PET materials and articles in which the recycled plastic is used behind a

Functional Barrier.

Novel Technology Development

4th Data Monitoring Report

Monitoring Report required by Article 13 of Regulation (EU) 2022/1616.

Issued on 30th of April 2025.

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Contents

1. Introduction

The novel technology for PET Functional barrier was notified as required under Article 10(2) and 10(3) of Commission Regulation (EU) 2022/1616 On 5th April 2023.

Article 13 of Commission Regulation (EU) 2022/1616 states the following:

"a recycler operating a decontamination installation in accordance with Article 11 of the regulation shall monitor the average contaminant level on the basis of a robust sampling strategy which samples the plastic input batches and the corresponding plastic output batches".

The enclosed report is the fourth monitoring report. It provides a summary of the data forthcoming from the monitoring, based on the latest information from 107 installations using this novel technology received in accordance with Article 13(3) along with the information required by Article 13(5) of the Regulation.

This report should be read in conjunction with the Novel Technology notification dossier referred as "PET materials and articles in which the recycled plastics is used behind a Functional Barrier", submitted on 5th April 2023 and its update of 25th January 2025.

It is important to note that the safety and integrity of these plastic materials is usually determined by extraction and/or migration rather than by direct analysis of the polymer itself. The latter, although required by Regulation 2022/1616, is known to encounter significant technical challenges in the form of obtaining reliable and reproducible results at ppb levels. In the interest of comprehensiveness, it has been observed that these analyses may, in certain instances, give rise to the generation of substances that could potentially be indistinguishable from contaminants. This has led to its limited utilisation and absence from proficiency testing as reported in the scientific literature (Nerin et al., 2022)[1].

Despite the advancement in this domain, the results presented in this report remain contingent upon further scrutiny to ensure accuracy due to the remaining inter-laboratory and inter-sample variation observed. It is also important to note that significant sample degradation during analysis cannot yet be totally excluded even if certain precautions such as to limit the desorption/extraction temperature to 150°C have been implemented. The implementation of the 150°C extraction temperature was derived from an extensive Round Robin exercise conducted by Petcore Europe involving 26 laboratories, analysing three materials at extraction temperatures of 100°C, 150°C and 200°C. Of these temperatures, 150°C was found to be the best compromise between the complete and repeatable extraction of volatile substances while minimising the formation of substances related to heat induction.

2. Brief description of the Novel Recycling Technology- Art. 13(5)(a)

There have been no changes to the Novel Recycling Technology as described in the original notification dossier and its subsequent update of 25th of January 2025.

The FB Novel Recycling Technology consists of using recycled PET (rPET) as the B central layer of A/B/A structures. Therefore, the B layer is made of rPET or blends of rPET with virgin PET, and the A layers are made of virgin PET or a blend of virgin and mechanically recycled PET from a process that has received a positive opinion from EFSA.

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

[1] (PDF) Guidance in selecting analytical techniques for identification and quantification of non-intentionally added substances (NIAS) in food contact materials (FCMS) (researchgate.net)

- A drying and crystallization phase of the washed flakes, which is operated usually under stirring and air flow, at temperatures ranging from 140 to 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[2]. In this case the rPET of the future B layer comes in contact with the virgin PET (or mixture between virgin and mechanically recycled PET originated from a process that was object of a positive opinion delivered by EFSA) 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.
- 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.

The different equipment configurations that are covered by the FB Novel Technology notification dossier are listed in table 1.

Table 1. equipment configurations 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	yes	Single screw and satellitar	Yes

The equipment configurations were grouped into 2 groups: single screw (X1X2W) and twin screw (Y1Y2). In all the processes operating the equipment configurations reported in Table 1, washed and dried rPET flakes are supplied to converters, accompanied by suitable specifications. They are then co-extruded to become the B layer within the A/B/A structures with different A/B/A ratios and different thicknesses.

In case more information on the process is needed we suggest consulting the original notification dossier at https://www.petcore-europe.org/functional-barrier.html

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

3. Summary of the reasoning on the capability of the novel technology and the recycling process(es) to manufacture recycled plastic materials and articles that meet the requirements of Article 3 of the Regulation (EC) No 1935/2004 and that are microbiologically safe - Art. 13(5)(b)

In the original notification dossier the data of the decontamination capability was calculated from challenge tests carried out in actual processes with/under the equipment configurations of Table 1. These data were used in combination with migration modelling to ascertain the maximum concentration of rPET in the B layer at which the safe level of migration of surrogates is still met. This was done for a wide range of A/B/A structures manufactured with the equipment configuration groups (X1X2W and Y1Y2) and for the different food contact applications.

4. Description of the applied sampling strategy - Art. 13(5)(g)

As the developer of the FB Novel technology, the consortium has been established by PETCORE Europe AISBL ("PETCORE") and EUPC AISBL ("EUPC") has collaborated with recyclers to establish a sampling strategy, to determine the analysis to be conducted for this monitoring report, and to select seven third-party laboratories to conduct the required analysis.

The samples that were the subject of the testing were provided by the consortium members. These samples were selected to represent commonly used input material and the corresponding A/B/A sheets that have been obtained in the operating lines and are normally supplied to the marketplace.

The objective was to encompass all operational lines in use by supplying two samples per recycling line, one corresponding to the input material and the second to the output material. At the time of closing of this report, the results for 107 lines out of the 156 were available. The delay is primarily attributable to delays in the sampling process and limitations in laboratory capacity.

The input material and the corresponding A/B/A sheets containing different percentages of virgin and rPET have been analysed in order to carry out a complete screening of intentional and non-intentionally added substances. The analysis has been carried out on flakes and sheets submitted to cryogenic grinding, and subsequently extracted in conditions described in Annex II. This allowed to detect the concentration of all substances present in the sheets.

In summary:

- The analysis of substances with a molecular weight of up to 1000 Dalton has been made by screening methods performed by 7 different laboratories located in different EU Countries, and using similar testing methods but not identical.
- In total 107 samples for input and the correspondent 107 samples for output sheet after decontamination have been analysed.
- Out of the 107 samples for output sheet, 79 correspond to equipment configuration group Y1Y2 and 28 to equipment configuration group X1X2W. The proportion of samples is in line with the distribution of configurations among the total number of installations.

The screening analysis was carried out for volatile substances, semi-volatile substances and non-volatile substances.

5. List of all substances with a molecular weight below 1000 Dalton found in the plastic inputs and recycled plastic outputs and the 20 first detected incidental contaminants - Art. 13(5)(c)

The analysis of substances with a molecular weight of up to 1000 Dalton has been made by screening methods described in Annex II and conducted in 7 different laboratories. In total 107 samples for input and the correspondent 107 samples for output sheet after decontamination have been analysed. Out of the 107 samples for output sheet, 79 correspond to equipment configuration group Y1Y2 and 28 to equipment configuration group X1X2W.

The substances detected with a frequency above 5% in the plastic input and its recycled output are reported in Annex I.

The substances were sorted in descending order by their relative occurrence in the plastic input. This relative occurrence (frequency of detection) was determined by dividing the number of samples in which the particular substance was detected by the total number of samples analysed.

Although some differences do appear between equipment configuration groups, it is premature to firmly attribute them to differences in equipment configuration rather than to their debatable statistical significance, bearing in mind that in one case they reflect the result of 79 analyses and in the other of only 28, not even taking into account interlaboratory variation and differences in LOD and LOQ.

As indicated in the preceding monitoring reports, the analysis of the recycled PET material indicates the presence of three distinguishable types of substances. However, for the purposes of this report and to the greatest extent possible in alignment with the terminology utilised in Regulation (EU) 2022/1616, the substances have been categorized into two groups:

1. **Incidental substances** that are often introduced into the input material:
    - due to the previous use of the PET so mainly in food contact applications. Examples include substances such as limonene. These contaminants enter the material during its initial use phase and can persist to some extent through the recycling process.
    - due to the contamination by other polymers. These substances are either present or formed as by-products when the contaminating polymers are subjected to heat and/or to other recycling conditions. For example, benzene is generated from residues of PVC, styrene from residues of polystyrene, BPA from residues of polycarbonate and/or epoxyresins.
2. **PET-Related Substances**: These are substances inherent to the chemical composition of PET or are generated during the processing and/or recycling process. Examples include PET oligomers and acetaldehyde.

It has to be noted, however, that the analytical methods do not distinguish between incidental contaminants and PET reaction products. In this report, incidental contaminants were assigned by comparing the analytical data of the input samples with virgin PET pellets and PET sheet samples analysed under the same conditions and using the same analytical methods.

In any case, it is worth to highlight that the analysis for the detection and quantification of substances in a polymer is very challenging, especially when they are present at very low concentrations, i.e. ppb levels. Although significant advances are regularly reported in the literature, reliable quantification of these substances to the ppb level and without compromising the integrity of the polymer is rarely feasible and certainly not standardized even for the most qualified laboratories. The results presented in this report, particularly in terms of minute quantities of ppb, should therefore be treated with caution.

Tables 2-4 list the 20 most frequently detected and identified incidental contaminants in the input material using the different analytical methods specified in Annex II.

The average concentration of a given incidental contaminant was calculated by only taking into account the samples in which it was detected according to the following rules:

- If the incidental contaminant was detected but below the quantification limit, the concentration used to calculate the average concentration was the limit of quantification.
- If the incidental contaminant was not detected in the output (frequency of 0%), it appears as Non Detected with the detection limit indicated in brackets.

