PET Depolymerization to BHET and Purification via Crystallization

Detailed information required by Article 10(3) of Regulation (EU) 2022/1616 as part of the notification for the development of a novel technology

4 April 2023

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1. Introduction

This dossier provides detailed information on 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*'- as required under Article 10(3) of Commission Regulation (EU) 2022/1616. This technology 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.

This technology builds on the principle of breaking the polymer matrix to access more easily to the contaminants that are usually physically bonded to the polymer and therefore trapped by the matrix. Contrary to mechanical recycling that focuses on the decontamination of the PET polymer, this technology breaks selectively certain chemical bonds of the PET polymer (in this case by a glycolysis reaction), to give a starting molecule -*BHET*- from which the PET polymer can be remade again (Figure 1).

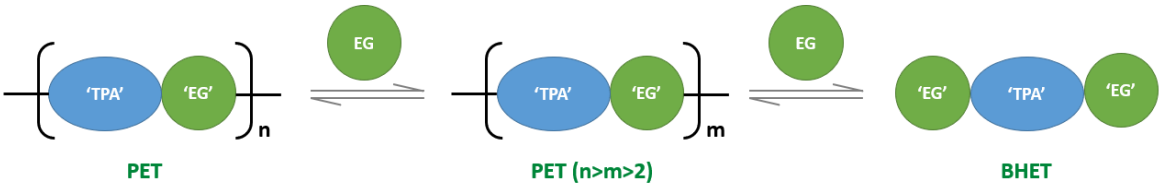


Figure 1. Schematic representation of PET glycolysis.

The different chapters in this dossier make reference to the specific requirements under Article 10(3).

2. Characterization of the novel technology – Art 10(3)(a)

In the most commercially prevalent production process of virgin PET, the key starting substances are terephthalic acid (TPA) and ethylene glycol (EG) which, in a first esterification reaction, form BHET. In the subsequent polycondensation[1] reactions, this BHET is further polymerised to form PET and an excess of EG that is removed by distillation. Both reactions (esterification and polycondensation) are reversible, which means that PET under excess of EG can be depolymerized to form BHET. Such glycolysis reaction is the starting point of the present novel technology. The obtained BHET is then further purified.

By breaking down the polymer matrix of waste PET, contaminants and additives that are present in the polymer matrix from prior usage of the material 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). Therefore, this novel recycling technology can recycle highly contaminated input materials that cannot be recycled by mechanical recycling processes (Welle, 2021).

In this section the novel technology is characterized based on the properties of recycling technologies set out in Article 3(2) of Regulation (EU) 2022/1616.

[1] Polycondensation reaction is a chemical condensation for producing a polymer by linking single or multiple kinds of monomers to form long chains releasing water or a similar simple substance in this case EG.

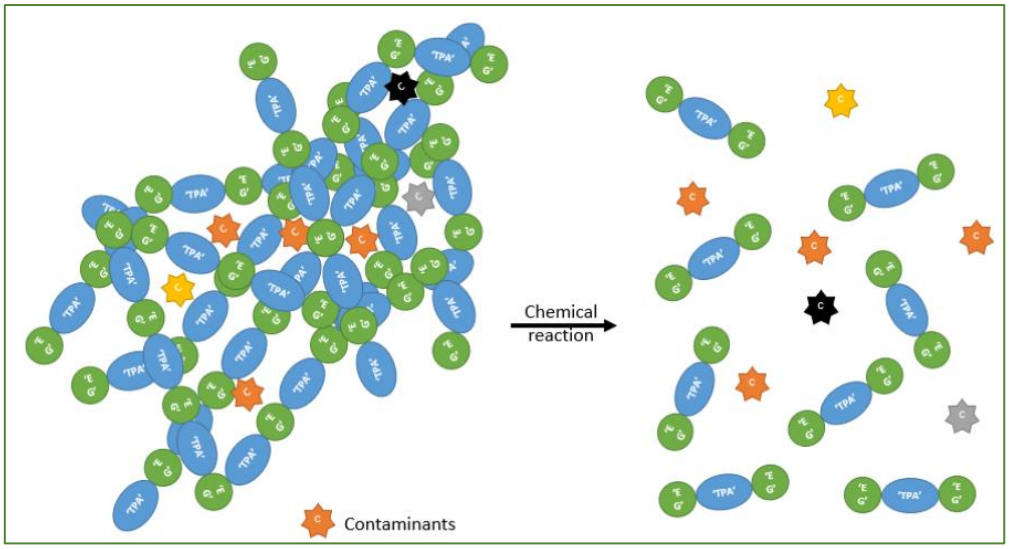


Figure 2. Schematic representation of the release of contaminants during glycolysis.

2(a). Type, mode of collection and origin of the input material.

The novel technology uses the 3 different waste streams. The characteristics and pre-processing steps of each of these waste streams are described below.

2(a)(1). PET waste from packaging: Post-consumer and post-industrial PET packaging waste from food and non-food contact applications

This waste stream contains:

- Post-consumer PET packaging waste (e.g: bottles, preforms, thermoformed mono- and multi-layer trays) originating from municipal waste collected as per the infrastructure available in the different European Member States. This can be separate collection as part of extended producer responsibility (EPR) systems or deposit and return systems (DRS) as well as mixed collection of municipal solid waste with post-collection separation.

  The collected waste is further pre-processed to minimise contamination with other non-PET waste fractions. Pre-processing operations similar to what is used for mechanical recycling are carried out. Such pre-processing typically consists of de-baling, pre-washing, automatic sorting with magnets, eddy current and/or NIR which is sometimes combined with manual sorting, grinding into flakes, hot washing and rinsing, float-sink separation, drying, fines removal, flake sorting via air separation and/or NIR and laser sorting.

- Reject PET from post-consumer mechanical recycling processes: PET flakes, fines and dust rejected from post-consumer mechanical recycling processes due to size and color.

  No pre-processing is required for this waste.

- Post-industrial PET waste (e.g.: floor sweeping chips, lumps, PET multilayer skeletons).

  Apart from size reduction like shredding and milling, no pre-processing is required for this waste.

This waste stream deviates from the requirements for collection and pre-processing of Article 6 of Regulation (EU) 2022/1616 due to the following:

- Even though the waste originates from the EU market and industry states that PET produced in Europe complies with Regulation (EU) 10/2011, compliance of the waste materials with Regulation (EU) 10/2011 cannot be entirely confirmed since some plastic waste originates from non-food contact applications that do not have specific compositional regulatory requirements.
- Not all plastic waste might have been subject to separate collection since this depends on the collection infrastructure available in the different Member States.
- Some of the plastic waste originates from non-food contact applications and likely has higher contaminant levels than the reference contaminant level of 3 mg/kg set by EFSA (2011) for waste originating from food contact applications. Franz and Welle (2020) investigated contamination levels in PET containers used for dishwashing products, antifreeze products, mouthwash products, sanitary products, shampoo products and shower gel or liquid soap products and concluded that the levels of contamination in mixed non-food PET collection are generally expected to range from sub-mg/kg concentrations 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.

The minimum input material specification used by the recyclers for this waste stream can be found in Annex I. It is controlled as per the recycler's quality assurance system.

