PET Depolymerization to BHET and Purification via Crystallization

Report Monitoring Contamination Levels

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

10 April 2025 – updated 23 January 2026

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1. Introduction

The novel technology -*'Polyethylene terephthalate (PET) depolymerization to bis(2-hydroxyethyl)terephthalate (BHET) followed by a series of purification steps of which the main step is crystallization'* was notified as required under Articles 10(2) and 10(3) of Commission Regulation (EU) 2022/1616 on 7 April 2023.

According to Article 13 of Commission Regulation (EU) 2022/1616 *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.*

This report summarises the data forthcoming from the monitoring period October 2024-April 2025.

2. Brief description of the novel technology

This novel technology builds on the principle of breaking the polymer matrix to allow more easy access to the contaminants that may be present in the collected PET waste stream and that are usually physically bonded to the polymer and trapped by the matrix. This recycling technology, therefore, counters the difficulties and efficiency limitations often encountered to purify relatively insoluble polymers such as PET when using traditional methods such as extraction and/or partial solubilisation and reprecipitation.

Contrary to mechanical recycling that focuses on the decontamination of the PET polymer, this technology breaks selectively certain chemical bonds of the PET polymer to give a starting molecule -*BHET*- from which the PET polymer can be remade again. The depolymerization is done through glycolysis by heating the PET waste in a reactor in the presence of an excess of ethylene glycol (EG), a monomer which is also used in the manufacturing of PET (Figure 1).

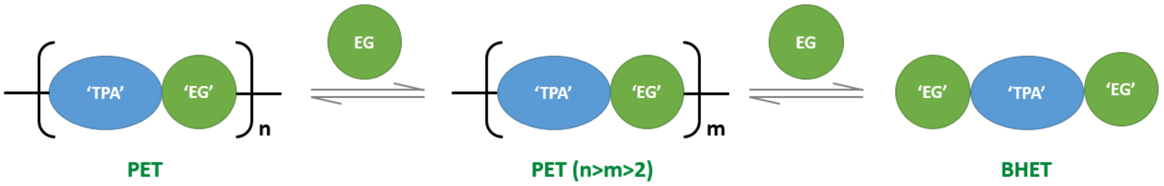

Figure 1. Schematic representation of PET glycolysis; TPA: purified terephthalic acid; EG: ethyleneglycol; BHET: bis(2-hydroxyethyl)terephthalate.

By breaking down the polymer matrix of waste PET, contaminants that may be present in the collected PET waste stream are released into the reaction medium; they are no longer physically bound or difficult to access. This allows impurities to be removed in much higher quantities and more efficiently than with mechanical recycling technologies (Figure 2) by standard physical processes like solid/liquid separation, distillation, active substrate adsorption, crystallisation and washing and drying. Therefore, this novel recycling technology can recycle highly contaminated input materials that cannot be recycled by mechanical recycling processes (Welle, 2021).

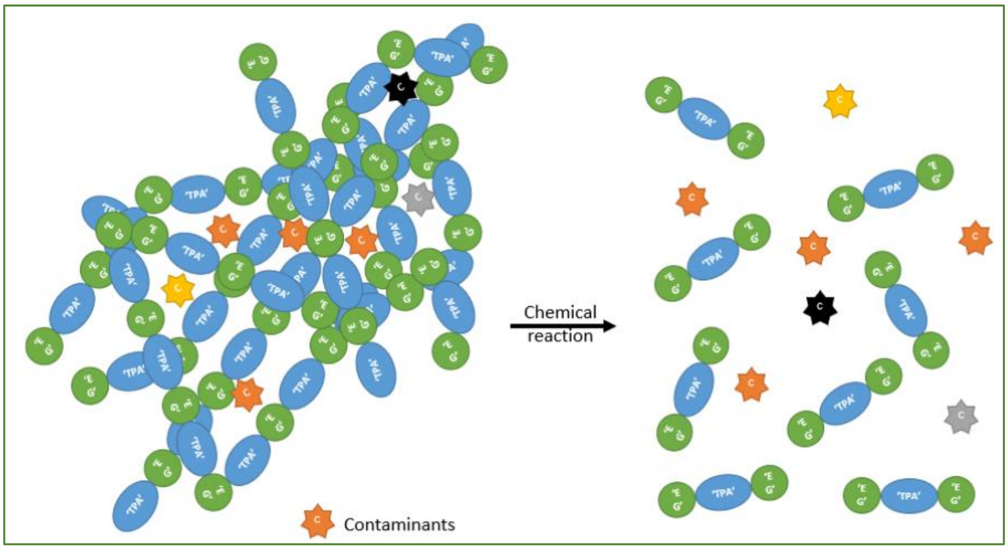

Figure 2. Schematic representation of the release of contaminants during glycolysis.

The novel technology can use 3 different waste streams:

- PET waste originating from packaging: Post-consumer and post-industrial PET packaging waste from food and non-food contact applications.
- Post-consumer and post-industrial polyester textile.
- Post-consumer[1] or post-industrial PET film.

These waste streams can deviate from the requirements for collection and pre-processing of Article 6 of Regulation (EU) 2022/1616 due to the following:

- Compliance with Regulation (EU) 10/2011 cannot always be confirmed.
- The waste not always originates from food contact applications.
- Not all plastic waste might have been subject to separate collection.
- The waste does not always originate from municipal waste or from food retail or other food businesses.

So far, recyclers that apply this novel technology for the production of BHET to be used in food contact applications only use PET waste originating from packaging from both food contact and non-food contact applications.
In this report a wider variety of input materials have been used. The input material was either:

- 100% clear PET food contact waste, or
- 100% polyester-rich post-consumer colored textile waste, or
- 70% clear PET food contact waste + 30% post-consumer non-food contact film.

Irrespective of the type, mode of collection and origin of the input material, the output contains minimum 85% of BHET. Together with the identified BHET 'alike' co-products like MHET[2] (CAS# 71949-

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[1] Post-consumer plastic waste as defined in the proposal for a Regulation on packaging and packaging waste, published on 30 November 2022 (European Commission, 2022): 'post-consumer plastic waste' means plastic waste that is generated from plastic products that have been placed on the market.

[2] TPA having reacted with only one molecule of EG

29-6), BHEI[3] (CAS# 3644-99-3), BHEET[4] (CAS# 65133-69-9), BHET[5] dimer (CAS# 2144-69-6), EG (CAS# 107-21-1) and diethylene glycol (DEG, CAS# 111-46-6) (Figure 3) that, as indicated by their structure and further confirmed through analysis, will be repolymerized together with the BHET output in the post-processing step, the purity of the obtained output could be considered as 99.9%.

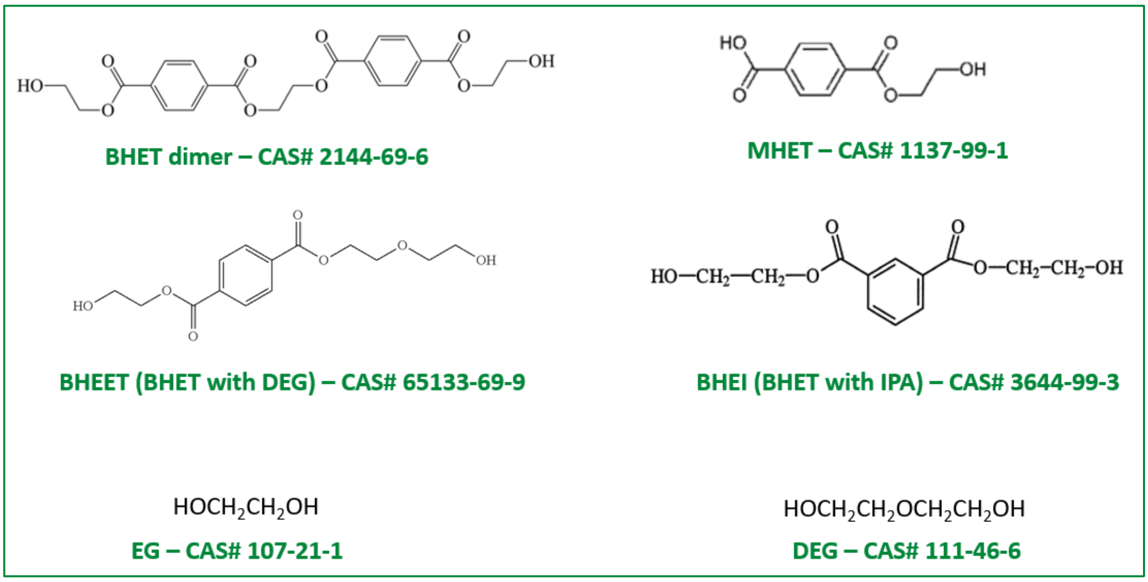

Figure 3. Main co-products formed during the glycolysis depolymerization of PET with ethylene glycol to BHET.

