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Subject:	ANNEXES to the COMMISSION REGULATION (EU) .../... on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008

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Delegations will find attached document D79492/04 ANNEXES 1 to 3.

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Encl.: D79492/04 ANNEXES 1 to 3



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ANNEXES 1 to 3

## ANNEXES

to the

**COMMISSION REGULATION (EU) .../...**

**on recycled plastic materials and articles intended to come into contact with foods, and  
repealing Regulation (EC) No 282/2008**

## ANNEX I

### **Suitable Recycling technologies as referred to in Article 3**

Table 1 contains the following information:

- Column 1: number assigned to the recycling technology;
- Column 2: name of the recycling technology;
- Column 3: types of polymer that the recycling technology allow to recycle;
- Column 4: short description of the recycling technology and reference to a detailed description in Table 3;
- Column 5: the type of input that the recycling technology can decontaminate, where
- PCW: ‘post-consumer waste’ means plastic waste collected in accordance with Article 6;
  - FG: ‘food-grade’ means plastic that was as primary material compliant with Regulation (EU) No 10/2011;
  - ‘Non-food PCW’ means packaging that was not used to package food and may not have been manufactured in full compliance with Regulation (EU) No 10/2011 and other post-consumer plastic materials which were not intended for contact with food;
  - ‘Non-food %’ (% w/w) means the maximum amount of non-food PCW present in the input;
- Column 6: the type of output manufactured with the recycling technology;
- Column 7: if ‘yes’ is indicated in column 7, individual recycling processes shall be authorised in accordance with Articles 17 to 19;
- Column 8: reference to table 4 on specifications and requirements applicable to the use of the technology in accordance with Article 4(4)(b), supplementing the requirements in Article 6 to 8;
- Column 9: derogations from Articles 6 to 8 in accordance with Article 4(4)(b), and derogations from Article 9(8);
- Column 10: if ‘yes’ is indicated in column 10, the recycling technology shall only be used as part of a recycling scheme in accordance with Article 9

**Table 1: List of suitable recycling technologies**

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Recycling technology number	Technology name	Polymer type (detailed specification in Table 2)	Short description of the recycling technology (detailed specification in Table 3)	Specification of plastic input	Specification of output	Subject to the authorisation of individual processes	Specifications and requirements (reference to table 4)	Derogations (reference to table 5)	Recycling scheme applies
1	Post-consumer mechanical PET recycling	PET (2.1)	Mechanical recycling (3.1)	Only PET PCW containing maximum 5% of materials and articles that were used in contact with non-food materials or substances.	Decontaminated PET, final materials and articles not to be used in microwave and conventional ovens; additional specifications may apply to output from individual processes	Yes	-	-	No

2	Recycling from product loops which are in a closed and controlled chain	All polymers manufactured as primary materials in compliance with Regulation (EU) No 10/2011	Basic cleaning and microbiological decontamination during remoulding (3.2)	Chemically uncontaminated plastic materials and articles produced from a single polymer or from compatible polymers which were used or intended for use under the same conditions of use and solely obtained from a product loop which is in a closed and controlled chain, and excludes collection from consumers	Remoulded materials and articles intended to be used for the same purpose and under the same conditions of use as the materials and articles circulated in the recycling scheme from which the plastic input was obtained.	No	4.1	-	Yes
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**Table 2: Detailed specification of polymers**

Reference number	Acronym	Resin number and/or Recycling symbol, if any <sup>1</sup>	Detailed specification for the purposes of this Regulation
2.1	PET	1	polyethylene terephthalate polymer made by the polycondensation of the comonomers ethylene glycol and terephthalic acid or dimethyl terephthalate, of which the polymeric backbone contains up to 10% w/w other comonomers listed in table 1 of Annex I to Regulation (EU) 10/2011, such as isophthalic acid and diethyleneglycol

<sup>1</sup>: as defined in Decision 97/129/EC, ASTM D7611 or GB/T 16288-2008

**Table 3: Detailed description of the decontamination technology**

Reference number	Name	Detailed description
3.1	Mechanical recycling	This recycling technology recovers collected plastics via mechanical and physical processes, typically sorting, grinding, washing, separating materials, drying, and re-crystallisation to produce plastic input which retains the chemical identity of the

