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 2nd December 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 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].

Despite the advancement in this domain, the results presented in this report still remain contingent upon further scrutiny to ensure accuracy due to the limitations of the sensitivity of the analytical methods and 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 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 or blends of pre-processed 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.

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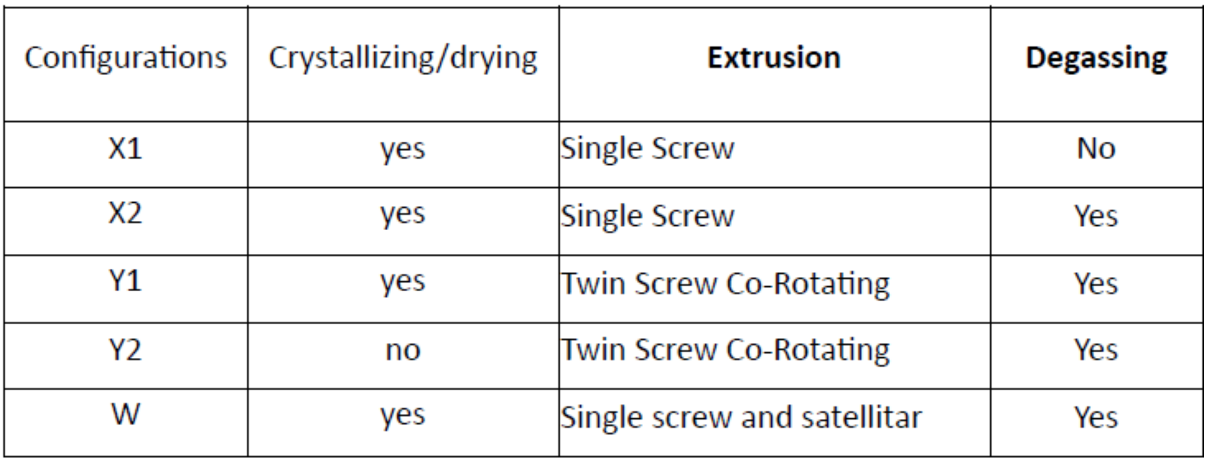
[1] (PDF) Guidance in selecting analytical techniques for identification and quantification of non-intentionally added substances (NIAS) in food contact materials (FCMS) (researchgate.net)

The 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.
- 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

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[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 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 98 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 8 different laboratories located in different EU Countries, and using similar testing methods but not identical.
- In total 98 samples for input and the correspondent 98 samples for output sheet after decontamination have been analysed.
- Out of the 98 samples for output sheet, 73 correspond to equipment configuration group Y1Y2 and 25 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 8 different laboratories. In total 98 samples for input and the correspondent 98 samples for output sheet after decontamination have been analysed. Out of the 98 samples for output sheet, 73 correspond to equipment configuration group Y1Y2 and 25 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 73 analyses and in the other of only 25, 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 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 as should any conclusions based on them.

Tables 2-4 list the 21 (for all configurations), 23 (for X1X2W configurations) and 22 (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, 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.

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	84.69	753.55	62.24	222.34
benzene	71-43-2	67.35	547.03	90.82	1555.14
toluene	108-88-3	63.27	1272.28	48.98	217.31
adipic acid, bis(2-ethylhexyl) ester	103-23-1	37.76	29244.30	31.63	13240.82
2,2-bis(4-hydroxyphenyl)propane	80-05-7	32.65	923.88	40.82	1073.65
ethylbenzene	100-41-4	31.63	491.50	7.14	115.70
styrene	100-42-5	26.53	369.69	38.78	145.62
pentanal	110-62-3	22.45	240.83	3.06	154.26
2-heptanone	110-43-0	21.43	513.25	1.02	467.03
phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	31570-04-4	19.39	9404.27	6.12	2348.86
n-hexane	110-54-3	19.39	263.66	14.29	292.83
oxidized irgafos 168	95906-11-9	18.37	2676.36	10.2	3075.84
heptane	142-82-5	18.37	184.15	13.27	74.68
oleic acid	112-80-1	17.35	20654.79	6.12	15136.39
γ-terpinene	99-85-4	17.35	141.48	0	ND (<10 - <50)
acetonitrile	75-05-8	17.35	344.61	17.35	278.95
p-xylene	106-42-3	17.35	966.14	9.18	65.33
2,4-di-tert-butylphenol	96-76-4	16.33	3827.85	1.02	8116.67
1-butanol	71-36-3	14.29	321.68	0	ND (<10 - <150)
p-cymene	99-87-6	14.29	229.91	0	ND (<15 - <150)
1-hydroxy-4-(p-toluidino)anthraquinone	81-48-1	14.29	2737.54	14.29	3184.62

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

ND: not detected

Table 3: List of the first 23 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	80	697.84	44	158.49
benzene	71-43-2	72	829.54	84	973.78
toluene	108-88-3	72	1585.92	56	169.98
2,2-bis(4-hydroxyphenyl)propane	80-05-7	40	831.67	52	1114.91
adipic acid, bis(2-ethylhexyl) ester	103-23-1	36	15546.44	32	9628.53
ethylbenzene	100-41-4	36	555.44	0	ND (<10 - <150)
oxidized irgafos 168	95906-11-9	32	3111.64	16	2747.61
oleic acid	112-80-1	28	24241.01	12	11027.23
p-xylene	106-42-3	28	826.45	8	76.68
phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	31570-04-4	28	9480.20	4	115.50
1-hydroxy-4-(p-toluidino)anthraquinone	81-48-1	24	3078.94	20	1136.93
2-heptanone	110-43-0	24	242.21	0	ND (<10 - <17)
acetonitrile	75-05-8	24	380.03	24	342.79
heptane	142-82-5	24	127.29	16	87.44
n-hexane	110-54-3	24	331.53	24	304.92
pentanal	110-62-3	24	212.06	4	324.90
styrene	100-42-5	24	406.47	36	199.28
2-nonanone	821-55-6	20	259.60	0	ND (<10 - <50)
4(1h)-quinazolinone, 2-methyl-	1769-24-0	20	495.87	12	174.67
benzene, 1,2,3-trimethyl- or isomer	526-73-8	20	228.54	0	ND (<10 - <50)
butyraldehyde	123-72-8	20	250.98	8	514.69
naphthalene	91-20-3	20	172.61	12	69.16
o-xylene	95-47-6	20	476.66	4	116.67

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

Table 4: List of the first 22 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	86.3	771.24	68.49	236.39
benzene	71-43-2	65.75	441.08	93.15	1734.67
toluene	108-88-3	60.27	1143.97	46.58	236.79
adipic acid, bis(2-ethylhexyl) ester	103-23-1	38.36	33647.19	31.51	14497.27
2,2-bis(4-hydroxyphenyl)propane	80-05-7	30.14	965.79	36.99	1053.78
ethylbenzene	100-41-4	30.14	465.34	9.59	115.70
styrene	100-42-5	27.4	358.66	39.73	128.97
pentanal	110-62-3	21.92	251.61	2.74	68.94
2-heptanone	110-43-0	20.55	621.67	1.37	467.03
γ-terpinene	99-85-4	20.55	109.48	0	ND (<10 - <50)
n-hexane	110-54-3	17.81	232.33	10.96	283.77
2,4-di-tert-butylphenol	96-76-4	16.44	3845.21	1.37	8116.67
heptane	142-82-5	16.44	212.58	12.33	69.00
phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	31570-04-4	16.44	9359.98	6.85	2795.53
acetonitrile	75-05-8	15.07	325.28	15.07	244.12
1-butanol	71-36-3	13.7	339.85	0	ND (<30 - <150)
benzoic acid	65-85-0	13.7	2036.29	10.96	2264.94
oleic acid	112-80-1	13.7	18144.44	4.11	19245.56
oxidized irgafos 168	95906-11-9	13.7	2328.14	8.22	3294.67
p-cymene	99-87-6	13.7	165.68	0	ND (<30 - <150)
p-xylene	106-42-3	13.7	1063.92	9.59	62.09
tetrahydrofuran	109-99-9	13.7	938.58	5.48	255.50

* 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 and al., 2004).
- Benzene: most probably formed from the breakdown of contaminating PVC material through a heat induced reaction (Thoden van Velzen *et al.*, 2020)
- Adipic acid, bis (2-ethylhexyl) ester: 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.