The specifications of the obtained BHET including its impurities are controlled at batch level using High Performance Liquid Chromatography (HPLC)[6], Gas Chromatography (GC)[7], Colorimetry[8], X-Ray Fluorescence Spectroscopy (XRF)[9] or Inductively Coupled Plasma Mass Spectrometry (ICP-MS)[10] or Atomic Emission Spectroscopy (ICP-AES)[11], Karl Fischer Titration[12], optical microscopy and test polymerizations. Other analysis techniques may occasionally be used as well.

The output BHET is used for the manufacture of PET and its common copolyesters. Up to 100% BHET can be used for the production of PET.

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[3] isophthalic acid (IPA) having reacted with two molecules of EG

[4] TPA having reacted with one molecule of EG and one molecule of DEG

[5] BHET that has reacted with itself

[6] HPLC: analytical technique for the separation, identification and quantification of non-volatile substances.

[7] GC: analytical technique for the separation, identification and quantification of volatile and semi-volatile substances.

[8] Colorimetry: analytical technique for the determination of the concentration of colored compounds in a solution.

[9] XRF: analytical technique for the qualitative and quantitative determination of the elemental composition of a material.

[10] ICP-MS: analytical technique for the detection and quantification of metals and several non-metals in samples at very low concentrations.

[11] ICP-AES: analytical technique for the qualitative and quantitative determination of the elemental composition of a sample.

[12] Karl Fischer titration: classic titration method to determine trace amounts of water in a sample.

The final recycled PET and its common co-polyesters are intended to be used for the manufacturing of materials and articles for contact with similar foods and under similar conditions for which virgin PET is intended:

- All types of foodstuffs;
- Hotfill and/or long term storage at room temperature and below;
- Use for microwaveable applications.

3. Summary of the reasoning on the capability of the novel technology and the recycling processes to manufacture recycled plastic materials and articles that comply with Article 3 of Regulation (EC) No 1935/2004 and that are microbiologically safe

The pre-processing, decontamination and post-processing processes of recycling processes applying this novel technology are described in paragraph 2. The novel technology combines the transformation of the polymer into its building block BHET to facilitate the removal of all the impurities by traditional and well recognized purification techniques.

The physical processes that are used (solid/liquid separation; distillation; adsorption on active substrates; crystallization, washing and drying) are common processes used in the chemical industry to purify most of its reagents and products. They rely on robust scientific principles that are compulsory for the obtention of highly purified molecules in the medical devices and pharmaceutical industries. As a result, the BHET obtained by recycling processes that apply this novel technology is of very high purity: BHET + polymerizable co-products >99.9% as confirmed by the analysis conducted on the purified BHET output batches as part of this monitoring program.

The decontamination efficiency of a recycling process using this novel technology, assessed by Welle (2021) using a challenge study, was shown to be at least > 99.94% for all surrogate contaminants. Based on this decontamination efficiency, it could be calculated that, for the non-volatile surrogate contaminants, the novel technology is able to reduce contaminant levels of minimum 1300 mg/kg in the input material down to a concentration in the output (Cmod) that would not lead to the exceedance of the dietary exposure in infants of 0.0025 µg/kg bw/day[13] (EFSA, 2011; Appendix III,C). For volatile surrogate contaminants, this calculated maximum contaminant level in the input material is lower mainly because of the limitations of the detection limit of the analytical method and the lower initial contaminant levels in the challenge test. Since the boiling points of these volatile surrogates are below the temperature of the glycolysis process and considering the different decontamination steps that are applied in this technology, it can be assumed that the decontamination efficiency for volatiles is at least as high as for non-volatiles.

Since the submission of the Novel Technology dossier, EFSA published a new scientific guidance. Following this guidance (EFSA, 2024, Appendix D, Table D.1), the concentration of non-volatile substances present in the input material that can be reduced by this novel technology in the worst case scenario A is minimum 1200 mg/kg (based on Cmod for methyl salicylate). For volatile surrogate contaminants, this calculated maximum contaminant level in the input material would be 67 mg/kg

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[13] human exposure threshold value for chemicals with structural alerts raising concern for potential genotoxicity (Kroes *et al.*, 2004),

(based on Cmod for toluene) but the real maximum contaminant level is likely to be much higher for the same reasons as indicated above.

Contaminant levels in post-consumer food contact PET waste is conservatively set by EFSA (2011) at 3 mg/kg PET. For non-food contact applications, Franz and Welle (2020) demonstrated that contaminants can be present in concentrations ranging from sub-mg/kg up to around 30 mg/kg on average with some exceptionally high levels of ethanol of up to 1100 mg/kg in some individual samples. These average levels are lower than the contaminant levels that this novel technology can handle.

Even though the waste used by the recyclers might not always comply with Regulation (EU) 10/2011, the obtained BHET output is 99.9% pure and is a di-ester of EG and TPA which is naturally formed during the normal production of PET. Both EG and TPA are authorized substances in Regulation (EU) No 10/2011 with identification number FCM227 and FCM785, respectively.

The BHET output produced by this novel technology can manufacture recycled plastic materials and articles that are microbiologically safe. Temperatures used during the glycolysis process and during post-processing –respectively, minimum 195°C and for minimum 1 hour and above 245°C for several hours– are more stringent than the typical conditions for sterilization used in the medical, pharmaceutical and food and beverage industry as reported by Jildeh *et al*. (2021).

4. List of all substances with a molecular weight below 1000 Dalton found in plastic input and corresponding output

As developer of the Novel Technology, PETCORE has coordinated with the recyclers the selection of the sampling strategy, the analysis to be performed and the third party laboratory. To ensure maximum comparability of the analysis results, it was decided to run the analysis at one single laboratory and therefore to collect all samples of the different Consortium members produced for food contact applications between the end of September 2024 and the end of March 2025. In total, 3 batches of plastic input material and the corresponding decontaminated BHET output samples have been analysed.

The choice of the third party laboratory was based on its experience and expertise in analysing PET samples, the state of the art of its analytical equipment and validated methods as well as the capability to identify and to risk assess non-intentionally added substances (NIAS) taking into account the specificity of this particular technology. The same laboratory was selected as the laboratory used for the second monitoring period.

The results of the analysis of substances in the plastic input and the corresponding BHET output samples can be found in Table 1. The substances detected in the samples were ordered by their relative occurrence in the input samples.

The frequency of detection was determined by dividing the number of samples in which a particular substance was detected by the total number of samples analysed. The concentration range of each substance is only given for those samples in which it was detected. If the substance was detected but below the quantification limit, the concentration provided is the limit of quantification. If the substance was not detected in the output (frequency of 0%), the limit of detection is reported in the Table.

Table 1. List of all organic substances with a molecular weight below 1000 Dalton in input and output samples.

