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►B REGULATION (EU) 2019/1009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 June 2019

laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003

(Text with EEA relevance)

(OJ L 170, 25.6.2019, p. 1)

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►M6	Commission Delegated Regulation (EU) 2022/1519 of 5 May 2022	L 236	5	13.9.2022
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►C4 Corrigendum, OJ L 91029, 15.12.2025, p. 1 (2025/1421)

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REGULATION (EU) 2019/1009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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(Text with EEA relevance)

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1. This Regulation applies to EU fertilising products.

This Regulation does not apply to:

(a) animal by-products or derived products which are subject to the requirements of Regulation (EC) No 1069/2009 when made available on the market;

(b) plant protection products covered by the scope of Regulation (EC) No 1107/2009.

2. This Regulation does not affect the application of the following legal acts:

(a) Directive 86/278/EEC;

(b) Directive 89/391/EEC;

(c) Directive 91/676/EEC;

(d) Directive 2000/60/EC;

(e) Directive 2001/18/EC;

(f) Regulation (EC) No 852/2004;

(g) Regulation (EC) No 882/2004;

(h) Regulation (EC) No 1881/2006;

(i) Regulation (EC) No 1907/2006;

(j) Regulation (EC) No 834/2007;

(k) Regulation (EC) No 1272/2008;

(l) Regulation (EU) No 98/2013;

(m) Regulation (EU) No 1143/2014;

(n) Regulation (EU) 2016/2031;

(o) Directive (EU) 2016/2284;

(p) Regulation (EU) 2017/625.

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Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) ‘fertilising product’ means a substance, mixture, micro- organism or any other material, applied or intended to be applied on plants or their rhizosphere or on mushrooms or their mycosphere, or intended to constitute the rhizosphere or mycosphere, either on its own or mixed with another material, for the purpose of providing the plants or mushrooms with nutrient or improving their nutrition efficiency;

(2) ‘EU fertilising product’ means a fertilising product which is CE marked when made available on the market;

(3) ‘substance’ means a substance as defined in point 1 of Article 3 of Regulation (EC) No 1907/2006;

(4) ‘mixture’ means a mixture as defined in point 2 of Article 3 of Regulation (EC) No 1907/2006;

(5) ‘micro-organism’ means a micro-organism as defined in point 15 of Article 3 of Regulation (EC) No 1107/2009;

(6) ‘liquid form’ means a suspension or a solution, where a suspension is a two-phase dispersion in which solid particles are maintained in suspension in the liquid phase, and a solution is a liquid that is free of solid particles, or a gel and includes pastes;

(7) ‘solid form’ means form characterised by structural rigidity and resistance to changes of shape or volume and in which the atoms are tightly bound to each other, either in a regular geometric lattice (crystalline solids) or in an irregular manner (an amorphous solid);

(8) ‘% by mass’ means a percentage of the mass of the entire EU fertilising product in the form in which it is made available on the market;

(9) ‘making available on the market’ means any supply of an EU fertilising product for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(10) ‘placing on the market’ means the first making available of an EU fertilising product on the Union market;

(11) ‘manufacturer’ means any natural or legal person who manufactures an EU fertilising product or has an EU fertilising product designed or manufactured, and markets that EU fertilising product under his or her name or trademark;

(12) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his or her behalf in relation to specified tasks;

(13) ‘importer’ means any natural or legal person established within the Union who places an EU fertilising product from a third country on the Union market;

(14) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes an EU fertilising product available on the market;

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(15) ‘economic operators’ means the manufacturer, the authorised representative, the importer and the distributor;

(16) ‘technical specification’ means a document that prescribes technical requirements to be fulfilled by an EU fertilising product, by its production process or by the methods for its sampling and analysis;

(17) ‘harmonised standard’ means harmonised standard as defined in point 1(c) of Article 2 of Regulation (EU) No 1025/2012;

(18) ‘accreditation’ means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;

(19) ‘national accreditation body’ means national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;

(20) ‘conformity assessment’ means the process demonstrating whether the requirements of this Regulation relating to an EU fertilising product have been fulfilled;

(21) ‘conformity assessment body’ means a body that performs conformity assessment activities including testing, certification and inspection;

(22) ‘recall’ means any measure aimed at achieving the return of an EU fertilising product that has already been made available to the end-user;

(23) ‘withdrawal’ means any measure aimed at preventing an EU fertilising product in the supply chain from being made available on the market;

(24) ‘Union harmonisation legislation’ means any Union legislation harmonising the conditions for the marketing of products;

(25) ‘CE marking’ means a marking by which the manufacturer indicates that the EU fertilising product is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.

Article 3

Free movement

1. Member States shall not impede, for reasons relating to composition, labelling or other aspects covered by this Regulation, the making available on the market of EU fertilising products which comply with this Regulation.

2. By way of derogation from paragraph 1 of this Article, a Member State which, on 14 July 2019 benefits from a derogation from Article 5 of Regulation (EC) No 2003/2003 in relation to cadmium content in fertilisers granted in accordance with Article 114(4) TFEU may continue to apply the national limit values for cadmium content in fertilisers which are applicable in that Member State on 14 July 2019 to EU fertilising products until such time as harmonised limit values for cadmium content in phosphate fertilisers which are equal to or lower than the limit values applicable in the Member State concerned on 14 July 2019 are applicable at Union level.

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3. This Regulation shall not prevent Member States from maintaining or adopting provisions for the purpose of protecting human health and the environment which are in compliance with the Treaties, concerning the use of EU fertilising products, provided that those provisions do not require modification of EU fertilising products which are in compliance with this Regulation and do not influence the conditions for making them available on the market.

Article 4

Product requirements

1. An EU fertilising product shall:

(a) meet the requirements set out in Annex I for the relevant product function category;

(b) meet the requirements set out in Annex II for the relevant component material category or categories; and

(c) be labelled in accordance with the labelling requirements set out in Annex III.

2. For any aspects not covered by Annex I or II, EU fertilising products shall not present a risk to human, animal or plant health, to safety or to the environment.

3. By 16 July 2020, the Commission shall publish a guidance document for manufacturers and market surveillance authorities with clear information and examples concerning the visual appearance of the label referred to in Annex III.

Article 5

Making available on the market

EU fertilising products shall only be made available on the market if they comply with this Regulation.

CHAPTER II

OBLIGATIONS OF ECONOMIC OPERATORS

Article 6

Obligations of manufacturers

1. When placing EU fertilising products on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements set out in Annexes I and II.

2. Before placing EU fertilising products on the market, manufacturers shall draw up the technical documentation and carry out the relevant conformity assessment procedure referred to in Article 15, or have it carried out.

Where compliance of an EU fertilising product with the applicable requirements laid down in this Regulation has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.

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3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for 5 years after the EU fertilising product covered by those documents has been placed on the market.

On request, manufacturers shall make a copy of the EU declaration of conformity available to other economic operators.

4. Manufacturers shall ensure that procedures are in place for EU fertilising products that are part of a series production to remain in conformity with this Regulation. Changes in the production process or in the characteristics of those EU fertilising products and changes in the harmonised standards, common specifications referred to in Article 14 or other technical specifications by reference to which conformity of an EU fertilising product is declared or by application of which its conformity is verified shall be adequately taken into account.

When deemed appropriate with regard to the performance of, or the risks presented by, an EU fertilising product, manufacturers shall carry out sample testing of such EU fertilising products made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming EU fertilising products and recalls of such EU fertilising products, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that the packaging of the EU fertilising products which they have placed on the market bears a type number, batch number or other element allowing their identification or, where the EU fertilising products are supplied without packaging, that the required information is provided in a document accompanying each fertilising product.

6. Manufacturers shall indicate their name, registered trade name or registered trade mark and the postal address at which they can be contacted on the packaging of the EU fertilising product or, where the EU fertilising product is supplied without packaging, in a document accompanying the EU fertilising product. The postal address shall indicate a single point at which the manufacturer can be contacted. Such information shall be in a language easily understood by end-users and market surveillance authorities and shall be clear, understandable and legible.

7. Manufacturers shall ensure that EU fertilising products are accompanied by the information required under Annex III. Where an EU fertilising product is supplied in a package, the information shall appear on a label which is affixed to that package. Where the package is too small to contain all the information, the information that cannot be provided on the label shall be provided in a separate leaflet accompanying that package. Such a leaflet shall be regarded as part of the label. Where the EU fertilising product is supplied without packaging, all the information shall be provided in a leaflet. The label and the leaflet shall be accessible for inspection purposes when the EU fertilising product is made available on the market. The information shall be in a language which can be easily understood by end-users, as determined by the Member State concerned, and shall be clear, understandable and intelligible.

8. Manufacturers who consider or have reason to believe that an EU fertilising product which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that EU fertilising product into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where manufacturers consider or have reason to believe that an EU fertilising product which they have placed on the market presents a risk to

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human, animal or plant health, to safety or to the environment, they shall immediately inform the competent national authorities of the Member States in which they made the EU fertilising product available on the market to that effect, giving details, in particular, of any non-compliance and of any corrective measures taken.

9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the EU fertilising product with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by an EU fertilising product which they have placed on the market.

Article 7

Authorised representative

1. A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 6(1) and the obligation to draw up technical documentation referred to in Article 6(2) shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

(a) keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities for 5 years after the EU fertilising product covered by those documents has been placed on the market;

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of an EU fertilising product;

(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by EU fertilising products covered by the authorised representative's mandate.

Article 8

Obligations of importers

1. Importers shall place only compliant EU fertilising products on the market.

2. Before placing an EU fertilising product on the market, importers shall ensure that the appropriate conformity assessment procedure referred to in Article 15 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the EU fertilising product is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 6(5) and (6).

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Where an importer considers or has reason to believe that an EU fertilising product is not in conformity with this Regulation, the importer shall not place the EU fertilising product on the market until it has been brought into conformity. Furthermore, where the EU fertilising product presents a risk to human, animal or plant health, to safety or to the environment, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3. Importers shall indicate their name, registered trade name or registered trade mark and the postal address at which they can be contacted on the packaging of the EU fertilising product or, where the EU fertilising product is supplied without packaging, in a document accompanying the EU fertilising product. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

4. Importers shall ensure that EU fertilising products are accompanied by the information required under Annex III. Where an EU fertilising product is supplied in a package, the information shall appear on a label which is affixed to that package. Where the package is too small to contain all the information, the information that cannot be provided on the label shall be provided in a separate leaflet accompanying that package. Such a leaflet shall be regarded as part of the label. Where the EU fertilising product is supplied without packaging, all the information shall be provided in a leaflet. The label and the leaflet shall be accessible for inspection purposes when the EU fertilising product is made available on the market. The information shall be in a language which can be easily understood by end-users, as determined by the Member State concerned.

5. Importers shall ensure that, while an EU fertilising product is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the requirements set out in Annex I or III.

6. When deemed appropriate with regard to the performance of, or the risks presented by an EU fertilising product, importers shall carry out sample testing of such EU fertilising products made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming EU fertilising products and recalls of such EU fertilising products, and shall keep distributors informed of any such monitoring.

7. Importers who consider or have reason to believe that an EU fertilising product which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that EU fertilising product into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where importers consider or have reason to believe that an EU fertilising product which they have placed on the market presents a risk to human, animal or plant health, to safety or to the environment, they shall immediately inform the competent national authorities of the Member States in which they made the EU fertilising product available on the market to that effect, giving details, in particular, of any non-compliance and of any corrective measures taken.

8. Importers shall, for 5 years after the EU fertilising product has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

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On request, importers shall make a copy of the EU declaration of conformity available to other economic operators.

9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the EU fertilising product with this Regulation in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by an EU fertilising product which they have placed on the market.

Article 9

Obligations of distributors

1. When making an EU fertilising product available on the market distributors shall act with due care in relation to the requirements of this Regulation.

2. Before making an EU fertilising product available on the market distributors shall verify that it is accompanied by the required documents, including the information referred to in Article 6(7) or Article 8 (4) provided in the manner specified therein, in a language which can be easily understood by end-users in the Member State in which the EU fertilising product is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3) respectively.

Where a distributor considers or has reason to believe that an EU fertilising product is not in conformity with this Regulation, the distributor shall not make the EU fertilising product available on the market until it has been brought into conformity. Furthermore, where the EU fertilising product presents a risk to human, animal or plant health, to safety or to the environment, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

3. Distributors shall ensure that, while an EU fertilising product is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the requirements set out in Annex I or III.

4. Distributors who consider or have reason to believe that an EU fertilising product which they have made available on the market is not in conformity with this Regulation shall make sure that the corrective measures necessary to bring that EU fertilising product into conformity, to withdraw it or to recall it, as appropriate, are taken. Furthermore, where distributors consider or have reason to believe that an EU fertilising product which they have made available on the market presents a risk to human, animal or plant health, to safety or to the environment, they shall immediately inform the competent national authorities of the Member States in which they made the EU fertilising product available on the market to that effect, giving details, in particular, of any non-compliance and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the EU fertilising product with this Regulation. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by EU fertilising products which they have made available on the market.

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Article 10

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Regulation, and shall be subject to the obligations of the manufacturer under Article 6, where that importer or distributor places an EU fertilising product on the market under his or her name or trademark or modifies an EU fertilising product already placed on the market in such a way that compliance with this Regulation may be affected.

Article 11

Packaging and repackaging by importers and distributors

Where an importer or distributor packages or repackages an EU fertilising product and is not considered a manufacturer pursuant to Article 10, that importer or distributor shall:

(a) ensure that the packaging bears his or her name, registered trade name or registered trade mark and postal address preceded by the words ‘packaged by’ or ‘repackaged by’; and

(b) keep a specimen of the original information referred to in Article 6 (7) or Article 8(4) at the disposal of the market surveillance authorities for 5 years after having made the EU fertilising product available on the market.

Article 12

Identification of economic operators

1. Economic operators shall, on request, identify the following to the market surveillance authorities:

(a) any economic operator who has supplied them with an EU fertilising product;

(b) any economic operator to whom they have supplied an EU fertilising product.

2. The economic operators shall be able to present the information referred to in the first paragraph for 5 years after they have been supplied with the EU fertilising product and for 5 years after they have supplied the EU fertilising product.

CHAPTER III

CONFORMITY OF EU FERTILISING PRODUCTS

Article 13

Presumption of conformity

1. EU fertilising products which are in conformity with harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, shall be presumed to be in conformity with the requirements set out in Annexes I, II and III covered by those standards or parts thereof.

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2. Tests for verifying the conformity of EU fertilising products with the requirements set out in Annexes I, II and III shall be performed in a reliable and reproducible manner. Tests which are in conformity with harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, shall be presumed to be reliable and reproducible to the extent that the tests are covered by those standards or parts thereof.

Article 14

Common specifications

1. The Commission may adopt implementing acts laying down common specifications for the requirements set out in Annex I, II or III or tests referred to in Article 13(2) where:

(a) those requirements or tests are not covered by harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*;

(b) the Commission observes undue delays in the adoption of requested harmonised standards; or

(c) the Commission has decided in accordance with the procedure referred to in Article 11(5) of Regulation (EU) No 1025/2012 to maintain with restriction or to withdraw the references to the harmonised standards or parts thereof by which those requirements or tests are covered.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 45(3).

2. EU fertilising products which are in conformity with common specifications or parts thereof shall be presumed to be in conformity with the requirements set out in Annexes I, II and III covered by those common specifications or parts thereof.

3. Tests for verifying the conformity of EU fertilising products with the requirements set out in Annexes I, II and III which are in conformity with common specifications or parts thereof shall be presumed to be reliable and reproducible to the extent that the tests are covered by those common specifications or parts thereof.

Article 15

Conformity assessment procedures

1. Conformity assessment of an EU fertilising product with the requirements laid down in this Regulation shall be carried out under the applicable conformity assessment procedure in accordance with Annex IV.

2. Records and correspondence relating to conformity assessment procedures shall be drawn up in the official language or languages of the Member State where the notified body carrying out the conformity assessment procedures is established, or in a language accepted by that body.

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Article 16

EU declaration of conformity

1. The EU declaration of conformity shall state that the fulfilment of the requirements laid down in this Regulation has been demonstrated.

2. The EU declaration of conformity shall have the model structure set out in Annex V, shall contain the elements specified in the relevant modules set out in Annex IV and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the EU fertilising product is placed or made available on the market.

3. Where an EU fertilising product is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall state the Union acts concerned and their publication references. It may be a dossier made up of relevant individual EU declarations of conformity.

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the EU fertilising product with the requirements laid down in this Regulation.

Article 17

General principles of CE marking

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

Article 18

Rules and conditions for affixing the CE marking

1. The CE marking shall be affixed visibly, legibly and indelibly to the packaging of the EU fertilising product or, where the EU fertilising product is supplied without packaging, to a document accompanying the EU fertilising product.

2. The CE marking shall be affixed before the EU fertilising product is placed on the market.

3. The CE marking shall be followed by the identification number of the notified body, where required under Annex IV.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his or her authorised representative.

4. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

Article 19

End-of-waste status

This Regulation lays down criteria in accordance with which material that constitutes waste, as defined in Directive 2008/98/EC, can cease to be waste, if it is contained in a compliant EU fertilising product. In such cases, the recovery operation under this Regulation shall be

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performed before the material ceases to be waste, and the material shall be considered to comply with the conditions laid down in Article 6 of that Directive and therefore to have ceased to be waste from the moment that the EU declaration of conformity was drawn up.

CHAPTER IV

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 20

Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Regulation.

Article 21

Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 26.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 of this Article shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 of this Article to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 22. In addition that body shall have arrangements to cover liabilities arising out of its activities.

4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article 22

Requirements relating to notifying authorities

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

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4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

5. A notifying authority shall safeguard the confidentiality of the information it obtains.

6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Article 23

Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

Article 24

Requirements relating to notified bodies

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2. A conformity assessment body shall be established under the national law of a Member State and have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the EU fertilising products it assesses.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, purchaser, owner or user of fertilising products nor the representative of any of those parties. This shall not preclude the use of fertilising products that are necessary for the operations of the conformity assessment body or the use of fertilising products for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture, marketing or use of fertilising products or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

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5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annex IV and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of EU fertilising products in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out the conformity assessment tasks shall have the following:

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the requirements set out in Annexes I, II and III, of the applicable harmonised standards referred to in Article 13 and common specifications referred to in Article 14 and of the relevant provisions of Union harmonisation legislation and of national legislation;

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

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8. The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annex IV, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under Article 36 and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 25

Presumption of conformity of notified bodies

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* it shall be presumed to comply with the requirements set out in Article 24 in so far as the applicable harmonised standards cover those requirements.

Article 26

Subsidiaries of and subcontracting by notified bodies

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 24 and shall inform the notifying authority accordingly.

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annex IV.

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Article 27

Application for notification

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the EU fertilising product or products for which that body claims to be competent, as well as by an accreditation certificate issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 24.

Article 28

Notification procedure

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 24.

2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and EU fertilising product or products concerned and the accreditation certificate referred to in Article 27(2).

4. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification.

Only such a body shall be considered a notified body for the purposes of this Regulation.

5. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

Article 29

Identification numbers and lists of notified bodies

1. The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.

2. The Commission shall make publicly available the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified.

The Commission shall ensure that the list is kept up to date.

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Article 30

Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 24 or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Article 31

Challenge of the competence of notified bodies

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requiring the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 45(2).

Article 32

Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annex IV.

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Notified bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the EU fertilising product with this Regulation.

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3. Where a notified body finds that the requirements set out in Annex I, II or III, or corresponding harmonised standards, common specifications referred to in Article 14 or other technical specifications, have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate or approval decision.

4. Where, in the course of the monitoring of conformity following the issue of a certificate or an approval decision, a notified body finds that an EU fertilising product no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate or the approval decision, if necessary.

5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates or approval decisions, as appropriate.

Article 33

Appeal against decisions of notified bodies

Member States shall ensure that an appeal procedure against decisions of the notified bodies is available.

Article 34

Information obligation on notified bodies

1. Notified bodies shall inform the notifying authority of the following:

(a) any refusal, restriction, suspension or withdrawal of a certificate or approval decision;

(b) any circumstances, affecting the scope of or conditions for notification;

(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

(d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2. Notified bodies shall provide the other bodies notified under this Regulation carrying out similar conformity assessment activities covering the same EU fertilising products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 35

Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

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Article 36

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Regulation are put in place and properly operated in the form of a sectoral group of notified bodies.

Notified bodies shall participate in the work of that group, directly or by means of designated representatives.

CHAPTER V

UNION MARKET SURVEILLANCE, CONTROL OF EU FERTILISING PRODUCTS ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE

Article 37

Union market surveillance and control of EU fertilising products entering the Union market

Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to EU fertilising products.

Article 38

Procedure at national level for dealing with EU fertilising products presenting a risk

1. Where the market surveillance authorities of one Member State have sufficient reason to believe that an EU fertilising product presents a risk to human, animal or plant health, to safety or to the environment, they shall carry out an evaluation in relation to the EU fertilising product concerned covering all relevant requirements laid down in this Regulation. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the EU fertilising product does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take all appropriate corrective action, within a reasonable period prescribed by the market surveillance authorities and commensurate with the nature of the risk, to bring the EU fertilising product into compliance with those requirements, to withdraw the EU fertilising product from the market or to recall it.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the EU fertilising products concerned that the economic operator has made available on the market throughout the Union.

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4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the EU fertilising product being made available on their national market, to withdraw the EU fertilising product from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant EU fertilising product, the origin of that EU fertilising product, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to any of the following:

(a) failure of the EU fertilising product to meet the requirements set out in Annex I, II or III;

(b) shortcomings in the harmonised standards referred to in Article 13;

(c) shortcomings in the common specifications referred to in Article 14.

6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the EU fertilising product concerned, and, in the event of disagreement with the adopted national measure, of their objections.

7. Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the EU fertilising product from the market, are taken without delay in respect of the EU fertilising product concerned.

9. Obligations of the market surveillance authorities under this Article shall be without prejudice to the possibility for Member States to regulate fertilising products which are not EU fertilising products.

Article 39

Union safeguard procedure

1. Where, on completion of the procedure set out in Article 38(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union law, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act in the form of a decision determining whether the national measure is justified or not.

If the national measure is considered justified, the decision shall order all Member States to take the necessary measures to ensure that the non-compliant EU fertilising product is withdrawn from their market, and to inform the Commission accordingly.

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If the national measure is considered unjustified, the decision shall order the Member State concerned to withdraw that measure.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2. Where the national measure is considered justified and the non-compliance of the EU fertilising product is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 38(5) of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

3. Where the national measure is considered justified and the non-compliance of the EU fertilising product is attributed to shortcomings in the common specifications referred to in point (c) of Article 38(5), the Commission shall, without delay, adopt implementing acts amending or repealing the common specifications concerned.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 45(3).

Article 40

Compliant EU fertilising products which present a risk

1. Where, having carried out an evaluation under Article 38(1), a Member State finds that although an EU fertilising product is in compliance with this Regulation it presents a risk to human, animal or plant health, to safety or to the environment, it shall without delay require the relevant economic operator to take all appropriate measures, within a reasonable period prescribed by the market surveillance authority and commensurate with the nature of the risk, to ensure that the EU fertilising product concerned, when made available on the market, no longer presents that risk, to withdraw the EU fertilising product from the market or to recall it.

2. The economic operator shall ensure that corrective action is taken in respect of all the EU fertilising products concerned that the economic operator has made available on the market throughout the Union.

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the EU fertilising product concerned, the origin and the supply chain of that EU fertilising product, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall adopt an implementing act in the form of a decision determining whether the national measure is justified or not, and where necessary, ordering appropriate measures.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 45(3).

On duly justified imperative grounds of urgency relating to the protection of human, animal or plant health, safety or the environment, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 45(4).

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5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

Article 41

Formal non-compliance

1. Without prejudice to Article 38, where a Member State makes one of the following findings with regard to an EU fertilising product, it shall require the relevant economic operator to put an end to the non-compliance concerned:

(a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 18 of this Regulation;

(b) the identification number of the notified body has been affixed in violation of Article 18 or has not been affixed, where required by Article 18;

(c) the EU declaration of conformity has not been drawn up or has not been drawn up correctly;

(d) the technical documentation is either not available or not complete;

(e) the information referred to in Article 6(6) or Article 8(3) is absent, false or incomplete;

(f) any other administrative requirement provided for in Article 6 or Article 8 is not fulfilled.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the EU fertilising product being made available on the market or ensure that it is recalled or withdrawn from the market.

Obligations of Member States in this respect shall be without prejudice to the possibility for them to regulate fertilising products which are not EU fertilising products.

CHAPTER VI

DELEGATED POWERS AND COMMITTEE PROCEDURE

Article 42

Amendments of Annexes

1. The Commission is empowered to adopt delegated acts in accordance with Article 44 amending Annex I, with the exception of cadmium limit values and the definitions, or other elements relating to the scope, of product function categories, and amending Annexes II, III and IV, for the purposes of adapting those Annexes to technical progress and of facilitating internal market access and free movement for EU fertilising products:

(a) which have the potential to be the subject of significant trade on the internal market, and

(b) for which there is scientific evidence that they:

(i) do not present a risk to human, animal or plant health, to safety or to the environment, and

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(ii) ensure agronomic efficiency.

When adopting delegated acts which introduce new contaminant limit values in Annex I, the Commission shall take into account scientific opinions of the European Food Safety Authority, the European Chemicals Agency or the Commission's Joint Research Centre, as relevant.

Where the Commission adopts delegated acts in order to add or review component material categories so as to include materials that can be considered to be recovered waste or by-products within the meaning of Directive 2008/98/EC, those delegated acts shall explicitly exclude such materials from component material categories 1 and 11 of Annex II to this Regulation.

When adopting delegated acts under this paragraph, the Commission shall prioritise in particular animal by-products, by-products within the meaning of Directive 2008/98/EC, and recovered waste, in particular from the agricultural sector and the agro-food industry, as well as materials and products already lawfully placed on the market in one or more Member States.

2. Without undue delay after 15 July 2019, the Commission shall assess struvite, biochar and ash-based products. If that assessment concludes that the criteria in point (b) of paragraph 1 are fulfilled, the Commission shall adopt delegated acts pursuant to paragraph 1 to include those materials in Annex II.