Table 2. List of the first 21 most frequently detected incidental contaminants in the input material, their frequency of detection and average amounts in input and output samples (all equipment configurations)

Substance	CAS	INPUT		OUTPUT	
		Frequency	Average* (µg/kg PET)	Frequency	Average* (µg/kg PET)
limonene	138-86-3	88.79%	1187.88	67.29%	152.06
benzene	71-43-2	71.03%	428.70	98.13%	1292.65
toluene	108-88-3	47.66%	1562.81	44.86%	94.51
adipic acid, bis(2-ethylhexyl) ester	103-23-1	43.93%	12303.13	38.32%	4883.18
2,2-bis(4-hydroxyphenyl)propane	80-05-7	31.78%	5026.84	47.66%	3217.49
benzoic acid	65-85-0	30.84%	2505.69	26.17%	3286.57
p-cymene	99-87-6	25.23%	140.07	0%	ND (<17 - <150)
γ-terpinene	99-85-4	23.36%	227.39	0%	ND (<10 - <150)
phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	31570-04-4	23.36%	12439.85	13.08%	7109.18
ethylbenzene	100-41-4	21.5%	388.82	3.74%	42.41
2-nonanone	821-55-6	19.63%	250.28	0%	ND (<10 - <150)
2-heptanone	110-43-0	19.63%	311.00	0.93%	50.00
1-butanol	71-36-3	19.63%	588.60	0.93%	174.00

akr-30 pentaerythritol triacrylate (petia)	3524-68-3	19.63%	1116.40	19.63%	1390.71
styrene	100-42-5	18.69%	523.97	29.91%	132.12
eucalyptol	470-82-6	17.76%	309.93	0.93%	52.67
cyclohexane	110-82-7	16.82%	205.81	8.41%	148.60
pentanal	110-62-3	16.82%	292.29	1.87%	131.36
p-xylene	106-42-3	16.82%	256.48	13.08%	64.36
oxidized irgafos 168	95906-11-9	16.82%	2557.13	11.21%	2742.32

* average concentration calculated by only taking into account the samples in which it was detected
ND: not detected

Table 3. List of the first 20 most frequently detected incidental contaminants in the input material, their frequency of detection and average amounts in input and output samples (X1X2W).

Substance	CAS	INPUT		OUTPUT	
		Frequency	Average (µg/kg PET)	Frequency	Average (µg/kg PET)
limonene	138-86-3	75%	866.52	25%	46.20
benzene	71-43-2	60.71%	249.24	96.43%	900.45
toluene	108-88-3	53.57%	358.91	53.57%	72.22
1-butanol	71-36-3	35.71%	793.79	3.57%	174.00
adipic acid, bis(2-ethylhexyl) ester	103-23-1	25%	20671.33	25%	9202.21
benzoic acid	65-85-0	25%	2252.98	21.43%	2224.29
p-cymene	99-87-6	25%	91.39	0%	ND (<17)
2,2-bis(4-hydroxyphenyl)propane	80-05-7	21.43%	4114.93	46.43%	1813.51
akr-30 pentaerythritol triacrylate (petia)	3524-68-3	21.43%	1176.67	21.43%	1330.83
cyclohexane	110-82-7	21.43%	160.19	7.14%	76.57
2-aminobenzamide	88-68-6	17.86%	11714.54	0%	ND (<50 - <333)
2-heptanone	110-43-0	17.86%	135.81	0%	ND (<10 - <17)
acetonitrile	75-05-8	17.86%	328.54	17.86%	214.32
caffeine	58-08-2	17.86%	14715.36	7.14%	2115.53
n-hexane	110-54-3	17.86%	193.23	3.57%	276.67
oxidized irgafos 168	95906-11-9	17.86%	2293.67	21.43%	3485.56
phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	31570-04-4	17.86%	12556.00	10.71%	26097.78
1,2-diethyl benzene	135-01-3	14.29%	165.87	0%	ND (<17)
1-methyl-3-propyl-benzene	1074-43-7	14.29%	282.03	0%	ND (<17)
2,4-di-tert-butylphenol	96-76-4	14.29%	4581.67	7.14%	1324.88
2,5-bis(5-tert-butyl-2-benzoxa-zolyl)thiophene	7128-64-5	14.29%	2951.17	7.14%	897.83
2-nonanone	821-55-6	14.29%	68.04	0%	ND (<17)
cumene	98-82-8	14.29%	73.31	0%	ND (<17)
ethyl acetate + 1,3-dioxolane	141-78-6 + 646-06-0	14.29%	165.84	10.71	105.56
ethyltoluene (isomers)	25550-14-5	14.29%	1701.37	0%	ND (<17)
heptane	142-82-5	14.29%	58.95	0%	ND (<17)

indane	496-11-7	14.29%	58.56	0%	ND (<17)
myristyl myristate	3234-85-3	14.29%	498.41	10.71	542.33
p-xylene	106-42-3	14.29%	139.05	17.86%	55.34
pentane, 2,2,4-trimethyl-	540-84-1	14.29%	112.24	0%	ND (<17)
propyl-benzene	103-65-1	14.29%	304.34	0%	ND (<17)
stearamide	124-26-5	14.29%	1536.25	17.86%	1549.33
xylenes (isomers)	1330-20-7	14.29%	901.97	7.14%	297.96
γ-terpinene	99-85-4	14.29%	187.63	0%	ND (<10 - <17)

* average concentration calculated by only taking into account the samples in which it was detected
ND: not detected

Table 4. List of the first 20 most frequently detected incidental contaminants in the input material, their frequency of detection and average amounts in input and output samples (Y1Y2).

Substance	CAS	INPUT		OUTPUT	
		Frequency	Average* (µg/kg PET)	Frequency	Average* (µg/kg PET)
limonene	138-86-3	93.67%	1279.07	82.28%	163.46
benzene	71-43-2	74.68%	480.40	98.73%	1428.42
adipic acid, bis(2-ethylhexyl) ester	103-23-1	50.63%	10810.96	43.04%	3993.97
toluene	108-88-3	45.57%	2064.43	41.77%	104.64
2,2-bis(4-hydroxyphenyl)propane	80-05-7	35.44%	5221.96	48.1%	3697.80
benzoic acid	65-85-0	32.91%	2573.72	27.85%	3576.28
γ-terpinene	99-85-4	26.58%	234.96	0%	ND (<10 - <150)
ethylbenzene	100-41-4	25.32%	418.16	2.53%	44.91
p-cymene	99-87-6	25.32%	157.11	0%	ND (<17 - <150)
phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	31570-04-4	25.32%	12410.81	13.92%	1930.47
styrene	100-42-5	25.32%	504.54	31.65%	140.22
eucalyptol	470-82-6	22.78%	311.04	1.27%	52.67
pentanal	110-62-3	22.78%	292.29	1.27%	113.71
2-nonanone	821-55-6	21.52%	293.16	0%	ND (<10 - <150)
2-heptanone	110-43-0	20.25%	365.75	1.27%	50.00
2-propanol	67-63-0	18.99%	424.17	1.27%	660.67
akr-30 pentaerythritol triacrylate (petia)	3524-68-3	18.99%	1092.29	18.99%	1414.67
hexanoic acid	142-62-1	17.72%	172.41	0%	ND (<10 - <50)
p-xylene	106-42-3	17.72%	290.02	11.39%	69.37
salicylic acid, methyl ester	119-36-8	17.72%	530.71	0%	ND (<10 - <100)

* average concentration calculated by only taking into account the samples in which it was detected
ND: not detected

Among the substances most frequently detected (not necessarily the highest in terms of presence levels) in the input are limonene, benzene, toluene, a plasticizer (adipic acid, bis(2-ethylhexyl) ester) and BPA. They are also among the most frequently detected in the output but are generally present at significantly lower concentrations, benzene being one exception.

6. List of contaminating materials regularly present in the plastic input - Art. 13(5)(d)

The contaminating materials present in the plastic input are controlled by the specifications delivered by the producers of flakes. The content of (food grade) PET originating from food contact in the plastic input is ≥95%.

Other contaminating materials include:

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

7. Analysis of the most likely origin of the identified contaminants referred to in points (c) and (d) - Art. 13(5)(e)

Contaminating materials

Depending on the collection and sorting process, post-consumer PET waste can contain a limited amount of other plastic materials such as polyolefins, polyvinyl Chloride (PVC), polyamide (PA), ethylene vinyl alcohol (EVOH), polystyrene (PS) and of fillers. These materials originate from the following sources:

- Polyolefins like polyethylene (PE) and polypropylene (PP) are used to manufacture bottle closures and are present in a wide range of other plastic packaging products.
- PVC is used in the manufacturing of certain labels and sleeves for bottles as well as for certain packaging materials
- PS homopolymers and copolymers are used in disposable cups and other packaging materials.
- EVOH is used as oxygen barrier in food packaging.
- PA is often used as moisture barrier layer in flexible packaging films.
- Fillers are used in plastic packaging materials to strengthen their mechanical properties and enhance their performance.

Incidental contaminants

The most likely origin of these incidental contaminants detected in the input material (Annex I) is as follows[3][4]:

[3] Journal of Preventive Medicine and Hygiene.
[4] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0872

- Limonene: is a component of citrus juices and a very common flavor used in beverages. As a significant part of the input waste is made of beverage bottles limonene is found in nearly all post-consumer PET waste streams (Franz and al., 2004).
- Benzene: most probably formed from PVC through an heat induced reaction.
- Adipic acid, bis (2-ethylhexyl) ester and dioctyladipate: common plasticizer(s) for PVC. Traces of PVC could possibly account for the presence of these plasticisers.
- Toluene, ethylbenzene, p-cymene, p-xylene, o-xylene and xylenes (mix) are typical components of aromatic solvents used in certain solvent based inks and/or adhesives and/or coatings.
- BPA: most probable source is the contamination by polycarbonate or epoxy products used in coatings and/or adhesives and/or inks.
- PETIA: is a typical acrylate used in UV curing inks.
- Terpinene: major component of essential oils made from citrus fruits with strong antioxidant activity. It is widely used in food flavors and cosmetics (European commission 2012)
- Benzoic acid: and/or sodium benzoate are used in food but also in toothpaste, shower gel, shampoo, moisturizers and sunscreens
- Phosphorous acid, tris(2,4-di-tert-butylphenyl)ester: widely known as Irgafos 168 is an antioxidant used in plastics, adhesives and sealants, coating products and inks and toners (ECHA)
- 2-nonanone: substance used in washing & cleaning products, cosmetics and personal care products.
- 1-butanol: substance used in coatings, adhesives and sealants, as well as in washing & cleaning products.
- 2-heptanone: substance reported as being used in coatings, adhesives and sealants, cosmetics and personal care products as well as in washing & cleaning products.
- Styrene: besides its use in PS packaging materials, it is also used to make a wide range of block copolymers (SIS, SBS, ...) and of copolymers for paints and coating or adhesives, fragrances and air fresheners.
- Pentanal (also called valeraldehyde) and eucalyptol (also called 1,8-Cineole) are common food flavoring agents. They are also used in personal care and cosmetics.
- 2-aminobenzamide also called anthranilamide is an acetaldehyde scavenger for PET.
- Acetonitrile: solvent, intermediate used in many chemical synthesis can also be a byproduct of acrylonitrile (polyacrylonitrile, ABS,…).

8. Measurement or estimation of the migration levels to food contaminants present in the recycled plastic materials and articles - Art. 13(5)(f)

Following the analysis conducted on the A/B/A sheets a worst case estimation of the migration levels was calculated based on the average levels of incidental contaminants measured in the sheets (Tables 5 to 7) and assuming their total migration to food using an average thickness of 450 microns, a PET density of 1.34 and a Surface to Volume of 6 square dm for 1 kg of food.