2(a)(2). Post-consumer and post-industrial polyester textile

This waste stream contains separately collected post-consumer or post-industrial polyester textile waste such as clothes, cut-offs, selvedge, carpets, curtains and linings. The main non-PET fractions are cotton, elastane, nylon, dyes, and trimmings (buttons/zippers); other fibers like wool and silk can technically be encountered. Industrial fiber textiles from various sources might also be used such as tire cord fabric or seatbelts as well as non-woven fabrics like mats and felt.

Pre-processing of post-consumer textile waste consists of manual sorting based on textile typology (label information) and/or NIR sorting[2][3][4]. For post-industrial textile waste, sorting is based on the manufacturer's knowledge of the fabric. After the sorting, the PET textile is shredded or otherwise mechanically treated and may be further sorted to remove trimmings and other non-PET solids.

This waste stream deviates 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 be confirmed.
- The waste originates from non-food contact applications.

The minimum input material specification used by the recyclers for this waste stream can be found in Annex I. It is controlled as per the recycler's quality assurance system.

[2] Damayanti *et al*. (2021)
[3] https://www.tomra.com/en/discover/waste-metal-recycling/customer-stories/sysav-industri-ab
[4] https://www.fibersort.com

2(a)(3). Post-consumer[5] or post-industrial PET film

This waste stream contains PET films like metallized film, siliconized film, printed film and coated film separately collected by industry. It can be pre-consumer like off-cuts and scraps from film converters or post-consumer like label release liners and waste from hot foil packaging decoration.

As the waste is collected from the individual industrial sites, the composition of the waste is known and well characterised. Pre-processing consists of milling, shredding and densifying of the waste.

This waste stream deviates 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 be confirmed.
- It does not originate from municipal waste or from food retail or other food businesses.

The minimum input material specification used by the recyclers for this waste stream can be found in Annex I. It is controlled as per the recycler's quality assurance system.

2(b). Specific combination of physical and chemical concepts, principles and practices used to decontaminate the input material.

PET polymer is decontaminated by depolymerization through glycolysis and a subsequent further decontamination and purification of the reaction mixture. For completeness, also the post-processing, in which the obtained BHET is repolymerised into PET, is also described.

2(b)(1). Glycolysis

During this step the pre-processed input material may be extruded to feed a reactor where it reacts with an excess of EG to make BHET that is soluble in the reaction medium. This reaction can be reversible and needs to be properly controlled by a set of parameters that include ratio of EG:PET, temperature, pressure and residence time. Depending on the setup, the EG:PET molar ratios vary from [redacted] and temperature can vary from [redacted] when carried on at atmospheric reflux or can be up to the PET melting temperature when carried out under pressure. Residence time can range from one to several hours. Reactors can be continuously stirred tanks, plug flow, batch, or a combination thereof.

A catalyst may be used to accelerate the reaction and/or to decrease the reaction temperature. During this step the PET chains are broken into smaller molecules and ultimately into bis(2-hydroxyethyl)terephthalate (BHET) (Figure 3). As the PET polymer matrix is broken, contaminants are no longer hidden in the matrix, they are released into the reaction medium and become available to be removed by standard physical processes. In this first step, the temperature being above 190°C for longer than an hour, the volatile contaminants having boiling point below 190 °C are removed.

[5] 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.

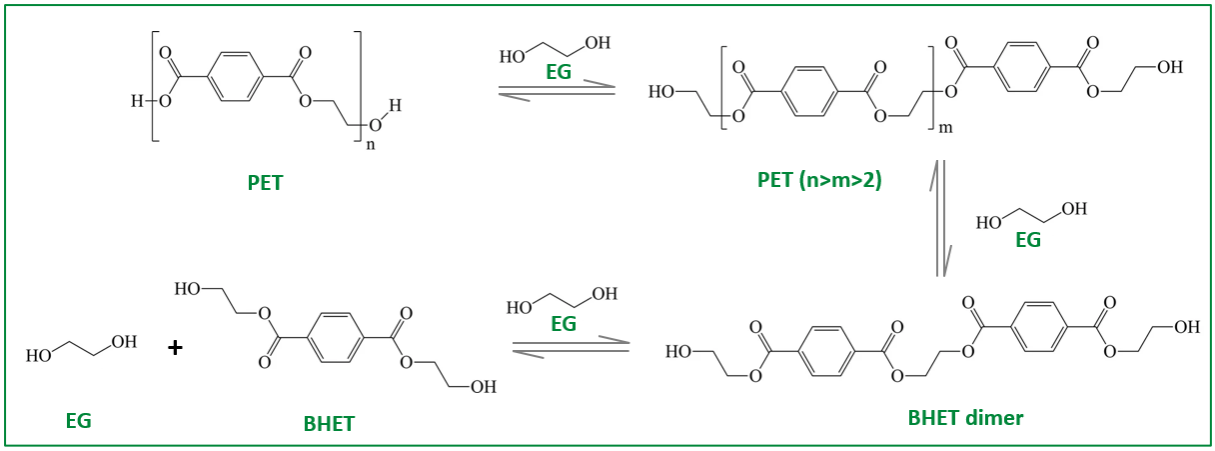


Figure 3. The glycolysis depolymerization of PET with ethylene glycol to BHET.

The main product obtained in the glycolysis reaction is BHET which corresponds to a molecule of TPA that reacted with two molecules of EG (='EG'-'TPA'-'EG') with removal of water. Some co-products (Figure 4) are formed via transesterification reactions (Langer *et al*., 2020), incomplete glycolysis, etherification, hydrolysis. They correspond to:

- TPA having reacted with only one molecule of EG = MHET
- TPA having reacted with one molecule of EG and one molecule of DEG = BHEET
- BHET that has reacted with itself =BHET dimer
- EG.

Other co-products can be formed from co-monomers that can be used in the normal production of PET. These correspond to:

- isophthalic acid (IPA) having reacted with two molecules of EG = BHEI
- diethylene glycol (DEG)

These products are part of the BHET family and further called 'BHET co-products' in this document.

