PET Flake Injection

Novel Technology Development

Data Monitoring Report

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

10 October 2025

To be completed on receipt of the delayed analysis report

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Introduction

The novel technology '*PET Flake Injection*' was notified as required under Articles 10(2) and 10(3) of Commission Regulation (EU) 2022/1616 on 17th March 2023.

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

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

On 10 October 2023, 10 April 2024 and 10 October 2024, a first, second and third report discussing the monitoring data and the information as required by Article 13(5) have been published. The enclosed report is based on the latest information from all installations using the novel technology received in accordance with Article 13(3) for the fourth monitoring period and provides the information required by Article 13(5) of the Regulation.

The different subsections (a) to (j) of Article 13(5) are discussed separately.

a) Brief description of the novel technology – Art 13(5)(a)

The Flake Injection process has the capability to combine depolymerised recycled Polyethylene Terephthalate (rPET) with virgin material at different stages of a conventional PET production process for subsequent food contact use.

The input material of the Flake Injection process is previously processed PET as detailed in Table 2 of ANNEX I of COMMISSION REGULATION (EU) 2022/1616 that is deliberately depolymerized (pre-processed) before it enters the high surface area decontamination polymerisation reactor. Referring to the flow scheme Appendix I: Flake Injection – PET Production Process; previously processed PET may be introduced directly to injection point 1. or partially depolymerised with ethylene glycol, in either a stir-tank reactor or an extruder, to a defined degree of polymerisation to correspond with that of the polymer in the PET production process at the injection points labelled 2 to 6 in the flow scheme *or any points in-between*. This initial depolymerisation process of the previously processed PET allows for filtration of the intermediate polymer to remove solid contaminants before the introduction of the recycled material into a PET production process at a blend rate of up to 100% recycled content. The high surface area decontamination polymerisation technology increases the Intrinsic Viscosity (IV) of the PET polymer and removes polymerisation by-products under high vacuum of less than 20mbar, with a high temperature greater than 260^{o}C and with a residence time greater than 30 minutes. This high surface area polymerisation technology also serves as a Decontamination Technology to efficiently remove vapourised contaminants that may have been introduced into the process further upstream by the addition of previously processed PET. Following the high surface area polymerisation and decontamination, the polymer melt is filtered for either direct use, or granulation, in the manufacture of food contact materials or articles or for introduction into a Solid State Polycondensation (SSP) process or a Conditioning Silo should further processing be needed to meet the material parameters required for its end use.

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

All references in this section are references to documents available in the dossier submitted in accordance to Articles 10(2) and 10(3) of Commission Regulation (EU) 2022/1616 on 17th March 2023.

Flake To Resin (FTR)

Ref. ANNEX II Table 1 (1) Decontamination efficiencies of the Novel Technology have been determined by Welle (2008).

Table VI. Concentrations (determined using the HFIP extraction method) of the surrogates in the investigated PET samples of Trial 2 (cocktail A at 10 ml min^{-1}, 50% PCR flakes).

	Concentration (ppm)						
	Toluene	Chloroform	Chlorobenzene	Phenyl cyclohexane	Methyl salicylate	Benzophenone	Lindane
Calculated contamination concentration	3295	5194	1255	327	1004	885	775
Before deep-cleansing	1999 ± 28	3075 ± 47	655 ± 9	163 ± 2	<1.0	345 ± 1	133 ± 1
After deep-cleansing (final product)	<2.7	<0.8	<0.9	<0.2	<1.0	<0.2	<0.8

The study concludes that the cleaning efficiencies for the applied surrogates are above or far above 99.9%. The high cleaning efficiencies are due to the high diffusion rates of compounds in the molten PET.

Based on EFSA's criteria for safety evaluation of PET recycling processes - if a recycling process is able to reduce an input reference contamination of 3 mg/kg PET to a Cres (Residual Concentration) not higher than a Cmod (Modelled Concentration) corresponding to the relevant migration criterion, the potential dietary exposure cannot be higher than 0.0025 µg/kg bw/day and recycled PET manufactured with such recycling process is not considered of safety concern.

