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

Interim report

Monitoring Interim Report by Article 13 of Regulation (EU) 2022/1616. 10th of April 2024.

Second monitoring programme for the project "PET materials and articles in which the recycled plastic is used behind a Functional Barrier"

Introduction

In accordance with the requirements of Article 13 of Regulation (EU) 2022/1616, we are herewith reporting the results of the second monitoring programme relative to the placing into the market of PET- base A/B/A structures, where the A consist in Virgin PET and B layer is made of r-PET or a blend of Recycled PET (rPET), virgin PET and offcuts (PIR) in variable proportions.

This report should be read in conjunction with the Novel Technology notification dossier referred as "PET materials and articles in which the recycled plastic is used behind a Functional Barrier", submitted on 5 April 2023.

The submission of the dossier was made by a consortium 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.

The results presented in this report have not been validated and are subject to further investigation for accuracy due to the large inter-laboratory and inter-sample variation observed. Significant sample degradation during analysis cannot be excluded at this time.

It is important to note that the safety and integrity of these materials is usually determined by extraction and/or migration and not by direct analysis of the polymer. The latter, although required by Regulation 2022/1616, is known to pose numerous technical problems in terms of obtaining reliable and reproducible results without damaging the polymer and has therefore not been commonly used and has not been subjected to proficiency testing as reported in the scientific literature (Nerin et al., 2022)[1].

Any conclusion based on these results is therefore premature and should be treated with caution.

1. Description of the Functional Barrier technology

rPET is used in food contact packaging for two main applications: direct contact with food and indirect contact with food. For indirect contact with food, the recycled PET is mildly decontaminated, and subsequently embossed between two layers of virgin PET, or PET originating from super-clean processes, suitable for direct food contact. In this case, the layer in contact with food acts as

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[1] Nerin, C., Bourdoux, S., Faust, B., Gude, T., Lesueur, C., Simat, T., Stoermer, A., Van Hoek, E., Oldring, P. (2022). Guidance in selecting analytical techniques for the identification and quantification of non-intentionally added substances (NIAS) in food contact materials (FCMS). Food Additives & Contaminants: Part A, vol 39(3): 620-643. https://doi.org/10.1080/19440049.2021.2012599**)**

“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)1935/2004, in particular with art 3 thereof.

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

Starting from hot washed and dried flakes of PET derived from post-consumer collection that comply with the requirements of Article 6 of Regulation (EU) 2022/1616, 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 (mixed or not with virgin PET and offcuts-PIR) 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. 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 for few seconds. A 3-layer sheet (A/B/A) comes out from the coextrusion process and it is immediately cooled down in a rolled stack press.

The following configurations of processes are covered by the Novel Technology dossier:

Table 1: configurations of the equipment covered by the notification

Configurations	Crystallizing/drying	**Extrusion**	**Degassing**
X1	yes	Single Screw	No
X2	yes	Single Screw	Yes
Y1	yes	Twin Screw Co-Rotating	Yes
Y2	no	Twin Screw Co-Rotating	Yes
W	no	Single screw and satellitar	Yes

The process configurations have been identified as X1, X2, Y1, Y2 and W to simplify the text of the submission.

In all the processes operating the equipment reported in Table 1, hot washed and dried RPET flakes are supplied to the manufacturers of the ABA structure (the 'recycler' as per Regulation EU 2022/1616) complying with the suitable specifications, and are co-extruded to produce the A/B/A structures with different A:B:A ratios and different thicknesses.

The input material is PET Post-Consumer recyclate containing maximum 5% of materials and articles that were used in contact with non-food materials or substances. The input material is fully compliant with the requirements of Article 6 of Regulation (EU) 2022/1616.

2. Capability of decontamination of the Functional Barrier technology

The original submitted Novel Technology dossier reported the outcomes of the decontamination efficiency associated to the above-mentioned process configurations. The decontamination efficiency was demonstrated using model contaminating substances, referred as “surrogate contaminants”, that are normally used for testing the decontamination capabilities of PET recycling processes. Based on that data, modelling of migration of surrogate contaminants has been carried out. The software used for the migration modelling was SML365, developed by AKTS (Sierre- Switzerland). The concentration used for the migration modelling was calculated starting from 3 mg/kg (EFSA assumption), and applying the decontamination efficiency of each process configuration, determined via challenge tests, prior to entering of the material into the die.