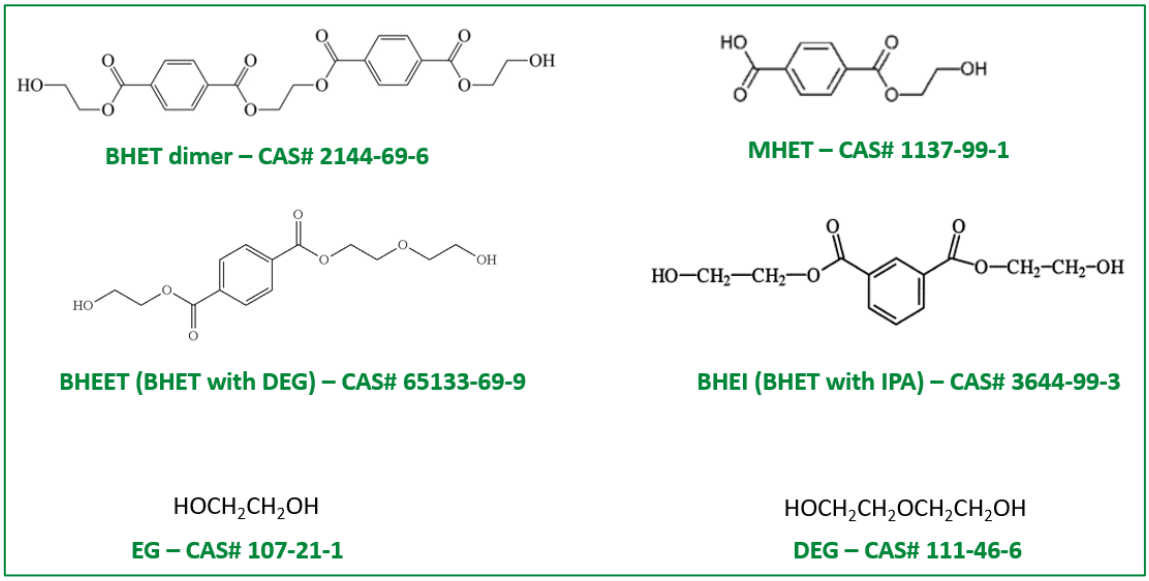


Figure 4. Main co-products formed during the glycolysis depolymerization of PET with ethylene glycol to BHET.

2(b)(2). Further decontamination and purification

The reaction medium is then decontaminated and purified using a series of steps whose number and sequence depends on the recycler albeit that crystallization is always a principal decontamination step to obtain ultra-pure BHET. Several of the following decontamination and purification steps are used:

- Solid/Liquid separation[6] such as filtration, decantation or centrifugation: removal of unreacted solids like polyethylene (PE), polypropylene (PP), polyvinyl chloride (PVC), unreacted or partially reacted PET, and/or undissolved solids like inorganic pigments, aluminium, glass, wood, paper and sand from the reaction medium.
- Distillation[7]: operated at different ranges of temperature and pressure depending on the position in the decontamination process and the type of contaminants and impurities to remove.
- Active substrate adsorption[8]: removal of organic and inorganic contaminants such as dyes and additives from the reaction medium.
- Crystallization: crystallization of BHET in water and/or EG (in varying ratios depending on the process) with removal of remaining carry-over impurities that are soluble in water/EG. Highly polar molecules will remain in the solvent and will not crystallize. Crystallization is a highly selective separation and purification technique that is also used across the pharmaceutical industry. The majority of impurities remaining from the previous steps are rejected by the growing BHET crystals, and only some BHET 'alike' co-products like MHET (CAS# 71949-29-6), BHEI (CAS# 3644-99-3), BHEET (CAS# 65133-69-9) and BHET dimer (CAS# 2144-69-6) crystallize together with the BHET.
- Washing and drying.

The excess of EG used for depolymerization is purified through distillation to be recovered and then recirculated into the glycolysis reactor.

Irrespective of the type, mode of collection and origin of the input material, the obtained BHET output has a minimum purity of 85%. Adding the identified BHET co-products 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 obtained purity could be considered as 99.9%.

[6] Involves the separation of two phases, solid and liquid, from a suspension. It is used in many processes for the: a. recovery of valuable solid component (the liquid being discarded); b. liquid recovery (the solids being discarded); c. recovery of both solid and liquid; or d. recovery of neither phase (e.g., when a liquid is being cleaned prior to discharge, as in the prevention of water pollution.

[7] The distillation process is the dominant separation method for organic mixtures separation, it is the process of separating the components or substances from a liquid mixture by using selective boiling and condensation. It can also be used to purify a product.

[8] Adsorption is a surface-based process in which adsorbed molecules or ions are attracted to a solid adsorbent surface. In the adsorption of molecules, several forces such as van der Waals forces, hydrophobic and electrostatic interactions, and hydrogen bonding may exist. The concept of adsorption is based on adsorbents, which commonly have porous structures that increase the total exposed surface area required for the fast and efficient adsorption of molecules (Al-Tohamy *et al*., 2022).

The purity of the obtained BHET is controlled at batch level using High Performance Liquid Chromatography (HPLC)[9], Gas Chromatography (GC)[10], Colorimetry[11], X-Ray Fluorescence Spectroscopy (XRF)[12] or Inductively Couples Plasma Mass Spectrometry (ICP-MS)[13] or Atomic Emission Spectroscopy (ICP-AES)[14], and Karl Fischer Titration[15].

The BHET output specification can be found in Annex II.

2(b)(3). Post-processing

The output BHET is used for the manufacture of PET and its common copolyesters. It can replace the molar equivalent of 1 TPA and 1 EG, while yielding 1 excess EG. Up to 100% BHET can be used for the production of PET.

For the manufacturing of PET and its common copolyesters, the output is introduced in the polymerization process during the esterification and/or prepolycondensation stages, where large BHET concentrations naturally form during polymerization starting from TPA or MEG. The reaction temperature at those stages is typically [redacted] under high vacuum. The remainder of the process is identical to typical PET polycondensation, which uses temperatures between [redacted] and vacuum to remove ethylene glycol to drive the reaction towards a long chain length, typically a degree of polymerization (DP) of 100 or IV of 0.8 dL/g. Since the polyester chains are continuously transesterified in the melt, and the polycondensation steps take several hours, the resulting PET has the same statistical chain length distribution with a polydispersity of 2 for PET from TPA and EG as for PET from BHET.

2(c). Type and intended use of the final recycled plastic materials and articles

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 as virgin PET is intended for which is:

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

[9] HPLC: analytical technique for the separation, identification and quantification of non-volatile substances.
[10] GC: analytical technique for the separation, identification and quantification of volatile and semi-volatile substances.
[11] Colorimetry: analytical technique for the determination of the concentration of colored compounds in a solution.
[12] XRF: analytical technique for the qualitative and quantitative determination of the elemental composition of a material.
[13] ICP-MS: analytical technique for the detection and quantification of metals and several non-metals in samples at very low concentrations.
[14] ICP-AES: analytical technique for the qualitative and quantitative determination of the elemental composition of a sample.
[15] Karl Fischer titration: classic titration method to determine trace amounts of water in a sample.

2(d). The need or absence thereof for the evaluation and authorization of recycling processes applying that technology, and the criteria therefore.

See point 7.

3. An explanation of any deviations from the requirements set out in Articles 6, 7 and 8, or whether the novel technology applies a recycling scheme – Art 10(3)(b)

A full assessment of the compliance of the novel technology with Articles 6, 7 and 8 can be found in Annex III.

The technology does not apply a recycling scheme.

4. Reasoning and scientific evidence demonstrating that the technology can produce safe recycled plastics – Art 10(3)(c)

The pre-processing, decontamination and post-processing processes of recycling processes applying this novel technology are described in detail in section 2(b). It 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% (Annex II).

In addition, the analysis conducted on the purified BHET (HPLC, GC, Colorimetry, XRF or ICP-MS or ICP-AES, and Karl Fischer Titration) confirm a high level of purity.