3. The Commission may only adopt delegated acts pursuant to paragraph 1 amending Annex II to this Regulation to include in the component material categories materials that cease to be waste following a recovery operation if recovery rules in that Annex, adopted no later than the inclusion, ensure that the materials comply with the conditions laid down in Article 6 of Directive 2008/98/EC.

4. The Commission may only adopt delegated acts pursuant to paragraph 1 amending Annex II to add new micro-organisms or strains of micro-organisms, or additional processing methods to the component material category for such organisms after having verified which strains of the additional micro-organism fulfil the criteria in point (b) of paragraph 1, on the basis of the following data:

(a) name of the micro-organism;

(b) taxonomic classification of the micro-organism: genus, species, strain and procurement method;

(c) scientific literature reporting about safe production, conservation and use of the micro-organism;

(d) taxonomic relation to micro-organism species fulfilling the requirements for a Qualified Presumption of Safety as established by the European Food Safety Authority;

(e) information on the production process, including, where relevant, processing methods such as spray drying, fluid-bed drying, static drying, centrifugation, deactivation by heat, filtration and grinding;

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(f) information on the identity and residue levels of residual intermediates, toxins or microbial metabolites in the component material; and

(g) natural occurrence, survival and mobility in the environment.

5. The Commission may only adopt delegated acts pursuant to paragraph 1 amending Annex II to this Regulation to add derived products within the meaning of Regulation (EC) No 1069/2009 in the component material categories where an end point in the manufacturing chain has been determined in accordance with Article 5(2) of that Regulation.

The Commission shall assess such derived products with respect to relevant aspects not taken into account for the purpose of determining an end point in the manufacturing chain in accordance with Regulation (EC) No 1069/2009. If that assessment concludes that the criteria in point (b) of paragraph 1 of this Article are fulfilled, the Commission shall adopt delegated acts pursuant to paragraph 1 of this Article to include those materials in the table in component material category 10 in Part II of Annex II to this Regulation without undue delay whenever such an end point is determined.

6. By 16 July 2024, the Commission shall assess biodegradability criteria for polymers referred to in point 2 of component material category 9 in Part II of Annex II and test methods to verify compliance with those criteria and, where appropriate, shall adopt delegated acts pursuant to paragraph 1 which lay down those criteria.

Such criteria shall ensure that:

(a) the polymer is capable of undergoing physical and biological decomposition in natural soil conditions and aquatic environments across the Union, so that it ultimately decomposes only into carbon dioxide, biomass and water;

(b) the polymer has at least 90 % of the organic carbon converted into carbon dioxide in a maximum period of 48 months after the end of the claimed functionality period of the EU fertilising product indicated on the label, and as compared to an appropriate standard in the biodegradation test; and

(c) the use of polymers does not lead to accumulation of plastics in the environment.

7. By 16 July 2022, the Commission shall adopt delegated acts in accordance with Article 44 supplementing point 3 of component material category 11 in Part II of Annex II to this Regulation by laying down criteria on agronomic efficiency and safety for the use of by-products within the meaning of Directive 2008/98/EC in EU fertilising products. Such criteria shall reflect present product manufacturing practices, technological developments and the latest scientific evidence.

8. The Commission is empowered to adopt delegated acts in accordance with Article 44 amending Annex I, with the exception of cadmium limit values, and Annexes II, III and IV in the light of new scientific evidence. The Commission shall use this empowerment where, based on a risk assessment, an amendment proves necessary to ensure that any EU fertilising product complying with the requirements of this Regulation does not, under normal conditions of use, present a risk to human, animal, or plant health, to safety or to the environment.

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Article 43

Separate delegated acts for separate component material categories

When exercising its power to adopt delegated acts pursuant to Article 42, the Commission shall adopt a separate delegated act in respect of each component material category in Annex II. Those delegated acts shall include any amendments to Annexes I, III and IV which are necessary as a consequence of amendments to Annex II.

Article 44

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 42 shall be conferred on the Commission for a period of five years from 15 July 2019. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 42 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 42 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

Article 45

Committee procedure

1. The Commission shall be assisted by the Committee on fertilising products. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

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3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

CHAPTER VII

AMENDMENTS

Article 46

Amendments to Regulation (EC) No 1069/2009

Regulation (EC) No 1069/2009 is amended as follows:

(1) in Article 5, paragraphs 2 and 3 are replaced by the following:

‘2. For derived products referred to in Articles 32, 35 and 36 which no longer pose any significant risk to public or animal health, an end point in the manufacturing chain may be determined, beyond which they are no longer subject to the requirements of this Regulation.

Those derived products may subsequently be placed on the market without restrictions under this Regulation and shall no longer be subject to official controls in accordance with this Regulation.

The Commission is empowered to adopt delegated acts in accordance with Article 51a supplementing this Regulation by determining an end point in the manufacturing chain, beyond which derived products referred to in this paragraph are no longer subject to the requirements of this Regulation.

3. In the event of risks to public or animal health, Articles 53 and 54 of Regulation (EC) No 178/2002 concerning emergency health measures shall apply *mutatis mutandis* to the derived products referred to in Articles 32, 33 and 36 of this Regulation.

4. Within six months after 15 July 2019, the Commission shall initiate a first assessment of derived products referred to in Article 32 that are already widely used in the Union as organic fertilisers and soil improvers. This assessment shall cover at least the following products: meat meal, bone meal, meat-and-bone meal, hydrolysed proteins of Category 3 materials, processed manure, compost, biogas digestion residues, feather meal, glycerine and other products of Category 2 or 3 materials derived from the production of biodiesel and renewable fuels, as well as petfood, feed and dog chews that have been refused for commercial reasons or technical failures, and derived products from blood of animals, hides and skins, hoofs and horns, guano of bats and birds, wool and hair, feather and downs, and pig bristles. Where the assessment concludes that those derived products no longer pose any significant risk to public or animal health, the Commission shall determine an end point in the manufacturing chain pursuant to paragraph 2 of this Article without undue delay and in any case no later than six months after the assessment is finalised.’;

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(2) the following Article is inserted:

'Article 51a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 5(2) shall be conferred on the Commission for a period of five years from 15 July 2019. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 5(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making (*).

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 5(2) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

(*) OJ L 123, 12.5.2016, p. 1.'

Article 47

Amendments to Regulation (EC) No 1107/2009

Regulation (EC) No 1107/2009 is amended as follows:

(1) in Article 2(1), point (b) is replaced by the following:

'(b) influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient or a plant biostimulant;';

(2) in Article 3, the following point is added:

'34. "plant biostimulant" means a product stimulating plant nutrition processes independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere:

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(a) nutrient use efficiency;

(b) tolerance to abiotic stress;

(c) quality traits;

(d) availability of confined nutrients in soil or rhizosphere.';

(3) in Article 80, the following paragraph is added:

'8. To a product which was granted an authorisation under Article 32(1) based on an application submitted before 15 July 2019, and which after that date falls under the definition in point 34 of Article 3, this Regulation shall continue to apply for the duration provided in the authorisation.'

CHAPTER VIII

TRANSITIONAL AND FINAL PROVISIONS

Article 48

Penalties

Member States shall lay down rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, without delay, notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.

Article 49

Report

By 16 July 2026, the Commission shall submit to the European Parliament and to the Council a report assessing the application of this Regulation and its overall impact as to the attainment of its objectives, including the impact on small and medium-sized enterprises. That report shall include:

(a) an assessment of the functioning of the internal market for fertilising products, including conformity assessment and market surveillance effectiveness and an analysis of the effects of optional harmonisation on production, market shares and trade flows of EU fertilising products and fertilising products placed on the market under national rules;

(b) a review of the limit values for cadmium content in phosphate fertilisers, with a view to assessing the feasibility of reducing these limit values to a lower appropriate level on the basis of available technologies and scientific evidence on cadmium exposure and accumulation in the environment, taking into account environmental factors, in particular in the context of soil and climatic conditions, health factors, as well as socio-economic factors, including considerations of security of supply;

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(c) an assessment of the application of restrictions on levels of contaminants set out in Annex I and an assessment of any new relevant scientific information as regards the toxicity and carcinogenicity of contaminants that becomes available, including the risks from uranium contamination in fertilising products.

The report shall take due account of technological progress and innovation as well as standardisation processes affecting production and use of fertilising products. It shall be accompanied, if appropriate, by a legislative proposal.

Article 50

Biodegradability review

By 16 July 2024, the Commission shall carry out a review in order to assess the possibility of determining biodegradability criteria of mulch films, and the possibility of incorporating them into component material category 9 in Part II of Annex II.

Article 51

Repeal of Regulation (EC) No 2003/2003

Regulation (EC) No 2003/2003 is repealed with effect from 16 July 2022.

References to the repealed Regulation shall be construed as references to this Regulation.

Article 52

Transitional provisions

Member States shall not impede the making available on the market of products which were placed on the market as fertilisers designated ‘EC fertiliser’ in conformity with Regulation (EC) No 2003/2003 before 16 July 2022. However, Chapter V of this Regulation shall apply *mutatis mutandis* to such products.

Article 53

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 16 July 2022.

However:

(a) Articles 4(3), 14, 42, 43, 44, 45, 46 and 47 shall apply from 15 July 2019; and

(b) Articles 20 to 36 shall apply from 16 April 2020.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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ANNEX I

Product Function Categories (PFCs) of EU fertilising products

PART I

DESIGNATION OF PFCS

1. Fertiliser

A. Organic fertiliser

I. Solid organic fertiliser

II. Liquid organic fertiliser

B. Organo-mineral fertiliser

I. Solid organo-mineral fertiliser

II. Liquid organo-mineral fertiliser

C. Inorganic fertiliser

I. Inorganic macronutrient fertiliser

(a) Solid inorganic macronutrient fertiliser

(i) Straight solid inorganic macronutrient fertiliser

(A) Straight solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content

(ii) Compound solid inorganic macronutrient fertiliser

(A) Compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content

(b) Liquid inorganic macronutrient fertiliser

(i) Straight liquid inorganic macronutrient fertiliser

(ii) Compound liquid inorganic macronutrient fertiliser

II. Inorganic micronutrient fertiliser

(a) Straight inorganic micronutrient fertiliser

(b) Compound inorganic micronutrient fertiliser

2. Liming material

3. Soil improver

A. Organic soil improver

B. Inorganic soil improver

4. Growing medium

5. Inhibitor

A. Nitrification inhibitor

B. Denitrification inhibitor

C. Urease inhibitor

6. Plant biostimulant

A. Microbial plant biostimulant

B. Non-microbial plant biostimulant

7. Fertilising product blend

▼B

PART II

REQUIREMENTS RELATED TO PFCS

1. This Part sets out the requirements related to the PFCs to which EU fertilising products belong by virtue of their claimed function.

2. The requirements laid down in this Annex for a given PFC apply to EU fertilising products in all subcategories of that PFC.

3. The claim that an EU fertilising product complies with the function set out in this Annex for the relevant PFC shall be supported by the product's mode of action, the relative content of its various components, or any other relevant parameter.

4. Where compliance with a given requirement (such as absence of a given contaminant) follows certainly and uncontestably from the nature or manufacturing process of an EU fertilising product, that compliance can be presumed in the conformity assessment procedure without verification (such as testing), at the responsibility of the manufacturer.

▼M1

5. Residues of a pharmacologically active substance within the meaning of Regulation (EC) No 470/2009 of the European Parliament and of the Council ([1]) may be present in an EU fertilising product only if that substance is either:

   — included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 ([2]), or

   — has had a reference point for action established in accordance with Commission Regulation (EU) 2019/1871 ([3]), and the substance or its residues are present in the EU fertilising product at a level below that reference point.

5a. An EU fertilising product may contain an active substance within the meaning of Article 2(2) of Regulation (EC) No 1107/2009 only if that EU fertilising product does not have a plant protection function within the meaning of Article 2(1) of that Regulation.

▼B

6. Phosphonates shall not be intentionally added to any EU fertilising product. Unintentional presence of phosphonates shall not exceed 0,5 % by mass.

7. The requirements in this Annex are expressed in oxidised form for certain nutrients. Where compliance is assessed based on the presence of the nutrient in question in its elemental form, the following conversion factors shall be used:

   phosphorus (P) = phosphorus pentoxide (P_2O_5) × 0,436;

   potassium (K) = potassium oxide (K_2O) × 0,830;

   calcium (Ca) = calcium oxide (CaO) × 0,715;

   magnesium (Mg) = magnesium oxide (MgO) × 0,603;

   sodium (Na) = sodium oxide (Na_2O) × 0,742;

   sulphur (S) = sulphur trioxide (SO_3) × 0,400.

([1]) Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

([2]) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

([3]) Commission Regulation (EU) 2019/1871 of 7 November 2019 on reference points for action for non-allowed pharmacologically active substances present in food of animal origin and repealing Decision 2005/34/EC (OJ L 289, 8.11.2019, p. 41).

▼B

8. The requirements in this Annex are expressed by reference to organic carbon (C_{org}). Where compliance is assessed based on organic matter the following conversion factor applies:

   organic carbon (C_{org}) = organic matter × 0,56.

PFC 1: FERTILISER

A fertiliser shall be an EU fertilising product the function of which is to provide nutrients to plants or mushrooms.

PFC 1(A): ORGANIC FERTILISER

1. An organic fertiliser shall contain:

   — organic carbon (C_{org}) and

   — nutrients

   of solely biological origin.

   An organic fertiliser may contain peat, leonardite and lignite, but no other material which is fossilized or embedded in geological formations.

2. Contaminants in an organic fertiliser must not exceed the following limit values:

   (a) cadmium (Cd): 1,5 mg/kg dry matter,

   (b) hexavalent chromium (Cr VI): 2 mg/kg dry matter,

   (c) mercury (Hg): 1 mg/kg dry matter,

   (d) nickel (Ni): 50 mg/kg dry matter,

   (e) lead (Pb): 120 mg/kg dry matter, and

   (f) inorganic arsenic (As): 40 mg/kg dry matter.

   Biuret ($C_2H_5N_3O_2$) must not be present in an organic fertiliser.

3. The copper (Cu) content in an organic fertiliser must not exceed 300 mg/kg dry matter, and the zinc (Zn) content in an organic fertiliser must not exceed 800 mg/kg dry matter.

4. Pathogens in an organic fertiliser must not exceed the limits set out in the following table:

Micro-organisms to be tested	Sampling plans			Limit
	n	c	m	M
Salmonella spp.	5	0	0	Absence in 25 g or 25 ml
►**M10** *Escherichia coli* or enterococci ◄	5	5	0	1 000 in 1 g or 1 ml

   Where:

   n = number of samples to be tested,

   c = number of samples where the number of bacteria expressed in colony forming units (CFU) is between m and M,

   m = threshold value for the number of bacteria expressed in CFU that is considered satisfactory,

   M = maximum value of the number of bacteria expressed in CFU.

PFC 1(A)(I): SOLID ORGANIC FERTILISER

1. A solid organic fertiliser shall be in solid form.

2. A solid organic fertiliser shall contain at least one of the following declared primary nutrients: nitrogen (N), phosphorus pentoxide (P_2O_5) or potassium oxide (K_2O).

   Where a solid organic fertiliser contains only one declared primary nutrient, that nutrient content shall be at least the following:

▼B

(a) 2,5 % by mass of total nitrogen (N),

(b) 2 % by mass of total phosphorus pentoxide (P_2O_5), or

(c) 2 % by mass of total potassium oxide (K_2O).

Where a solid organic fertiliser contains more than one declared primary nutrient, those nutrient contents shall be at least the following:

(a) 1 % by mass of total nitrogen (N),

(b) 1 % by mass of total phosphorus pentoxide (P_2O_5), or

(c) 1 % by mass of total potassium oxide (K_2O).

The sum of those nutrient contents shall be at least 4 % by mass.

3. Organic carbon (C_{org}) content in a solid organic fertiliser shall be at least 15 % by mass.

PFC 1(A)(II): LIQUID ORGANIC FERTILISER

1. A liquid organic fertiliser shall be in liquid form.

2. A liquid organic fertiliser shall contain at least one of the following declared primary nutrients: nitrogen (N), phosphorus pentoxide (P_2O_5) or potassium oxide (K_2O).

Where a liquid organic fertiliser contains only one declared primary nutrient, that nutrient content shall be at least the following:

(a) 2 % by mass of total nitrogen (N),

(b) 1 % by mass of total phosphorus pentoxide (P_2O_5), or

(c) 2 % by mass of total potassium oxide (K_2O).

Where a liquid organic fertiliser contains more than one declared primary nutrient, those nutrient contents shall be at least the following:

(a) 1 % by mass of total nitrogen (N),

(b) 1 % by mass of total phosphorus pentoxide (P_2O_5), or

(c) 1 % by mass of total potassium oxide (K_2O).

The sum of those nutrient contents shall be at least 3 % by mass.

3. Organic carbon (C_{org}) content in a liquid organic fertiliser shall be at least 5 % by mass.

PFC 1(B): ORGANO-MINERAL FERTILISER

1. An organo-mineral fertiliser shall be a co-formulation of:

(a) one or more inorganic fertilisers, as specified in PFC 1(C), and

(b) one or more materials containing:

— organic carbon (C_{org}); and

— nutrients

of solely biological origin.

▼B

An organo-mineral fertiliser may contain peat, leonardite and lignite, but no other material which is fossilized or embedded in geological formations.

2. Where one or more of the inorganic fertilisers in the co-formulation is a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content, as specified in PFC 1(C)(I)(a)(i-ii)(A), an organo-mineral fertiliser shall not contain 16 % or more by mass of nitrogen (N) as a result of ammonium nitrate (NH_4NO_3).

3. Contaminants in an organo-mineral fertiliser must not exceed the following limit values:

(a) cadmium (Cd):

(i) where an organo-mineral fertiliser has a total phosphorus (P) content of less than 5 % phosphorus pentoxide (P_2O_5)-equivalent by mass: 3 mg/kg dry matter, or

(ii) where an organo-mineral fertiliser has a total phosphorus (P) content of 5 % phosphorus pentoxide (P_2O_5)-equivalent or more by mass ('phosphate fertiliser'): 60 mg/kg phosphorus pentoxide (P_2O_5);

(b) hexavalent chromium (Cr VI): 2 mg/kg dry matter;

(c) mercury (Hg): 1 mg/kg dry matter;

(d) nickel (Ni): 50 mg/kg dry matter;

(e) lead (Pb): 120 mg/kg dry matter;

(f) inorganic arsenic (As): 40 mg/kg dry matter; and

(g) biuret ($C_2H_5N_3O_2$): 12 g/kg dry matter.

4. The copper (Cu) content in an organo-mineral fertiliser must not exceed 600 mg/kg dry matter, and the zinc (Zn) content in an organo-mineral fertiliser must not exceed 1 500 mg/kg dry matter. However, these limit values shall not apply where copper (Cu) or zinc (Zn) has been intentionally added to an organo-mineral fertiliser for the purpose of correcting a soil micronutrient deficiency and is declared in accordance with Annex III.

5. Pathogens in an organo-mineral fertiliser must not exceed the limits set out in the following table:

Micro-organisms to be tested	Sampling plans			Limit
	n	c	m	M
Salmonella spp.	5	0	0	Absence in 25 g or 25 ml
►**M10** *Escherichia coli* or enterococci ◄	5	5	0	1 000 in 1 g or 1 ml

Where:

n = number of samples to be tested,

c = number of samples where the number of bacteria expressed in CFU is between m and M,

m = threshold value for the number of bacteria expressed in CFU that is considered satisfactory,

M = maximum value of the number of bacteria expressed in CFU.

▼B

PFC 1(B)(I): SOLID ORGANO-MINERAL FERTILISER

1. A solid organo-mineral fertiliser shall be in solid form.

2. A solid organo-mineral fertiliser shall contain at least one of the following declared primary nutrients: nitrogen (N), phosphorus pentoxide (P_2O_5) or potassium oxide (K_2O).

   Where a solid organo-mineral fertiliser contains only one declared primary nutrient, that nutrient content shall be at least the following:

   (a) 2,5 % by mass of total nitrogen (N), out of which 1 % by mass shall be organic nitrogen (N_{org}),

   (b) 2 % by mass of total phosphorus pentoxide (P_2O_5), or

   (c) 2 % by mass of total potassium oxide (K_2O).

   Where a solid organo-mineral fertiliser contains more than one declared primary nutrient, those nutrient contents shall be at least the following:

   (a) 2 % by mass of total nitrogen (N), out of which 0,5 % by mass shall be organic nitrogen (N_{org}),

   (b) 2 % by mass of total phosphorus pentoxide (P_2O_5), or

   (c) 2 % by mass of total potassium oxide (K_2O).

   The sum of those nutrient contents shall be at least 8 % by mass.

3. Organic carbon (C_{org}) content in a solid organo-mineral fertiliser shall be at least 7,5 % by mass.

4. In a solid organo-mineral fertiliser, each physical unit shall contain organic carbon (C_{org}) and all the nutrients in their declared content. A physical unit refers to one of the component pieces of a product, such as granules or pellets.

PFC 1(B)(II): LIQUID ORGANO-MINERAL FERTILISER

1. A liquid organo-mineral fertiliser shall be in liquid form.

2. A liquid organo-mineral fertiliser shall contain at least one of the following declared primary nutrients: nitrogen (N), phosphorus pentoxide (P_2O_5) or potassium oxide (K_2O).

   Where a liquid organo-mineral fertiliser contains only one declared primary nutrient, that nutrient content shall be at least the following:

   (a) 2 % by mass of total nitrogen (N), out of which 0,5 % by mass shall be organic nitrogen (N_{org}),

   (b) 2 % by mass of total phosphorus pentoxide (P_2O_5), or

   (c) 2 % by mass of total potassium oxide (K_2O).

   Where a liquid organo-mineral fertiliser contains more than one declared primary nutrient, those nutrient contents shall be at least the following:

   (a) 2 % by mass of total nitrogen (N), out of which 0,5 % by mass shall be organic nitrogen (N_{org}),

   (b) 2 % by mass of total phosphorus pentoxide (P_2O_5), or

   (c) 2 % by mass of total potassium oxide (K_2O).

▼B

The sum of those nutrient contents shall be at least 6 % by mass.

3. Organic carbon (C_{org}) content in a liquid organo-mineral fertiliser shall be at least 3 % by mass.

PFC 1(C): INORGANIC FERTILISER

1. An inorganic fertiliser shall be a fertiliser containing or releasing nutrients in a mineral form, other than an organic or organo-mineral fertiliser.

2. In addition to the requirements of either PFC 1(C)(I) or PFC 1(C)(II), an inorganic fertiliser which contains more than 1 % by mass of organic carbon (C_{org}), other than organic carbon (C_{org}) from:

— chelating or complexing agents referred to in point 3 of component material category (CMC) 1 in Part II of Annex II,

▼M6

— nitrification, denitrification or urease inhibiting compounds referred to in point 4 of CMC 1 in Part II of Annex II,

▼B

— coating agents referred to in point 1(a) of CMC 9 in Part II of Annex II,

— urea (CH_4N_2O), or

— calcium cyanamide ($CaCN_2$)

shall meet the requirement that pathogens in an inorganic fertiliser must not exceed the limits set out in the following table:

Micro-organisms to be tested	Sampling plans			Limit
	n	c	m	M
Salmonella spp.	5	0	0	Absence in 25 g or 25 ml
►M10 *Escherichia coli* or enterococci ◄	5	5	0	1 000 in 1 g or 1 ml

Where:

n = number of samples to be tested,

c = number of samples where the number of bacteria expressed in CFU is between m and M,

m = threshold value for the number of bacteria expressed in CFU that is considered satisfactory,

M = maximum value of the number of bacteria expressed in CFU.

PFC 1(C)(I): INORGANIC MACRONUTRIENT FERTILISER

1. An inorganic macronutrient fertiliser shall be aimed at providing plants or mushrooms with one or more of the following macronutrients:

(a) primary macronutrients: nitrogen (N), phosphorus (P) or potassium (K),

(b) secondary macronutrients: calcium (Ca), magnesium (Mg), sodium (Na) or sulphur (S).

2. Contaminants in an inorganic macronutrient fertiliser must not exceed the following limit values:

(a) cadmium (Cd):

(i) where an inorganic macronutrient fertiliser has a total phosphorus (P) content of less than 5 % phosphorus pentoxide (P_2O_5)-equivalent by mass: 3 mg/kg dry matter, or

(ii) where an inorganic macronutrient fertiliser has a total phosphorus (P) content of 5 % phosphorus pentoxide (P_2O_5)-equivalent or more by mass (‘phosphate fertiliser’): 60 mg/kg phosphorus pentoxide (P_2O_5);

▼B

(b) hexavalent chromium (Cr VI): 2 mg/kg dry matter,

(c) mercury (Hg): 1 mg/kg dry matter,

(d) nickel (Ni): 100 mg/kg dry matter,

(e) lead (Pb): 120 mg/kg dry matter,

(f) arsenic (As): 40 mg/kg dry matter,

(g) biuret ($C_2H_5N_3O_2$): 12 g/kg dry matter,

(h) perchlorate (ClO_4-): 50 mg/kg dry matter.

3. The copper (Cu) content in an inorganic macronutrient fertiliser must not exceed 600 mg/kg dry matter, and the zinc (Zn) content in an inorganic macronutrient fertiliser must not exceed 1 500 mg/kg dry matter. However, these limit values shall not apply where copper (Cu) or zinc (Zn) has been intentionally added to an inorganic macronutrient fertiliser for the purpose of correcting a soil micronutrient deficiency and is declared in accordance with Annex III.

PFC 1(C)(I)(a): SOLID INORGANIC MACRONUTRIENT FERTILISER

A solid inorganic macronutrient fertiliser shall be in solid form.

PFC 1(C)(I)(a)(i): STRAIGHT SOLID INORGANIC MACRONUTRIENT FERTILISER

1. A straight solid inorganic macronutrient fertiliser shall have a declared content of:

(a) only one macronutrient (nitrogen (N), phosphorus (P), potassium (K), calcium (Ca), magnesium (Mg), sodium (Na), sulphur (S)), or

(b) only one primary macronutrient (nitrogen (N), phosphorus (P), potassium (K)) and one or more secondary macronutrients (calcium (Ca), magnesium (Mg), sodium (Na), sulphur (S)).

