EXPLANATION OF THIS GUIDANCE

Three separate documents are relevant to Annex II:

- **Regulation (EU) …/…** :
  Several provision set out obligations to recyclers for which Annex II (Compliance Monitoring Summary Sheet) to Regulation (EU) …/… is relevant. This annex nearly fully consist of tables, plus a number of binding directions. These tables provide the templates that should be used by recyclers for the creation of the compliance monitoring summary sheet;
- **Templates in MS-Word (.docx) format:**
  These templates are provided as the actual templates; they contain exactly the same information as the Annexes, but in contrast to the legal text they can be edited and used to be filled out in accordance with the Regulation;
- **This guidance document**
  This document provides **guidance and examples** to explain and facilitate the use of the templates set out in Annex II

All three documents contain the same tables, however this guidance document provides three types of information. A different font type has been used to distinguish these:

- **Legal obligations:** This information fully corresponds to the information given in Annex II to the Regulation, and is binding. It includes the headers and the structure of the tables and row and column headers. It is typeset in black **Times Roman** font.
- **Guiding Instructions:** These instructions provide direction to fill out the tables, while they should be followed where that is possible, these instructions are non-binding. Given the wide variety of business situations, there could be valid reasons to deviate from these instructions. As long as clearly justified by the situation in a recycling facility, the intention of the documents in Annex II is still met, and if agreed with the competent authorities, such deviations are therefore acceptable. Non-binding instructions are typeset in dark blue **Calibri** font.
- **Examples:** Most fields have not been left empty but provide an example of the information that should be provided. Any correspondence between a real process and an example is coincidental. Examples are typeset in purple **Courier** font.

The templates can be found in MS-Word format on the Commissions website, at the same location this document and other information on plastic recycling is provided: LINK

The templates should be used unaltered, however they may be implemented in an information system for automated completion. Different from this document, **only one font should be used** to complete the templates for business use, preferably Times Roman.

GUIDANCE ON 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

Recycling installations have in accordance with the Regulation three parts:

- **Pre-processing:** this includes for instance sorting, shredding and cleaning operations to produce the plastic input
- **Decontamination:** this involves all installations that achieve decontamination for the purpose of manufacturing recycled plastic suitable for contact with food
- **Post-processing:** Installations further processing the decontaminated output of the decontamination stage, but that do not decontaminate; typical examples would be pelletizing or production of sheets, mixing with other materials, manufacture of pre-forms, blowing of bottles and printing.

While the information in this section refers to the 'recycling installation' as a whole that is located at the recycling facility, in certain cases the recycling installation may include more than one decontamination installation. This document should however be filled out for each decontamination installation. If there are shared installations, e.g. if several decontamination installations all use plastic input from the same pre-processing installation located at the facility, that should be explained in section 2.2 – the information in this section should be specific for each decontamination installation.

Installation name	This name should be based on the EU Register number of the decontamination installation. Please provide a meaningful name that distinguishes it from potential other installations located at the same facility.

Applied recycling technology in accordance with Annex I	Mechanical PET recycling Note that; schemes, as used by closed loop recycling, are exempt from this document.
EU Register number (recycling installation number, 'RIN')	RIN01234
Facility Address	Circular Road 5 Green City Memberland
Recycling Facility Number ('RFN')	RFN015
Contact details	Ms I. Goodlaw, tel: +78 09-12 43 56 987, I.Goodlaw@WasteEnders.EU Multiple contacts may be listed here if relevant
Position/Role of contact persons	Quality Manager The contact person should be the person with the practical responsibility and knowledge on the information as well as the management of this document; if several persons are listed their responsibilities should be briefly explained here, to help a competent authority to easily choose the appropriate person, depending on a certain question. It should not be for instance a managing director, unless that director would have detailed knowledge on the information in this document.
Relevant national register numbers, if any	Some competent authorities may provide numbers that could be relevant for listing here, in particular if relevant to the administration of this installation.
Notification date (Article 25(1)(a))	01-februari-2023

1.2. Identification of the recycler

Company Name	Waste Enders Ltd.
EU Register number (Recycler Operator Number, 'RON')	RON0021
Address of the head office	Main street 451 Circleburg Otherland This should be the head office where the legal responsibility for the operations of the company is located, not that of the recycling facility, unless the head office is located there.
Contact details	Mr B. Ossy, tel: +76 33 46 34 5 131, B.Ossy@WasteEnders.EU Ms A. Vocat, tel: +76 33 46 34 5 146, A.Vocat@WasteEnders.EU Multiple contacts may be listed here if relevant

Position/Role of main contact person	Mr Ossy: CEO of WasteEnders; Ms Vocat: lawyer responsible for the recycling operations. Here people with knowledge on legal matters and/or the overall management of the recycling operations should be listed, if any.
Relevant national register numbers, if any	Some competent authorities and/or other organisations such as chambers of commerce may provide numbers applicable to the company that could be relevant for listing here.
Authorisation holder? (Yes/No/ Not applicable)	YES If this company is the authorisation holder of the process applied in the decontamination installation, this should indicate yes. Where an authorisation is not applicable, e.g. in case of a novel technology this should be stated

1.3. Recycling process authorisation Decision (if any)

This section should be adapted for a novel technology; section A may be removed, section B should list the developer and appropriate contacts.