4(a). Challenge study

4(a)(1). Introduction

In addition to the above, the decontamination efficiency of a recycling process using this novel technology has been assessed by Welle (2021) using a challenge study. In this study, post-consumer PET flakes were artificially contaminated with the surrogates chloroform, toluene, chlorobenzene, phenyl cyclohexane, methyl salicylate, benzophenone and methyl stearate. The decontamination process used in the study consisted of a depolymerization of the contaminated post-consumer PET flakes using glycolysis, followed by filtration to remove unreacted residues, active carbon adsorption and crystallization. The conditions of the decontamination processes used by the recyclers that apply this novel technology are at least as severe as the conditions used in the study of Welle (2021).

4(a)(2). Decontamination efficiency

The concentration of surrogates was analysed in the contaminated post-consumer PET flakes as well as the BHET obtained after the decontamination process. Since the concentrations of the surrogates in the obtained BHET were below the analytical detection limits, no absolute decontamination efficiency of the decontamination process (glycolysis followed by decontamination and purification) can be calculated but the study demonstrates that the cleaning efficiencies are at least > 99.94% for all surrogate contaminants (Table 1). The decontamination efficiencies obtained in the challenge study are much higher than decontamination efficiencies typically obtained with mechanical recycling processes (examples EFSA, 2012; EFSA, 2023), indicating that processes operating under this novel technology can handle much higher contaminant levels in the input material than the contaminant levels in post-consumer food contact PET waste, conservatively set by EFSA (2011) at 3 mg/kg PET and used as restriction for mechanical PET recycling processes that waste with a maximum fraction of non-food PET of 5%.

4(a)(3). Application of EFSA criteria and establishment safe limits

Using the decontamination efficiencies of the challenge study, the maximum contaminant levels in the input material that a decontamination process using this novel technology is able to reduce to a concentration that does not give rise to concern for a risk to human health can be calculated applying the same principles as EFSA uses in its opinion for the safety evaluation of a mechanical PET recycling process (EFSA, 2011). EFSA calculated, for each surrogate, the maximum concentration in recycled PET that would lead to a dietary exposure in infants not exceeding 0.0025 µg/kg bw/day[16] (Cmod) (EFSA, 2011; Appendix III,C). The maximum contaminant levels in the input material that a decontamination process using this novel technology can handle were calculated using this Cmod and the decontamination efficiencies established in the challenge study (Table 1).

The results indicate that, for the non-volatile surrogate contaminants, this technology is able to handle contaminant levels in the input material of minimum 1300 mg/kg. 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 (Table 1) 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. Using the data for the non-volatile surrogates, it can therefore be demonstrated that this novel technology is capable of removing at least 400 times higher levels of contaminants than mechanical PET recycling processes are required to do (EFSA, 2011) and therefore, can handle more heavily contaminated waste streams than mechanical recycling of PET can do.

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

Table 1. Surrogates and their characteristic, cleaning efficiency of the decontamination process and maximum concentration of contaminants in the input material that the decontamination process can eliminate ensuring a migration below 0.1 µg/kg food.

Surrogate	Molecular Weight (g/mol)	Boiling Point (°C)	Functional Group	Physical Properties	Obtained cleaning efficiency decontamination process[a]	Cmod[b] (mg/kg PET)	Conservative contaminant levels in input that the decontamination process can handle (mg/kg input)
Toluene	92.1	110.6	aromatic hydrocarbon	volatile, non-polar	>99.94%	0.09	150
Chlorobenzene	112.6	132.4	halogenated aromatic hydrocarbon	volatile, medium-polar, aggressive to PET	>99.99%	0.09	900
Chloroform	119.4	61.2	halogenated hydrocarbon	volatile, polar, aggressive towards PET	>99.98%	0.10	500
Methyl salicylate	152.2	223.3	aromatic ester	non-volatile, polar	>99.99%	0.13	1300
Phenyl cyclohexane	160.3	240	aromatic hydrocarbon	non-volatile, non-polar	>99.99%	0.14	1400
Benzophenone	182.2	305.4	aromatic ketone	non-volatile, polar	>99.99%	0.16	1600
Methyl stearate	298.5	351.9	aliphatic ester	non-volatile, polar	>99.99%	0.32	3200

[a] Cleaning efficiencies obtained by Welle (2021).

[b] Cmod: Modelled concentration in PET correlating with the migration criteria (0.1 µg/kg in food for infant exposure scenario). Conservative estimation (based on generally recognized migration modelling) of the concentration of a substance (surrogate or other contaminant) in PET which would cause a migration of 0.1 µg/kg in food after 365 days contact at 25°C.

4(b). Capacity to handle waste that deviates from the requirements in Article 6 of Regulation (EU) 2022/1616

In point 2(a) the different waste streams that will be recycled by this novel technology are described. As indicated in that section, some of these waste streams deviate from the requirements set in Article 6 of Regulation (EU) 2022/1616 for mechanical recycling processes as:

1. not all waste originates from food-contact applications, and
2. not all waste originates from plastic materials and articles manufactured in accordance with Regulation (EU) No 10/2011.

The following sections provide the scientific justification for such deviations from the requirements in Article 6 of Regulation (EU) 2022/1616.

4(b)(1). Capacity to handle waste from non-food contact applications

Post-consumer and post-industrial PET packaging waste from food and non-food contact applications

As indicated in point 2(a)(1), post-consumer and post-industrial PET packaging waste from food and non-food contact applications, used by the recycling processes operating this novel technology, also contains waste from non-food contact applications. Franz and Welle (2020) demonstrated that it is expected that waste originating from non-food contact applications contains contaminants 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 levels are lower than the contaminant levels that this novel technology can handle, as calculated based on the data of the challenge study (see point 4(a)). This indicates that this novel technology is capable of handling post-consumer and post-industrial PET packaging waste from food and non-food contact applications, even if the non-food contact fraction would be 100%, and that the BHET output from this waste stream can be used for the manufacture of recycled plastic materials and articles that comply with Article 3 of Regulation (EC) No 1935/2004. This is confirmed by the analysis and risk assessment of non-intentionally added substances (NIAS) in the BHET obtained from this waste stream (see below point 4(c)).

Post-consumer and post-industrial textile waste

Post-consumer and post-industrial textile waste typically contains higher levels of contaminants than post-consumer and post-industrial PET packaging waste due to the potential treatment of textile polyester fibres with dyes and additives (BfR, 2012; Undas *et al*., 2023). Even though it can be assumed that the novel technology is capable of handling such wastes –due to the fact that contaminants present in textile are released in the reaction medium allowing their efficient removal with scientifically proven robust separation technologies–, this cannot be proven with the existing standard challenge tests, such as the one conducted by Welle (2021). This is due to the design of such challenge study and the limitations of the detection limits of the analytical methods which do not allow to demonstrate that the decontamination efficiency of the novel technology is higher than 99.94%.

However, data from laboratory trials indicate that BHET obtained from textile waste streams with this novel technology is of similar purity as BHET obtained from post-consumer and post-industrial PET packaging waste and complies with the specifications set in Annex II. This is also confirmed

through NIAS analysis (see point 4(c)). However, prior to the placing on the market for use in food contact applications of BHET from this waste stream, the stability of the process will be confirmed through further testing as part of the monitoring program, required by Article 13 of Regulation (EU) 2022/1616.