2. Where a straight solid inorganic macronutrient fertiliser contains only one declared macronutrient (nitrogen (N), phosphorus (P), potassium (K), calcium (Ca), magnesium (Mg), sodium (Na), sulphur (S)), that macronutrient content shall be at least the following:

(a) 10 % by mass of total nitrogen (N),

(b) 12 % by mass of total phosphorus pentoxide (P_2O_5),

(c) 6 % by mass of total potassium oxide (K_2O),

(d) 5 % by mass of total magnesium oxide (MgO),

▼M7

(e) 9 % by mass of total calcium oxide (CaO),

▼B

(f) 10 % by mass of total sulphur trioxide (SO_3), or

(g) 1 % by mass of total sodium oxide (Na_2O).

However, the total sodium oxide (Na_2O) content shall not exceed 40 % by mass.

Where a straight solid inorganic macronutrient fertiliser contains only one declared primary macronutrient (nitrogen (N), phosphorus (P), potassium (K)) and one or more declared secondary macronutrients (calcium (Ca), magnesium (Mg), sodium (Na), sulphur (S)):

(a) that primary macronutrient content shall be at least the following:

(i) 3 % by mass of total nitrogen (N),

(ii) 3 % by mass of total phosphorus pentoxide (P_2O_5), or

(iii) 3 % by mass of total potassium oxide (K_2O);

▼B

(b) that or those secondary macronutrient contents shall be at least the following:

(i) 1,5 % by mass of total magnesium oxide (MgO),

(ii) 1,5 % by mass of total calcium oxide (CaO),

(iii) 1,5 % by mass of total sulphur trioxide (SO_3), or

(iv) 1 % by mass of total sodium oxide (Na_2O).

However, the total sodium oxide (Na_2O) content shall not exceed 40 % by mass.

The sum of all declared primary and secondary macronutrient contents shall be at least 18 % by mass.

PFC 1(C)(I)(a)(ii): COMPOUND SOLID INORGANIC MACRONUTRIENT FERTILISER

1. A compound solid inorganic macronutrient fertiliser shall have a declared content of:

(a) more than one primary macronutrient (nitrogen (N), phosphorus (P), potassium (K)), or

(b) more than one secondary macronutrient (calcium (Ca), magnesium (Mg), sodium (Na), sulphur (S)) and no primary macronutrient (nitrogen (N), phosphorus (P), potassium (K)).

2. A compound solid inorganic macronutrient fertiliser shall contain more than one of the following declared macronutrients in at least the following contents:

(a) 3 % by mass of total nitrogen (N),

(b) 3 % by mass of total phosphorus pentoxide (P_2O_5),

(c) 3 % by mass of total potassium oxide (K_2O),

(d) 1,5 % by mass of total magnesium oxide (MgO),

(e) 1,5 % by mass of total calcium oxide (CaO),

(f) 1,5 % by mass of total sulphur trioxide (SO_3), or

(g) 1 % by mass of total sodium oxide (Na_2O).

However, the total sodium oxide (Na_2O) content shall not exceed 40 % by mass.

The sum of all declared macronutrient contents shall be at least 18 % by mass.

PFC 1(C)(I)(a)(i-ii)(A): STRAIGHT OR COMPOUND SOLID INORGANIC MACRONUTRIENT AMMONIUM NITRATE FERTILISER OF HIGH NITROGEN CONTENT

1. A straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content shall be ammonium nitrate (NH_4NO_3)-based and contain 28 % or more by mass of nitrogen (N) as a result of ammonium nitrate (NH_4NO_3).

2. Any matter other than ammonium nitrate (NH_4NO_3) shall be inert towards ammonium nitrate (NH_4NO_3).

3. A straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content shall be made available to the end-user only in packaged form. The package shall be closed in such a way or by such a device that, when it is opened, the fastening, the fastening seal or the package itself is irreparably damaged. Valve sacks may be used.

▼B

4. The oil retention of a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content, following two thermal cycles as described under point 4.1 in Module A1 in Part II of Annex IV, must not exceed 4 % by mass.

5. The detonation resistance of a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content shall be such, that:

   — following five thermal cycles as described under point 4.3 in Module A1 in Part II of Annex IV,

   — in two detonation resistance tests as described under point 4.4 in Module A1 in Part II of Annex IV,

   one or more of the supporting lead cylinders is crushed by less than 5 %.

6. The % by mass of combustible material measured as carbon (C) must not exceed:

   — 0,2 % for a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content having a nitrogen (N) content of at least 31,5 % by mass, and

   — 0,4 % for a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content having a nitrogen (N) content of at least 28 % but less than 31,5 % by mass.

7. A solution of 10 g of a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content in 100 ml of water must have a pH of at least 4,5.

8. Not more than 5 % by mass shall pass through a 1 mm mesh sieve, and not more than 3 % by mass shall pass through a 0,5 mm mesh sieve.

9. The copper (Cu) content shall not be higher than 10 mg/kg, and the chlorine (Cl) content shall not be higher than 200 mg/kg.

PFC 1(C)(I)(b): LIQUID INORGANIC MACRONUTRIENT FERTILISER

A liquid inorganic macronutrient fertiliser shall be in liquid form.

PFC 1(C)(I)(b)(i): STRAIGHT LIQUID INORGANIC MACRONUTRIENT FERTILISER

1. A straight liquid inorganic macronutrient fertiliser shall have a declared content of:

   (a) only one macronutrient (nitrogen (N), phosphorus (P), potassium (K), calcium (Ca), magnesium (Mg), sodium (Na), sulphur (S)), or

   (b) only one primary macronutrient (nitrogen (N), phosphorus (P), potassium (K)) and one or more secondary macronutrients (calcium (Ca), magnesium (Mg), sodium (Na), sulphur (S)).

2. Where a straight liquid inorganic macronutrient fertiliser contains only one declared macronutrient (nitrogen (N), phosphorus (P), potassium (K), calcium (Ca), magnesium (Mg), sodium (Na), sulphur (S)), that macronutrient content shall be at least the following:

   (a) 5 % by mass of total nitrogen (N),

   (b) 5 % by mass of total phosphorus pentoxide (P_2O_5),

   (c) 3 % by mass of total potassium oxide (K_2O),

   (d) 2 % by mass of total magnesium oxide (MgO),

   (e) 6 % by mass of total calcium oxide (CaO),

   (f) 5 % by mass of total sulphur trioxide (SO_3), or

   (g) 1 % by mass of total sodium oxide (Na_2O).

▼B

However, the total sodium oxide (Na_2O) content shall not exceed 40 % by mass.

Where a straight liquid inorganic macronutrient fertiliser contains only one declared primary macronutrient (nitrogen (N), phosphorus (P), potassium (K)), and one or more declared secondary macronutrients (calcium (Ca), magnesium (Mg), sodium (Na), sulphur (S)):

(a) that primary macronutrient content shall be at least the following:

(i) 1,5 % by mass of total nitrogen (N),

(ii) 1,5 % by mass of total phosphorus pentoxide (P_2O_5), or

(iii) 1,5 % by mass of total potassium oxide (K_2O); and

(b) that or those secondary macronutrient contents shall be at least the following:

(i) 0,75 % by mass of total magnesium oxide (MgO),

(ii) 0,75 % by mass of total calcium oxide (CaO),

(iii) 0,75 % by mass of total sulphur trioxide (SO_3), or

(iv) 0,5 % by mass of total sodium oxide (Na_2O).

However, the total sodium oxide (Na_2O) content shall not exceed 20 % by mass.

The sum of all declared primary and secondary macronutrient contents shall be at least 7 % by mass.

PFC 1(C)(I)(b)(ii): COMPOUND LIQUID INORGANIC MACRONUTRIENT FERTILISER

1. A compound liquid inorganic macronutrient fertiliser shall have a declared content of:

(a) more than one primary macronutrient (nitrogen (N), phosphorus (P), potassium (K)), or

(b) more than one secondary macronutrient (calcium (Ca), magnesium (Mg), sodium (Na), sulphur (S)), and no primary macronutrient (nitrogen (N), phosphorus (P), potassium (K)).

2. A compound liquid inorganic macronutrient fertiliser shall contain more than one of the following declared nutrients in at least the following contents:

(a) 1,5 % by mass of total nitrogen (N),

(b) 1,5 % by mass of total phosphorus pentoxide (P_2O_5),

(c) 1,5 % by mass of total potassium oxide (K_2O),

(d) 0,75 % by mass of total magnesium oxide (MgO),

(e) 0,75 % by mass of total calcium oxide (CaO),

(f) 0,75 % by mass of total sulphur trioxide (SO_3), or

(g) 0,5 % by mass of total sodium oxide (Na_2O).

However, the total sodium oxide (Na_2O) content shall not exceed 20 % by mass.

The sum of all declared nutrient contents shall be at least 7 % by mass.

PFC 1(C)(II): INORGANIC MICRONUTRIENT FERTILISER

1. An inorganic micronutrient fertiliser shall be an inorganic fertiliser other than an inorganic macronutrient fertiliser aimed at providing plants or mushrooms with one or more of the following micronutrients: boron (B), cobalt (Co), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo) or zinc (Zn).

▼B

2. Inorganic micronutrient fertilisers shall be made available to the end-user only in packaged form.

3. Contaminants in an inorganic micronutrient fertiliser must not exceed the following limit values:

Contaminant	Limit values of contaminants expressed in mg, in relation to the total micronutrient content expressed in kg (mg/kg of total micronutrient content, which means boron (B), cobalt (Co), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo) and zinc (Zn))
Arsenic (As)	1 000
Cadmium (Cd)	200
Lead (Pb)	600
Mercury (Hg)	100
Nickel (Ni)	2 000

PFC 1(C)(II)(a): STRAIGHT INORGANIC MICRONUTRIENT FERTILISER

1. A straight inorganic micronutrient fertiliser shall have a declared content of not more than one micronutrient.

2. A straight inorganic micronutrient fertiliser shall belong to one of the typologies, and shall comply with the corresponding description and minimum micronutrient content requirements in the following table:

Typology	Description	Minimum micronutrient content
▼M1 Micronutrient salt fertiliser	A chemically obtained straight solid inorganic micronutrient fertiliser containing a mineral ion salt as its essential ingredient	10 % by mass of micronutrient salt fertiliser shall consist of a micronutrient
▼B Micronutrient oxide or hydroxide fertiliser	A chemically obtained straight solid inorganic micronutrient fertiliser containing oxide or hydroxide as its essential ingredient	10 % by mass of a micronutrient oxide or hydroxide fertiliser shall consist of a micronutrient
Micronutrient-based fertiliser	A straight inorganic micronutrient fertiliser combining a micronutrient salt fertiliser with one or more other micronutrient salt fertilisers and/or with a single micronutrient chelate	5 % by mass of a micronutrient-based fertiliser shall consist of a micronutrient
Micronutrient solution fertiliser	An aqueous solution of different forms of a straight inorganic micronutrient fertiliser	2 % by mass of a micronutrient solution fertiliser shall consist of a water-soluble micronutrient
Micronutrient suspension fertiliser	A suspension of different forms of a straight inorganic micronutrient fertiliser	2 % by mass of a micronutrient suspension fertiliser shall consist of a micronutrient

▼B

Typology	Description	Minimum micronutrient content
▼C1		
Micronutrient chelated fertiliser	A water-soluble straight inorganic micronutrient fertiliser in which the declared micronutrient is chemically combined with chelating agent(s) fulfilling the requirements of CMC 1 in Part II of Annex II	— 5 % by mass of a micronutrient chelated fertiliser shall consist of a water-soluble micronutrient, and — at least 80 % of the water-soluble micronutrient shall be chelated by a chelating agent fulfilling the requirements of CMC 1 in Part II of Annex II
▼M1		
UVCB ([1]) micronutrient chelates	A water-soluble straight inorganic micronutrient fertiliser in which the declared micronutrient is chemically combined with chelating agent(s) fulfilling the requirements of CMC 1 in Part II of Annex II	— 5 % by mass of UVCB micronutrient chelates shall consist of water-soluble micronutrient, and at least 80 % of the water-soluble micronutrient shall be chelated (chelated fraction) and at least 50 % of the water soluble micronutrient shall be chelated by specific chelating agents fulfilling the requirements of CMC 1 in Part II of Annex II
▼C1		
Micronutrient complexed fertiliser	A water-soluble straight inorganic micronutrient fertiliser in which the declared micronutrient is chemically combined with complexing agent(s) fulfilling the requirements of CMC 1 in Part II of Annex II	— 5 % by mass of a micronutrient complexed fertiliser shall consist of a water-soluble micronutrient, and — at least 80 % of the water-soluble micronutrient shall be complexed by a complexing agent fulfilling the requirements of CMC 1 in Part II of Annex II

▼B

([1]) UVCB: Substance of unknown or variable composition, complex reaction products or biological materials.

PFC 1(C)(II)(b): COMPOUND INORGANIC MICRONUTRIENT FERTILISER

1. A compound inorganic micronutrient fertiliser shall have a declared content of more than one micronutrient.

2. The sum of all declared micronutrient contents in a compound inorganic micronutrient fertiliser shall be at least:

   (a) 2 % by mass for fertilisers in liquid form;

   (b) 5 % by mass for fertilisers in solid form.

PFC 2: LIMING MATERIAL

1. A liming material shall be an EU fertilising product the function of which is to correct soil acidity.

   A liming material shall contain oxides, hydroxides, carbonates or silicates of the nutrients calcium (Ca) or magnesium (Mg).

2. Contaminants in a liming material must not exceed the following limit values:

   (a) cadmium (Cd): 2 mg/kg dry matter,

   (b) hexavalent chromium (Cr VI): 2 mg/kg dry matter,

   (c) mercury (Hg): 1 mg/kg dry matter,

   (d) nickel (Ni): 90 mg/kg dry matter,

▼B

(e) lead (Pb): 120 mg/kg dry matter,

(f) arsenic (As): 40 mg/kg dry matter.

3. The copper (Cu) content in a liming material must not exceed 300 mg/kg dry matter, and the zinc (Zn) content in a liming material must not exceed 800 mg/kg dry matter.

4. The following parameters determined on the basis of the mass of a liming material shall be met:

(a) minimum neutralising value: 15 (equivalent CaO) or 9 (equivalent HO-),

(b) minimum reactivity: 10 % (hydrochloric acid test) or 50 % after 6 months (incubation test), and

(c) minimum grain size: at least 70 % < 1 mm, except for burnt limes, granulated liming material and chalk (at least 70 % of the liming material shall pass through a 1 mm sieve).

PFC 3: SOIL IMPROVER

A soil improver shall be an EU fertilising product the function of which is to maintain, improve or protect the physical or chemical properties, the structure or the biological activity of the soil to which it is added.

PFC 3(A): ORGANIC SOIL IMPROVER

1. An organic soil improver shall consist of material 95 % of which is of solely biological origin.

An organic soil improver may contain peat, leonardite and lignite, but no other material which is fossilized or embedded in geological formations.

2. Contaminants in an organic soil improver must not exceed the following limit values:

(a) cadmium (Cd): 2 mg/kg dry matter,

(b) hexavalent chromium (Cr VI): 2 mg/kg dry matter,

(c) mercury (Hg): 1 mg/kg dry matter,

(d) nickel (Ni): 50 mg/kg dry matter,

(e) lead (Pb): 120 mg/kg dry matter, and

(f) inorganic arsenic (As): 40 mg/kg dry matter.

3. The copper (Cu) content in an organic soil improver must not exceed 300 mg/kg dry matter, and the zinc (Zn) content in an organic soil improver must not exceed 800 mg/kg dry matter.

4. Pathogens in an organic soil improver must not exceed the limits set out in the following table:

Micro-organisms to be tested	Sampling plans			Limit
	n	c	m	M
Salmonella spp.	5	0	0	Absence in 25 g or 25 ml
►**M10** *Escherichia coli* or enterococci ◄	5	5	0	1 000 in 1 g or 1 ml

▼B

Where:

n = number of samples to be tested,

c = number of samples where the number of bacteria expressed in CFU is between m and M,

m = threshold value for the number of bacteria expressed in CFU that is considered satisfactory,

M = maximum value of the number of bacteria expressed in CFU.

5. An organic soil improver shall contain 20 % or more dry matter.

6. Organic carbon (C_{org}) content in an organic soil improver shall be at least 7,5 % by mass.

PFC 3(B): INORGANIC SOIL IMPROVER

1. An inorganic soil improver shall be a soil improver other than an organic soil improver.

2. Contaminants in an inorganic soil improver must not exceed the following limit values:

(a)	cadmium (Cd):	1,5 mg/kg dry matter,
(b)	hexavalent chromium (Cr VI):	2 mg/kg dry matter,
(c)	mercury (Hg):	1 mg/kg dry matter,
(d)	nickel (Ni):	100 mg/kg dry matter,
(e)	lead (Pb):	120 mg/kg dry matter,
(f)	inorganic arsenic (As):	40 mg/kg dry matter.

3. The copper (Cu) content in an inorganic soil improver must not exceed 300 mg/kg dry matter, and the zinc (Zn) content in an inorganic soil improver must not exceed 800 mg/kg dry matter.

▼M1

4. Pathogens in an inorganic soil improver that contains more than 1 % by mass of organic carbon (C_{org}) must not exceed the limits set out in the following table:

Micro-organisms to be tested	Sampling plans			Limit
	n	c	m	M
Salmonella spp.	5	0	0	Absence in 25 g or 25 ml
►**M10** *Escherichia coli* or enterococci ◄	5	5	0	1 000 in 1 g or 1 ml

Where:

n = number of samples to be tested,

c = number of samples where the number of bacteria expressed in CFU is between m and M,

m = threshold value for the number of bacteria expressed in CFU that is considered satisfactory,

M = maximum value of the number of bacteria expressed in CFU.

▼B

PFC 4: GROWING MEDIUM

1. A growing medium shall be an EU fertilising product other than soil in situ, the function of which is for plants or mushrooms to grow in.

   For the purpose of this point, plants include algae.

2. Contaminants in a growing medium must not exceed the following limit values:

▼B

(a) cadmium (Cd): 1,5 mg/kg dry matter,

(b) hexavalent chromium (Cr VI): 2 mg/kg dry matter,

(c) mercury (Hg): 1 mg/kg dry matter,

(d) nickel (Ni): 50 mg/kg dry matter,

(e) lead (Pb): 120 mg/kg dry matter, and

(f) inorganic arsenic (As): 40 mg/kg dry matter.

▼M1

2a. By derogation from point 2(d), the limit value for nickel (Ni) in a growing medium totally composed by mineral constituents and offered for professional use in horticulture, green roofs or green walls, shall apply to the bioavailable content of the contaminant.

▼B

3. The copper (Cu) content in a growing medium must not exceed 200 mg/kg dry matter, and the zinc (Zn) content in a growing medium must not exceed 500 mg/kg dry matter.

4. Pathogens in a growing medium must not exceed the limits set out in the following table:

Micro-organisms to be tested	Sampling plans			Limit
	n	c	m	M
Salmonella spp.	5	0	0	Absence in 25 g or 25 ml
►**M10** *Escherichia coli* or enterococci ◄	5	5	0	1 000 in 1 g or 1 ml

Where:

n = number of samples to be tested,

c = number of samples where the number of bacteria expressed in CFU is between m and M,

m = threshold value for the number of bacteria expressed in CFU that is considered satisfactory,

M = maximum value of the number of bacteria expressed in CFU.

PFC 5: INHIBITOR

An inhibitor shall be an EU fertilising product the function of which is to improve the nutrient release patterns of a product providing plants with nutrients by delaying or stopping the activity of specific groups of micro-organisms or enzymes.

PFC 5(A): NITRIFICATION INHIBITOR

1. A nitrification inhibitor shall inhibit the biological oxidation of ammoniacal nitrogen (NH_3-N) to nitrite nitrogen (NO_2-), thus slowing the formation of nitrate nitrogen (NO_3-).

2. The ammoniacal nitrogen (NH_3-N) oxidation rate shall be measured by:

(a) ammoniacal nitrogen (NH_3-N) disappearance, or

(b) the sum of nitrite nitrogen (NO_2-) and nitrate nitrogen (NO_3-) production with respect to time.

Compared to a control sample where the nitrification inhibitor has not been added, a soil sample containing the nitrification inhibitor shall show a 20 % reduction in ammoniacal nitrogen (NH_3-N) oxidation rate based on an analysis carried out 14 days after application at the 95 % confidence level.

▼B

PFC 5(B): DENITRIFICATION INHIBITOR

1. A denitrification inhibitor shall inhibit the formation of nitrous oxide (N_2O) by slowing down or blocking the conversion of nitrate (NO_3-) to dinitrogen (N_2) without influencing the nitrification process as described in PFC 5(A).

2. Compared to a control sample where the denitrification inhibitor has not been added, an *in vitro* test containing the denitrification inhibitor shall show a 20 % reduction in rate of the release of nitrous oxide (N_2O) based on an analysis carried out 14 days after application at the 95 % confidence level.

PFC 5(C): UREASE INHIBITOR

1. A urease inhibitor shall inhibit hydrolytic action on urea (CH_4N_2O) by the urease enzyme, primarily targeted to reduce ammonia volatilisation.

2. Compared to a control sample where the urease inhibitor has not been added, an *in vitro* test containing the urease inhibitor shall show a 20 % reduction in the rate of hydrolysis of urea (CH_4N_2O) based on an analysis carried out 14 days after application at the 95 % confidence level.

PFC 6: PLANT BIOSTIMULANT

1. A plant biostimulant shall be an EU fertilising product the function of which is to stimulate plant nutrition processes independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere:

   (a) nutrient use efficiency,

   (b) tolerance to abiotic stress,

   (c) quality traits, or

   (d) availability of confined nutrients in the soil or rhizosphere.

2. Contaminants in a plant biostimulant must not exceed the following limit values:

(a)	cadmium (Cd):	1,5 mg/kg dry matter,
(b)	hexavalent chromium (Cr VI):	2 mg/kg dry matter,
(c)	lead (Pb):	120 mg/kg dry matter,
(d)	mercury (Hg):	1 mg/kg dry matter,
(e)	nickel (Ni):	50 mg/kg dry matter, and
(f)	inorganic arsenic (As):	40 mg/kg dry matter.

3. The copper (Cu) content in a plant biostimulant must not exceed 600 mg/kg dry matter, and the zinc (Zn) content in a plant biostimulant must not exceed 1 500 mg/kg dry matter.

4. The plant biostimulant shall have the effects that are claimed on the label for the plants specified thereon.

▼B

PFC 6(A): MICROBIAL PLANT BIOSTIMULANT

1. A microbial plant biostimulant shall consist of a micro-organism or a consortium of micro-organisms referred to in CMC 7 in Part II of Annex II.

2. Pathogens in a microbial plant biostimulant must not exceed the limits set out in the following table:

Micro-organisms/their toxins, metabolites	Sampling plans		Limit
	n	c	
Salmonella spp.	5	0	Absence in 25 g or 25 ml
Escherichia coli	5	0	Absence in 1 g or 1 ml
Listeria monocytogenes	5	0	Absence in 25 g or 25 ml
Vibrio spp.	5	0	Absence in 25 g or 25 ml
Shigella spp.	5	0	Absence in 25 g or 25 ml
Staphylococcus aureus	5	0	Absence in 25 g or 25 ml
►**M10** Enterococci ◄	5	2	10 CFU/g
Anaerobic plate count unless the microbial plant biostimulant is an aerobic bacterium	5	2	10^5 CFU/g or ml
Yeast and mould count unless the microbial plant biostimulant is a fungus	5	2	1 000 CFU/g or ml

Where:

n = number of units comprising the sample,

c = number of sample units giving values over the defined limit.

3. When the microbial plant biostimulant is in liquid form, the plant biostimulant shall have a pH optimal for contained micro-organisms and for plants.

PFC 6(B): NON-MICROBIAL PLANT BIOSTIMULANT

1. A non-microbial plant biostimulant shall be a plant biostimulant other than a microbial plant biostimulant.

2. Pathogens in a non-microbial plant biostimulant must not exceed the limits set out in the following table:

Micro-organisms to be tested	Sampling plans			Limit
	n	c	m	M
Salmonella spp.	5	0	0	Absence in 25 g or 25 ml
►**M10** *Escherichia coli* or enterococci ◄	5	5	0	1 000 in 1 g or 1 ml

▼B

Where:

n = number of samples to be tested,

c = number of samples where the number of bacteria expressed in CFU is between m and M,

m = threshold value for the number of bacteria expressed in CFU that is considered satisfactory,

M = maximum value of the number of bacteria expressed in CFU.

PFC 7: FERTILISING PRODUCT BLEND

1. A fertilising product blend shall be an EU fertilising product composed of two or more EU fertilising products of PFC 1 to PFC 6 for which the compliance with the requirements of this Regulation of each component EU fertilising product in the blend has been demonstrated in accordance with the conformity assessment procedure applicable to that component EU fertilising product.

2. The blending shall not change the nature of each component EU fertilising product and shall not have an adverse effect on human, animal or plant health, on safety, or on the environment, under reasonably foreseeable conditions of storage or use of the fertilising product blend.

▼M6

2a. An inhibiting compound in a blend shall be present in a concentration, which is within the range of concentrations that ensures the achievement of the reduction rates in the conditions referred to in PFC 5 in Part II of this Annex and, respectively, in point 4 of CMC 1 in Part II of Annex II, at the level of the blend.

▼B

3. ►M6 The manufacturer of the blend shall assess the conformity of the blend with the requirements set out in points 1, 2 and 2a of this PFC, ensure the blend's compliance with the labelling requirements laid down in Annex III, and assume responsibility pursuant to Article 16(4) of this Regulation for the compliance of the blend with the requirements of this Regulation by: ◄

(a) drawing up an EU declaration of conformity for the fertilising product blend in accordance with Article 6(2) of this Regulation, and

(b) being in possession of the EU declaration of conformity of each of the component EU fertilising products.