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[3] Journal of Preventive Medicine and Hygiene.

[4] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0872

- BPA: most probable source is the contamination by polycarbonate or epoxy products used in coatings and/or adhesives and/or 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).
- Phosphorous acid, tris(2,4-di-tert-butylphenyl)ester: widely known as Irgafos 168 is a common antioxidant used in plastics, adhesives and sealants, coating products and inks and toners (ECHA).
- 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,…).
- 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.
- oxidized Irgafos 168 is one of the molecules resulting from the oxidation of Irgafos 168.
- oleic acid could be generated by the hydrolysis of triglycerides present in olive oil but also in other vegetable oils like sunflower and palm oils,
- n-hexane and heptane are aliphatic solvents, the origin of their presence in PET is still under investigation.
- 2,4-di-tert-butylphenol is a raw material for the production of several commercially important antioxidants and phenolic benzotriazole-type UV absorbers. It can also be generated by the hydrolysis of Irgafos 168.
- Tetrahydrofuran is an industrial solvent and is also used in analytical chromatography.

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 equipment configurations).

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	62.24	222.34	8.04
benzene	78.11	71-43-2	90.82	1555.14	56.26
toluene	92.14	108-88-3	48.98	217.31	7.86
adipic acid, bis(2-ethylhexyl) ester	370.6	103-23-1	31.63	13240.82	479.05
2,2-bis(4-hydroxyphenyl)propane	228.29	80-05-7	40.82	1073.65	38.84
ethylbenzene	106.16	100-41-4	7.14	115.70	4.19
styrene	104.15	100-42-5	38.78	145.62	5.27
pentanal	86.13	110-62-3	3.06	154.26	5.58
2-heptanone	114.19	110-43-0	1.02	467.03	16.90
phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	646.94	31570-04-4	6.12	2348.86	84.98
n-hexane	86.18	110-54-3	14.29	292.83	10.59
oxidized irgafos 168	662.9	95906-11-9	10.2	3075.84	111.28
heptane	100.2	142-82-5	13.27	74.68	2.70
oleic acid	285.5	112-80-1	6.12	15136.39	547.63
γ-terpinene	136.23	99-85-4	0	ND (<10 - <50)	<0.36 - <1.81
acetonitrile	41.05	75-05-8	17.35	278.95	10.09
p-xylene	106.16	106-42-3	9.18	65.33	2.36
2,4-di-tert-butylphenol	206.32	96-76-4	1.02	8116.67	293.66
1-butanol	74.12	71-36-3	0	ND (<10 - <150)	<0.36 - <5.43
p-cymene	134.22	99-87-6	0	ND (<15 - <150)	<0.54 - <5.43
1-hydroxy-4-(p-toluidino)anthraquinone	329.3	81-48-1	14.29	3184.62	115.22

* 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 (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	44	158.49	5.73
benzene	78.11	71-43-2	84	973.78	35.23
toluene	92.14	108-88-3	56	169.98	6.15
2,2-bis(4-hydroxyphenyl)propane	228.29	80-05-7	52	1114.91	40.34
adipic acid, bis(2-ethylhexyl) ester	370.6	103-23-1	32	9628.53	348.36
ethylbenzene	106.16	100-41-4	0	ND (<10 - <150)	<0.36 - <5.43
oxidized irgafos 168	662.9	95906-11-9	16	2747.61	99.41
oleic acid	285.5	112-80-1	12	11027.23	398.97
p-xylene	106.16	106-42-3	8	76.68	2.77
phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	646.94	31570-04-4	4	115.50	4.18
1-hydroxy-4-(p-toluidino)anthraquinone	329.3	81-48-1	20	1136.93	41.13
2-heptanone	114.19	110-43-0	0	ND (<10 - <17)	<0.36 - <0.62
acetonitrile	41.05	75-05-8	24	342.79	12.40
heptane	100.2	142-82-5	16	87.44	3.16
n-hexane	86.18	110-54-3	24	304.92	11.03
pentanal	86.13	110-62-3	4	324.90	11.75
styrene	104.15	100-42-5	36	199.28	7.21
2-nonanone	142.24	821-55-6	0	ND (<10 - <50)	<0.36 - <1.81
4(1h)-quinazolinone, 2-methyl-	160.17	1769-24-0	12	174.67	6.32
benzene, 1,2,3-trimethyl- or isomer	120.19	526-73-8	0	ND (<10 - <50)	<0.36 - <1.81
butyraldehyde	72.11	123-72-8	8	514.69	18.62
naphthalene	128.169	91-20-3	12	69.16	2.50
o-xylene	106.16	95-47-6	4	116.67	4.22

* 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 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	68.49	236.39	8.55
benzene	78.11	71-43-2	93.15	1734.67	62.76
toluene	92.14	108-88-3	46.58	236.79	8.57
adipic acid, bis(2-ethylhexyl) ester	370.6	103-23-1	31.51	14497.27	524.51
2,2-bis(4-hydroxy-phenyl)propane	228.29	80-05-7	36.99	1053.78	38.13
ethylbenzene	106.16	100-41-4	9.59	115.70	4.19
styrene	104.15	100-42-5	39.73	128.97	4.67
pentanal	86.13	110-62-3	2.74	68.94	2.49
2-heptanone	114.19	110-43-0	1.37	467.03	16.90
γ-terpinene	136.23	99-85-4	0	ND (<10 - <50)	<0.36 - <1.81
n-hexane	86.18	110-54-3	10.96	283.77	10.27
2,4-di-tert-butylphenol	206.32	96-76-4	1.37	8116.67	293.66
heptane	100.2	142-82-5	12.33	69.00	2.50
phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	646.94	31570-04-4	6.85	2795.53	101.14
acetonitrile	41.05	75-05-8	15.07	244.12	8.83
1-butanol	74.12	71-36-3	0	ND (<30 - <150)	<1.09 - <5.43
benzoic acid	122.12	65-85-0	10.96	2264.94	81.95
oleic acid	285.5	112-80-1	4.11	19245.56	696.30
oxidized irgafos 168	662.9	95906-11-9	8.22	3294.67	119.20
p-cymene	134.22	99-87-6	0	ND (<30 - <150)	<1.09 - <5.43
p-xylene	106.16	106-42-3	9.59	62.09	2.25
tetrahydrofuran	72.11	109-99-9	5.48	255.50	9.24

* 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:

- 34 samples for 10 days at 20°C
- 52 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.

It is worth remembering that samples tested for migration are not necessarily intended for use in the conditions under which they were tested; rather, they are intended to illustrate migration results under different conditions. Consequently, samples tested at 60°C for ten days are not necessarily intended for use in ambient conditions. Moreover, Regulation 10/2011 permits the application of reduction factors for specific migration in certain foods. Therefore, the final conformity assessment of the article in question should take into account the SML after the relevant reduction factor has been applied to its food category.