		<p>collected plastic.</p> <p>The critical stage of this recycling technology is the decontamination during which the plastic input is subjected for at least a minimum time to heat, and a vacuum or flowing gas, in order to remove incidental contamination down to a level that is without health concern. This stage may be followed by further recycling and conversion stages, such as filtration, regranulation, compounding, extrusion and moulding stages.</p> <p>The use of this recycling technology retains the polymeric chains that constitute the plastic, and may increase their molecular weight. A small unintentional decrease in molecular weight may also occur.</p>
3.2	Recycling from product loops which are in a closed and controlled chain	<p>A recycling technology that recycles plastic input only originating from entities participating in closed cycles consisting of manufacturing, distribution or catering stages, and which participate in a recycling scheme in accordance with Article 9.</p> <p>Plastic input originates only from materials and articles that are intended and used for food contact, and any contamination other than surface residues from food and labelling, can be ruled out. The plastic input may contain shredded materials and articles, as well as off-cuts and scraps from the production of plastic materials and articles. The scheme excludes the collection of materials and articles as plastic input if these have been provided to consumers for use outside of the premises and/or control of the entities participating in the recycling scheme.</p> <p>The decontamination technology applied as part of this recycling technology provides for microbiological decontamination by high temperature during remoulding preceded by basic surface cleaning by washing or other means</p>

	<p>suitable for preparing the material for remoulding. In addition it may add new plastic to prevent quality loss of the recycled plastic that would make it unsuitable for the use that it was intended for.</p> <p>The recycled plastic is used only for manufacturing plastic materials and articles for contact with the same foods and under the same conditions as the collected materials and articles were intended for, and for which compliance to Regulation (EU) No 10/2011 was initially verified.</p>
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**Table 4: specifications and requirements applicable to the use of the technology in accordance with Article 4(4)**

Reference number	Specifications / requirements
4.1	<ul style="list-style-type: none"> <li>(a) the technology and its operation shall fully correspond with the description provided in point 3.2 of table 3;</li> <li>(b) where materials are subject to re-use within the distribution chain, without recycling operations, they shall be cleaned regularly and sufficiently to prevent the build-up of residues originating from food, usage and labelling;</li> <li>(c) the use, re-use, cleaning in accordance with point (b), and recycling shall be implemented in a way designed to prevent incidental contamination of the plastic input that cannot be removed with surface cleaning;</li> <li>(d) the use of any labelling or printing on the plastic materials and articles which cannot be fully removed with the cleaning applied before remoulding shall be excluded;</li> </ul>

	<p>(e) the document provided in accordance with article 9(3) shall provide explicit instructions and procedures to food business operators participating in the recycling scheme to prevent the introduction of external material and incidental contamination;</p> <p>(f) the plastic input and the recycled plastic shall at all times fully comply with Regulation (EU) No 10/2011; accumulation of constituents of the plastic material, present due to repeated recycling, such as residues of additives, or degeneration products, shall be considered non-intentionally added substances in accordance with Article 6(4)(a) of Regulation (EU) No 10/2011. Their presence shall not exceed a level that is regarded as unsafe in a risk assessment in accordance with article 19 of that Regulation. Where needed to ensure the quality of the recycled plastic materials and articles, new plastic manufactured in accordance with that Regulation shall be added;</p> <p>(g) there is documented scientific evidence demonstrating that the plastic materials and articles recycled as part of the scheme do not pose a risk to human health due to:</p> <ul style="list-style-type: none"> <li>– accumulation of constituents of the plastic material, such as residues of additives, or degeneration products resulting from repeated recycling; or</li> <li>– the presence of common residues from other sources such as food, detergents and labelling</li> </ul>
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**Table 5: derogations applicable to the use of the technology in accordance with Article 4(5)**

Reference number	Specifications / requirements

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## ANNEX II

### **Template for the Compliance Monitoring Summary Sheet in accordance with Article 26 of Regulation (EU) .../...**

The template shall be completed taking account of the definitions set out in Regulation (EC) No 2023/2006 on good manufacturing practices, and Annex B thereof.

Abbreviations used in this document in accordance with Regulation (EC) No 2023/2006:

QA: Quality Assessment  
SOP: Standard Operating Procedure  
SOP code: a SOP code is comprised of two numbers, the number of the SOP and the number of the document in which it is described in the format SOPNr – DocNr; the document number shall correspond to the document number listed in section 2.3, the SOP number to the numbering system of the recycler.

#### **1. SECTION 1: IDENTIFICATION**

The numbers (RIN, RFN, RON, RAN, NTN) referred to in this section shall correspond to the numbers in the Union Register laid down in accordance with Article 24 of Regulation (EU) .../...