A: identification of the authorisation Decision for the process that the installation applies:

EU Register number (Recycling Process Authorisation Number, 'RAN')	RAN0987

B: authorisation holder – the name of the authorisation holder and its address must be the same as on the authorisation Decision

Name of authorisation holder	Mr B. Ossy, tel: +76 33 46 34 5 131, B.Ossy@WasteEnders.EU
Address	Main street 451 Circleburg Otherland
Contact details	Ms A. Vocat, tel: +76 33 46 34 5 146, A.Vocat@WasteEnders.EU
Position/Role	Ms Vocat is responsible for administrative matters related to the authorisation

1.4. EFSA Documents

This section should be left empty for technologies under development, or if no authorisation is applicable to the process

EFSA Question number	EFSA-Q-2020-12345
EFSA Publication date of the opinion	2021
EFSA Publication number (output number)	ON9876
Confidentiality Decision number	COM/5455 Only if applicable and known to the recycler

Confidentiality Decision date	12-12-2021 Only if applicable and known to the recycler

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

Here additional persons relevant for the operation of the recycling installation may be listed if they that are relevant for specific aspects of its operation Competent Authorities should not consider these persons as primary contacts, but could use this list if they are directed by the main contact to do so in order to understand specific matters.

Name	Position/Role	contact details
Mr G. Rinder	Foreman of pre-processing installation	G.Rinder@WasteEnders.EU
Ms C. Leaner	Teamleader of operators of the decontamination installation	C.Leaner@WasteEnders.EU
Ms J. Erlen-Mayer	Laboratory Analist	J.Mayer@WasteEnders.EU
Mr P. Aperlove	Responsible for compliance documentation	P.Aperlove@WasteEnders.EU
Mr C. Friendly	Responsible for the sales of recycled plastic	C.Friendly@WasteEnders.EU

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

Describe in a maximum of 500 words how the operation of the installation ensures compliance of final recycled material with the Regulation, and particularly why it is safe; the description should be complete without references to other sources such as publications, the EFSA opinion or, if any, the Commission Decision. It should discuss the input specifications, the configuration of the installation, the use of critical control parameters, the output, and the quality control procedures. This statement should demonstrate that obligations under Articles 4-of the Regulation 8 are correctly implemented.

"We receive bales of PET bottles from certified waste collection and sorting facilities. We do a documentary check on each incoming batch to verify whether it meets our input specifications. The input should consist only of post-consumer PET with a non-food content of less than 5%. We further sort this input to take out labels and caps, we wash it, do a final hand sorting, shred it, wash the flakes again and dry them. This product it stored in 2m^3 big bags, of which we take a sample to verify whether it was cleaned to specs and there is only PET. These big bags are only used internally and are then transported as plastic input to the decontamination installation, which we operate according to the authorisation, we control pressure, residence time and temperature as critical parameters. It consists of a pre-heater, an SPP reactor, and an extruder, the latter two are critical to decontamination and are in accordance with the authorisation of our process. In our SOP manual there are procedures defined for operation and corrective actions. Material that is not produced according to the specifications is used to make packaging straps not suitable for food contact. Material meeting the specifications is pelletized, and packed in 1000 kg big bags. We do a quality check during which we control that indeed the production data shows the critical parameters were met for an entire production batch. Batches consist of 10 000 kg, and for each batch we do an analytical check to determine whether the gas chromatogram shows unexpected peaks, and we check that the acetaldehyde content does not exceed our internal standards. If so, the batch is awarded food grade status, and sold for use in contact with all foods at 100%. We apply the required labelling to the batches, and the compliance documentation states the required batch numbers, and the instruction that the material is not for oven and microwave use. A final check is done to see whether the labelling is correct and the documents correspond to the actual batch" (339 words)

2.1.2. Recycler's statement explaining correspondence to the authorised process

This section is applicable only to authorised processes.

Describe in a maximum of 500 words why the process as operated fully corresponds to the process as evaluated by the European Food Safety Authority in the assessment on which basis the authorisation has been granted. Explain why the present equipment can be regarded as equivalent to the equipment used in the challenge test, the ability to operate in accordance with the critical parameters, and explain why apparent differences, if any, are not relevant to the authorisation. For example:

"The equipment in present use operates according to the same principles as the equipment on which the application was based. It applies a pre-heating step, a crystalliser (identified in the EFSA opinion as step 1), a solid state polymerisation reactor (step 2), and an extruder (step 3). The challenge test was performed in a laboratory, and the conditions under which we operate are more severe than those in the challenge test; the temperature is approx. 5 degrees higher, the pressure is the same, and the residence time is normally 10 minutes longer, and does not include the heating phase. However, the capacity of the main crystalliser has been increased by 30% over the crystalliser described in the EFSA dossier. Apart from a change in its length, which was not subject to the evaluation by the EFSA, no further changes have been made. Due to its lengthening the minimum residence time required in accordance with the critical parameter table can still be met despite the capacity increase and the larger material flow through the crystalliser." (174 words)