Ref. ANNEX II Table 1 (2) *Fraunhofer_Dossier-FTR_20061109.pdf*

Reversed Approach

Based on Safety Evaluation of Polyethylene Terephthalate Chemical Re-cycling Processes. Frank Welle. 'Reversed Approach'.

Ref. ANNEX II Table 1 (3) *Chemical_recycling_submitted.pdf*

FTR: Calculated maximum concentration (Reference Contamination – the level of contamination that the process can remove, i.e. Cmod:Cres =1) corresponding to a migration of 0.1 µg/l after storage for 365 d at 25 °C (EU cube, AP = 3.1, tau 1577 K, bottle wall thickness 200 µm, density of PET 1.4 g/cm^3). Decontamination Efficiency of 99.9%.

mm Hg (25°C)	oC	g.mol^{-1}	**FTR**	**Reference Contamination**	**Decontamination Efficiency**	***Cres***	***Cmod***	
Vapour Pressure	**BP**	**Mw**	**Surrogate**	**mg/kg**	**%**	**mg/kg**	**mg/kg**	**Cmod:Cres**
28.4	110.6	92.1	Toluene	**90**	99.9%	0.09	0.09	1.0
197	61.1	119.4	Chloroform	**100**	99.9%	0.10	0.10	1.0
12	131.7	112.6	Chlorobenzene	**90**	99.9%	0.09	0.09	1.0
0.0343	222.9	152.2	Methyl Salicylate	**130**	99.9%	0.13	0.13	1.0
0.04	240.1	160.3	Phenyl Cyclohexane	**140**	99.9%	0.14	0.14	1.0
0.00193	305.4	182.2	Benzophenone	**160**	99.9%	0.16	0.16	1.0
9.40E-06	311.0	290.8	Lindane	**310**	99.9%	0.31	0.31	1.0

Artenius.

EFSA-Q-2011-00969 - EFSA refused to evaluate as out of the scope of Regulation (EC) 282/2008.

Ref. ANNEX II Table 1 (7) EFSA Letter Related to Artenius Unique Process.pdf

Ref. ANNEX II Table 1 (8) Fraunhofer Institute. Challenge Test.pdf

US FDA Guidance

Use of Recycled Plastics in Food Packaging (Chemistry Considerations): Guidance for Industry.

U.S. Department of Health and Human Services Food and Drug Administration Center for Food Safety and Applied Nutrition July 2021

VIII. Elimination of Data Recommendations for 3° Recycling Processes for PET and PEN

Based on a comprehensive review of all surrogate testing data submitted over the past decade for 3° recycling processes for PET and polyethylene naphthalate (PEN), FDA concludes that 3° recycling of PET or PEN by methanolysis or glycolysis results in the production of monomers or oligomers that are readily purified to produce a finished polymer that is suitable for food-contact use. Both 3° processes will clean the polyester sufficiently to allow it to be considered of suitable purity, even assuming 100% migration of residual surrogate to food. This is a significant difference from the surrogate testing of 2° recycling processes. Secondary recycling processes often produce PET that is insufficiently cleaned to withstand 100% migration calculations for the residual surrogates. Under these circumstances, FDA recommends additional migration tests to demonstrate that the finished PET meets the 1.5 µg/person/day EDI limit.

Based on a determination that 3° recycling processes produce PET or PEN of suitable purity for food contact use, FDA no longer recommends that such recyclers submit data for agency evaluation. Because 3° processes for polymers other than PET and PEN were not the subject of FDA reviews, recyclers who wish to engage in 3° recycling of polymers other than PET and PEN are encouraged to submit data for evaluation.

Ref. ANNEX II Table 1 (9) Recycled-Plastics-Food-Packaging-Chemistry-ConsiderationsGuidance-04112022-1321.pdf

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

As developer of the Novel Technology, PET EUROPE has coordinated with the recyclers regarding the selection of the sampling strategy, the analysis to be performed and the selection of a third-party laboratory. The choice of the laboratory was based on its experience and expertise in analysing PET samples, the relevance 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 particularity of this specific technology.