##### **1.1 Identification of the recycling installation**

<b>Installation name</b>	
<b>Applied recycling technology in accordance with Annex I</b>	
<b>EU Register number (recycling installation number, 'RIN')</b>	
<b>Facility Address</b>	
<b>Recycling Facility Number ('RFN')</b>	
<b>Contact details</b>	
<b>Position/Role of contact persons</b>	
<b>Relevant national register numbers, if any</b>	
<b>Notification date (Article 25(1)(a))</b>	

##### **1.2 Identification of the recycler**

<b>Company Name</b>	
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<b>EU Register number (Recycler Operator Number, 'RON')</b>	
<b>Address of the head office</b>	
<b>Contact details</b>	
<b>Position/Role of main contact person</b>	
<b>Relevant national register numbers, if any</b>	
<b>Authorisation holder? (Yes/No/ Not applicable)</b>	

**1.3. Recycling process authorisation Decision or novel technology**

A: identification of the authorisation Decision or novel technology used by the process that the installation applies:

<b>EU Register number, i.e. Recycling Process Authorisation Number ('RAN'), Novel Technology Number ('NTN')</b>	
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B: authorisation holder or novel technology developer –

<b>Name of authorisation holder* / of the technology developer** as applicable</b>	
<b>Address</b>	
<b>Contact details</b>	
<b>Position/Role</b>	

\* the name of the authorisation holder and its address must be the same as on the authorisation Decision

\*\*The technology developer that notified the novel technology used by the process which the installation applies, in accordance with Article 10(2)

**1.4. Document references used by the European Food Safety Authority ('EFSA')**

<b>EFSA Question number</b>	
<b>EFSA Publication date of the opinion</b>	
<b>EFSA Publication number (output number)</b>	
<b>Confidentiality Decision number</b>	
<b>Confidentiality Decision date</b>	

**1.5. Additional responsible person(s) for the operation of the recycling installation**

<b>Name</b>	<b>Position/Role</b>	<b>contact details</b>
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**2. Section 2: Operation of the recycling installation**

**2.1. Written Statements**

A maximum of 3000 characters including spaces shall apply both to sections 2.1.1 and 2.1.2

*2.1.1 Recyclers’ statement explaining the production and quality of the recycled plastic*

*2.1.2. Recycler’s statement explaining correspondence to the authorised process*

This section is applicable only to authorised processes.

**2.2 Recycling operations at the recycling facility**

The following information shall be provided in this section:

- A diagram of the main manufacturing stages that are part of the recycling process and which are carried out at the recycling facility (‘site diagram’);
- A table describing those manufacturing stages and the material streams connecting them carried out at the recycling facility and corresponding to that diagram.

*2.2.1. Diagram of the main manufacturing stages carried out at the recycling facility (site diagram)*

*2.2.2. Description of the main manufacturing stages carried out at the recycling facility and the streams connecting them*

Stage Number	Name	Description	Average Processed Tonnage per year
Stream Number	Name	Description	Average Stream size

**2.3. Internal Documents**

Provide a comprehensive list of documents relevant to the operation of the process and quality management and other administrative procedures related thereto, as well as documents related to the authorisation. The documents shall be numbered and these numbers shall be used in section 3 to refer to these documents. The recycler may apply its own numbering system.

Document type	Document Number	Related production stage	Title	Description	Date, version, author

## 2.4. Batch definitions

The following batches shall be defined in accordance with the table below:

- **Entry Batch:** the unprocessed plastic entering the recycling facility from suppliers;
- **Input Batch:** input plastic processed at the facility entered at the decontamination stage;
- **Output Batch:** the recycled plastic resulting from the decontamination stage; and,
- **Exit Batch:** the recycled plastic (or recycled plastic materials and articles) leaving the facility for further processing or use.
- Any other intermediate batches corresponding to a QA check.

Where either the entry or input batch is the same because no further QA checks take place, only the input batch shall be defined. The same approach shall be used for the output and exit batches. Where there are different types of entry and or exit batches, these shall be defined separately, and be given a meaningful name.

The QA shall be numbered in the same way as in the site diagram (section 2.2.1)

Batch type	Internal Batch name	Stream/QA No.	Definition/Description	Typical size range	Traceability rule

## 2.5. Process diagram of the decontamination installation

Add a piping and instrumentation diagram in accordance with section 4.4 of ISO 10628-1:2014, taking account of ISO 10628-2.

## 2.6. Control of critical decontamination operations

The table below shall include a reference to steps, stages, or operations that EFSA identified as critical, a control criterion for each critical parameter, the involved control instruments, and the description of corrective actions in case the control criterion fails. Further information of the evaluation of complex control rules shall be added if relevant.

