PET Flake Injection

Novel Technology Development

Initial information report required by Article 10(3) of Regulation (EU) 1616/2022 to be included along with a Novel Technology Development notification.

Article 10 - Requirements for the development of a novel technology

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Developer

PET EUROPE – Producers' Association.

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Novel Technology Summary – Flake Injection

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 and is deliberately depolymerized (pre-processed) before it enters into the high surface area decontamination polymerisation reactor.

Referring to the flow scheme ANNEX 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°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.

Recycling Facilities/Technologies

Company	**Address**
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JBF BAHRAIN W.L.	Building : 461, Road : 1508, Block : 115 ,P O Box : 50397, B I I P, Salman Industrial City, Al Hidd, Kingdom of Bahrain
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Equipolymers GmbH	Equipolymers GmbH, Werk Schkopau, Building K80, 06258 Schkopau, DE
DuPont Teijin Films Luxembourg S.A.	P.O. Box 1681, L-1016 Luxembourg.
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CuRe Technology BV	Eerste Bokslootweg 17, 7821 AT Emmen, NL
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Article 10.3

Article 10.3(a) - Characterisation of the novel technology based on the properties of recycling technologies set out in Article 3(2)

Article 3.2(a) Input Material (Type, Collection, Origin)

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.

The flakes may be sourced from recycling facilities where the feedstock of post-consumer PET packaging has been manufactured from food grade PET material in compliance with Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food or the global regional equivalent.

Product Description:	Recycled PET flakes produced by mechanical recycling of pre-processed PET

Article 3.2(b) Decontamination (Physical, Chemical, Principles, Practices)

Stir-Tank Reactor or Extruder:

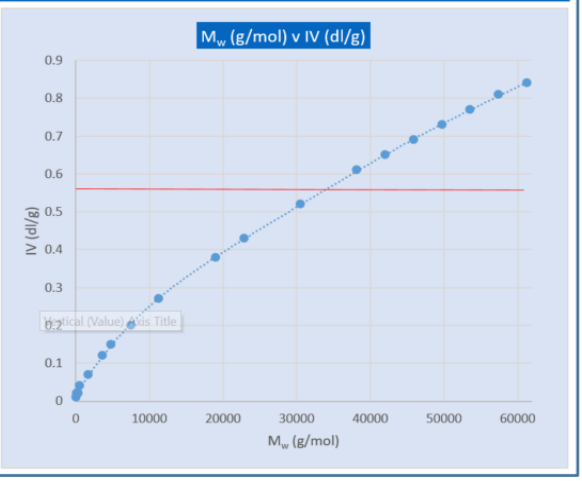
Previously processed PET undergoes pre-processing such as sorting, grinding, washing, and/or compacting, filtration and pelletisation before it may be introduced directly to injection point 1. or partially depolymerised with ethylene glycol, in either a stir-tank reactor or an extruder, to a defined 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 (ANNEX I) or any points in-between.

This initial depolymerisation pre-processing 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.

Degree of polymerisation, as measured by molecular weight, is based on Intrinsic Viscosity (IV) range necessary for fabrication of intended downstream articles. It is known in the PET industry that some limited articles must be processed with PET at an IV of 0.57dl/g, but most applications require a much higher IV, hence 0.55dl/g was selected to be below this known useful limit.

PET Molecular Weight and Intrinsic Viscosity

DP (average)	M_n (g/mol)	M_w (g/mol)	IV (dl/g)	Conversion	*
0.32	62	62	0.01	0%	(MEG)
0.86	166	166	0.02	0%	(PTA)
1	192	192	0.02	0%	(PET r.u.)
1.32	254	316	0.02	24%	(BHET)
2	384	576	0.04	50%	
5	960	1728	0.07	80%	
10	1920	3648	0.12	90%	
13	2500	4800	0.15	92.32%	
20	3840	7488	0.2	95.00%	
30	5760	11328	0.27	96.67%	
50	9600	19008	0.38	98.00%	
60	11520	22848	0.43	98.33%	
80	15360	30528	0.52	98.75%	
100	19200	38208	0.61	99.00%	
110	21120	42048	0.65	99.09%	
120	23040	45888	0.69	99.17%	
130	24960	49728	0.73	99.23%	
140	26880	53568	0.77	99.29%	
150	28800	57408	0.81	99.33%	
160	30720	61248	0.84	99.38%	



High Surface Area Polymerisation:

Despite the injection point of the previously processed PET polymer into the PET production process, all homogenised recyclate and virgin material (plastic input) must pass through a High Surface Area Polymerisation reactor.