2.2. Recycling operations at the recycling facility

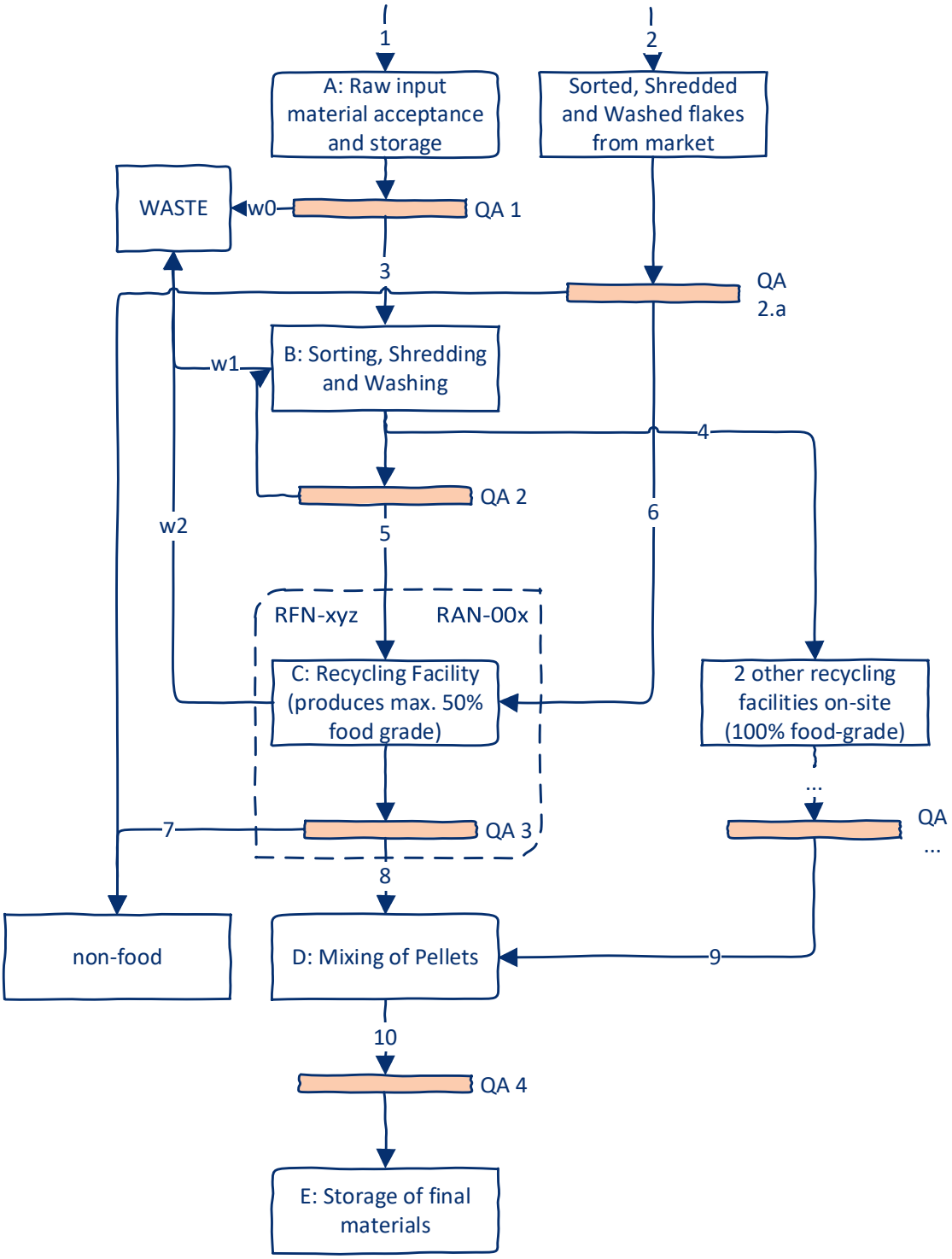
The following information shall be provided in this section:

- 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

The recycler should provide a diagram of the main production stages applied at the recycling facility where the recycling installation is located. Recycling stages such as waste collection and sorting or conversion stages that are not located at the recycling facility should not be indicated. However, supporting stages, such as internal waste gathering of discarded material during the recycling process, and other decontamination stages that share resources with the decontamination installation that is subject to this particular compliance monitoring summary sheet should be indicated.

- The diagram should contain only simple blocks, enumerated with letters, and with numbered input and output streams represented by an arrow. The description of these streams as well as average processed *tonnages* should be indicated in the table below the diagram. The numbering system may be chosen by the recycler, but should be consistent with the numbering used in other sections of this document (particularly 2.4, 2.5 and 3) and correspond to the numbering used in the recycling facility.
- Where there are many operations taking place at the recycling facility which are unrelated to the food contact recycling process to which this document applies, these should be omitted.
- If there are shared resources for several food contact decontamination installations, such as shared sorting and washing operations, this should be clear from the diagram, and all food contact installations should be shown.
- A single block should normally comprise all subsequent operations of which the finally resulting output is subject to quality assessment, represent input operations or intermediate storage operations of batches. If there is no quality assessment or no storage between two subsequent operations, these may be represented as a single block, unless that would impede the understanding of the diagram.
- A dashed line should be drawn around the block or blocks that represent the decontamination operations to which this document applies.
- QA stages should be explicitly indicated with a bar, as shown in the example.



