

Test:	007		
Campione *Sample*:	A003010111 011		
Parametro ***Parameter***	**Risultato** **Result** ***(mg/kg)***	**Migrazione massima teorica*** ***Theoretical specific migration**** **(mg/kg)**	**Limite** ***Limit*** **(mg/kg)**
Ethylene glycol	< 100	< 1	30
Diethylene glycol	< 100	< 1	

Grammatura/weight: 2,1 g/dm^2

* Calcolata considerando il fattore 6 dm^2/kg / *Calculated considering the 6 dm^2/kg factor*

Abbreviazioni / *Abbreviations*:

mg/kg = Milligrammi per chilogrammo / *Milligram per kilogram*

< = inferiore a / less than

Strumento / *Instrument*: GC-MS (2782503 - 2782504)

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2.8 Determinazione del contenuto residuo di acido tereftalico (CAS 100-21-0) e di acido isoftalico (CAS 121-91-5) / *Determination of residual content of terephthalic acid (CAS 100-21-0) and isophthalic acid (CAS 121-91-5)*

Metodo *Method*	Estrazione / Extraction: n-Esano/n-Hexane Analisi / Analysis: GC-MS
Limite *Limit*	*Reg. (EU) n.10/2011 GUUE L12 del 15/01/2011 e successivi aggiornamenti / and amendments*

Test:	008		
Campione *Sample*:	A003010111 011		
Parametro ***Parameter***	**Risultato** **Result** ***(mg/kg)***	**Migrazione massima teorica*** ***Theoretical specific migration**** **(mg/kg)**	**Limite** ***Limit*** **(mg/kg)**
terephthalic acid	< 100	< 1	7,5
isophthalic acid	< 100	< 1	5

Grammatura/weight: 2,1 g/dm^2

* Calcolata considerando il fattore 6 dm^2/kg / *Calculated considering the 6 dm^2/kg factor*

Abbreviazioni / *Abbreviations*:

mg/kg = Milligrammi per chilogrammo / *Milligram per kilogram*

< = inferiore a / less than

Strumento / *Instrument*: GC-MS (2782503 - 2782504)

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2.9 Determinazione del contenuto di 2,2-bis (4-idrossifenil) propano (CAS 80-05-7) / *Total content of 2,2-bis(4-hydroxyphenyl)propane (CAS 80-05-7)*

Metodo *Method*	Estrazione / Extraction: Acetonitrile according French Decree N° 2012-1442 of 24 December 2012 Analisi / Analysis: GC-MS
Limite *Limit*	*Reg. (EU) n.10/2011 GUUE L12 del 15/01/2011 e successivi aggiornamenti / and amendments*

Test:	009		
Campione *Sample*:	A003010111 011		
Parametro ***Parameter***	**Risultato** **Result** ***(mg/kg)***	**Migrazione massima teorica*** ***Theoretical specific migration**** **(mg/kg)**	**Limite** ***Limit*** **(mg/kg)**
2,2-bis (4-idrossifenil) propano *2,2-bis(4-hydroxyphenyl)propane*	< 1	< 0,01	0,05

Grammatura/weight: 2,1 g/dm^2

* Calcolata considerando il fattore 6 dm^2/kg / *Calculated considering the 6 dm^2/kg factor*

Abbreviazioni / *Abbreviations*:

mg/kg = Milligrammi per chilogrammo / *Milligram per kilogram*

< = inferiore a / *less than*

Strumento / *Instrument*: GC-MS (2782503-2782504);

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2.10 Determinazione del contenuto di Anidride Piromellitica (CAS 89-32-7) / *Total content of Pyromellitic Anhydride (CAS 89-32-7)*

Metodo *Method*	Estrazione / Extraction: n-Esano/n-Hexane Analisi / Analysis: GC-MS
Limite *Limit*	*Reg. (EU) n.10/2011 GUUE L12 del 15/01/2011 e successivi aggiornamenti / and amendments*