By using decontamination capability data calculated from challenge tests carried out in actual processes representing the equipment configurations of Table 1, and using the above mentioned commercially available migration simulation model it has been successfully demonstrated that after the decontamination, the remaining concentration of the surrogate contaminants introduced during the challenge test is below the threshold level indicated by EFSA as safe. Depending on the thickness of the A/B/A structures, and on conditions at which the said final A/B/A structures are used, the threshold level may be reached with different ratio RPET/virgin PET in layer B. Suitable curves showing this ratio, for different thicknesses are reported in the original notification.

In this second monitoring program, NIAS screening analysis has been carried out from input and output materials for the different equipment configurations that have been provided by members of the consortium, and originating from recycling installations in different EU Countries.

- Input measurements has been performed directly from rPET flakes.
- Output measurements have been performed on the sheets that have been produced by consortium members on a certain equipment configuration, made with the rPET flakes mentioned above to guarantee the traceability of the process.

3. List of contaminating substances with molecular weight < 1000 Dalton

Screening analyses on input and output materials for the different equipment configuration have been provided by the members of the consortium and have been carried out by a number of selected laboratories chosen by the members. These are shown in the tables 2 to 5.

Table 2 and 3 report on the most occurring substances as detected from screening analysis carried out respectively on input and output materials for the equipment configuration X1 and X2. The analysis has been carried out on 14 samples decontaminated via technology X1 and 11 samples decontaminated via technology X2, provided by the members of the consortium, originating from recycling installations in different EU Countries.

Table 4 and 5 report on the most occurring substances as detected from screening analysis carried out respectively on input and output materials for the equipment configuration Y1 and Y2. The analysis has been carried out on 4 samples decontaminated via technology Y1 and 45 samples decontaminated via technology Y2, provided by the members of the consortium, originating from recycling installations in different EU Countries.

The obtained data of the substances are subject to further validation, following the proficiency test among the participating laboratories that the Consortium is currently performing.

Table 2: Most occurring substances at the input on equipment configuration X1 and X2.

substance	cas_nr	mw	sml (µgr/KG)
2-methyl-1,3-dioxolane	497-26-7	88	
acetaldehyde	75-07-0	44	
acetic acid, butyl ester	123-86-4		
benzene	71-43-2	78	
2,2-bis(4-hydroxyphenyl)propane	80-05-7	228	600
γ-terpinene	99-85-4	136	
phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	31570-04-4	647	
2-[2-hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl]benzotriazole	70321-86-7	447	1.500
acetic acid	64-19-7	60	
benzaldehyde	100-52-7	106	
d-limonene	5989-27-5	136	
ethyleneglycol	107-21-1	62	
isophthalic acid	121-91-5		
limonene	138-86-3	136	
pet oligomers			
terephthalic acid	100-21-0	166	
tpa-eg oligomers			
2-ethyl-1-hexanol	104-76-7	130	30.000
3,6,13,16-tetraoxatricyclo[16.2.2.2(8,11)]tetracosa-8,10,18,20,21,23-hexaene-2,7,12,17-tetrone	1000398-77-0	384	
formic acid	64-18-6	46	
oleamide	301-02-0	282	
oxidized irgafos 168	95906-11-9	663	
toluene	108-88-3	92	

Table 3: Most occurring substances at the output on equipment configuration X1 and X2.

substance	cas_nr	mw	sml (µgr/Kg)
2-methyl-1,3-dioxolane	497-26-7	88	
acetaldehyde	75-07-0	44	
benzene	71-43-2	78	
2,2-bis(4-hydroxyphenyl)propane	80-05-7	228	600
acetic acid	64-19-7	60	
isophthalic acid	121-91-5		
pet oligomers			
terephthalic acid	100-21-0	166	
tpa-eg oligomers			
3,6,13,16-tetraoxatricyclo[16.2.2.2(8,11)]tetracosa-8,10,18,20,21,23-hexaene-2,7,12,17-tetrone	000398-77-	384	
formic acid	64-18-6	46	
limonene	138-86-3	136	
acetic acid, butyl ester	123-86-4		
2-[2-hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl]benzotriazole	70321-86-7	447	1.500
ethyleneglycol	107-21-1	62	
toluene	108-88-3	92	
xylenes		106	
acetone	67-64-1	58	
benzaldehyde	100-52-7	106	
styrene	100-42-5	104	
bis(2-ethylhexyl) sebacate	122-62-3	427	
d-limonene	5989-27-5	136	
acetophenone	98-86-2	120	
benzoic acid	65-85-0	122	
ethylbenzene	100-41-4	106	