4. Economic operators making fertilising product blends available on the market shall respect the following provisions of this Regulation with regard to the EU declaration of conformity of each component EU fertilising product as well as of the blend:

(a) Article 6(3) (manufacturers' obligation to keep the EU declaration of conformity);

(b) point (a) of Article 7(2) (authorised representatives' obligation to keep the EU declaration of conformity);

(c) Article 8(8) (importers' obligation to keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities).

▼B

ANNEX II

Component Material Categories (CMCs)

An EU fertilising product shall consist solely of component materials complying with the requirements for one or more of the CMCs listed in this Annex.

The component materials, and the input materials used to produce them, shall not contain any of the substances for which maximum limit values are indicated in Annex I in such quantities as to jeopardise the EU fertilising product's compliance with the applicable requirements of that Annex.

PART I

DESIGNATION OF CMCS

CMC 1: Virgin material substances and mixtures

CMC 2: Plants, plant parts or plant extracts

CMC 3: Compost

CMC 4: Fresh crop digestate

CMC 5: Digestate other than fresh crop digestate

CMC 6: Food industry by-products

CMC 7: Micro-organisms

CMC 8: Nutrient polymers

CMC 9: Polymers other than nutrient polymers

CMC 10: Derived products within the meaning of Regulation (EC) No 1069/2009

CMC 11: By-products within the meaning of Directive 2008/98/EC

▼M2

CMC 12: Precipitated phosphate salts and derivates

▼M3

CMC 13: Thermal oxidation materials and derivates

▼M4

CMC 14: Pyrolysis and gasification materials

▼M5

CMC 15: Recovered high purity materials

▼B

PART II

REQUIREMENTS RELATED TO CMCS

This Part defines the component materials of which EU fertilising products shall solely consist.

CMC 1: VIRGIN MATERIAL SUBSTANCES AND MIXTURES

1. An EU fertilising product may contain substances and mixtures, except [1]:

   (a) waste within the meaning of Directive 2008/98/EC,

   (b) substances or mixtures which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC,

   (c) substances formed from precursors which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC, or mixtures containing such substances,

[1] The exclusion of a material from CMC 1 does not prevent it from being an eligible component material by virtue of another CMC stipulating different requirements. See, for instance, CMC 3 on compost, CMCs 4 and 5 on digestate, CMCs 8 and 9 on polymers, CMC 10 on derived products within the meaning of Regulation (EC) No 1069/2009 or CMC 11 on by-products within the meaning of Directive 2008/98/EC.

▼B

(d) by-products within the meaning of Directive 2008/98/EC,

(e) animal by-products or derived products within the meaning of Regulation (EC) No 1069/2009,

▼M1

(f) polymers, other than:

— polymers that are the result of a polymerisation process that has taken place in nature, independently of the extraction process with which they have been extracted and that have not been chemically modified within the meaning of Article 3(40) of Regulation (EC) No 1907/2006,

— biodegradable polymers, or

— polymers with a water-solubility higher than 2 g/L in the following conditions:

— temperature 20^0 C

— pH 7

— loading: 10 g/1 000 mL

— test time: 24h,

▼B

(g) compost, ►M2 ———————— ◄

(h) digestate,

▼M2

(i) precipitated phosphate salts or derivates, which are recovered from waste or are by-products within the meaning of Directive 2008/98/EC,

▼M3

(j) thermal oxidation materials or derivates which are recovered from waste or are by-products within the meaning of Directive 2008/98/EC, ►M5 ———————— ◄

▼M4

(k) pyrolysis and gasification materials, which are recovered from waste or are by-products within the meaning of Directive 2008/98/EC ►M5 , or ◄

▼M5

(l) ammonium salts, sulphate salts, phosphate salts, elemental sulphur, calcium carbonate or calcium oxide, which are recovered from waste within the meaning of Article 3, point 1, of Directive 2008/98/EC.

▼M6

2. All substances incorporated into the EU fertilising product, on their own or in a mixture, except polymers, shall have been registered pursuant to Regulation (EC) No 1907/2006 ([2]), with a dossier containing:

(a) the information provided for by Annexes VI, VII and VIII to Regulation (EC) No 1907/2006;

(b) a chemical safety report pursuant to Article 14 of Regulation (EC) No 1907/2006 covering the use as a fertilising product,

unless explicitly covered by one of the registration obligation exemptions provided for by Annex IV to Regulation (EC) No 1907/2006 or by points 6, 7, 8, 9 or 10 (only for magnesia) of Annex V to that Regulation.

([2]) In the case of a substance recovered in the European Union, this condition is fulfilled if the substance is the same, within the meaning of point (d)(i) of Article 2(7) of Regulation (EC) No 1907/2006, as a substance registered with a dossier containing the information here indicated, and if information is available to the fertilising product manufacturer within the meaning of point (d)(ii) of Article 2(7) of Regulation (EC) No 1907/2006.

▼B

3. Where the substance or one of the substances in the mixture is intended to enhance the long term availability to plants of micronutrients in the EU fertilising product, that substance shall be either a chelating agent or a complexing agent, and the following rules shall apply:

(a) The chelating agent shall be an organic substance consisting in a molecule which:

(i) has two or more sites that donate electron pairs to a central transition metal cation (zinc (Zn), copper (Cu), iron (Fe), manganese (Mn), magnesium (Mg), calcium (Ca) or cobalt (Co)), and

(ii) is large enough to form a five- or six- membered cyclic structure.

▼M1

The EU fertilising product shall remain stable for at least 3 days in a solution having any pH within the range declared as guaranteeing acceptable stability.

▼B

(b) The complexing agent shall be an organic substance forming a flat or steric structure with one di- or tri- valent transition metal cation (zinc (Zn), copper (Cu), iron (Fe), manganese (Mn) or cobalt (Co)).

The EU fertilising product shall remain stable in water solution at pH 6 and 7 for at least 1 day.

▼M6

4. Where the substance or one of the substances in the mixture is intended to improve the EU fertilising product's nutrient release patterns by delaying or stopping the activity of specific groups of micro-organisms or enzymes, that substance shall be a nitrification, a denitrification or a urease inhibiting compound, and the following rules shall apply:

(a) The nitrification inhibiting compound shall inhibit the biological oxidation of ammoniacal nitrogen (NH_3-N) contained in the EU fertilising product to nitrite nitrogen (NO_2^-), thus slowing the formation of nitrate nitrogen (NO_3^-).

The ammoniacal nitrogen (NH_3-N) oxidation rate shall be measured by either of the following:

(i) ammoniacal nitrogen (NH_3-N) disappearance;

(ii) the sum of nitrite nitrogen (NO_2^-) and nitrate nitrogen (NO_3^-) production with respect to time.

Compared to a control sample where the nitrification inhibiting compound has not been added, a soil sample containing the nitrification inhibiting compound shall show a 20 % reduction in ammoniacal nitrogen (NH_3-N) oxidation rate based on an analysis carried out 14 days after application at the 95 % confidence level.

The nitrification inhibiting compound shall be present in the EU fertilising product in a concentration, which is within the range of concentrations that ensures the achievement of such a reduction.

At least 50 % of the total nitrogen (N) content of the EU fertilising product shall consist of the nitrogen (N) forms ammonium (NH_4^+) and urea (CH_4N_2O).

(b) The denitrification inhibiting compound shall inhibit the formation of nitrous oxide (N_2O) contained in the EU fertilising product by slowing down or blocking the conversion of nitrate (NO_3^-) to dinitrogen (N_2) without influencing the nitrification process as described in PFC 5(A).

▼M6

Compared to a control sample where the denitrification inhibiting compound has not been added, an *in vitro* test containing the denitrification inhibiting compound shall show a 20 % reduction in rate of the release of nitrous oxide (N_2O) based on an analysis carried out 14 days after application at the 95 % confidence level.

The denitrification inhibiting compound shall be present in the EU fertilising product in a concentration, which is within the range of concentrations that ensures the achievement of such a reduction.

(c) The urease inhibiting compound shall inhibit hydrolytic action on urea (CH_4N_2O) contained in the EU fertilising product by the urease enzyme, primarily targeted to reduce ammonia volatilisation.

Compared to a control sample where the urease inhibiting compound has not been added, an in vitro test containing the urease inhibiting compound shall show a 20 % reduction in the rate of hydrolysis of urea (CH_4N_2O) based on an analysis carried out 14 days after application at the 95 % confidence level.

The urease inhibiting compound shall be present in the EU fertilising product in a concentration, which is within the range of concentrations that ensures the achievement of such a reduction.

At least 50 % of the total nitrogen (N) content of the EU fertilising product shall consist of the nitrogen (N) form urea (CH_4N_2O).

▼B

CMC 2: PLANTS, PLANT PARTS OR PLANT EXTRACTS

▼M1

An EU fertilising product may contain plants, plant parts or plant extracts having undergone no processing other than cutting, grinding, milling, sieving, sifting, centrifugation, pressing, drying, frost treatment, freeze-drying, extraction with water, supercritical CO_2 extraction, or fiberisation at a temperature not higher than 100 °C and without any additives except water.

▼B

For the purpose of this point, plants include mushrooms and algae and exclude blue-green algae (cyanobacteria).

CMC 3: COMPOST

1. An EU fertilising product may contain compost obtained through aerobic composting of exclusively one or more of the following input materials:

(a) bio-waste within the meaning of Directive 2008/98/EC resulting from separate bio-waste collection at source;

▼M1

_____

(c) living or dead organisms or parts thereof, which are unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which are extracted from air by any means, except:

(i) materials originating from mixed municipal waste,';

(ii) sewage sludge, industrial sludge or dredging sludge, and

(iii) animal by-products or derived products within the scope of Regulation (EC) No 1069/2009.

▼B

(d) composting additives which are necessary to improve the process performance or the environmental performance of the composting process provided that:

▼M6

(i) the additive complies with the requirement set out in point 2 in CMC 1 and

▼B

(ii) the total concentration of all additives does not exceed 5 % of the total input material weight; or

▼M1

(e) any material listed in points (a) or (c) or in point 1a which:

▼B

(i) has previously been composted or digested, and

(ii) contains no more than 6 mg/kg dry matter of PAH_{16} ([3]).

▼M1

1a. Notwithstanding point 1, an EU fertilising product may contain compost obtained through aerobic composting of Category 2 or Category 3 materials or derived products thereof, in accordance with the conditions set out in Article 32(1) and (2) and in the measures referred to in Article 32(3) of Regulation (EC) No 1069/2009, alone or mixed with input materials referred to in point 1, provided that:

(a) the end point in the manufacturing chain has been determined in accordance with the third subparagraph of Article 5(2) of Regulation (EC) No 1069/2009, and

(b) the conditions in points 2 and 3 are met.

▼B

2. The composting shall take place in a plant:

▼M1

(a) in which production lines for the processing of input materials referred to in points 1 and 1a are clearly separated from production lines for the processing of input materials other than those referred to in points 1 and 1a, and

▼B

(b) where physical contacts between input and output materials are avoided, including during storage.

3. The aerobic composting shall consist of controlled decomposition of biodegradable materials, which is predominantly aerobic and which allows the development of temperatures suitable for thermophilic bacteria as a result of biologically produced heat. All parts of each batch shall be either regularly and thoroughly moved and turned or subject to forced ventilation in order to ensure the correct sanitation and homogeneity of the material. During the composting process, all parts of each batch shall have one of the following temperature-time profiles:

— 70 °C or more for at least 3 days,

— 65 °C or more for at least 5 days,

— 60 °C or more for at least 7 days, or

— 55 °C or more for at least 14 days.

([3]) Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene.

▼B

4. The compost shall contain:

   (a) no more than 6 mg/kg dry matter of PAH_{16} ([4]);

   (b) no more than 3 g/kg dry matter of macroscopic impurities above 2 mm in any of the following forms: glass, metal or plastics; and

   (c) no more than 5 g/kg dry matter of the sum of the macroscopic impurities referred to in point (b).

   From 16 July 2026, the presence of plastics above 2 mm within the maximum limit value referred to in point (b) shall be no more than 2,5 g/kg dry matter. By 16 July 2029 the limit-value of 2,5 g/kg dry matter for plastics above 2 mm shall be re-assessed in order to take into account the progress made with regards to separate collection of bio-waste.

5. The compost shall meet at least one of the following stability criteria:

   (a) Oxygen uptake rate:

      — Definition: an indicator of the extent to which biodegradable organic matter is being broken down within a specified time period. The method is not suitable for material with a content of particle sizes > 10 mm that exceeds 20 %,

      — Criterion: maximum 25 mmol O_2/kg organic matter/h; or

   (b) Self heating factor:

      — Definition: the maximum temperature reached by a compost in standardised conditions as an indicator of the state of its aerobic biological activity,

      — Criterion: minimum Rottegrad III.

▼M10

6. Where compliance with the requirement in point 4(a) follows certainly and uncontestably from the nature or the recovery process of the compost or the manufacturing process of the EU fertilising product, that compliance may be presumed in the conformity assessment procedure without verification (such as testing), under the responsibility of the manufacturer.

▼B

CMC 4: FRESH CROP DIGESTATE

1. An EU fertilising product may contain digestate obtained through anaerobic digestion of exclusively one or more of the following input materials:

   (a) plants or plant parts grown for the production of biogas. For the purpose of this point, plants include algae and exclude blue-green algae (cyanobacteria);

   (b) digestion additives which are needed to improve the process performance or the environmental performance of the digestion process provided that:

▼M6

      (i) the additive complies with the requirement set out in point 2 in CMC 1 and

▼B

      (ii) the total concentration of all additives does not exceed 5 % of the total input material weight; or

   (c) any material referred to in point (a) that has previously been digested.

2. The anaerobic digestion shall take place in a plant:

   (a) in which production lines for the processing of input materials referred to in point 1 are clearly separated from production lines for the processing of input materials other than those referred to in point 1, and

([4]) Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene.

▼B

(b) where physical contacts between input and output materials are avoided, including during storage.

3. The anaerobic digestion shall consist of controlled decomposition of biodegradable materials, which is predominantly anaerobic and at temperatures suitable for mesophilic or thermophilic bacteria. All parts of each batch shall be regularly and thoroughly moved and turned in order to ensure the correct sanitation and homogeneity of the material. During the digestion process, all parts of each batch shall have one of the following temperature-time profiles:

(a) thermophilic anaerobic digestion at 55 °C for at least 24 hours followed by a hydraulic retention time of at least 20 days;

(b) thermophilic anaerobic digestion at 55 °C with a treatment process including pasteurisation as described in point 1 of Section 1 of Chapter I of Annex V to Commission Regulation (EU) No 142/2011 ([5]);

(c) thermophilic anaerobic digestion at 55 °C followed by composting in:

— 70 °C or more for at least 3 days,

— 65 °C or more for at least 5 days,

— 60 °C or more for at least 7 days, or

— 55 °C or more for at least 14 days;

(d) mesophilic anaerobic digestion at 37-40 °C with a treatment process including pasteurisation as described in point 1 of Section 1 of Chapter I of Annex V to Regulation (EU) No 142/2011; or

(e) mesophilic anaerobic digestion at 37-40 °C followed by composting in:

— 70 °C or more for at least 3 days,

— 65 °C or more for at least 5 days,

— 60 °C or more for at least 7 days, or

— 55 °C or more for at least 14 days.

▼M6

3a. An EU fertilising product may contain a solid or liquid fraction, obtained by mechanical separation of a digestate compliant with points 1 to 3.

3b. An EU fertilising product may contain a digestate compliant with points 1 to 3, or a fraction compliant with point 3a, from which all or part of the soluble ammonium and/or of the phosphate has been removed to recover nitrogen and/or phosphorus, without the intention to otherwise modify the digestate or the fraction.

3c. An EU fertilising product may contain a digestate compliant with points 1 to 3 or point 3b, as well as a fraction compliant with point 3a, which have undergone only physical processing to remove water without the intention to otherwise modify the digestate or the fraction.

3d. Additives needed in the post processing of a digestate or a fraction in accordance with points 3a, 3b and 3c may be used provided that:

(a) the additive complies with the requirement set out in point 2 in CMC 1;

([5]) Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).

▼M6

(b) the concentration of the additives needed in each of the processes does not exceed 5 % of the weight of the digestate or fraction used as input in the respective process.

▼B

4. ►M6 The digestate or a fraction referred to in points 3a, 3b and 3c shall meet at least one of the following stability criteria: ◄

(a) Oxygen uptake rate:

— Definition: an indicator of the extent to which biodegradable organic matter is being broken down within a specified time period. The method is not suitable for material with a content of particle sizes > 10 mm that exceeds 20 %;

— Criterion: maximum 25 mmol O_2/kg organic matter/h; or

(b) Residual biogas potential:

— Definition: an indicator of the gas released from a digestate in a 28 day period and measured against the volatile solids contained within the sample. The test is run in triplicate, and the average result is used to demonstrate compliance with the criterion. The volatile solids are those solids in a sample of material that are lost on ignition of the dry solids at 550 °C;

— Criterion: maximum 0,25 l biogas/g volatile solids.

CMC 5: DIGESTATE OTHER THAN FRESH CROP DIGESTATE

1. An EU fertilising product may contain digestate obtained through anaerobic digestion of exclusively one or more of the following input materials:

(a) bio-waste within the meaning of Directive 2008/98/EC resulting from separate bio-waste collection at source;

▼M1

———————

(c) living or dead organisms or parts thereof, which are unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which are extracted from air by any means, except:

(i) materials originating from mixed municipal waste,';

(ii) sewage sludge, industrial sludge or dredging sludge, and

(iii) animal by-products or derived products within the scope of Regulation (EC) No 1069/2009.

▼B

(d) digestion additives which are necessary to improve the process performance or the environmental performance of the digestion process provided that:

▼M6

(i) the additive complies with the requirement set out in point 2 in CMC 1 and

▼B

(ii) the total concentration of all additives does not exceed 5 % of the total input material weight; or

▼M1

(e) any material listed in points (a) or (c) or in point 1a which:

▼B

(i) has previously been composted or digested, and

(ii) contains no more than 6 mg/kg dry matter of PAH_{16} ([6]).

([6]) Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene.

▼M1

1a. Notwithstanding point 1, an EU fertilising product may contain digestate obtained through anaerobic digestion of Category 2 or Category 3 materials or derived products thereof, in accordance with the conditions set out in Article 32(1) and (2) and in the measures referred to in Article 32(3) of Regulation (EC) No 1069/2009, alone or mixed with input materials referred to in point 1, provided that:

(a) the end point in the manufacturing chain has been determined in accordance with the third subparagraph of Article 5(2) of Regulation (EC) No 1069/2009, and

(b) the conditions in points 2 and 3 are met.

▼B

2. The anaerobic digestion shall take place in a plant:

▼M1

(a) in which production lines for the processing of input materials referred to in points 1 and 1a are clearly separated from production lines for the processing of input materials other than those referred to in points 1 and 1a, and

▼B

(b) where physical contacts between input and output materials are avoided, including during storage.

3. The anaerobic digestion shall consist of controlled decomposition of biodegradable materials, which is predominantly anaerobic and at temperatures suitable for mesophilic or thermophilic bacteria. All parts of each batch shall be regularly and thoroughly moved and turned in order to ensure the correct sanitation and homogeneity of the material. During the digestion process, all parts of each batch shall have one of the following temperature-time profiles:

(a) thermophilic anaerobic digestion at 55 °C for at least 24 hours followed by a hydraulic retention time of at least 20 days;

(b) thermophilic anaerobic digestion at 55 °C with a treatment process including pasteurisation as described in point 1 of Section 1 of Chapter I of Annex V to Regulation (EU) No 142/2011;

(c) thermophilic anaerobic digestion at 55 °C followed by composting in:

— 70 °C or more for at least 3 days,

— 65 °C or more for at least 5 days,

— 60 °C or more for at least 7 days, or

— 55 °C or more for at least 14 days;

(d) mesophilic anaerobic digestion at 37-40 °C with a treatment process including pasteurisation as described in point 1 of Section 1 of Chapter I of Annex V to Regulation (EU) No 142/2011; or

(e) mesophilic anaerobic digestion at 37-40 °C followed by composting in:

— 70 °C or more for at least 3 days,

— 65 °C or more for at least 5 days,

— 60 °C or more for at least 7 days, or

— 55 °C or more for at least 14 days.

▼M6

3a. An EU fertilising product may contain a solid or liquid fraction obtained by mechanical separation of a digestate compliant with points 1 to 3.

▼M6

3b. An EU fertilising product may contain a digestate compliant with points 1 to 3, or a fraction compliant with point 3a, from which all or part of the soluble ammonium and/or of the phosphate has been removed to recover nitrogen and/or phosphorus, without the intention to otherwise modify the digestate or the fraction.

3c. An EU fertilising product may contain a digestate compliant with points 1 to 3 or point 3b, as well as a fraction compliant with point 3a, which have undergone only physical processing to remove water without the intention to otherwise modify the digestate or the fraction.

3d. Additives needed in the post processing of a digestate or a fraction in accordance with points 3a, 3b and 3c may be used provided that:

(a) the additive complies with the requirement set out in point 2 in CMC 1;

(b) the concentration of the additives needed in each of the processes does not exceed 5 % of the weight of the digestate or fraction used as input in the respective process.

4. The digestate or the fraction referred to in points 3a, 3b and 3c shall not contain more than 6 mg/kg dry matter of PAH_{16} ([7]).

▼B

5. ►M6 The digestate or the fraction referred to in points 3a, 3b and 3c shall contain: ◄

(a) no more than 3 g/kg dry matter of macroscopic impurities above 2 mm in any of the following forms: glass, metal or plastics; and

(b) no more than 5 g/kg dry matter of the sum of the macroscopic impurities referred to in point (a).

From 16 July 2026, the presence of plastics above 2 mm within the maximum limit value referred to in point (a) shall be no more than 2,5 g/kg dry matter. By 16 July 2029 the limit-value of 2,5 g/kg dry matter for plastics above 2 mm shall be re-assessed in order to take into account the progress made with regards to separate collection of bio-waste.

6. ►M6 The digestate or the fraction referred to in points 3a, 3b and 3c shall meet at least one of the following stability criteria: ◄

(a) Oxygen uptake rate:

— Definition: an indicator of the extent to which biodegradable organic matter is being broken down within a specified time period. The method is not suitable for material with a content of particle sizes > 10 mm that exceeds 20 %.

— Criterion: maximum 25 mmol O_2/kg organic matter/h; or

(b) Residual biogas potential:

— Definition: an indicator of the gas released from a digestate in a 28 day period and measured against the volatile solids contained within the sample. The test is run in triplicate, and the average result is used to demonstrate compliance with the criterion. The volatile solids are those solids in a sample of material that are lost on ignition of the dry solids at 550 °C.

([7]) Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene.

▼B

— Criterion: maximum 0,25 l biogas/g volatile solids.

▼M10

7. Where compliance with the requirement in point 4 follows certainly and uncontestably from the nature or the recovery process of the digestate, or the fraction thereof, or the manufacturing process of the EU fertilising product, that compliance may be presumed in the conformity assessment procedure without verification (such as testing), under the responsibility of the manufacturer.

▼B

CMC 6: FOOD INDUSTRY BY-PRODUCTS

1. An EU fertilising product may contain component material consisting of one of the following substances:

(a) food industry factory lime, i.e. a material from the food processing industry obtained by carbonation of organic matter, using exclusively burnt lime from natural sources;

(b) molasses, i.e. a viscous by-product of the refining of sugarcane or sugar beets into sugar;

(c) vinasse, i.e. a viscous by-product of the fermentation process of molasses into ethanol, ascorbic acid or other products;

(d) distillers grains, i.e. by-products resulting from the production of alcoholic beverages;

(e) plants, plant parts or plant extracts having undergone only heat treatment or heat treatment in addition to processing methods referred to in CMC 2; or

(f) lime from drinking water production, i.e. residue which is released by production of drinking water from groundwater or surface water and consists, mainly, of calcium carbonate.

▼M6

2. All substances incorporated into the EU fertilising product, on their own or in a mixture, shall comply with the requirement set out in point 2 in CMC 1.

▼B

CMC 7: MICRO-ORGANISMS

An EU fertilising product belonging to PFC 6(A) may contain micro-organisms, including dead or empty-cell micro-organisms and non-harmful residual elements of the media on which they were produced, which:

— have undergone no other processing than drying or freeze-drying; and

— are listed in the following table:

Azotobacter spp.
Mycorrhizal fungi
Rhizobium spp.
Azospirillum spp.

CMC 8: NUTRIENT POLYMERS

1. An EU fertilising product may contain polymers exclusively made up of monomer substances complying with the criteria set out in points 1 and 2 of CMC 1, where the purpose of the polymerisation is to control the release of nutrients from one or more of the monomer substances.

▼B

2. At least 60 % of the polymers shall be soluble in a phosphate buffer solution with a pH of 7,5 at 100 °C.

3. The final degradation products shall be only ammonia (NH_3), water and carbon dioxide (CO_2).

4. The polymers shall not contain more than 600 ppm of free formaldehyde.

CMC 9: POLYMERS OTHER THAN NUTRIENT POLYMERS

1. An EU fertilising product may contain polymers other than nutrient polymers only in cases where the purpose of the polymer is:

(a) to control the water penetration into nutrient particles and thus the release of nutrients (in which case the polymer is commonly referred to as a ‘coating agent’),

(b) to increase the water retention capacity or wettability of the EU fertilising product, or

(c) to bind material in an EU fertilising product belonging to PFC 4.

▼M11

1a. An EU fertilising product belonging to PFC 3 may contain a polymer in the form of a mulch film.

▼B

2. From 16 July 2026, the polymers referred to in point 1(a) and (b) shall comply with the biodegradability criteria established by delegated acts referred to in Article 42(6). In the absence of such criteria, an EU fertilising product placed on the market after that date shall not contain such polymers.

▼M11

2a. The polymer in a mulch film referred to in point 1a shall comply with the biodegradability criteria set out in Appendix 2 to this Annex.

▼B

3. ►M11 For the polymers referred to in point 1(a) and (b) and in point 1a, neither the polymer, nor its degradation by-products, shall show any overall adverse effect on animal or plant health, or on the environment, under reasonably foreseeable conditions of use in the EU fertilising product. The polymers referred to in point 1(a) and (b) and point 1a shall pass a plant growth acute toxicity test, an earthworm acute toxicity test and a nitrification inhibition test with soil micro-organisms as follows: ◄

(a) In the plant growth acute toxicity test, the germination rate and the plant biomass of the tested plant species grown on the soil exposed to the test material shall be more than 90 % of the germination rate and the plant biomass of the same plant species grown on corresponding blank soil not exposed to the test material.