Post-consumer or post-industrial PET film

Since waste batches of post-consumer and post-industrial PET film are collected from individual industrial sites, the composition of these waste films is known and well characterized. Based on this composition information, it can be assumed that the novel technology is capable of handling such wastes. However, prior to the placing on the market for use in food contact applications of BHET from this waste stream, further trials and analyses will be conducted, to have this confirmed. This includes an analysis and risk assessment of NIAS, analysis of primary aromatic amines and inorganic compounds in order to confirm compliance with plastics Regulation (EU) No 10/2011.

4(b)(2). Capacity to produce PET compliant with Plastics Regulation (EU) No 10/2011 from waste not compliant with this regulation

The obtained BHET output is an 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 2011 with identification number FCM227 and FCM785, respectively. Since the purity of the obtained BHET output is 99.9% and the presence of non-PET substances in the PET produced from BHET output is below 0.1 mg/kg and demonstrated to be of no safety concern (see point 4(c)), it is demonstrated that the recycled plastic materials and articles comply with the requirements set out in Chapters II, III and V of Regulation (EU) No 10/2011, even if the BHET output is obtained from waste that does not comply with the compositional requirements of plastics Regulation (EU) No 10/2011.

4(c). Compliance confirmation through analysis

4(c)(1). Post-consumer and post-industrial PET packaging waste from food and non-food contact applications

NIAS analysis

Results of GC- and HPLC-analyses of NIAS in BHET produced from post-consumer and post-industrial PET packaging waste from food and non-food contact applications (see point 2(a)(1)) using this novel technology and of PET produced with this BHET confirm the results obtained with and conclusions drawn from the challenge study (see point 4(b)(i)). Concentrations of volatile substances in the BHET output were below 17 mg/kg (total) with EG (used as reaction solvent in the glycolysis reaction and monomer for the production of PET; FCM 227 with SML=30 mg/kg) being the most abundant substance with a concentration up to 11 mg/kg. All other volatile substances were found in concentrations lower than 1 mg/kg. For semi-volatile and non-volatile substances, higher concentrations were found in the BHET output samples with a total concentration of up to 6400 mg/kg. The main substances were identified as alkyl esters of terephthalic acid which are typical BHET co-products that are formed during of the glycolysis reaction (see Figure 4). Such substances are typically also generated as intermediates during the standard virgin PET production process starting from TPA and EG. Also cyclic oligomers have been detected like C[TPA+EG]$_2$ (CAS 24388-68-9),

C[TPA+EG]+[TPA+DEG] (CAS 29278-57-7) and C[TPA+DEG] (18189-01-0). Apart from the cyclic oligomer TPA_2-EG-DEG, none of the substances that were detected in the BHET output, were present in the PET polymer made with this BHET output in concentrations higher than 0.1 mg/kg. This indicates that they were repolymerised during the post-processing process. The cyclic oligomer C[TPA+EG]+[TPA+DEG] (MW 428.39 g/mol) was found in the BHET and PET sample in concentrations of 14.2 mg/kg and 9 mg/kg, respectively. The PET sample also contained other cyclic oligomers which typically are also found in virgin PET (Ubeda *et al*., 2018; Brenz *et al*., 2020). Literature data show that levels for the C[TPA+EG]+[TPA+DEG]detected in PET containers range from 2.5 to 281 mg/kg (Schreier *et al*., 2023).

In silico genotoxicity assessment shows no genotoxicity alert for linear or cyclic PET oligomers or possible products of hydrolysis or metabolism (Tsochatzis *et al*., 2020). Linear PET oligomers are assigned to Cramer class I while cyclic PET oligomers are assigned to Cramer class III (Tsochatzis *et al*., 2020). Applying the Threshold of Toxicological Concern (TTC) concept, a maximum exposure of 1.5 µg/kg bw/day and 30 µg/kg bw/day is considered to be of no health concern for Cramer class III and Cramer class I substances, respectively (EFSA, 2019). In the infants' scenario (food consumption of 150 g/kg bw/day (EFSA, 2016)), this can be translated into a maximum migration limit of 10 µg/kg food and 200 µg/kg food for Cramer class III and Cramer class I substances, respectively.
Schreier *et al*. (2023) modelled the maximum concentration of oligomer substances that can be present in a PET bottle and tray wall without exceeding the migration threshold for genotoxic substance of 0.15 µg/kg food (adult scenario). The modelling included applications such as storage at ambient or elevated temperatures (25°C or 40°C, respectively) for beverage bottles and short-term and long-term heating applications (70°C or 100°C) for microwaveable and ovenable trays. All calculations were performed using a worst case partition coefficient ($K_{P/F}$) of 1 and diffusion coefficients (D_p) for oligomers predicted using an activation energy-based (EA-based) model which is a realistic model as well as with the generally recognised worst case A_p model that is also used by EFSA for the evaluation of mechanical recycling processes (EFSA, 2011) and which is recognised to overestimate migration by at least 5 times. For a migration threshold of 0.15µg/kg food, which is below the migration threshold for PET oligomers in the infant's scenario, the max concentration of the smallest oligomers in a bottle or tray wall was calculated to be 0.1 mg/kg using the worst case A_p migration model and 0.5 mg/kg using the realistic EA-based model. As indicated above, apart from the cyclic oligomer C[TPA+EG]+[TPA+DEG], none of the oligomers present in the BHET output were detected in concentrations above 0.1 mg/kg in the produced PET. For the cyclic oligomer C[TPA+EG]+[TPA+DEG], the realistic model indicates that it would not migrate in concentrations above the migration threshold of the infant's scenario. As such, it can be concluded that the PET oligomers, detected in the BHET output are not a safety concern.

Compliance with Regulation (EU) No 10/2011

In addition, compliance with Annex II of plastics Regulation (EU) No 10/2011 is confirmed through analysis of primary aromatic amines and inorganic compounds. No primary aromatic amines have been detected above the limit of detection which ranged from 0.22 to 5.3 µg/kg BHET and data from the analysis of inorganic substances confirm compliance with their limits in plastic and/or the specific migration limits in food.

Absence of substances of concern

No bisphenol A (BPA), adipates or phthalates have been detected in BHET output above their limit of detection which was 1µg/kg for BPA, between 10.4 and 43.3 µg/kg for adipates and between 9.6 and 25 µg/kg for phthalates.

4(c)(2). Post-consumer and post-industrial textile waste

NIAS analysis

A GC- and HPLC-analysis of NIAS in BHET produced from post-consumer and post-industrial textile waste using this novel technology demonstrates that the substances detected are almost identical as the substances detected in the BHET produced from post-consumer and post-industrial PET packaging waste (see above). Concentrations of volatile substances in the BHET output were below 16 mg/kg (total) with EG (used as reaction solvent in the glycolysis reaction and monomer for the production of PET; FCM 227 with SML=30 mg/kg) being the most abundant substance with a concentration up to 10 mg/kg. All other volatile substances were found in concentrations lower than 1 mg/kg. For semi-volatile and non-volatile substances, higher concentrations were found in the BHET output samples with a total concentration of up to 7000 mg/kg. The main substances were identified as alkyl esters of terephthalic acid which are typical BHET co-products that are formed during the glycolysis reaction (see Figure 4). None of these NIAS have been detected in concentrations above 0.1 mg/kg in PET samples produced from this BHET indicating that they were repolymerised during the post-processing process. The risk analysis as performed for the NIAS detected in the BHET obtained from post-consumer and post-industrial PET packaging waste (see above) is valid for the NIAS detected in the BHET obtained from post-consumer and post-industrial textile waste.