Table 5. Worst case migration calculation of incidental contaminants present in the output samples (All configurations).

Substance	MW (g/mol)	CAS	OUTPUT		TOTAL MIGRATION CALCULATION** Average* (µg/kg food)
			Frequency	Average* (µg/kg PET)	
limonene	136.23	138-86-3	67.29%	152.06	5.50
benzene	78.11	71-43-2	98.13%	1292.65	46.77
toluene	92.14	108-88-3	44.86%	94.51	3.42
adipic acid, bis(2-ethylhexyl) ester	370.6	103-23-1	38.32%	4883.18	176.67
2,2-bis(4-hydroxyphenyl)pro-pane	228.29	80-05-7	47.66%	3217.49	116.41
benzoic acid	112.12	65-85-0	26.17%	3286.57	118.91
p-cymene	134.22	99-87-6	0%	ND (<17 - <150)	<0.62 - <5.43
γ-terpinene	136.23	99-85-4	0%	ND (<10 - <150)	<0.36 - <5.43
phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	646.94	31570-04-4	13.08%	7109.18	257.21
ethylbenzene	106.16	100-41-4	3.74%	42.41	1.53
2-nonanone	142.24	821-55-6	0%	ND (<10 - <150)	<0.36 - <5.43
2-heptanone	114.19	110-43-0	0.93%	50.00	1.81
1-butanol	74.12	71-36-3	0.93%	174.00	6.30
akr-30 pentaerythritol tri-acrylate (petia)	336.06	3524-68-3	19.63%	1390.71	50.32
styrene	104.15	100-42-5	29.91%	132.12	4.78
eucalyptol	154.25	470-82-6	0.93%	52.67	1.91
cyclohexane	84.16	110-82-7	8.41%	148.60	5.38
pentanal	86.13	110-62-3	1.87%	131.36	4.75
p-xylene	106.16	106-42-3	13.08%	64.36	2.33
oxidized irgafos 168	662.9	95906-11-9	11.21%	2742.32	99.22

* average concentration calculated by only taking into account the samples in which it was detected

** total migration to food using an average thickness of 450 microns, a PET density of 1.34 and a Surface to Volume of 6 square dm for 1 kg of food

ND: not detected

Table 6. Worst case migration calculation of incidental contaminants present in the output samples (X1X2W).

Substance	MW (g/mol)	CAS	OUTPUT		TOTAL MIGRATION CALCULATION** Average* (µg/kg food)
			Frequency	Presence Average* (µg/kg PET)	
limonene	136.23	138-86-3	25%	46.20	1.67
benzene	78.11	71-43-2	96.43%	900.45	32.58
toluene	92.14	108-88-3	53.57%	72.22	2.61
1-butanol	74.12	71-36-3	3.57%	174.00	6.3
adipic acid, bis(2-ethylhexyl) ester	370.6	103-23-1	25%	9202.21	332.94
benzoic acid	112.12	65-85-0	21.43%	2224.29	80.47
p-cymene	134.22	99-87-6	0%	ND (<17)	<0.62
2,2-bis(4-hydroxyphenyl)propane	228.29	80-05-7	46.43%	1813.51	65.61
akr-30 pentaerythritol triacrylate (petia)	336.06	3524-68-3	21.43%	1330.83	48.15
cyclohexane	84.16	110-82-7	7.14%	76.57	2.77
2-aminobenzamide	136.15	88-68-6	0%	ND (<50 - <333)	<1.81 - <12.05
2-heptanone	114.19	110-43-0	0%	ND (<10 - <17)	<0.36 - <0.62
acetonitrile	41.05	75-05-8	17.86%	214.32	7.75
caffeine	194.19	58-08-2	7.14%	2115.53	76.54
n-hexane	86.18	110-54-3	3.57%	276.67	10.01
oxidized irgafos 168	662.9	95906-11-9	21.43%	3485.56	126.11
phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	646.94	31570-04-4	10.71%	26097.78	944.22
1,2-diethyl benzene	134.22	135-01-3	0%	ND (<17)	<0.62
1-methyl-3-propyl-benzene	134.22	1074-43-7	0%	ND (<17)	<0.62
2,4-di-tert-butylphenol	206.32	96-76-4	7.14%	1324.88	47.93
2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	430.6	7128-64-5	7.14%	897.83	32.48
2-nonanone	142.24	821-55-6	0%	ND (<17)	<0.62
cumene	120.19	98-82-8	0%	ND (<17)	<0.62
ethyl acetate + 1,3-dioxolane		141-78-6 + 646-06-0	10.71	105.56	3.82
ethyltoluene (isomers)	120.19	25550-14-5	0%	ND (<17)	<0.62
heptane	100.2	142-82-5	0%	ND (<17)	<0.62
indane	118.18	496-11-7	0%	ND (<17)	<0.62
myristyl myristate	424.7	3234-85-3	10.71	542.33	19.62
p-xylene	106.16	106-42-3	17.86%	55.34	2.00
pentane, 2,2,4-trimethyl-	114.23	540-84-1	0%	ND (<17)	<0.62
propyl-benzene	120.19	103-65-1	0%	ND (<17)	<0.62
stearamide	283.5	124-26-5	17.86%	1549.33	56.05
xylenes (isomers)	106.16	1330-20-7	7.14%	297.96	10.78
γ-terpinene	136.23	99-85-4	0%	ND (<10 - <17)	<0.36 - <0.62

* average concentration calculated by only taking into account the samples in which it was detected

** total migration to food using an average thickness of 450 microns, a PET density of 1.34 and a Surface to Volume of 6 square dm for 1 kg of food

ND: not detected

Table 7. Worst case migration calculation of incidental contaminants present in the output samples (Y1Y2).

Substance	MW (g/mol)	CAS	OUTPUT		TOTAL MIGRATION CALCULATION** Average* (µg/kg food)
			Frequency	Average* (µg/kg PET)	
limonene	136.23	138-86-3	82.28%	163.46	5.91
benzene	78.11	71-43-2	98.73%	1428.42	51.68
adipic acid, bis(2-ethylhexyl) ester	370.6	103-23-1	43.04%	3993.97	144.5
toluene	92.14	108-88-3	41.77%	104.64	3.79
2,2-bis(4-hydroxyphenyl)propane	228.29	80-05-7	48.1%	3697.80	133.79
benzoic acid	112.12	65-85-0	27.85%	3576.28	129.39
γ-terpinene	136.23	99-85-4	0%	ND (<10 - <150)	<0.36 - <5.43
ethylbenzene	106.16	100-41-4	2.53%	44.91	1.62
p-cymene	134.22	99-87-6	0%	ND (<17 - <150)	<0.62 - <5.43
phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	646.94	31570-04-4	13.92%	1930.47	69.84
styrene	104.15	100-42-5	31.65%	140.22	5.07
eucalyptol	154.25	470-82-6	1.27%	52.67	1.91
pentanal	86.13	110-62-3	1.27%	113.71	4.11
2-nonanone	142.24	821-55-6	0%	ND (<10 - <150)	<0.36 - <5.43
2-heptanone	114.19	110-43-0	1.27%	50.00	1.81
2-propanol	60.1	67-63-0	1.27%	660.67	23.90
akr-30 pentaerythritol tri-acrylate (petia)	336.06	3524-68-3	18.99%	1414.67	51.18
hexanoic acid	116.16	142-62-1	0%	ND (<10 - <50)	<0.36 - <1.81
p-xylene	106.16	106-42-3	11.39%	69.37	2.51
salicylic acid, methyl ester	152.15	119-36-8	0%	ND (<10 - <100)	<0.36 - <3.62

* average concentration calculated by only taking into account the samples in which it was detected

** total migration to food using an average thickness of 450 microns, a PET density of 1.34 and a Surface to Volume of 6 square dm for 1 kg of food

ND: not detected

In addition specific migration testing in ethanol 95% (simulant replacing D2, identified as worst case by modelling) has been conducted for three of the most representative incidental contaminants, namely:

1. Benzene substance formed during the degradation of PVC present as a contaminant in the input material. It is not excluded, however that benzene may also be generated by certain analytical methods.
2. 2,2-bis(4-hydroxyphenyl)propane (BPA), formed from contamination of the input material by polycarbonate and also contamination from other sources (e.g. inks, coatings etc.).

3. Limonene, substance present because of contamination by food (juices, soft drinks in PET bottles).

It is important to highlight that, when used with PET, the simulant Ethanol 95% is recognised[5] as being worst case compared to fatty food because of its ability to swell and even partially hydrolyse the PET. The results therefore obtained constitute an upper level that won't be reached in the actual conditions.

The testing conditions have been selected to cover different equipment configurations and a wide range of packaging trays applications ranging from refrigerated to ambient conditions and long term storage fatty food:

- 14 samples for 10 days at 20°C
- 83 samples for 10 days at 40°C
- 10 samples for 10 days at 60°C

The results for all configurations are summarised in Tables 8-10. It is important to mention that the averages depend strictly on the assumptions taken into account for the average calculation:

- Average based on the measured values where the substance was detected.
- Average based on the measured values and, in case of non-detection, consider 0 as the value to be included in the calculation of the average.

The tables 8-10 illustrate how these two options influence the average migration results measured in particular when the substance is occasionally detected.

Table 8. Migration testing of 3 incidental contaminants present in the output samples (all configurations).

Substance	MW (g/mol)	CAS	Migration testing			
			Test condition	Frequency of detection	Average of detected* (µg/kg food)	Average of all** (µg/kg food)
limonene	136.23	138-86-3	10d @ 20°C	0%	/	/
			10d @ 40°C	2.41%	8.07	0.19
			10d @ 60°C	0%	/	/
benzene	78.11	71-43-2	10d @ 20°C	35.71%	0.12	0.043
			10d @ 40°C	46.99%	2.25	1.058
			10d @ 60°C	60%	6.00	3.599
2,2-bis(4-hydroxy-phenyl)propane	228.29	80-05-7	10d @ 20°C	14.29%	12.00	1.71
			10d @ 40°C	43.37%	15.48	6.71
			10d @ 60°C	10%	6.00	0.60

* average concentration calculated by only taking into account the migration solutions in which it was detected

** average based on the values measured in the migration solutions and, in case of non-detection, consider 0 as the value to be included in the calculation of the average

[5] Frank Welle, Roland Franz. Migration measurement and modelling from poly(ethylene terephthalate) (PET) into softdrinks and fruit juices in comparison with food simulants. Food Additives and Contaminants, 2009, 25 (08), pp.1033-1046. 10.1080/02652030701837381. hal-00577443

Table 9. Migration testing of 3 incidental contaminants present in the output samples (configurations X1X2W).