Site diagram from a site that receives material from collection, and buys washed flakes from the market. The site operates three recycling facilities, only the facility to which the CMSS relates should be detailed.

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
A	Raw material acceptance and storage	At this stage the quality of the input material delivered by the suppliers is verified by means of certificates and testing.	20 000 tonnes/yr
B	Sorting, Shredding and Washing	At this stage the input material is taken from storage and coloured PET, foreign plastics and materials are sorted out, the remaining bottles are shredded, and a hot caustic wash takes place.	19 000 tonnes/yr
C	Decontamination stage	Decontamination stages as described in the EFSA opinion	5 000 tonnes/yr
D	Mixing of pellets	Pellets are mixed to achieve food contact grade material with 50% virgin material	10 000 tonnes/yr
E	Storage of final materials	Big bags with premixed pellets are stored until shipment to clients	10 000 tonnes/yr
Stream Number	**Name**	**Description**	**Average Stream size**
1	Raw input from suppliers	Trucks with bales of bottles arrive from suppliers	20 000 tonnes/yr
2	Input flakes bought on market	Conventionally recycled flakes are procured on market and are recycled using the decontamination stages – before verification of quality	1 500 tonnes/yr
3	Accepted raw material to sorting	Raw material transferred from raw material storage to sorting and washing operations	19 000 tonnes/yr
4	To other FCM recycling facilities on-site	PET flakes transfer to other recycling facilities that are on-site, includes storage in big bags	6 000 tonnes/yr
5	Input to FCM recycling facility	PET flakes transfer to recycling facility , includes storage in big bags	5 000 tonnes/yr
6	Input flakes bought on market	Conventionally recycled flakes are procured on market and are recycled using the decontamination stages – after verification of quality	1 000 tonnes/yr
7	Insufficient decontamination	Material processed in the decontamination stage at process settings unsuitable for food contact; did not meet	1 000 tonnes/yr (+ 1 000 tonnes/yr

		criteria in QA 3 – to non-food applications	from other facilities)
8	Decontaminated unmixed food-grade PET	PET pellets decontaminated under conditions compliant with the critical parameters.	5 000 tonnes/yr
9	Decontaminated unmixed food-grade PET	PET pellets decontaminated in the other recycling facilities.	5 000 tonnes/yr
10	Mixed recycled PET	To provide an average quality and good IV the recycling streams originating from the three facilities are mixed to meet the quality requirements of the customers	10 000 tonnes/yr
w0	Immediately rejected material	Raw materials that are not meeting the quality requirements regarding origin – including from industrial sources	1 000 tonnes/yr
w1	Waste generated in sorting and washing	Foreign materials, including labels, metals, other plastics, caps, and dirt.	8 000 tonnes/yr
w2	Start-up/shut-down waste	Waste created during start-up and shut down of the facility, e.g. partially decomposed PET, and purged PET from the extruder and reactor.	Small <100 tonnes/yr

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
GMP Manual	GMP 1	As defined in section 2.2	Title	Give a short and meaningful description of the purpose and the scope of the document	Dd/mm/yyyy, Vx.x, MD
SOP definitions	SOP 1		Title	Give a short and meaningful description of the purpose and the scope of the document	Dd/mm/yyyy, Vx.x, MD
Equipment manual	EQP 1		Title	Give a short and	Dd/mm/yyyy, Vx.x, MD

				meaningful description of the purpose and the scope of the document	
EFSA Opinion	Misc 1	C	EFSA opinion on…	The actual EFSA opinion, including confidential information	12/12/2018, EFSA

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)

As the same set of documents apply to a batch which result from the QA checks at the main manufacturing stages, several different batches will be used during a recycling process. These are to be defined in this section. Note that in between batches the amount and the quality of the material change because of sorting and cleaning operations, mixing of batches, or intermediate storage and the QA checks themselves. Therefore, to facilitate quality management, control and enforcement, it is important to clearly define the different type of batches used in the processes – for the sake of this example, the table has been made complex on purpose:

