DRAFT GUIDANCE TO ANNEX II AND II TO REGULATION (EU) 2022/1616

Version: 0.6, 04 April 2025

DISCLAIMER

This document is being developed to facilitate the completion of the template laid down in Annex II to Regulation (EU) 2022/1616 by recyclers and its verification by competent authorities. The Commission Services encourage its use, subject to the following:

- *Guidance cannot take precedence over the wording provided in Regulation (EU) No 2022/1616. It is intended to assist recyclers and Competent Authorities in the uniform application of Annex II and III of Regulation (EU) 2022/1616. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.*
- *This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.*
- *A recycler or a competent authority may conclude on an approach that deviates from this draft when taking account of the wording of Regulation (EU) 2022/1616, other applicable legislation, the specifics of a recycling installation, or national circumstances. That alternative approach should then take precedence over this draft.*
- *The Commission services welcome observations and suggestions on the use of this draft. Please send these to SANTE-FCM-CONSULTATIONS@ec.europa.eu.*

This document provides three types of information, distinguished by font and colour:

- **Legal obligations:** This information fully corresponds to the information given in Annex II to the Regulation. It includes the headers and the structure of the tables and row and column headers. It is typeset in black **Times Roman** font. That black text therefore corresponds to binding legislation.
- **Guiding Instructions:** These instructions provide direction to fill out the tables. While they should be followed where that is possible to ensure a uniform approach, 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. The templates should be used unaltered, but may be implemented in an digital information system.

The Reader should use only <u>one font in one color</u> to complete the templates for business use, preferably Times Roman. The use of colors serves only in this document the purpose of making a distinction between legal text, guiding instructions, and examples.

ANNEX II

Template for the Compliance Monitoring Summary Sheet in accordance with Article 26 of Regulation (EU) 2022/1616

A compliance monitoring summary sheet ('CMSS') is to provide rapid and effortless overview to competent authorities of how the recycler manufactures recycled plastic and operates their quality assurance system in order to achieve compliance with Regulation (EU) 2022/1616. It also sets out how the recycler monitors the compliance of individual batches and ensures the traceability thereof.

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.

CHANGES to version 0.6:

- Regulation (EU) No 2023/2006: the GMP Regulation was amended on 16 march 2025. This changed Annex B. Point 1 and point 3 have been added, the only change to point 2 is that it is now point 2. Point 3 now defines 'Quality Assessment Stages', a term used in this Annex (see below).

- The authorisation of recycling processes is underway, but only a few processes have been assigned a RAN. It is foreseeable that the authorisation process will take significant time. Where there is no Authorisation, information on the authorisations cannot be provided in the CMSS, such as that required in section 1.3. These fields should be left blank. However, the European Food Safety Authority ('EFSA') has already published favourable opinions on the majority of recycling processes applied by recycling installations. The guiding instructions in section 1.3 and 1.4 have been updated to further clarify this situation. Article 31(1) of Regulation (EU) 2022/1616 allows processes for which an application for authorisation was received before 10 July 2023 to be used to place recycled plastic on the market.

A Quality Assessment ('QA') stage is defined in point 3 of Regulation (EU) No 2023/2006.

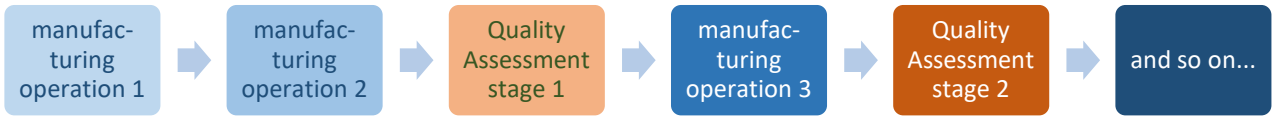

Figure 1: Quality Assessment stages follow on or more manufacturing operations

At a QA stage, one or more tests in accordance with point 2(e) of Annex B to Regulation (EC) No 2023/2006 are to be performed on the batch, and the production parameters used during the manufacturing operations immediately prior to the QA state used to manufacture the batch should be verified. The analysis and/or verification is to establish whether the applicable critical limits referred to in point 2, point (c) of that Annex are met.