Substance	MW	CAS	PET INPUT		BHET OUTPUT		Decontamination efficiency
			frequency	conc (mg/kg)	frequency	conc (mg/kg)	
Benzene	78.11	71-43-2	100%	0.0126 to 0.0214	33%	0.0093	26.23% to >87.14%
Toluene	92.14	108-88-3	100%	0.0102 to 0.012	33%	0.0331	-175.59% to >74.95%
Phenol	94.11	108-95-2	100%	0.0313 to 0.0981	33%	<0.0091	>70.96% to >97.20%
Styrene	104.15	100-42-5	100%	0.0247 to 0.2292	67%	0.4784 to 0.5127	-1838.99% to >98.8%
o-Xylene	106.16	95-47-6	100%	0.1074 to 1.8926	67%	<0.0091	>91.54% to >99.85%
1-Hexanol, 2-ethyl-	130.23	104-76-7	100%	<0.1	0%	<0.0303	/
Furan, 2-pentyl-	138.21	3777-69-3	100%	0.0156 to 0.9198	67%	0.1052 to 0.1648	63.36% to >82.38%
Nonanal	142.24	124-19-6	100%	0.0416 to 0.0822	67%	<0.0231	>53.33% to >53.34%
Erucamide	337.6	112-84-5	100%	<3.45 to 62.7	0%	<0.96	>98.47
1,3-Dioxolane, 2-methyl-	88.11	497-26-7	67%	<0.0311	33%	<0.0311	
Hexanal	100.16	66-25-1	67%	<0.0091 to 0.0242	67%	<0.0091	>62.46%
Pentanoic acid	102.13	109-52-4	67%	0.207 to 0.4037	0%	<0.0056	>97.31% to >98.62%
Anisole	108.14	100-66-3	67%	0.0134 to 0.0227	0%	<0.0028	>79.48% to >87.86%
Benzyl alcohol	108.14	100-51-6	67%	>1	67%	0.1631 to 0.2006	>79.94% to >83.69%
Acetic acid, butyl ester	116.16	123-86-4	67%	<0.0184	0%	<0.0056	/
Benzene, propyl-	120.19	103-65-1	67%	0.6454 to >1	0%	<0.0028	>99.57% to 99.73%
Benzene, 1,2,4-trimethyl-	120.19	95-63-6	67%	0.0739 to 0.1138	33%	0.0286	74.89% to >92.18%
Benzene, 1,2,3-trimethyl-	120.19	526-73-8	67%	0.2142 - 0.369	67%	0.4249 to 0.5224	-143.91% to -15.15%
Naphthalene	128.17	91-20-3	67%	0.0267 to 0.0416	67%	<0.0091 to 0.0359	-34.82% to >78.15%
Hexanal, 2-ethyl-	128.21	123-05-7	67%	0.0403 to 0.0634	67%	0.0153 to 0.0745	-84.98% to 75.92%
p-Cymene	134.22	99-87-6	67%	<0.0183 to 0.0349	67%	0.581 to 0.6406	>-3073.97% to -1737.08%
D-limonene	136.23	5989-27-5	67%	<0.0139 to 1.3909	0%	<0.0042	>96.97%
gamma-Terpinene	136.23	99-85-4	67%	<0.0139	0%	<0.0042	/
Ethanol, 2-phenoxy-	138.16	122-99-6	67%	0.0567 to 0.0957	67%	<0.011 to 0.0129	>80.63% to 86.47%
2-Nonanone	142.24	821-55-6	67%	0.1778 to 0.2575	33%	0.0573	67.78% to >98.71%
Octanoic acid	144.21	124-07-2	67%	<0.0184	0%	<0.0056	/
2-(2-Hydroxyethoxy)ethylacetate	144.21	2093-20-1	67%	0.0288 to 0.0427	67%	<0.0184 to 0.021	27.11% to >56.90%
Benzaldehyde, 4-(1-methylethyl)-	148.2	122-03-2	67%	0.0338 to 0.0409	33%	<0.0108	>68.15% to >92.03%
Benzyl acetate	150.17	140-11-4	67%	<0.0184 to 0.0377	67%	>1	-5337.74% to -2552.52%
Phenol, 4-(1,1-dimethylpropyl)-	164.24	80-46-6	67%	<0.0091 to 0.0199	0%	<0.0028	>86.15%
C[TPA+EG]	192.17	7337-79-3	67%	88.6 to 614	0%	<14	PET oligomer

Table 1. List of all organic substances with a molecular weight below 1000 Dalton in input and output samples. (continued)

Substance	MW	CAS	PET INPUT		BHET OUTPUT		Decontamination efficiency
			frequency	conc (mg/kg)	frequency	conc (mg/kg)	
Cyclotetradecane	196.37	295-17-0	67%	0.0168 to 0.0278	33%	<0.0091	>67.36% to >83.63%
Cyclopentane, undecyl-	224.42	6785-23-5	67%	0.0389 to 0.0545	67%	0.0249 to 0.0271	35.91% to 50.21%
2-Heptadecanone	254.5	2922-51-2	67%	0.031 to 0.0578	67%	<0.0137	>55.79% to >76.29%
C[TPA+EG]2	384.3	24388-68-9	67%	35.3 to 59	0%	<14	PET oligomer
L[TPA+EG]2	402.4	23186-89-2	67%	54.1 to 74.2	0%	<14	PET oligomer
C[TPA+EG]+[TPA+DEG]	428.4	29278-57-7	67%	579 to 777	0%	<14	PET oligomer
L[TPA+EG]+[TPA+DEG]	446.4	x	67%	96.7 to 176	0%	<14	PET oligomer
C[TPA+DEG]2	472.4	16104-98-6	67%	101 to 107	0%	<14	PET oligomer
C[TPA+EG]3 or isomer	576.5	7441-32-9	67%	92.8 to 147	0%	<14	PET oligomer
C[IPA+EG]3 or isomer	576.5	x	67%	155 to 189	0%	<14	PET oligomer
L[TPA+EG]3	594.5	16958-96-6	67%	48.2 to 80.3	0%	<14	PET oligomer
C[TPA+EG]2+[TPA+DEG]	620.6	873422-64-1	67%	135 to 175	0%	<14	PET oligomer
Ethoxylated compound			67%	149 to 209	0%	<25	>83.88% to >88.04%
Benzaldehyde	106.12	100-52-7	33%	1.4	0%	<0.0033	>99.77%
p-Xylene	106.16	16-42-3	33%	0.5918	0%	<0.0028	>99.54%
Ethanol, 2-butoxy-	118.17	111-76-2	33%	6.48	0%	<0.0303	>99.53%
Benzyl chloride	126.58	100-44-7	33%	0.011	0%	<0.0028	>74.93%
Azulene	128.169	275-51-4	33%	0.0541	0%	<0.0028	>94.92%
n-Butyl ether	130.229	142-96-1	33%	0.032	0%	<0.0028	>91.40%
Butane, 1-(2-chloroethoxy)-	136.62	10503-96-5	33%	0.0481	0%	<0.0028	>94.28%
Benzene, 1,4-dichloro-	147	106-46-7	33%	0.2989	0%	<0.0028	>99.08%
Biphenyl	154.21	92-52-4	33%	<0.0091	0%	<0.0028	
Monomethyl terephthalate	180.16	1679-64-7	33%	347.2	0%	<14	>95.97%
Dodecanoic acid	200.32	143-07-7	33%	<0.0184	33%	0.0744	-304.35%
Butylated Hydroxytoluene	220.35	128-37-0	33%	<0.0091	0%	<0.0028	
TXIB (2,2,4- Trimethyl-1,3-pentanedioldiisobutyrate	286.41	6846-50-0	33%	32.1	0%	<1.13	>96.48
Di-O-benzoyldiethylene glycol (=diethylene glycol dibenzoate)	314.3	120-55-8	33%	5625	0%	<14	>99.75%
Tinuvin 326	315.8	3896-11-5	33%	86.8	0%	<29.8	>65.67
Bisphenol A dimethacrylate	364.4	3253-39-2	33%	859.6	0%	<14	>98.37%
Bis(2-ethylhexyl) adipate	370.6	103-23-1	33%	5.9	0%	<1.17	>80.17
Bis(2-ethylhexyl) phthalate	390.6	117-81-7	33%	1.91	0%	<1.2	>37.17%
Trybutyl o-acetylcitrate	402.5	77-90-7	33%	2.62	0%	<1.13	>56.87
Derived from 9,9’-Bis[4-(2-hydroxyethoxy)phenyl]fluorene) - LOST C2H4	410.5		33%	265.8	0%	<0.85	>99.68%
Derived from 9,9’-Bis[4-(2-hydroxyethoxy)phenyl]fluorene) - LOST C2H2	412.5		33%	189.3	0%	<0.85	>99.55%