This high surface area polymerisation technology serves as a decontamination technology by removing volatile contaminants that may have been introduced into the process further upstream by the addition of previously processed PET, and also volatile polymerisation by-products, under a high vacuum of less than 20mbar, with a temperature greater than 260°C and with a residence time greater than 30 minutes.

The high surface area polymerisation technology increases the Intrinsic Viscosity (IV) of the PET polymer to a useful level required to manufacture finished products or articles.

Article 3.2(c) rPET Materials & Articles (Type, Use)

The recycled PET obtained from this process is intended to be used at up to 100% for the manufacture of materials and articles for contact with all types of foodstuffs for long-term storage at room temperature, with or without hotfill and includes PET suitable to be used in microwave and conventional ovens.

Article 3.2(d) Evaluation & Authorisation (need/absence)

Due to the high diffusion rates of compounds in molten PET in the high surface area polymerisation technology, which is the critical stage of this recycling technology, the plastic input is decontaminated to a level which does not pose a risk to human health. The conditions that the plastic input is subjected to are more severe than parameters established for Mechanical Recycling processes which are deemed Suitable Technologies. These processes have been evaluated by the EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP), and positive scientific opinions have been adopted.

Extensive work has been carried out which clearly demonstrates the PET produced from Flake Injection technologies, which have been operating safely in full compliance with Regulation (EU) 10/2011 in the European Union for more than 12 years, is comparable to virgin PET in terms of Non-Intentionally Added Substances (NIAS), and the safety of the PET articles produced, has been demonstrated through migration testing and modelling throughout this period.

Refer also to Article 10.3(c) - Extensive reasoning and scientific evidence and studies – meets requirements of Article 3 of Regulation (EC) No 1935/2004.

Note also that following the high surface area polymerisation and decontamination, the polymer melt is filtered for subsequent use 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.

Article 10.3(b) - Deviations from Articles 6, 7 and 8

Article 6 - Requirements for collection and pre-processing

> *1.(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;*

The global regional equivalent of Regulation (EU) No 10/2011 may apply for internationally sourced material. Note: EFSA have issued positive opinions for recycling processes located in many countries outside of the European Union.

Article 7 - Requirements for decontamination

1. *The plastic input and 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 authorisation.*
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 authorisation. Recyclers shall ensure compliance with Regulation (EC) No 2023/2006.*

Once Novel Technology – Flake Injection - has been deemed Suitable Technology then the specifications and requirements will be added as a new row referencing this technology, in Table 1 of Annex I of COMMISSION REGULATION (EU) 2022/1616, will be met.

Article 8 - Post-processing and use of recycled plastic materials and articles

Following the high surface area polymerisation and decontamination, the polymer melt is filtered for subsequent use 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.

Article 10.3(c) - Extensive reasoning and scientific evidence and studies – meets requirements of Article 3 of Regulation (EC) No 1935/2004

Flake To Resin (FTR)

Ref. ANNEX II Table 1 (1) *Decontamination efficiency of a new post-consumer poly(ethylene terephthalate) (PET) recycling concept*. FRANK WELLE. Fraunhofer Institute for Process Engineering and Packaging (IVV), Giggenhauser Straße 35, 85354 Freising, Germany.

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 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)	°C	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-Considerations-Guidance-04112022-1321.pdf*

Article 10.3(d) - Description of typical recycling processes using the technology, including a block diagram *(Simplified Flow Scheme)* of the main manufacturing stages.

Previously processed PET undergoes pre-processing such as sorting, grinding, washing, and/or compacting, filtration and pelletisation before it may be introduced directly to injection point 1.

Post-consumer previously processed PET is partially depolymerised with ethylene glycol, in either a stir-tank reactor (Plastic Input B) or an extruder (Plastic Input C), to a defined degree of polymerisation (IV Range).

The degree of polymerisation is controlled to correspond with that of the virgin pre-polymer in the PET production process at the injection points labelled 2 to 6 in the flow scheme. The depolymerisation process of the post-consumer rPET allows for filtration of the polymer to remove solid contaminants before the introduction of the recycled material into the PET production process.

Pre-processed PET Input A – Direct to Paste Vessel

Pre-processed PET Input B – Stir-Tank Reactor.
Injection points:

2.) Esterification Vessels
3.) Low Polymerisation Vessels

Pre-processed PET Input C – Extruder.
Injection points:

4.) Esterification Vessels
5.) Low Polymerisation Vessels
6.) Before High Surface Area Polymerisation Reactor

Typically such processes are anticipated to run at 50% recycled content or less, but a blend rate of up to 100% recycled content is possible for processes with an injection point 6a capability.