The results shall be considered to be valid only if in the controls (i.e. blank soil):

— the seedling emergence is at least 70 %;

— the seedlings do not exhibit visible phytotoxic effects (e.g. chlorosis, necrosis, wilting, leaf and stem deformations) and the plants exhibit only normal variation in growth and morphology for that particular species;

▼B

— the mean survival of emerged control seedlings is at least 90 % for the duration of the study; and

— environmental conditions for a particular species are identical and growing media contain the same amount of soil matrix, support media, or substrate from the same source.

(b) In the earthworm acute toxicity test, the observed mortality and the biomass of surviving earthworms in a soil exposed to the test material shall not differ by more than 10 % compared to those from the corresponding blank soil not exposed to the test material. The results shall be considered to be valid, if:

— the percent mortality observed in the control (i.e. blank soil) is less than 10 %, and

— the average loss of biomass (mean weight) of the worms in the blank soil does not exceed 20 %.

(c) In the nitrification inhibition test with soil micro-organisms, the nitrite formation in soil exposed to the test material shall be more than 90 % of those from the corresponding blank soil not exposed to the test material. The results shall be considered to be valid, if the variation between replicate control samples (blank soil) and test samples is less than 20 %.

▼M11

4. The polymer referred to in point 1a shall pass an earthworm chronic toxicity test so that:

(a) after an incubation period of 28 days, the observed mortality and the biomass of surviving adult earthworms in a soil exposed to the test material shall not differ by more than 10 % compared to those from the corresponding blank soil not exposed to the test material;

(b) after an incubation period of 56 days, the observed number of offspring in a soil exposed to the test material shall not differ by more than 10 % compared to those from the corresponding blank soil not exposed to the test material.

The results shall be considered to be valid only if in the controls (i.e. blank soil):

(a) after an incubation period of 28 days, the observed adult mortality is no more than 10 %;

(b) after an incubation period of 56 days each replicate (containing 10 adults) produces at least 30 offspring; and

(c) the coefficient of variation of reproduction is no more than 30 %.

Appendix 2

Biodegradability criteria of polymers for mulch films referred to in section CMC 9, point 1a

1. The biodegradability of polymers in mulch films referred to in section CMC 9, point 1a, shall be demonstrated in the following two environmental compartments:

▼**M11**

(a) compartment 1: soil;

(b) compartment 2: fresh, estuarine or marine water, or water sediment interface.

2. The polymer shall achieve:

(a) in compartment 1:

(1) ultimate degradation of at least 90 % relative to the degradation of the reference material within 24 months plus the functionality period of the product as indicated on the label; or

(2) mineralisation of at least 90 %, measured as evolved CO_2, over a maximum of 24 months plus the functionality period of the product as indicated on the label:

(b) in compartment 2:

(1) ultimate degradation of at least 30 % relative to the degradation of the reference material in 12 months; or

(2) ultimate degradation of at least 90 % relative to the degradation of the reference material in 24 months plus the functionality period of the product as indicated on the label.

3. To demonstrate the biodegradability criteria in point 2(a), one of the following test methods shall be used:

(a) EN ISO 17556:2019. Plastics – Determination of the ultimate aerobic biodegradability of plastic materials in soil by measuring the oxygen demand in a respirometer or the amount of carbon dioxide evolved;

(b) ISO/CD 23517:2021. Plastics – Soil biodegradable materials for mulch films for use in agriculture and horticulture;

(c) ASTM D5988-96:2018. Standard Test Method for Determining Aerobic Biodegradation in Soil of Plastic Materials.

4. When there is no phase transition (glass transition or melting transition) between 25 °C and 37 °C, the temperature during testing in accordance with points 3(a), (b) and (c) may be adjusted at 37 °C.

In such a case, the relevant criterion in point 2(a) shall be considered as being demonstrated if the polymer achieves:

(a) at least 45 % ultimate degradation or mineralisation as referred to in point 2(a) in a separate test at 25 °C in 10 months, whereby degradation or mineralisation shall be progressing, and the plateau phase shall not have been reached, unless the degradation or mineralisation is at least 90 %; and

▼M11

(b) one of the following criteria:

(i) ultimate degradation of at least 90 % relative to degradation of the reference material within 10 months plus the functionality period of the product as indicated on the label; or

(ii) mineralisation of at least 90 %, measured as evolved CO_2, over a maximum of 10 months plus the functionality period of the product as indicated on the label.

5. To demonstrate the biodegradability criteria in point 2(b), one of the following test methods shall be used:

(a) EN/ISO 14851:2019 Determination of the ultimate aerobic biodegradability of plastic materials in an aqueous medium. Method by measuring the oxygen demand in a closed respirometer;

(b) EN/ISO 14852:2021 Determination of the ultimate aerobic biodegradability of plastic materials in an aqueous medium. Method by analysis of evolved carbon dioxide;

(c) ASTM D6691:2018 Standard Test Method for Determining Aerobic Biodegradation of Plastic Materials in the Marine Environment by a Defined Microbial Consortium or Natural Sea Water Inoculum;

(d) EN/ISO 19679:2020 Plastics – Determination of aerobic biodegradation of non-floating plastic materials in a seawater/sediment interface – Method by analysis of evolved carbon dioxide;

(e) EN/ISO 18830:2017 Plastics – Determination of aerobic biodegradation of non-floating plastic materials in a seawater/sandy sediment interface – Method by measuring the oxygen demand in closed respirometer.

6. Polymers may be tested in any of the following forms:

(a) in the form of the film placed on the market;

(b) in a powder form of the milled film.

7. The following materials may be used as reference materials:

(a) positive controls: biodegradable materials such as micro-crystalline cellulose powder, ashless cellulose filters or poly-β-hydroxybutyrate;

(b) negative controls: non-biodegradable polymers such as polyethylene or polystyrene.

▼M8

CMC 10: DERIVED PRODUCTS WITHIN THE MEANING OF REGULATION (EC) No 1069/2009

1. An EU fertilising product may contain derived products within the meaning of Regulation (EC) No 1069/2009 having reached the end point in the manufacturing chain as determined in accordance with that Regulation, and which are listed in the following table and as specified therein:

▼**M8**

No	The component material	Additional requirements
	Processed manure fulfilling the conditions in Article 3 (d) of Delegated Regulation (EU) 2023/1605 ([1])	1.1. An EU fertilising product may contain processed manure only if it was treated to reach an end point according to Regulation (EC) No 1069/2009 at the latest 36 months before signing the EU declaration of conformity for the respective product and the material underwent additional processing so that at least one of the following conditions is met: (a) at least 90 % by dry mass of the material can pass through a sieve with a mesh of 0,25 mm; (b) the material has been granulated under pressure, pelletised, dried at temperatures higher than 100 °C or has undergone any equivalent process that ensures that the content of viable weed seeds and plant propagules in the processed manure is no more than 3 units/l; or (c) the material fulfills at least one of the stability criteria set out in point 5 of CMC 3. 1.2. The material referred to in point 1.1 may undergo one or more of the following additional processes: (a) the processing methods referred to in CMC 2; (b) biological treatment involving nitrification and denitrification; (c) mechanical separation of the solid and liquid fractions; (d) processes to recover nutrients and/or organic carbon, without the intention to otherwise modify the material; (e) chemical processing to modify the pH without the intention to otherwise modify the material; (f) physical processing to remove water and to transform the material into powder, granules or pellets, without the intention to otherwise modify the material. 1.3. Additives needed in the processing referred to in points 1.1 and 1.2 may be used provided that: (a) the additive complies with the requirement set out in point 2 of CMC 1; (b) the concentration of the additives needed in each of the processes does not exceed 5 % of the weight of the processed manure or fraction used as input in the respective process. 1.4. The processed manure shall contain no more than 6 mg/kg dry matter of PAH_{16} ([2]). 1.5. The processed manure to be used as component material in an EU fertilising product shall be stored in a way that protects it against precipitation and direct sunlight.

([1]) Commission Delegated Regulation (EU) 2023/1605 of 22 May 2023 supplementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council as regards the determination of end points in the manufacturing chain of certain organic fertilisers and soil improvers (OJ L 198, 8.8.2023, p. 1).

([2]) Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a] anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h] anthracene and benzo[ghi]perylene.

▼M8

2. Where compliance with the requirement set out in point 1.4 follows certainly and uncontestably from the nature or the processing of the component material or the manufacturing process of the EU fertilising product, such compliance may be presumed in the conformity assessment procedure without verification (such as testing), under the responsibility of the manufacturer.

▼B

CMC 11: BY-PRODUCTS WITHIN THE MEANING OF DIRECTIVE 2008/98/EC

1. An EU fertilising product may contain by-products within the meaning of Directive 2008/98/EC, except ([8]):

(a) animal by-products or derived products within the meaning of Regulation (EC) No 1069/2009,

▼M1

(b) polymers, other than:

— polymers that are the result of a polymerisation process that has taken place in nature, independently of the extraction process with which they have been extracted and that have not been chemically modified within the meaning of Article 3(40) of Regulation (EC) No 1907/2006,

— biodegradable polymers, or

— polymers with a water-solubility higher than 2 g/L in the following conditions:

— temperature 20^0 C

— pH 7

— loading: 10 g/1 000 mL

— test time: 24h,

▼B

(c) compost, ►M2 ———— ◄

(d) digestate,

▼M2

(e) precipitated phosphate salts or derivates, which are recovered from waste or are by-products within the meaning of Directive 2008/98/EC,

▼M3

(f) thermal oxidation materials or derivates, which are recovered from waste or are by-products within the meaning of Directive 2008/98/EC, ►M5 ———— ◄

▼M4

(g) pyrolysis and gasification materials, which are recovered from waste or are by-products within the meaning of Directive 2008/98/EC ►M5 , or ◄

▼M5

(h) ammonium salts, sulphate salts, phosphate salts, elemental sulphur, calcium carbonate or calcium oxide, which are recovered from waste within the meaning of Article 3, point 1, of Directive 2008/98/EC.

([8]) The exclusion of a material from CMC 11 does not prevent it from being an eligible component material by virtue of another CMC stipulating different requirements. See, for instance, CMC 3 on compost, CMCs 4 and 5 on digestate, CMCs 8 and 9 on polymers or CMC 10 on derived products within the meaning of Regulation (EC) No 1069/2009.

▼M6

2. The by-products shall comply with the requirement set out in point 2 in CMC 1.

▼B

3. From 16 July 2022, the by-products shall comply with the criteria established by delegated act referred to in Article 42(7). An EU fertilising product placed on the market after that date shall not contain by-products referred to in point 1 which do not comply with such criteria.

▼M2

CMC 12: PRECIPITATED PHOSPHATE SALTS AND DERIVATES

1. An EU fertilising product may contain precipitated phosphate salts obtained through precipitation exclusively from one or more of the following input materials:

   (a) wastewaters and sewage sludge from municipal wastewater treatment plants, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;

   (b) wastewaters and sludge from processing of foods, beverages, pet foods, animal feeds, or dairy products, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009, unless processing steps involved contact with biocidal products within the meaning of Article 3(1), point (a), of Regulation (EU) No 528/2012 of the European Parliament and of the Council ([9]) other than those defined as product-type 4 of main group 1 of Annex V to that Regulation;

   (c) bio-waste within the meaning of Article 3, point 4, of Directive 2008/98/EC resulting from separate bio-waste collection at source, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;

   (d) processing residues within the meaning of Article 2, point (t), of Directive 2009/28/EC of the European Parliament and of the Council ([10]) from the production of bioethanol and biodiesel derived from materials referred to in this point, sub-points (b), (c) and (e);

   (e) living or dead organisms or parts thereof, which are unprocessed or processed only by manual, mechanical or gravitational means, dissolution in water, flotation, extraction with water, steam distillation or heating solely to remove water, or which are extracted from air by any means, except ([11]):

      — materials originating from mixed municipal waste,

      — sewage sludge, industrial sludge or dredging sludge,

      — animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;

   (f) substances and mixtures, other than ([11]):

([9]) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

([10]) Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC (OJ L 140 5.6.2009, p. 16).

([11]) The exclusion of an input material from a sub-point does not prevent it from being an eligible input material by virtue of another sub-point.

▼M2

— those referred to in sub-points (a) to (e),

— waste within the meaning of Article 3,point 1, of Directive 2008/98/EC,

— substances or mixtures which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC,

— substances formed from precursors which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC, or mixtures containing such substances,

— non-biodegradable polymers,

— animal by-products or derived products within the scope of Regulation (EC) No 1069/2009.

In addition, precipitated phosphate salts shall be obtained through precipitation from any input material referred to in sub-points (a) to (f), or a combination thereof, processed by manual, mechanical or gravitational means, solid-liquid fractionation using biodegradable polymers, dissolution in water, flotation, extraction with water, steam distillation or heating solely to remove water, thermal hydrolysis, anaerobic digestion or composting. The temperature under such processes shall not be raised above 275 °C.

2. The precipitation process shall take place under controlled conditions in a reactor. In addition, only input materials, which are not contaminated with other material streams, or input materials, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009, which have been unintentionally contaminated with other material streams in a one-off incident resulting only in trace levels of exogenous compounds shall be used.

In the plant where the precipitation takes place, physical contacts between input and output materials shall be avoided after the precipitation process, including during storage.

3. The precipitated phosphate salts shall contain:

(a) a minimum phosphorus pentoxide (P_2O_5) content of 16 % of the dry matter content;

(b) a maximum organic carbon (C_{org}) content of 3 % of the dry matter content;

(c) no more than 3 g/kg dry matter of macroscopic impurities above 2 mm in any of the following forms: organic matter, glass, stones, metal and plastics;

▼**M2**

(d) no more than 5 g/kg dry matter of the sum of the macroscopic impurities referred to in sub-point (c).

4. An EU fertilising product may contain derivates from precipitated phosphate salts produced through one or more chemical manufacturing steps that react the precipitated phosphate salts with materials referred to in sub-point 1(f) that are consumed in or used for chemical processing.

The derivate manufacturing process shall be executed so as to intentionally modify the chemical composition of the precipitated phosphate salts.

5. The precipitated phosphate salts used for the derivates shall comply with points 1, 2 and 3.

6. Notwithstanding point 1, an EU fertilising product may contain precipitated phosphate salts obtained through precipitation from Category 2 or Category 3 materials or derived products thereof, in accordance with the conditions set out in Article 32(1) and (2) of Regulation (EC) No 1069/2009 and in the measures referred to in Article 32(3) of that Regulation, alone or mixed with input materials referred to in point 1, provided that both of the following conditions are fulfilled:

(a) the end point in the manufacturing chain has been determined in accordance with Article 5(2), third subparagraph, of Regulation (EC) No 1069/2009;

(b) the conditions in points 2 and 3 are met.

An EU fertilising product may also contain derivates from such precipitated phosphate salts, obtained in accordance with the conditions set out in point 4.

7. In the plant where the precipitation takes place, the production lines for the processing of input materials allowed for the precipitated phosphate salts and derivates referred to in points 1, 4 and 6 shall be clearly separated from production lines for the processing of other input materials.

8. Where for the PFC of an EU fertilising product containing or consisting of precipitated phosphate salts or derivates or both there are no requirements regarding *Salmonella* spp., *Escherichia coli* or ►**M10** enterococci ◄ in Annex I, those pathogens shall not exceed the limits set out in the following table:

Micro-organisms to be tested	Sampling plans			Limit
	n	c	m	M
Salmonella spp.	5	0	0	Absence in 25 g or 25 ml
►**M10** *Escherichia coli* or enterococci ◄	5	5	0	1 000 in 1 g or 1 ml

Where:

n = number of samples to be tested,

c = number of samples where the number of bacteria expressed in CFU is between m and M,

m = threshold value for the number of bacteria expressed in CFU that is considered satisfactory,

M = maximum value of the number of bacteria expressed in CFU.

▼M2

9. Pathogens in an EU fertilising product containing or consisting of precipitated phosphate salts obtained from materials referred to in sub-point 1(a) or derivates from such precipitated phosphate salts or both shall not exceed the limits set out in the following table:

Micro-organisms to be tested	Sampling plans			Limit
	n	c	m	M
Clostridium perfringens	5	5	0	100 CFU in 1 g or 1 ml
Ascaris sp. viable eggs	5	0	0	Absence in 25 g or 25 ml

Where:

n = number of samples to be tested,

c = number of samples where the number of bacteria expressed in CFU is between m and M,

m = threshold value for the number of bacteria expressed in CFU that is considered satisfactory,

M = maximum value of the number of bacteria expressed in CFU.

10. The requirements set out in points (8) and (9), as well as the requirements for *Salmonella* spp., *Escherichia coli* or ►**M10** enterococci ◄ set in the corresponding PFC of an EU fertilising product consisting only of precipitated phosphate salts or derivates or both shall not apply when those precipitated phosphate salts or all of the biogenic input materials used in the precipitation process have undergone one of the following processes:

(a) pressure sterilisation through the heating to a core temperature of more than 133 °C for at least 20 minutes at an absolute pressure of at least 3 bars, whereby the pressure must be produced by the evacuation of all air in the sterilisation chamber and the replacement of the air by steam (‘saturated steam’);

(b) processing in a pasteurisation or hygienisation unit that reaches a temperature of 70 °C for at least one hour.

11. Precipitated phosphate salts obtained from materials referred to in sub-point 1(a) and derivates obtained from such precipitated phosphate salts shall have no more than 6 mg/kg dry matter of PAH_{16} ([12])

12. The sum of aluminium (Al) and iron (Fe) in precipitated phosphate salts or derivates shall not exceed 10 % of the dry matter of the precipitated phosphate salts or the derivates.

▼M6

13. The precipitated phosphate salts or derivates shall comply with the requirement set out in point 2 in CMC 1.

▼M2

14. For the purposes of points 3, 11 and 12, the dry matter of precipitated phosphate salts and derivates shall be measured using vacuum drying at 40 °C until constant weight to avoid the loss of crystal-bound water.

▼M10

15. Where compliance with one of the requirements in points 11 and 12 follows certainly and uncontestably from the nature or the recovery process of the precipitated phosphate salt or the derivate, or the manufacturing process of the EU fertilising product, that compliance may be presumed in the conformity assessment procedure without verification (such as testing), under the responsibility of the manufacturer.

([12]) Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene.

▼M3

CMC 13: THERMAL OXIDATION MATERIALS OR DERIVATES

1. An EU fertilising product may contain thermal oxidation materials obtained through thermochemical conversion under non-oxygen-limiting conditions exclusively from one or more of the following input materials:

(a) living or dead organisms or parts thereof, which are unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which are extracted from air by any means, except ([13]):

— materials originating from mixed municipal waste,

— sewage sludge, industrial sludge or dredging sludge, and

— animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;

(b) vegetable waste from the food processing industry and fibrous vegetable waste from virgin pulp production and from production of paper from virgin pulp, if not chemically modified;

(c) bio-waste fraction resulting from subsequent treatment operations of bio-waste separately collected for recycling within the meaning of Directive 2008/98/EC, for which incineration delivers the best environmental outcome in accordance with Article 4 of that Directive other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;

(d) materials resulting from a controlled microbial or thermochemical conversion process using exclusively the input materials referred to in sub-points (a), (b), and (c);

(e) sewage sludge from municipal wastewater treatment plants, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;

(f) materials from the independently operated treatment of waste water not covered by Council Directive 91/271/EEC ([14]) from food processing, pet food, feed, milk and drink industries, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;

(g) waste within the meaning of Directive 2008/98/EC with the exception ([13]) of:

— input materials referred to in sub-points (a) to (f),

— hazardous waste within the meaning of Article 3, point 2 of Directive 2008/98/EC,

— materials originating from mixed municipal waste,

— bio-waste within the meaning of Article 3, point 4 of Directive 2008/98/EC resulting from separate bio-waste collection at source, and

— animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;

([13]) The exclusion of an input material from a sub-point does not prevent it from being an eligible input material by virtue of another sub-point.

([14]) Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment (OJ L 135, 30.5.1991, p. 40).

▼M3

(h) auxiliary fuels (natural gas, liquefied gas, natural gas condensate, process gases and components thereof, crude-oil, coal, coke as well as their derived materials), when used to process input materials referred to in sub-points (a) to (g);

(i) substances which are used in production processes of the iron and steel industry; or

(j) substances and mixtures, with the exception ([13]) of:

— input materials referred to in sub-points (a) to (i),

— waste within the meaning of Article 3, point 1 of Directive 2008/98/EC,

— substances or mixtures which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC,

— substances formed from precursors which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC, or mixtures containing such substances, and

— animal by-products or derived products within the scope of Regulation (EC) No 1069/2009.

2. Notwithstanding point 1, an EU fertilising product may contain thermal oxidation materials obtained through thermochemical conversion under non-oxygen-limiting conditions from Category 2 or Category 3 materials or derived products thereof, in accordance with the conditions set out in Article 32(1) and (2) of Regulation (EC) No 1069/2009 and in the measures referred to in Article 32(3) of that Regulation, alone or mixed with input materials referred to in point 1, provided that both of the following conditions are fulfilled:

(a) the end point in the manufacturing chain has been determined in accordance with Article 5(2), third subparagraph of Regulation (EC) No 1069/2009;

(b) the conditions in points 3, 4, and 5 are met.

3. The thermal oxidation shall take place under non-oxygen limiting conditions in such a way that the gas resulting from the thermochemical conversion process is raised, after the last injection of combustion air, in a controlled and homogeneous fashion and even under the most unfavourable conditions to a temperature of at least 850 °C for at least 2 seconds. These conditions shall apply to all input materials, with the exemption of:

(a) the input materials referred to in points 1(a), (b) and (h), or resulting from a controlled microbial or thermochemical conversion process using exclusively those materials, and

(b) input materials referred to in point 2,

for which a temperature of at least 450 °C for at least 0,2 seconds shall apply;

▼M3

4. The thermal oxidation shall take place in an incineration or combustion chamber. The chamber may only process input materials, which are not contaminated with other material streams, or input materials, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009, which have been contaminated with other material streams unintentionally in a one-off incident resulting only in trace levels of exogenous compounds.

   All of the following conditions shall be met in the plant, where the thermal oxidation takes place:

   (a) the production lines for the processing of input materials referred to in points 1 and 2 shall be clearly separated from production lines for the processing of other input materials,

   (b) the input material shall be oxidised in such a way that the total organic carbon (C_{org}) content of the resulting slags and bottom ashes is less than 3 % by dry matter of the material,

   (c) physical contact between input and output materials shall be avoided after the thermochemical conversion process, including during storage.

5. The thermal oxidation materials shall be ashes or slags, and have no more than:

   (a) 6 mg/kg dry matter of PAH_{16} ([15]),

   (b) 20 ng WHO toxicity equivalents ([16]) of PCDD/F ([17])/kg dry matter.

6. An EU fertilising product may contain derivates from thermal oxidation materials that have been produced from the input materials referred to in points 1 and 2 that meet the conditions of point 5 and that have been manufactured by a thermochemical conversion process in accordance with points 3 and 4.

   The derivate manufacturing process shall be executed so as to intentionally modify the chemical composition of the thermal oxidation material.

   The derivate manufacturing process shall be of the following nature:

   (a) chemical manufacturing: derivates are produced through one or more chemical manufacturing steps that react thermal oxidation materials with input materials referred to in sub-point 1(j) that are consumed in or used for chemical processing whereas non-biodegradable polymers shall not be used;

   (b) thermochemical manufacturing: derivates are produced through one or more manufacturing steps that thermochemically react thermal oxidation materials with reactants referred to in points 1 and 2 that are consumed in or used for chemical processing.

([15]) Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k] fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene.

([16]) van den Berg M., L.S. Birnbaum, M. Denison, M. De Vito, W. Farland, et al. (2006) The 2005 World Health Organization Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds. Toxicological sciences: an official journal of the Society of Toxicology 93:223-241. doi:10.1093/toxsci/kfl055.

([17]) Polychlorinated dibenzo-p-dioxins and dibenzofurans.

▼M3

Thermal oxidation materials that display one or more of the hazardous properties listed in Annex III to Directive 2008/98/EC shall not be mixed or reacted, either with waste, substances or materials with the intention of reducing hazardous substances to levels below the limit values for the hazardous property as laid down in Annex III to that Directive. Using a mass balance approach, manufacturers that use thermal oxidation materials with hazardous properties must demonstrate the removal or transformation of the contaminants to levels below the limit values laid down in Annex III to Directive 2008/98/EC.

7. Contaminants in an EU fertilising product containing or consisting of thermal oxidation materials or derivates must not exceed the following limit values:

(a) total chromium (Cr): 400 mg/kg dry matter, if the thermal oxidation materials or derivates are from input materials referred to in sub-points 1(e), (g) or (i);

(b) thallium (Tl): 2 mg/kg dry matter, if the thermal oxidation materials or derivates are from input materials referred to in sub-points 1(e), (g), (h) or (i);

The chlorine (Cl^-) content shall not be higher than 30 g/kg of dry matter. However, this limit value shall not apply to EU fertilising products produced through a manufacturing process where a Cl^- containing compound has been added with the intention of producing alkali metal salts or alkaline earth metal salts, and is declared in accordance with Annex III;

The vanadium (V) content shall not be higher than 600 mg/kg dry matter if the thermal oxidation materials or derivates are from input materials referred to in sub-points 1(g) or (i).

▼M6

8. The thermal oxidation materials or derivates shall comply with the requirement set out in point 2 in CMC 1.

▼M10

9. Where compliance with one of the requirements in points 5 and 7 follows certainly and uncontestably from the nature or the recovery process of the thermal oxidation material or the derivate, or the manufacturing process of the EU fertilising product, that compliance may be presumed in the conformity assessment procedure without verification (such as testing), under the responsibility of the manufacturer.