Table 1. List of all organic substances with a molecular weight below 1000 Dalton in input and output samples. (continued)

Substance	MW	CAS	PET INPUT		BHET OUTPUT		Decontamination efficiency
			frequency	conc (mg/kg)	frequency	conc (mg/kg)	
9,9'-Bis[4-(2-hydroxyethoxy)phenyl]fluorene)	438.5	117344-32-8	33%	274.2	0%	<0.85	>99.69%
Derived from 9,9'-Bis[4-(2-hydroxyethoxy)phenyl]fluorene) - H2 more	440.5		33%	206.8	0%	<0.85	>99.59%
NI (Compound with Chlorine in the Molecular Formula)	434.92		33%	NQ	0%		
NI (Compound with Chlorine in the Molecular Formula)	488.97		33%	NQ	0%		
NI (Compound with Chlorine in the Molecular Formula)	506.47		33%	NQ	0%		
NI	308		33%	NQ	0%		
Ni (Compound with Chlorine in the Molecular Formula)	372		33%	NQ	0%		
benzene, 1,3-dimethyl (m-xylene)	106.16	108-38-3	0%	<0.0056	33%	<0.0184	
Anethole	148.2	104-46-1	0%	<0.0028	67%	0.0373 to 0.0753	-2637.09% to -1256.73%
Bis (2-Hydroxyethyl) terephthalate lost C2H4O (=MHET)	210.18	1137-99-1	0%	<0.43 to <5.3	100%	overloaded	BHET co-product
2,4,7,9-Tetramethyl-5-decyn-4,7-diol	226.35	126-86-3	0%	<0.0042	33%	0.1609	-3775.90%
Bis (2-Hydroxyethyl) terephthalate gain CH2	268.26	x	0%	<5.3	33%	overloaded	BHET co-product
Phthalic acid, diisobutyl ester	278.34	84-69-5	0%	<0.0056	67%	0.0233 to 0.0883	-1485.10% to -318.49%
Bis (2-Hydroxyethyl) terephthalate gain C2H2O	296.27	x	0%	<0.43	67%	overloaded	BHET co-product
Bis (2-Hydroxyethyl)(2-Hydroxyethyl)terephthalate gain C2H4O (=BHEET))	298.29	65133-69-9	0%	<0.43 to <5.3	100%	overloaded	BHET co-product
Bis (2-Hydroxyethyl)(2-Hydroxyethyl)terephthalate gain C4H8O)	342.34	26850-76-0	0%	<0.43	67%	overloaded	BHET co-product
L[TPA + EG]2 + EG gain (=BHET dimer)	446.4	2144-69-6	0%	<5.3	100%	4810 to 7090	BHET co-product
L[TPA + EG]2 + EG gain C2H4O (=L[TPA + EG]2 + DEG)) or isomer	490.5	x	0%	<5.3	67%	1800 to 1990	BHET co-product
L[TPA + EG]2 + EG gain C2H4O (=L[TPA + EG]2 + DEG)) or isomer	490.5	x	0%	<5.3	67%	1660 to 2050	BHET co-product

NI: not identified

Levels of bisphenol A, bisphenol S and bisphenol F were below the limit of detection of the analytical method in both the input and output samples.

For this report, inorganic substances and primary aromatic amines were only analysed in (some of) the input material samples. Table 2 summarises the levels of inorganic substances in 2 out of the 3 input samples. Table 3 summarises the results of the analysis of the primary aromatic amines. None of the analysed substances have been detected in the 3 input samples.

Table 2. Summary of the results of the analysis of inorganic compounds

Element	**PET INPUT**		**BHET OUTPUT**	
	Frequency*	**conc (mg/kg)**	**frequency**	**conc (mg/kg)**
Al	0%	<2.57	NA	NA
Sb	100%	155.04	NA	NA
Pb	0%	<0.005	NA	NA
Ca	100%	9.42	NA	NA
Co	0%	<0.008	NA	NA
Fe	100%	4.16	NA	NA
Ge	0%	<0.004	NA	NA
K	0%	<0.07	NA	NA
Cu	100%	2.095	NA	NA
Mg	0%	<10.07	NA	NA
Ni	0%	0.006	NA	NA
Ti	0%	<0.028	NA	NA
Zn	50%	1.79	NA	NA
Cl	0%	<0.157	NA	NA
P	50%	83.74	NA	NA
Br	0%	<0.004	NA	NA

* Only 2 of the 3 samples were analysed. Frequency reflects the frequency in those 2 samples.
LOD: limit of detection; ND: not detected; NA: not analysed

Table 3. Summary of the analysis of primary aromatic amines

Substance	PET INPUT		BHET OUTPUT	
	frequency	conc (µg/kg)	frequency	conc (µg/kg)
p-Phenylenediamine	0%	<5.22	NA	NA
m- Phenylenediamine	0%	<5.22	NA	NA
2,6-Toluenediamine	0%	<0.96	NA	NA
4-Methoxy-m-phenylenediamine	0%	<0.96	NA	NA
2,4-Toluenediamine	0%	<0.96	NA	NA
1,5-Diaminonaphthalene	0%	<1.08	NA	NA
Aniline	0%	<0.72	NA	NA
Benzidine	0%	<2.76	NA	NA
o-Anisidine	0%	<6.6	NA	NA
4,4-Oxidianiline	0%	<1.32	NA	NA
o-Toluidine	0%	<2.22	NA	NA
4-Chloroaniline	0%	<2.1	NA	NA
4,4-Methylenedianiline	0%	<1.38	NA	NA
o-Dianisidine	0%	<0.2	NA	NA
2-Methoxy-5-m-toluidine	0%	<2.64	NA	NA
3,3-Dimethylbenzidine	0%	<1.2	NA	NA
2,4-Dimethylaniline	0%	<0.19	NA	NA
4,4’-Thiodianiline	0%	<4.62	NA	NA
2,6-Dimethylaniline	0%	<0.19	NA	NA
2-Naphtylamine	0%	<0.52	NA	NA
4,4-Methylenedi-o-toluidine	0%	<5.34	NA	NA
4-Aminobiphenyl	0%	<2.7	NA	NA
4-Aminoazobenzene	0%	<1.14	NA	NA
5-Nitro-o-toluidine	0%	<0.37	NA	NA
2,4,5-Trimethylaniline	0%	<1.38	NA	NA
4-Chloro-o-toluidine	0%	<4.2	NA	NA
o-Aminoazotoluene	0%	<0.32	NA	NA
3,3-Dichlorobenzidine	0%	<8.4	NA	NA
4,4-Methylene-bis-(2-chloroaniline)	0%	<0.29	NA	NA

NA: not analysed.

5. List of contaminating materials regularly present in the plastic input

The plastic input used for the different batches of BHET complies with the plastic input specifications reported in the Novel Technology dossier.

For the clear PET food contact plastic input, the list of contaminating materials regularly present is provided in Table 4.

The polyester-rich post-consumer colored textile waste contains synthetic fibers with more than 98% PET.

The post-consumer non-food contact film contains 98% PET and about 1% silicone-based materials.

Table 4. Contaminating materials regularly present in the plastic input from packaging.

Contaminant	Value (wt% in input)
Polyolefins	<10
Other polymers (PVC, PA, EVOH, PS)	<1
Inert materials	≤5
Fillers like carbon black, talc,…	<5

The fraction of plastics not intended for contact with food in the plastic input used for the production of the BHET output batches reported in this report is between <5% in the case of PET food contact waste plastic input and 100% in the case of post-consumer textile input.