However, prior to the placing on the market for use in food contact applications of BHET from this waste stream, this analysis will be completed by analyses on primary aromatic amines and inorganic compounds in order to confirm compliance with the requirements of Annex II of plastics regulation (EU) No 10/2011. In addition, additional analytical testing of halogens will need to confirm absence of fluorinated and brominated substances that might be present as additives in textile.

4(d). Microbiological safety

In the medical, pharmaceutical and food and beverage industry, sterilization is used to inactivate biological contaminants like viruses, bacteria and bacterial spores, yeast and molds and their spores. There are different sterilization processes amongst which sterilization by heat. Sterilization by heat deactivates microorganisms through the coagulation of cellular proteins. Typical sterilization times and temperatures for dry sterilization are 180°C for 30 min, 170°C for 1h or 160°C for 3h. For sterilization with wet heat, times and temperatures typically range from and 121°C for 30 min to 135°C for 10 min at 2 bar (Jildeh *et al*., 2021).

The glycolysis process that is used in this novel technology is carried out at a temperature of minimum 195°C and for minimum 1 hour. In addition, during post-processing the output BHET is repolymerized at temperatures above 245°C for several hours. Such conditions are more stringent than the typical conditions for sterilization as reported by Jildeh *et al*. (2021). Therefore, it can be concluded that this novel technology can manufacture recycled plastic materials and articles that are microbiologically safe.

5. Description of one or more typical recycling processes using the technology – Art 10(3)(d)

5(a). Pre-processing

Post-consumer PET packaging waste from food and non-food contact applications is pre-processed using operations similar to those applied for the pre-processing of waste used for the mechanical recycling of PET. A block diagram of the typical main pre-processing stages can be found in Figure 5.

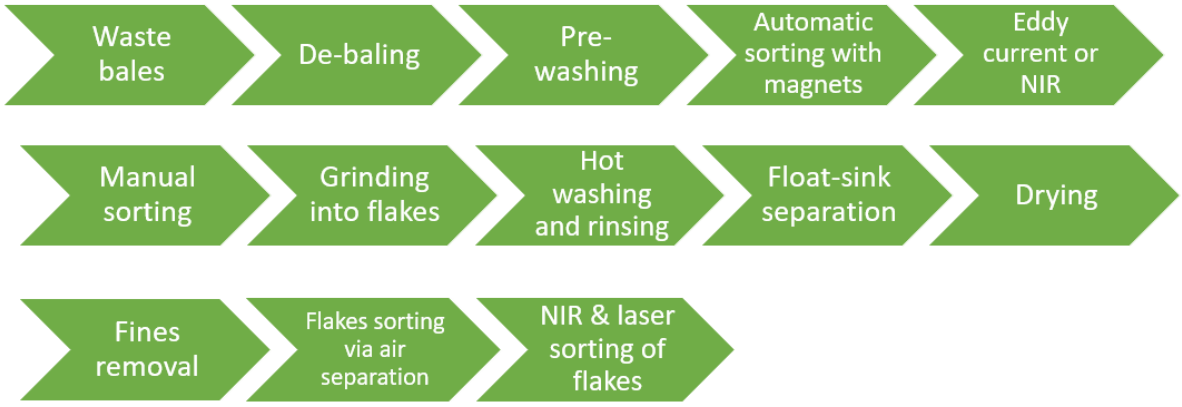


Figure 5. Typical pre-processing steps for post-consumer PET packaging waste from food and non-food contact applications.

5(b). Decontamination process – PET depolymerization to BHET and purification via crystallization

A typical decontamination process with description of the different steps is shown in the block diagram in Figure 6. However, several variations are possible as indicated in point 1(b).

The specifics of the individual recycling processes that apply this novel technology cannot be provided in this dossier as this is considered confidential information between the participants in the consortium that acts as developer. However, more information can be obtained from the Consortium members provided confidential treatment of the information can be guaranteed.