There should always be a QA stage where material enters the recycling facility, and where recycled plastic or plastic materials and articles leave it. A QA stage would also be needed to verify compliance with the critical parameters used in the decontamination installation.

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

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) 2022/1616

Recycling installations have in accordance with the Regulation three parts:

- **Pre-processing:** this includes unit operations such as for instance sorting, shredding and cleaning operations to produce the plastic input
- **Decontamination:** this involves only the unit operations that together achieve decontamination for the purpose of manufacturing recycled plastic suitable for contact with food; usually this are the unit operations considered in EFSA opinions as 'critical steps'
- **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.

The information in section 1.1 should refer to the 'recycling installation' as a whole, i.e. all recycling operations located at the recycling facility. In certain cases the recycling installation may include more than one decontamination installation. The input used by these decontamination installations may be produced either in a shared pre-processing installation, or partially or wholly in parallel. This is to be futher detailed in section 2.2.

For each decontamination installation located at the recycling facility, a separate CMSS is to be completed; the information in section 1.1 (and largely that in section 2.2) is common to all those CMSS. See also figure 2.

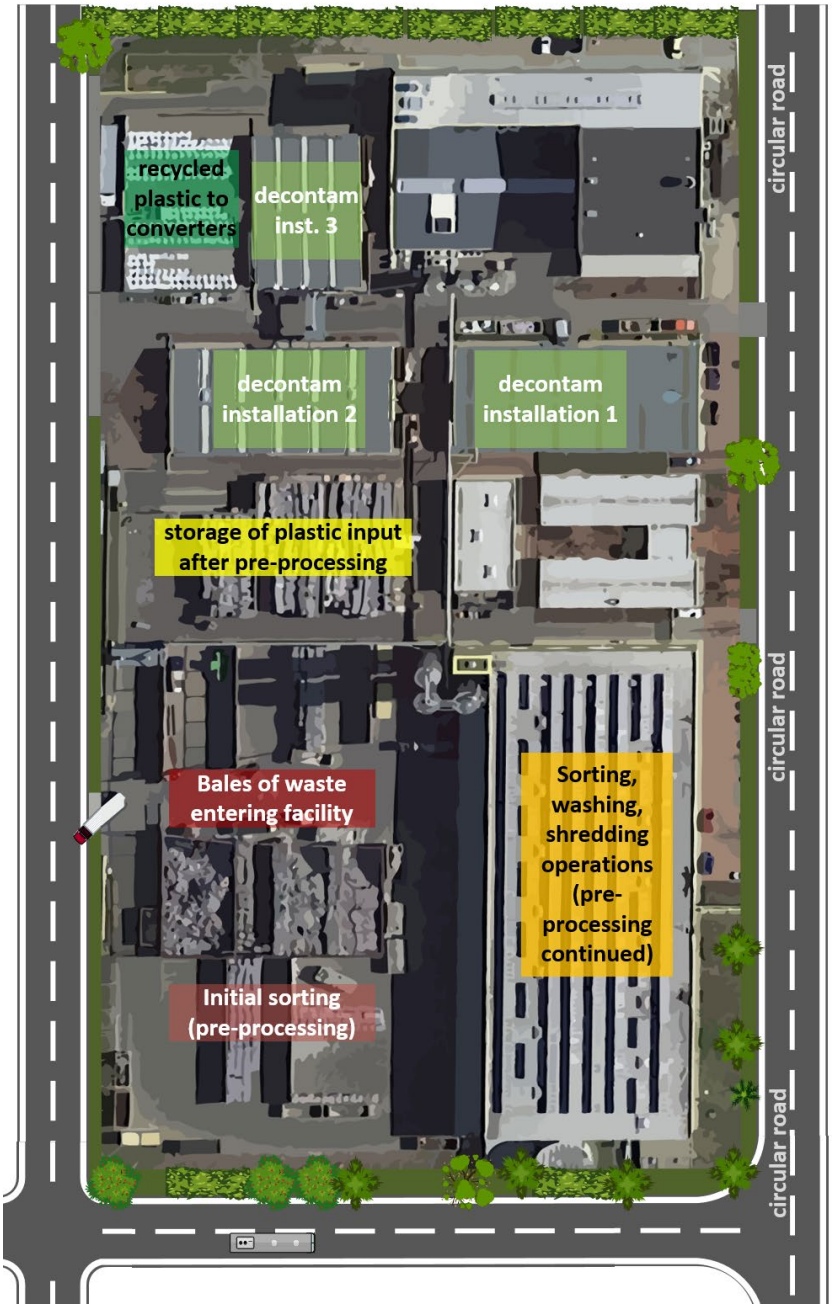

Figure 2: Illustration showing a recycling facility, based on a modified aerial photograph of an existing facility. At this imaginary facility three decontamination installation are located (green areas), which all decontaminate the same input material produced by means of shared pre-processing operations at the same facility; basic sorting takes place outside (red), which is then continued in a sorting and washing installation (amber) to manufacture the plastic input. This intermediate materials is stored outside (yellow area), as well as in three silos in the middle until decontamination.

1.1 Identification of the recycling installation

Installation name	This name should correspond 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')	EU3-3CR-1ID
