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

Functional Barrier.

Novel Technology Development

5th Data Monitoring Report

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

Issued on 14th May 2026.

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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 fifth monitoring report. It provides a summary of the data forthcoming from the monitoring, based on the latest information from 98 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 plastic 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].

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 pre-processed PET input as the B central layer of A/B/A structures. Therefore, the B layer is made of pre-processed PET input (pPET input) or blends of pPET input 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:

- 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.

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

- 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 below 290°C (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 PET input plastic (= pre-processed PET flakes or pellets) 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

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.

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

These data were used in combination with migration modelling to ascertain the maximum concentration of decontaminated pre-processed PET input 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 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 eight 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 that 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 76 lines out of the 180 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 6 different laboratories located in different EU Countries, and using similar testing methods but not identical.
- In total 76 samples for input and the correspondent 76 samples for output sheet after decontamination have been analysed.
- Out of the 76 samples for output sheet, 58 correspond to equipment configuration group Y1Y2 and 18 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 6 different laboratories. In total 76 samples for input and the correspondent 76 samples for output sheet after decontamination have been analysed. Out of the 76 samples for output sheet, 58 correspond to equipment configuration group Y1Y2 and 18 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 still not possible 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 58 analyses and in the other of only 18, not even taking into account interlaboratory variation and differences in LOD and LOQ between the labs. It should also be noted that laboratories have different capabilities in terms of their detection and quantification limits.

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 styrene-based polymers, 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 remains 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 as should any conclusions based on them even if maximum precautions have been taken to make them as robust and realistic as possible.

Tables 2-4 list the 21 (for all configurations), 19 (for X1X2W configurations) and 21 (for Y1Y2 configurations) 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.

Among the substances most frequently detected (not necessarily the highest in terms of presence levels) in the input are limonene, benzene, toluene, xylenes and γ-terpinene). They are also among the most frequently detected in the output but are generally present at significantly lower concentrations, benzene being one exception.

It is important to note that ppm levels of acetonitrile have been quantified in both the input and output samples that were analysed by one laboratory. However, the precise reason for its presence remains unclear. An investigation is underway to ascertain the potential origins of this substance presence, with the possibility of contamination in the laboratory being a contributing factor that cannot be discounted. Therefore, the acetonitrile levels are not indicated in this report.

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	88.16	3036.86	53.95	220.75
benzene	71-43-2	42.11	1360.39	67.11	2810.71
1-hydroxy-4-(p-toluidino)anthra-quinone	81-48-1	40.79	1858.95	38.16	2401.20
toluene	108-88-3	39.47	6316.93	39.47	328.58
xylene (isomers)	1330-20-7	32.89	3877.51	17.11	2130.46
γ-terpinene	99-85-4	31.58	593.19	0	ND (<10 - <150)
adipic acid, bis(2-ethylhexyl) ester	103-23-1	28.95	29037.18	26.32	11041.45
2,5-bis(5-tert-butyl-2-benzoxa-zolyl)thiophene	7128-64-5	27.63	1463.58	22.37	1834.64
arachidic acid	506-30-9	26.32	1309.60	27.63	1654.72
ethylbenzene	100-41-4	23.68	1483.81	2.63	208.33
styrene	100-42-5	22.37	697.73	32.89	1724.46
1-butanol	71-36-3	21.05	947.77	0	ND (<3 - <150)
2-nonanone	821-55-6	21.05	542.50	0	ND (<3 - <150)
2-heptanone	110-43-0	18.42	721.81	1.32	251.97
2-decanone	693-54-9	18.42	1033.51	1.32	1103.31
5-hydroxyferulic acid	1782-55-4	15.79	156.38	15.79	191.98
p-cymene	99-87-6	14.47	281.02	0	ND (<10 - <150)
dioctyl terephthalate	4654-26-6	13.16	77.09	14.47	91.07
diisononyl phthalate (dinp)	28553-12-0	13.16	580.67	18.42	322.69
2-propanol	67-63-0	13.16	288.46	9.21	64.78
tetrahydrofuran	109-99-9	13.16	651.85	3.95	275.80

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

Table 3: List of the first 19 most frequently detected incidental contaminants in the input material, their frequency of detection and average amounts in input and output samples (equipment configurations X1X2W).

Substance	CAS	INPUT		OUTPUT	
		Frequency (%)	Average* (µg/kg PET)	Frequency (%)	Average* (µg/kg PET)
limonene	138-86-3	77.78	6722.30	50	305.96
toluene	108-88-3	61.11	825.67	61.11	280.58
benzene	71-43-2	38.89	1642.25	88.89	2628.3
xylene (isomers)	1330-20-7	33.33	1779.77	27.78	1068.98
γ-terpinene	99-85-4	33.33	1028.96	0	ND (<17 - <150)
1-butanol	71-36-3	27.78	867.59	0	ND (<10 - <150)
2-butanone	78-93-3	22.22	1588.35	0	ND (<150)
ethylbenzene	100-41-4	22.22	448.86	0	ND (<150)
styrene	100-42-5	22.22	488.09	38.89	557.71
tetrahydrofuran	109-99-9	22.22	775.80	0	ND (<17 - <500)
1-hydroxy-4-(p-toluidino)anthraquinone	81-48-1	16.67	765.95	16.67	1826.87
1-propanol	71-23-8	16.67	634.99	0	ND (<150)
2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	7128-64-5	16.67	296.67	11.11	8232.17
2-n-butylacrolein	1070-66-2	16.67	416.86	0	ND (<150)
arachidic acid	506-30-9	16.67	544.51	16.67	5110.92
benzoic acid	65-85-0	16.67	1527.60	11.11	1357.18
eucalyptol	470-82-6	16.67	954.08	0	ND (<10 - <150)
n-hexane	110-54-3	16.67	1902.98	16.67	1218.48
pentanal	110-62-3	16.67	899.33	0	ND (<150)

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

Table 4: 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 (equipment configurations Y1Y2).

Substance	CAS	INPUT		OUTPUT	
		Frequency (%)	Average* (µg/kg PET)	Frequency (%)	Average* (µg/kg PET)
limonene	138-86-3	91.38	2063.35	55.17	196.79
1-hydroxy-4-(p-toluidino)anthraquinone	81-48-1	48.28	1976.06	44.83	2467.47
benzene	71-43-2	43.1	1281.47	60.34	2894.09
adipic acid, bis(2-ethylhexyl) ester	103-23-1	34.48	31364.55	31.03	12128.28
toluene	108-88-3	32.76	9496.08	32.76	356.36
xylene (isomers)	1330-20-7	32.76	4539.95	13.79	2793.89
2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	7128-64-5	31.03	1658.07	25.86	981.64
γ-terpinene	99-85-4	31.03	447.94	0	ND (<10 - <150)
arachidic acid	506-30-9	29.31	1444.62	31.03	1078.69
2-nonanone	821-55-6	24.14	435.14	0	ND (<3 - <150)
ethylbenzene	100-41-4	24.14	1779.51	3.45	208.33
styrene	100-42-5	22.41	762.24	31.03	2178.19
2-decanone	693-54-9	20.69	756.92	0	ND (<3 - <17)
2-heptanone	110-43-0	20.69	612.26	0	ND (<10 - <150)
1-butanol	71-36-3	18.97	984.22	0	ND (<3 - <150)
5-hydroxyferulic acid	1782-55-4	18.97	168.87	18.97	204.87
2-propanol	67-63-0	15.52	119.18	12.07	64.78
p-cymene	99-87-6	15.52	180.68	0	ND (<10 - <150)
diisononyl phthalate (dinp)	28553-12-0	13.79	513.75	18.97	339.10
dioctyl terephthalate	4654-26-6	13.79	70.94	13.79	78.55
tri-n-butyl acetyl citrate	77-90-7	13.79	330.82	5.17	259.37

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

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 labels. They 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 in certain other 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 most plastic packaging materials to strengthen their mechanical properties, enhance their performance and/or economical reasons.