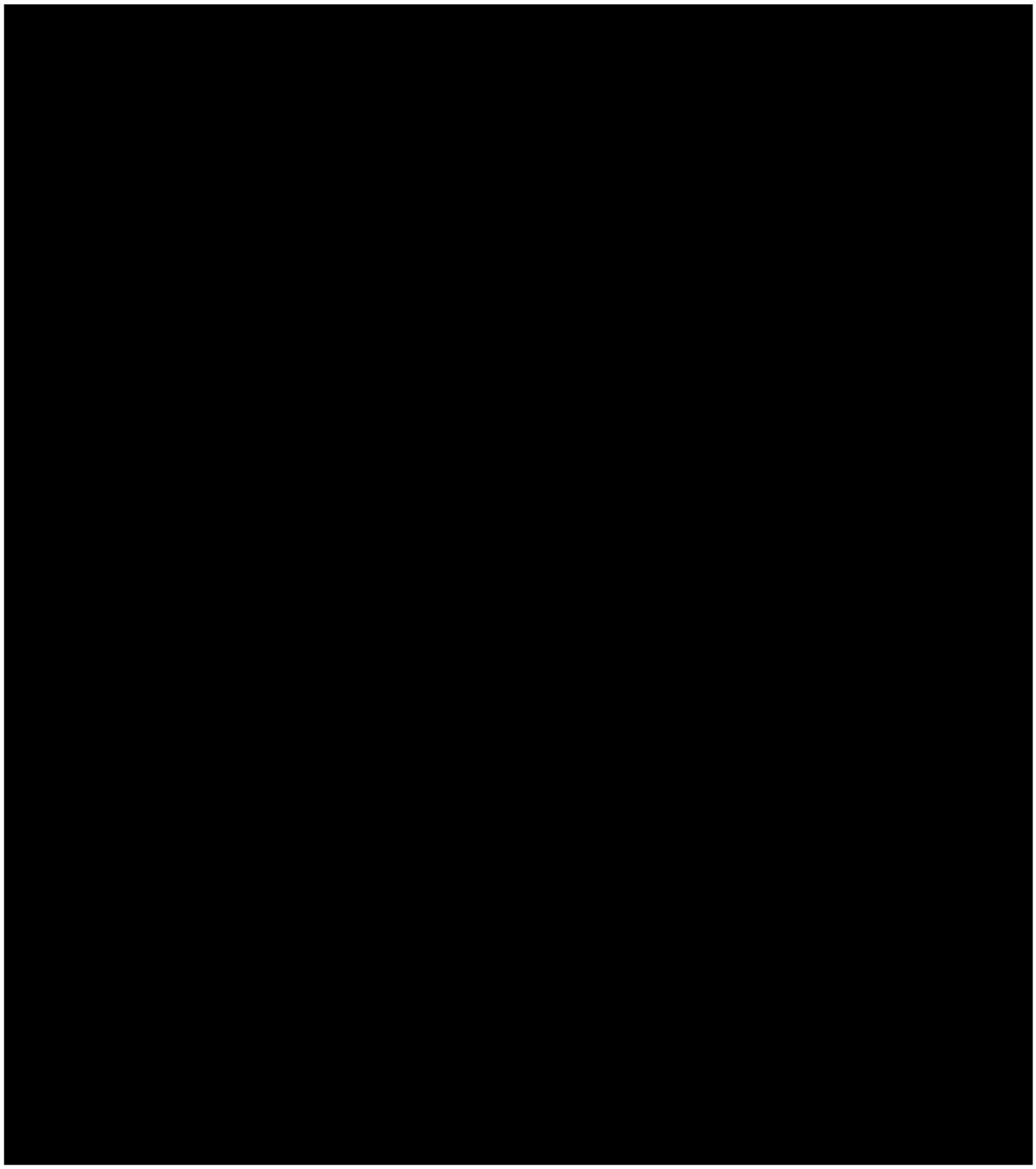


Figure 6. Typical decontamination process block diagram.

5(c). Post-processing

The BHET output is introduced into the polymerization at the esterification and/or prepolycondensation stages, where large BHET concentrations naturally form during polymerization starting from TPA or MEG (Figure 7). The reaction temperatures at those stages is typically [redacted] under high vacuum. The remainder of the process is identical to typical PET polycondensation, which uses temperatures between [redacted] and vacuum to remove ethylene glycol to drive the reaction towards a long chain length, typically DP 100 or IV 0.8 dL/g. Since the polyester chains are continuously transesterifying in the melt and the polycondensation steps take several hours, the resulting PET

obtains the same statistical chain length distribution with a polydispersity of 2 for PET from TPA and EG as for BHET.

The BHET can be introduced in concentrations up to 100%.

Figure 7. PET polymerization process with introduction of BHET in the esterification reactor and/or pre-polycondensation stage.

6. An explanation describing why the technology is to be considered different from existing technologies and is to be considered novel – Art 10(3)(e)

This novel technology differs from the post-consumer mechanical PET recycling technology, listed as suitable recycling technology in Annex I of Regulation (EU) 2022/1616, since it uses a chemical reaction to intentionally break the PET into small starting molecules. This recycling technology does not retain the polymeric chains that constitute the plastic but rather converts the polymer in its starting building blocks which are discrete substances that can be easily solubilized, crystallized and distilled and therefore purified though well established and recognized processes commonly used in the chemical industry.

7. EFSA criteria for potential future evaluation of recycling processes that apply the novel technology – Art 10(3)(f)

This novel technology applies depolymerisation to break down the polymer matrix of waste PET. As a result, the contaminants and additives that are present in the polymer matrix from prior usage of the material are released into the reaction medium; they are no longer physically bound or difficult to access. This facilitates their removal by traditional and well recognized purification techniques 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% (Annex II) and can easily be analysed by highly sensitive analytical methods.

Therefore there is in principle no need for a separate authorization of individual recycling processes that apply this technology provided the final product BHET is produced within the established specifications (Annex II) and it can be fully characterized/this can be confirmed by the defined and validated analytical methods in Annex IV.

8. Estimate of the expected number of decontamination installations – Art 10(3)(f)

The expected decontamination installations that will be operated to develop the novel technology and the foreseen addresses of the recycling facilities where they will be located can be found in Table 2.

Table 2. Decontamination installations operated to develop the novel technology.

	Axens/IFPEN	**Garbo**	**Ioniqa**	**SK Chemicals**
Name of the developer	PETCORE EUROPE			
Address	Avenue de Broqueville 12, 1150 Brussels, BELGIUM			
Contact Person	raphael.jaumotte@petcore-europe.org			
Name of the novel technology	Glycolysis based Polyester depolymerization			
URL	https://www.petdepolymerisationrecycling.com/			
Individual companies represented	Axens 89, Boulevard Franklin Roosevelt 92500 RUEIL-MALMAISON France	ChemPET S.r.l. Via Prati Nuovi, 9 28065 Cerano (Novara) Italy	Circular PET Plastic Upcycling B.V. Merseyweg 10 3197 KG, Rotterdam The Netherlands	Shuye – SK Chemicals (Shantou) Co., Ltd. 10th Floor of Finance Building ,YiMing Road of Chenghai District, Shantou City, Guangdong Province, China
Foreseen locations	Toray Film Europe Pl. d'Arménie 01700 Saint-Maurice-de-Beynost France	ChemPET S.r.l. Via Prati Nuovi, 9 28065 Cerano (Novara) Italy	Circular PET Plastic Upcycling B.V. Urmonderbaan 22 6167 RD, Geleen The Netherlands	Shuye – SK Chemicals (Shantou) Co., Ltd. Jinhu Circular Economy Zone, No.3, Sijiang Road, Yanhong, Chenghai, Shantou City, Guangdong Province, China

Annex I – Plastic input material specifications.

1. PET waste from packaging: Post-consumer and post-industrial PET packaging waste from food and non-food contact applications

Property	Value
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

2. Post-consumer and post-industrial polyester textile

Property	Value
[redacted]	[redacted]
[redacted]	[redacted]

3. Post-consumer or post-industrial PET film

Property	Value
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Annex II – BHET output specification

Purity dry BHET (%):

BHET: ≥ 85%

BHET + Co-products: ≥ 99.9%

With following co-products:

Compound	CAS#	Specification
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Specifications:

Component/Property	Specification range	Units
[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

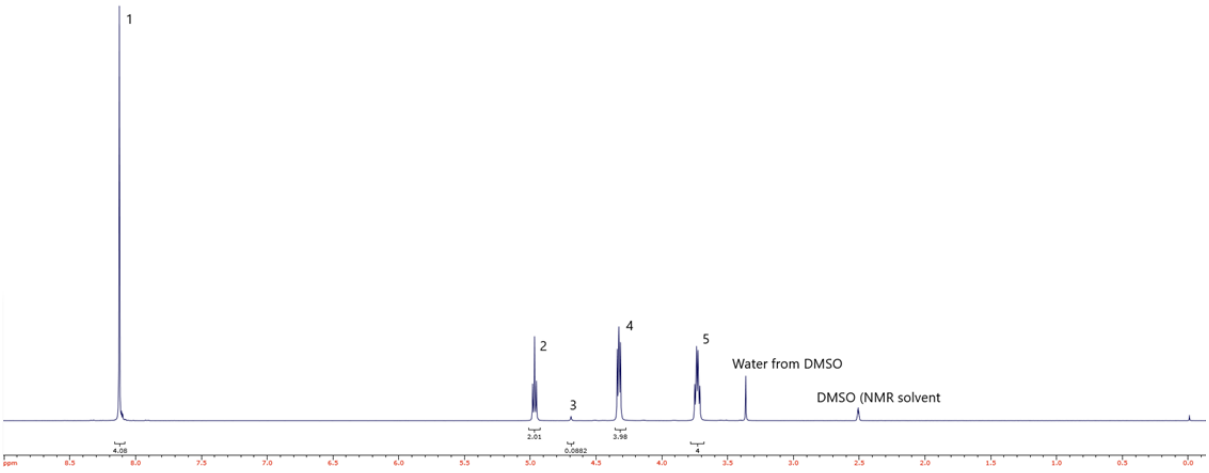
Annex III – Assessment of compliance of the novel technology with the requirements of article 6, 7 and 8 of regulation (EU) 2022/1616