Facility Address	Circular Road 5 Green City Memberland
Recycling Facility Number ('RFN')	EU3-3CR-1FX
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	Certain competent authorities may provide other register numbers that could be relevant for listing here, or require the use thereof, 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')	EU3-3CR-1O5
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 or novel technology

- For Mechanical PET recycling processes section A should be left blank if the process is used in accordance with the transitional provisions set out in Article 31(1), thus if not yet authorised but used based on an application for authorisation received by EFSA before 10 July 2023. In that case section B is to refer to the present applicant. Note that the applicant may have changed when the application was transferred to a third party. Therefore, the name of the present applicant may differ from that mentioned in the EFSA opinion. RAN numbers will be assigned upon authorisation.
- This section should also be adapted for a novel technology; section A should provide the NTN if available or left blank, section B should list the developer as referred to in Article 10 of the Regulation and its appropriate contacts.

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

EU Register number, i.e. Recycling Process Authorisation Number ('RAN'), Novel Technology Number ('NTN')	EU3-3CR-1AP

B: authorisation holder or novel technology developer –

Name of authorisation holder* / of the technology	Mr B. Ossy, tel: +76 33 46 34 5 131, B.Ossy@WasteEnders.EU

developer as applicable**	
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

* 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')

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 and compliance	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

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

Describe in a maximum of 3000 characters including spaces 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 2m3 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" (2031 characters with spaces)

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 3000 characters including spaces 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." (1051 characters including spaces)

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)

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 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.