The output is 99.9% BHET and co-products and does not contain other materials.

6. Analysis of the likely origin of the identified contaminants identified in paragraph 4 and 5

Contaminating materials

Plastic input:

Depending on the collection and sorting process, post-consumer PET waste can contain a limited amount of other polymers and materials like polyolefins, polyvinyl Chloride (PVC), polyamide (PA), ethylene vinyl alcohol (EVOH), polystyrene (PS) and fillers. These polymers and 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 products, including bottle labels
- 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 flexible and non-flexible food packaging.
- PA is often used as barrier layer in flexible packaging films.
- Fillers are used in many plastic packaging materials to modify their properties and enhance their performance.

For post-consumer textile input, the contaminating materials do also originate from textile accessories like zippers.

BHET output

In the BHET output, no contaminating materials are present.

Contaminating substances

Plastic input

The likely origin of the substances detected in the input material (Table 1) depends partially on the type of plastic input that is used.

Nine substances were detected in all three types of plastic input:

- benzene: can originate from the breakdown of contaminating PVC material (Thoden van Velzen *et al.*, 2020)
- toluene; o-xylene: typical components of aromatic solvents used in certain solvent based inks and/or adhesives and/or coatings.
- phenol: can originate from the degradation of antioxidants or UV stabilizers present in certain plastic polymers or from phenol-containing disinfectants or cleaning agents.
- styrene: monomer used in the manufacture of thermoplastic used in packaging materials and articles (ECHA, 2025). The substance is authorised in Annex I of plastics Regulation (EU) 10/2011.
- 2-ethyl-1-hexanol: could originate from plasticizers and polymer additives used in contaminating materials (other plastics). The substance is authorised in Annex I of plastics Regulation (EU) 10/2011.
- 2-pentyl-furan: can be used as flavouring agent in food (European Commission, 2012) and can be found in heat-processed foods or frying oils, as a result of the decomposition of lipid oxidation products (Lorenzo and Pico, 2017). In case of textile waste, the substance might originate from the oxidation of unsaturated fatty acids in spin finishes, oils, and lubricants.
- nonanal: arises often from the oxidation of the unsaturated fatty acids linoleic acid and oleic acid which are present in almost all food oils and, in case of textile, in spin finishes, oils and lubricants.
- erucamide: lubricant and anti-static agent used in food packaging industry. In the textile industry, it enhances the smoothness of fibers, reducing friction in synthetic fabrics like polyester.

Additional substances detected in PET food packaging and in the combined PET food packaging/PET film input:

- 2-methyl-1,3-dioxolane: reaction product of acetaldehyde (PET degradation product) and ethylene glycol (Kesaboina and Lofgren, 2012).
- hexanal: arises often from the oxidation of the unsaturated fatty acids linoleic acid which are present in almost all food oils and in bio-based lubricants.
- organic acids: can be formed as a result of hydrolysis or oxidation of certain additives or additive carriers used in the production of food contact materials (fatty acid esters, polyolefin waxes and/or mineral oils). In addition, it can be by-products of complex breakdown processes that occur in residues of food/cosmetics waste.
- anisole: is used as fragrance in cosmetic products (Cosmile Europe, 2025). It is also used in personal care, or pharmaceutical products (e.g., lotions, mouthwashes, air fresheners).
- benzyl alcohol: is widely used solvent used in several applications and natural ingredient of several essential oils.

- propyl benzene: is used as a nonpolar organic solvent in various industries, including printing and the dyeing of textiles.
- p-cymene: abundant in several essential oils and is used as a flavouring agent or fragnance ingredient.
- D-limonene: since a large fraction of PET bottles is used to pack flavoured beverages, the flavour substance limonene is found in nearly all post-consumer PET waste streams (Franz *et al*., 2004).
- γ-terpinene: major component of essential oils made from citrus fruits with strong antioxidant activity. It is widely used in food, flavours and cosmetics (European Commission, 2012).
- 2-phenoxy ethanol: could originate from cosmetics or cleaning agents or from solvents used in adhesives and inks.
- 2-nonanone: is used in washing & cleaning products, cosmetics and personal care products.
- linear and cyclic PET oligomers: are substances formed during the PET polymerization and processing steps (Hoppe *et al*., 2017)
- 2-(2-ethoxyethoxy) ethanol: is used in washing & cleaning products, plant protection products, polishes and waxes, coating products, perfumes and fragrances, cosmetics and personal care products, pharmaceuticals, air care products, hydraulic fluids, inks and toners and fuels (ECHA, 2024).

The levels of incidental contaminants in the PET food packaging input and in the combined PET food packaging/PET film input are generally below 3 mg/kg PET, which is the level conservatively set by EFSA as incidental contaminant level in food contact PET waste (EFSA, 2024).

Post-consumer textile waste typically contains much higher levels of contaminants due to the potential treatment of textile polyester fibers with dyes and additives (BfR, 2012; Undas *et al*., 2023). The following additional substances have been detected in the textile input sample in levels up to 860 mg/kg :

- 2-butoxy ethanol: is widely used in domestic and industrial products. It is used as solvent for paints and surface coatings, as well as cleaning products and inks. It can be present in liquid soaps and dry cleaning solutions.
- benzaldehyde: potentially originating from oxidation/degradation of aromatic residues, fragrance components.
- p-xylene: is a typical component of aromatic solvents used in certain solvent based inks and/or adhesives and/or coatings.
- 1,4-dichlorobenzene: is used as a disinfectant, pesticide, and deodorant, most familiarly in mothballs.
- benzylchloride: can be used as a chemical intermediate in the production of dyes, perfumes, photographic chemicals and pharmaceutical products.
- bisphenol A dimethacrylate: The use of BPA-based substances has been reported in polyester textiles (SCCS, 2021). BPA-dimethacrylate is functional binder or crosslinker that can be used in colorants or coatings for polyester textiles.
- 9,9’-bis[4-(2-hydroxyethoxy)phenyl]fluorene and degradation compounds: is a fluorene-based diol that can be used in polyester textiles for colorfastness purposes.

- bis (2-ethylhexyl) adipate and bis(2-ethylhexyl) phthalate: are common plasticizer(s) for PVC. Traces of PVC could possibly account for the presence of these plasticisers.
- TXIB (2,2,4- Trimethyl-1,3-pentanedioldiisobutyrate): is not typically used in polyester fiber but can be used as a plasticizer for the manufacture of flexible plastics.
- Tinuvin 326: bumetrizole is a benzotriazole substance . Benzotriazole substances are known to be used in textiles as UV-stabilizers but no specific reference on the use of Tinuvin 326 in textiles was found.

BHET output

As detailed in the Novel Technology dossier[14], the BHET output material contains co-products like MHET, BHEET, BHET dimer and other PET oligomers.

Apart from these co-products, some volatile substances have been detected in the BHET sample produced from PET food packaging input and in the BHET sample produced from combined PET food packaging/PET film input (Table 1). The origin of these substances is not identified. It should be verified whether these substances could have originated from contamination during sample shipment or sample storage given that the samples were not shipped in air-tight sampling containers.

In the BHET sample produced from textile waste only dodecanoic acid was detected apart from the BHET co-products.

7. Estimation of the migration level of contaminants to food

Given that the product resulting from the recycling process is BHET — a starting substance which will undergo further polymerisation to produce the final PET polymer — an estimate based on the total migration of all substances detected in BHET would not be realistic. Furthermore, when assessing the purity of a starting substance for the production of virgin plastic polymers in accordance with Article 3a of Commission Regulation (EU) No 10/2011, any impurities present should be subject to a risk assessment taking into account their fate during subsequent manufacturing steps.

The majority of substances detected in the BHET output samples (Table 1) are BHET co-products like MHET, BHEET and PET oligomers that will repolymerize during the PET production process (post-processing process). Therefore, they will no longer be present in the final PET polymer and the evaluation of their migration into the food is irrelevant. It is also likely that the organic acids will react with the PET chain during the repolymerization process but, in the event they would remain unreacted, a risk assessment is performed.