Batch type	Internal Batch name	Stream/QA No.	Definition/Description	Typical size range	Traceability rule
Entry	Raw Bales	3/QA1	Bales of waste and uncleaned bottles procured on the market as one consignment, containing also metal waste.	24-32 bales	DoCs received from suppliers are entered in database and receive batch number at QA1
Input	Intermediate washed and flaked (IWF-	5/QA2	On-site conventionally recycled and	80 tons (one silo)	Input batch numbers contained in

	batch)		sorted material		the intermediate batch receive and IWF batch number in database system assigned in QA2
Input	Intermediate washed and flaked (ExtIWF-batch)	6/QA2.a	Big-bags with conventionally recycled flakes (i.e. caustic washed, dried and sorted) procured on the market as one consignment, subject to the same paperwork	12-28 big bags	DoCs received from suppliers are entered in database and receive batch number
output	50% intermediate recycled (IRM50)	8/QA3	The process is continuous. Batches are defined according to run-length in accordance with a given set of parameters, which are kept constant during the run. Once a new run with different parameters has started or the processes did not meet specifications, a new IRM50 batch is automatically created.	1-100 tons (max one silo)	IWF batch numbers contained in the IRM50 batch run receive an IRM50 batch number in database system, following validation in QA3
Other	100% foodgrade recycled (FGR100)	9/QA	Material from the other recycling facilities which can produce material that can be used 100%	1-100 tons (max one silo)	FGR100 batch numbers contained in the silo batch run receive an silo batch number in database system.
Exit	100% foodgrade recycled	10/QA4	Batch of recycled material 50/50	1-200 tons (packed	Single silo batch number

	(FGR150)		as placed on the market, with single DoC document	in 500 kg big bags, or 25 tons bulk)	

2.5. Process diagram of the decontamination installation

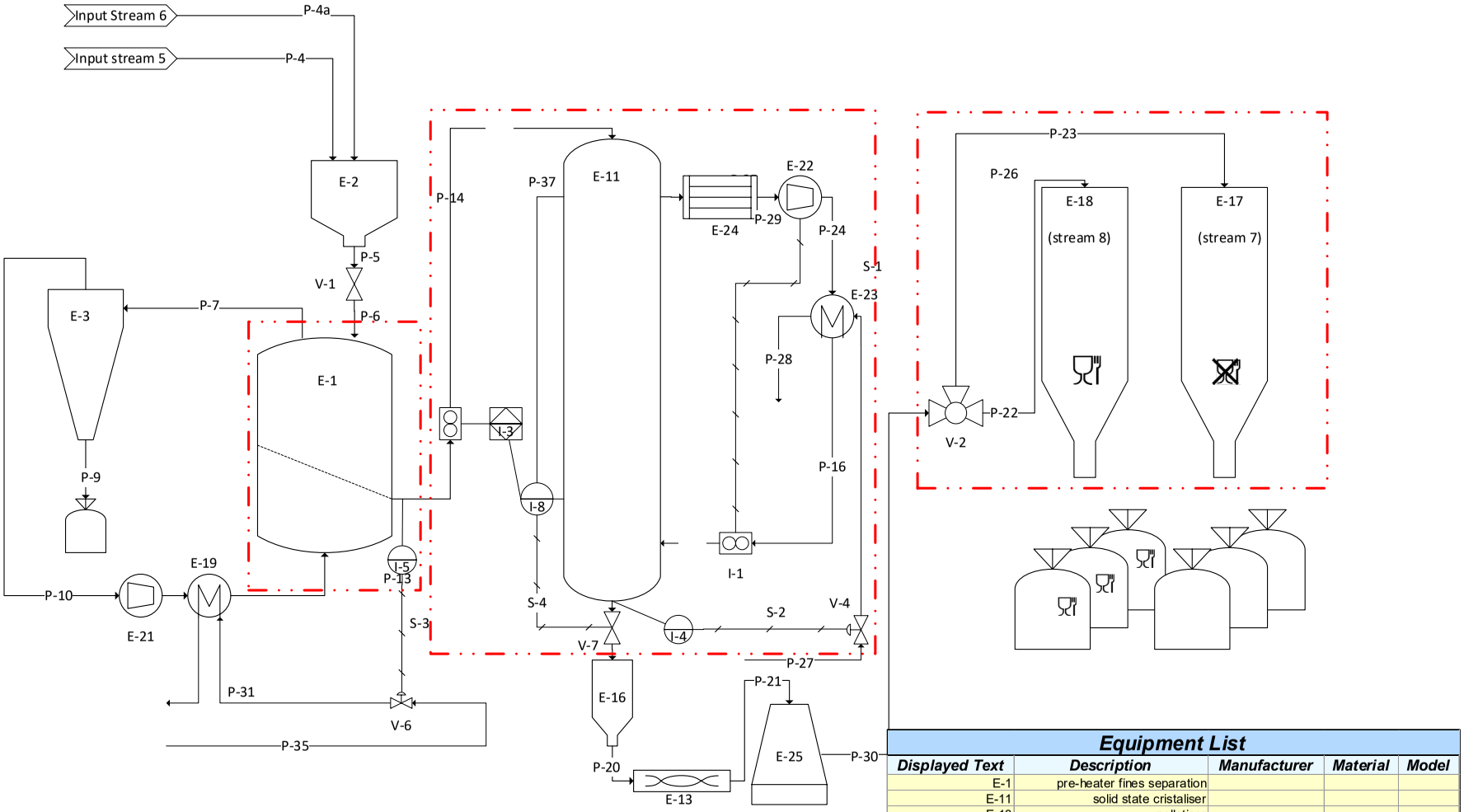
Add a piping and instrumentation diagram in accordance with section 4.4 of ISO 10628-1:2014, taking account of ISO 10628-2.