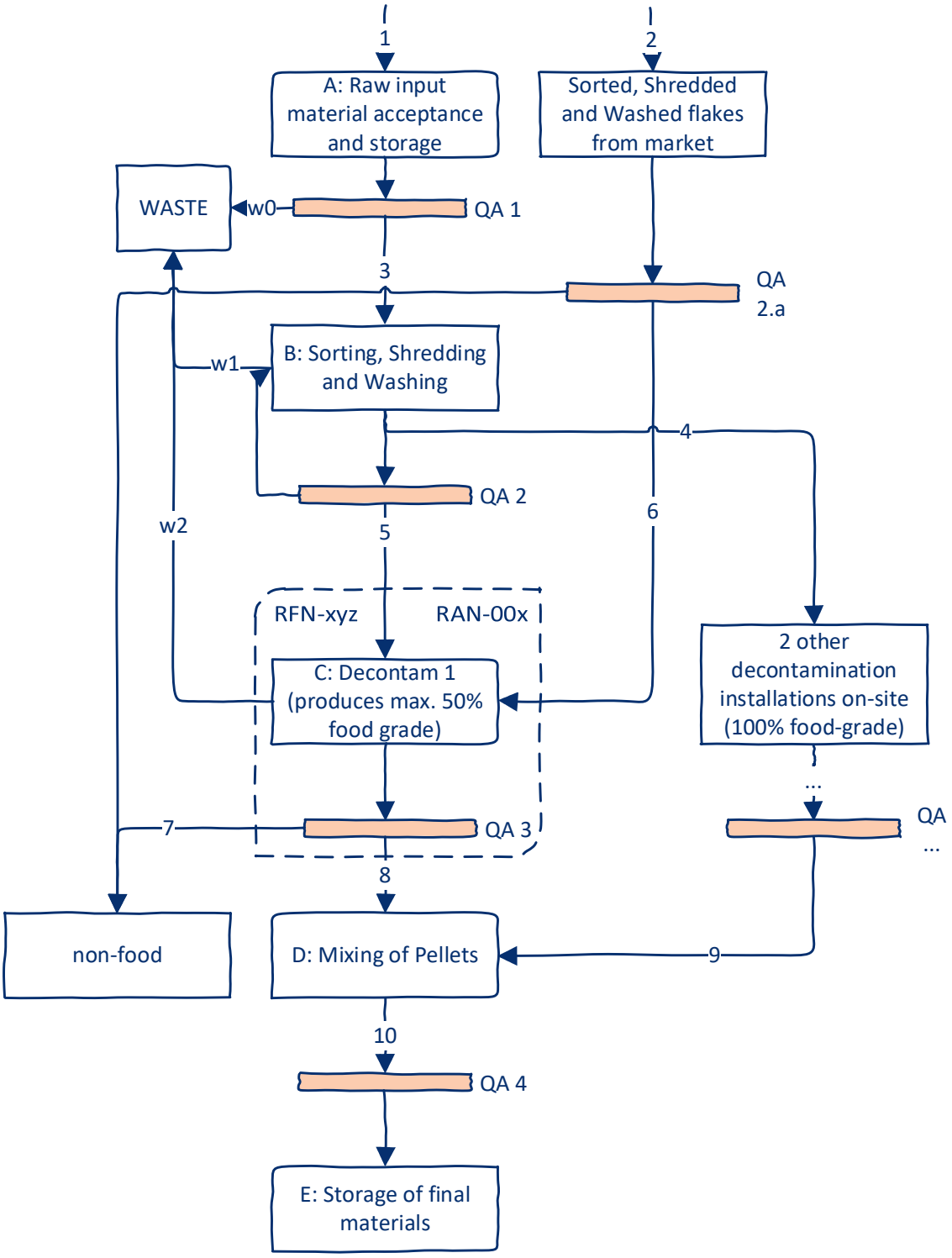

Figure 3: Example site diagram of main manufacturing stages at a recycling facility. The Manufacturing operations and QA stages follow the structure explained in Figure 1.

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

Stage Number	Name	Descripion	Average Processed Tonnage per year

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 criteria in QA 3 – to non-food applications	1 000 tonnes/yr (+ 1 000 tonnes/yr 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	PET pellets decontaminated in	5 000

	unmixed food-grade PET	the other recycling facilities.	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 clear 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 clear 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 clear description of the purpose and the scope of the document	Dd/mm/yyyy, Vx.x, MD

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 as 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-batch)	5/QA2	On-site conventionally recycled and sorted material	80 tons (one silo)	Input batch numbers contained in 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	10/QA4	Batch of recycled	1-200 tons	Single silo batch number

	recycled (FGR150)		material 50/50 as placed on the market, with single DoC document	(packed 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.