For some of the substances detected in the BHET output samples it cannot be confirmed that they will polymerize or react during the PET production process. These substances have been subject to the following risk assessment:

- Exposure: the worst case migration levels were calculated by making the assumption of no reaction and 100% migration and by applying a beverage/PET bottle ratio of 250 ml/20 g BHET and using the concentrations measured in the BHET output. In case the substance was not detected in none of the BHET outputs, the limit of detection (LOD) of the analytical method was used for the calculations.

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[14] Dossier submitted on 7 April 2023 as required under Article 10(3) of Commission Regulation (EU) 2022/1616

- 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). The infant exposure scenario A was applied to establish the migration limits (EFSA , 2024) (Table 5).

Table 5. Migration limits for different 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	0.00962	0.0481	0.0962
Organophosphates or carbamates	0.3	1.15	5.75	11.5
Cramer class III substances	1.5	5.8	29	58
Cramer class II substances	9	34.6	173	346
Cramer class I	30	115	575	1150

*EFSA scenario A (infant consuming water) (EFSA, 2024)

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

  c. Specific case: For benzene the safety limit/regulatory limit that has been applied is the limit in drinking water.
  d. Unidentified substances are considered to have a potential for genotoxicity as a worst case approach.

- 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.

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[15] Toxtree version v3.1.0, May 2018

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 E_A, 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 (Schreier *et al*, 2023)
4. To conduct migration testing under the conditions of use.

The result of this risk assessment is summarized in Table 6. As demonstrated in the Table, none of the substances present in the BHET output material does give rise to a safety concern at the concentrations present or, for substances present in the input plastic but not in het BHET output, at the LOD levels. It should, however, be noted that the concentration of benzylacetate in BHET was outside the calibration range and was reported as >1 mg/kg. Comparing this with the Cmod, there is a safety margin of 480. In addition, some of the substances detected in the plastic input material were not identified and/or quantified. These substances were not reported to be present in the output BHET material but a limit of detection was not provided. Therefore, a risk assessment for these substances cannot be provided.

Note: In this risk assessment, the decontamination efficiency of the next manufacturing stages was not taken into consideration. Welle (2008) reported that the PET polymerisation process has a decontamination efficiency of at least 99.9%. This decontamination efficiency provides an extra safety margin of 1000 for volatile substances.

Table 6. Summary of risk assessment of substances in the BHET output

Substance	MW	CAS	Frequency OUTPUT (%)	Concentration Output (mg/kg BHET) = Cres	Worst Case Calculation (µg/kg food)*	Hazard	Migration Limit (µg/kg food)	Migration limit applying OF (µg/kg food)	Cmod EFSA A_p model (mg/kg BHET)	Cmod Welle E_A model (mg/kg BHET)
Styrene	104.15	100-42-5	67%	0.4784 to 0.5127	38.27 to 41.02	FCM193 w/o SML	60000			
o-Xylene	106.16	95-47-6	67%	<0.0091	<0.73	Toxtree: Cramer I	115.38 for sum			
p-Xylene	106.16	16-42-3	0%	<0.0028	<0.22					
m-xylene	106.16	108-38-3	33%	<0.0184	<1.47					
Furan, 2-pentyl-	138.21	3777-69-3	67%	0.1052 to 0.1648	8.42 to 13.18	EFSA opinion ((EC) No. 1334/2008); Toxtree: Cramer III	5.77	28.85		
Nonanal	142.24	124-19-6	67%	<0.0231	<1.85	EFSA/JECFA opinion ((EC) No. 1334/2008); Toxtree: Cramer I	115.38 for sum			
Hexanal	100.16	66-25-1	67%	<0.0091	<0.73					
Hexanal, 2-ethyl-	128.21	123-05-7	67%	0.0153 to 0.0745	1.22 to 5.96					
Benzyl alcohol	108.14	100-51-6	67%	0.1631 to 0.2006	13.04 to 16.05	FCM194 w/o SML	60000			
Benzene, 1,2,4-trimethyl-	120.19	95-63-6	33%	0.0286	<0.46 to 2.29	Toxtree: Cramer I	115.38 for sum			
Benzene, 1,2,3-trimethyl-	120.19	526-73-8	67%	0.4249 to 0.5224	33.99 to 41.79					
Naphthalene	128.17	91-20-3	67%	<0.0091 to 0.0359	<0.73 to 2.87	Toxtree: Cramer III	5.77			
p-Cymene	134.22	99-87-6	67%	0.581 to 0.6406	46.44 to 51.25	Toxtree: Cramer I	115.38			
Ethanol, 2-phenoxy-	138.16	122-99-6	67%	<0.011 to 0.0129	<0.88 to 1.04	Toxtree: Cramer II	34.62			
2-(2-Hydroxyethoxy)ethylacetate	144.21	2093-20-1	67%	<0.0184 to 0.021	<1.47 to 1.68	Toxtree: Cramer III	5.77			
Anethole	148.2	104-46-1	67%	0.0373 to 0.0753	2.98 to 6.02	Toxtree: Cramer I	115.38			
Phthalic acid, diisobutyl ester	278.34	84-69-5	67%	0.0233 to 0.0883	1.86 to 7.06	SML(T)=60mg/kg (table 2 of Annex I)	600 as lowest of all limits for the 4 substances			
Bis(2-ethylhexyl) adipate	370.6	103-23-1	0%	<1.17	<93.6	FCM207 with SML=18mg/kg and SML(T)=60mg/kg				
Bis(2-ethylhexyl) phthalate	390.6	117-81-7	0%	<1.2	<96	FCM283 with SML(T)=0.6mg/kg and SML(T)=60mg/kg				
Trybutyl o-acetylcitrate	402.5	77-90-7	0%	<1.13	<90.4	FCM138 with SML(T)=60mg/kg				

Table 6. Summary of risk assessment of substances in the BHET output (continued)

Substance	MW	CAS	Frequency OUTPUT (%)	Concentration Output (mg/kg BHET) = Cres	Worst Case Calculation (µg/kg food)*	Hazard	Migration Limit (µg/kg food)	Migration limit applying OF (µg/kg food)	Cmod EFSA A_p model (mg/kg BHET)	Cmod Welle E_A model (mg/kg BHET)
benzylacetate	150.17	140-11-4	67%	>1	>80.00	EFSA opinion ((EC) No. 1334/2008); Toxtree: Cramer I	115.38	1153.8	480 (toluene as reference)	
Cyclopentane, undecyl-	224.42	6785-23-5	67%	0.0249 to 0.0271	1.99 to 2.17	Toxtree: Cramer III	5.77			
2-Heptadecanone	254.5	2922-51-2	67%	<0.0137	<1.1	EFSA opinion ((EC) No. 1334/2008); Toxtree: Cramer I	115.38			
Benzene	78.11	71-43-2	33%	0.0093	0.74	EU Drinking water limit: 1 µg/L	1			
Toluene	92.14	108-88-3	33%	0.00331	2.65	Toxtree: Cramer I	115.38			
Phenol	94.11	108-95-2	33%	<0.0091	<0.73	FCM241 with SML=3mg/kg	3000			
1,3-Dioxolane, 2-methyl-	88.11	497-26-7	33%	<0.018	<1.44	Toxtree: Cramer III	5.77			
2-Nonanone	142.24	821-55-6	33%	0.0573	4.58	JECFA opinion ((EC) No. 1334/2008); Toxtree: Cramer I	115.38			
Benzaldehyde, 4-(1-methylethyl)-	148.2	122-03-2	33%	<0.0108	<0.86	EFSA opinion ((EC) No. 1334/2008); Toxtree: Cramer I	115.38			
Cyclotetradecane	196.37	295-17-0	33%	<0.0091	<0.73	Toxtree: Cramer II	34.62			
2,4,7,9-Tetramethyl-5-decyn-4,7-diol	226.35	126-86-3	33%	0.1609	12.87	Toxtree: Cramer III	5.77	57.7		
Dodecanoic acid	200.32	143-07-7	33%	0.0744	5.95	FCM330 w/o SML	60000 for sum			
Octanoic acid	144.21	124-07-2	0%	<0.0056	<0.45	FCM304 w/o SML				
1-Hexanol, 2-ethyl-	130.23	104-76-7	0%	<0.0303	<2.42	FCM209 with SML=30mg/kg	30000			
Pentanoic acid	102.13	109-52-4	0%	<0.0056	<0.45	Toxtree: Cramer I	115.38			
Anisole	108.14	100-66-3	0%	<0.0028	<0.22	EFSA opinion ((EC) No. 1334/2008); Toxtree: Cramer I	115.38			
Acetic acid, butyl ester	116.16	123-86-4	0%	<0.0056	<0.45	JECFA opinion ((EC) No. 1334/2008); Toxtree: Cramer I	115.38			
Benzene, propyl-	120.19	103-65-1	0%	<0.0028	<0.22	Toxtree: Cramer I	115.38			