Substance	MW (g/mol)	CAS	Migration testing			
			Test condition	Frequency of detection	Average of detected* (µg/kg food)	Average of all** (µg/kg food)
limonene	136.23	138-86-3	10d @ 20°C	0%	/	/
			10d @ 40°C	4.76%	12.6	0.45
			10d @ 60°C	0%	/	/
benzene	78.11	71-43-2	10d @ 20°C	0%	/	/
			10d @ 40°C	57.14%	3.90	2.23
			10d @ 60°C	80%	3.6	2.88
2,2-bis(4-hydroxy-phenyl)propane	228.29	80-05-7	10d @ 20°C	50%	12	6.00
			10d @ 40°C	38.1%	12	4.57
			10d @ 60°C	0%	/	/

* average concentration calculated by only taking into account the migration solutions in which it was detected
** average based on the values measured in the migration solutions and, in case of non-detection, consider 0 as the value to be included in the calculation of the average

Table 10. Migration testing of 3 incidental contaminants present in the output samples (configurations Y1Y2).

Substance	MW (g/mol)	CAS	Migration testing			
			Test condition	Frequency of detection	Average of detected* (µg/kg food)	Average of all** (µg/kg food)
limonene	136.23	138-86-3	10d @ 20°C	0	/	/
			10d @ 40°C	1.61	3.54	0.057
			10d @ 60°C	0	/	/
benzene	78.11	71-43-2	10d @ 20°C	41.67	0.12	0.050
			10d @ 40°C	43.55	1.52	0.662
			10d @ 60°C	40	10.80	4.319
2,2-bis(4-hydroxy-phenyl)propane	228.29	80-05-7	10d @ 20°C	8.33	12.00	1.00
			10d @ 40°C	45.16	16.47	7.44
			10d @ 60°C	20	6.00	1.20

* average concentration calculated by only taking into account the migration solutions in which it was detected
** average based on the values measured in the migration solutions and, in case of non-detection, consider 0 as the value to be included in the calculation of the average

In the tables 11 to 13, the mean values for both the total migration calculation as the migration testing are derived through the methodical allocation of a value of 0 to each analysis where the substance

was not detected. As expected, the data confirm that the values obtained by worst case total migration calculation are always above the values obtained by migration testing with one exception for limonene in configurations X1X2W where migration of limonene has been found in one sample out of the 21 samples analysed.

Table 11. Comparison of total migration calculation with migration testing results (all configurations).

Substance	Total Migration Calculation Average of all* (µg/kg food)	Migration testing		
		Test condition	Frequency of detection	Average of all* (µg/kg food)
limonene	3.70	10d @ 20°C	0%	/
		10d @ 40°C	2.41%	0.19
		10d @ 60°C	0%	/
benzene	45.89	10d @ 20°C	35.71%	0.043
		10d @ 40°C	46.99%	1.058
		10d @ 60°C	60%	3.599
2,2-bis(4-hydroxy-phenyl)propane	55.48	10d @ 20°C	14.29%	1.71
		10d @ 40°C	43.37%	6.71
		10d @ 60°C	10%	0.60

* average based on the values measured in the samples and, in case of non-detection, consider 0 as the value to be included in the calculation of the average

Table 12. Comparison of total migration calculation with migration testing results (configurations X1X2W).

Substance	Total Migration Calculation Average of all* (µg/kg food)	Migration testing		
		Test condition	Frequency of detection	Average of all* (µg/kg food)
limonene	0.42	10d @ 20°C	0%	/
		10d @ 40°C	4.76%	0.45
		10d @ 60°C	0%	/
benzene	31.41	10d @ 20°C	0%	/
		10d @ 40°C	57.14%	2.23
		10d @ 60°C	80%	2.88
2,2-bis(4-hydroxy-phenyl)propane	30.46	10d @ 20°C	50%	6.00
		10d @ 40°C	38.1%	4.57
		10d @ 60°C	0%	/

* average based on the values measured in the samples and, in case of non-detection, consider 0 as the value to be included in the calculation of the average

Table 13. Comparison of total migration calculation with migration testing results (configurations Y1Y2).

Substance	Total Migration Calculation Average of all* (µg/kg food)	Migration testing		
		Test condition	Frequency of detection	Average of all* (µg/kg food)
limonene	4.87	10d @ 20°C	0	/
		10d @ 40°C	1.61	0.057
		10d @ 60°C	0	/
benzene	51.03	10d @ 20°C	41.67	0.050
		10d @ 40°C	43.55	0.662
		10d @ 60°C	40	4.319
2,2-bis(4-hydroxy-phenyl)propane	64.35	10d @ 20°C	8.33	1.00
		10d @ 40°C	45.16	7.44
		10d @ 60°C	20	1.20

* average based on the values measured in the samples and, in case of non-detection, consider 0 as the value to be included in the calculation of the average

9. Description of the analytical procedures and methods used – Art 13(5)(h)

The analysis of organic substances has been done through a non-targeted screening of volatile, semi-volatile and non-volatile substances with the methods indicated in the tables of Annex II.

10. Analysis and explanation of any discrepancies observed between contaminant levels expected and decontamination efficiency - Art. 13(5)(i)

As previously outlined, most substances originate from the contamination of the PET that occur in the use, disposal and collection phase. These substances are normally removed during the recycling process; for these substances a decontamination efficiency can in theory be calculated. Nevertheless, as discussed in the subsequent section, it is highly debatable whether this constitutes a sounded and reliable method of demonstrating cleaning efficiency taking into account the numerous practical limitations.

As indicated in Section 8, certain substances are generated during the process, either at the recycling and/or plastic processing stages. These substances are only present in the output, or their quantity increases in the output compared to the input.

Detected contaminant levels

The analytical results show a relatively high variation in concentration of the contaminants between the different samples ranging from non-detectable levels to some above 1000 µg/kg PET. In addition, there is also not always an explicable correlation between the levels detected in the input samples and those found in the output samples. This is due to the industrial scale of the recycling operations where the input batch is not perfectly homogenous combined with the fact that, in comparison, only relatively small sample sizes are used for the analysis.

The incidental contaminants detected with a high frequency in the input samples are not unexpected (see Section 7).

Some of the incidental contaminants were also detected in the output samples, but at a lower frequency and in most cases at a lower concentration.

A safety assessment was carried out based on the following considerations:

- Exposure: average total migration levels as determined in Tables 5-7.
- Hazard: the following principles were used in order of priority:
    a. For substances listed in Annex I of Regulation (EU) No 10/2011, the specific or overall migration limit is applied.
    b. For the other substances, the thresholds according to the Threshold of Toxicological Concern (TTC) approach and the latest EFSA guidance (2019) were used. The substances were assigned to the corresponding toxicity classes using the Toxtree software[6]:
        i. For DNA-reactive mutagens and/or carcinogens, the threshold is 0.0025 µg/kg body weight (bw) per day;
        ii. For organophosphates or carbamates, the threshold is 0.3 µg/kg bw per day;
        iii. All other substances were classified based on the extended Cramer rule bases into Cramer class I, II, or III substances for which thresholds of, respectively 30 µg/kg bw per day, 9 µg/kg bw per day and 1.5 µg/kg bw per day

In the case of substances with a structural alert for genotoxic carcinogenicity it has been assumed that if their use was permitted as a flavoring within EU[7], their genotoxic potential could be considered as having been overruled.

For the oxidized form of Irgafos the recent study conducted by the FDA on *the "Safety assessment for Tris(2,4-di-tert-butylphenyl) phosphite (Irgafos 168) used as an antioxidant and stabilizer in food contact applications*[8]" concludes that "*The concern for neurotoxicity was diminished by the finding of no neurotoxicity in studies performed in hens treated with Irgafos 168 and Irgafos168ate combined with the result from oral studies in other species. Subsequently, an ADI value of 1 mg/ kg bw/day (20 ppm) was derived for I-168 and its degradants*".

Worst case exposure assessment and hazard assessment for incidental contaminants are summarised in Tables 14-16.

Based on the above assumptions, the data indicate that the worst case total migration concentration are below the applied safety thresholds for adult and toddler food consumption scenarios, for all incidental contaminants with the exception of benzene and BPA. However for these two substances the actual migration results confirm that migration and therefore exposure to these two substances is below the worst case calculated values and ranges from non-detected to 4.3 ppb in the case of benzene and from non-detected to 7.4 ppb in the case of BPA.

<u>Decontamination efficiency</u>

[6] Toxtree version v3.1.0, May 2018

[7] Regulation (EC) No 1334/2008 on flavouring and certain food ingredients with flavouring properties for use in and on foods.

[8] Food and Chemical Toxicology 178 (2023)

The decontamination efficiency of the recycling technology used was evaluated specifically for the incidental contaminants in the PET materials. This evaluation was carried out by comparing the concentration of contaminants in the input materials to their concentration in the output materials after undergoing decontamination processes. It is important to acknowledge the fact that for most contaminants it is not possible to demonstrate decontamination efficiency at the present level of contaminants in the input, given the current limits of detection (LOD) and limits of quantitation (LOQ) in the output.

In addition to the technical difficulties of analysing polymers for the presence of contaminants at ppb levels, another key challenge in assessing decontamination efficiency by direct polymer analysis (a method not comparable to a challenge test) is to accurately correlate the variability and dispersion of input data with the corresponding variability and dispersion of output results. This discrepancy is largely due to the inhomogeneity of the input samples, as well as different sampling techniques and analytical methods/conditions used by the different laboratories. As a result, there may be significant scatter in the data, making it difficult to identify clear patterns or trends in decontamination efficiency across the different equipment configurations.