Incidental contaminants

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

- 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 *et al*., 2004)[5].
- Benzene: most probably formed from the breakdown of contaminating PVC material through a heat induced reaction (Thoden van Velzen *et al*., 2020)[6].
- Toluene, ethylbenzene, p-cymene, and xylenes (mix) are typical components of aromatic solvents used in certain solvent based inks and/or adhesives and/or coatings.
- Terpinene: major component of essential oils made from citrus fruits with strong antioxidant activity. It is widely used in food flavors and cosmetics.
- Adipic acid, bis (2-ethylhexyl) ester: common plasticizer(s) for PVC. Traces of PVC could possibly account for the presence of these plasticisers.
- 1-hydroxy-4-(p-toluidino)anthraquinone also known as solvent violet 13 is a common colorant used in PET. It has also been reported by certain members of this consortium as being intentionally added during the recycling process.
- 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 as a monomer in the manufacture of thermoplastics 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) is a common food flavoring agent. It is also used in personal care and cosmetics.
- Acetonitrile: solvent, intermediate used in many chemical synthesis can also be a byproduct of acrylonitrile (polyacrylonitrile, ABS,…).

[3] Journal of Preventive Medicine and Hygiene.

[4] European Commission (2012) Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC, applicable from 22/10/2012

[5] Franz, R.; Mauer, A.; Welle, F. (2004). 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 Addit. Contam. 2004, 21, 265–286. https://doi.org/10.1080/02652030310001655489

[6] Thoden van Velzen, E.U., Brouwer, M.T., Stärker, C., Welle, F. Effect of recycled content and rPET quality on the properties of PET bottles, part II: Migration. Packag Technol Sci. 2020;33:359–371. https://doi.org/10.1002/pts.2528

- Tetrahydrofuran is listed in the Annex I to Regulation (EC) No 10/2011. It is used as a monomer to make several polymers, as an industrial solvent and is also utilised in analytical chromatography.
- Arachidic acid also called eicosanoic acid is a saturated long-chain fatty acid and a minor constituent of peanut oil, coconut oil and corn oil. It is also used in the manufacture of pharmaceuticals, soaps, cosmetics, and food packaging because of its surfactant-like properties.
- 2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene is listed in Annex I to Regulation (EC) No 10/2011. It is used as an optical brightener for thermoplastic resins of polyvinyl chloride, acrylic resin, polyester fiber, paint, coating and printing ink.
- 2-n-butylacrolein also called 2-methylenehexanal. Its origin in PET has not yet been fully understood.
- 2-nonanone is listed in Annex I to Regulation (EC) No 1334/2008 on the use of flavourings and certain food ingredients with flavouring properties in foods; used in washing & cleaning products, cosmetics and personal care products.
- 2-decanone is frequently found in foods with the highest concentrations in milk and hop oil. 2-Decanone was also found at varying percentages in the essential oils of certain plants.
- 5-hydroxyferulic acid: Phenolic cinnamic acids and their derivatives are found in plants in different proportions, and fulfil specific functions. Their presence in PET is potentially linked to contamination by plant based substances and/or materials.[7]
- 2-propanol also called isopropanol is listed in Annex I to Regulation (EC) No 1334/2008 on the use of flavourings and certain food ingredients with flavouring properties in foods. It is also used amongst others in cosmetics, personal care and detergents.
- Diisononyl phthalate is a plasticiser.
- Dioctyl terephthalate is used as an alternative plasticiser to its phthalate equivalent.

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. It is evident that the proposed total migration, as based on the aforementioned principles, is both over estimative and unrealistic.

[7] Freitas et al. (2024): Plant-derived and dietary phenolic cinnamic acid derivatives: Anti-inflammatory properties. Food Chemistry 459 (2024) 140080. https://doi.org/10.1016/j.foodchem.2024.140080

Table 5. Worst case migration calculation of incidental contaminants present in the output samples (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	53.95	220.75	7.99
benzene	78.11	71-43-2	67.11	2810.71	101.69
1-hydroxy-4-(p-toluidino)anthraquinone	329.3	81-48-1	38.16	2401.20	86.88
toluene	91.24	108-88-3	39.47	328.58	11.89
xylene (isomers)	106.16	1330-20-7	17.11	2130.46	77.08
γ-terpinene	136.23	99-85-4	0	ND (<10 - <150)	<0.36 - <5.43
adipic acid, bis(2-ethylhexyl) ester	370.6	103-23-1	26.32	11041.45	399.48
2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	430.6	7128-64-5	22.37	1834.64	66.38
arachidic acid	312.5	506-30-9	27.63	1654.72	59.87
ethylbenzene	106.16	100-41-4	2.63	208.33	7.54
styrene	104.15	100-42-5	32.89	1724.46	62.39
1-butanol	74.12	71-36-3	0	ND (<3 - <150)	<0.11 - <5.43
2-nonanone	142.24	821-55-6	0	ND (<3 - <150)	<0.11 - <5.43
2-heptanone	114.19	110-43-0	1.32	251.97	9.12
2-decanone	156.26	693-54-9	1.32	1103.31	39.92
5-hydroxyferulic acid	210.18	1782-55-4	15.79	191.98	6.95
p-cymene	134.22	99-87-6	0	ND (<10 - <150)	<0.36 - <5.43
dioctyl terephthalate	390.6	4654-26-6	14.47	91.07	3.29
diisononyl phthalate (dinp)	418.6	28553-12-0	18.42	322.69	11.68
2-propanol	60.1	67-63-0	9.21	64.78	2.34
tetrahydrofuran	72.11	109-99-9	3.95	275.80	9.98

* 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 (equipment configurations 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	50	305.96	11.07
toluene	91.24	108-88-3	61.11	280.58	10.15
benzene	78.11	71-43-2	88.89	2628.3	95.09
xylene (isomers)	106.16	1330-20-7	27.78	1068.98	38.68
γ-terpinene	136.23	99-85-4	0	ND (<17 - <150)	<0.61 - <5.43
1-butanol	74.12	71-36-3	0	ND (<10 - <150)	<0.36 - <5.43
2-butanone	72.11	78-93-3	0	ND (<150)	<5.43
ethylbenzene	106.16	100-41-4	0	ND (<150)	<5.43
styrene	104.15	100-42-5	38.89	557.71	20.18
tetrahydrofuran	72.11	109-99-9	0	ND (<17 - <500)	<0.61 - <18.09
1-hydroxy-4-(p-toluidino)an-thraquinone	329.3	81-48-1	16.67	1826.87	66.10
1-propanol	60.1	71-23-8	0	ND (<150)	<5.43
2,5-bis(5-tert-butyl-2-benzox-azolyl)thiophene	430.6	7128-64-5	11.11	8232.17	297.84
2-n-butylacrolein	112.17	1070-66-2	0	ND (<150)	<5.43
arachidic acid	312.5	506-30-9	16.67	5110.92	184.91
benzoic acid	122.12	65-85-0	11.11	1357.18	49.10
eucalyptol	154.25	470-82-6	0	ND (<10 - <150)	<0.36 - <5.43
n-hexane	86.18	110-54-3	16.67	1218.48	44.08
pentanal	86.13	110-62-3	0	ND (<150)	<5.43

* 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 (equipment configurations Y1Y2).