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

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[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 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	1.96	6.00	0.12
			10d @ 60°C	10	15.40	1.54
benzene	78.11	71-43-2	10d @ 20°C	29.41	0.24	0.07
			10d @ 40°C	60.78	1.56	0.95
			10d @ 60°C	90	24.79	22.31
2,2-bis(4-hydroxyphenyl)propane	228.29	80-05-7	10d @ 20°C	2.94	7.20	0.21
			10d @ 40°C	17.31	6.61	1.14
			10d @ 60°C	40	6.79	2.72

* 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	11.11	6.00	0.67
			10d @ 60°C	0	ND	ND
benzene	78.11	71-43-2	10d @ 20°C	33.33	0.44	0.15
			10d @ 40°C	66.67	2.80	1.87
			10d @ 60°C	100	6.03	6.03
2,2-bis(4-hydroxyphenyl)propane	228.29	80-05-7	10d @ 20°C	0	ND	ND
			10d @ 40°C	22.22	4.78	1.06
			10d @ 60°C	28.57	12.48	3.57

* 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	0	ND	ND
			10d @ 60°C	33.33	15.40	5.13
benzene	78.11	71-43-2	10d @ 20°C	28	0.15	0.04
			10d @ 40°C	59.52	1.27	0.75
			10d @ 60°C	66.67	90.46	60.31
2,2-bis(4-hydroxyphenyl)propane	228.29	80-05-7	10d @ 20°C	4	7.20	0.29
			10d @ 40°C	16.28	7.13	1.16
			10d @ 60°C	66.67	1.10	0.73

* 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 with one exception for benzene in the equipment configurations Y1Y2 where migration of benzene at 60°C for 10 d exceeded the worst case calculated value.

However, this exception should be treated with caution: benzene was only detected in two out of three samples, and quantification was only achieved in one of these. One sample was tested in one laboratory and showed a concentration of 0.9 ppb. The other two samples, analysed in a different laboratory, showed a 'non-detect' result for one sample and detected the presence of benzene below the LOQ in the other. In this laboratory, the LOQ is very high at 0.03 mg/dm², which is equivalent to 0.18 mg/kg of food. For the purpose of calculating the mean concentration for the three samples, the concentration assigned to this specific sample was therefore the high LOQ. This means that the quantity reported under migration testing has never actually been measured and is likely to be significantly overestimated.

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	5.01	10d @ 20°C	0	ND
		10d @ 40°C	1.96	0.12
		10d @ 60°C	10	1.54
benzene	51.10	10d @ 20°C	29.41	0.07
		10d @ 40°C	60.78	0.95
		10d @ 60°C	90	22.31
2,2-bis(4-hydroxyphenyl)propane	15.85	10d @ 20°C	2.94	0.21
		10d @ 40°C	17.31	1.14
		10d @ 60°C	40	2.72

* 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	2.52	10d @ 20°C	0	ND
		10d @ 40°C	11.11	0.67
		10d @ 60°C	0	ND
benzene	29.59	10d @ 20°C	33.33	0.15
		10d @ 40°C	66.67	1.87
		10d @ 60°C	100	6.03
2,2-bis(4-hydroxyphenyl)propane	20.98	10d @ 20°C	0	ND
		10d @ 40°C	22.22	1.06
		10d @ 60°C	28.57	3.57

* 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	5.86	10d @ 20°C	0	ND
		10d @ 40°C	0	ND
		10d @ 60°C	33.33	5.13
benzene	58.46	10d @ 20°C	28	0.04
		10d @ 40°C	59.52	0.75
		10d @ 60°C	66.67	60.31
2,2-bis(4-hydroxyphenyl)propane	14.10	10d @ 20°C	4	0.29
		10d @ 40°C	16.28	1.16
		10d @ 60°C	66.67	0.73

* 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.

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)[6]. The toddler exposure scenario B was applied to establish the migration limits (EFSA, 2024)[7] (Table 14).

  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[8] is used to predict their genotoxic potential. This software is also used to further assign substances into Cramer classes I, II or III.

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[6] 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

[7] 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

[8] Toxtree version v3.1.0, May 2018

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[9].

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 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

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[9] 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

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.[10].
4. To conduct migration testing under the conditions of use.

However, for this report and with the exception of benzene and BPA, only step one was applied as it gives already a very satisfactory safety margin. In the case of benzene and BPA the migration testing results (step 4) have been used for the assessment.

In addition to the above considerations for the oxidized form of Irgafos the recent study conducted by the FDA[11] on the "Safety assessment for Tris(2,4-di-tert-butylphenyl) phosphite (Irgafos 168) used as an antioxidant and stabilizer in food contact applications " has been taken as the reference to establish the safe level. This study 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 was derived for I-168 and its degradants". when transposed to the exposure scenario B (toddler) this limit becomes 12.5 mg/kg food.

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 exposure to these two substances ranges from 0.07 to 22.31ppb in the case of benzene and from 0.21 to 2.72 in the case of BPA for all equipment configurations. In the case of configurations Y1Y2 the average migration of benzene when conducted at 60°C has been found to be 60.31 ppb. However strong reservations apply for this particular case as explained under section 8 of this document.

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[10] 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. https://doi.org/10.3390/molecules28010173

[11] https://www.fda.gov/science-research/fda-science-forum/updated-safety-assessment-tris24-di-tert-butylphenyl-phosphite-irgafos-168-used-food-contact

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 discrepancy is largely due to the inhomogeneity of the input samples, as well as different sampling techniques and slight 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 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		
			Fre-quency (%)	Average* (µg/kg PET)		Test condi-tions	Average of detected* (µg/kg food)	
limonene	136.23	138-86-3	62.24	222.34	8.04	10d @ 20°C	ND	Cramer I
						10d @ 40°C	6.00	
						10d @ 60°C	15.40	
benzene	78.11	71-43-2	90.82	1555.14	56.26	10d @ 20°C	0.24	WHO: 10 µg/L; EU Drinking water limit: 1 µg/L
						10d @ 40°C	1.56	
						10d @ 60°C	24.79	
toluene	92.14	108-88-3	48.98	217.31	7.86		NA	Cramer I
adipic acid, bis(2-ethylhexyl) ester	370.6	103-23-1	31.63	13240.82	479.05		NA	FCM207, SML= 18 mg/kg + SML(T)=60mg/kg
2,2-bis(4-hydroxy-phenyl)propane	228.29	80-05-7	40.82	1073.65	38.84	10d @ 20°C	7.20	EFSA (2023), EC (2025)
						10d @ 40°C	6.61	
						10d @ 60°C	6.79	
ethylbenzene	106.16	100-41-4	7.14	115.70	4.19		NA	Cramer I
styrene	104.15	100-42-5	38.78	145.62	5.27		NA	FCM193 w/o SML
pentanal	86.13	110-62-3	3.06	154.26	5.58		NA	Structural alert for genotoxic carcinogenicity but overruled because of JECFA evaluation
2-heptanone	114.19	110-43-0	1.02	467.03	16.90		NA	Cramer I
phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	646.94	31570-04-4	6.12	2348.86	84.98		NA	FCM671 w/o SML
n-hexane	86.18	110-54-3	14.29	292.83	10.59		NA	Cramer I
oxidized irgafos 168	662.9	95906-11-9	10.2	3075.84	111.28		NA	Organophosphate but toxicity threshold overruled following EFSA 2017 and FDA evaluations
heptane	100.2	142-82-5	13.27	74.68	2.70		NA	Cramer I
oleic acid	285.5	112-80-1	6.12	15136.39	547.63		NA	Cramer I

γ-terpinene	136.23	99-85-4	0	ND (<10 - <50)	<0.36 - <1.81		NA	Cramer I
acetonitrile	41.05	75-05-8	17.35	278.95	10.09		NA	Cramer III
p-xylene	106.16	106-42-3	9.18	65.33	2.36		NA	Cramer I
2,4-di-tert-butylphenol	206.32	96-76-4	1.02	8116.67	293.66		NA	Cramer I
1-butanol	74.12	71-36-3	0	ND (<10 - <150)	<0.36 - <5.43		NA	FCM123 w/o SML
p-cymene	134.22	99-87-6	0	ND (<15 - <150)	<0.54 - <5.43		NA	Cramer I
1-hydroxy-4-(p-toluidino)anthraquinone	329.3	81-48-1	14.29	3184.62	115.22		NA	Structural alert for genotoxic carcinogenicity overruled by positive listing in Commission decision (EU) 2024/367