▼M4

CMC 14: PYROLYSIS AND GASIFICATION MATERIALS

1. An EU fertilising product may contain pyrolysis or gasification materials obtained through the thermochemical conversion under oxygen-limiting conditions of exclusively one or more of the following input materials:

(a) living or dead organisms or parts thereof, which are unprocessed or processed only by manual, mechanical or gravitational means, by

▼M4

dissolution in water, by flotation, extraction with water, by steam distillation or by heating solely to remove water, or which are extracted from air by any means, except ([18]):

— materials originating from mixed municipal waste,

— sewage sludge, industrial sludge or dredging sludge, and

— animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;

(b) vegetable waste from the food processing industry and fibrous vegetable waste from virgin pulp production and from production of paper from virgin pulp, if not chemically modified;

(c) processing residues within the meaning of Article 2, point (t) of Directive 2009/28/EC from the production of bioethanol and biodiesel, derived from materials referred to in sub-points (a), (b) and (d);

(d) bio-waste within the meaning of Article 3, point 4 of Directive 2008/98/EC resulting from separate bio-waste collection at source, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009 or

(e) pyrolysis or gasification additives which are necessary to improve the process performance or the environmental performance of the pyrolysis or gasification process, provided that those additives are consumed in chemical processing or used for such processing and that total concentration of all additives do not exceed 25 % of the fresh matter of the total input material, with the exception ([18]) of:

— input materials referred to in sub-points (a) to (d),

— waste within the meaning of Article 3, point 1 of Directive 2008/98/EC,

— substances or mixtures which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC,

— substances formed from precursors which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC, or mixtures containing such substances,

— non-biodegradable polymers, and

— animal by-products or derived products within the scope of Regulation (EC) No 1069/2009.

An EU fertilising product may contain pyrolysis or gasification materials obtained through thermochemical conversion under oxygen-limiting conditions of any input material referred to in sub-points (a) to (e), or combination thereof, processed by manual, mechanical or gravitational means, by solid-liquid fractionation using biodegradable polymers, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, by composting or by anaerobic digestion.

2. The thermochemical conversion process shall take place under oxygen-limiting conditions in such a way that a temperature of at least 180 °C for at least two seconds is reached in the reactor.

The pyrolysis or gasification reactor may only process input materials, which are not contaminated with other material streams, or input materials, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009, which have been contaminated with other material streams unintentionally in a one-off incident resulting only in trace levels of exogenous compounds.

([18]) The exclusion of an input material from a sub-point does not prevent it from being an eligible input material by virtue of another sub-point.

▼M4

In the plant where the pyrolysis or gasification takes place, physical contacts between input and output materials shall be avoided after the thermochemical process, including during storage.

3. The pyrolysis and gasification materials shall have a molar ratio of hydrogen (H) to organic carbon (H/C_{org}) of less than 0,7, with testing to be performed in the dry and ash-free fraction for materials that have an organic carbon (C_{org}) content of less than 50 %. They shall have no more than:

   (a) 6 mg/kg dry matter of PAH_{16} ([19]),

   (b) 20 ng WHO toxicity equivalents ([20]) of PCDD/F ([21])/kg dry matter,

▼M6

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▼M4

4. Notwithstanding point 1, an EU fertilising product may contain pyrolysis or gasification materials obtained through the thermochemical conversion under oxygen-limiting conditions of Category 2 or Category 3 materials or derived products thereof, in accordance with the conditions set out in Article 32(1) and (2) of Regulation (EC) No 1069/2009 and in the measures referred to in Article 32(3) of that Regulation, alone or mixed with input materials referred to in point 1, provided that both of the following conditions are fulfilled:

   (a) the end point in the manufacturing chain has been determined in accordance with Article 5(2), third subparagraph of Regulation (EC) No 1069/2009;

   (b) the conditions in points 2 and 3 are met.

5. In the plant where the pyrolysis or gasification takes place, the production lines for the processing of input materials referred to in points 1 and 4 shall be clearly separated from production lines for the processing of other input materials.

6. In an EU fertilising product containing or consisting of pyrolysis and gasification materials:

   (a) the chlorine (Cl^-) content shall not be higher than 30 g/kg dry matter and

   (b) the thallium (Tl) content shall not be higher than 2 mg/kg dry matter, in case more than 5 % of pyrolysis or gasification additives relative to the fresh weight of total input material have been applied.

▼M6

7. The pyrolysis and gasification material shall comply with the requirement set out in point 2 in CMC 1.

▼M10

8. Where compliance with one of the requirements in points 3 and 6 follows certainly and uncontestably from the nature or the recovery process of the pyrolysis or gasification material, or the manufacturing process of the EU fertilising product, that compliance may be presumed in the conformity assessment procedure without verification (such as testing), under the responsibility of the manufacturer.

▼M5

CMC 15: RECOVERED HIGH PURITY MATERIALS

(1) An EU fertilising product may contain a recovered high purity material, which is ammonium salt, sulphate salt, phosphate salt, elemental sulphur, calcium carbonate or calcium oxide, or mixtures thereof, of a purity of at least 95 % dry matter of the material.

([19]) Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k] fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene.

([20]) van den Berg M., L.S. Birnbaum, M. Denison, M. De Vito, W. Farland, et al. (2006) The 2005 World Health Organization Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds. Toxicological sciences: an official journal of the Society of Toxicology 93:223-241. doi:10.1093/toxsci/kfl055.

([21]) Polychlorinated dibenzo-p-dioxins and dibenzofurans.

▼M5

(2) The high purity material shall be recovered from waste generated from:

(a) a production process that uses as input materials substances and mixtures other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009 ([22]), or

(b) a gas purification or emission control process designed to remove nutrients from off-gases derived from one or more of the following input materials and facilities:

(i) substances and mixtures, other than waste within the meaning of Article 3, point 1, of Directive 2008/98/EC;

(ii) plants or plant parts;

(iii) bio-waste within the meaning of Article 3, point 4, of Directive 2008/98/EC, resulting from separate bio-waste collection at source;

(iv) urban and domestic waste waters within the meaning of Article 2, points 1 and 2, respectively, of Directive 91/271/EEC ([23]);

(v) sludge within the meaning of Article 2, point (a), of Directive 86/278/EEC ([24]), which displays no hazardous properties listed in Annex III to Directive 2008/98/EC;

(vi) waste within the meaning of Article 3, point 1, of Directive 2008/98/EC, and fuels input to a waste co-incineration plant as defined in Directive 2010/75/EU of the European Parliament and of the Council ([25]) and operated according to the conditions of that Directive, on condition that these inputs display no hazardous properties listed in Annex III to Directive 2008/98/EC;

(vii) Category 2 or Category 3 materials or derived products thereof, in accordance with the conditions set out in Article 32(1) and (2) and in the measures referred to in Article 32(3) of Regulation (EC) No 1069/2009, provided that the off-gases are derived from a composting or digestion process in accordance with CMCs 3 and 5, respectively, in Annex II to this Regulation;

(viii) manure within the meaning of Article 3, point 20, of Regulation (EC) No 1069/2009 or derived products thereof; or

(ix) livestock housing facilities.

([22]) Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

([23]) Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment (OJ L 135, 30.5.1991, p. 40).

([24]) Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture (OJ L 181, 4.7.1986, p. 6).

([25]) Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17).

▼**M5**

The input materials referred to in points (i) to (vi) shall not contain animal by-products or derived products within the scope of Regulation (EC) No 1069/2009.

(3) The high purity material shall have an organic carbon (C_{org}) content of no more than 0,5 % dry matter of the material.

(4) The high purity material shall contain no more than:

(a) 6 mg/kg dry matter of polycyclic aromatic hydrocarbons (PAH_{16}) ([26]);

(b) 20 ng WHO toxicity equivalents ([27])/kg dry matter of the polychlorinated dibenzo-para-dioxins and dibenzofurans (PCDD/PCDF) ([28]).

(5) An EU fertilising product containing or consisting of high purity materials shall contain no more than:

(a) 400 mg/kg dry matter of total chromium (Cr); and

(b) 2 mg/kg dry matter of thallium (Tl).

(6) Where compliance with a given requirement laid down in points 4 and 5 (such as absence of a given contaminant) follows certainly and uncontestably from the nature or the recovery process of the high purity material or the manufacturing process of the EU fertilising product, that compliance may be presumed in the conformity assessment procedure without verification (such as testing), under the responsibility of the manufacturer.

(7) Where for the product function category of an EU fertilising product containing or consisting of high purity materials referred to in point 2(b) no requirements regarding *Salmonella* spp., *Escherichia coli* or ►**M10** Enterococci ◄ have been laid down in Annex I, those pathogens in the EU fertilising product shall not exceed the limits set out in the following table:

Micro-organisms to be tested	Sampling plans			Limit
	n	c	m	M
Salmonella spp.	5	0	0	Absence in 25 g or 25 ml
►**M10** *Escherichia coli* or enterococci ◄	5	5	0	1 000 in 1 g or 1 ml

Where:

n = number of samples to be tested,

c = number of samples where the number of bacteria expressed in colony forming units (CFU) is between m and M,

m = threshold value for the number of bacteria expressed in CFU that is considered satisfactory,

M = maximum value of the number of bacteria expressed in CFU.

([26]) Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene.

([27]) van den Berg M., L.S. Birnbaum, M. Denison, M. De Vito, W. Farland, et al. (2006) The 2005 World Health Organization Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds. Toxicological sciences: an official journal of the Society of Toxicology 93:223-241. doi:10.1093/toxsci/kfl055.

([28]) Sum of 2,3,7,8-TCDD, 1,2,3,7,8-PeCDD; 1,2,3,4,7,8-HxCDD; 1,2,3,6,7,8-HxCDD; 1,2,3,7,8,9-HxCDD; 1,2,3,4,6,7,8-HpCDD; OCDD; 2,3,7,8-TCDF; 1,2,3,7,8-PeCDF; 2,3,4,7,8-PeCDF; 1,2,3,4,7,8-HxCDF; 1,2,3,6,7,8-HxCDF; 1,2,3,7,8,9-HxCDF; 2,3,4,6,7,8-HxCDF; 1,2,3,4,6,7,8-HpCDF; 1,2,3,4,7,8,9-HpCDF; and OCDF.

▼**M5**

(8) The compliance of an EU fertilising product containing or consisting of high purity materials referred to in point 2(b) with requirements in point (7), or with the requirements for *Salmonella* spp., *Escherichia coli* or ►**M10** enterococci ◄ set out in Annex I for the corresponding PFC of the EU fertilising product shall be verified via testing, in accordance with point 5.1.3.1 in Module D1 – quality assurance of the production process in Part II of Annex IV.

The requirements in point (7) and the requirements for *Salmonella* spp., *Escherichia* coli or ►**M10** enterococci ◄ set out in Annex I for the corresponding PFC of an EU fertilising product consisting only of high purity materials referred to in point 2(b) shall not apply, when the high purity materials or all of the biogenic input materials used have undergone one of the following processes:

(a) pressure sterilisation through the heating to a core temperature of more than 133 °C for at least 20 minutes at an absolute pressure of at least 3 bars, whereby the pressure must be produced by the evacuation of all air in the sterilisation chamber and the replacement of the air by steam (‘saturated steam’);

(b) processing in a pasteurisation or hygienisation unit that reaches a temperature of 70 °C for at least one hour.

The requirements in point (7) and the requirements for *Salmonella* spp., *Escherichia* coli or ►**M10** enterococci ◄ set out in Annex I for the corresponding PFC of an EU fertilising product consisting only of high purity materials referred to in point 2(b) shall not apply, where the off-gases derive from an incineration process as defined in Directive 2010/75/EU.

(9) High purity materials that are stored in a way that does not protect them against precipitation and direct sunlight may be added to an EU fertilising product only if they have been manufactured maximum 36 months before signing the EU declaration of conformity for the respective EU fertilising product.

▼**M6**

(10) The high purity material shall comply with the requirement set out in point 2 in CMC 1.

▼B

ANNEX III

Labelling requirements

This Annex sets out the labelling requirements for EU fertilising products. The requirements laid down in Part II and Part III of this Annex for a given PFC, as specified in Annex I, apply to EU fertilising products in all subcategories of that PFC.

PART I

GENERAL LABELLING REQUIREMENTS

1. The following information shall be provided:

(a) for EU fertilising products in PFC 1 to PFC 6, the designation as indicated in Part I of Annex I of the PFC corresponding to the product's claimed function;

(b) for EU fertilising products in PFC 7, the designations as indicated in Part I of Annex I of all the PFCs corresponding to the claimed functions of the component EU fertilising products;

(c) the quantity of the EU fertilising product, indicated by mass or volume;

(d) instructions for intended use, including application rates, timing and frequency, and target plants or mushrooms;

(e) recommended storage conditions;

(f) for products containing a polymer belonging to CMC 9 in Part II of Annex II, the time period following use during which the nutrient release is being controlled or the water retention capacity is being increased (the 'functionality period'), which shall not be longer than the period between two applications in accordance with the use instructions referred to in point (d);

▼M11

(fa) for products belonging to PFC 3 containing a polymer referred to in Part II, section CMC 9, point 1a, of Annex II:

(a) the time period following use during which the soil improver will fulfil its function (the 'functionality period'), which shall not be longer than the period between two applications in accordance with the use instructions referred to in point (d) of this point;

(b) an instruction to apply the product in compliance with the buffer zones required for fertilising products in accordance with the relevant national rules or, in the absence of such rules, to apply the product at least 3 m from any surface water body;

(c) an instruction to follow the national measures on handling mulch films after their functionality period or, in the absence of such measures, to incorporate in soil the product after its functionality period and maintain it buried;

▼B

(g) any relevant information on measures recommended to manage risks to human, animal or plant health, to safety or to the environment; and

▼M1

(h) a list of all ingredients above 5 % by product weight or volume, or in the case of products in liquid form by dry weight, in descending order of magnitude, including the designations of the relevant CMCs as referred to in Part I of Annex II to this Regulation. Where the ingredient is a substance or a mixture, it shall be identified in accordance with Article 18 of Regulation (EC) No 1272/2008. Naturally occurring substances may be identified by their mineral names.

▼B

2. Where the EU fertilising product has functions described in two or more of the PFCs laid down in Annex I, only those functions for which the EU fertilising product has been subject to a successful conformity assessment in accordance with this Regulation may be claimed by using the corresponding PFC designations as indicated in Part I of Annex I.

▼M1

3. Where the EU fertilising product contains a component material which, if placed on the market as food or feed, would have been subject to maximum residue limits established pursuant to Regulation (EC) No 470/2009 or Regulation (EU) No 1831/2003 of the European Parliament and of the Council ([1]), maximum residue levels set in accordance with Regulation (EC) No 396/2005 of the European Parliament and of the Council ([2]), or maximum levels established pursuant to Council Regulation (EEC) No 315/93 ([3]) or Directive 2002/32/EC of the European Parliament and of the Council ([4]), and that component material contains a substance in exceedance of (one of) the corresponding limit value(s), the maximum concentration of that substance in the EU fertilising product shall be indicated, together with a warning that the EU fertilising product must not be used in such a manner as to risk leading to the exceedance of that limit in food or feed.

▼B

4. Where the EU fertilising product contains derived products within the meaning of Regulation (EC) No 1069/2009 other than manure, the following instruction shall be provided on the label: ‘Farmed animals shall not be fed, either directly or by grazing, with herbage from land to which the product has been applied unless the cutting or grazing takes place after the expiry of a waiting period of at least 21 days.’.

5. Where the EU fertilising product contains ricin, the following instruction shall be provided on the label: ‘Hazardous to animals in case of ingestion’.

6. Where the EU fertilising product contains unprocessed or processed cocoa shells, the following instruction shall be provided on the label: ‘Toxic to dogs and cats’.

▼M9

7. The end-user shall be instructed not to use the product in contact with soil, and in collaboration with the manufacturer, to make sure of a sound disposal of the product after end of use where the EU fertilising product:

(a) is a growing medium as referred to in Part II, section PFC 4, point 2a, of Annex I; or

([1]) Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

([2]) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

([3]) Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 37, 13.2.1993, p. 1).

([4]) Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10).

▼M9

(b) contains a polymer with the purpose of binding material in the product as referred to in Part II, section CMC 9, point 1(c) of Annex II, which does not meet any of the requirements in Part II, section CMC 1, point 1(f)(i), (ii), (iii) or (iv) of that Annex.

▼M4

7a. Where the EU fertilising product contains or consists of thermal oxidation materials and derivates as referred to in CMC 13 in Part II in Annex II or pyrolysis or gasification materials as referred to in CMC 14 in Part II of that Annex and has a manganese (Mn) content above 3,5 % by mass, the manganese content shall be declared.

▼M5

7b. Where the EU fertilising product contains or consists of high purity materials referred to in Part II, CMC 15, of Annex II and:

(a) has a selenium (Se) content exceeding 10 mg/kg dry matter, the selenium content shall be indicated;

(b) has a chloride (Cl-) content exceeding 30 g/kg dry matter, the chloride content shall be indicated, unless the EU fertilising product is produced through a manufacturing process where chloride containing substances or mixtures have been used with the intention of producing or including alkali metal salts or alkaline earth metal salts, and information on these salts is provided in accordance with Annex III.

When the content of selenium or chloride is indicated in accordance with point (a) and (b), it shall be clearly separated from nutrient declaration and it may be expressed as a range of values

Where the fact that such an EU fertilising product contains selenium or chloride below the limit values in points (a) and (b) follows certainly and uncontestably from the nature or recovery operation of the high purity material or the production process of the EU fertilising product containing such a material, as applicable, the label may contain no information on these parameters, without verification (such as testing), at the responsibility of the manufacturer.

▼M8

7c. Where an EU fertilising product contains processed manure as referred to in Part II, CMC 10, of Annex II, information about the possible air quality impacts of the release of ammonia from the product's use and an invitation to users to apply appropriate remediation measures shall be included on the label.

Where an EU fertilising product contains processed manure as referred to in Part II, CMC 10, of Annex II, the following warning shall be included on the label 'This product may contain aminopyralid or clopyralid and must not be used for the production of plants susceptible to these substances, such as beans, clover, lentils, peas, salat, sunflowers and tomatoes. This product must be used in such a manner as to avoid leading to the exceedance of the maximum residue levels for food or feed set in accordance with Regulation (EC) 396/2005', or a similar warning. Such a warning is not needed for EU fertilising products containing processed manure with no more than 50 µg aminopyralid or clopyralid/kg dry matter.

7d. Where an EU fertilising product contains a component material out of manure, the total content of nitrogen originated out of manure shall be indicated.

▼B

8. Information other than the information required under points 1 to 6:

▼B

(a) shall not mislead the user, for example by attributing to the product properties that it does not possess, or by suggesting that the product possesses unique characteristics which similar products also have;

(b) shall relate to verifiable factors;

(c) shall not make claims such as ‘sustainable’ or ‘environmentally friendly’ unless such claims refer to legislation, or clearly identified guidelines, standards or schemes, with which the EU fertilising product complies; and

(d) shall not make claims by means of statements or visual representations that the EU fertilising product prevents or treats plant diseases or protects plants against harmful organisms.

9. The phrase ‘poor in chloride’ or similar may only be used if the chloride (Cl-) content is below 30 g/kg of dry matter.

10. Where the nutrient content information requirements in this Annex are expressed in oxidised form, the nutrient content may be expressed in elemental form instead or in addition to the oxidised form in accordance with the following conversion factors:

phosphorus (P) = phosphorus pentoxide (P_2O_5) × 0,436;

potassium (K) = potassium oxide (K_2O) × 0,830;

calcium (Ca) = calcium oxide (CaO) × 0,715;

magnesium (Mg) = magnesium oxide (MgO) × 0,603;

sodium (Na) = sodium oxide (Na_2O) × 0,742;

sulphur (S) = sulphur trioxide (SO_3) × 0,400.

11. Where the information requirements in this Annex refer to organic carbon (C_{org}), the information may refer to organic matter instead of or in addition to organic carbon (C_{org}), in accordance with the following conversion factor:

organic carbon (C_{org}) = organic matter × 0,56.

PART II

PRODUCT-SPECIFIC LABELLING REQUIREMENTS

PFC 1: FERTILISER

1. The content of nutrients may be declared only where they are present in the EU fertilising product in the minimum quantity specified in Annex I for the relevant PFC.

2. If nitrogen (N) or phosphorus (P) are not declared nutrients, the content of nitrogen (N) or phosphorus pentoxide (P_2O_5) shall nevertheless be indicated if above 0,5 % by mass. That indication shall be separate from the nutrient declaration.

▼M6

3. The following rules apply to fertilisers containing inhibiting compounds, as specified in CMC 1 in Part II of Annex II:

(a) the label shall state the words ‘nitrification inhibitor’, ‘denitrification inhibitor’ or ‘urease inhibitor’, as relevant;

(b) the nitrification inhibiting compound content shall be expressed as a % by mass of the total nitrogen (N) present as ammonium nitrogen (NH_4^+) and urea nitrogen (CH_4N_2O);

(c) the denitrification inhibiting compound content shall be expressed as a % by mass of the nitrate (NO_3^-) present;

(d) the urease inhibiting compound content shall be expressed as a % by mass of the total nitrogen (N) present as urea nitrogen (CH_4N_2O).

▼B

4. The term ‘mineral fertiliser’ may be used only if the fertiliser belongs to PFC 1(C) and fulfils the following additional conditions:

(a) the mineral fertiliser must not cñontain more than 1 % by mass of organic carbon (C_{org}), other than organic carbon from:

(i) chelating or complexing agents referred to in point 3 of CMC 1 in Part II of Annex II,

▼M6

(ii) nitrification, denitrification or urease inhibiting compounds referred to in point 4 of CMC 1 in Part II of Annex II,

▼B

(iii) coating agents referred to in point 1(a) of CMC 9 in Part II of Annex II,

(iv) urea (CH_4N_2O), or

(v) calcium cyanamide ($CaCN_2$);

(b) where phosphorus (P) is a declared nutrient, the declared phosphorus content shall consist only of phosphorus in the phosphatic form, and the mineral fertiliser shall fulfil at least one of the following solubility criteria:

(i) water solubility: minimum level 40 % of total phosphorus (P),

(ii) solubility in neutral ammonium citrate: minimum level 75 % of total phosphorus (P), or

(iii) solubility in formic acid (only for soft rock phosphate): minimum level 55 % of total phosphorus (P);

(c) where nitrogen (N) is a declared nutrient, the declared nitrogen content shall consist only of the sum of nitric nitrogen, ammoniacal nitrogen, ureic nitrogen, and nitrogen from methylene-urea, from isobutylidene-diurea, and from crotonylidenediurea.

PFC 1(A): ORGANIC FERTILISER

The following information shall be provided:

(a) the declared primary nutrients nitrogen (N), phosphorus (P) or potassium (K), by their chemical symbols in the order N-P-K;

(b) the declared secondary nutrients calcium (Ca), magnesium (Mg), sodium (Na), or sulphur (S) by their chemical symbols in the order Ca-Mg-Na-S;

▼B

(c) numbers indicating the content of the declared nutrients total nitrogen (N), total phosphorus in the form of phosphorus pentoxide (P_2O_5) or total potassium in the form of potassium oxide (K_2O), followed by numbers in brackets indicating the total content of calcium oxide (CaO), magnesium oxide (MgO), sodium oxide (Na_2O) or sulphur trioxide (SO_3);

(d) the content of the following declared nutrients and other parameters, in the following order and as % by mass:

(i) nitrogen (N):

— total nitrogen (N);

— minimum amount of organic nitrogen (N_{org}), followed by a description of the origin of the organic matter used;

— nitrogen in the form of ammoniacal nitrogen;

(ii) total phosphorus pentoxide (P_2O_5);

(iii) total potassium oxide (K_2O);

(iv) calcium oxide (CaO), magnesium oxide (MgO), sodium oxide (Na_2O) and sulphur trioxide (SO_3), expressed:

— where those nutrients are totally soluble in water, only as the content soluble in water;

— where the soluble content of those nutrients is at least a quarter of the total content of those nutrients, as the total content and as the content soluble in water;

— in other cases, as the total content;

(v) organic carbon (C_{org});

(vi) dry matter;

(e) the ratio of organic carbon to total nitrogen (C_{org}/N);

(f) production date;

(g) the form of the physical unit of the product, such as powder or pellets, if applicable.

PFC 1(B): ORGANO-MINERAL FERTILISER

1. The following information shall be provided:

(a) the declared primary nutrients nitrogen (N), phosphorus (P) or potassium (K), by their chemical symbols in the order N-P-K;

(b) where applicable, the declared secondary nutrients calcium (Ca), magnesium (Mg), sodium (Na) or sulphur (S) by their chemical symbols in the order Ca-Mg-Na-S;

(c) numbers indicating the content of the declared nutrients total nitrogen (N), total phosphorus in the form of phosphorus pentoxide (P_2O_5) or total potassium in the form of potassium oxide (K_2O), followed by numbers in brackets indicating the total content of calcium oxide (CaO), magnesium oxide (MgO), sodium oxide (Na_2O) or sulphur trioxide (SO_3);

(d) the content of the following declared nutrients and other parameters, in the following order and as % by mass:

(i) nitrogen (N):

— total nitrogen (N);

— minimum amount of organic nitrogen (N_{org}), followed by a description of the origin of the organic matter used;

— nitrogen in the form of nitric nitrogen;

— nitrogen in the form of ammoniacal nitrogen;

— nitrogen in the form of urea nitrogen;

(ii) phosphorus pentoxide (P_2O_5):

— total phosphorus pentoxide (P_2O_5);

▼B

— water-soluble phosphorus pentoxide (P_2O_5);

— phosphorus pentoxide (P_2O_5) soluble in neutral ammonium citrate;

— where soft ground phosphate is present, phosphorus pentoxide (P_2O_5) soluble in formic acid;

(iii) potassium oxide (K_2O):

— total potassium oxide (K_2O);

— water soluble potassium oxide (K_2O);

(iv) calcium oxide (CaO), magnesium oxide (MgO), sodium oxide (Na_2O) and sulphur trioxide (SO_3), expressed:

— where those nutrients are totally soluble in water, only as the content soluble in water;

— where the soluble content of those nutrients is at least a quarter of the total content of those nutrients, as the total content and as the content soluble in water;

— in other cases, as the total content;

(v) organic carbon (C_{org});

(vi) dry matter,

(e) where urea (CH_4N_2O) is present, information about the possible air quality impacts of the release of ammonia from the fertiliser use, and an invitation to users to apply appropriate remediation measures.