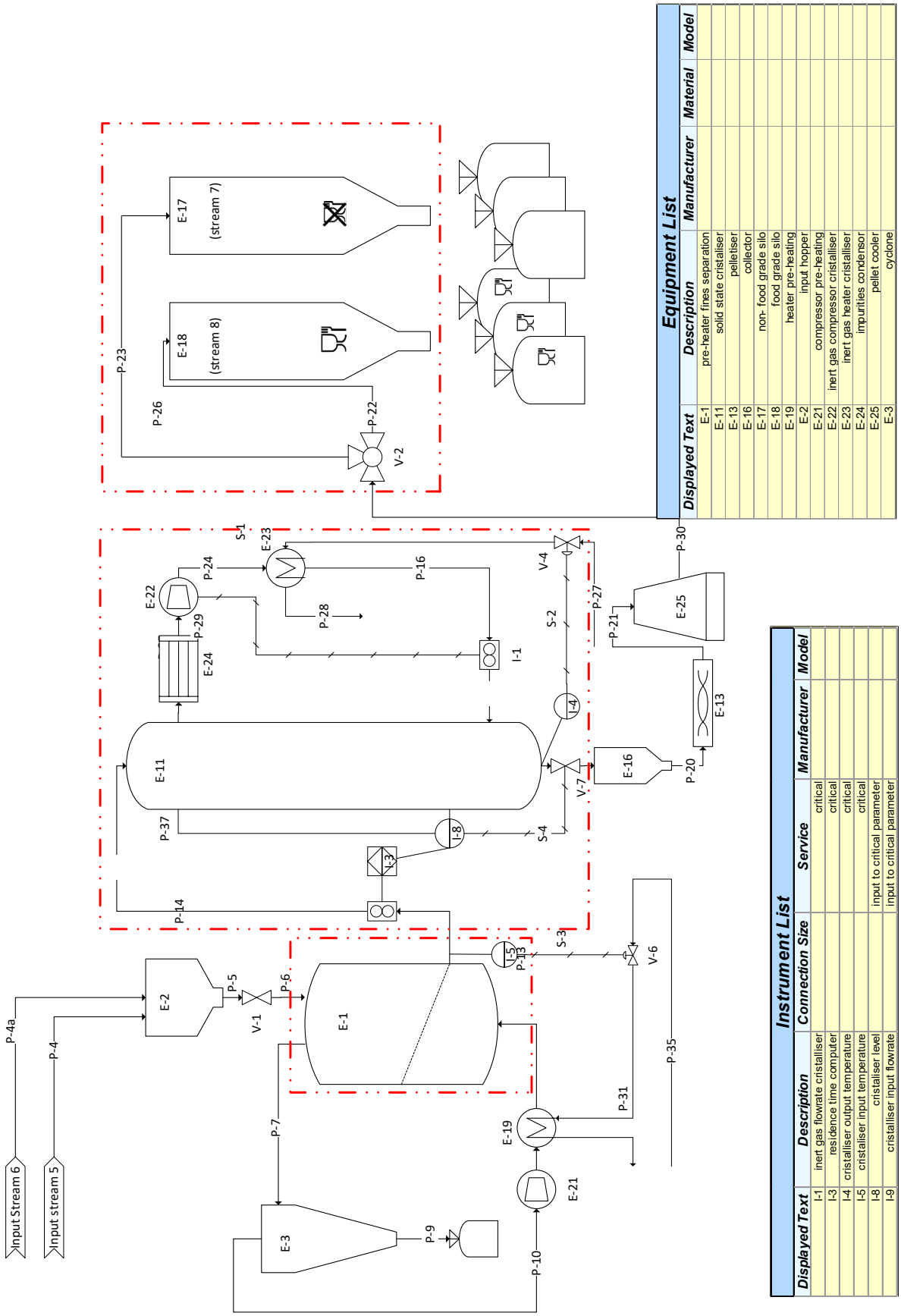

Figure 4: Piping and Instrumentation diagram of the decontamination installation. The steps/operations deemed critical by EFSA are marked with a red box

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 (SOPNr – DocNr)
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

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 may be added here to explain the evaluation of the criterion and/or the corrective action.