* 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)		Testing Con-ditions	Average of detected* (µg/kg food)	
limonene	136.23	138-86-3	44	158.49	5.73	10d @ 20°C	ND	Cramer I
						10d @ 40°C	6.00	
						10d @ 60°C	ND	
benzene	78.11	71-43-2	84	973.78	35.23	10d @ 20°C	0.44	WHO: 10 µg/L; EU Drinking water limit: 1 µg/L
						10d @ 40°C	2.80	
						10d @ 60°C	6.03	
toluene	92.14	108-88-3	56	169.98	6.15		NA	Cramer I
2,2-bis(4-hydroxy-phenyl)propane	228.29	80-05-7	52	1114.91	40.34	10d @ 20°C	ND	EFSA (2023), EC (2025)
						10d @ 40°C	4.78	
						10d @ 60°C	12.48	
adipic acid, bis(2-ethylhexyl) ester	370.6	103-23-1	32	9628.53	348.36		NA	FCM207, SML= 18 mg/kg + SML(T)=60mg/kg
ethylbenzene	106.16	100-41-4	0	ND (<10 - <150)	<0.36 - <5.43		NA	Cramer I
oxidized irgafos 168	662.9	95906-11-9	16	2747.61	99.41		NA	Organophosphate but toxicity threshold overruled following EFSA 2017 and FDA evaluations
oleic acid	285.5	112-80-1	12	11027.23	398.97		NA	Cramer I
p-xylene	106.16	106-42-3	8	76.68	2.77		NA	Cramer I
phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	646.94	31570-04-4	4	115.50	4.18		NA	FCM671 w/o SML
1-hydroxy-4-(p-toluidino)anthraquinone	329.3	81-48-1	20	1136.93	41.13		NA	Structural alert for genotoxic carcinogenicity but overrule because of JECFA evaluation
2-heptanone	114.19	110-43-0	0	ND (<10 - <17)	<0.36 - <0.62		NA	Cramer I
acetonitrile	41.05	75-05-8	24	342.79	12.40		NA	Cramer III

heptane	100.2	142-82-5	16	87.44	3.16		NA	Cramer I
n-hexane	86.18	110-54-3	24	304.92	11.03		NA	Cramer I
pentanal	86.13	110-62-3	4	324.90	11.75		NA	Structural alert for genotoxic carcinogenicity but overrule because of JECFA evaluation
styrene	104.15	100-42-5	36	199.28	7.21		NA	FCM193 w/o SML
2-nonanone	142.24	821-55-6	0	ND (<10 - <50)	<0.36 - <1.81		NA	Cramer I
4(1h)-quinazolinone, 2-methyl-	160.17	1769-24-0	12	174.67	6.32		NA	Cramer III
benzene, 1,2,3-trimethyl- or isomer	120.19	526-73-8	0	ND (<10 - <50)	<0.36 - <1.81		NA	Cramer I
butyraldehyde	72.11	123-72-8	8	514.69	18.62		NA	Structural alert for genotoxic carcinogenicity overruled by EFCA evaluation
naphthalene	128.169	91-20-3	12	69.16	2.50		NA	Cramer III
o-xylene	106.16	95-47-6	4	116.67	4.22		NA	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		
			Fre-quency (%)	Average* (µg/kg PET)		Testing Con-ditions	Average of detected* (µg/kg food)	
limonene	136.23	138-86-3	68.49	236.39	8.55	10d @ 20°C	ND	Cramer I
						10d @ 40°C	ND	
						10d @ 60°C	15.40	
benzene	78.11	71-43-2	93.15	1734.67	62.76	10d @ 20°C	0.15	WHO: 10 µg/L; EU Drinking water limit: 1 µg/L
						10d @ 40°C	1.27	
						10d @ 60°C	90.46	
toluene	92.14	108-88-3	46.58	236.79	8.57			Cramer I
adipic acid, bis(2-ethylhexyl) ester	370.6	103-23-1	31.51	14497.27	524.51			FCM207, SML= 18 mg/kg + SML(T)=60mg/kg
2,2-bis(4-hydroxy-phenyl)propane	228.29	80-05-7	36.99	1053.78	38.13	10d @ 20°C	7.20	EFSA (2023), EC (2025)
						10d @ 40°C	7.13	
						10d @ 60°C	1.10	
ethylbenzene	106.16	100-41-4	9.59	115.70	4.19			Cramer I
styrene	104.15	100-42-5	39.73	128.97	4.67			FCM193 w/o SML
pentanal	86.13	110-62-3	2.74	68.94	2.49			Structural alert for genotoxic carcinogenicity but overrule because of JECFA evaluation
2-heptanone	114.19	110-43-0	1.37	467.03	16.90			Cramer I
γ-terpinene	136.23	99-85-4	0	ND (<10 - <50)	<0.36 - <1.81			Cramer I
n-hexane	86.18	110-54-3	10.96	283.77	10.27			Cramer I
2,4-di-tert-butylphenol	206.32	96-76-4	1.37	8116.67	293.66			Cramer I
heptane	100.2	142-82-5	12.33	69.00	2.50			Cramer I

phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	646.94	31570-04-4	6.85	2795.53	101.14			FCM671 w/o SML
acetonitrile	41.05	75-05-8	15.07	244.12	8.83			Cramer III
1-butanol	74.12	71-36-3	0	ND (<30 - <150)	<1.09 - <5.43			FCM123 w/o SML
benzoic acid	122.12	65-85-0	10.96	2264.94	81.95			FCM246 w/o SML
oleic acid	285.5	112-80-1	4.11	19245.56	696.30			Cramer I
oxidized irgafos 168	662.9	95906-11-9	8.22	3294.67	119.20			Organophosphate but toxicity threshold overruled following EFSA 2017 and FDA evaluations
p-cymene	134.22	99-87-6	0	ND (<30 - <150)	<1.09 - <5.43			Cramer I
p-xylene	106.16	106-42-3	9.59	62.09	2.25			Cramer I
tetrahydrofuran	72.11	109-99-9	5.48	255.50	9.24			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

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

This report increases knowledge of, and the statistical significance of, PET contaminants in the input and/or output thanks to the large amount of new analytical data it provides. While it provides greater statistical significance, questions remain regarding the accuracy and reproducibility of the results obtained during tests on the polymer itself. Furthermore, the validity and practical significance of the parts-per-billion (ppb) level results require further examination before definitive conclusions can be drawn.

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 variability in certain 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.

However, it is essential to emphasise that, with the exception of one case for which there is an explanation, the actual migration is significantly lower than that calculated based on the concentration in the sheet and total migration. Consequently, this total migration calculation method can be considered a worst-case scenario when evaluating exposure and ensuring the safety of the material.