2. Where one or more of the micronutrients boron (B), cobalt (Co), iron (Fe), manganese (Mn) and molybdenum (Mo) are present in the minimum content indicated as % by mass in the following table, they:

— shall be declared if they are intentionally added to an organo-mineral fertiliser, and

— may be declared in other cases:

Micronutrient	Content of micronutrient (% by mass)		
	Solid organo-mineral fertiliser		Liquid organo-mineral fertiliser
	Intended for use on crops or grassland	Intended for horticultural use	
Boron (B)	0,01	0,01	0,01
Cobalt (Co)	0,002	n.a.	0,002
Iron (Fe)	0,5	0,02	0,02
Manganese (Mn)	0,1	0,01	0,01
Molybdenum (Mo)	0,001	0,001	0,001

3. Where one or both of the micronutrients copper (Cu) and zinc (Zn) are present, without being intentionally added, in the minimum content indicated as % by mass in the following table, they may be declared:

▼B

Micronutrient	Content of micronutrient (% by mass)		
	Solid organo-mineral fertiliser		Liquid organo-mineral fertiliser
	Intended for use on crops or grassland	Intended for horticultural use	
Copper (Cu)	0,01	0,002	0,002
Zinc (Zn)	0,01	0,002	0,002

4. Where copper (Cu) or zinc (Zn) is intentionally added to the organo-mineral fertiliser, the total content of copper (Cu) or zinc (Zn) shall be declared.

5. The micronutrients referred to in points 2, 3 and 4 shall be declared after the information on macronutrients. The following information shall be provided:

▼M1

(a) indication of the names and chemical symbols of the declared micronutrients, listed in the following order: boron (B), cobalt (Co), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo) and zinc (Zn), followed by the names of their counter-ions when the declared micronutrients are intentionally added;

▼B

(b) the total micronutrient content expressed as % by mass:

— where those micronutrients are totally soluble in water, only as the content soluble in water;

— where the soluble content of those micronutrients is at least a quarter of the total content of those micronutrients, as the total content and as the content soluble in water;

— in other cases, as the total content;

▼M1

(c) where the declared micronutrients are chelated by chelating gent(s) or complexed by complexing agent(s):

— the following qualifier as applicable, after the name and chemical identifier of the micronutrient:

‘chelated by [name of the chelating agent(s) or its(their) abbreviation]’/‘complexed by [name of the complexing agent(s) or its(their) abbreviation]’/‘chelated by [name of the chelating agent(s) or its(their) abbreviation] and complexed by [name of the complexing agent(s) or its (their) abbreviation]’;

— the amount of chelated/complexed micronutrient(s) as % by mass;

(ca) where the declared micronutrients are chelated by chelating agent(s), the pH range guaranteeing acceptable stability;

———————

▼B

(e) where micronutrients are intentionally added, the following statement: ‘To be used only where there is a recognised need. Do not exceed the application rate’.

▼B

6. Where an organo-mineral fertiliser has a cadmium (Cd) content equal to or lower than 20 mg/kg phosphorus pentoxide (P_2O_5), the statement ‘Low cadmium (Cd) content’ or similar, or a visual representation to that effect, may be added.

PFC 1(C): INORGANIC FERTILISER

PFC 1(C)(I): INORGANIC MACRONUTRIENT FERTILISER

1. The following information shall be provided:

(a) where applicable, the declared primary nutrients nitrogen (N), phosphorus (P) or potassium (K), by their chemical symbols in the order N-P-K;

(b) where applicable, the declared secondary nutrients calcium (Ca), magnesium (Mg), sodium (Na) or sulphur (S) by their chemical symbols in the order Ca-Mg-Na-S;

(c) numbers indicating the content of the declared nutrients total nitrogen (N), total phosphorus in the form of phosphorus pentoxide (P_2O_5) or total potassium in the form of potassium oxide (K_2O), followed by numbers in brackets indicating the total content of calcium oxide (CaO), magnesium oxide (MgO), sodium oxide (Na_2O) or sulphur trioxide (SO_3);

(d) the content of the following declared nutrients, in the following order and as % by mass:

(i) nitrogen (N):

— total nitrogen (N);

— nitrogen in the form of nitric nitrogen;

— nitrogen in the form of ammoniacal nitrogen;

— nitrogen in the form of urea nitrogen;

— nitrogen from urea formaldehyde, isobutylidenediurea, crotonylidenediurea;

— nitrogen from cyanamide nitrogen;

(ii) phosphorus pentoxide (P_2O_5):

— total phosphorus pentoxide (P_2O_5);

— water-soluble phosphorus pentoxide (P_2O_5);

— phosphorus pentoxide (P_2O_5) soluble in neutral ammonium citrate;

— where soft ground phosphate is present, phosphorus pentoxide (P_2O_5) soluble in formic acid;

(iii) water soluble potassium oxide (K_2O);

(iv) calcium oxide (CaO), magnesium oxide (MgO), sodium oxide (Na_2O) and sulphur trioxide (SO_3), expressed:

— where those nutrients are totally soluble in water, only as the content soluble in water;

— where the soluble content of those nutrients is at least a quarter of the total content of those nutrients, as the total content and as the content soluble in water;

— in other cases, as the total content;

▼B

(e) where urea (CH_4N_2O) is present, information about the possible air quality impacts of the release of ammonia from the fertiliser use, and an invitation to users to apply appropriate remediation measures.

2. Where an inorganic macronutrient fertiliser has a cadmium (Cd) content equal to or lower than 20 mg/kg phosphorous pentoxide (P_2O_5), the statement ‘Low cadmium (Cd) content’ or similar, or a visual representation to that effect, may be added.

PFC 1(C)(I)(a): SOLID INORGANIC MACRONUTRIENT FERTILISER

1. A solid inorganic macronutrient fertiliser may be labelled ‘complex’ only if each physical unit contains all the declared nutrients in their declared content.

2. The granulometry of a solid inorganic macronutrient fertiliser shall be indicated, expressed as % by mass of the product passing through a determined sieve.

▼M1

3. The form of the physical unit of the product shall be indicated with one, or a combination of two or more, of the following mentions:

(a) granules,

(b) pellets,

(c) powder, where at least 90 % by mass of the product can pass through a sieve with a mesh of 1 mm, or

(d) prills,

▼B

4. For coated solid inorganic macronutrient fertilisers, the name of the coating agents and the percentage of fertiliser coated by each coating agent shall be indicated and followed by:

(a) for polymer coated solid inorganic macronutrient fertilisers, the following marking: ‘The rate of nutrient releases can vary according to the temperature of the substrate. An adjustment of fertilisation may be necessary’; and

(b) for sulphur (S) coated solid inorganic macronutrient fertilisers and sulphur (S)/polymer coated solid inorganic macronutrient fertilisers, the following marking: ‘The rate of nutrient release can vary according to the temperature of the substrate and the biological activity. An adjustment of fertilisation may be necessary’.

5. Where one or more of the micronutrients boron (B), cobalt (Co), iron (Fe), manganese (Mn) and molybdenum (Mo) are present in the minimum content indicated in the following table as % by mass, they:

— shall be declared if they are intentionally added to the solid inorganic macronutrient fertiliser, and

— may be declared in other cases:

Micronutrient	Content of micronutrients (% by mass)	
	Intended for use on crops or grassland	Intended for horticultural use
Boron (B)	0,01	0,01
Cobalt (Co)	0,002	n.a.
Iron (Fe)	0,5	0,02
Manganese (Mn)	0,1	0,01
Molybdenum (Mo)	0,001	0,001

▼B

6. Where one or both of the micronutrients copper (Cu) and zinc (Zn) are present, without being intentionally added, in the minimum content indicated as % by mass in the following table, they may be declared:

Micronutrient	Content of micronutrients (% by mass)	
	Intended for use on crops or grassland	Intended for horticultural use
Copper (Cu)	0,01	0,002
Zinc (Zn)	0,01	0,002

7. Where copper (Cu) or zinc (Zn) is intentionally added to the solid inorganic macronutrient fertiliser the total content of copper (Cu) or zinc (Zn) shall be declared.

8. The micronutrients referred to in points 5, 6 and 7 shall be declared after the information on macronutrients. The following information shall be provided:

▼M1

(a) indication of the names and chemical symbols of the declared micronutrients, listed in the following order: boron (B), cobalt (Co), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo) and zinc (Zn), followed by the names of their counter-ions when the declared micronutrients are intentionally added;

▼B

(b) the total micronutrient content expressed as % by mass:

— where those micronutrients are totally soluble in water, only as the content soluble in water;

— where the soluble content of those micronutrients is at least a quarter of the total content of those micronutrients, as the total content and as the content soluble in water;

— in other cases, as the total content;

▼M1

(c) where the declared micronutrients are chelated by chelating agent(s) or complexed by complexing agent(s):

— the following qualifier, as applicable, after the name and chemical identifier of the micronutrient:

‘chelated by [name of the chelating agent(s) or its(their) abbreviation]’/‘complexed by [name of the complexing agent(s) or its(their) abbreviation]’/‘chelated by [name of the chelating agent(s) or its (their) abbreviation] and complexed by [name of the complexing agent(s) or its (their) abbreviation]’;

— the amount of chelated/complexed micronutrient(s) as % by mass;

(ca) where the declared micronutrients are chelated by chelating agent(s), the pH range guaranteeing acceptable stability;

———————

▼B

(e) where micronutrients are intentionally added, the following statement: ‘To be used only where there is a recognised need. Do not exceed the application rate’.

▼B

PFC 1(C)(I)(b): LIQUID INORGANIC MACRONUTRIENT FERTILISER

1. The label shall indicate whether the liquid inorganic macronutrient fertiliser is in suspension or in solution.

2. The nutrient content may be indicated as % by mass or volume.

3. Where one or more of the micronutrients boron (B), cobalt (Co), iron (Fe), manganese (Mn) and molybdenum (Mo) are present in the minimum content indicated in the following table as % by mass, they:

   — shall be declared if they are intentionally added to the liquid inorganic macronutrient fertiliser, and

   — may be declared in other cases:

Micronutrient	Content of micronutrient (% by mass)
Boron (B)	0,01
Cobalt (Co)	0,002
Iron (Fe)	0,02
Manganese (Mn)	0,01
Molybdenum (Mo)	0,001

4. Where one or both of the micronutrients copper (Cu) and zinc (Zn) are present, without being intentionally added, by at least 0,002 % by mass, they may be declared.

5. Where copper (Cu) or zinc (Zn) is intentionally added to the liquid inorganic macronutrient fertiliser the total content of copper (Cu) or zinc (Zn) shall be declared.

6. The micronutrients referred to in points 3, 4 and 5 shall be declared after the information on macronutrients. The following information shall be provided:

▼M1

(a) indication of the names and chemical symbols of the declared micronutrients, listed in the following order: boron (B), cobalt (Co), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo) and zinc (Zn), followed by the names of their counter-ions when the declared micronutrients are intentionally added;

▼B

(b) the total micronutrient content expressed as % by mass or volume:

   — where those micronutrients are totally soluble in water, only as the content soluble in water;

   — where the soluble content of those micronutrients is at least a quarter of the total content of those micronutrients, as the total content and as the content soluble in water;

   — in other cases, as the total content;

▼M1

(c) where the declared micronutrients are chelated by chelating agent(s) or complexed by complexing agent(s):

— the following qualifier, as applicable, after the name and chemical identifier of the micronutrient:

‘chelated by [name of the chelating agent(s) or its(their) abbreviation]’/‘complexed by [name of the complexing agent(s) or its(their) abbreviation]’/‘chelated by [name of the chelating agent(s) or its(their) abbreviation] and complexed by [name of the complexing agent(s) or its (their) abbreviation]’;

— the amount of chelated/complexed micronutrient(s) as % by mass;

(ca) where the declared micronutrients are chelated by chelating agent(s), the pH range guaranteeing acceptable stability;

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▼B

(e) where micronutrients are intentionally added, the following statement: ‘To be used only where there is a recognised need. Do not exceed the application rate’.

PFC 1(C)(II): INORGANIC MICRONUTRIENT FERTILISER

▼M1

1. The declared micronutrients in the inorganic micronutrient fertiliser shall be listed by their names and chemical symbols of the declared micronutrients, in the following order: boron (B), cobalt (Co), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo) and zinc (Zn), followed by the names of their counter-ions when the declared micronutrients are intentionally added.

2. Where the declared micronutrients are chelated by chelating agent(s) and each chelating agent can be identified and quantified and chelates at least 1 % water-soluble micronutrient, or the declared micronutrients are complexed by complexing agent(s), the following qualifiers shall be added, as applicable, after the name and chemical identifier of the micronutrient:

— ‘chelated by [name of the chelating agent(s) or its(their) abbreviation]’/‘complexed by [name of the complexing agent(s) or its(their) abbreviation]’/‘chelated by [name of the chelating agent(s) or its(their) abbreviation] and complexed by [name of the complexing agent(s) or its (their) abbreviation]’,

— the amount of chelated/complexed micronutrient(s) as % by mass.

2a. Where the declared micronutrients are chelated by chelating agent(s), the pH range guaranteeing acceptable stability shall be indicated.

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▼B

4. The following statement shall appear: ‘To be used only where there is a recognised need. Do not exceed the application rate’.

▼B

PFC 1(C)(II)(a): STRAIGHT INORGANIC MICRONUTRIENT FERTILISER

1. The label shall indicate the relevant typology, as referred to in the table under PFC 1(C)(II)(a) in Part II of Annex I.

2. The total micronutrient content shall be expressed as % by mass:

   — where the micronutrient is totally soluble in water, only as the content soluble in water;

   — where the soluble content of the micronutrient is at least a quarter of the total content of that micronutrient, as the total content and as the content soluble in water;

   — in other cases, as the total content.

PFC 1(C)(II)(b): COMPOUND INORGANIC MICRONUTRIENT FERTILISER

1. Micronutrients may be declared only if they are present in the minimum content indicated in the following table as % by mass:

Micronutrient	Content of micronutrient (% by mass)	
	Non-chelated, non-complexed	Chelated or complexed
Boron (B)	0,2	n.a.
Cobalt (Co)	0,02	0,02
Copper (Cu)	0,5	0,1
Iron (Fe)	2	0,3
Manganese (Mn)	0,5	0,1
Molybdenum (Mo)	0,02	n.a.
Zinc (Zn)	0,5	0,1

2. If the compound inorganic micronutrient fertiliser is in suspension or in solution, the label shall indicate ‘in suspension’ or ‘in solution’, as relevant.

3. The total micronutrient content shall be expressed as % by mass:

   — where the micronutrients are totally soluble in water, only as the content soluble in water;

   — where the soluble content of the micronutrients is at least half of the total content of those micronutrients, as the total content and as the content soluble in water;

   — in other cases, as the total content.

PFC 2: LIMING MATERIAL

The following parameters shall be declared in the following order:

— neutralising value;

— granulometry, expressed as % by mass of product passing through a sieve of 1,0 mm;

— total calcium oxide (CaO), expressed as % by mass;

— total magnesium oxide (MgO), expressed as % by mass;

— reactivity and method of determination of reactivity, except for oxide and hydroxide limes.

PFC 3: SOIL IMPROVER

1. The dry matter content expressed as % by mass shall be declared.

▼B

2. The following nutrients expressed as % by mass shall be declared, if exceeding 0,5 % by mass: nitrogen (N), phosphorus pentoxide (P_2O_5) and potassium oxide (K_2O).

PFC 3(A): ORGANIC SOIL IMPROVER

The following parameters shall be declared:

— pH;

— electrical conductivity, given as mS/m;

— organic carbon (C_{org}) content, expressed as % by mass;

— minimum amount of organic nitrogen (N_{org}), expressed as % by mass, followed by a description of the origin of the organic matter used;

— the ratio of organic carbon to total nitrogen (C_{org}/N).

PFC 4: GROWING MEDIUM

The following parameters shall be declared in the following order:

— electrical conductivity given as mS/m, except for mineral wool;

— pH;

— quantity:

  — for mineral wool, expressed as number of pieces and the three dimensions length, height, and width;

  — for other pre-shaped growing media, expressed as size in at least two dimensions;

  — for other growing media, expressed as total volume;

  — except for pre-shaped growing media, quantity expressed as volume of materials with a particle size greater than 60 mm, when present;

— nitrogen (N) extractable by $CaCl_2$/DTPA (calcium chloride/ diethylenetriaminepentaacetic acid; ‘CAT-soluble’), if above 150 mg/l;

— phosphorus pentoxide (P_2O_5) extractable by $CaCl_2$/DTPA (calcium chloride/ diethylenetriaminepentaacetic acid; ‘CAT-soluble’), if above 20 mg/l;

— potassium oxide (K_2O) extractable by $CaCl_2$/DTPA (calcium chloride/ diethylenetriaminepentaacetic acid; ‘CAT-soluble’), if above 150 mg/l;

— production date.

▼M6

PFC 5: INHIBITOR

1. All ingredients shall be declared by product weight or volume in descending order of magnitude.

2. The content of the inhibiting compound(s) as % by mass or volume shall be declared.

3. The use instructions referred to in point 1(d) in Part I of this Annex shall contain information on:

  (a) the types of EU fertilising products with which the inhibitor may be mixed, in particular:

▼M6

(i) for the nitrification inhibitor referred to in PFC 5(A) in Part II of Annex I, an EU fertilising product in which at least 50 % of the total nitrogen (N) content consists of the nitrogen (N) forms ammonium (NH_4^+) and urea (CH_4N_2O);

(ii) for the urease inhibitor referred to in PFC 5(C) in Part II of Annex I, an EU fertilising product in which at least 50 % of the total nitrogen (N) content consists of the nitrogen (N) form urea (CH_4N_2O);

(b) the minimum and maximum recommended concentration of inhibiting compound(s) when mixed with a fertiliser prior to its use:

(i) for the nitrification inhibitor referred to in PFC 5(A) in Part II of Annex I, as a % by mass of the total nitrogen (N) present as ammonium nitrogen (NH_4^+) and urea nitrogen (CH_4N_2O);

(ii) for the denitrification inhibitor referred to in PFC 5(B) in Part II of Annex I, as a % by mass of the nitrate (NO_3^-) present;

(iii) for the urease inhibitor referred to in PFC 5(C) in Part II of Annex I, as a % by mass of the total nitrogen (N) present as urea nitrogen (CH_4N_2O).

▼B

PFC 6: PLANT BIOSTIMULANT

The following information shall be provided:

(a) physical form;

(b) production and expiry date;

(c) application method(s);

(d) effect claimed for each target plant; and

(e) any relevant instructions related to the efficacy of the product, including soil management practices, chemical fertilisation, incompatibility with plant protection products, recommended spraying nozzles size, sprayer pressure and other anti-drift measures.

PFC 6(A): MICROBIAL PLANT BIOSTIMULANT

All intentionally added micro-organisms shall be indicated. Where the micro-organism has several strains, the intentionally added strains shall be indicated. Their concentration shall be expressed as the number of active units per volume or weight, or in any other manner that is relevant to the micro-organism, e.g. colony forming units per gram (cfu/g).

The label shall contain the following phrase: ‘Micro-organisms may have the potential to provoke sensitising reactions’.

PFC 7: FERTILISING PRODUCT BLEND

All the labelling requirements applicable to all component EU fertilising products apply to the fertilising product blend, and shall be expressed in relation to the final fertilising product blend.

▼B

Where the fertilising product blend contains one or more plant biostimulants belonging to PFC 6, the concentration of each plant biostimulant in the blend shall be indicated in g/kg or g/l at 20 °C.

▼M6

Where the fertilising product blend contains one or more inhibitors belonging to PFC 5, the use instructions referred to in point 3 in PFC 5 in Part II of this Annex shall not be added.

▼B

PART III

TOLERANCE RULES

1. The declared nutrient content or physico-chemical characteristics of an EU fertilising product may deviate from the actual value only in accordance with the tolerances established in this Part for the relevant PFC. The tolerances are intended to allow for deviations in manufacture, in the distribution chain, and during sampling and analysis.

2. The tolerances allowed in respect of the declared parameters indicated in this Part are negative and positive values.

3. By derogation from point 1, the actual content of a component, in an EU fertilising product, for which a minimum or a maximum content is specified in Annex I or Annex II may never be lower than the minimum content or exceed the maximum content.

▼M6

PFC 1: FERTILISER

The following tolerance rules apply to fertilisers containing nitrification, denitrification or urease inhibiting compounds, as specified in CMC 1 in Part II of Annex II:

Inhibiting compounds	Permissible tolerance for the declared content of inhibiting compounds
Concentration below or equal to 2 %	± 20 % of the declared value
Concentration of more than 2 %	± 0,3 percentage points in absolute terms

▼B

PFC 1(A): ORGANIC FERTILISER

Forms of the declared nutrient and other declared parameters	Permissible tolerance for the declared nutrient content and other declared parameters
Organic carbon (C_{org})	± 20 % relative deviation of the declared value up to a maximum of 2,0 percentage points in absolute terms
Dry matter content	± 5,0 percentage points in absolute terms
Total nitrogen (N)	± 50 % relative deviation of the declared value up to a maximum of 1,0 percentage point in absolute terms
Organic nitrogen (N_{org})	± 50 % relative deviation of the declared value up to a maximum of 1,0 percentage point in absolute terms
Total phosphorus pentoxide (P_2O_5)	± 50 % relative deviation of the declared value up to a maximum of 1,0 percentage point in absolute terms

▼B

Forms of the declared nutrient and other declared parameters	Permissible tolerance for the declared nutrient content and other declared parameters
Total potassium oxide (K_2O)	± 50 % relative deviation of the declared value up to a maximum of 1,0 percentage point in absolute terms
Total and water-soluble magnesium oxide (MgO), calcium oxide (CaO), sulphur trioxide(SO_3) or sodium oxide (Na_2O)	± 25 % of the declared content of those nutrients up to a maximum of 1,5 percentage points in absolute terms
Organic carbon (C_{org})/total nitrogen (N)	± 20 % relative deviation of the declared value up to a maximum of 2,0 percentage points in absolute terms
Quantity	± 1,5 % relative deviation of the declared value

PFC 1(B): ORGANO-MINERAL FERTILISER

Forms of the declared nutrient and other declared parameters	Permissible tolerance for the declared macronutrient content and other declared parameters
Organic carbon (C_{org})	± 20 % relative deviation of the declared value up to a maximum of 2,0 percentage points in absolute terms
Dry matter content	± 5,0 percentage points in absolute terms
Declared forms of inorganic nitrogen (N)	± 25 % relative deviation of the declared value up to a maximum of 2,0 percentage points in absolute terms
Organic nitrogen (N_{org})	± 50 % relative deviation of the declared value up to a maximum of 1,0 percentage point in absolute terms
Declared forms of phosphorus pentoxide (P_2O_5)	± 25 % relative deviation of the declared value up to a maximum of 1,5 percentage points in absolute terms
Declared forms of potassium oxide (K_2O)	± 25 % relative deviation of the declared value up to a maximum of 1,5 percentage points in absolute terms
Total and water-soluble magnesium oxide (MgO), calcium oxide (CaO), sulphur trioxide (SO_3)	± 25 % of the declared content of those nutrients up to a maximum of 1,0 percentage point in absolute terms
Total and water-soluble sodium oxide (Na_2O)	± 25 % of the declared content up to a maximum of 0,9 percentage point in absolute terms
Quantity	± 1,5 % relative deviation of the declared value

▼B

Micronutrient	Permissible tolerance for the declared content of forms of micronutrient
Concentration below or equal to 2 %	± 20 % of the declared value
Concentration of more than 2 % and below or equal to 10 %	± 20 % of the declared value up to a maximum of 1,0 percentage point in absolute terms
Concentration of more than 10 %	± 1,0 percentage point in absolute terms

PFC 1(C): INORGANIC FERTILISER

▼M1

Forms of the declared nutrient and other declared parameters	Permissible tolerance for the declared macronutrient content and other declared parameters
Declared forms of nitrogen (N)	± 25 % relative deviation of the declared value up to a maximum of 2 percentage points in absolute terms
Declared forms of phosphorus pentoxide (P_2O_5)	± 25 % relative deviation of the declared value up to a maximum of 2 percentage points in absolute terms
Declared forms of potassium oxide (K_2O)	± 25 % relative deviation of the declared value up to a maximum of 2 percentage points in absolute terms
Declared forms of nitrogen (N), phosphorus pentoxide (P2O5) or potassium oxide (K2O) in binary fertilisers	± 1,5 percentage points in absolute terms
Declared forms of nitrogen (N), phosphorus pentoxide (P2O5) or potassium oxide (K2O) in tertiary fertilisers	± 1,9 percentage points in absolute terms
Total and water-soluble magnesium oxide (MgO), calcium oxide (CaO), sulphur trioxide (SO_3)	-50 and +100 % relative deviation of the declared content of those nutrients up to a maximum of -2 and + 4 percentage points in absolute terms
Total and water soluble sodium oxide (Na_2O)	– 25 % of the declared content up to a maximum of 0,9 percentage point in absolute terms + 50 % of the declared content up to a maximum of 1,8 percentage points in absolute terms
Granulometry	± 20 % relative deviation of the declared percentage of material passing a specific sieve

▼M10

Quantity	± 1 % relative deviation of the declared value for products belonging to PFC 1(C)(I) ± 5 % relative deviation of the declared value for products belonging to PFC 1(C)(II)

▼M1

Micronutrient	Permissible tolerance for the declared content of forms of micronutrient
Concentration below or equal to 2 %	± 50 % of the declared value
Concentration of more than 2 % and below or equal to 10 %	± 50 % of the declared value up to a maximum of 1,0 percentage point in absolute terms
Concentration of more than 10 %	± 1,0 percentage point in absolute terms

▼M10

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▼B

PFC 2: LIMING MATERIAL

Forms of the declared nutrient and other declared parameters	Permissible tolerances for the declared parameter
Neutralising value	± 3
Granulometry	± 10 % relative deviation of the declared percentage of material passing a specific sieve.
Total calcium oxide (CaO)	± 3,0 percentage points in absolute terms
Total magnesium oxide (MgO)	
Concentration below 8 %	± 1,0 percentage point in absolute terms
Concentration between 8 to 16 %	± 2,0 percentage points in absolute terms
Concentration above or equal to 16 %	± 3,0 percentage points in absolute terms
Reactivities (hydrochloric acid test and incubation test)	± 5,0 percentage points in absolute terms
Quantity	± 1 % relative deviation of the declared value

PFC 3: SOIL IMPROVER

Forms of the declared nutrient and other declared parameters	Permissible tolerances for the declared parameter
pH	± 1,0 of the declared value
▼M1 Organic carbon (C_{org})	± 10 % relative deviation of the declared value up to a maximum of 3,0 percentage points in absolute terms
▼B Organic nitrogen (N_{org})	± 50 % relative deviation of the declared value up to a maximum of 1,0 percentage point in absolute terms
Total nitrogen (N)	± 20 % relative deviation up to a maximum of 1,0 percentage point in absolute terms
Total phosphorus pentoxide (P_2O_5)	± 20 % relative deviation up to a maximum of 1,0 percentage point in absolute terms
Total potassium oxide (K_2O)	± 20 % relative deviation up to a maximum of 1,0 percentage point in absolute terms
Dry matter content	± 10 % relative deviation of the declared value
Quantity	± 5 % relative deviation of the declared value
Electrical conductivity	± 75 % relative deviation of the declared value

▼B

PFC 4: GROWING MEDIUM

Forms for the declared nutrient and other declared parameters	Permissible tolerances for the declared parameter
Electrical conductivity	± 75 % relative deviation of the declared value
pH	± 1,0 of the declared value
Quantity by volume (litres or m^3)	± 5 % relative deviation of the declared value
Quantity (volume) determination of materials with particle size greater than 60 mm	± 5 % relative deviation of the declared value
Quantity (volume) determination of pre-shaped growing medium	± 5 % relative deviation of the declared value
Nitrogen (N) extractable by $CaCl_2$/ DTPA (calcium chloride/ diethylenetriaminepentaacetic acid; 'CAT-soluble')	± 75 % relative deviation of the declared value
Phosphorus pentoxide (P_2O_5) extractable by $CaCl_2$/DTPA (calcium chloride/ diethylenetriaminepentaacetic acid; 'CAT-soluble')	± 75 % relative deviation of the declared value
Potassium oxide (K_2O) extractable by $CaCl_2$/DTPA (calcium chloride/ diethylenetriaminepentaacetic acid; 'CAT-soluble')	± 75 % relative deviation of the declared value

PFC 5: INHIBITOR

Inhibiting compound	Permissible tolerance for the declared content of inhibiting compound
Concentration below or equal to 2 %	± 20 % of the declared value
Concentration of more than 2 %	± 10 % of the declared value up to a maximum of ± 2 % in absolute terms

▼B

Quantity: ± 5 % relative deviation of the declared value

▼M1

PFC 6: PLANT BIOSTIMULANT

The quantity of a plant biostimulant may deviate by ± 5 %.from the declared value.