Substance	MW (g/mol)	CAS	OUTPUT		TOTAL MIGRATION CALCULATION** Average* (µg/kg food)
			Fre-quency (%)	Average* (µg/kg PET)	
limonene	136.23	138-86-3	55.17	196.79	7.12
1-hydroxy-4-(p-toluidino)anthraquinone	329.3	81-48-1	44.83	2467.47	89.27
benzene	78.11	71-43-2	60.34	2894.09	104.71
adipic acid, bis(2-ethylhexyl) ester	370.6	103-23-1	31.03	12128.28	438.80
toluene	91.24	108-88-3	32.76	356.36	12.89
xylene (isomers)	106.16	1330-20-7	13.79	2793.89	101.08
2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	430.6	7128-64-5	25.86	981.64	35.52
γ-terpinene	136.23	99-85-4	0	ND (<10 - <150)	<0.36 - <5.43
arachidic acid	312.5	506-30-9	31.03	1078.69	39.03
2-nonanone	142.24	821-55-6	0	ND (<3 - <150)	<0.11 - <5.43
ethylbenzene	106.16	100-41-4	3.45	208.33	7.54
styrene	104.15	100-42-5	31.03	2178.19	78.81
2-decanone	156.26	693-54-9	0	ND (<3 - <17)	<0.11 - <0.61
2-heptanone	114.19	110-43-0	0	ND (<10 - <150)	<0.36 - <5.43
1-butanol	74.12	71-36-3	0	ND (<3 - <150)	<0.11 - <5.43
5-hydroxyferulic acid	210.18	1782-55-4	18.97	204.87	7.41
2-propanol	60.1	67-63-0	12.07	64.78	2.34
p-cymene	134.22	99-87-6	0	ND (<10 - <150)	<0.36 - <5.43
diisononyl phthalate (dinp)	418.6	28553-12-0	18.97	339.10	12.27
dioctyl terephthalate	390.6	4654-26-6	13.79	78.55	2.84
tri-n-butyl acetyl citrate	402.5	77-90-7	5.17	259.37	9.38

* 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[8] 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:

- 17 samples for 10 days at 20°C
- 46 samples for 10 days at 40°C
- 13 samples for 10 days at 60°C

It is important to note that the samples evaluated for migration in this report are not necessarily intended for utilisation in the conditions in which they were tested; rather, they are aimed to illustrate migration results under different conditions.

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 calculation options influence the average migration results measured in particular when the substance is occasionally detected.

[8] 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 8. Migration testing of 3 incidental contaminants present in the output samples (all equipment 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	ND	ND
			10d @ 40°C	2.17	9.83	0.21
			10d @ 60°C	0.00	ND	ND
benzene	78.11	71-43-2	10d @ 20°C	11.76	2.23	0.26
			10d @ 40°C	13.04	1.75	0.23
			10d @ 60°C	0	ND	ND
2,2-bis(4-hydroxyphenyl)propane	228.29	80-05-7	10d @ 20°C	0	ND	ND
			10d @ 40°C	21.74	3.08	0.67
			10d @ 60°C	38.46	20.84	8.02

* 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
ND: non detected

Table 9. Migration testing of 3 incidental contaminants present in the output samples (equipment 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	ND	ND
			10d @ 40°C	0	ND	ND
			10d @ 60°C	0	ND	ND
benzene	78.11	71-43-2	10d @ 20°C	0	ND	ND
			10d @ 40°C	0	ND	ND
			10d @ 60°C	0	ND	ND
2,2-bis(4-hydroxyphenyl)propane	228.29	80-05-7	10d @ 20°C	0	ND	ND
			10d @ 40°C	20	1.20	0.24
			10d @ 60°C	75	2.73	2.05

* 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
ND: non detected

Table 10. Migration testing of 3 incidental contaminants present in the output samples (equipment 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	ND	ND
			10d @ 40°C	2.78	9.83	0.27
			10d @ 60°C	0	ND	ND
benzene	78.11	71-43-2	10d @ 20°C	15.38	2.23	0.34
			10d @ 40°C	16.67	1.75	0.29
			10d @ 60°C	0	ND	ND
2,2-bis(4-hydroxy-phenyl)propane	228.29	80-05-7	10d @ 20°C	0	ND	ND
			10d @ 40°C	22.22	3.55	0.79
			10d @ 60°C	22.22	48.00	10.67

* 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
ND: non detected

In the tables 11 to 13, the mean values for both the total migration calculation as well as for 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 without any exception. This provides evidence that the single anomaly noted in the preceding report was attributable to the factors outlined therein, rather than a deficiency in the model itself.

Table 11. Comparison of total migration calculation with migration testing results (all equipment 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	4.31	10d @ 20°C	0	ND
		10d @ 40°C	2.13	0.21
		10d @ 60°C	0	ND
benzene	68.25	10d @ 20°C	11.76	0.26
		10d @ 40°C	13.04	0.23
		10d @ 60°C	0	ND
2,2-bis(4-hydroxy-phenyl)propane	12.44	10d @ 20°C	0	ND
		10d @ 40°C	21.74	0.67
		10d @ 60°C	38.46	8.02

* 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
ND: non detected

Table 12. Comparison of total migration calculation with migration testing results (equipment 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	5.53	10d @ 20°C	0	ND
		10d @ 40°C	0	ND
		10d @ 60°C	0	ND
benzene	84.53	10d @ 20°C	0	ND
		10d @ 40°C	0	ND
		10d @ 60°C	0	ND
2,2-bis(4-hydroxy-phenyl)propane	8.6	10d @ 20°C	0	ND
		10d @ 40°C	20	0.24
		10d @ 60°C	75	2.05

* 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
ND: non detected

Table 13. Comparison of total migration calculation with migration testing results (equipment 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	3.93	10d @ 20°C	0	ND
		10d @ 40°C	2.78	0.27
		10d @ 60°C	0	ND
benzene	63.18	10d @ 20°C	15.38	0.34
		10d @ 40°C	16.67	0.29
		10d @ 60°C	0	ND
2,2-bis(4-hydroxy-phenyl)propane	13.63	10d @ 20°C	0	ND
		10d @ 40°C	22.22	0.79
		10d @ 60°C	22.22	10.67

* 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
ND: non detected

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)

The analytical results obtained for this monitoring period confirm previous findings such that most substances originate from the contamination of the PET that occurred 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 and as already pointed it out in the previous report and 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.

Also as in previous report and as further 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 Therefore, their presence in the output would not be the result of a decontamination deficiency, but rather the result of decomposition occurring during recycling and/or during the analysis.

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 most probably 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. It is also not possible to completely rule out analytical artefacts, even if this is not the most likely causal explanation.

The incidental contaminants that were detected at the highest frequencies in the input samples were not unexpected for most of them and were also consistent with previous report.

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

In order to ensure maximum comparability of the results obtained from the analysis of xylenes, it has been decided that they should be consolidated into a single entry group. The objective of this approach is to eliminate any fluctuations in the isomers reported by the laboratories without prior assessment of the analytical boundaries when reporting them separately. Furthermore, since no distinction is made regarding their possible toxicological effects, it is logical for them to be reported together.

An evaluation was conducted to ascertain the safety implications of the most prevalent incidental contaminants in the input that are also detected in the output. This evaluation was conducted in conjunction with the application of the following criteria:

- Exposure: average total migration calculation levels as indicated in Tables 5-7 The worst case migration levels were calculated by making the assumption of 100% 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. In case the substance was not detected in the plastic output, the limit of detection (LOD) of the analytical method was used.

- Hazard: the following principles were used in order of priority:
  a. If the substance is listed in Annex I to Regulation (EU) No 10/2011 and has an SML, the specified limit is applied. If the limit belongs to a group, the group limit is applied to the sum of all the substances in the group. If the substance is listed in Annex I to the Regulation (EU) No 10/2011 with no SML, the 60 mg/kg food limit is applied.
  b. For the remaining substances, the human exposure threshold values according to the Threshold of Toxicological Concern (TTC) approach were used (EFSA, 2019)[9]. The toddler exposure scenario B was applied to establish the migration limits (EFSA, 2024)[10] (Table 14).

[9] EFSA Scientific Committee, More, S. J., Bampidis, V., Benford, D., Bragard, C., Halldorsson, T. I., Hernández-Jerez, A. F., Hougaard, B. S., Koutsoumanis, K. P., Machera, K., Naegeli, H., Nielsen, S. S., Schlatter, J. R., Schrenk, D., Silano, V., Turck, D., Younes, M., Gundert-Remy, U., Kass, G. E. N., … Wallace, H. M. (2019). Guidance on the use of the threshold of toxicological concern approach in food safety assessment. EFSA Journal, 17(6), 5708. https://doi.org/10.2903/j.efsa.2019.5708

[10] EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids), Lambré, C., Barat Baviera, J. M., Bolognesi, C., Chesson, A., Cocconcelli, P. S., Crebelli, R., Gott, D. M., Grob, K., Mengelers, M., Mortensen, A., Rivière, G., Steffensen, I.-L., Tlustos, C., Van Loveren, H., Vernis, L., Zorn, H., Dudler, V., Milana, M. R., …Lampi, E. (2024). Scientific Guidance on the criteria for the evaluation and on the preparation of applications for the safety assessment of post-consumer mechanical PET recycling processes intended to be used for manufacture of materials and articles in contact with food. EFSA Journal, 22(7), e8879. https://doi.org/10.2903/j.efsa.2024.8879

The potential for genotoxicity of substances was assessed using EFSA or JECFA evaluations prepared for example in support of their inclusion in Regulation (EC) 1334/2008 on flavourings and food ingredients with flavouring properties or Regulation (EC) No 1333/2008 on food additives. In the absence of such an evaluation, the Toxtree software[11] is used to predict their genotoxic potential. This software is also used to further assign substances into Cramer classes I, II or III.