Critical operation (and ref to EFSA opinion)	Control criterion	Measuring or Control Instrument (reference to 2.5)	Short description of corrective actions if control rule is not met	SOP code (SOPNr – DocNr)

2.6.1. *Further information on complex control rules, where relevant*

## 2.7. Relevant standard operating procedure for Operation

The table below shall provide a reference to each SOP used for the operation of the installation, provide a short description thereof, and indicate the location where it is carried out.

SOP code	Short description	Location)

### 3. Section 3: Quality Assessment

#### 3.1. List of quality assessment stages

Each QA stage shall be described using the table below:

QA stage and number	Assessment name	Definition/Description	Criterion	Records	SOP Code (SOPNr – DocNr)

There shall be at least four stages (unless there is no difference between entry and input or output and exit – see section 2.4):

- entry stage (the first QA stage where the material enters the facility),
- input stage (where the plastic input enters the decontamination process)
- output stage (where the material leaves the decontamination process)
- exit stage (where the recycled plastic or the recycled plastic materials and articles leave the facility)

Additional intermediate stages shall be added where relevant for the quality of the material in other stages. Those intermediate stages shall be given a meaningful name.

#### 3.2. Relevant standard operating procedures applied at QA stages

The table below shall provide a reference to each standard operating procedure used at QA stages, provide a short description thereof, and indicate the location where it is carried out.

Quality Assessment (QA) No (ref 3.1)	SOP code (SOPNr – DocNr)	Short description	Location (of QA)

### 4. Section 4: Record repository

#### 4.1 Quality assessment recording systems

Quality Assessment No (ref 3.1)	Name	Definition/Description	Location	Backup	SOP Code (SOPNr)	Modification prevention

					– DocNr)	

**4.2. List of standard operating procedures codes for recording system**

Quality Assessment No (ref 3.1)	SOP code (SOPNr – DocNr)	Short description	Location (of entry into recording system)

**4.3. Other relevant records/systems**

Procedure	Description / Documentation

## ANNEX III

### Templates for declaration of compliance

#### Part A: Declaration of compliance to be used by recyclers

RECYCLERS DECLARATION of COMPLIANCE with REGULATION (EU) 2022/XXX					
<p>I, the undersigned, declare in name of [ADD NAME OF RECYCLER] as identified in section 1.1, that the recycled plastic material identified in section 1.2 was produced in accordance with <i>[Regulation (EU) .../...PO please add reference to this Regulation]</i>. The recycled material to which this declaration applies is suitable for use in contact with food, provided it is used in accordance with the restrictions set out section 3 of this declaration, and with the instructions in this declaration and with the labelling on the product.</p> <p>Hereby I declare that the contents of this declaration is correct to the best of my knowledge and in compliance with <i>[Regulation (EU) .../...PO please add reference to this Regulation]</i>.</p>					
Section 1: Identification					
1.1 Recycler		1.2 Recycled product		1.3 Competent authority	
1.1.1 Name		1.2.1 Tradename / designation		1.3.1 Name	
1.1.2 FCM-RON*		1.2.2 Batch No.		1.3.2 Address	
1.1.3 Country		1.2.3 FCM-RIN*		1.3.3 Country/ region	
1.1.4 FCM-RFN*		1.2.4 Other information		1.3.4 assigned Registration Number	
Section 2: Compliance					
2.1 Basis for authorisation or permission to operate (tick one box only)					
2.1.1	<input type="checkbox"/>	Authorisation Decision	RAN*		
2.1.2	<input type="checkbox"/>	Recycling scheme	RSN*		
2.1.3	<input type="checkbox"/>	No authorisation or recycling scheme required			
2.1.4	<input type="checkbox"/>	Novel technology	NTN*		
<p>2.2 Results of compliance assessment as listed in the compulsory quality assessment stages in table 3.1 of Annex II; compulsory only if 2.1.1 ticked</p> <p>Important: Fields 2.2.2 to 2.2.4 may be left blank, provided field 2.2.5 is ticked</p>					
Stage**	Decision criteria and outcome(s)			Batch Number(s)	
2.2.1 Exit					
2.2.2 Entry					
2.2.3 Input					
2.2.4 Output					
2.2.5 The undersigned confirms that the information required in fields 2.2.2 to 2.2.4 will be made available to competent authority upon its request, within 3 working days				<input type="checkbox"/>	

Section 3: Instructions and information to users of the product			
3.1	Instructions to converters		
3.1.1	Maximum recycled content (w/w%)	%	
3.1.2	Present recycled content (w/w%)	%	
3.1.3	Restrictions of use***		
3.1.4	Other instructions		
3.2	Instructions to users further down the supply chain, including end users		
3.2.1	Restrictions of use***		
3.2.2	Summary of labelling		
3.2.3	Other instructions		
Section 4: Signature			
4.1	Signature and company stamp		
4.2	Name of person signing		
4.3	Role/position of person signing		
4.4	Date and place		

\* RAN – recycling authorisation number; RON – recycling operator number (recyclers); RIN – recycling installation number; RSN – recycling scheme number; NTN – novel technology number; RFN – Recycling facility number.