Table 6. Summary of risk assessment of substances in the BHET output (continued)

Substance	MW	CAS	Frequency OUTPUT (%)	Concentration Output (mg/kg BHET) = Cres	Worst Case Calculation (µg/kg food)*	Hazard	Migration Limit (µg/kg food)	Migration limit applying OF (µg/kg food)	Cmod EFSA A_p model (mg/kg BHET)	Cmod Welle E_A model (mg/kg BHET)
D-limonene	136.23	5989-27-5	0%	<0.0042	<0.34	EFSA opinion ((EC) No. 1334/2008); Toxtree: Cramer I	115.38			
gamma-Terpinene	136.23	99-85-4	0%	<0.0042	<0.34	EFSA opinion ((EC) No. 1334/2008); Toxtree: Cramer I	115.38			
Phenol, 4-(1,1-dimethylpropyl)-	164.24	80-46-6	0%	<0.0028	<0.22	Toxtree: Cramer I	115.38			
Benzaldehyde	106.12	100-52-7	0%	<0.0033	<0.26	FCM195 w/o SML	60000			
Ethanol, 2-butoxy-	118.17	111-76-2	0%	<0.0303	<2.42	EFSA opinion ((EC) No. 1334/2008); Toxtree: Cramer I	115.38			
Benzyl chloride	126.58	100-44-7	0%	<0.0028	<0.22	Toxtree: Cramer III	5.77			
Azulene	128.169	275-51-4	0%	<0.0028	<0.22	Toxtree: Structural alert genotox carcinogenicity	0.01	0.0481	0.04 (toluene as reference)	
n-Butyl ether	130.229	142-96-1	0%	<0.0028	<0.22	Toxtree: Cramer III	5.77			
Butane, 1-(2-chloroethoxy)-	136.62	10503-96-5	0%	<0.0028	<0.22	Toxtree: Cramer I	115.38			
Benzene, 1,4-dichloro-	147	106-46-7	0%	<0.0028	<0.22	Toxtree: Cramer III	5.77			
Biphenyl	154.21	92-52-4	0%	<0.0028	<0.22	Toxtree: Cramer III	5.77			
Monomethyl terephthalate	180.16	1679-64-7	0%	<14	<1120	Toxtree: Cramer I	115.38			
Butylated Hydroxytoluene	220.35	128-37-0	0%	<0.0028	<0.22	FCM315 - SML=3mg/kg	3000			
TXIB (2,2,4- Trimethyl-1,3-pentanedioldiisobutyrate	286.41	6846-50-0	0%	<1.13	<90.4	FCM497 with SML=5mg/kg	5000			
diethylene glycol dibenzoate	314.3	120-55-8	0%	<14	<1120	Toxtree: Cramer III	5.77	57.7	24 (toluene as reference)	
Tinuvin 326	315.8	3896-11-5	0%	<29.8	<2384	FCM470 with SML(T)=30mg/kg	30000			
Erucamide	337.6	112-84-5	0%	<0.96	<76.8	FCM271 w/o SML	60000			
Bisphenol A dimethacrylate	364.4	3253-39-2	0%	<14	<1120	Toxtree: Cramer III	5.77	57.7	24 (toluene as reference)	

Table 6. Summary of risk assessment of substances in the BHET output (continued)

Substance	MW	CAS	Frequency OUTPUT (%)	Concentration Output (mg/kg BHET) = Cres	Worst Case Calculation (µg/kg food)*	Hazard	Migration Limit (µg/kg food)	Migration limit applying OF** (µg/kg food)	Cmod EFSA A_p model (mg/kg BHET)	Cmod Welle E_A model (mg/kg BHET)
Derived from 9,9'-Bis[4-(2-hydroxyethoxy)phenyl]fluorene) - LOST C2H4	410.5		0%	<0.85	<68	Structural alert for genotoxic carcinogenicity	0.01	0.096	0.29 (methylstearate (MW 298.5) as reference)	90 for MW 400
Derived from 9,9'-Bis[4-(2-hydroxyethoxy)phenyl]fluorene) - LOST C2H2	412.5		0%	<0.85	<68					
9,9'-Bis[4-(2-hydroxyethoxy)phenyl]fluorene	438.5	117344-32-8	0%	<0.85	<68					
Derived from 9,9'-Bis[4-(2-hydroxyethoxy)phenyl]fluorene) - H2 more	440.5		0%	<0.85	<68					
Ethoxylated compound			0%	<25		Unknown -> worst case = structural alert for genotoxic carcinogenicity	0.01	0.096	24 (toluene as reference)	90 for MW 400
NI	308		0%	ND						
NI (Compounds with a Characteristic Spectrum that Contain Chlorine in their Molecular Formula)	372		0%	ND						
	434.92		0%	ND						
	488.97		0%	ND						
	506.47		0%	ND						

* applying a beverage/PET bottle ratio of 250 ml/20 g BHET

OF= overestimation factor (EFSA, 2024); ND: not detected but no limit of detection provided; NI: not identified

8. Sampling strategy

For this monitoring report, samples of all produced BHET output batches and of their corresponding input batch were collected. All samples were analytically screened for the following substances:

- Volatile substances,
- Semi-volatile substances,
- Non-volatile substances,
- Inorganic substances,
- Primary aromatic amines.
- Bisphenols A, F and S
- Common plastic additives.

The analytical screening was performed by a third party analytical laboratory selected on the basis of its experience and expertise in analysing PET samples and state of the art of its analytical equipment and validated methods.

9. Analytical procedures and methods

Samples of plastic input batches and their corresponding output batches were shipped to the laboratory in polyolefin sampling bags with some of them having been labelled with permanent markers. Contamination during shipment or due to the permanent marker cannot be excluded.

The analytical procedures and method used for the analysis of the samples as well as their limits of detection and quantification are summarised in Table 7.

For volatile and semi-volatile substances, a solid phase microextraction in headspace mode connected to GC-MS method (HS-SPME-GC-MS) is used which is a versatile technique employed in a wide range of industries and research areas to identify, quantify, and characterize volatile and semi-volatile compounds in plastic/polymer samples. The concentration of the volatile and semi volatile compounds on the SPME microfibre increases a lot the sensitivity of the method in such a way that most of the volatile substances can be detected at very low concentrations. The adsorption conditions for SPME of 20 mins@80°C specifically allow the exhaustive extraction of volatile substances present in PET without degrading the sample. The detection is done by MS and Mass Spectrometry–Data Independent AnaLysis (MS-DIAL), an open-source software platform, is used for identifying compounds from the MS chromatograms. Its capabilities include deconvolution of complex MS data, retention time alignment, and identification of a wide range of metabolites, including those present at low concentrations or with unknown structures (Estremera *et al.*, 2025). It minimizes subjective human assessment by applying standardized, algorithm-based peak deconvolution and library-driven identification with transparent scoring metrics. Substances were (semi-)quantified by injecting known concentrations of commercially available standards corresponding to the detected substances.. Calibration curves were prepared from these standards for quantification. In the absence of a pure standard of the identified substance, the identified substance was quantified with another substance of similar chemical structure.