The genotoxicity alert raised by the Toxtree software has also been cleared for substances listed on the European positive list of starting materials for organic substances authorised by the European Commission for use in the manufacture of materials or products that come into contact with water intended for human consumption[12].

Table 14: Migration limits for the different toxicological classes of substances

	Human exposure threshold value (EFSA, 2019) (µg/kg bw/per day)	Migration limit* (µg/kg food)	Migration limit* in case of worst case calculation or modelling (µg/kg food)	
			substances ≤ 150 Da	substances > 150 Da
Genotoxic substances	0.0025	0.0313	0.156	0.31
Organophosphates or carbamates	0.3	3.75	18.75	37.50
Cramer class III substances	1.5	18.75	93.75	187.50
Cramer class II substances	9	112.5	562.5	1125
Cramer class I	30	375	1875	3750

*scenario B toddler.

c. Specific case: For benzene the safety limit/regulatory limit that has been applied is the limit in drinking water.

- Risk assessment: for each substance, the migration limit that was defined based on the hazard assessment, was compared to the worst case exposure levels. If the worst case exposure level is lower than the migration limit, it was concluded that the substance does not give rise to safety concern.

  In case the worst-case exposure level exceeded the determined migration limit, the following was considered in order of priority:

  1. The application of overestimation factors: Since EFSA (2024) acknowledges that generally recognized diffusion migration models overestimate migration by a factor of 5 for

[11] Toxtree version v3.1.0, May 2018

[12] Commission Implementing Decision (EU) 2024/367 of 23 January 2024 laying down rules for the application of Directive (EU) 2020/2184 of the European Parliament and of the Council by establishing the European positive lists of starting substances, compositions and constituents authorised for use in the manufacture of materials or products that come into contact with water intended for human consumption

substances ≤ 150 Da and by a factor of 10 for substances > 150 Da, the worst case exposure levels that were calculated using 100% migration can be considered to also overestimate migration by at least these factors.

2. The application of migration modelling applying the modelling parameters used by EFSA (2024): the modelled concentration in PET (Cmod) that corresponds to a migration that is not expected to give rise to a dietary exposure that would exceed the established migration limit was calculated. The Cmod was calculated for the established migration limits for genotoxic substances, Cramer I, II and III substances for different surrogate contaminants. The concentration of the incidental contaminant in the output material (Cres) was compared to the calculated Cmod of a surrogate contaminant that is representative for the incidental contaminant. If the Cres is not higher than the Cmod, it was concluded that the substance does not give rise to safety concern.
3. The application of migration modelling applying a more realistic migration model based on experimentally determined activation energies of diffusion Ea, whereas the conventional prediction model is based on a fixed activation energy of 100 kJ/mol for all migrants independent from their molecular weight or volume.[13].
4. To conduct migration testing under the conditions of use.

However, for this report and with the exception of benzene, BPA and 1-hydroxy-4-(p-toluidino)anthraquinone, only step one was applied as it gives already a very satisfactory safety margin. In the case of 1-hydroxy-4-(p-toluidino)anthraquinone the overestimation factor of 10 is applied taking into consideration its molecular weight. For benzene and BPA, the migration testing results (step 4) have been used for the assessment.

Worst case exposure assessment and hazard assessment for incidental contaminants are summarised in Tables 15-17.

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 average exposure to these two substances ranges from Non Detected to 2.23ppb in the case of benzene and from Non Detected to 20.84 ppb in the case of BPA for all equipment configurations. In the case of configurations Y1Y2 the average migration of benzene ranges from Non Detected to 2.23 ppb and from Non detected to 48.00 ppb in the case of BPA

Out of the 76 samples tested for BPA migration only 15 showed detected levels of BPA. Within these 15 samples only the corresponding output of 3 of them showed presence of BPA and amongst these 3 only 2 of them showed BPA in the corresponding input. Out of the 76 samples tested for BPA migration 13 samples were tested at 60°C, and BPA migration was only detected in five of them. Of these 5 samples one exhibited a level of BPA migration that was 30 times higher than the levels observed in the remaining four. This unexpected finding could not be attributed to a parallel high content in input or output. Consequently, this value and its impact on the mean should be regarded with a degree of caution, as it is most probably an isolated case.

[13] Schreier, V.N.; Odermatt, A.; Welle, F. Migration Modeling as a Valuable Tool for Exposure Assessment and Risk Characterization of Polyethylene Terephthalate Oligomers. Molecules 2023, 28, 173.

Decontamination efficiency

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 issue should be interpreted primarily as a consequence of the practical analytical limitations, rather than as shortcomings of the technology itself. The primary cause is the inherent heterogeneity of the input materials, differences in sampling approaches, and variability in analytical methods and conditions across laboratories.

As a result, there may be significant scatter in the data, making it difficult to establish robust correlations or identify clear trends in decontamination efficiency across different equipment configurations.

Table 15. 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)	Migration testing		
			Frequency (%)	Average* (µg/kg PET)		Test conditions	Average of detected* (µg/kg food)	
limonene	136.23	138-86-3	53.95	220.75	7.99	10d @ 20°C	ND	Toxtree: Cramer I
						10d @ 40°C	9.83	
						10d @ 60°C	ND	
benzene	78.11	71-43-2	67.11	2810.71	101.69	10d @ 20°C	2.23	WHO: 10 µg/L; EU Drinking water limit: 1 µg/L
						10d @ 40°C	1.75	
						10d @ 60°C	ND	
1-hydroxy-4-(p-toluidino)anthraquinone	329.3	81-48-1	38.16	2401.20	86.88		NA	Toxtree: Structural alert for genotoxic carcinogenicity overruled by JECFA evaluation and positive listing in Commission decision (EU) 2024/367 -> Cramer III
toluene	91.24	108-88-3	39.47	328.58	11.89		NA	Toxtree: Cramer I
xylene (isomers)	106.16	1330-20-7	17.11	2130.46	77.08		NA	Toxtree: Cramer I
γ-terpinene	136.23	99-85-4	0	ND (<10 - <150)	<0.36 - <5.43		NA	Toxtree: Cramer I
adipic acid, bis(2-ethylhexyl) ester	370.6	103-23-1	26.32	11041.45	399.48		NA	FCM207, SML= 18 mg/kg + SML(T)=60mg/kg
2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	430.6	7128-64-5	22.37	1834.64	66.38		NA	FCM500; SML=0.6 mg/kg
arachidic acid	312.5	506-30-9	27.63	1654.72	59.87		NA	FCM345 w/o SML
ethylbenzene	106.16	100-41-4	2.63	208.33	7.54		NA	Toxtree: Cramer I
styrene	104.15	100-42-5	32.89	1724.46	62.39		NA	FCM193 w/o SML
1-butanol	74.12	71-36-3	0	ND (<3 - <150)	<0.11 - <5.43		NA	FCM123 w/o SML
2-nonanone	142.24	821-55-6	0	ND (<3 - <150)	<0.11 - <5.43		NA	Toxtree: Cramer I
2-heptanone	114.19	110-43-0	1.32	251.97	9.12		NA	Toxtree: Cramer I
2-decanone	156.26	693-54-9	1.32	1103.31	39.92		NA	Toxtree: Cramer I

5-hydroxyferulic acid	210.18	1782-55-4	15.79	191.98	6.95		NA	Toxtree: Cramer I
p-cymene	134.22	99-87-6	0	ND (<10 - <150)	<0.36 - <5.43		NA	Toxtree: Cramer I
dioctyl terephthalate	390.6	4654-26-6	14.47	91.07	3.29		NA	Toxtree: Cramer I
diisononyl phthalate (dinp)	418.6	28553-12-0	18.42	322.69	11.68		NA	Toxtree: structural alert for nongenotoxic carcinogenicity -> Cramer I
2-propanol	60.1	67-63-0	9.21	64.78	2.34		NA	Toxtree: Cramer I I
tetrahydrofuran	72.11	109-99-9	3.95	275.80	9.98		NA	FCM246, SML=0.6 mg/kg