Finally, it is important to reiterate that the migration testing itself should be considered a worst-case scenario. This is because it has been conducted using 95% ethanol, a simulant that produces much higher 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. Only benzene exceeds the WHO limit in one case, but the reason for this is explained on page 18. 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	97.96	98.98
acetaldehyde	C2H4O	75-07-0	93.88	95.92
limonene	C10H16	138-86-3	84.69	62.24
benzene	C6H6	71-43-2	67.35	90.82
hexanal	C6H12O	66-25-1	66.33	39.8
toluene	C7H8	108-88-3	63.27	48.98
acetic acid, ethyl ester	C4H8O2	141-78-6	60.2	20.41
ethyleneglycol	C2H6O2	107-21-1	57.14	58.16
acetic acid	C2H4O2	64-19-7	53.06	47.96
ethanol	C2H6O	64-17-5	53.06	45.92
acetone	C3H6O	67-64-1	45.92	36.73
3-((12-acetoxyoctadecanoyl)oxy)propane-1,2-diyl diacetate	C27H48O8	330198-91-9	42.86	24.49
2-[2-hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl]benzotriazole	C30H29N3O	70321-86-7	42.86	43.88
nonanal	C9H18O	124-19-6	39.8	26.53
adipic acid, bis(2-ethylhexyl) ester	C22H42O4	103-23-1	37.76	31.63
2,2-bis(4-hydroxyphenyl)propane	C15H16O2	80-05-7	32.65	40.82
ethylbenzene	C8H10	100-41-4	31.63	7.14
terephthalic acid	C8H6O4	100-21-0	30.61	30.61
2-ethyl-1-hexanol	C8H18O	104-76-7	29.59	4.08
hexamethyl cyclotrisiloxane	C6H18O3Si3	541-05-9	28.57	27.55
1,4-benzenedicarboxylic acid, bis(2-hydroxyethyl) ester	C12H14O6	959-26-2	27.55	28.57
probable pet oligomer (cyclic dimer)			26.53	26.53
styrene	C8H8	100-42-5	26.53	38.78
probable pet oligomer (dimer ether)			26.53	26.53
pet oligomers			25.51	26.53
prob. dichloromethane	CH2Cl2	75-09-2	24.49	18.37
cyclic ester of (2) phthtalic acid with (2) ethylene glycol			24.49	25.51
terephthalic acid, bis(2-ethylhexyl)ester	C24H38O4	6422-86-2	24.49	31.63
methyl formate	C2H4O2	107-31-3	24.49	22.45
pentanal	C5H10O	110-62-3	22.45	3.06
2-heptanone	C7H14O	110-43-0	21.43	1.02
phthalic acid, bis(2-ethylhexyl) ester	C24H38O4	117-81-7	21.43	25.51
formic acid	CH2O2	64-18-6	19.39	3.06
solvent blue 104	C32H30N2O2	116-75-6	19.39	16.33
palmitic acid	C16H32O2	57-10-3	19.39	16.33

Name	Formula	CAS	Frequency INPUT (%)	Frequency OUTPUT (%)
phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	C42H63O3P	31570-04-4	19.39	6.12
n-hexane	C6H14	110-54-3	19.39	14.29
cyclotetrasiloxane, octamethyl-	C8H24O4Si4	556-67-2	18.37	20.41
stearic acid	C18H36O2	57-11-4	18.37	17.35
oxidized irgafos 168	C42H63O4P	95906-11-9	18.37	10.2
heptane	C7H16	142-82-5	18.37	13.27
1,4-dioxane	C4H8O2	123-91-1	18.37	32.65
2-pentyl-furan	C9H14O	3777-69-3	17.35	4.08
oleic acid	C18H34O2	112-80-1	17.35	6.12
γ-terpinene	C10H16	99-85-4	17.35	0
l[eg/pa/eg/pa]			17.35	18.37
aliphatic hydrocarbons			17.35	3.06
l(eg/pa/eg/pa/eg/pa)			17.35	14.29
acetonitrile	C2H3N	75-05-8	17.35	17.35
p-xylene	C8H10	106-42-3	17.35	9.18
2,4-di-tert-butylphenol	C14H22O	96-76-4	16.33	1.02
c(deg/pa/deg/pa)			16.33	15.31
c(eg/pa/eg/pa/eg/pa)			16.33	17.35
c(deg/pa/eg/pa)			16.33	17.35
c(deg/pa/eg/pa/eg/pa)			16.33	15.31
unknown			15.31	9.18
1-butanol	C4H10O	71-36-3	14.29	0
c(eg/pa/eg/pa/eg/pa/eg/pa)			14.29	16.33
acetic acid, methyl ester	C3H6O2	79-20-9	14.29	3.06
p-cymene	C10H14	99-87-6	14.29	0
1-hydroxy-4-(p-toluidino)anthraquinone	C21H15NO3	81-48-1	14.29	14.29
octanal	C8H16O	124-13-0	13.27	3.06
o-xylene	C8H10	95-47-6	13.27	3.06
2-nonanone	C9H18O	821-55-6	13.27	0
dimethylsilanediol	C2H8O2Si	1066-42-8	13.27	21.43
heptanal	C7H14O	111-71-7	13.27	3.06
2-decanone	C10H20O	693-54-9	12.24	0
octadecanoic acid, 2,3-bis(acetyloxy)propyl ester	C25H46O6	33599-07-4	12.24	6.12
butyraldehyde	C4H8O	123-72-8	12.24	6.12
cyclohexane	C6H12	110-82-7	12.24	9.18
aibn	C8H12N4	78-67-1	12.24	7.14
naphthalene	C10H8	91-20-3	11.22	9.18
2-butanone	C4H8O	78-93-3	11.22	1.02
pet oligomer (cyclic dimer)			11.22	11.22
tetrahydrofuran	C4H8O	109-99-9	11.22	4.08
4(1h)-quinazolinone	C8H6N2O	491-36-1	10.2	9.18