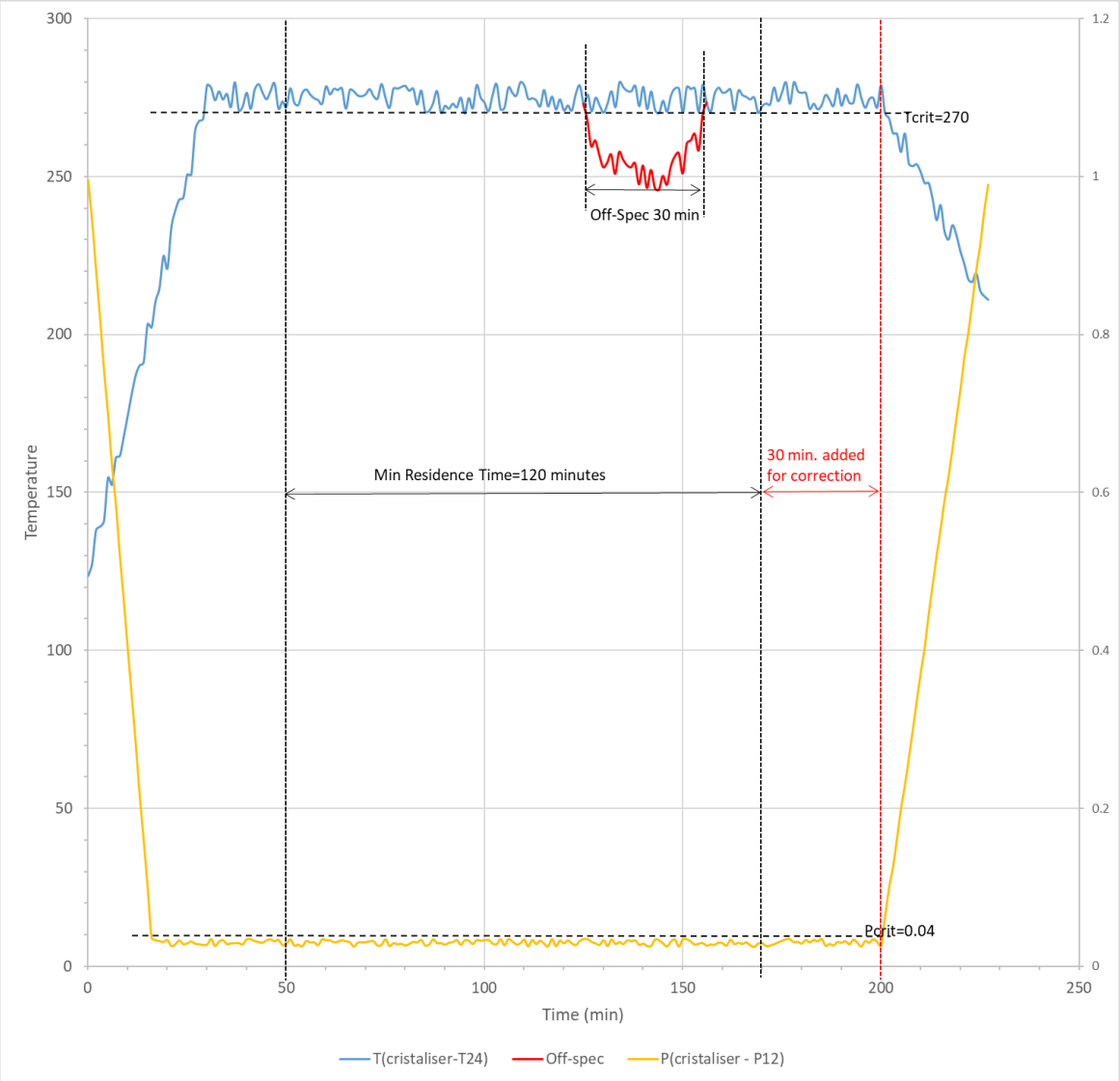

Figure 5: Example of graph to explaining the use of control rules in case of transient behaviour.
In this graph, the critical pressure and temperature are indicated by means of dotted lines. The measured temperature and pressure have to remain above, respectively, the critical temperature and below the 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 defined in the operation manual, SOP-op_5

Note: the graph in this example is representative of batch operation, and does not necessarily 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.

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)
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. 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)

Note: this table should be copied for each QA stage

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. 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 is post-consumer	Post-consumer Y/N	Post-consumer (y/n)	xxxx.2
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 should indicate checks equivalent to QA1 and QA 2 where carried out and results are given	Fail documentation is not complete or correct	Pass (y/n))	xxxE.2
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	Fail when settings are	pass (y/n), may be	XxxZ.2

		desired output useable with 50% virgin	different	assigned a different category	
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	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: exit stage; blending and pre-market verification

QA stage and number	Assessment name	Definition/Description	Criterion	Records	SOP Code
QA4.1	Blending	Is either mixed with 50% virgin materials or labelling showing max 50% content is provided	50 % met, or labelling	pass (y/n), batch nr	XXXF.1
QA4.2	Production traceable	Traceability to QA3 records is validated and QA3 stage is passed. Assign batch number (Exit batch)	Records from previous stages validated	Exit Batch Nr	XxxF.2

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)
QA1	XXXX.1	Procedure to check all papers from waste deliveries, enter them into the system (paper documents are scanned and stored); certificates 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 Quality assessment recording systems

Quality Assessment No (ref 3.1)	Name	Definition/Description	Location	Backup	SOP Code (SOPNr – DocNr)	Modification prevention
QA1	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.1rs	System locks record after signing by operator; 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	MatInventMana	This is a	ERM	Backup	Xxxx.3	System

to QA 3.5	ger	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	Database	server at cloud provider; paper notes kept in archive	rs	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 which allows for traceability for up to 5 years	ERM Database	Backup server at cloud provider; paper notes kept in archive	Xxxx.4rs	System locks record after signing by operator; signed paper record

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)
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.

