

Brussels, XXX SANTE/10932/2021 ANNEX CIS (POOL/E2/2021/10932/10932-EN ANNEX CIS.docx) [...](2021) XXX draft

ANNEXES 1 to 3

ANNEXES

to the

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

on recycled plastic materials and articles intended to come into contact with foods

EN EN

ANNEX I

Suitable Recycling technologies as referred to in Article 3(2)

Table 1 contains the following information:

Column 1: assignment number of 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 %' 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(3) and (4);
- Column 9: derogations from Articles 6 to 8 in accordance with Article 4(5);
- 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 technolog y number	Technolog y name	Polymer type (detailed specification in Table 2)	Short description of the recycling technology (detailed specification in Table 3)	Specification of input	Specification of output	Subject to the authorisatio n of individual processes	Specification s and requirements (reference to table 4)	Derogation s (reference to table 5)	Recyclin g scheme applies
1	Post- consumer mechanical PET recycling	PET (2.1)	Mechanical recycling (3.1)	Only PET PCW containing maximum 5% materials and articles not used in contact with food.	Decontaminate d PET; additional specifications may apply to output from individual processes	Yes	-	-	

2	Closed-	All polymers	J	Chemically		No	4.1	Yes
	Loop	manufacture	and	uncontaminate	articles			
	Recycling	d as primary	microbiological	d used	remoulded into			
		materials in	decontaminatio	materials and	the same			
		compliance	n during	articles solely	materials and			
		with	remoulding	obtained from	articles as those			
		Regulation	(3.2)	a closed loop;	originating			
		(EU) No		polymers not	from the			
		10/2011		collected in	recycling			
				mixed form,	scheme from			
				and/or from	which the			
				consumers	plastic input			
					was obtained			

Table 2: Detailed specification of polymers

Reference number	Acronym	Resin number and/or Recycling symbol, if any ¹	Detailed specification for the purposes of this Regulation
2.1	PET	1	Plastic consisting of at least 90% polyethylene terephthalate homopolymer made by the polycondensation of ethylene glycol and terephthalic acid or dimethyl terephthalate

¹: 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	A decontamination technology during which the polymeric chains that constitute the plastic are not intentionally changed and their molecular weight is not decreased, and during which either a vacuum or an inert gas mixture and heat is applied to remove incidental contamination
3.2	Closed Loop	A recycling technology that recycles plastic input only originating from the use or continued re-use of plastic materials

recycling	and articles in a food distribution chain, or catering services,
	based on a recycling scheme. Particular to this technology is that
	its input must originate from a product loop which is in a closed
	and controlled chain ensuring that only materials and articles
	which have been intended for food contact are used and any
	contamination can be ruled out. Materials and articles can
	therefore not be provided to consumers for use outside the
	premises and/or control of the participating food business
	operators. The decontamination technology part of the recycling
	technology provides for microbiological decontamination by
	high temperature and basic cleaning by means of surface
	washing.

Table 4: specifications and requirements applicable to the use of the technology in accordance with Article 4(4)

Reference number	Speci	fications / requirements
4.1	(a)	only plastic used by consumers within the premises or under control of food business operators participating in the recycling scheme shall be part of that scheme;
	(b)	where materials are subject to re-use within the distribution chain, they shall be cleaned regularly and sufficiently to prevent the build-up of residues originating from food, usage and labelling;
	(c)	the use, re-use, intermediate 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 washing;
	(d)	the document provided in accordance with article 9(4) shall provide

	explicit instructions and procedures to food business operators participating in the recycling scheme to prevent the introduction of external material and the incidental contamination;
(e)	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 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;
(f)	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:
	 accumulation of constituents of the plastic material, such as residues of additives, or degeneration products resulting from repeated recycling; or
	 the presence of common residues for other sources such as food, detergents and labelling

Table 5: derogations applicable to the use of the technology in accordance with Article 4(5)

Reference number	Specifications / requirements

ANNEX II

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

Quality Assessment stages:

For the purpose of the compliance monitoring summary sheet, a Quality Assessment ('QA') stage shall refer to a specific operation in the recycling process during which the quality assessment takes place of batches of material resulting from the manufacturing stage immediately prior to the QA stage.

At a QA stage, one or more tests in accordance with point 2(e) of Annex B to Regulation (EC) No 2023/2006 shall be performed on the batch, and/or the production parameters used during that manufacturing stage for the manufacturing of the batch shall be verified. The analysis and/or verification shall establish whether the assessed material meets the quality standards applied in the recycling process.

There shall always be a QA stage where material enters the recycling process located at the facility, and where recycled plastic or plastic materials and articles leave the facility.

At the QA stage, a record with the outcome of the QA shall be compiled and kept in the recording system.