Despite the injection point of the rPET pre-polymer into the PET production process, all homogenised recyclate and virgin material (plastic input) must pass through a High Surface Area Polymerisation reactor.

The high surface area 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°C and with a residence time greater than 30 minutes.

This high surface area polymerisation technology serves as the Decontamination Technology to efficiently remove any contaminants that may have been introduced into the process further upstream by the addition of recycled post-consumer flakes.

Due to the high diffusion rates of compounds in molten PET in the high surface area polymerisation technology, which is the critical stage of this recycling technology, the plastic input is decontaminated to a level which does not pose a risk to human health. The conditions that the plastic input is subjected to are more severe than parameters established for Mechanical Recycling processes which are deemed Suitable Technologies. These processes have been evaluated by the EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP), and positive scientific opinions have been adopted.

Note also that following the high surface area polymerisation and decontamination, the polymer melt is filtered for subsequent use 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.

Solid State Polycondensation (SSP)

Before being transferred to the SSP, the decontaminated pellets are first crystallised at high temperature in e.g. a fluid bed crystalliser. These crystallised pellets are then continuously introduced into the solid state polycondensation reactor at a predefined temperature and for a predefined residence time to ensure that the final PET IV and product specification has been established.

Conditioning Silo

Similar to the SSP process but operated at a lower temperature to ensure that the final PET IV and product specification has been established.

Article 10.3(e) - Why the technology is considered NOVEL

Article 3(6) - Any recycling technology that has not been subject to a decision on its suitability in accordance with Article 15 or 16 shall be regarded as a novel technology for the purpose of this Regulation.

> *Article 15 - Decision on the suitability of a novel technology.*
> *Article 16 - Safeguard clause concerning the placing on the market of recycled plastic materials and articles manufactured with a novel or suitable recycling technology.*

Article 10.3(f) - Evaluation criteria

Referring to section: 'Reversed Approach', based on the level of contamination acceptable, determined from the decontamination efficiency of High Surface Area Polymerisation technology of

greater than 99.9% for all surrogates, testing of the Plastic Input material should not be critical but the input material will be analysed per the below proposed schedule.

NIAS testing has already been carried on typical flake samples.

A risk assessment in accordance with Article 19 of the Plastics Regulation (Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food) will be performed on the Intermediate Material produced.

Novel Technology Monitoring

There shall be at least four stages (unless there is no difference between entry and input or output and exit):

- Entry stage (the first QA stage where the material enters the facility) - Flake analysis.
- Input stage (where the plastic input enters the decontamination process) - Plastic Input (6) no analysis required.
- Output stage (where the material leaves the decontamination process) - Can be sampled and analysed after the Post Processing Stage.
- Exit stage (where the recycled plastic or the recycled plastic materials and articles leave the facility) - Analysis before sale.

Typical VOCs such as Benzene to be analysed every Output/Exit Batch using appropriate techniques.

Considering the high temperatures used during the decontamination process, the possibility of contamination by microorganisms can be discounted. The recycling process also provides for microbiological decontamination by high temperature during post-processing.

Article 10.3(g) - Recycling Facilities

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Indorama Ventures Corlu PET	Karamehmet Mahallesi Avrupa Serbest Bölgesi 3. Sokak No:2 Ergene/Tekirdağ/Türkiye
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Octal SAOC	FZC, Raysut Area, P.O.B. 383, PC 217, Salalah, Sultanate of Oman
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Polyplex Europa Polyester Film Sanayi Ve Ticaret Anonim Sirketi	Karamehmet Mh. Avrupa Serbest Bolgesi 3. Sokak No: 4, Ergene/Tekirdag, Turkey
SELENIS PORTUGAL, S.A.	Quinta S. Vicente, Estrada Nacional 246, 7300-436 Portalegre, Portugal
POLISAN HELLAS S.A.	2nd Industrial Area of Volos (Building Block 9a), Gr 37500 Volos, Greece

Glossary

IV	Intrinsic Viscosity
Flake	Generic term for previously processed PET (Post Consumer, Post Industrial, Pellets, Regrind)
NIAS	Non-Intentionally Added Substances
SSP	Solid State Polycondensation
rPET	Recycled Polyethylene Terephthalate
VOC	Volatile Organic Compound
Blend Rate	Percentage of recycled, previously processed PET, added to the PET production process

ANNEX I

FLAKE INJECTION – PET Production Process

Key:
Flake – Pre-processed PET material
(Post Consumer, Post Industrial, Pellets, Regrind)