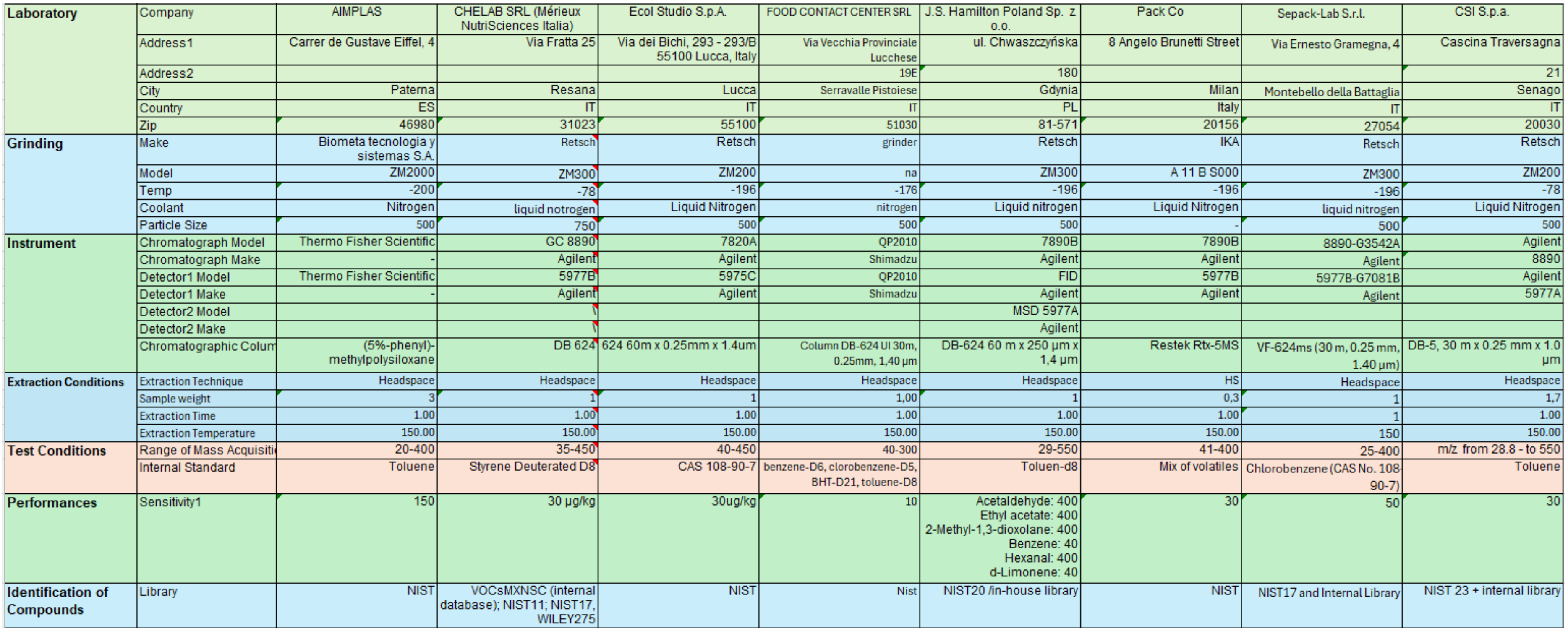
Name	Formula	CAS	Frequency INPUT (%)	Frequency OUTPUT (%)
benzaldehyde	C7H6O	100-52-7	10.2	6.12
dimethyl ether	C2H6O	115-10-6	10.2	7.14
hydrocarbons			10.2	7.14
benzoic acid	C7H6O2	65-85-0	10.2	8.16
4(1h)-quinazolinone, 2-methyl-	C9H8N2O	1769-24-0	10.2	7.14
bis(2-hydroxyethyl) phthalate	C12H14O6	84-73-1	10.2	11.22
1-pentanol	C5H12O	71-41-0	10.2	0
sum of pet oligomers			10.2	10.2
tri-n-butyl acetyl citrate	C20H34O8	77-90-7	10.2	4.08
eucalyptol	C10H18O	470-82-6	9.18	1.02
pet cyclic trimer	C30H24O12	7441-32-9	9.18	9.18
ethylene terephthalate cyclic tetramer	C40H32O16	16104-96-4	9.18	9.18
2-n-butyl-2-cyclopentenone	C9H14O	5561-05-7	9.18	0
acetic acid, butyl ester	C6H12O2	123-86-4	9.18	0
isophthalic acid	C8H6O4	121-91-5	9.18	9.18
2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	C26H26N2O2S	7128-64-5	9.18	10.2
2-propanol	C3H8O	67-63-0	9.18	6.12
2-propenal	C3H4O	107-02-8	9.18	4.08
aldehydes			9.18	4.08
akr-30 pentaerythritol triacrylate (petia)	C14H18O7	3524-68-3	8.16	8.16
xylene (isomers)			8.16	2.04
cyclic ester of (2) diethylene glycol with (2) phthalic acid			8.16	9.18
bis(2-ethylhexyl) sebacate	C26H50O4	122-62-3	8.16	8.16
benzene, 1,2,3-trimethyl- or isomer	C9H12	526-73-8	8.16	0
pet cyclic dimer	C20H16O8	24388-68-9	8.16	8.16
l(pa/eg)			8.16	10.2
pet oligomer (ether dimer)			8.16	8.16
erucamide	C22H43NO	112-84-5	8.16	9.18
cyclic (tpa-eg)3			8.16	8.16
propane, 2-methoxy-2-methyl-	C5H12O	1634-04-4	8.16	0
octane	C8H18	111-65-9	8.16	9.18
salicylic acid, methyl ester	C8H8O3	119-36-8	8.16	0
benzene, 1,3-dimethyl-	C8H10	108-38-3	7.14	3.06
caffeine	C8H10N4O2	58-08-2	7.14	7.14
cyclopentasiloxane, decamethyl-	C10H30O5Si5	541-02-6	7.14	5.1
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	7.14	7.14
1,3-dioxolane	C3H6O2	646-06-0	7.14	7.14

Name	Formula	CAS	Frequency INPUT (%)	Frequency OUTPUT (%)
benzene, 1,2,4-trimethyl- or isomer	C9H12	95-63-6	7.14	0
ftalan dietylu	C12H14O4	84-66-2	7.14	2.04
methacrylic acid, methyl ester	C5H8O2	80-62-6	7.14	22.45
hexanoic acid	C6H12O2	142-62-1	7.14	0
2-aminobenzamide	C7H8N2O	88-68-6	7.14	2.04
c[eg/pa/eg/pa/eg/pa/eg/pa] eg=ethylene glycol pa=phthalic acid		16104-96-4 (for TPA)	6.12	6.12
cyclic tpa2-eg-deg			6.12	3.06
2-methoxyethyl acetate	C5H10O3	110-49-6	6.12	5.1
1,3,5-trimethyl-benzene	C9H12	108-67-8	6.12	4.08
c[deg/pa/eg/pa/eg/pa] pa=phthalic acid deg=diethylen glycol eg=ethylen glycol		873422-64-1 (for TPA)	6.12	6.12
anethole	C10H12O	104-46-1	6.12	0
c[deg/pa/eg/pa] pa=phthalic acid deg=di-ethylen glycol eg=ethylen glycol		29278-57-7 (for TPA)	6.12	6.12
c[eg/pa/eg/pa/eg/pa] pa=phthalic acid eg=ethylene glycol		7441-32-9 (for TPA)	6.12	6.12
1-methoxy-2-propanone	C4H8O2	5878-19-3	6.12	3.06
2-(1-cyano-1-methylethyl)diazenecarbox-amide	C5H8N4O	10288-28-5	6.12	1.02
2-n-butylacrolein	C7H12O	1070-66-2	6.12	0
cyclic ester of (2) terephthalic acid with (2) ethylene glycol			6.12	6.12
c[deg/pa/deg/pa] deg=diethylen glycol pa=phthalic acid		16104-98-6 (for TPA)	6.12	6.12
c[eg/pa/eg/pa/eg/pa/eg/pa/eg/pa] eg=ethylene glycol pa=phthalic acid		16104-97-5 (for TPA)	6.12	6.12
cyclohexasiloxane, dodecamethyl-	C12H36O6Si6	540-97-6	5.1	7.14
o-cymene	C10H14	527-84-4	5.1	2.04
1-hexadecanol	C16H34O	36653-82-4	5.1	3.06
phenol, 2,4-bis(1-methyl-1-phenylethyl)-	C24H26O	2772-45-4	5.1	6.12
ftalan di-izo-butylu (dibp)	C16H22O4	84-69-5	5.1	5.1
2-(2’-hydroxy-3’-tert-butyl-5’-methylphenyl)-5-chlorobenzotriazole	C17H18ClN3O	3896-11-5	5.1	3.06
cyclopentanone	C5H8O	120-92-3	5.1	18.37
benzyl acetate	C9H10O2	140-11-4	5.1	2.04
2-propyl-1-heptanol	C10H22O	10042-59-8	5.1	1.02
cyclic[tpa+eg]2+[ipa+deg]			5.1	5.1
dioctyl adipate	C22H42O4	123-79-5	5.1	6.12
styrene derivatives			5.1	1.02
xylene		95-74-6	5.1	1.02
cyclic[tpa+deg]2			5.1	5.1
xylenes (isomers)		1330-20-7	5.1	0
2,3-butanedione	C4H6O2	431-03-8	5.1	11.22
linoleic acid	C18H32O2	60-33-3	5.1	3.06
1,2-ethanediol, monobenzoate	C9H10O3	94-33-7	5.1	6.12
l[eg/pa/eg/pa/eg/pa/eg/pa]			5.1	11.22

Name	Formula	CAS	Frequency INPUT (%)	Frequency OUTPUT (%)
isopropyl acetate	C5H10O2	108-21-4	5.1	3.06
isophthalaldehyde	C8H6O2	626-19-7	5.1	0
benzene, 1-ethyl-4-methyl- or isomer	C9H12	622-96-8	5.1	0
cyclic[tpa+eg]+[ipa+eg]			5.1	5.1
cyclic[tpa+eg]2+[ipa+eg]			5.1	5.1
cyclic[tpa+eg]3+[ipa+eg]			5.1	5.1