The diagram should be drawn taking into account the following guidelines:

- Where ISO 10628-2 does not provide a suitable symbol for certain specific equipment, an alternative symbol that clearly represents that equipment may be used
- Steps deemed critical by the EFSA should be clearly marked, for instance, by encircling the equipment that is part of such a step by a line of a different colour
- All instrumentation used to control the critical parameters should be included in the diagram, other instrumentation may be left out if it is clear that that instrumentation is not relevant to the control purposes of the Regulation, and cannot be confused with equipment that is relevant
- The physical numbering in the manufacturing facility, and the indication in the control and/or SCADA[1] system should correspond to the numbering in the diagram

On the next page an example diagram is provided to illustrate the use of these guidelines; this example is purely imaginative and any resemblance to a real process is therefore a coincidence. Note that the instrumentation used to control the critical parameters is explicitly marked. Not all information required under section 4.4 of ISO 10628-1:2014 has been included in this example.

[1] SCADA: Supervisory control and data acquisition system; the computer system that retains all data on the processing of the material.



Instrument List

Displayed Text	Description	Connection Size	Service	Manufacturer	Model
I-1	inert gas flowrate cristalliser		critical		
I-3	residence time computer		critical		
I-4	cristalliser output temperature		critical		
I-5	cristaliser input temperature		critical		
I-8	cristaliser level		input to critical parameter		
I-9	cristalliser input flowrate		input to critical parameter		

Equipment List

Displayed Text	Description	Manufacturer	Material	Model
E-1	pre-heater fines separation			
E-11	solid state cristaliser			
E-13	pelletiser			
E-16	collector			
E-17	non- food grade silo			
E-18	food grade silo			
E-19	heater pre-heating			
E-2	input hopper			
E-21	compressor pre-heating			
E-22	inert gas compressor cristalliser			
E-23	inert gas heater cristalliser			
E-24	impurities condensor			
E-25	pellet cooler			
E-3	cyclone			

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.

The control criteria provided in this section should ensure the control of the recycling facility by means of the critical parameters set out in the EFSA opinion. These critical parameters are available to the authorisation holder and should be set out in the table below. The EFSA opinion, including the possibly confidential annex with the table of critical parameters, should be available at the recycling facility and be included in the list of documents in section 2.3.

If no EFSA opinion is applicable, the operator should define the critical operations and critical parameters.

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
Step 1; pre-heater	T >200°C	I-5	During Normal operation controlled by a PI controller; when 20°C or more below set-point for 5 minutes the batch will be rejected.	SOP-op_1
Step 2; crystalliser	t residence > 20 min.	I-3; calculated from I-9 and I-8	During Normal operation controlled by a computer controller; when residence time is 18-20 minutes for more than 2 minutes the batch will be rejected, when below 18 minutes for the batch will always be rejected.	SOP- op_2
	T >270°C	I-4	During Normal operation controlled by a PI controller; when 10°C or more below set-point for 2 minutes the batch will be rejected.	SOP- op_3
	Inert gas flow > 60 Nl/s	I-1		SOP- op_4