1. SECTION 1: IDENTIFICATION

1.1 Identification of the recycling installation

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

1.2.	Identification of the recycler	
	Company Name	
	EU Register number (Recycler Operator Number, 'RON')	
	Address of the head office	
	Contact details	
	Position/Role of main contact person	
	Relevant national register numbers, if any	
	Authorisation holder? (Yes/No/ Not applicable)	
1.3.	Recycling process authorisati	on Decision (if any)
A: ident	ification of the authorisation De	cision for the process that the installation applies:
	EU Register number (Recycling Process Authorisation Number, 'RAN')	
	orisation holder – the name of on the authorisation Decision	the authorisation holder and its address must be the
	Name of authorisation holder	
	Address	
	Contact details	
	Position/Role	
1.4.	EFSA Documents	
	EFSA Question number	
	EFSA Publication date of the opinion	
	EFSA Publication number (output number)	
	Confidentiality Decision number	
	Confidentiality Decision date	

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

Name	Position/Role	contact details

2. Section 2: Operation of the recycling installation

2.1. Written Statements

- 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 located the recycling facility;
- A table describing those manufacturing stages and the material streams connecting them located at the recycling facility and corresponding to that diagram.
- 2.2.1. Diagram of the main manufacturing stages located the recycling facility
- 2.2.2. Description of the main manufacturing stages located the recycling facility and the streams connecting them

Stage Number	Name	Descripion	Average Processed Tonnage
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 is 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

^{*} SOP: Standard Operating Procedure

2.6.1. Further information on complex control rules, where relevant

2.7. Relevant SOP 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. Internal Process QA

Each QA stage shall be described using the table below:

QA stage and number	Assessment name	Definition/Description	Criterion	Records	SOP Code
		_			

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 SOP applied at QAstages

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	Short description	Location (of QA)

4. Section 4: Record repository

4.1 QA Recording systems

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

4.2. List of SOP codes for recording system

Quality	SOP code	Short description	Location (of
---------	----------	-------------------	--------------

Assessment (QA) No (ref 3.1)		entry into recording system)

4.3. Other relevant records/systems

Procedure	Description / Documentation

ANNEX III

Templates for declaration of compliance

RECYCLERS DECLARATION of COMPLIANCE with REGULATION (EU) 2022/XXX

Part A: Declaration of compliance to be used by recyclers

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 Regulation (EU) 2022/XXXX. 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, to which purpose I provide adequate instructions in this declaration and labelling on the product. Hereby I declare that the contents of this declaration is correct to the best of my knowledge and in compliance with Regulation (EU) 2022/XXXX. Section 1: Identification 1.1 Recycler 1.2 Recycled product 1.3 Competent authority 1.3.1 1.1.1 1.2.1 Name Tradename / Name designation 1.1.2 1.2.2 1.3.2 FCM-RON* Batch No. Address 1.1.3 1.2.3 1.3.3 FCM-RIN* Country Country/ region 1.1.4 1.2.4 Other 1.3.4 FCM-RFN* information assigned Registration Number Section 2: Compliance 2.1 Basis for authorisation or permission to operate (tick one box only) 2.1.1 Authorisation RAN* Decision 2.1.2 RSN* Recycling scheme 2.1.3 No authorisation or recycling scheme required 2.1.4 Novel NTN* technology 2.2 Results of compliance assessment as listed the compulsory quality assessment stages in table 3.1 of Annex II to Regulation (EU) 2022/XXXX (Compulsory only if 2.1.1 ticked, 2.2.2 and 2.2.3 only to be filled in if different from 2.2.1 and 2.2.4 respectively) Stage Decision criteria and outcome(s) Batch Number(s) 2.2.1 Entry 2.2.2 Input 2.2.3 Output 2.2.4 Exit Section 3: Instructions and information to users of the product 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 fur	ther 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: Sign	nature		
4.1 Signature a	and company stamp		
4.2 Name of person signing			
4.3 Role/positi	on of person signing		
4.4 Date and pl	lace		

^{*} 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.

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

CONVERTERS DECLARATION of COMPLIANCE with REGULATION (EU) 2022/XXXX I, the undersigned in section 4, 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) 2022/XXXX. 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, to which purpose I provided adequate instructions and labelling on the product. Hereby I declare that the contents of this declaration is correct to the best of my knowledge and in compliance with Regulation (EU) 2022/XXXX. Section 1 Identification 1.1 Converter 1.2 Product with recycled 1.3 Competent authority content 1.1.1 1.2.1 1.3.1 Name Tradename / Name designation 1.2.2 1.1.2 1.3.2 Address Batch No. Address

^{**} 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.

1.1.3	1.2.4 Other		1.3.3	
Country	info		Country/	
			region	
			1.3.4 Reg.	
			number	
Section 2: Co	mpliance			
2.1				
2.1.1	Origin of recycled content; FCM-RII	N		
2.1.2	Batch numbers recycled content			
2.1.3	Maximum recycled content indicated	l by recyc	ler (Part A, 3.1.1)	% w/w
2.1.4	Actual recycled content of this produ	ıct		% w/w
2.1.5	Restrictions provided in the Declarat	ion of cor	npliance received	
	from the recycler are met			
2.1.6	Addition of additives or other	☐ Adde	d in compliance	☐ No additions
	substances		gulation (EU) No	
		10/2011		
	tructions and information to users of the			
3.2	Instructions to users further down the	e supply c	hain, including end us	sers
3.2.1	Type or types of food with which it			
	is intended to be put in contact			
3.2.2	Time and temperature of treatment			
	and storage in contact with the			
	food			
3.2.3	The highest food contact surface			
	area to volume ratio for which			
	compliance has been verified		T	1
3.2.4	List of added substances with	FCM	Other designation	SML*
	migration limits; add rows as	No.*	(CAS No., chemica	d (mg/kg food)
	required.		name)	
	(note: FCM Number and specific			
	migration limit ('SML') may not			
	exist for certain substances)			
	Other relevant information in			
3.2.5	accordance with points 7 and 9 of Annex IV of Regulation (EU) No			
	10/2011			
Section 4: Sig		<u> </u>		
	and company stamp			
4.1 Signature	and company stamp			
12 Name of r	person signing			
	tion of person signing			
4.4 Date and				
+.4 Date and	prace			