Table 14. Worst case exposure assessment and hazard assessment of the incidental contaminants (all equipment configurations)

Substance	MW (g/mol)	CAS	OUTPUT		TOTAL MIGRATION CALCULATION** Average* (µg/kg food)	
			Frequency	Average* (µg/kg PET)		
limonene	136.23	138-86-3	67.29%	152.06	5.50	Cramer I
benzene	78.11	71-43-2	98.13%	1292.65	46.77	WHO: 10 µg/L
toluene	92.14	108-88-3	44.86%	94.51	3.42	Cramer I
adipic acid, bis(2-ethylhexyl) ester	370.6	103-23-1	38.32%	4883.18	176.67	FCM207, SML= 18 mg/kg + SML(T)=60mg/kg
2,2-bis(4-hydroxyphenyl)propane	228.29	80-05-7	47.66%	3217.49	116.41	EFSA (2023), EC (2025)
benzoic acid	112.12	65-85-0	26.17%	3286.57	118.91	FCM116 w/o SML
p-cymene	134.22	99-87-6	0%	ND (<17 - <150)	<0.62 - <5.43	Cramer I
γ-terpinene	136.23	99-85-4	0%	ND (<10 - <150)	<0.36 - <5.43	Cramer I
phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	646.94	31570-04-4	13.08%	7109.18	257.21	FCM671 w/o SML
ethylbenzene	106.16	100-41-4	3.74%	42.41	1.53	Cramer I
2-nonanone	142.24	821-55-6	0%	ND (<10 - <150)	<0.36 - <5.43	Cramer I
2-heptanone	114.19	110-43-0	0.93%	50.00	1.81	Cramer I
1-butanol	74.12	71-36-3	0.93%	174.00	6.30	FCM123 w/o SML
akr-30 pentaerythritol triacrylate (petia)	336.06	3524-68-3	19.63%	1390.71	50.32	Cramer I
styrene	104.15	100-42-5	29.91%	132.12	4.78	FCM193 w/o SML

eucalyptol	154.25	470-82-6	0.93%	52.67	1.91	Cramer II
cyclohexane	84.16	110-82-7	8.41%	148.60	5.38	Cramer I
pentanal	86.13	110-62-3	1.87%	131.36	4.75	Structural alert for genotoxic carcinogenicity
p-xylene	106.16	106-42-3	13.08%	64.36	2.33	Cramer I
oxidized irgafos 168	662.9	95906-11-9	11.21%	2742.32	99.22	Organophosphate

* average concentration calculated by only taking into account the samples in which it was detected

** total migration to food using an average thickness of 450 microns, a PET density of 1.34 and a Surface to Volume of 6 square dm for 1 kg of food

ND: not detected

Table 15. Worst case exposure assessment and hazard assessment of the incidental contaminants (X1X2W)

Substance	MW (g/mol)	CAS	OUTPUT		TOTAL MIGRATION CALCULA-TION** Average* (µg/kg food)	
			Fre-quency	Average* (µg/kg PET)		
limonene	136.23	138-86-3	25%	46.20	1.67	Cramer I
benzene	78.11	71-43-2	96.43%	900.45	32.58	WHO: 10 µg/L
Toluene	92.14	108-88-3	53.57%	72.22	2.61	Cramer I
1-butanol	74.12	71-36-3	3.57%	174.00	6.3	FCM123 w/o SML
adipic acid, bis(2-ethylhexyl) ester	370.6	103-23-1	25%	9202.21	332.94	FCM207, SML= 18 mg/kg + SML(T)=60mg/kg
benzoic acid	112.12	65-85-0	21.43%	2224.29	80.47	FCM116 w/o SML
p-cymene	134.22	99-87-6	0%	ND (<17)	<0.62	Cramer I
2,2-bis(4-hydroxy-phenyl)propane	228.29	80-05-7	46.43%	1813.51	65.61	EFSA (2023), EC (2025)
akr-30 pentae-rythritol triacry-late (petia)	336.06	3524-68-3	21.43%	1330.83	48.15	Cramer I
cyclohexane	84.16	110-82-7	7.14%	76.57	2.77	Cramer I
2-aminoben-zamide	136.15	88-68-6	0%	ND (<50 - <333)	<1.81 - <12.05	FCM164, SML=0.05 mg/kg
2-heptanone	114.19	110-43-0	0%	ND (<10 - <17)	<0.36 - <0.62	Cramer I
acetonitrile	41.05	75-05-8	17.86%	214.32	7.75	Cramer III
caffeine	194.19	58-08-2	7.14%	2115.53	76.54	Cramer III
n-hexane	86.18	110-54-3	3.57%	276.67	10.01	Cramer I
oxidized irgafos 168	662.9	95906-11-9	21.43%	3485.56	126.11	Organophosphate
phosphorous acid, tris(2,4-di-tert-bu-tylphenyl)ester	646.94	31570-04-4	10.71%	26097.78	944.22	FCM671 w/o SML
1,2-diethyl ben-zene	134.22	135-01-3	0%	ND (<17)	<0.62	Cramer I
1-methyl-3-pro-pyl-benzene	134.22	1074-43-7	0%	ND (<17)	<0.62	Cramer I

2,4-di-tert-butylphenol	206.32	96-76-4	7.14%	1324.88	47.93	Cramer I
2,5-bis(5-tert-butyl-2-benzox-azolyl)thiophene	430.6	7128-64-5	7.14%	897.83	32.48	Cramer III
2-nonanone	142.24	821-55-6	0%	ND (<17)	<0.62	Cramer I
cumene	120.19	98-82-8	0%	ND (<17)	<0.62	Cramer I
ethyl acetate + 1,3-dioxolane		141-78-6 + 646-06-0	10.71	105.56	3.82	FCM327 w/o SML + FCM363, SML=5mg/kg
ethyltoluene (isomers)	120.19	25550-14-5	0%	ND (<17)	<0.62	Cramer I
heptane	100.2	142-82-5	0%	ND (<17)	<0.62	Cramer I
indane	118.18	496-11-7	0%	ND (<17)	<0.62	Cramer III
myristyl myristate	424.7	3234-85-3	10.71	542.33	19.62	Cramer I
p-xylene	106.16	106-42-3	17.86%	55.34	2.00	Cramer I
pentane, 2,2,4-trimethyl-	114.23	540-84-1	0%	ND (<17)	<0.62	Cramer I
propyl-benzene	120.19	103-65-1	0%	ND (<17)	<0.62	Cramer I
stearamide	283.5	124-26-5	17.86%	1549.33	56.05	FCM306 w/o SML
xylenes (isomers)	106.16	1330-20-7	7.14%	297.96	10.78	Cramer I
γ-terpinene	136.23	99-85-4	0%	ND (<10 - <17)	<0.36 - <0.62	Cramer I

*** average concentration calculated by only taking into account the samples in which it was detected**

**** total migration to food using an average thickness of 450 microns, a PET density of 1.34 and a Surface to Volume of 6 square dm for 1 kg of food**

ND: not detected

Table 16. Worst case exposure assessment and hazard assessment of the incidental contaminants (Y1Y2)

Substance	MW (g/mol)	CAS	OUTPUT		TOTAL MIGRATION CALCULATION** Average* (µg/kg food)	
			Frequency	Average* (µg/kg PET)		
limonene	136.23	138-86-3	82.28%	163.46	5.91	Cramer I
benzene	78.11	71-43-2	98.73%	1428.42	51.68	WHO: 10 µg/L
adipic acid, bis(2-ethylhexyl) ester	370.6	103-23-1	43.04%	3993.97	144.5	FCM207, SML= 18 mg/kg + SML(T)=60mg/kg
toluene	92.14	108-88-3	41.77%	104.64	3.79	Cramer I
2,2-bis(4-hydroxy-phenyl)propane	228.29	80-05-7	48.1%	3697.80	133.79	EFSA (2023), EC (2025)
benzoic acid	112.12	65-85-0	27.85%	3576.28	129.39	FCM116 w/o SML
γ-terpinene	136.23	99-85-4	0%	ND (<10 - <150)	<0.36 - <5.43	Cramer I
ethylbenzene	106.16	100-41-4	2.53%	44.91	1.62	Cramer I
p-cymene	134.22	99-87-6	0%	ND (<17 - <150)	<0.62 - <5.43	Cramer I
phosphorous acid, tris(2,4-di-	646.94	31570-04-4	13.92%	1930.47	69.84	FCM671 w/o SML

tert-butylphenyl)ester						
styrene	104.15	100-42-5	31.65%	140.22	5.07	FCM193 w/o SML
eucalyptol	154.25	470-82-6	1.27%	52.67	1.91	Cramer II
pentanal	86.13	110-62-3	1.27%	113.71	4.11	Structural alert for genotoxic carcinogenicity
2-nonanone	142.24	821-55-6	0%	ND (<10 - <150)	<0.36 - <5.43	Cramer I
2-heptanone	114.19	110-43-0	1.27%	50.00	1.81	Cramer I
2-propanol	60.1	67-63-0	1.27%	660.67	23.90	FCM118 w/o SML
akr-30 pentaerythritol triacrylate (petia)	336.06	3524-68-3	18.99%	1414.67	51.18	Cramer I
hexanoic acid	116.16	142-62-1	0%	ND (<10 - <50)	<0.36 - <1.81	FCM329 w/o SML
p-xylene	106.16	106-42-3	11.39%	69.37	2.51	Cramer I
salicylic acid, methyl ester	152.15	119-36-8	0%	ND (<10 - <100)	<0.36 - <3.62	FCM284 w/o SML

* average concentration calculated by only taking into account the samples in which it was detected

** total migration to food using an average thickness of 450 microns, a PET density of 1.34 and a Surface to Volume of 6 square dm for 1 kg of food

ND: not detected

11. Discussion of the differences with previous reports published in accordance with this paragraph, if any - Art. 13(5)(j)

The numerous analyses carried out for this report give it greater statistical significance, although questions remain as to the accuracy of the results when carrying out measurements in the polymer itself. Additionally, the validity and practical significance of the results at the ppb level may necessitate further scrutiny.

Out of the results it is generally observed that the concentrations of contaminants measured in the input and output remain relatively comparable to those measured in previous reports. The migration measurements obtained in this study are consistent with those reported previously and with the results of the migration simulations presented in the preceding report within the limitations of the analytical methods.

However, the findings also demonstrate considerable variability in the outcomes, along with substantial disparities in LOD and LOQ across different laboratories. This underscores the necessity for optimal standardisation of analytical methodologies and conditions, including those for sampling and sample preparation. Moreover, it is imperative to adhere to guidelines when calculating frequencies and mean values, in order to ensure consistency in the approach and the validity of conclusions drawn.

Therefore, despite the substantial number of analyses conducted, it is still premature to draw firm conclusions about certain specific trends, particularly the influence of the equipment configuration and the correlation between migration results and certain migration simulations conducted previously under very specific conditions.