* 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; NA: not analysed

Table 16. Worst case exposure assessment and hazard asses (equipment configurations X1X2W)

Substance	MW (g/mol)	CAS	OUTPUT		Total Migration Calculation** Average* (µg/kg food)	Migration testing		
			Fre-quency (%)	Average* (µg/kg PET)		Test condi-tions	Average of detected* (µg/kg food)	
limonene	136.23	138-86-3	52.63	322.64	11.67	10d @ 20°C	ND	Toxtree: Cramer I
						10d @ 40°C	ND	
						10d @ 60°C	ND	
toluene	91.24	108-88-3	63.16	870.38	31.49		NA	Toxtree: Cramer I
benzene	78.11	71-43-2	89.47	2653.47	96.00	10d @ 20°C	ND	WHO: 10 µg/L; EU Drinking water limit: 1 µg/L
						10d @ 40°C	ND	
						10d @ 60°C	ND	
xylene (isomers)	106.16	1330-20-7	27.78	1068.98	38.68		NA	Toxtree: Cramer I
γ-terpinene	136.23	99-85-4	0	ND (<17 - <150)	<0.61 - <5.43		NA	Toxtree: Cramer I
1-butanol	74.12	71-36-3	0	ND (<10 - <150)	<0.36 - <5.43		NA	FCM123 w/o SML
2-butanone	72.11	78-93-3	0	ND (<150)	<5.43		NA	Toxtree: Cramer I
ethylbenzene	106.16	100-41-4	0	ND (<150)	<5.43		NA	Toxtree: Cramer I
styrene	104.15	100-42-5	38.89	557.71	20.18		NA	FCM193 w/o SML
tetrahydrofuran	72.11	109-99-9	0	ND (<17 - <500)	<0.61 - <18.09		NA	FCM246, SML=0.6 mg/kg
1-hydroxy-4-(p-tolui-dino)anthraquinone	329.3	81-48-1	16.67	1826.87	66.10		NA	Toxtree: Structural alert for genotoxic carcinogenic-ity overruled by JECFA evaluation and positive list-ing in Commission decision (EU) 2024/367 -> Cramer III
1-propanol	60.1	71-23-8	0	ND (<150)	<5.43		NA	Toxtree: Cramer I
2,5-bis(5-tert-butyl-2-benzoxazolyl)thio-phene	430.6	7128-64-5	11.11	8232.17	297.84		NA	FCM500; SML=0.6 mg/kg
2-n-butylacrolein	112.17	1070-66-2	0	ND (<150)	<5.43		NA	Toxtree: Structural alert for genotox carcinogen; Structural alert for S. typhimurium mutagenicity but Unlikely to be a S. typhimurium TA100 muta-gen based on QSAR; Cramer II

arachidic acid	312.5	506-30-9	16.67	5110.92	184.91		NA	FCM345 w/o SML
benzoic acid	122.12	65-85-0	11.11	1357.18	49.10		NA	FCM246 w/o SML
eucalyptol	154.25	470-82-6	0	ND (<10 - <150)	<0.36 - <5.43		NA	Toxtree: Cramer I
n-hexane	86.18	110-54-3	16.67	1218.48	44.08		NA	Toxtree: Cramer I
pentanal	86.13	110-62-3	0	ND (<150)	<5.43		NA	Toxtree: Structural alert for genotoxic carcinogenicity overruled by JECFA evaluation and positive listing in (EC) No. 1334/2008 -> 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; NA: not analysed

Table 17. Worst case exposure assessment and hazard asses (equipment configurations Y1Y2)

Substance	MW (g/mol)	CAS	OUTPUT		Total Migration Calculation** Average* (µg/kg food)	Migration testing		
			Frequency (%)	Average* (µg/kg PET)		Test conditions	Average of detected* (µg/kg food)	
limonene	136.23	138-86-3	55.17	196.79	7.12	10d @ 20°C	ND	Toxtree: Cramer I
						10d @ 40°C	9.83	
						10d @ 60°C	ND	
1-hydroxy-4-(p-toluidino)anthraquinone	329.3	81-48-1	44.83	2467.47	89.27		NA	Toxtree: Structural alert for genotoxic carcinogenicity overruled by JECFA evaluation and positive listing in Commission decision (EU) 2024/367 -> Cramer III
benzene	78.11	71-43-2	60.34	2894.09	104.71	10d @ 20°C	2.23	WHO: 10 µg/L; EU Drinking water limit: 1 µg/L
						10d @ 40°C	1.75	
						10d @ 60°C	ND	
adipic acid, bis(2-ethylhexyl) ester	370.6	103-23-1	31.03	12128.28	438.80		NA	FCM207, SML= 18 mg/kg + SML(T)=60mg/kg
toluene	91.24	108-88-3	32.76	356.36	12.89		NA	Toxtree: Cramer I
xylene (isomers)	106.16	1330-20-7	13.79	2793.89	101.08		NA	Toxtree: Cramer I
2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	430.6	7128-64-5	25.86	981.64	35.52		NA	FCM500; SML=0.6 mg/kg
γ-terpinene	136.23	99-85-4	0	ND (<10 - <150)	<0.36 - <5.43		NA	Toxtree: Cramer I
arachidic acid	312.5	506-30-9	31.03	1078.69	39.03		NA	FCM345 w/o SML
2-nonanone	142.24	821-55-6	0	ND (<3 - <150)	<0.11 - <5.43		NA	Toxtree: Cramer I
ethylbenzene	106.16	100-41-4	3.45	208.33	7.54		NA	Toxtree: Cramer I
styrene	104.15	100-42-5	31.03	2178.19	78.81		NA	FCM193 w/o SML
2-decanone	156.26	693-54-9	0	ND (<3 - <17)	<0.11 - <0.61		NA	Toxtree: Cramer I
2-heptanone	114.19	110-43-0	0	ND (<10 - <150)	<0.36 - <5.43		NA	Toxtree: Cramer I

1-butanol	74.12	71-36-3	0	ND (<3 - <150)	<0.11 - <5.43		NA	FCM123 w/o SML
5-hydroxyferulic acid	210.18	1782-55-4	18.97	204.87	7.41		NA	Toxtree: Cramer I
2-propanol	60.1	67-63-0	12.07	64.78	2.34		NA	Toxtree: Cramer I
p-cymene	134.22	99-87-6	0	ND (<10 - <150)	<0.36 - <5.43		NA	Toxtree: Cramer I
diisononyl phthalate (dinp)	418.6	28553-12-0	18.97	339.10	12.27		NA	Toxtree: structural alert for nongenotoxic carcino-genicity -> Cramer I
dioctyl terephthalate	390.6	4654-26-6	13.79	78.55	2.84		NA	Toxtree: Cramer I
tri-n-butyl acetyl citrate	402.5	77-90-7	5.17	259.37	9.38		NA	FCM138 with SML(T)=60mg/kg

* 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; NA: not analysed

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

The report enhances understanding of, and the statistical significance of, PET contaminants in the input and/or output, thanks to the substantial new analytical data it provides. While it contributes to the existing body of knowledge by providing greater statistical significance, questions remain regarding the accuracy and reproducibility of the results obtained during tests conducted on the polymer itself. The validity and practical significance of the results at the parts-per-billion (ppb) level and in many cases very close to the LOD and LOQ require further scientific scrutiny before definitive conclusions can be drawn.

A general observation of the results indicates that the type and concentrations of contaminants measured in the input and output remain relatively comparable to those measured in previous reports. The migration results obtained in this study demonstrate consistency with those reported in previous studies, as well as with the results of the migration simulations presented in a preceding report. These findings remain of course subject to the limitations inherent to the analytical methods employed.