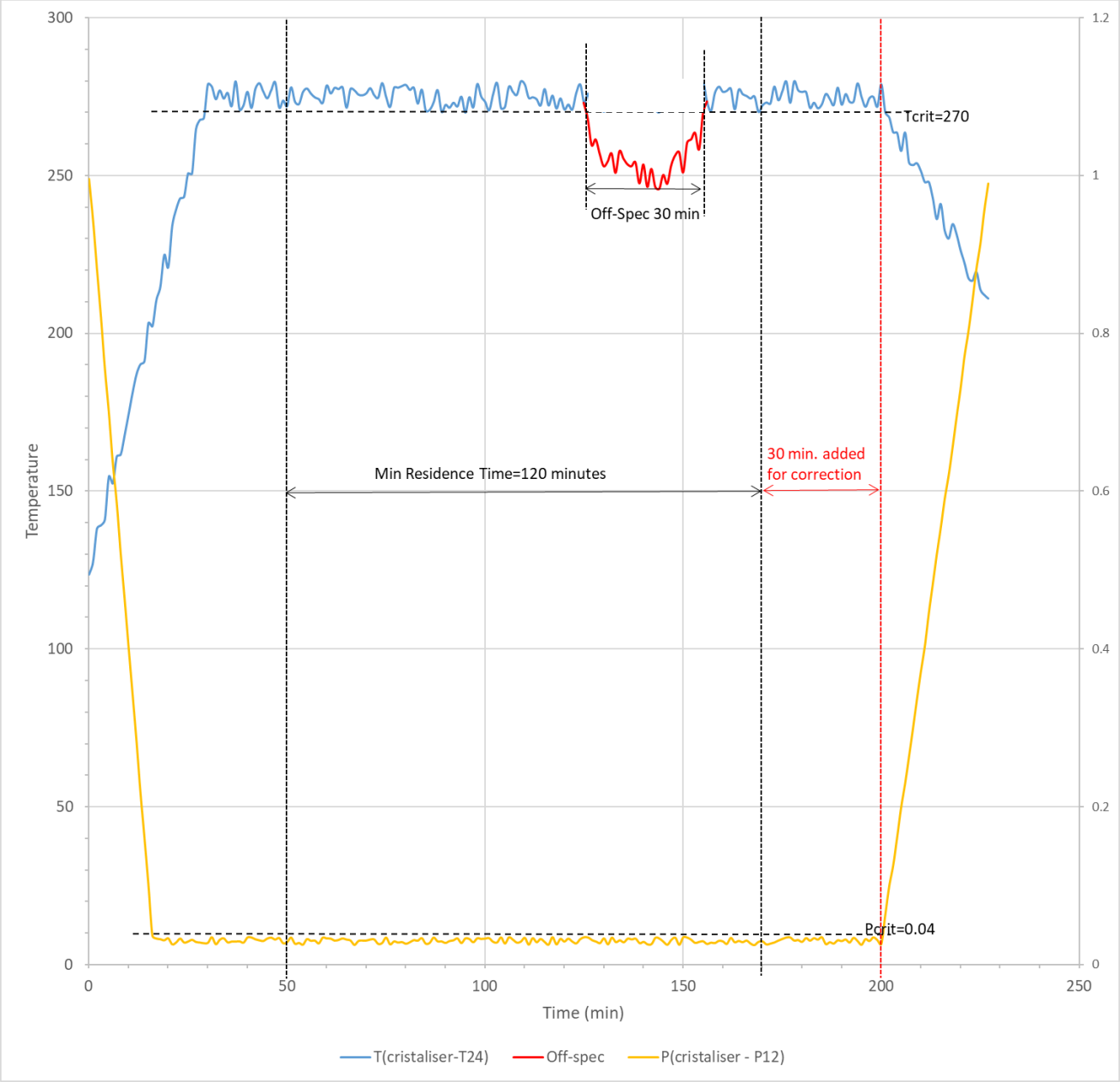
* SOP: Standard Operating Procedure

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

Where the evaluation of a control criterion is complex, for instance, because it involves a complex corrective action, several parameters, or transient conditions, further information should be added in this section to explain the evaluation of the criterion and/or the corrective action.

Example of graph to explaining the use of control rules in case of transient behaviour:

Note: the graph in this example is representative of batch operation, and neither corresponds to the schematic which is given as an example in section 2.5, nor to the table in the first part of 2.6.



In this graph, the critical pressure and temperature are indicated by means of dotted lines. The measured temperature and pressure have to remain above, respectively, the critical temperature and below the critical pressure for the minimum residence time. The correction

procedure for a period of 30 minutes during which the temperature is below the critical temperature is to add 30 minutes to the total processing time, prolonging the residence time of 120 minutes as would be prescribed by the EFSA opinion with 30 minutes.

The full procedure is laid down in the operation manual, SOP-op_5

2.1. 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)
SOP-op_1	Procedure to set and operate the pre-heater at the right temperature, corrective actions, and rejection procedures	Control room
⋮	⋮	⋮
⋮	⋮	⋮
SOP-op_4	Procedure to set and operate the inert gas-flow in the crystalliser, corrective actions, and rejection procedures	Control room

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)

The combined assessments at the entry and input stages should ensure that the input requirements in accordance with the Regulation are met. Note that some of these requirements may be set out in the authorisation of the recycling process. At the output stage, it should be verified that at least the critical parameters are met, and at the exit stage it should be verified whether the recycled plastic or plastic materials and articles leaving the facility meet the requirements of the Regulation, and particularly whether post-processing operations done at the facility comply with the Regulation, and whether other requirements such as on documentation, labelling and instructions are also met.

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.

QA 1: acceptance of waste from local collection and sorting

QA stage and number	Assessment name	Definition/Description	Criterion	Records	SOP Code
QA1.1	Supplier Certificate	Check whether the supplier certificate is present and correct, and stored in the management system. link to input batch in management system	Certificate accepted in system	Delivery number, certificate, pass (y/n), batch nr	XXXX.1
QA1.2	Post-Consumer	Visual check whether the plastic	Post-consumer	Post-consumer	xxxx.2

		is post-consumer	Y/N	(y/n)	
QA1.3	Quality Check	Quality Check following the Methodology guidelines to check the quality of baled PET waste published by PRE (detailed pass criteria in SOP with reference to section 3.4 of PRE document – includes check of non-food %)	Pass Y/N	Pass Y/N; estimated non-food (%), table 3.4 PRE document	Xxxx.3

QA 2: Washed and sorted Input to recycling facility

QA stage and number	Assessment name	Definition/Description	Criterion	Records	SOP Code
QA2.1	Foreign plastics	Checks whether plastics other than PET are present in washed and sorted flake, should not be the case.	Fail when >1%	pass (y/n),	XXXY.1
QA2.2	Foreign materials	Check whether the material is fully free from paper and metal	Fail when >10 ppm	Pass (y/n))	xxxY.2
QA2.3	Batch Nr assignment	Assign batch number (IWF-batch)	-	IWF Batch Nr	XxxY.3