Analysis for the detection and quantification of substances in polymer represents a major challenge, especially when they are present at very low levels i.e. ppb levels. Although significant advances are regularly reported in the literature, reliable quantification of these substances to the ppb level and without compromising the integrity of the polymer is rarely feasible and certainly not standardized even for the most qualified laboratories. What is presented in this report has been obtained with the state-of-the-art analytical equipment (Table 6) that allows the detection of minute concentrations of various organic substances present in the input and output materials. The list of substances with a molecular weight below 1000 Dalton detected in the plastic input and its recycled output is given in Appendix II. The substances were sorted in descending order by their relative occurrence in the plastic input. The analytical methods do not distinguish between incidental contaminants and PET reaction products such as PET oligomers. In this report, incidental contaminants were identified by comparing the analytical data of the input samples with virgin PET samples analyzed under the same conditions and by the same analytical methods.

Table 1 lists the 20 most frequently detected and identified incidental contaminants in the input material using the different analytical methods specified in section h.

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 average concentration of the incidental contaminants was calculated by taking into account only those samples in which it was detected. If the incidental contaminant was detected but below the quantification limit, the concentration used to calculate the average concentration was the limit of quantification. If the incidental contaminant was not detected in the output (frequency of 0%), the limit of detection is reported in the Table.

In several samples 2-butenal was detected as it was also the case during the previous monitoring cycles. However, the laboratory did further research which indicated that 2-butenal is formed during the analysis in the GC-MS by the condensation reaction of acetaldehyde. Therefore, the results of 2-butenal were not reported in this report and should also be removed in the previous reports.

This novel technology allows the input material to be introduced into the decontamination process at variable ratios of input material/virgin material. Therefore, the input material is sometimes diluted during the process with virgin material. The concentrations provided in Table 1 are the concentrations of incidental contaminants prior to any possible dilution. However, the dilution with virgin material is taken into account for the evaluation of the decontamination efficiency (section i).

Table 1: List of the first 20 detected incidental contaminants in the input material, their frequency of detection and average amounts in input and output samples.

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For the inorganic analysis, a summary of the obtained analytical results is given in Table 2.

Table 2. Summary of the analytical results for inorganic elements.

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The levels of antimony are low compared to what is expected for PET. The laboratory assumes that this is due to the fact that the samples, after dissolution as part of the sample preparation, have been stored longer than usual before being measured. As a result, Sb-glycolate might have slightly precipitated. The high average level of cobalt in the output material is due to the intentional addition of a cobalt-containing substance during the production of the output material by one of the members of the consortium.

None of the analysed primary aromatic amines (Table 7) were detected in the input or output samples. In addition, no BPA, BPF or BPS was detected in the samples with targeted analysis.

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

Table 3 lists the contaminating materials regularly present in the PET plastic input.

Table 3. Contaminating materials regularly present in the PET plastic input.

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

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

An estimation of the migration levels was made based on the average levels of incidental contaminants in the output samples in which they were detected (Table 1) and assuming a worst case total migration to food using the average weight of 27.2g PET for a one litre PET bottle (Table 4). Since EFSA (2024) acknowledges that generally recognised diffusion migration models overestimate migration by a factor of 5 for substances ≤ 150 Da and by a factor 10 for substances > 150 Da, this worst case total migration also overestimates migration by at least these factors.

Table 4. Worst case migration of incidental contaminants present in the output samples.

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*considering 1L beverage filled in a PET bottle of 27.2g

The worst case estimation of the migration levels of the inorganic substances is shown in Table 5.

Table 5. Worst case migration of incidental contaminants present in the output samples.

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*considering 1L beverage filled in a PET bottle of 27.2g

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

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h) Description of the analytical procedures and methods used - Art 13(5)(h)

Samples of PET input batches and their corresponding output batches were labelled for traceability purposes and shipped in clear and hermetically sealed containers.

The sample preparation methods and analytical procedures and methods used for the analysis of the samples as well as their limits of detection and quantification are summarised in Table 6. In all cases, 3 independent replicates were analysed.

Table 6. Applied analytical procedures and methods including their limits of detection and quantification.

