Compliance Monitoring Summary Sheet in accordance with Article 26 of Regulation (EU) 2022/1616 for NEXTLOOPP Novel Technology

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

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

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

1. SECTION 1: IDENTIFICATION

The numbers (RIN, RFN, RON, RAN, NTN) referred to in this section shall correspond to the numbers in the Union Register laid down in accordance with Article 24 of Regulation (EU) 2022/1616

1.1 Identification of the recycling installation

Installation name	[Insert unique meaningful local identity of installation, a separate CMSS is required for each decontamination installation]
Applied recycling technology in accordance with Annex I	Not applicable – Novel technology
EU Register number (recycling installation number, 'RIN')	[Insert RIN only]
Facility Address	[Insert facility address]
Recycling Facility Number ('RFN')	[Insert RFN only]
Contact details	[Name, tel: +44, some.one@facility.com - remove blue hyperlink colour] [Multiple contacts]
Position/Role of contact persons	[Insert position e.g. 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.] [Other contact roles]
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, otherwise Not applicable]
Notification date (Article 25(1)(a))	[Insert date installation notification was made]

1.2. Identification of the recycler

Company Name	[Insert company name]
EU Register number (Recycler Operator Number, 'RON')	[Insert RON only]
Address of the head office	[Insert registered/legally responsible address]
Contact details	[Name, tel: +44, some.one@hq.com - remove blue hyperlink colour] [Multiple contacts]
Position/Role of main contact person	[Name: Role, Persons 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, otherwise Not applicable]
Authorisation holder? (Yes/No/ Not applicable)	Not applicable

1.3. Recycling process authorisation Decision or novel technology

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

EU Register number, i.e. Recycling Process Authorisation Number ('RAN'), Novel Technology Number ('NTN')	[Insert NTN only]

B: authorisation holder or novel technology developer –

Name of authorisation holder* / of the technology developer as applicable**	NEXTLOOPP LTD
Address	Suite 5 66 Westbourne Terrace London England W2 3UJ
Contact details	Edward Kosior, tel: +44 870 383 3388, edkosior@nextek.org Paul Marshall, tel: +44 870 383 3388, paul.marshall@nextek.org
Position/Role	Edward Kosior, Managing Director of NEXTLOOPP LTD Paul Marshall, responsible for the administration of the novel technology developer responsibilities

* 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')

EFSA Question number	Not applicable – Novel technology
EFSA Publication date of the opinion	Not applicable
EFSA Publication number (output number)	Not applicable
Confidentiality Decision number	Not applicable
Confidentiality Decision date	Not applicable

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

Name	**Position/Role**	**contact details**
[Name]	[Site Manager]	[Email]
[Name]	[Production Manager]	[Email]
[Name]	[Quality Manager]	[Email]

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

The facility receives bales of PP packaging from authorised waste collection and sorting facilities. Each batch of input material is visually inspected to ensure it is the agreed material type and in accordance with waste documentation before offloading. Each visually accepted batch is placed into storage along with a unique identification code indicating an input batch number, the material type and supplier. Each input batch will have a 20 kg sample taken for material composition analysis. Each batch should meet the agreed compositional specifications with corrective action plans in place to address non-conformances. Input batches can only be used after it has been authorised by the quality department.

[Insert information about bale sorting]

The accept materials from the sorting processes are assessed frequently by taking a 20 kg sample from the accept stream periodically, and a material composition analysis carried out. The analysis should show that no more than 5% of the PP material consists of non-food articles, with corrective action plans in place to address non-conformances.

[Insert information about granulation, washing and drying]

[Insert information about flake sorting]

The flake sorted material is sampled every 6 hours for novel technology contamination monitoring purposes, representing the input batches to the decontamination process.

The flake sorted material enters the first decontamination step in the melt phase. The specialised extruder is operated in accordance with the critical parameters provided in the novel technology initial report, controlling and monitoring temperature, degassing pressure and throughput rate. The molten material is filtered to remove physical contamination and then pelletised. The extrusion process is automated so that if a parameter is out of specification material, material is automatically diverted away from the next decontamination step.

The pelletised material enters the second decontamination step in the solid state. The vacuum vessel is operated in accordance with the critical parameters provided in the novel technology initial report, controlling and monitoring temperature, pressure, and residence time. It is a batch process so that if a parameter is out of specification corrective action plans are in place to correct or extend the decontamination step.