Notwithstanding, the findings also demonstrate variability in certain outcomes, along with substantial disparities in LOD and LOQ across different laboratories. This underscores the necessity of standardising analytical methodologies and conditions, encompassing those for sampling and sample preparation, to ensure the reliability, reproducibility and comparability of results. Furthermore, it is imperative to adhere to standardized guidelines when calculating frequencies and mean values. This is essential to ensure consistency in the approach and the validity of the conclusions drawn.

Despite the extensive number of analyses conducted, it is clear that while the safety of the technology can be confirmed, it is still premature to draw firm and definitive conclusions about the differences linked to the equipment configuration (X1X2W versus Y1Y2).

Nevertheless, it is essential to re-emphasise that, the actual migration is significantly lower than that calculated based on a total migration from the concentration measured in the sheet. Consequently, this total migration calculation method can be maintained and remained considered a worst-case scenario when evaluating exposure and ensuring the safety of the material.

Finally, it is important to reiterate once more that the migration testing conducted for this report (and previous ones) should be considered a worst-case scenario. This is because it has been conducted using 95% ethanol, a simulant that yields much higher migration results than fatty food itself when used with PET due to its swelling properties and the possibility of inducing PET hydrolysis.

More importantly none of the 20 most frequently found contaminants in the input material remain in the output in quantities that could migrate into food and endanger human health, when evaluated with the internationally recognised scientific principles on risk assessment presented in this document and/or the safety limits established for comparable and/or higher exposure applications. For BPA, current detection limits do not yet allow confirmation below 1 ppb.

Annex I - List of all substances with a molecular weight below 1.000 Dalton found in the plastic inputs to each of the decontamination installations and in the recycled plastic output thereof, sorted in descending order by their relative occurrence

Name	Formula	CAS	Frequency INPUT (%)	Frequency OUTPUT (%)
2-methyl-1,3-dioxolane	C4H8O2	497-26-7	97.37	93.42
limonene	C10H16	138-86-3	88.16	53.95
ethanol	C2H6O	64-17-5	56.58	39.47
acetaldehyde	C2H4O	75-07-0	52.63	52.63
hexanal	C6H12O	66-25-1	48.68	25
benzene	C6H6	71-43-2	42.11	67.11
1-hydroxy-4-(p-toluidino)anthraquinone	C21H15NO3	81-48-1	40.79	38.16
toluene	C7H8	108-88-3	39.47	39.47
nonanal	C9H18O	124-19-6	38.16	17.11
acetic acid, ethyl ester	C4H8O2	141-78-6	38.16	6.58
pet cyclic trimer	C30H24O12	7441-32-9	38.16	38.16
ethylene terephthalate cyclic tetramer	C40H32O16	16104-96-4	38.16	38.16
h-[tpa-eg]3-oh			34.21	34.21
ethylene terephthalate cyclic dimer	C20H16O8	16709-52-7	34.21	34.21
h-[tpa-eg]3-eg-oh			34.21	32.89
cyclic deg-pa-deg-pa			34.21	34.21
pet cyclic dimer [tg]2g			34.21	34.21
h-[tpa-eg]4-eg-oh			34.21	31.58
xylenes (isomers)	C8H10	1330-20-7	32.89	17.11
γ-terpinene	C10H16	99-85-4	31.58	0
2-[2-hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl]benzotriazole	C30H29N3O	70321-86-7	30.26	34.21
cyclic (tpa-eg)3			30.26	28.95
cyclic tpa2-eg-deg			30.26	17.11
pet cyclic trimer-c2h4o			30.26	32.89
adipic acid, bis(2-ethylhexyl) ester	C22H42O4	103-23-1	28.95	26.32
acetonitrile	C2H3N	75-05-8	28.95	30.26
[tpa-eg]2-oh			27.63	27.63
pet h-[tg]2g-oh			27.63	28.95
2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	C26H26N2O2S	7128-64-5	27.63	22.37
octanal	C8H16O	124-13-0	26.32	3.95
arachidic acid	C20H40O2	506-30-9	26.32	27.63
1,4-benzenedicarboxylic acid, bis(2-hydroxyethyl) ester	C12H14O6	959-26-2	25	28.95
ethylbenzene	C8H10	100-41-4	23.68	2.63
styrene	C8H8	100-42-5	22.37	32.89
2-ethyl-1-hexanol	C8H18O	104-76-7	22.37	0

Name	Formula	CAS	Frequency INPUT (%)	Frequency OUTPUT (%)
1-butanol	C4H10O	71-36-3	21.05	0
1,4-dioxane	C4H8O2	123-91-1	21.05	26.32
2-nonanone	C9H18O	821-55-6	21.05	0
heptanal	C7H14O	111-71-7	21.05	1.32
3-((12-acetoxyoctadecanoyl)oxy)propane-1,2-diyl diacetate	C27H48O8	330198-91-9	19.74	18.42
2-heptanone	C7H14O	110-43-0	18.42	1.32
acetone	C3H6O	67-64-1	18.42	15.79
pet cyclic dimer	C20H16O8	24388-68-9	18.42	18.42
2-decanone	C10H20O	693-54-9	18.42	1.32
ethyleneglycol	C2H6O2	107-21-1	17.11	19.74
bis(2-hydroxyethyl) terephthalate	C12H14O6	41479-14-5	17.11	17.11
5-hydroxyferulic acid	C10H10O5	1782-55-4	15.79	15.79
stearic acid	C18H36O2	57-11-4	15.79	10.53
acetic acid	C2H4O2	64-19-7	14.47	7.89
sum of pet oligomers			14.47	14.47
l(eg/pa/eg/pa/eg/pa)			14.47	14.47
erucamide	C22H43NO	112-84-5	14.47	14.47
p-cymene	C10H14	99-87-6	14.47	0
c(deg/pa/deg/pa)			14.47	14.47
c(eg/pa/eg/pa/eg/pa/eg/pa)			14.47	14.47
c(deg/pa/eg/pa)			14.47	14.47
c(eg/pa/eg/pa/eg/pa)			14.47	14.47
l[eg/pa/eg/pa]			14.47	15.79
c(deg/pa/eg/pa/eg/pa)			14.47	14.47
l(pa/eg)			14.47	14.47
dioctyl terephthalate	C24H38O4	4654-26-6	13.16	14.47
diisononyl phthalate (dinp)	C26H42O4	28553-12-0	13.16	18.42
isophthalic acid	C8H6O4	121-91-5	13.16	14.47
2-propanol	C3H8O	67-63-0	13.16	9.21
tetrahydrofuran	C4H8O	109-99-9	13.16	3.95
probable pet oligomer (cyclic dimer)			11.84	10.53
pentanal	C5H10O	110-62-3	11.84	1.32
tri-n-butyl acetyl citrate	C20H34O8	77-90-7	11.84	3.95
2-butanone	C4H8O	78-93-3	11.84	1.32
n-hexane	C6H14	110-54-3	11.84	13.16
hydrocarbons			11.84	6.58
benzoic acid	C7H6O2	65-85-0	10.53	11.84
probable pet oligomer (dimer ether)			10.53	10.53
3-hydroxy-7,8,2'-trimethoxyflavone, trimethylsilyl ether			10.53	10.53
1-hexadecanol	C16H34O	36653-82-4	10.53	11.84
prob. dichloromethane	CH2Cl2	75-09-2	10.53	3.95