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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; TXRF: Total Reflexion XR FLuorescence; HFIP: 1,1,1,3,3,3-hexafluoroisopropanol
LOD: limit of detection; LOQ: limit of quantification

Table 7. List of primary aromatic amines analysed.

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

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Table 8. Classification of the incidental contaminants

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*considering 1L beverage filled in a PET bottle of 27.2g

Table 9. Results of the safety evaluation of the incidental contaminants

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Decontamination efficiency

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

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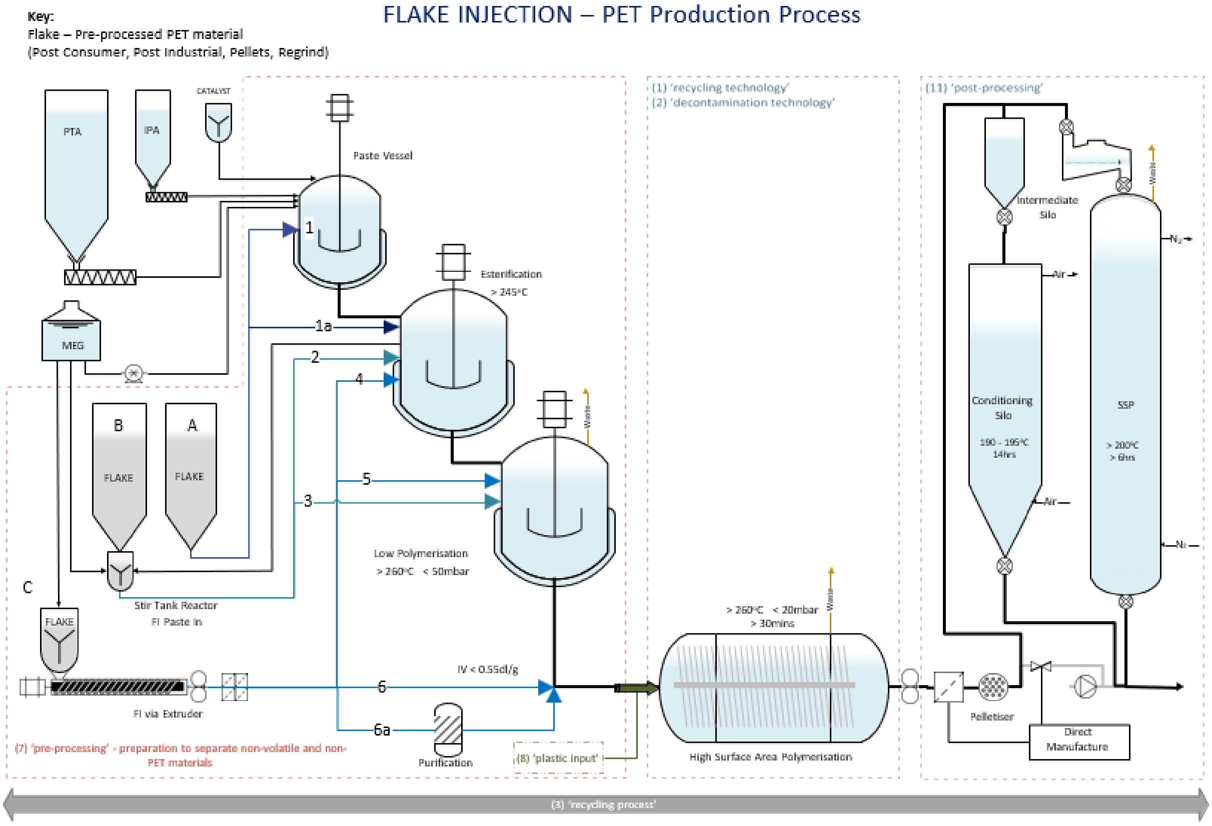
Appendix I –.FLAKE INJECTION – PET Production Process



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

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Glossary of Terms

Cmod	Modelled concentration
DEG	diethylene glycol
EG	ethylene glycol
GC	gas chromatography
HPLC	high performance liquid chromatography
ICP-MS	Inductively Coupled Plasma Mass Spectrometry
MS	Mass Spectrometry
NIAS	non-intentionally added substances
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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