\*\* Filling out the fields for the exit stage (the batch that is placed on the market and which is accompanied by this declaration) is compulsory. The completion of the other fields is voluntary, but in case this information is not provided by means of this declaration, it shall be made available to a competent authority, upon its request, within three working days.

\*\*\* Restrictions of use shall correspond to any applicable conditions in the field of application of the recycled plastic, in accordance with Annex I for the applied technology, Article 7, 8, or 9, the Authorisation of the recycling process, if any, or any other restriction the recycler deems necessary.

**Part B: Declaration of compliance to be used by converters if the converted plastic material contains recycled plastic**

CONVERTERS DECLARATION of COMPLIANCE with REGULATION (EU) 2022/XXXX					
<p>I, the undersigned, declare in name of [ADD NAME OF CONVERTER] as identified in section 1.1, that the recycled plastic material identified in section 1.2 was produced in accordance with [Regulation (EU) .../... PO please add reference to this Regulation]. The recycled material to which this declaration applies is suitable for use in contact with food, provided it is used in accordance with the restrictions set out section 3 of this declaration, and with the instructions in this declaration and with the labelling on the product.</p> <p>Hereby I declare that the contents of this declaration is correct to the best of my knowledge and in compliance with [Regulation (EU) .../...PO please add reference to this Regulation]</p>					
Section 1 Identification					
1.1 Converter		1.2 Product with recycled plastic		1.3 Competent authority	
1.1.1 Name		1.2.1 Tradename / designation		1.3.1 Name	
1.1.2 Address		1.2.2 Batch No.		1.3.2 Address	
1.1.3 Country		1.2.4 Other info		1.3.3 Country/ region	
				1.3.4 Reg. number	
Section 2: Compliance					
2.1					
2.1.1	Origin of recycled plastic; RIN numbers				
2.1.2	Batch numbers recycled plastic from decontamination installation				
2.1.3	Maximum recycled content indicated by recycler (Part A, 3.1.1)				% w/w
2.1.4	Actual recycled content of this product				% w/w
2.1.5	Restrictions provided in the Declaration of compliance received from the recycler are met				<input type="checkbox"/>
2.1.6	Addition of additives or starting substances	<input type="checkbox"/> Added additives or starting substances comply with Regulation (EU) No 10/2011		<input type="checkbox"/> No additions	
Section 3: Instructions and information to users of the product					
3.2	Instructions to users further down the supply chain, including end users				
3.2.1	The product identified in section 1.2 is a: (tick as applicable; both may apply)	(A) a recycled plastic for further conversion stages			<input type="checkbox"/>
		(B) a final plastic material or article suitable for contact with food without further processing.			<input type="checkbox"/>
3.2.2	Type or types of food with which it is intended to be put in contact				
3.2.3	Time and temperature of treatment and storage in contact with the food				
3.2.4	The highest food contact surface area to volume ratio for which compliance has been verified				

3.2.5	List of added substances with migration limits; add rows as required. (note: FCM Number and specific migration limit ('SML') may not exist for certain substances)	FCM No.*	Other designation (CAS No., chemical name)	SML* (mg/kg food)
3.2.6	Other relevant information and instructions, including in accordance with points 7 and 9 of Annex IV of Commission Regulation (EU) No 10/2011 <sup>1</sup>			
3.2.7	The recycled plastic to which this declaration applies is contained in a layer in a multi-layer material or article subject respectively to Articles 13 or 14 of Regulation (EU) No 10/2011 that contains plastic manufactured in accordance with that Regulation in another layer or layers. A separate declaration of compliance in accordance with Article 15 of that Regulation regarding that layer or those layers is available and must be taken into account.	<input type="checkbox"/>		
<b>Section 4: Signature</b>				
4.1 Signature and company stamp				
4.2 Name of person signing				
4.3 Role/position of person signing				
4.4 Date and place				

<sup>1</sup> Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food Text with EEA relevance (OJ L 12, 15.1.2011).