It is however, essential to emphasise that the migration results indicate that the actual migration is significantly lower than that calculated based on the concentration in the sheet and considering total

migration. Consequently, this total migration calculation method can be regarded as a worst-case scenario for evaluating exposure and ensuring the safety of the material. Only limonene in one of the samples tested gave a migration result of 0.45 µg/kg food while the worst case calculation was 0.42 µg/kg food.

Finally, it is important to reiterate that even the migration testing should be considered as a worst case scenario.This is because it has been conducted using ethanol 95%, a simulant that, when used with PET, produces much higher results than fatty food itself due to its swelling properties and the possibility of inducing PET hydrolysis.

Annex I -Substances with Molecular Weight less than 1000 Da, and relevant occurrence, found in the input and output material.

Name	CAS	Formula	Frequency INPUT (%)	Frequency OUTPUT (%)
2-methyl-1,3-dioxolane	497-26-7	C4H8O2	100	100
acetaldehyde	75-07-0	C2H4O	92.52	92.52
limonene	138-86-3	C10H16	88.79	67.29
benzene	71-43-2	C6H6	71.03	98.13
3-((12-acetoxyoctadecanoyl)oxy)propane-1,2-diyl diacetate	330198-91-9	C27H48O8	67.29	50.47
2-[2-hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl]benzotriazole	70321-86-7	C30H29N3O	65.42	59.81
hexanal	66-25-1	C6H12O	65.42	46.73
acetic acid	64-19-7	C2H4O2	55.14	37.38
acetic acid, ethyl ester	141-78-6	C4H8O2	51.4	21.5
ethanol	64-17-5	C2H6O	49.53	43.93
ethyleneglycol	107-21-1	C2H6O2	48.6	52.34
toluene	108-88-3	C7H8	47.66	44.86
acetone	67-64-1	C3H6O	44.86	39.25
adipic acid, bis(2-ethylhexyl) ester	103-23-1	C22H42O4	43.93	38.32
nonanal	124-19-6	C9H18O	37.38	13.08
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		36.45	36.45
cyclic[tpa+eg]2+[ipa+deg]			35.51	35.51
cyclic[tpa+deg]2			35.51	35.51
cyclic[tpa+eg]2+[ipa+eg]			34.58	35.51
terephthalic acid, bis(2-ethylhexyl)ester	6422-86-2	C24H38O4	33.64	34.58
cyclic[tpa+eg]+[ipa+deg]			33.64	30.84
cyclic[tpa+eg]3+[ipa+eg]			33.64	32.71
cyclic[tpa+eg]+[ipa+eg]			31.78	26.17
2,2-bis(4-hydroxyphenyl)propane	80-05-7	C15H16O2	31.78	47.66
1,4-benzenedicarboxylic acid, bis(2-hydroxyethyl) ester	959-26-2	C12H14O6	31.78	40.19
benzoic acid	65-85-0	C7H6O2	30.84	26.17
linear[tpa+eg]2+deg			28.04	30.84
2-ethyl-1-hexanol	104-76-7	C8H18O	28.04	2.8
solvent blue 104	116-75-6	C32H30N2O2	28.04	22.43
cyclic ester of (2) phthtalic acid with (2) ethylene glycol			26.17	26.17
probable pet oligomer (dimer ether)			26.17	26.17

Name	Formula	CAS	Frequency INPUT (%)	Frequency OUTPUT (%)
3-hydroxy-7,8,2'-trimethoxyflavone, tri-methylsilyl ether	1000454-19-8		28.0	27.0
probable pet oligomer (cyclic dimer)			28.0	28.0
p-cymene	99-87-6	C10H14	27.0	0
cyclic[tpa+eg]+[tpa+deg]2			27.0	30.0
c[deg/pa/eg/pa] pa=phthalic acid deg=diethylen glycol eg=ethylen glycol			26.0	26.0
terephthalic acid	100-21-0	C8H6O4	26.0	26.0
c[eg/pa/eg/pa/eg/pa] pa=phthalic acid eg=ethylene glycol			26.0	26.0
methyl formate	107-31-3	C2H4O2	26.0	26.0
c[deg/pa/eg/pa/eg/pa] pa=phthalic acid deg=diethylen glycol eg=ethylen glycol			26.0	26.0
γ-terpinene	99-85-4	C10H16	25.0	0
pet oligomers			25.0	25.0
phosphorous acid, tris(2,4-di-tert-bu-tylphenyl)ester	31570-04-4	C42H63O3P	25.0	14.0
c[eg/pa/eg/pa/eg/pa/eg/pa] eg=eth-ylene glycol pa=phthalic acid			24.0	25.0
cyclic[tpa+eg]4+[ipa+eg]			24.0	27.0
benzaldehyde	100-52-7	C7H6O	23.0	6.0
hexamethyl cyclotrisiloxane	541-05-9	C6H18O3Si3	23.0	14.0
linear[tpa+eg]2+eg			23.0	23.0
ethylbenzene	100-41-4	C8H10	23.0	4.0
c[eg/pa/eg/pa/eg/pa/eg/pa/eg/pa] eg=ethylene glycol pa=phthalic acid			22.0	26.0
2-nonanone	821-55-6	C9H18O	21.0	0
2-heptanone	110-43-0	C7H14O	21.0	1.0
1-butanol	71-36-3	C4H10O	21.0	1.0
akr-30 pentaerythritol triacrylate (petia)	3524-68-3	C14H18O7	21.0	21.0
linear[tpa+eg]3+eg			20.0	19.0
formic acid	64-18-6	CH2O2	20.0	10.0
styrene	100-42-5	C8H8	20.0	32.0
hydrocarbons			20.0	20.0
1,4-dioxane	123-91-1	C4H8O2	20.0	26.0
eucalyptol	470-82-6	C10H18O	19.0	1.0
dimethylsilanediol	1066-42-8	C2H8O2Si	19.0	27.0
prob. dichloromethane	75-09-2	CH2Cl2	18.0	12.0
cyclohexane	110-82-7	C6H12	18.0	9.0
heptanal	111-71-7	C7H14O	18.0	1.0
pentanal	110-62-3	C5H10O	18.0	2.0
probable pet oligomer			18.0	7.0
p-xylene	106-42-3	C8H10	18.0	14.0
oxidized irgafos 168	95906-11-9	C42H63O4P	18.0	12.0
acetic acid, methyl ester	79-20-9	C3H6O2	17.0	10.0
n-hexane	110-54-3	C6H14	17.0	8.0

Name	CAS	Formula	Frequency INPUT (%)	Frequency OUTPUT (%)
bis(2-ethylhexyl) sebacate	122-62-3	C26H50O4	15.89	8.41
cis-11-eicosenamide	10436-08-5	C20H39NO	15.89	12.15
c[deg/pa/deg/pa] deg=diethylen glycol pa=phthalic acid			15.89	15.89
xylenes (isomers)	1330-20-7		14.95	6.54
octadecanoic acid, 2-(acetyloxy)-1-[(acetyloxy)methyl]ethyl ester	55401-62-2	C25H46O6	14.95	2.8
phthalic acid, bis(2-ethylhexyl) ester	117-81-7	C24H38O4	14.95	23.36
cyclic[tpa+eg]4+[tpa+deg]			14.95	8.41
aldehydes			14.95	8.41
c[deg/pa/eg/pa/eg/pa/eg/pa] pa=phthalic acid eg=ethylene glycol deg=diethylene glycol			14.95	14.95
2-propanol	67-63-0	C3H8O	14.95	0.93
2-aminobenzamide	88-68-6	C7H8N2O	14.95	0.93
salicylic acid, methyl ester	119-36-8	C8H8O3	14.95	0
isophthalic acid, 2-chloroethyl ethyl ester	1000345-86-8		14.02	14.02
2,4-di-tert-butylphenol	96-76-4	C14H22O	14.02	8.41
hexanoic acid	142-62-1	C6H12O2	14.02	1.87
1-hydroxy-4-(p-toluidino)anthraquinone	81-48-1	C21H15NO3	13.08	12.15
2-pentyl-furan	3777-69-3	C9H14O	13.08	3.74
palmitic acid	57-10-3	C16H32O2	13.08	11.21
4(1h)-quinazolinone, 2-methyl-	1769-24-0	C9H8N2O	13.08	8.41
stearamide	124-26-5	C18H37NO	13.08	16.82
2,5-bis(5-tert-butyl-2-benzoxazolyl)thio-phene	7128-64-5	C26H26N2O2S	13.08	11.21
myristyl myristate	3234-85-3	C28H56O2	12.15	5.61
1,2-ethanediol, monobenzoate	94-33-7	C9H10O3	12.15	10.28
1-pentanol	71-41-0	C5H12O	12.15	0.93
cyclohexasiloxane, dodecamethyl-	540-97-6	C12H36O6Si6	12.15	12.15
4(1h)-quinazolinone	491-36-1	C8H6N2O	12.15	15.89
ftalan dietylu	84-66-2	C12H14O4	12.15	10.28
octanal	124-13-0	C8H16O	12.15	0
2-propenal	107-02-8	C3H4O	12.15	5.61
dioctyl adipate	123-79-5	C22H42O4	12.15	9.35
o-xylene	95-47-6	C8H10	11.21	3.74
caffeine	58-08-2	C8H10N4O2	11.21	11.21
trimethylbenzenes (isomers)	25551-13-7	C9H12	11.21	0
sydowinin a, 2tms derivative	1000480-70-9		11.21	11.21
palmitamide	629-54-9	C16H33NO	11.21	9.35
2-n-butyl-2-cyclopentenone	5561-05-7	C9H14O	11.21	0
acetylated mono- and diglycerides of fatty acids			11.21	10.28

