ANNEX IV

Conformity assessment procedures

PART II

DESCRIPTION OF CONFORMITY ASSESSMENT PROCEDURES

MODULE D1 – QUALITY ASSURANCE OF THE PRODUCTION PROCESS

5. Quality system

5.1. The manufacturer shall implement a quality system which shall ensure compliance of the EU fertilising products with the requirements of this Regulation that apply to them.

5.1.1. The quality system shall cover the quality objectives and the organisational structure with responsibilities and powers of the management with regard to product quality.

5.1.1.1. For compost belonging to CMC 3 and digestate belonging to CMC 5, as defined in Annex II, senior management of the manufacturer's organisation shall:

(a) ensure that sufficient resources (people, infrastructure, equipment) are available to create and implement the quality system;

(b) appoint a member of the organisation's management who shall be responsible for:
- ensuring that quality management processes are established, approved, implemented and maintained;
- reporting to senior management of the manufacturer on the performance of the quality management and any need for improvement;
- ensuring the promotion of awareness of customer needs and legal requirements throughout the manufacturer's organisation, and for making the personnel aware of the relevance and importance of the quality management requirements to meet the legal requirements of this Regulation;
- ensuring that each person whose duties affect the product quality is sufficiently trained and instructed; and
- ensuring the classification of the quality management documents mentioned under point 5.1.4;

(c) conduct an internal audit every year, or sooner than scheduled if triggered by any significant change that may affect the quality of the EU fertilising product; and

(d) ensure that appropriate communication processes are established within and outside the organisation and that communication take place regarding the effectiveness of the quality management.

5.1.2. The quality system shall cover the manufacturing, quality control and quality assurance techniques, processes and systematic actions.

5.1.2.1. For compost belonging to CMC 3 and digestate belonging to CMC 5, as defined in Annex II, the quality system shall ensure compliance with the composting and digestion process criteria specified in that Annex.

5.1.3. The quality system shall cover the examinations and tests to be carried out before, during and after manufacture with a specified frequency.

5.1.3.1. For compost belonging to CMC 3 and digestate belonging to CMC 5, as defined in Annex II, the examinations and tests shall comprise the following elements:

(a) The following information shall be recorded for each batch of input materials:

(i) date of delivery;

(ii) amount by weight (or estimation based on the volume and density);

(iii) identity of the input material supplier;

(iv) input material type;

(v) identification of each batch and delivery location on site. A unique identification code shall be assigned throughout the production process for quality management purposes; and

(vi) in case of refusal, the reasons for the rejection of the batch and where it was sent.

(b) Qualified staff shall carry out a visual inspection of each consignment of input materials and verify compatibility with the specifications of input materials laid down in CMC 3 and CMC 5 in Annex II.

(c) The manufacturer shall refuse any consignment of any given input material where visual inspection raises any suspicion of:

— the presence of hazardous or damageable substances for the composting or digestion process or for the quality of the final EU fertilising product, or

— incompatibility with the specifications laid down in CMC 3 and CMC 5 in Annex II, in particular by presence of plastics leading to exceedence of the limit value for macroscopic impurities.

(d) The staff shall be trained on:

— potential hazardous properties that may be associated with input materials, and

— features that allow hazardous properties and the presence of plastics to be recognised.

(e) Samples shall be taken on output materials, to verify that they comply with the component material specifications for compost and digestate laid down in CMC 3 and CMC 5 in Annex II, and that the properties of the output material do not jeopardise the EU fertilising product's compliance with the relevant requirements in Annex I.

(f) The output material samples shall be taken on a regular basis with at least the following frequency:

Annual input(tonnes)	**Samples / year**
≤ 3 000	1
3 001 – 10 000	2
10 001 – 20 000	3
20 001 – 40 000	4
40 001 – 60 000	5

60 001 – 80 000	6
80 001 – 100 000	7
100 001 – 120 000	8
120 001 – 140 000	9
140 001 – 160 000	10
160 001 – 180 000	11
> 180 000	12

(g) If any tested output material sample fails one or more of the applicable limits specified in the relevant sections of Annexes I and II, the person responsible for quality management referred to in point 5.1.1.1(b) shall:

(i) clearly identify the non-conforming output materials and their storage place,

(ii) analyse the reasons of the non-conformity and take any necessary action to avoid its repetition,

(iii) record in the quality records referred to in point 5.1.4 if reprocessing takes place, or if the output material is eliminated.

5.1.4. The quality system shall cover the manufacturer's quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

5.1.4.1. For compost belonging to CMC 3 and digestate belonging to CMC 5, as defined in Annex II, the quality records shall demonstrate effective control of input materials, production, storage and compliance of input- and output materials with the relevant requirements of this Regulation. Each document shall be legible and available at its relevant place(s) of use, and any obsolete version shall be promptly removed from all places where it is used, or at least identified as obsolete. The quality management documentation shall at least contain the following information:

(a) a title,

(b) a version number,

(c) a date of issue,

(d) the name of the person who issued it,

(e) records about the effective control of input materials,

(f) records about the effective control of the production process,

(g) records about the effective control of the output materials,

(h) records of non-conformities,

(i) reports on all accidents and incidents that occur to the site, their known or suspected causes and actions taken,

(j) records of the complaints expressed by third parties and how they have been addressed,

(k) a record of the date, type and topic of training followed by the persons responsible for the quality of the product,

(l) results of internal audit and actions taken, and

(m) results of external audit review and actions taken.

5.1.5. The quality system shall cover the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

5.1.5.1. For compost belonging to CMC 3 and digestate belonging to CMC 5, as defined in Annex II, the manufacturer shall establish an annual internal audit program in order to verify the compliance of the quality system with the following components:

(a) a procedure that defines the responsibilities and requirements for planning and conducting internal audits, establishing records and reporting results shall be established and documented. A report identifying the non-conformities to the quality scheme shall be prepared and all corrective actions shall be reported. The records of the internal audit shall be annexed to the quality management documentation;

(b) priority shall be given to non-conformities identified by external audits;

(c) each auditor shall not audit his or her own work;

(d) the management responsible for the area audited shall ensure that the necessary corrective actions are taken without undue delay;

(e) internal audit realised in the frame of another quality management system can be taken into account provided that it is completed by an audit of the requirements to this quality system.

5.1.6. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of all the quality management elements set out in points 5.1.1 to 5.1.5.

5.2. The manufacturer shall lodge an application for assessment of his or her quality system with the notified body of his or her choice, for the EU fertilising products concerned. The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his or her name and address as well,

— a written declaration that the same application has not been lodged with any other notified body,

— all relevant information for the EU fertilising product category envisaged,

— the documentation concerning the quality system containing all the elements set out in point 5.1,

— the technical documentation referred to in point 2.

5.3.1. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 5.1.

5.3.2. It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

5.3.3. In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and

product technology concerned, and knowledge of the applicable requirements of this Regulation. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 2 in order to verify the manufacturer's ability to identify the relevant requirements of this Regulation and to carry out the necessary examinations with a view to ensuring compliance of the EU fertilising product with those requirements.

5.3.4. The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

5.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

5.5.1. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

5.5.2. The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 5.1 or whether reassessment is necessary.

5.5.3. It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2019/1009 of the European Parliament and of the Council, Division 5..