For semi-volatile and non-volatile substance, the samples were first extracted after total dissolution of the sample. The PET input samples were dissolved in 1,1,1,3,3,3-hexafluoroisopropanol (HFIP). The BHET output samples were also dissolved in HFIP, and subsequent dilutions were prepared using water. This approach was adopted because, in the analyses reported on 10 April 2024, BHET was dissolved in ethanol, which led to sample precipitation. The extracts were analysed using GC/MS and

LC/MS-QToF for semi-volatile and non-volatile substances, respectively. High-resolution MS detectors like the QToF provide accurate masses isotopic patterns and intensities, which can lead to theoretical information about composition of fragments (Peters *et al*. 2019). This allows for the identification of unknown NIAS. The identification of a given substance was based on its retention time, mass spectrum and the comparison of its analysis against commercial standards. PET oligomers were quantified with the commercially available $C_{20}H_{16}O_8$ PET oligomer standard. Ethoxylated compounds were quantified using the commercial standard Brij 52 (CAS 9004-95-9). Bis(2-ethylhexyl) phthalate and 9,9'-Bis[4-(2-hydroxyethoxy)phenyl]fluorene (and its degradation products) were quantified with a pure standard of these substances.

Common plastic additives have been analysed by UPLC-MS-MS utilizing a targeted single ion reporting mode. For the BHET samples, the overload of BHET was driven to the waste.

The application ranges of the above used non-targeted screening methods overlap but the sensitivity of the methods is different. In case the same substance was detected by different methods, the highest concentration of both analyses was reported.

Table 7. Applied analytical procedures and methods including their limits of detection and quantification.

	Sample preparation	**Analytical method**	**LOD**	**LOQ**
Non-target screening of volatile and semi-volatile substances	PET samples: Cryogenic milling BHET samples: /	HS-SPME-GC/MS	Between 0.00275 and 0.0303 mg/kg PET or BHET	Between 0.00908 and 0.1 mg/kg PET or BHET
Non-target screening of semi and non-volatile substances	PET samples: Cryogenic milling, dissolution in HFIP followed by precipitation of the polymer in methanol. BHET samples: solution in HFIP	UPLC-MS-QTOF	Between 0.3 and 8.9 mg/kg PET; Between 0.85 and 14 mg/kg BHET	Between 1.1 and 17.7 mg/kg PET; Between 26 and 49 mg/kg BHET
Bisphenols A, S and F		UPLC-QqQ negative mode	0.0385 mg/kg PET 1 mg/kg BHET	
Common plastic additives		UPLC-QqQ-MS	Between 0.305 and 1.724 mg/kg PET; Between 0.85 and 29.8 mg/kg BHET	/
Targeted analysis of inorganic substances (Annex II of EU 10/2011)		Total Reflection XR Fluorescence	Between 0.004 and 10.065 mg/kg PET	/
Primary aromatic amines	Migration in 3% acetic acid, 10d@60°C	UPLC-QqQ-MS	Between 0.19 and 8.4 µg/kg PET or BHET	Between 0.63 and 27.72 µg/kg PET or BHET

HS: Head Space; SPME: Solid phase micro-extraction; GC: Gas chromatography; MS: Mass spectroscopy; QqQ: triple quadrupole; QToF: Quadrupole- time-of-flight; UPLC: ultra-high performance liquid chromatography; HFIP: 1,1,1,3,3,3-hexafluoroisopropanol
LOD: limit of detection; LOQ: limit of quantification

For the screening for primary aromatic amines a dedicated method was used as the concentration level of interest is so low that general non-target screening methods cannot detect them (Nerin *et al*., 2022). The primary aromatic amines were analysed after migration into 3% acetic acid for 10 days at 60°C.

Inorganic substances were analysed using Total Reflection X-ray Fluorescence after total dissolution of the sample.

10. Discrepancies between expected contaminant levels and the decontamination efficiency

Based on the results of a challenge study involving artificially high levels of contamination, the decontamination efficiency of this Novel Technology was demonstrated to be at least 99.94% (see Novel Technology dossier). To be able to demonstrate such high level of decontamination efficiency in commercial samples, the concentration of contaminants in the input material would need to be 1667 times higher than the detection limit of the analytical method. For this report, however, samples that are not from food-contact origin and that have higher concentrations of contaminants than the reference level of incidental contaminants of 3 mg/kg PET, considered by EFSA in its scientific guidance (2024) have been used. The limits of detection of the analytical methods were not high enough to demonstrate a decontamination efficiency of 99.94%. However, decontamination efficiencies of >99% have been demonstrated for several substances, with the highest decontamination efficiency of >99.77% for benzaldehyde.

Lower decontamination efficiencies were reported for some of the volatile substances and in some of the samples than were expected based on the challenge study. As described in section 6, the origin of some of the volatile substances present in the BHET output is not identified. It should be verified whether these substances could have originated from contamination during sample shipment or sample storage given that the samples were not shipped in air-tight sampling containers.

11. Differences with previous published monitoring reports

This monitoring report discusses the analysis results of some BHET samples produced with the Novel Technology from different types of plastic input material to those reported previously. The incidental contaminant concentration in some of the input material is more than 200 times higher than the reference level of incidental contaminants of 3 mg/kg PET, considered by EFSA in its scientific guidance (2024) for waste originating from food contact applications. The Novel Technology was able to remove these contaminants to non-detectable levels that do not raise safety concerns (see section 7). However, the limits of detection of the substances and achieving a high enough resolution in the analysis of the very pure output substance remains challenging.

Furthermore, as discussed in the previous section 10, some of the BHET output samples contained some volatile substances that were not expected. Even though they are present in low concentrations and do not pose a safety concern (see section 7), this item requires follow-up in the next monitoring reports. As contamination during sample shipment and storage could be the cause, more special care will be taken during sampling and shipment.

The sample preparation methodology for non-volatile substances in the BHET output samples has been adapted to avoid precipitation of the sample solution(see section 9). This likely had an influence on the number and levels of BHET co-products detected in the samples. The very high concentration of BHET in the output samples remains a challenge for analysis of low-level oligomers that co-elute.

Disclaimer

PETCORE Europe is providing this report and related information solely as the entity representing certain business operators (the "**Business Operators**") in accordance with Articles 10.1, §2 and 13.4-5 of the Commission Regulation (EU) 2022/1616 on recycled plastic materials and articles intended to come into contact with foods (the "**Regulation**"), in the name and on behalf of said Business Operators.

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The work and this document have been prepared following the recommendations of the Pierstone Memorandum to PETCORE Europe '**Assessment of the publication of data pursuant to Regulation 2022/1616 under competition law '.**

ABBREVIATIONS

BHEI	bis(2-hydroxyethyl)isophthalate
BHEET	2-hydroxyethyl[2-(2-hydroxyethoxy-)ethyl]terephthalate
BHET	bis(2-hydroxyethyl)terephthalate
Cmod	Modelled concentration
DEG	diethylene glycol
Ea	activation energy
EG	ethylene glycol
GC	gas chromatography
HPLC	high performance liquid chromatography
ICP-MS	Inductively Coupled Plasma Mass Spectrometry
ICP-AES	Inductively Coupled Plasma Atomic Emission Spectroscopy
IPA	isophthalic acid
MHET	mono(2-hydroxyethyl)terephthalate
NIAS	non-intentionally added substances
PE	polyethylene
PET	polyethylene terephthalate
PP	polypropylene
PVC	polyvinyl chloride
SML	specific migration limit
TPA	terephthalic acid
XRF	X-ray fluorescence spectroscopy

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By deconstructing the PET matrix, contaminants are released into the reaction medium and become easier to remove through conventional purification techniques such as solid/liquid separation, distillation, adsorption, crystallization, and washing/drying. This enables the recycling of highly contaminated input materials unsuitable for mechanical recycling.