Annex II: Summary of testing methods

Testing laboratories and relevant methods of analysis for volatile substances

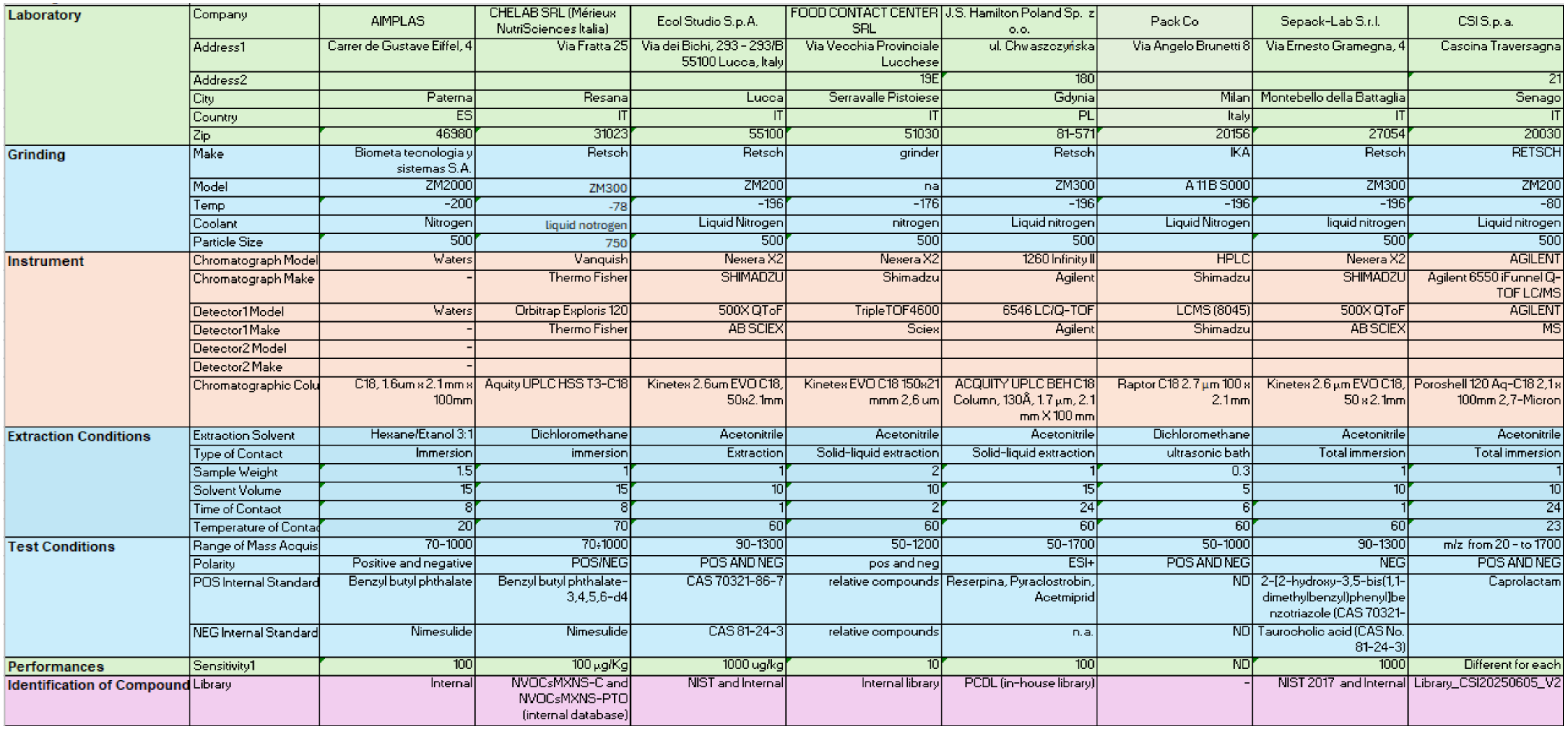


Laboratory	Company	AIMPLAS	CHELAB SRL (Mérieux NutriSciences Italia)	Ecol Studio S.p.A.	FOOD CONTACT CENTER SRL	J.S. Hamilton Poland Sp. z o.o.	Pack Co	Sepack-Lab S.r.l.	CSI S.p.a.
	Address1	Carrer de Gustave Eiffel, 4	Via Fratta 25	Via dei Bichi, 293 - 293/B 55100 Lucca, Italy	Via Vecchia Provinciale Lucchese	ul. Chwaszczyńska	8 Angelo Brunetti Street	Via Ernesto Gramegna, 4	Cascina Traversagna
	Address2				19E	180			21
	City	Paterna	Resana	Lucca	Serravalle Pistoiese	Gdynia	Milan	Montebello della Battaglia	Senago
	Country	ES	IT	IT	IT	PL	Italy	IT	IT
	Zip	46980	31023	55100	51030	81-571	20156	27054	20030
Grinding	Make	Biometa tecnologia y sistemas S.A.	Retsch	Retsch	grinder	Retsch	IKA	Retsch	Retsch
	Model	ZM2000	ZM300	ZM200	na	ZM300	A 11 B S000	ZM300	ZM200
	Temp	-200	-78	-196	-176	-196	-196	-196	-78
	Coolant	Nitrogen	liquid notrogen	Liquid Nitrogen	nitrogen	Liquid nitrogen	Liquid Nitrogen	liquid nitrogen	Liquid Nitrogen
	Particle Size	500	750	500	500	500	-	500	500
Instrument	Chromatograph Model	Thermo Fisher Scientific	GC 8890	7820A	QP2010	7890B	7890B	8890-G3542A	Agilent
	Chromatograph Make	-	Agilent	Agilent	Shimadzu	Agilent	Agilent	Agilent	8890
	Detector1 Model	Thermo Fisher Scientific	5977B	5975C	QP2010	FID	5977B	5977B-G7081B	Agilent
	Detector1 Make	-	Agilent	Agilent	Shimadzu	Agilent	Agilent	Agilent	5977A
	Detector2 Model		\			MSD 5977A			
	Detector2 Make		\			Agilent			
	Chromatographic Colum	(5%-phenyl)-methylpolysiloxane	DB 624	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	Restek Rtx-5MS	VF-624ms (30 m, 0.25 mm, 1.40 µm)	DB-5, 30 m x 0.25 mm x 1.0 µm
Extraction Conditions	Extraction Technique	Headspace	Headspace	Headspace	Headspace	Headspace	HS	Headspace	Headspace
	Sample weight	3	1	1	1,00	1	0,3	1	1,7
	Extraction Time	1.00	1.00	1.00	1.00	1.00	1.00	1	1.00
	Extraction Temperature	150.00	150.00	150.00	150.00	150.00	150.00	150	150.00
Test Conditions	Range of Mass Acquisiti	20-400	35-450	40-450	40-300	29-550	41-400	25-400	m/z from 28.8 - to 550
	Internal Standard	Toluene	Styrene Deuterated D8	CAS 108-90-7	benzene-D6, clorobenzene-D5, BHT-D21, toluene-D8	Toluen-d8	Mix of volatiles	Chlorobenzene (CAS No. 108-90-7)	Toluene
Performances	Sensitivity1	150	30 µg/kg	30ug/kg	10	Acetaldehyde: 400 Ethyl acetate: 400 2-Methyl-1,3-dioxolane: 400 Benzene: 40 Hexanal: 400 d-Limonene: 40	30	50	30
Identification of Compounds	Library	NIST	VOCsMXNSC (internal database); NIST11; NIST17, WILEY275	NIST	Nist	NIST20 /in-house library	NIST	NIST17 and Internal Library	NIST 23 + internal library

