ANNEX II

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

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

1.2. Identification of the recycler

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

1.3. Recycling process 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’)** |  |

B: authorisation holder or novel technology developer –

|  |  |
| --- | --- |
| **Name of authorisation holder\* / of the technology developer\*\* as applicable** |  |
| **Address** |  |
| **Contact details** |  |
| **Position/Role** |  |

\* 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** |  |
| **EFSA Publication date of the opinion** |  |
| **EFSA Publication number (output number)** |  |
| **Confidentiality Decision number** |  |
| **Confidentiality Decision date** |  |

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

|  |  |  |
| --- | --- | --- |
| **Name** | **Position/Role** | **contact details** |
|  |  |  |

2. Section 2: Operation of the recycling installation

2.1. Written Statements

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

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

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

This section is applicable only to authorised processes.

2.2 Recycling operations at the recycling facility

The following information shall be provided in this section:

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

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

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Stage Number** | **Name** | **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 recyclermay 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** |
|  |  |