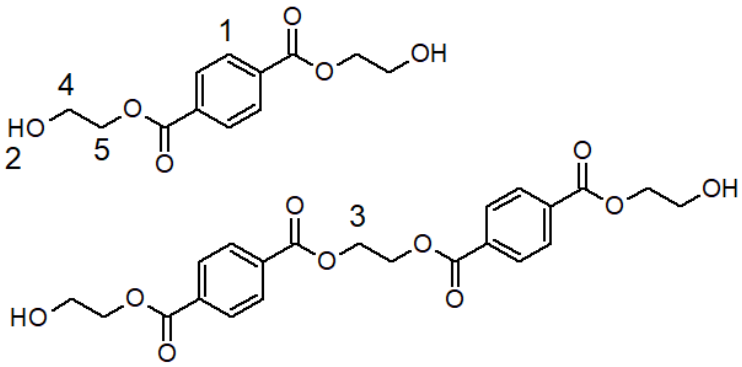
Requirements	Compliance
Article 6 **- Requirements for collection and pre-processing**	
1. Waste management operators that participate in the supply chain of plastic input shall ensure that the collected plastic waste meets the following requirements:	
(a) the plastic waste originates only from municipal waste, or from food retail or other food businesses if it was only intended and used for contact with food, including waste discarded from a recycling scheme in accordance with Article 9(6);	For some waste streams: YES. For other waste streams: NO – see point 2(a).
(b) the plastic waste originates only from plastic materials and articles manufactured in accordance with Regulation (EU) No 10/2011 or recycled plastic materials and articles manufactured in accordance with this Regulation;	For some waste streams: YES. For other waste streams: NO – see point 2(a).
(c) the plastic waste is subject to separate collection;	For most waste streams: YES but it is dependent on the waste collection infrastructure in the Member States which are evolving over time – see point 2(a).
(d) the presence of plastic materials and articles that are different from the plastic for which the decontamination process is intended, including caps, labels and adhesives, other materials and substances, and remaining food is reduced to a level specified in the requirements for the plastic input provided by the recycler and which shall not compromise the achieved level of decontamination.	YES
2. For the purposes of paragraph 1, point (c), the plastic waste shall be considered as collected separately when one of the following conditions is fulfilled:	
(a) it consists only of plastic materials and articles meeting the requirements of paragraph 1, points (a) and (b), and which have been collected separately for recycling from any other waste;	For some waste streams: YES. For other waste streams: NO – see point 2(a).

Requirements	Compliance
(b) it is collected together with other packaging waste fractions of municipal waste or with other non-packaging plastic, metal, paper or glass fractions of municipal waste collected separately from residual waste for recycling, and the following requirements are met:	
(i) the collection system collects only non-hazardous waste;	YES
(ii) the collection of waste and the subsequent sorting are designed and carried out to minimise contamination of collected plastic waste from any plastic waste not meeting the requirements of paragraph 1, points (a) and (b), or other waste;	For some waste streams: YES. For other waste streams: NO – see point 2(a).
3. The plastic waste shall be controlled throughout collection and pre-processing by means of quality assurance systems. The quality assurance systems shall:	
(a) ensure the conditions and requirements set out in paragraph 1 and 2 are met;	Not all waste streams comply with the requirements of paragraph (1)and (2) – see above and point 2(a)
(b) ensure traceability of each batch up to the point of the first sorting of collected plastic waste; and,	YES
(c) be certified by an independent third party.	By 10 October 2024
Articles 4, 5, 6 and 7 of Commission Regulation (EC) No 2023/2006 as well as point B of the Annex to that Regulation shall apply *mutatis mutandis* as regards good manufacturing practice, quality control and assurance systems and the relevant documentation.	
Article 7 **- Requirements for decontamination**	
1. The plastic input and the output of the applied decontamination process shall meet the specifications set out in column 3, 5, and 6 of table 1 of Annex I for the relevant recycling technology and, if applicable, the specific criteria set out in the authorization.	Not applicable
2. The decontamination process shall be carried out in accordance with the relevant specifications and requirements laid out in column 8 of table 1 of Annex I and, if applicable, the specific criteria set out in the authorization. Recyclers shall ensure compliance with Regulation (EC) No 2023/2006.	Not applicable except for compliance with Regulation (EC) No 2023/2006: YES

Requirements	Compliance
3. The decontamination installation shall meet the following requirements:	
(a) it is located at a single recycling facility, which is organised so as to ensure that no new contamination of recycled plastic or recycled plastic materials and articles can occur;	YES
(b) its configuration and operation corresponds to that of the recycling process it applies;	YES
(c) it is operated as described in the compliance monitoring summary sheet established in accordance with Article 26.	YES
4. A repository of records used to record information on the quality of individual batches as defined in section 4.1 of the compliance monitoring summary sheet referred to in paragraph 3(c) shall be maintained. Records stored in that repository shall be retained for a period of at least 5 years.	YES
Article 8 **- Post-processing and use of recycled plastic materials and articles**	
1. Converters shall comply with the following requirements:	The novel technology dossier does not include the converter process.
(a) post-process recycled plastic in accordance with the instructions provided by the recycler or the supplying converter in accordance with Article 5(3);	
(b) where relevant, provide to subsequent converters instructions in accordance with Article 5, paragraphs (3), (4) and (5); and,	
(c) where relevant, provide instructions to the users of the recycled plastic materials and articles in accordance with Article 5(6).	
2. Food business operators shall use recycled plastic materials and articles in accordance with the instructions received in accordance with Article 5(6).	The novel technology dossier does not include the process of the food business operator.
They shall communicate relevant instructions to consumers of food packed in such materials and articles, and/or to other food business operators, where relevant.	
3. Retailers of recycled plastic materials and articles not yet in contact with food shall communicate relevant instructions to the users of such materials and articles where such instructions are not apparent from labelling already applied to those materials and articles.	Not applicable

Annex IV – ^{1}H NMR spectrum of output BHET





ABBREVIATIONS

BHEI	bis(2-hydroxyethyl)isophthalate
BHEET	2-hydroxyethyl[2-(2-hydroxyethoxy-)ethyl]terephthalate
BHET	bis(2-hydroxyethyl)terephthalate
DEG	diethylene glycol
D_p	diffusion coefficient
DRS	deposit and return systems
EG	ethylene glycol
EPR	extended producer responsibility
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
$K_{P/F}$	partition coefficient
MHET	mono(2-hydroxyethyl)terephthalate
NIAS	non-intentionally added substances
NIR	near infrared
PE	polyethylene
PET	polyethylene terephthalate
PP	polypropylene
PVC	polyvinyl chloride
TPA	terephthalic acid
TTC	Threshold of Toxicological Concern
XRF	X-ray fluorescence spectroscopy

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