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

Laboratory	Company	AIMPLAS	CHELAB SRL (Mérieux NutriSciences Italia)	Ecol Studio S.p.A.	FOOD CONTACT CENTER SRL	J.S. Hamilton Poland Sp. z o.o.	Pack Co	Sepack-Lab S.r.l.	CSI S.p.a.
	Address1	Carrer de Gustave Eiffel, 4	Via Fratta 25	Via dei Bichi, 293 - 293/B 55100 Lucca, Italy	Via Vecchia Provinciale Lucchese	ul. Chwaszczyńska	8 Angelo Brunetti Street	Via Ernesto Gramegna, 4	Cascina Traversagna
	Address2				19E	180			21
	City	Paterna	Resana	Lucca	Serravalle Pistoiese	Gdynia	Milan	Montebello della Battaglia	Senago
	Country	ES	IT	IT	IT	PL	Italy	IT	IT
	Zip	46980	31023	55100	51030	81-571	20156	27054	20030
Grinding	Make	Biometa tecnologia y sistemas S.A.	Retsch	Retsch	grinder	Retsch	IKA	Retsch	Retsch
	Model	ZM2000	ZM300	ZM200	na	ZM300	A 11 B S000	ZM300	ZM200
	Temp	-200	-78	-196	-176	-196	-196	-196	-78
	Coolant	Nitrogen	liquid notrogen	Liquid nitrogen	nitrogen	Liquid nitrogen	Liquid Nitrogen	liquid nitrogen	Liquid Nitrogen
	Particle Size	500	750	500	500	500	-	500	500
Instrument	Chromatograph Model	Thermo Fisher Scientific	7890B	Intuvo 9000	GC8890	G3540A	GC-MS	7890A	AGILENT
	Chromatograph Make	-	Agilent	Agilent	Agilent	Agilent	Agilent	Agilent	7890B Series GC
	Detector1 Model	Thermo Fisher Scientific	G7039A	5977B	TQ7000E	5977B GC/MSD	G3440A	G3171A	AGILENT
	Detector1 Make	-	Agilent	Agilent	Agilent	Agilent	Agilent	Agilent	G7081B Single Quadrupole GC/MS System with 5977B MSD
	Detector2 Model		\			FID	ND		
	Detector2 Make		\			Agilent	ND		
	Chromatographic Colum	(5%-phenyl)-methylpolysiloxane	DB-5ms	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	DB-5HT	HP-5MS UI (30 m, 0.25 mm, 0.25 μm)	DB-1701, 15 m x 0.25 mm x 1.0 μm
Extraction Conditions	Extraction Solvent	Hexane/Ethanol 3/1	Dichloromethane	Dichloromethane	Dichloromethane	Dichloromethane	Dichloromethane	Acetonitrile	DICHLOROMETHANE
	Type of Contact	Immersion	immersion	Extraction	Solid-liquid extraction	Solid-liquid extraction	ultrasonic bath	Total immersion	Total immersion
	Sample Weight	1,5	1	2.5	2	1	0.3	1	1
	Solvent Volume	15	15	40	10	15	5	10	10
	Time of Contact	8	8	2	2	24	6	1	24
	Temperature of Contact	20	70	25	60	40	60	60	23
Test Conditions	Range Of Mass Acquisitio	25-300	35÷1000	40-650	42-600	30-800	33-750 amu	45-700	m/z from 30 - to 800
	Internal Standard	-	4,4-difluorobiphenyl	CAS 131-16-8	Chlorobenzene-d5; Naphthalene-d8; BHT-d21; Phenantrene-d4	MOSH/MOAH Standard 150-600 μg/mL	Methyl Heptadecanoate	Dipropyl phthalate (CAS No. 131-16-8)	Methyl heptadecanoate (metilmergarato MC17), CAS 1731-92-6
	Quantification	Toluene	\	Semiquantitative		semi quantitative via FID	ND	Semi-quantification	
Performances	Sensitivity1	100.00	100	100 ug/kg	10.00	0.10	200	1000	1000.00
Identification of Compounds	Library	NIST	SVOCsMXNSC (internal database); NIST11; NIST17, WILEY275	NIST	NIST v2,4 25 March 2020	NIST	ND	NIST17 and Internal library	NIST 23 + internal library

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



Laboratory	Company	AIMPLAS	CHELAB SRL (Mérieux NutriSciences Italia)	Ecol Studio S.p.A.	FOOD CONTACT CENTER SRL	J.S. Hamilton Poland Sp. z o.o.	Pack Co	Sepack-Lab S.r.l.	CSI S.p.a.
	Address1	Carrer de Gustave Eiffel, 4	Via Fratta 25	Via dei Bichi, 293 - 293/B 55100 Lucca, Italy	Via Vecchia Provinciale Lucchese	ul. Chwaszczyńska	Via Angelo Brunetti 8	Via Ernesto Gramegna, 4	Cascina Traversagna
	Address2				19E	180			21
	City	Paterna	Resana	Lucca	Serravalle Pistoiese	Gdynia	Milan	Montebello della Battaglia	Senago
	Country	ES	IT	IT	IT	PL	Italy	IT	IT
	Zip	46980	31023	55100	51030	81-571	20156	27054	20030
Grinding	Make	Biometa tecnologia y sistemas S.A.	Retsch	Retsch	grinder	Retsch	IKA	Retsch	RETSCH
	Model	ZM2000	ZM300	ZM200	na	ZM300	A 11 B S000	ZM300	ZM200
	Temp	-200	-78	-196	-176	-196	-196	-196	-80
	Coolant	Nitrogen	liquid notrogen	Liquid Nitrogen	nitrogen	Liquid nitrogen	Liquid Nitrogen	liquid nitrogen	Liquid nitrogen
	Particle Size	500	750	500	500	500		500	500
Instrument	Chromatograph Model	Waters	Vanquish	Nexera X2	Nexera X2	1260 Infinity II	HPLC	Nexera X2	AGILENT
	Chromatograph Make	-	Thermo Fisher	SHIMADZU	Shimadzu	Agilent	Shimadzu	SHIMADZU	Agilent 6550 iFunnel Q-TOF LC/MS
	Detector1 Model	Waters	Orbitrap Exploris 120	500X QToF	TripleTOF4600	6546 LC/Q-TOF	LCMS (8045)	500X QToF	AGILENT
	Detector1 Make	-	Thermo Fisher	AB SCIEX	Sciex	Agilent	Shimadzu	AB SCIEX	MS
	Detector2 Model	-							
	Detector2 Make	-							
	Chromatographic Colu	C18, 1.6um x 2.1 mm x 100mm	Aquity UPLC HSS T3-C18	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	Raptor C18 2.7 µm 100 x 2.1 mm	Kinetex 2.6 µm EVO C18, 50 x 2.1mm	Poroshell 120 Aq-C18 2,1x 100mm 2,7-Micron
Extraction Conditions	Extraction Solvent	Hexane/Etanol 3:1	Dichloromethane	Acetonitrile	Acetonitrile	Acetonitrile	Dichloromethane	Acetonitrile	Acetonitrile
	Type of Contact	Immersion	immersion	Extraction	Solid-liquid extraction	Solid-liquid extraction	ultrasonic bath	Total immersion	Total immersion
	Sample Weight	1.5	1	1	2	1	0.3	1	1
	Solvent Volume	15	15	10	10	15	5	10	10
	Time of Contact	8	8	1	2	24	6	1	24
	Temperature of Contac	20	70	60	60	60	60	60	23
Test Conditions	Range of Mass Acquis	70-1000	70÷1000	90-1300	50-1200	50-1700	50-1000	90-1300	m/z from 20 - to 1700
	Polarity	Positive and negative	POS/NEG	POS AND NEG	pos and neg	ESI+	POS AND NEG	NEG	POS AND NEG
	POS Internal Standard	Benzyl butyl phthalate	Benzyl butyl phthalate-3,4,5,6-d4	CAS 70321-86-7	relative compounds	Reserpina, Pyraclostrobin, Acetmiprid	ND	2-[2-hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl]benzotriazole (CAS 70321-	Caprolactam
	NEG Internal Standard	Nimesulide	Nimesulide	CAS 81-24-3	relative compounds	n. a.	ND	Taurocholic acid (CAS No. 81-24-3)	
Performances	Sensitivity1	100	100 µg/Kg	1000 ug/kg	10	100	ND	1000	Different for each
Identification of Compound	Library	Internal	NVOCsMXNS-C and NVOCsMXNS-PTO (internal database)	NIST and Internal	Internal library	PCDL (in-house library)	-	NIST 2017 and Internal	Library_CSI20250605_V2