Name	Formula	CAS	Frequency INPUT	Frequency OUTPUT
phthalic anhydride	85-44-9	C8H4O3	12.0	11.0
linear[tpa+eg]+eg			12.0	12.0
tetradecamethylcycloheptasiloxane (d7)	107-50-6	C14H42O7Si7	11.0	10.0
cyclic[tpa+eg]3+[ipa+deg]			11.0	10.0
heptane	142-82-5	C7H16	11.0	3.0
oleic acid	112-80-1	C18H34O2	11.0	5.0
2,2'-(1,4-phenylene)bis[4H-3,1-benzoxa-zin-4-one]	18600-59-4	C22H12N2O4	11.0	3.0
ethyltoluene (isomers)	25550-14-5		11.0	0
dof / 2-ethylhexyl fumarate	141-02-6	C20H36O4	11.0	6.0
acetonitrile	75-05-8	C2H3N	11.0	12.0
1,3-dioxolane	646-06-0	C3H6O2	10.0	8.0
2-chloroethyl benzoate	939-55-9	C9H9ClO2	10.0	11.0
2-decanone	693-54-9	C10H20O	10.0	0
linear[tpa+eg]3+deg			10.0	12.0
triethylene glycol monobutyl ether	143-22-6	C10H22O4	10.0	4.0
n,n-bis(2-hydroxyethyl)dodecylamine	1541-67-9	C16H35NO2	10.0	7.0
propyl-benzene	103-65-1	C9H12	10.0	0
butyraldehyde	123-72-8	C4H8O	10.0	2.0
stearic acid	57-11-4	C18H36O2	10.0	10.0
benzoic acid, 4-methyl-, 2-hydroxyethyl ester	28129-15-9	C10H12O3	10.0	8.0
erucamide	112-84-5	C22H43NO	10.0	16.0
linear[tpa+eg]+deg			10.0	12.0
unknown			10.0	0
acetic acid, butyl ester	123-86-4	C6H12O2	9.0	1.0
1-stearoylglycerol (1-monostearin)	123-94-4	C21H42O4	9.0	6.0
ketones			9.0	4.0
aibn	78-67-1	C8H12N4	9.0	10.0
oleamide	301-02-0	C18H35NO	9.0	4.0
tri-n-butyl acetyl citrate	77-90-7	C20H34O8	9.0	3.0
phenol, 2,4-bis(1-methyl-1-phe-nylethyl)-	2772-45-4	C24H26O	9.0	5.0
2-butanone	78-93-3	C4H8O	9.0	0
phthalic anhydri+A140:A144	109-60-4	C5H10O2	9.0	1.0
c[deg/pa/deg/pa] deg= diethylen glycol pa= phthalic acid			9.0	9.0
octadecanoic acid, 2,3-bis(acety-loxy)propyl ester	33599-07-4	C25H46O6	9.0	6.0
benzene, 1,3-dimethyl-	108-38-3	C8H10	8.0	4.0
propane, 2-methoxy-2-methyl-	1634-04-4	C5H12O	8.0	0
1-methyl-3-propyl-benzene	1074-43-7	C10H14	8.0	0
cyclopentasiloxane, decamethyl-	541-02-6	C10H30O5Si5	8.0	9.0
n'n-dibutylformamide	761-65-9	C9H19NO	8.0	6.0
propylene oxide	75-56-9	C3H6O	8.0	4.0

Name	CAS	Formula	Frequency INPUT (%)	Frequency OUTPUT (%)
l[eg/pa/eg/pa/eg/pa] pa=phthalic acid eg=ethylene glycol			7.48	7.48
l[eg/pa/eg/pa] pa=phthalic acid eg=eth-ylene glycol			7.48	7.48
cumene	98-82-8	C9H12	7.48	0
palmitoleamide	106010-22-4	C16H31NO	7.48	6.54
pentane, 2,2,4-trimethyl-	540-84-1	C8H18	7.48	1.87
9-octadecenenitrile, (z)-	112-91-4	C18H33N	7.48	7.48
c[eg/pa/eg/pa/eg/pa] pa=phthalic acid eg=ethylene glycol	7441-32-9 (for TPA)		6.54	6.54
tetradecanamide	638-58-4	C14H29NO	6.54	4.67
l[eg/pa/eg/pa/eg/pa/eg/pa] pa=phthalic acid eg=ethylene glycol			6.54	6.54
c[deg/pa/eg/pa] pa=phthalic acid deg=di-ethylen glycol eg=ethylen glycol	29278-57-7 (for TPA)		6.54	6.54
c[deg/pa/eg/pa/eg/pa] pa=phthalic acid deg=diethylen glycol eg=ethylen glycol	873422-64-1 (for TPA)		6.54	6.54
tetrahydrofuran	109-99-9	C4H8O	6.54	0
c[eg/pa/eg/pa/eg/pa/eg/pa] eg=ethylene glycol pa=phthalic acid	16104-96-4 (for TPA)		6.54	6.54
l[pa/eg] pa=phthalic acid eg=ethylen glycol			6.54	7.48
pet oligomer (cyclic dimer)			6.54	6.54
c[deg/pa/deg/pa] deg=diethylen glycol pa=phthalic acid	16104-98-6 (for TPA)		6.54	6.54
c[eg/pa/eg/pa/eg/pa/eg/pa/eg/pa/eg/pa] pa=phthalic acid eg=ethylen glycol			6.54	10.28
cyclic ester of (2) terephthalic acid with (2) ethylene glycol			6.54	6.54
anethole	104-46-1	C10H12O	6.54	0
linear[tpa+eg]2			6.54	9.35
ethyl acetate + 1,3-dioxolane	141-78-6 + 646-06-0		6.54	3.74
c[eg/pa/eg/pa/eg/pa/eg/pa/eg/pa] eg=ethylene glycol pa=phthalic acid	16104-97-5 (for TPA)		6.54	6.54
c[deg/pa/eg/pa/eg/pa/eg/pa] pa=phthalic acid eg=ethylene glycol deg=diethylene gly-col	2222729-29-3 (for TPA)		5.61	4.67
3,6,9,12,15,18-hexaoxaoctacosan-1-ol [	5168-89-8	C22H46O7	5.61	0
nonylphenol ethoxylates (npeo5)			5.61	5.61
hexadecanoic acid, hexadecyl ester	540-10-3	C32H64O2	5.61	8.41
cyclohexene, 1-methyl-4-(1-methylethyli-dene)-	586-62-9	C10H16	5.61	0
6-methylheptyl methacrylate	28675-80-1	C12H22O2	5.61	2.8
c[deg/pa/eg/pa/eg/pa/eg/pa] eg=ethylene glycol deg=diethylene glycol pa=phthalic acid			5.61	5.61
peg8-(ch2)9-ch3			5.61	0
benzophenone	119-61-9	C13H10O	5.61	1.87
1-dodecanol	112-53-8	C12H26O	5.61	0
1-hexadecanol	36653-82-4	C16H34O	5.61	3.74

Name	Formula	CAS	Frequency INPUT	Frequency OUTPUT
benzaldehyde, 3,4-dimethyl-	5973-71-7	C9H10O	5.61	1.87
carbonic acid, eicosyl vinyl ester	1000382-54-3		5.61	9.35
1,3-benzenedicarboxylic acid, bis(2-ethylhexyl) ester	137-89-3	C24H38O4	5.61	3.74
pet oligomer (ether dimer)			5.61	4.67
peg7-(ch2)9-ch3			5.61	0
bis(2-hydroxyethyl) phthalate	84-73-1	C12H14O6	5.61	5.61
linoleic acid	60-33-3	C18H32O2	5.61	3.74
2-isopropyl-5-methyl-1-heptanol	91337-07-4	C11H24O	5.61	2.8
1,2-diethyl benzene	135-01-3	C10H14	5.61	0

Annex II: Summary of testing methods

Testing laboratories and relevant methods of analysis for volatile substances

Laboratory	Company	AIMPLAS	CHELAB SRL	Ecol Studio s.p.a.	Food Contact Center	J.S. Hamilton Poland Sp. z o.o.	Pack Co	Sepack Lab S.r.l.
	Address1	Carrer de Gustave Eiffel, 4	VIA FRATTA 25	Via dei Bichi 293 -55100- Lucca-Italy	Via del Redolone 65	Chwaszczyńska 180	8 Angelo Brunetti Street	4 Ernesto Gramegna Street
	Address2	Carrer del Comte Alessandro Volta, 1				0		
	City	Paterna	RESANA	Lucca	Serravalle Pistoiese	Gdynia	Milan	Montebello della Battaglia (PV)
	Country	Spain	ITALY	Italy	Pistoia	Poland	Italy	Italy
	Zip	46980	31023	ND	51034	81-571	20156	27054
Sample	Date of Arrival	27/11/2024	10/01/2025	04/11/2024	17/12/2024	04/11/2024	15/11/2024	06/11/2024
	Client Sample Reference Number	FBESY2POLISUR02OU03	FBITY2ITH3HG0IDIN03	RPET FLAKES	FBITY2ITC8JI0I9OU04	FBDEY2DEB-2A0-0IDIN03	FBITY2CIER1IN01	FBITY2CARTONPB1IN01
	Laboratory Sample Reference Number	24-4357-2	25.501085.0001-2-3	24LD07549	FC241307.01	687554/24/GDY	738-24-IN	24LD02941
	Date of Analysis Start	28/11/2024	10/01/2025	05/11/2024	17/12/2024	12/11/2024	20/11/2024	02/12/2024
	Date of Report	15/01/2025	12/02/2025	20/12/2024	31/01/2025	29/11/2024	20/11/2024	09/01/2025
Grinding	Make	Biometa tecnologia y sistemas S.A.	Retsch	Retsch	grinder	Retsch	IKA	Retsch
	Model	ZM2000	ZM300	ZM200	na	ZM300	A 11 B S000	ZM200
	Temp [°C]	-200	-78	-196	-196	-196	-196	-196
	Coolant	liquid nitrogen	dry ice	liquid nitrogen	liquid nitrogen	liquid nitrogen	liquid nitrogen	liquid nitrogen
	Particle Size [µm]	500	<750	500	500-750	500-750	<750	<750
Instrument	Chromatograph Model	Thermo Fisher Scientific	GC 8890	Gas Chromatograph 7820A	QP2010	7890B	7890B	8890-G3542A
	Chromatograph Make	-	Agilent	Agilent	Shimadzu	Agilent	Agilent	Agilent
	Detector1 Model	Thermo Fisher Scientific	5977B	Single Quadrupole 5975C	QP2010	FID	5977B	5977B-G7081B
	Detector1 Make	-	Agilent	Agilent	Shimadzu	Agilent	Agilent	Agilent
	Chromatographic Column	(5%-phenyl)-methylpolysiloxane	DB 624	DB-624 60m x 0.25mm x 1.4um	J&W DB-624 Ultra Inert GC Column, 30 m, 0.25 mm, 1.40	DB-624 60 m x 250 µm x 1,4 µm	Restek Rtx-5MS	VF-624ms (30 m, 0.25 mm, 1.40 µm)
Extraction Conditions	Extraction Technique	Thermal desorption	thermal desorption in headspace vial	Static Headspace	HS	Multi-headspace extraction	HS	Head space
	Sample weight [g]	3	1	1	1	1	0,3	1
	Extraction Time [h]	1	1	1	1	1	1	1
	Extraction Temperature [°C]	150	150	150	150	150	150	150
Test Conditions	Range of Mass Acquisition [Dalton]	20-400	35-450	40-450	40-300	0	41-400	25-400
	Internal Standard	Toluene	Styrene Deuterated D8	CAS108-90-7	Pentyl benzene	0	Mix of volatiles	Chlorobenzene (CAS No. 108-90-7)
Performances	Sensitivity1 [µg/kg]	150	30	30	10	Acetaldehyde: 400 2-Methyl-1,3-dioxolane: 400 Benzene: 40 d-Limonene: 40	30	50
Identification of Compounds	Library	NIST	VOCsMXNSC (internal database); NIST11; NIST17,	NIST	Nist	NIST, Internal	NIST	NIST17 and Internal Library