ANNEX III

Article 5(2) of Regulation (EU) No 2022/1616 requires that a declaration of compliance in accordance with Article 29 must accompany recycled plastic when that is placed on the market. Article 29 sets out the following:

Article 29

Specific requirements for declarations of compliance for recyclers and converters

1. Recyclers shall provide a declaration of compliance in accordance with the description and template set out in Part A of Annex III.

2. The declaration of compliance shall include instructions to converters that are sufficient for ensuring that converters can further process the recycled plastic into recycled plastic materials and articles that are in compliance with Article 3 of Regulation (EC) 1935/2004. These instructions shall be based on the specifications, requirements or restrictions set out for the recycling technology applied and, where applicable, the recycling process used.

3. Converters shall provide a declaration of compliance in accordance with the description and the template set out in Part B of Annex III;

Annex III therefore consists of two parts:

- Part A is to be used by Recyclers that operate a decontamination installation. According to Article 2(3)(16); a 'recycler' means any natural or legal person who applies a decontamination process;
- Part B is to be used by all converters that use recycled plastic in their product. According to Article(2)(17); a 'converter' means any natural or legal person that carries out one or more post-processing unit operations;

In a typical supply chain there could be several situations in which the roles are not clear:

- A situation that is expected to be rather common occurs in case a recycler decontaminates the plastic, but, before placing it on the market performs post-processing, such as adding primary plastic to lower the recycled content in the material. This means that this business operator places the plastic on the market does so in its role as a converter. Therefore, the business operator should use part B.
- It may be the case that a distributer places recycled plastic on the market. The distributer is neither a recycler nor a converter. As the recycled plastic is to be accompanied by the declaration of compliance, the distributer should simply pass on the declaration of compliance received with the plastic.
- As follows from Article 5(2) and (6), recycled plastic materials and articles should not be accompanied by a declaration of compliance. These should be labelled in accordance with Article 15 of Regulation (EC) No 1935/2004. However, in some cases a converter may not be certain whether there are no further conversion stages. In that case the converter could either communicate to its customers that further conversion operations should not be done, or provide a declaration of compliance. In this case section 3.2.1.B would need checking, and further instruction could apply.

Please note that:

- Certain information in declarations of compliance is batch based; the declaration of compliance is therefore unique to each batch and is to be provided with it.
- Article 5(3)-(5) require that containers with recycled plastic are labelled in addition.
- The templates provided in Annex III should be used unmodified, but may be provided by means any medium, whether paper or digitally. Downloadable templates are provided on the website of the Commission in all language versions.

- **Part A: Declaration of compliance to be used by recyclers**

RECYCLERS DECLARATION of COMPLIANCE with REGULATION (EU) 2022/XXX					
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) 2022/1616. 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. Hereby I declare that the contents of this declaration is correct to the best of my knowledge and in compliance with Regulation (EU) 2022/1616.					
Section 1: Identification					
1.1 Recycler		1.2 Recycled product		1.3 Competent authority	
1.1.1 Name	Waste Enders Ltd.	1.2.1 Tradename / designation	WE100RC	1.3.1 Name	Health Agency of Otherland
1.1.2 FCM-RON*	RON0021	1.2.2 Batch No.	34234P4 **Note:** this is not necessarily the same as in 2.2.1, e.g. if an exit batch is split and sold in multiple lots	1.3.2 Address	Rueroad 23 Headcity
1.1.3 Country	Otherland	1.2.3 FCM-RIN*	RIN01234	1.3.3 Country/ region	Partland Otherland
1.1.4 FCM-RFN*	RFN015	1.2.4 Other information	Grade for dilution in post-processing	1.3.4 assigned Registration Number	OLRec76

Section 2: Compliance				
2.1 Basis for authorisation or permission to operate (tick one box only)				
2.1.1	✓	Authorisation Decision	RAN*	unassigned
2.1.2	☐	Recycling scheme	RSN*	
2.1.3	☐	No authorisation or recycling scheme required	**Note:** as long as there are no authorisation decisions a RAN cannot be filled in section 2.1.1; this section should be checked but the RAN number should be left blank or indicate 'unassigned'; field 2.1.3 should not be used in this situation	
2.1.4	☐	Novel technology	NTN*	