Table 4: Most occurring substances in the input on equipment configuration Y1, Y2 and W.

substance	cas_nr	mw	sml (µgr/Kg)
2-methyl-1,3-dioxolane	497-26-7	88	
benzene	71-43-2	78	
acetaldehyde	75-07-0	44,05	
benzaldehyde	100-52-7	106,04	
2,2-bis(4-hydroxyphenyl)propane	80-05-7	228,29	600
acetic acid, butyl ester	123-86-4		
terephthalic acid	100-21-0	166,13	
acetic acid	64-19-7	60,05	
isophthalic acid	121-91-5		
pet oligomers			
tpa-eg oligomers			
formic acid	64-18-6	46	
limonene	138-86-3	136	
acetophenone	98-86-2	120	
oleamide	301-02-0	281,5	
aibn	78-67-1	164	
ethyleneglycol	107-21-1	62,07	
toluene	108-88-3	92	
2-pentyl-furan	3777-69-3	138	
3,6,13,16-tetraoxatricyclo[16.2.2.2(8,11)]tetracosa-8,10,18,20,21,23-hexaene-2,7,12,17-tetrone	1000398-77-0	384,09	

Table 5: Most occurring substances in the output on equipment configuration Y1, Y2 and W.

substance	cas_nr	mw	sml (µgr/Kg)
benzene	71-43-2	78	
2-methyl-1,3-dioxolane	497-26-7	88	
acetaldehyde	75-07-0	44,05	
2,2-bis(4-hydroxyphenyl)propane	80-05-7	228,29	600
terephthalic acid	100-21-0	166,13	
isophthalic acid	121-91-5		
pet oligomers			
tpa-eg oligomers			
acetic acid	64-19-7	60,05	
acetic acid, ethyl ester	141-78-6		
formic acid	64-18-6	46	
limonene	138-86-3	136	
3,6,13,16-tetraoxatricyclo[16.2.2.2(8,11)]tetracosa-8,10,18,20,21,23-hexaene-2,7,12,17-tetrone	000398-77-	384,09	
acetone	67-64-1	58	
benzaldehyde	100-52-7	106,04	
toluene	108-88-3	92	
ethyleneglycol	107-21-1	62,07	
acetophenone	98-86-2	120	
xylenes		106	
2-pentyl-furan	3777-69-3	138	
aibn	78-67-1	164	

4. List of contaminating materials in plastic input.

The input material is PET Post-Consumer recyclate containing maximum 5% of materials and articles that were used in contact with non-food materials or substances. The input material is fully compliant with the requirements of Article 6 of regulation (EU) 2022/1616.

The contaminating materials present in the plastic input are regularly controlled by the waste management and/or preprocessing operators up to the following specifications:

- PVC ≤ 50 ppm
- Polyolefins ≤ 100 ppm
- Other plastics ≤ 50 ppm
- Metals ≤ 10 ppm
- Paper and wood fibres ≤ 10 ppm
- Other inert materials ≤ 5%

5. Most likely origin of contaminants

There are several sources to which the presence of substances in the input and output plastic can be attributed. The final consortium report will provide data on the potential origin of the most frequently detected ones.

6. Measurement or estimation of the migration level

In the present interim report, the consortium concentrates on the detection of substances present in input and output of the equipment configurations that are part of the notification dossier. An analysis of migration data related to the most frequent substances detected will be made available.

7. Sampling strategy (art 13 (5) (g))

A plan and protocol have been established to harmonize sampling of the installations in accordance to article 13 and 32(3) of EU 2022/1616.

The sampling has been performed with traceability of input and output for the different installations. For that purpose, a dedicated digital platform has been created to collect standardized results of the different samples from the selected laboratories.

This is a totally new environment that has been created specifically for this monitoring program, and that is subject to performance evaluation. A proficiency test will be carried out to support the assessment of the performance.

8. Explanation of discrepancies between input and output

The set of analysis examined during the first monitoring period originated from historical data, and was affected by different testing approaches used. In the second monitoring period a more rigorous approach was used, with a harmonized sampling and testing system. This makes the data obtained in the second monitoring period more coherent but still shows discrepancies at this stage that needs in-depth investigation as explained in the introduction.

The approach of the second interim monitoring period will be retained for the next reporting phases and will constitute a robust database for the Functional Barrier Novel Technology.