Each output can be up to 30,000 kg, derived from multiple input batches. Each output batch is sampled for quality control tests. Quality control tests include monitoring of volatiles by gas chromatography and other physical properties. An accelerated migration test is performed on each batch to provide customers assurance that the recycled material will be suitable for their purpose. Each output batch sample will be analysed by solvent extraction followed by gas chromatography mass spectrometry for novel technology contamination monitoring purposes, representing the output batches to the decontamination process. A certificate of analysis is provided for each output batch.

Output batches are either transported in containers or tankers, or divided into smaller FIBC units. All units have required labelling applied to them prior to shipping, along with instruction documentation with the shipment.

[Too many characters.]

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

This section is applicable only to authorised processes.

2.2 Recycling operations at the recycling facility

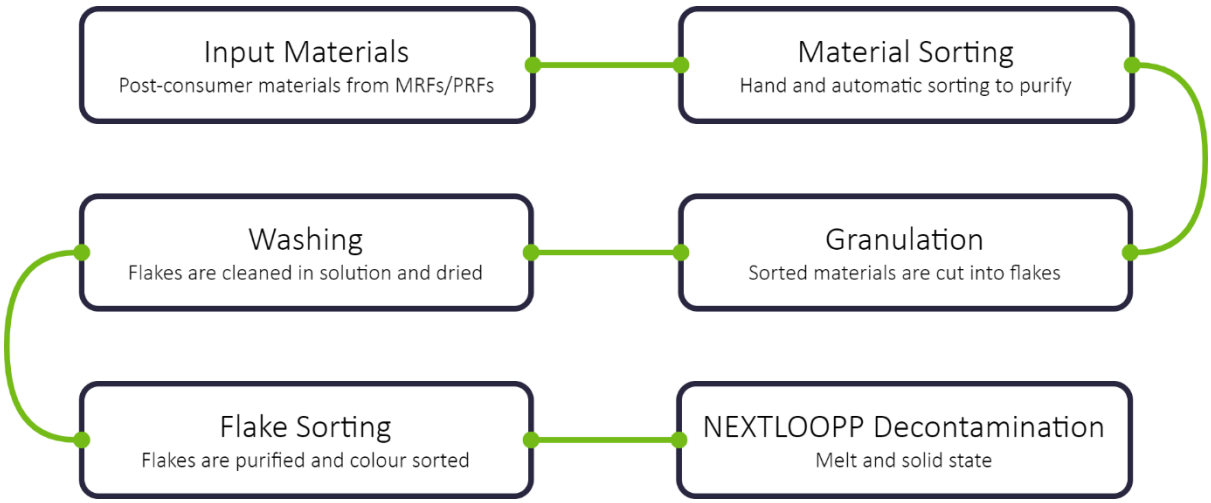
The following information shall be provided in this section:

– A diagram of the main manufacturing stages that are part of the recycling process and which are carried out at the recycling facility ('site diagram');

– A table describing those manufacturing stages and the material streams connecting them carried out at the recycling facility and corresponding to that diagram.

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

[Insert simple block diagram]



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
Stream Number	**Name**	**Description**	**Average Stream size**

2.3. Internal Documents

Provide a comprehensive list of documents relevant to the operation of the process and quality management and other administrative procedures related thereto, as well as

documents related to the authorisation. The documents shall be numbered and these numbers shall be used in section 3 to refer to these documents. The recycler may apply its own numbering system.

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

2.4. Batch definitions

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

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

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

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

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

2.5. Process diagram of the decontamination installation

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

2.6. Control of critical decontamination operations

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

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

2.6.1. Further information on complex control rules, where relevant

2.7. Relevant standard operating procedure for Operation

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

SOP code	Short description	Location)

3. Section 3: Quality Assessment

3.1. List of quality assessment stages

Each QA stage shall be described using the table below:

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

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

– entry stage (the first QA stage where the material enters the facility),

– input stage (where the plastic input enters the decontamination process)

– output stage (where the material leaves the decontamination process)

– exit stage (where the recycled plastic or the recycled plastic materials and articles leave the facility)

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

3.2. Relevant standard operating procedures applied at QA stages

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

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

4. Section 4: Record repository

4.1 Quality assessment recording systems

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

4.2. List of standard operating procedures codes for recording system

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

4.3. Other relevant records/systems

Procedure	**Description / Documentation**