Testing laboratories and relevant methods of analysis for semi-volatile substances

Laboratory	Company	AIMPLAS	CHELAB SRL	Ecol Studio s.p.a.	Food Contact Center	J.S. Hamilton Poland Sp. z o.o.	Pack Co	Sepack Lab S.r.l.
	Address1	Carrer de Gustave Eiffel, 4	VIA FRATTA 25	Via dei Bichi 293, 55100 - Lucca- Italy	Via del Redolone 65	Chwaszczyńska 180	Via Angelo Brunetti 8	4 Ernesto Gramegna Street
	Address2	Carrer del Comte Alessandro Volta, 1						
	City	Paterna	RESANA	Lucca	Serravalle Pistoiese	Gdynia	Milan	Montebello della Battaglia (PV)
	Country	Spain	ITALY	Italy	Pistoia	Poland	Italy	Italy
	Zip	46980	31023	NDA	51034	81-571	20156	27054
Sample	Date of Arrival	27/11/2024	10/01/2025	04/11/2024	17/12/2024	06/11/2024	15/11/2024	06/11/2024
	Client Sample Reference Num	FBESY2POLISUR02OU03	FBITY2ITH3HG0IDIN03	RPET FLAKES	FBITY2ITC8JI0I9OU04	FBDEY2DEB-2A0-0IDIN03	FBITY2CIER1IN01	FBITY2CARTONPB1IN01
	Laboratory Sample Reference	24-4357-2	25.501085.0001-2-3	24LD07549	FC241307.01	687554/24/TYC	738-IN-24	24LD02943
	Date of Analysis Start	28/11/2024	10/01/2025	05/11/2024	17/12/2024	15/11/2024	27/11/2024	02/12/2024
	Date of Report	15/01/2025	12/02/2025	20/12/2024	31/01/2025	27/11/2024	28/11/2024	09/01/2025
Grinding	Make	Biometa tecnologia y sistemas S.A.	Retsch	Retsch	grinder	Retsch	IKA	Retsch
	Model	ZM2000	ZM300	ZM200	na	ZM300	A 11 B S000	ZM200
	Temp [°C]	-196	-78	-196	-196	-196	-196	-196
	Coolant	liquid nitrogen	dry ice	liquid nitrogen	liquid nitrogen	liquid nitrogen	liquid nitrogen	liquid nitrogen
	Particle Size [µm]	500	<750	500	500-750	500-750	<750	<750
Instrument	Chromatograph Model	Thermo Fisher Scientific	7890B	Gas Chromatograph Intuvo 9000	GC8890	G3540A	GC-MS	7890A
	Chromatograph Make	-	Agilent	Agilent	Agilent	Agilent	Agilent	Agilent
	Detector1 Model	Thermo Fisher Scientific	G7039A	Single Quadrupole 5977B	TQ7000E	5977B GC/MSD	G3440A	G3171A
	Detector1 Make	-	Agilent	Agilent	Agilent	Agilent	Agilent	Agilent
	Detector2 Model		\			FID	ND	
	Detector2 Make		\			Agilent	ND	
	Chromatographic Column	(5%-phenyl)-methylpolysiloxane	DB-5ms	DB35 30m x 250um x 0.25um	Column DB-5 30m, 0.25mm, 0.25µm	OPTIMA DELTA-3 ID: 30 m x 0,32 mm x,0,25 µm	DB-5HT	HP-5MS UI (30 m, 0.25 mm, 0.25 µm)
Extraction Conditions	Extraction Solvent	Hexane/Ethanol 3/1	Dichloromethane	Dichloromethane	Dichloromethane	Dichloromethane	Dichloromethane	Acetonitrile
	Type of Contact	Immersion	immersion	Extraction	/	Solid-liquid extraction	ultrasonic bath	Total immersion
	Sample Weight [g]	1,5	1	5	2	1	0.3	1
	Solvent Volume [ml]	15	15	80	10	15	5	10
	Time of Contact [h]	8	8	2	2	24	6	1
	Temperature of Contact [°C]	20	70	25	60	40	60	60
Test Conditions	Range Of Mass Acquisition [D	25-300	35÷1000	40-650	30-550	30-800	33-750 amu	45-700
	Internal Standard	-	4,4-difluorobiphenyl	CAS 131-16-8	Benzene, pentyl CAS 538-68-1	MOSH/MOAH Standard 150-600 µg/mL	Methyl Heptadecanoate	Dipropyl phthalate (CAS No. 131-16-8)
	Quantification	Toluene	\	Semiquantitative	/	semi quantitative via FID	ND	Semi-quantification
Performances	Sensitivity1 [µg/kg]	100	100	100	10	100.00	200	1000
Identification of Compounds	Library	NIST	SVOCsMXNSC (internal database); NIST11; NIST17, WILEY275	NIST	NIST v2,4 25 March 2020	NIST	ND	NIST17 and Internal library

Testing laboratories and relevant methods of analysis for non-volatile substances

Laboratory	Company	AIMPLAS	CHELAB SRL	Ecol Studio s.p.a.	Food Contact Center	J.S. Hamilton Poland Sp. z o.o.	Pack Co	Sepack Lab S.r.l.
	Address1	Carrer de Gustave Eiffel, 4	VIA FRATTA 25	Via dei Bichi 293, 55100 - Lucca- Italy	Via del Redolone 65	Chwaszczyńska 180	Via Angelo Brunetti 8	4 Ernesto Gramegna Street
	Address2	Carrer del Comte Alessandro Volta, 1						
	City	Paterna	RESANA	Lucca	Serravalle Pistoiese	Gdynia	Milan	Montebello della Battaglia (PV)
	Country	Spain	ITALY	Italy	Pistoia	Poland	Italy	Italy
	Zip	46980	31023	NDA	51034	81-571	20156	27054
Sample	Date of Arrival	27/11/2024	10/01/2025	04/11/2024	17/12/2024	06/11/2024	15/11/2024	06/11/2024
	Client Sample Reference Num	FBESY2POLISUR02OU03	FBITY2ITH3HG0IDIN03	RPET FLAKES	FBITY2ITC8JI0I9OU04	FBDEY2DEB-2A0-0IDIN03	FBITY2CIER1IN01	FBITY2CARTONPB1IN01
	Laboratory Sample Reference	24-4357-2	25.501085.0001-2-3	24LD07549	FC241307.01	687554/24/TYC	738-IN-24	24LD02944
	Date of Analysis Start	28/11/2024	10/01/2025	05/11/2024	17/12/2024	15/11/2024	27/11/2024	02/12/2024
	Date of Report	15/01/2025	12/02/2025	20/12/2024	31/01/2025	03/12/2024	28/11/2024	09/12/2024
Grinding	Make	Biometa tecnologia y sistemas S.A.	Retsch	Retsch	grinder	Retsch	IKA	Retsch
	Model	ZM2000	ZM300	ZM200	na	ZM300	A 11 B S000	ZM200
	Temp [°C]	-200	-78	-196	-196	-196	-196	-196
	Coolant	liquid nitrogen	dry ice	liquid nitrogen	n2	liquid nitrogen	liquid nitrogen	liquid nitrogen
	Particle Size [µm]	500	<750	500	500-750	500-750	500-750	<750
Instrument	Chromatograph Model	Waters	Vanquish	Nexera X2	Nexera X2	1260 Infinity II	HPLC	Nexera X2
	Chromatograph Make	-	Thermo Fisher	SHIMADZU	Shimadzu	Agilent	Shimadzu	SHIMADZU
	Detector1 Model	Waters	Orbitrap Exploris 120	TRIPLETOF 4600	TripleTOF4600	6546 LC/Q-TOF	LCMS (8045)	500X QToF
	Detector1 Make	-	Thermo Fisher	AB SCIEX	Sciex	Agilent	Shimadzu	AB SCIEX
	Chromatographic Column	C18, 1.6um x 2.1 mm x 100mm	Aquity UPLC HSS T3-C18	Kinetex 2.6 µm EVO C18, 50 x 2.1mm	Kinetex EVO C18 150x21 mmm 2,6 um	ACQUITY UPLC BEH C18 Column, 130Å, 1.7 µm, 2.1 mm X 100 mm	Raptor C18 2.7 µm 100 x 2.1 mm	Kinetex 2.6 µm EVO C18, 50 x 2.1mm
Extraction Conditions	Extraction Solvent	Hexane/Etanol 3:1	Dichloromethane	Acetonitrile	Acetonitrile	Acetonitrile	Dichloromethane	Acetonitrile
	Type of Contact	Immersion	immersion	Total immersion	/	Solid-liquid extraction	ultrasonic bath	Total immersion
	Sample Weight [g]	1.5	1	1	2	1	0.3	1
	Solvent Volume [ml]	15	15	10	10	15	5	10
	Time of Contact [h]	8	8	16	2	24	6	1
	Temperature of Contact [°C]	20	70	60	60	60	60	60
Test Conditions	Range of Mass Acquisition [D	70-1000	70÷1000	100 - 1600	20-1200	50-1700	50-1000	90-1300
	Polarity	Positive and negative	POS/NEG	POS AND NEG	pos and neg	ESI+	POS AND NEG	POS
	POS Internal Standard	Benzyl butyl phthalate	Benzyl butyl phthalate-3,4,5,6-d4	Reserpina (CAS N. 50-55-5)	relative compounds	Reserpina, Pyraclostrobin, Acetmiprid	ND	2-[2-hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl]benzotriazole (CAS 70321-86-7)
	NEG Internal Standard	Nimesulide	Nimesulide	Taurocholic acid (CAS N. 81-24-3)	relative compounds	n.a.	ND	Taurocholic acid (CAS No. 81-24-3)
Performances	Sensitivity1 [µg/kg]	100	100	1000	10	100	ND	1000
Identification of Compounds	Library	Internal	NIST, Internal	NIST 2017 and Internal	Internal library	PCDL (in-house library)	-	NIST 2017 and Internal