QA 2.a: Washed and sorted Input from external supplier to recycling facility

QA stage and number	Assessment name	Definition/Description	Criterion	Records	SOP Code
QA2.a.1	Certification check	We check yearly whether our supplier has an appropriate quality assurance system in place, and has been accredited for quality assessment steps similar to QA 1 and QA 2	Fail when appropriate accreditation is not there (once/yr from first acquisition)	pass (y/n),	XXXE.1
QA2.a.2	Documentation check	Verify for each batch whether the correct Documentation is delivered – this	Fail documentation is not complete or correct	Pass (y/n))	xxxE.2

		should indicate checks equivalent to QA1 and QA 2 where carried out and results are given			
QA2.a.3	Physical verification	Check whether appearance an smell are as expected, verification in lab if anomalies	Fail if anomalies observed and confirmend	Pass (y/n))	xxxE.3
QA2.a.4	Batch Nr assignment	Assign batch number (ExtIWF-batch)	-	IWF Batch Nr	XxxE.4

QA 3: output material

QA stage and number	Assessment name	Definition/Description	Criterion	Records	SOP Code
QA3.1	EFSA Critical Parameters	Check whether parameters are accordance with section 2.6; where needed corrective action is taken	Fail when critical parameters are not fully met and corrective action insufficient or absent	pass (y/n),	XXXZ.1
QA3.2	Quality Type	Check whether the settings are suitable for the desired output useable with 50% virgin	Fail when settings are different	pass (y/n), may be assigned a different category	XxxZ.2
QA3.3	IV check	Check whether IV is according to specifications (not needed for Authorisation)	Fail when <90	Measured IV	xxxZ.3
QA3.4	Batch Nr assignment	Assign batch number (IRM1-batch)	-	IRM1 Batch Nr	XxxZ.4
QA3.5	Production pass	Verification that both QA3.1 and QA3.2 are pass, for inclusion in main recording system	QA3.1 and QA3.2 are a pass	Pass (y/n)	XxxZ.5

QA 4: blending and pre-market verification

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

number					
QA4.1	Blending	Is mixed with 50% virgin materials	50 % met	pass (y/n), batch nr	XXXF.1
QA4.2	Batch Nr assignment	Assign batch number (Output batch)	-	Output Batch Nr	XxxF.2

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)
QA1	XXXX.1	Procedure to check all papers from waste deliveries, to enter them into the system (paper documents are scanned and stored); quality papers are checked for waste origin	Shed at weighbridge
⋮	⋮	⋮	⋮
⋮	⋮	⋮	⋮
⋮	⋮	⋮	⋮
QA4.2	XXXF.2	Procedure to assign Batch numbers to batches that are ready to be sold on the market	Blending facility quality room

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**
QA1	MatInventManager	This is a software system in which data is recorded on the size and quality	ERM Database	Backup server at cloud provider; paper	XXXX.1rs	System locks record after signing by operato

		of each batch and which allows for traceability for up to 5 years		notes kept in archive		r; signed paper record
QA2	MatInventManager	This is a software system in which data is recorded on the size and quality of each batch and which allows for traceability for up to 5 years	ERM Database	Backup server at cloud provider; paper notes kept in archive	xxxx.2rs	System locks record after signing by operator; signed paper record
QA3.1 and QA 3.2	Recycling SCADA System	This system keeps track of all processing parameters of the recycling facility – it also records manual inputs and corrections	Facility control system	Local backup server; paper operating forms stored in archive; paper notes kept in archive	Xxxx.3DA	System locks record after signing by operator; signed paper record
QA 3.3 to QA 3.5	MatInventManager	This is a software system in which data is recorded on the size and quality of each batch and which allows for traceability for up to 5 years	ERM Database	Backup server at cloud provider; paper notes kept in archive	Xxxx.3rs	System locks record after signing by operator; signed paper record
QA4	MatInventManager	This is a software system in which data is recorded on the size and quality of each batch and	ERM Database	Backup server at cloud provider; paper notes kept in	Xxxx.4rs	System locks record after signing by operator; signed

		which allows for traceability for up to 5 years		archive		paper record

4.2. List of SOP codes for recording system

Quality Assessment (QA) No (ref 3.1)	SOP code	Short description	Location (of entry into recording system)
QA1	xxxx.1rs	Standard operating procedure for the use of the recording system for the entry of batches entering the facility, including procedures to enter and modify batches.	Weighbridge shed
⋮	⋮	⋮	⋮
QA3.1	xxxx.3DA	Operating procedure for ensuring that the control settings for the critical parameters are entered correctly – the SCADA system will further ensure the pass data is retained.	Main control room
⋮	⋮	⋮	⋮
⋮	⋮	⋮	⋮

4.3. Other relevant records/systems

This section allows the recycler to specify other procedures it deems relevant to the operation of the recycling system in accordance with the Regulation.

Procedure	Description / Documentation
WASTE	Our waste procedure ensures that all plastic that is not suitable for recycling, or results from waste created during the recycling process is appropriately discarded. This procedure is also important to account for the difference in the mass balance between the amount of material entering the facility and leaving the facility.