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 Important: Fields 2.2.2 to 2.2.4 may be left blank, provided field 2.2.5 is ticked		
Stage**	Decision criteria and outcome(s)	Batch Number(s)
2.2.1 Exit	Blending: labelling required; production traceable: Pass	34234
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			✓ (**Note:** it is voluntary to provide 2.2.2-2.2.4, if this is not provided any competent authority should be able to request this information)
Section 3: Instructions and information to users of the product			
3.1	Instructions to converters		
3.1.1	Maximum recycled content (w/w%)	50%	
3.1.2	Present recycled content (w/w%)	100%	
3.1.3	Restrictions of use***	Not to be used in contact with food if the recycled content exceeds 50%; Final material with 50% recycled content or less not to be used in microwave and conventional ovens;	
3.1.4	Other instructions		
3.2	Instructions to users further down the supply chain, including end users		
3.2.1	Restrictions of use***	Final material with 50% recycled content or less not to be used in microwave and conventional ovens;	
3.2.2	Summary of labelling	not to be used in microwave and conventional ovens	
3.2.3	Other instructions	The restriction of use in field 3.2.1 are only valid if the material is diluted to 50% recycled content; if not diluted, the restrictions in field 3.1.3 should be given to users of the recycled plastic	
Section 4: Signature			
4.1 Signature and company stamp		Signed	
4.2 Name of person signing		Mr P. Aperlove	
4.3 Role/position of person signing		Compliance officer	
4.4 Date and place		10 October 2022	

- * 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					
I, the undersigned, declare in name of Waste Enders Ltd. as identified in section 1.1, that the recycled plastic material identified in section 1.2 was produced in accordance with Regulation (EU) 2022/1616. 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. Hereby I declare that the contents of this declaration is correct to the best of my knowledge and in compliance with Regulation (EU) 2022/1616.					
Section 1 Identification					
1.1 Converter		1.2 Product with recycled plastic		1.3 Competent authority	
1.1.1 Name	Waste Enders Ltd.	1.2.1 Tradename / designation	WEFCRC	1.3.1 Name	Health Agency of Otherland
1.1.2 Address	See RON0021	1.2.2 Batch No.	23488FC	1.3.2 Address	Rueroad 23 Headcity
1.1.3 Country	Otherland	1.2.4 Other info		1.3.3 Country/ region	Partland Otherland
Note: here the address is provided by reference in field 1.1.2 as this is actually the recycler itself that acts as converter by diluting the recycled plastic to 50% - this should be acceptable as the list with recycling operators provides the addresses and is subject to verification.				1.3.4 Reg. number	OLRec76
Section 2: Compliance					
2.1 **note:** traceability to the decontamination installation where the recycled plastic was produced should always be maintained, if the material in the converted plastic originates from multiple installations all corresponding RIN and batch number should be provided in sections 2.1.1. and 2.1.2					
2.1.1	Origin of recycled plastic; RIN numbers			RIN01234	
2.1.2	Batch numbers recycled plastic from decontamination installation			34234	
2.1.3	Maximum recycled content indicated by recycler (Part A, 3.1.1)			50 % w/w	
2.1.4	Actual recycled content of this product			50 % w/w	
2.1.5	Restrictions provided in the Declaration of compliance received from the recycler are met			☐	
2.1.6	Addition of additives or starting substances	☐ Added additives or starting substances comply with Regulation (EU) No 10/2011		✓ 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	✓		
		(B) a final plastic material or article suitable for contact with food without further processing.	☐		
3.2.2	Type or types of food with which it is intended to be put in contact	All foods			
3.2.3	Time and temperature of treatment	not to be used in microwave and			

	and storage in contact with the food	conventional ovens		
3.2.4	The highest food contact surface area to volume ratio for which compliance has been verified	24/dm		
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[2]	-		
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.			☐
Section 4: Signature				
4.1 Signature and company stamp		Signed		
4.2 Name of person signing		Mr P. Aperlove		
4.3 Role/position of person signing		Compliance officer		
4.4 Date and place		10 October 2022		

[2] 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).