Name	Formula	CAS	Frequency INPUT (%)	Frequency OUTPUT (%)
l[eg/pa/eg/pa/eg/pa/eg/pa]			10.53	14.47
2-n-butylacrolein	C7H12O	1070-66-2	10.53	0
cyclic ester of (2) diethylene glycol with (2) phthalic acid			10.53	10.53
cyclic ester of (2) phthtalic acid with (2) ethylene glycol			10.53	10.53
2-pentyl-furan	C9H14O	3777-69-3	10.53	0
oxidized irgafos 168	C42H63O4P	95906-11-9	9.21	9.21
butyraldehyde	C4H8O	123-72-8	9.21	3.95
octane	C8H18	111-65-9	9.21	5.26
octadecanoic acid, 2,3-bis(acetyloxy)propyl ester	C25H46O6	33599-07-4	9.21	5.26
phthalic acid, bis(2-ethylhexyl) ester	C24H38O4	117-81-7	9.21	5.26
dimethylsilanediol	C2H8O2Si	1066-42-8	9.21	11.84
benzene, 1,3-dimethyl-	C8H10	108-38-3	9.21	3.95
methyl formate	C2H4O2	107-31-3	9.21	9.21
eucalyptol	C10H18O	470-82-6	9.21	0
cyclic tpa3-eg2-deg			9.21	2.63
branched alkane			9.21	1.32
terephthalic acid, bis(2-ethylhexyl)ester	C24H38O4	6422-86-2	9.21	7.89
cymene			9.21	0
dodecanal	C12H24O	112-54-9	9.21	5.26
solvent blue 104	C32H30N2O2	116-75-6	7.89	6.58
2-aminobenzamide	C7H8N2O	88-68-6	7.89	1.32
c(eg/pa/eg/pa/eg/pa/eg/pa/eg/pa)			7.89	9.21
stearylamine (oda)	C18H39N	124-30-1	7.89	0
terephthalic acid	C8H6O4	100-21-0	7.89	10.53
nonylphenol ethoxylates (npeo7)			7.89	3.95
oleic acid	C18H34O2	112-80-1	7.89	3.95
benzaldehyde	C7H6O	100-52-7	7.89	3.95
nonylphenol ethoxylates (npeo5)			7.89	3.95
n-propyl acetate	C5H10O2	109-60-4	7.89	0
butane	C4H10	106-97-8	7.89	5.26
cyclotetrasiloxane, octamethyl-	C8H24O4Si4	556-67-2	6.58	5.26
octylphenol ethoxylates (opeo7)			6.58	5.26
triacetin	C9H14O6	102-76-1	6.58	5.26
2-cyclohexen-1-ol, 1-methyl-4-(1-meth-ylethenyl)-, trans-	C10H16O	7212-40-0	6.58	0
cumene	C9H12	98-82-8	6.58	0
ethyl acetate + 1,3-dioxolane		141-78-6 + 646-06-0	6.58	0
salicylic acid, methyl ester	C8H8O3	119-36-8	6.58	0
palmitic acid	C16H32O2	57-10-3	6.58	5.26

Name	Formula	CAS	Frequency INPUT (%)	Frequency OUTPUT (%)
o-cymene	C10H14	527-84-4	6.58	1.32
cyclopentanone	C5H8O	120-92-3	6.58	10.53
4(1h)-quinazolinone, 2-methyl-	C9H8N2O	1769-24-0	6.58	1.32
4(1h)-quinazolinone	C8H6N2O	491-36-1	6.58	3.95
dioctyl adipate	C22H42O4	123-79-5	6.58	2.63
2,2-bis(4-hydroxyphenyl)propane	C15H16O2	80-05-7	6.58	13.16
ftalan dietylu	C12H14O4	84-66-2	6.58	3.95
solvent green 3	C28H22N2O2	128-80-3	6.58	5.26
cyclohexane	C6H12	110-82-7	6.58	1.32
dof / 2-ethylhexyl fumarate	C20H36O4	141-02-6	5.26	7.89
lauryl sulfate	C12H26O4S	151-41-7	5.26	5.26
triethyleneglycol	C6H14O4	112-27-6	5.26	2.63
linear and branched alkanes			5.26	3.95
linoleic acid	C18H32O2	60-33-3	5.26	1.32
2,4-diaminoanisol	C7H10N2O	615-05-4	5.26	1.32
trichloroethylene	C2HCl3	79-01-6	5.26	1.32
propyl-benzene	C9H12	103-65-1	5.26	0
c(deg/pa/eg/pa/eg/pa/eg/pa)			5.26	5.26
methyl vinyl ketone	C4H6O	78-94-4	5.26	0
butyl carbitol	C8H18O3	112-34-5	5.26	6.58
ketone			5.26	3.95
tetracosane	C24H50	646-31-1	5.26	0
.beta.-bisabolene	C15H24	495-61-4	5.26	3.95
dihydroxyacetone	C3H6O3	96-26-4	5.26	5.26
acetic acid, methyl ester	C3H6O2	79-20-9	5.26	5.26
1-ethyl-3-methyl-benzene	C9H12	620-14-4	5.26	0
1-propanol	C3H8O	71-23-8	5.26	0
octadecanoic acid, 2-(acetyloxy)-1-[(acetyloxy)methyl]ethyl ester	C25H46O6	55401-62-2	5.26	1.32
hexanoic acid	C6H12O2	142-62-1	5.26	1.32
1,1-diethoxypentane	C9H20O2	3658-79-5	5.26	3.95
heptadecanoic acid	C17H34O2	506-12-7	5.26	5.26
7,9-di-tert-butyl-1-oxaspiro(4,5)deca-6,9-diene-2,8-dione	C17H24O3	82304-66-3	5.26	5.26
benzene, 1,2,4-trimethyl- or isomer	C9H12	95-63-6	5.26	0
probable pet oligomer			5.26	0
hexanedioic acid, dimethyl ester	C8H14O4	627-93-0	5.26	0

Annex II: Summary of testing methods

Testing laboratories and relevant methods of analysis for volatile substances

Laboratory	Company	AIMPLAS	CSI S.p.a.	Ecol Studio S.p.A.	FOOD CONTACT CENTER SRL	J.S. Hamilton Poland Sp. z o.o.	Sepack-Lab S.r.l.
	Address1	Carrer de Gustave Eiffel, 4	Cascina Traversagna	Via dei Bichi, 293 - 293/B 55100 Lucca, Italy	Via Vecchia Provinciale Lucchese	ul. Chwaszczyńska	Via Ernesto Gramegna, 4
	Address2		21		19E	180	
	City	Paterna	Senago	Lucca	Serravalle Pistoiese	Gdynia	Montebello della Battaglia
	Country	ES	IT	IT	IT	PL	IT
	Zip	46980	20030	55100	51030	81-571	27054
Sample	Date of Arrival	10/02/2026	26/02/2026	12/02/2026	20/01/2026	2026-03-20	13/02/2026
	Client Sample Reference Number	FBITY2ITH5I30IOIN03	FBESY2ES1-5RS-0IKIN02	ad oms 23-12-2025	FBUKY2UNI-6MN-0IOIN02	FBLTY2LT0XCL2I4IN02	MONFLAKE020226
	Laboratory Sample Reference Numb	26-0403-1	0470fdc26_1	26LD01480	FC260116.01	262014-1/26/TYC/GDY/PBPNIO	26LD00330
	Date of Analysis Start	24/02/2026	20/03/2026	02/03/2026	21/01/2026	2026-03-30	19/02/2026
	Date of Report	21/04/2026	08/04/2026	25/03/2026	20/02/2026	2026-04-16	13/03/2026
Grinding	Make	Biometa tecnologia y sistemas S.A.	Retsch	Retsch	grinder	Retsch	Retsch
	Model	ZM2000	ZM200	ZM200	na	ZM300	ZM300
	Temp	-200	-78	-196	-176	-196	-196
	Coolant	Nitrogen	Liquid Nitrogen	Liquid nitrogen	nitrogen	Liquid nitrogen	liquid nitrogen
	Particle Size	500	500	500	500	500	500
Instrument	Chromatograph Model	Thermo Fisher Scientific	Agilent	7820A	GC8890	7890B	8890-G3542A
	Chromatograph Make	-	8890	Agilent	Agilent	Agilent	Agilent
	Detector1 Model	Thermo Fisher Scientific	Agilent	5975C	TQ7000E	FID	5977B-G7081B
	Detector1 Make	-	5977A	Agilent	Agilent	Agilent	Agilent
	Detector2 Model					MSD 5977A	
	Detector2 Make					Agilent	
	Chromatographic Column	(5%-phenyl)-methylpolysiloxane	DB-5, 30 m x 0.25 mm x 1.0 µm	624 60m x 0.25mm x 1.4um	Column DB-624 UI 30m, 0.25mm, 1,40 µm	DB-624 60 m x 250 µm x 1,4 µm	VF-624ms (30 m, 0.25 mm, 1.40 µm)
Extraction Conditions	Extraction Technique	Headspace	Headspace	Headspace	Headspace	Headspace	Headspace
	Sample weight	3	1.7	1	1,00	1	1
	Extraction Time	1.00	1.00	1.00	1.00	1.00	1
	Extraction Temperature	150.00	150.00	150.00	150.00	150.00	150
Test Conditions	Range of Mass Acquisition	20-400	m/z from 28.8 - to 550	40-450	40-300	29-550	25-400
	Internal Standard	Toluene	Toluene	CAS 108-90-7	benzene-D6, clorobenzene-D5, BHT-D21, toluene-D8	Furan-D4, Tetrahydrofuran-D8, Toluen-D8, Isophorone-D8	Chlorobenzene (CAS No. 108-90-7)
Performances	Sensitivity1	150	30	30 ug/kg	10	1000 Benzen:40 D-limonene: 40 2-methyl-1,3-	50
Identification of Compound	Library	NIST	NIST 23 + internal library	NIST	Nist	NIST20 /in-house library	NIST17 and Internal Library