Test:	010		
Campione *Sample*:	A003010111 011		
Parametro ***Parameter***	**Risultato** **Result** ***(mg/kg)***	**Migrazione massima teorica*** ***Theoretical specific migration**** **(mg/kg)**	**Limite** ***Limit*** **(mg/kg)**
Pyromellitic Anhydride	< 1	< 0,01	0,05

Grammatura/weight: 2,1 g/dm^2

* Calcolata considerando il fattore 6 dm^2/kg / *Calculated considering the 6 dm^2/kg factor*

Abbreviazioni / *Abbreviations*:

mg/kg = Milligrammi per chilogrammo / *Milligram per kilogram*

< = inferiore a / *less than*

Strumento / *Instrument*: GC-MS (2782503-2782504);

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2.11 Determinazione della migrazione specifica di Perfluoro alchil sulfonate PFAS (Laboratorio 2) / *Determination of specific migration of Perfluoro alchil sulfonate PFAS (Laboratorio 2)*

Metodo / *Method*: La migrazione è condotta in accordo al Capo V, Articlo 18 del Regolamento Europeo 10/2011 e successivi aggiornamenti / The migratory behaviour is examined with reference to Chapter V, Article 18 of Commission Regulation 10/2011 and its amendments

Analisi / Analysis: LC-MS/MS

Simulante ***Food simulant***	**Durata test / Temperatura** ***Test duration / Temperature***
Etanolo 95% Ethanol 95%	10 giorni / 60°C + 2 ore / 100°C *10 day(s) / 60°C* + 2 hour(s) / 100°C

Test:	011	
Campione *Sample*:	A003010111 011	
Rapporto migrazione *Migration ratio*	100 ml / 1 dm^2	
Parametro ***Parameter***	**Risultato Result** ***(mg/kg)***	**Incertezza Uncertainty (mg/kg)**
PFAS	<0,001	-

Abbreviazioni / *Abbreviations*:

mg/kg = Milligrammi per chilogrammo / *Milligram per kilogram*

< = inferiore a / *less than*

NR = Non rilevabile / not detectable < 0,01 mg/kg

Test report N 0001086070/10 AZ 408590

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2.12 Contenuto toale Cloro / *Chlorine total content*

Metodo MS-0041687
Test method

Test:	012	
Campione / *Sample*:	A003010111 011	
Parametro ***Parameter***	**Contenuto** ***Content*** ***(mg/kg)***	**Incertezza** ***Uncertainty*** ***(mg/kg)***
Cloro / *Chlorine*	<300	-

Abbreviazioni / Abbreviations:

mg/kg = milligrammi per chilogrammo / Milligram per kilogram

< = inferiore a / less than

Strumento / *Instrument*: XRF (2938911);

2.13 Determinazione del contenuto di polietilenglicole (EO = 1-50) eteri di alcoli primari (C8-C22) lineari e ramificati (Ref. N. 77708)/ *Total content of Polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C8- C22) alcohols (Ref. N. 77708)*

Metodo
Method Metodo interno del laboratorio / *In-house method*

Limite
Limit *Reg. (EU) n.10/2011 GUUE L12 del 15/01/2011 e successivi aggiornamenti / and amendments*

Test:	013		
Campione *Sample*:	A003010111 011		
Parametro ***Parameter***	**Risultato Result** ***(mg/kg)***	**Migrazione massima teorica*** ***Theoretical specific migration**** **(mg/kg)**	**Limite** ***Limit*** **(mg/kg)**
polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C 8-C 22) alcohols	< 1	< 0,01	1,8

Grammatura/weight: 2,1 g/dm^2

* Calcolata considerando il fattore 6 dm^2/kg / *Calculated considering the 6 dm^2/kg factor*

Abbreviazioni / *Abbreviations*:

mg/kg = Milligrammi per chilogrammo / *Milligram per kilogram*

< = inferiore a / less than

Lab. Cod. Sap: 1898278 Test report N FD-21-002438

Fine test report / *End of test report*