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

Laboratory	Company	AIMPLAS	CSI S.p.a.	Ecol Studio S.p.A.	FOOD CONTACT CENTER SRL	J.S. Hamilton Poland Sp. z o.o.	Sepack-Lab S.r.l.
	Address1	Carrer de Gustave Eiffel, 4	Cascina Traversagna	Via dei Bichi, 293 - 293/B 55100 Lucca, Italy	Via Vecchia Provinciale Lucchese	ul. Chwaszczyńska	Via Ernesto Gramegna, 4
	Address2		21		19E	180	
	City	Paterna	Senago	Lucca	Serravalle Pistoiese	Gdynia	Montebello della Battaglia
	Country	ES	IT	IT	IT	PL	IT
	Zip	46980	20030	55100	51030	81-571	27054
Grinding	Make	Biometa tecnologia y sistemas S.A.	Retsch	Retsch	grinder	Retsch	Retsch
	Model	ZM2000	ZM200	ZM200	na	ZM300	ZM300
	Temp	-200	-78	-196	-176	-196	-196
	Coolant	Nitrogen	Liquid Nitrogen	Liquid nitrogen	nitrogen	Liquid nitrogen	liquid nitrogen
	Particle Size	500	500	500	500	500	500
Instrument	Chromatograph Model	Thermo Fisher Scientific	AGILENT	Intuvo 9000	GC8890	G3540A	7890A
	Chromatograph Make	-	7890B Series GC	Agilent	Agilent	Agilent	Agilent
	Detector1 Model	Thermo Fisher Scientific	AGILENT	5977B	TQ7000E	5977B GC/MSD	G3171A
	Detector1 Make	-	G7081B Single Quadrupole GC/MS System with 5977B MSD	Agilent	Agilent	Agilent	Agilent
	Detector2 Model					FID	
	Detector2 Make					Agilent	
	Chromatographic Columr	(5%-phenyl)-methylpolysiloxane	DB-1701, 15 m x 0.25 mm x 1.0 µm	35MS UI 35x0.25x0.25	Column DB-5 UI 30m, 0.25mm, 0.25µm	OPTIMA DELTA-3 ID: 30 m x 0,32 mm x,0,25 µm	HP-5MS UI (30 m, 0.25 mm, 0.25 µm)
Extraction Conditions	Extraction Solvent	Hexane/Ethanol 3/1	DICHLOROMETHANE	Dichloromethane	Dichloromethane	Dichloromethane	Acetonitrile
	Type of Contact	Immersion	Total immersion	Extraction	Solid-liquid extraction	Solid-liquid extraction	Total immersion
	Sample Weight	1,5	1	2.5	2	1	1
	Solvent Volume	15	10	40	10	15	10
	Time of Contact	8	24	2	2	24	1
	Temperature of Contact	20	23	25	60	40	60
Test Conditions	Range Of Mass Acquisitic	25-300	m/z from 30 - to 800	40-650	42-600	30-800	45-700
	Internal Standard	-	Methyl heptadecanoate (metilmergarato MC17), CAS 1731-92-6	CAS 131-16-8	Chlorobenzene-d5; Naphthalene-d8; BHT-d21; Phenantrene-d4	MOSH/MOAH Standard 150-600 µg/mL	Dipropyl phthalate (CAS No. 131-16-8)
	Quantification	Toluene and 4,4'-Difluorobiphenyl		Semiquantitative		semi quantitative via FID	Semi-quantification
Performances	Sensitivity1	100.00	1000.00	100 ug/kg	10.00	0.10	1000
Identification of Compounds	Library	NIST	NIST 23 + internal library	NIST and Internal	NIST v2,4 25 March 2020	NIST	NIST17 and Internal library

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

Laboratory	Company	AIMPLAS	CSI S.p.a.	Ecol Studio S.p.A.	FOOD CONTACT CENTER SRL	J.S. Hamilton Poland Sp. z o.o.	Sepack-Lab S.r.l.
	Address1	Carrer de Gustave Eiffel, 4	Cascina Traversagna	Via dei Bichi, 293 - 293/B 55100 Lucca, Italy	Via Vecchia Provinciale Lucchese	ul. Chwaszczyńska	Via Ernesto Gramegna, 4
	Address2		21		19E	180	
	City	Paterna	Senago	Lucca	Serravalle Pistoiese	Gdynia	Montebello della Battaglia
	Country	ES	IT	IT	IT	PL	IT
	Zip	46980	20030	55100	51030	81-571	27054
Grinding	Make	Biometa tecnologia y sistemas S.A.	Retsch	Retsch	grinder	Retsch	Retsch
	Model	ZM2000	ZM200	ZM200	na	ZM300	ZM300
	Temp	-200	-78	-196	-176	-196	-196
	Coolant	Nitrogen	Liquid Nitrogen	Liquid nitrogen	nitrogen	Liquid nitrogen	liquid nitrogen
	Particle Size	500	500	500	500	500	500
Instrument	Chromatograph Model	Waters	AGILENT	Nexera X2	Nexera X2	1260 Infinity II	Nexera X2
	Chromatograph Make	-	Agilent 6550 iFunnel Q-TOF LC/MS	SHIMADZU	Shimadzu	Agilent	SHIMADZU
	Detector1 Model	Waters	AGILENT	500X QToF	TripleTOF4600	6546 LC/Q-TOF	500X QToF
	Detector1 Make	-	MS	AB SCIEX	Sciex	Agilent	AB SCIEX
	Detector2 Model	-					
	Detector2 Make	-					
	Chromatographic Column	C18, 1.6um x 2.1 mm x 100mm	Poroshell 120 Aq-C18 2,1 x 100mm 2,7-Micron	Kinetex 2.6um EVO C18, 50x2.1mm	Kinetex EVO C18 150x21 mmm 2,6 um	ACQUITY UPLC BEH C18 Column, 130Å, 1.7 µm, 2.1 mm X 100 mm	Kinetex 2.6 µm EVO C18, 50 x 2.1mm
Extraction Conditions	Extraction Solvent	Hexane/Etanol 3:1	Acetonitrile	Acetonitrile	Acetonitrile	Acetonitrile	Acetonitrile
	Type of Contact	Immersion	Total immersion	Extraction	Solid-liquid extraction	Solid-liquid extraction	Total immersion
	Sample Weight	1.5	1	1	2	1	1
	Solvent Volume	15	10	10	10	15	10
	Time of Contact	8	24	1	2	24	1
	Temperature of Contact	20	23	60	60	60	60
Test Conditions	Range of Mass Acquisition	70-1000	m/z from 20 - to 1700	90-1300	50-1200	50-1700	90-1300
	Polarity	Positive and negative	POS AND NEG	POS AND NEG	pos and neg	ESI+	POS
	POS Internal Standard	Benzyl butyl phthalate		Benzotriazole BT-d10	relative compounds	Reserpina, Pyraclostrobin,	Benzotriazole BT-d10
	NEG Internal Standard	Nimesulide		CAS 81-24-3	relative compounds	n.a.	Taurocholic acid (CAS No. 81-24-3)
Performances	Sensitivity1	100	Different for each compound	1000 ug/kg	10	100	1000
Identification of Compounds	Library	Internal	Library_CSI20250605_V2	NIST and Internal	Internal library	PCDL (in-house library)	NIST 2017 and Internal