▼B

PFC 6(A): MICROBIAL PLANT BIOSTIMULANT

The actual concentration(s) of micro-organisms may deviate by no more than 15 % from the declared value(s).

▼B

PFC 7: FERTILISING PRODUCT BLEND

▼M1

Declared parameter	Permissible tolerance for the declared parameter
Quantity	the tolerance is the sum of the relative proportion of each component EU fertilising product multiplied by the tolerance for the PFC for that fertilising product. If the proportion of each EU fertilising product in the fertilising product blend cannot be determined, the tolerance is that of the PFC with the strictest quantity tolerance value.

▼B

Where the fertilising product blend contains one or more plant biostimulants belonging to PFC 6, the following tolerances shall apply for the declared concentration of each plant biostimulant:

Declared concentration in g/kg or g/l at 20 °C	Permissible tolerance
Up to 25	± 15 % relative deviation
More than 25 up to 100	± 10 % relative deviation
More than 100 up to 250	± 6 % relative deviation
More than 250 up to 500	± 5 % relative deviation
More than 500	± 25 g/kg or ± 25 g/l

▼B

ANNEX IV

Conformity assessment procedures

PART I

APPLICABILITY OF CONFORMITY ASSESSMENT PROCEDURES

This Part sets out the applicability of conformity assessment procedure modules, as specified in Part II of this Annex, to EU fertilising products depending on their CMCs as specified in Annex II, and their PFCs as specified in Annex I.

1. APPLICABILITY OF INTERNAL PRODUCTION CONTROL (MODULE A)

1.1. Module A may be used for an EU fertilising product composed solely of one or more of the following component materials:

▼M6

(a) virgin material substances or mixtures as specified in CMC 1 in Part II of Annex II, except a nitrification, a denitrification or a urease inhibiting compound,

▼B

(b) fresh crop digestates as specified in CMC 4 in Part II of Annex II,

(c) food industry by-products as specified in CMC 6 in Part II of Annex II,

▼C2

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▼B

(e) nutrient polymers as specified in CMC 8 in Part II of Annex II,

(f) by-products within the meaning of Directive 2008/98/EC as specified in CMC 11 in Part II of Annex II.

1.2. Module A may also be used for a fertilising product blend as specified in PFC 7.

1.3. By derogation from points 1.1 and 1.2, Module A must not be used for:

(a) a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content, as specified in PFC 1 (C)(I)(a)(i-ii)(A), or a fertilising product blend as specified in PFC 7 containing 28 % or more by mass of nitrogen (N) from an EU fertilising product belonging to PFC 1(C)(I)(a)(i-ii)(A),

(b) an inhibitor as specified in PFC 5, or

(c) a plant biostimulant as specified in PFC 6.

2. APPLICABILITY OF INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT TESTING (MODULE A1)

Module A1 shall be used for a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content, as specified in PFC 1(C)(I)(a)(i-ii)(A), and for a fertilising product blend as specified in PFC 7 containing 28 % or more by mass of nitrogen (N) from an EU fertilising product belonging to PFC 1(C)(I)(a)(i-ii)(A).

3. APPLICABILITY OF EU-TYPE EXAMINATION (MODULE B) FOLLOWED BY CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL (MODULE C)

3.1. Module B followed by Module C may be used for an EU fertilising product composed solely of one or more of the following component materials:

▼M6

(a) nitrification, denitrification or urease inhibiting compound as specified in CMC 1 in Part II of Annex II,

▼B

(b) plants, plant parts or plant extracts as specified in CMC 2 in Part II of Annex II,

▼C3

(ba) micro-organisms as specified in CMC 7 in Part II of Annex II,

▼B

(c) polymers other than nutrient polymers as specified in CMC 9 in Part II of Annex II,

(d) derived products within the meaning of Regulation (EC) No 1069/2009 as specified in CMC 10 in Part II of Annex II,

(e) CMCs referred to in point 1.1 of this Part.

▼M1

3.2. Module B followed by Module C may also be used for a fertilising product blend as specified in PFC 7.

▼B

3.3. By derogation from points 3.1 and 3.2, Module B followed by Module C must not be used for a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content, as specified in PFC 1(C)(I)(a)(i-ii)(A), or a fertilising product blend as specified in PFC 7 containing 28 % or more by mass of nitrogen (N) from an EU fertilising product belonging to PFC 1(C)(I)(a)(i-ii)(A).

4. APPLICABILITY OF QUALITY ASSURANCE OF THE PRODUCTION PROCESS (MODULE D1)

4.1. Module D1 may be used for any EU fertilising product.

4.2. By derogation from point 4.1, Module D1 must not be used for a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content, as specified in PFC 1(C)(I)(a)(i-ii)(A), or a fertilising product blend as specified in PFC 7 containing 28 % or more by mass of nitrogen (N) from an EU fertilising product belonging to PFC 1(C)(I)(a)(i-ii)(A).

PART II

DESCRIPTION OF CONFORMITY ASSESSMENT PROCEDURES

MODULE A – INTERNAL PRODUCTION CONTROL

1. Description of the module

Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down under points 2, 3 and 4, and ensures and declares on his or her sole responsibility that the EU fertilising products concerned satisfy the requirements of this Regulation that apply to them.

2. Technical documentation

2.1. The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the EU fertilising product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).

2.2. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and intended use of the EU fertilising product. The technical documentation shall contain, where applicable, at least the following elements:

▼B

(a) a general description of the EU fertilising product, the PFC corresponding to the claimed function of the EU fertilising product and description of the intended use,

(b) a list of component materials used, the CMCs as referred to in Annex II to which they belong and information about their origin or manufacturing process,

(c) the EU declarations of conformity for the component EU fertilising products of the fertilising product blend,

(d) drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product,

(e) a specimen of the label or the leaflet, or both, referred to in Article 6(7)containing the information required in accordance with Annex III,

(f) a list of the harmonised standards referred to in Article 13, common specifications referred to in Article 14 and/or other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,

▼M1

(g) results of calculations made, examinations carried out, etc.,

▼B

(h) test reports,

(i) where the EU fertilising product contains or consists of by-products within the meaning of Directive 2008/98/EC, technical and administrative evidence that the by-products comply with the criteria established by delegated act referred to in Article 42(7) of this Regulation, and with the national measures transposing Article 5(1) of Directive 2008/98/EC and, where applicable, implementing acts referred to in Article 5(2) or national measures adopted under Article 5(3) of that Directive,

▼M1

(j) where the EU fertilising product contains total chromium (Cr) above 200 mg/kg dry matter, information about the maximum quantity and exact source of total chromium (Cr).

▼B

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured EU fertilising products with the technical documentation referred to under point 2 and with the requirements of this Regulation that apply to them.

4. CE marking and EU declaration of conformity

4.1. The manufacturer shall affix the CE marking to each individual packaging of the EU fertilising product that satisfies the applicable requirements of this Regulation, or, where it is supplied without packaging, in a document accompanying the EU fertilising product.

4.2. The manufacturer shall draw up a written EU declaration of conformity for an EU fertilising product or type and keep it together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market. The EU declaration of conformity shall identify the EU fertilising product or type for which it has been drawn up.

4.3. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

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5. Authorised representative

The manufacturer's obligations set out under point 4 may be fulfilled by his or her authorised representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.

MODULE A1 – INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT TESTING

1. Description of the module

Internal production control plus supervised product testing is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down under points 2, 3, 4, and 5, and ensures and declares on his or her sole responsibility that the EU fertilising products concerned satisfy the requirements of this Regulation that apply to them.

2. Technical documentation

2.1. The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the EU fertilising product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).

2.2. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and intended use of the EU fertilising product. The technical documentation shall contain, where applicable, at least the following elements:

(a) a general description of the EU fertilising product, the PFC corresponding to the claimed function of the EU fertilising product and description of the intended use,

(b) a list of component materials used, the CMCs as referred to in Annex II to which they belong and information about their origin or manufacturing process,

(c) the EU declarations of conformity for the component EU fertilising products of the fertilising product blend,

(d) drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product,

(e) a specimen of the label or the leaflet, or both, referred to in Article 6(7) containing the information required in accordance with Annex III,

(f) the names and addresses of the sites, and of the operators of the sites, at which the product and its principal components were manufactured,

(g) a list of the harmonised standards referred to in Article 13, common specifications referred to in Article 14 and/or other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,

▼M1

(h) results of calculations made, examinations carried out, etc.,

▼B

(i) test reports, including the reports from product checks for oil retention and detonation resistance, referred to in point 4 and

▼B

(j) where the EU fertilising product contains or consists of by-products within the meaning of Directive 2008/98/EC, technical and administrative evidence that the by-products comply with the criteria established by delegated acts referred to in Article 42(7) of this Regulation, and with the national measures transposing Article 5(1) of Directive 2008/98/EC and, where applicable, implementing acts referred to in Article 5(2) or national measures adopted under Article 5(3) of that Directive.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured EU fertilising products with the technical documentation referred to in point 2 and with the requirements of this Regulation that apply to them.

4. Product checks for oil retention and detonation resistance

The thermal cycles and tests referred to in points 4.1 to 4.4 shall be carried out on a representative sample of the EU fertilising product every 3 months on behalf of the manufacturer, in order to verify conformity with:

(a) the oil retention requirement referred to in point 4 under PFC 1 (C)(I)(a)(i-ii)(A) in Annex I, and

(b) the detonation resistance requirement referred to in point 5 under PFC 1(C)(I)(a)(i-ii)(A) in Annex I.

The thermal cycles and tests shall be carried out under the responsibility of a notified body chosen by the manufacturer.

4.1. Thermal cycles prior to a test for compliance with the oil retention requirement referred to in point 4 under PFC 1(C)(I)(a)(i-ii)(A) in Annex I

4.1.1. Principle and definition

In a closed suitable laboratory flask, heat the sample from ambient temperature to 50 °C and maintain at this temperature for a period of two hours (phase at 50 °C). Thereupon cool the sample until a temperature of 25 °C is achieved and maintain at that temperature for two hours (phase at 25 °C). The combination of the successive phases at 50 °C and 25 °C forms one thermal cycle. After being subjected to two thermal cycles, the test sample is held at a temperature of 20 (± 3) °C for the determination of the oil retention value.

4.1.2. Apparatus

Normal laboratory apparatus, in particular:

(a) water baths or ovens thermostated at 25 ± 1 °C and 50 ± 1 °C respectively,

(b) suitable laboratory flasks with an individual capacity of 150 ml.

4.1.3. Procedure

4.1.3.1. Put each test sample of 70 ± 5 g into a suitable laboratory flask which is then closed.

4.1.3.2. After attaining the temperature of 50 °C and maintain that temperature for two hours, change the temperature of the flask to the 25 °C bath or oven and proceed as described in 4.1.1.

▼B

4.1.3.3. If using a water bath maintain the water of each bath at constant temperature and keep in motion by rapid stirring. Ensure the water level comes above the level of the sample. Protect the stopper from condensation by a foam rubber cap.

4.2. Oil retention test referred to in point 4 under PFC 1(C)(I)(a)(i-ii)(A) in Annex I

4.2.1. Description

The oil retention of an EU fertilising product shall be the quantity of oil retained by the EU fertilising product determined under the operating conditions specified and expressed as a % by mass.

The test shall be carried out on a representative sample of the EU fertilising product. Before being tested, the whole mass of the sample shall be thermally cycled two times in accordance with point 4.1.

The method is applicable to both prilled and granular fertilisers which do not contain oil soluble materials.

4.2.2. Principle

Total immersion of the test sample in gas oil for a specified period, followed by the draining away of surplus oil under specified conditions. Measurement of the increase in mass of the test portion.

4.2.3. Reagents

Gas oil with the following characteristics:

(a) viscosity max.: 5 mPas at 40 °C;

(b) density: 0,8 g/ml to 0,85 g/ml at 20 °C;

(c) sulphur content: ≤ 1,0 % (m/m);

(d) ash: ≤ 0,1 % (m/m).

4.2.4. Apparatus

Ordinary laboratory apparatus, and:

(a) balance, capable of weighing to the nearest 0,01 g;

(b) beakers, of capacity 500 ml;

(c) funnel, of plastic materials, preferably with a cylindrical wall at the upper end, diameter approximately 200 mm;

(d) test sieve, aperture 0,5 mm, fitting into the funnel;

Note: The size of the funnel and sieve is such as to ensure that only a few granules lie one above another and the oil is able to drain easily.

(e) filter paper, rapid filtering grade, creped, soft, mass 150 g/m^2;

(f) absorbent tissue (laboratory grade).

4.2.5. Procedure

4.2.5.1. Two individual determinations are carried out in quick succession on separate portions of the same test sample.

4.2.5.2. Remove particles smaller than 0,5 mm using the test sieve. Weigh to the nearest 0,01 g approximately 50 g of the sample into the beaker. Add sufficient gas oil to cover the prills or granules completely and stir carefully to ensure that the surfaces of all the prills or granules are fully wetted. Cover the beaker with a watch glass and leave to stand for one hour at 25 (± 2) °C.

▼B

4.2.5.3. Filter the entire contents of the beaker through the funnel containing the test sieve. Allow the portion retained by the sieve to remain there for one hour so that most of the excess oil can drain away.

4.2.5.4. Lay two sheets of filter paper (about 500 mm x 500 mm) on top of each other on a smooth surface; fold the four edges of both filter papers upwards to a width of about 40 mm to prevent the prills or granules from rolling away. Place two layers of absorbent tissue in the centre of the filter papers. Pour the entire contents of the sieve over the absorbent tissues and spread the prills or granules evenly with a soft, flat brush. After two minutes lift one side of the tissues to transfer the prills or granules to the filter papers beneath and spread them evenly over these with the brush. Lay another sheet of filter paper, similarly with its edges turned upward, on the sample and roll the prills or granules between the filter papers with circular movements while exerting a little pressure. Pause after every eight circular movements to lift the opposite corners of the filter papers and return to the centre the prills or granules that have rolled to the periphery. Keep to the following procedure: make four complete circular movements, first clockwise and then anticlockwise. Then roll the prills or granules back to the centre as described above. This procedure is to be carried out three times (24 circular movements, corners lifted twice). Carefully insert a new sheet of filter paper between the bottom sheet and the one above it and allow the prills or granules to roll onto the new sheet by lifting the edges of the upper sheet. Cover the prills or granules with a new sheet of filter paper and repeat the same procedure as described above. Immediately after rolling, pour the prills or granules into a tared dish and reweigh to the nearest 0,01 g to determine the mass of the quantity of gas oil retained.

4.2.5.5. Repeating the rolling procedure and reweighing

If the quantity of gas oil retained in the portion is found to be greater than 2,00 g, place the portion on a fresh set of filter papers and repeat the rolling procedure, lifting the corners in accordance with point 4.2.5.4 (two times eight circular movements, lifting once). Then reweigh the portion.

4.2.5.6. Two oil retention tests per sample are to be carried out.

4.2.6. Test report

4.2.6.1. Expression of the results

4.2.6.1.1. Method of calculation and formula

The oil retention, from each determination (point 4.2.5.1) expressed as a % by mass of the sieved test portion, is given by the equation:

$$\text{Oil retention} = \frac{m_2 - m_1}{m_1} \times 100$$

where:

m_1 is the mass, in grams, of the sieved test portion (point 4.2.5.2),

m_2 is the mass, in grams, of the test portion according to points 4.2.5.4 and 4.2.5.5 respectively as the result of the last weighing.

▼B

4.2.6.1.2. Take as the result the arithmetic mean of the two individual determinations.

4.2.6.2. The test report shall form part of the technical documentation.

4.3. Thermal cycles prior to the detonation resistance test referred to in point 5 under PFC 1(C)(I)(a)(i-ii)(A) in Annex I

4.3.1. Principle and definition

In a tight box heat the sample from ambient temperature to 50 °C and maintain at this temperature for a period of one hour (phase at 50 °C). Thereupon cool the sample until a temperature of 25 °C is achieved and maintain at that temperature for one hour (phase at 25 °C). The combination of the successive phases at 50 °C and 25 °C forms one thermal cycle. After being subjected to the required number of thermal cycles, the test sample is held at a temperature of 20 ± 3 °C pending the execution of the detonation resistance test.

4.3.2. Apparatus

Method 1

(a) A water bath, thermostated in a temperature range of 20 to 51 ° C with a minimum heating and cooling rate of 10 °C/h, or two water baths, one thermostated at a temperature of 20 °C, the other at 51 °C. The water in the bath(s) is continuously stirred; the volume of the bath shall be large enough to guarantee ample circulation of the water.

(b) A stainless steel box, watertight all around and provided with a temperature recording device in the centre. The outside width of the box is 45 ± 2 mm and the wall thickness is 1,5 mm (see Figure 1 as an example). The height and length of the box can be chosen to suit the dimensions of the water bath, e.g. length 600 mm, height 400 mm.

Method 2

(a) Suitable oven, thermostated in a temperature range of 20 °C to 51 °C with a minimum heating and cooling rate of 10 °C/h.

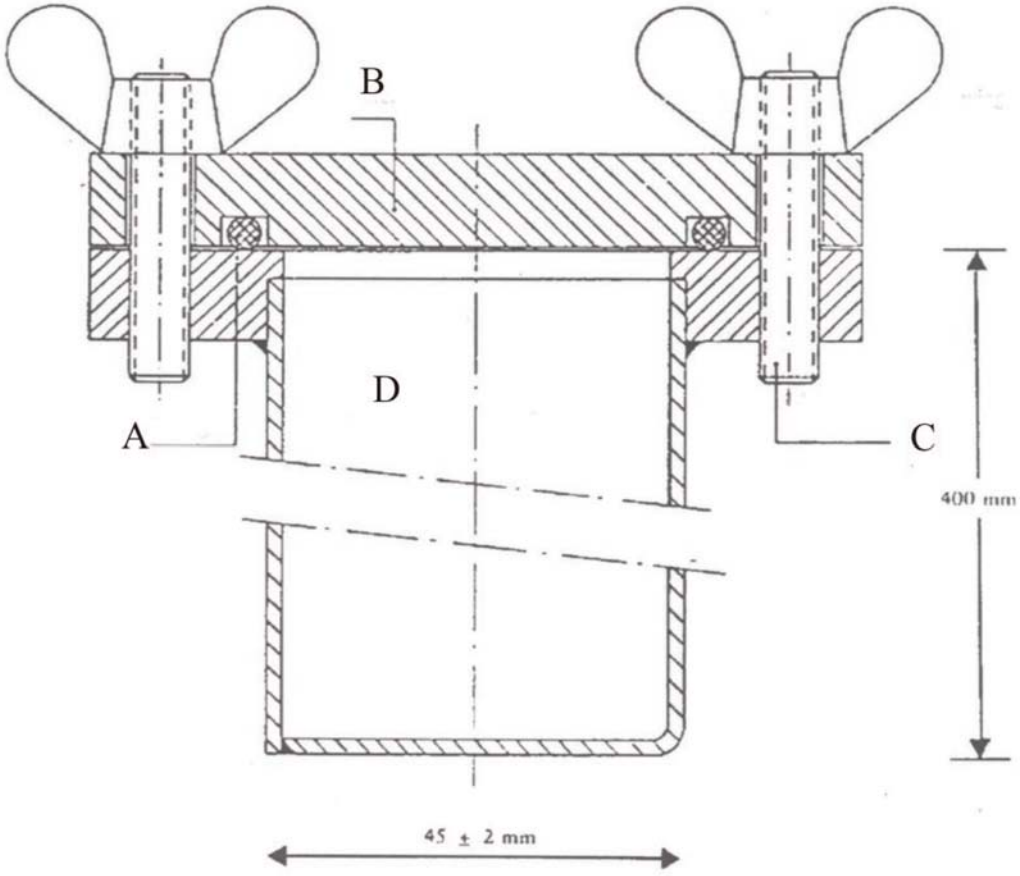
(b) Suitable airtight plastics boxes or bags provided with a suitable temperature recording device in the centre of the sample or a stainless steel box as described in point (b) of method 1 of point 4.3.2. Once filled, the outside thickness of the box or bag shall be maximum 45 mm.

4.3.3. Procedure

Place a quantity of fertilisers sufficient for the detonation resistance test into the boxes or bags and close them. Place the stainless steel boxes in the water bath (method 1) or the boxes or bags in the oven (method 2). Heat the water or oven to 51 °C and measure the temperature in the centre of the fertiliser. One hour after the temperature at the centre has reached 50 °C start cooling. One hour after the temperature at the centre has reached 25 °C start heating for the second cycle. In the case of two water baths or ovens, transfer the boxes or bags to the other bath or oven after each heating/cooling period.

▼B

Figure 1



A: O-ring

B: Cover

C: Bolt

D: Box

4.4. Detonation resistance test referred to in point 5 under PFC 1(C)(I)(a)(i-ii)(A) in Annex I

4.4.1. Description

4.4.1.1. The test shall be carried out on a representative sample of the EU fertilising product. Before being tested for resistance to detonation, the whole mass of the sample is to be thermally cycled five times in accordance with point 4.3.

4.4.1.2. The EU fertilising product shall be subjected to the detonation resistance test in a horizontal steel tube under the following conditions (the details of the materials are in point 4.4.3):

(a) seamless steel tube:

(i) Tube length: 1 000 mm at least,

(ii) Nominal external diameter: 114 mm at least,

(iii) Nominal wall thickness: 5 mm at least,

(b) booster: the type and mass of the booster chosen shall be such as to maximise the detonation pressure applied to the sample in order to determine its susceptibility to the transmission of detonation,

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(c) temperature of the sample: 15 °C to 25 °C,

(d) witness lead cylinders for detecting detonation: 50 mm diameter and 100 mm height,

(e) placed at 150 mm intervals and supporting the tube horizontally.

NOTE: The test is to be carried out twice. The test is deemed conclusive if in both tests one or more of the supporting lead cylinders is crushed by less than 5 %.

4.4.2. Principle

The test sample is confined in a steel tube and subjected to detonation shock from an explosive booster charge. Propagation of the detonation is determined from the degree of crushing of lead cylinders on which the tube rests horizontally during the test.

4.4.3. Materials

(a) Plastic explosive containing 83 % to 86 % penthrite

— density: 1 500 kg/m^3 to 1 600 kg/m^3

— detonation velocity: 7 300 m/s to 7 700 m/s

— mass: (500 ± 1) g;

or any other plastic explosive with similar detonation characteristics.

(b) Seven lengths of flexible detonating cord with non-metallic sleeve

— filling mass: 11 g/m to 13 g/m

— length of each cord: (400 ± 2) mm.

(c) Compressed pellet of secondary explosive, recessed to receive detonator

— explosive: hexogen/wax 95/5 or similar secondary explosive, with or without added graphite

— density: 1 500 kg/m^3 to 1 600 kg/m^3

— diameter: 19 mm to 21 mm

— height: 19 mm to 23 mm

— mass of the compressed pellet: maximum 10 g

— central recess to receive detonator: maximal diameter 7,0 to 7,3 mm, depth about 12 mm. In case of detonators with large diameters, the diameter of the recess shall be slightly larger (e.g. 0,5 mm) than the diameter of the detonator.

(d) Seamless steel tube as specified in ISO 65 – 1981 – Heavy Series, with nominal dimensions DN 100 (4")

— outside diameter: 113,1 mm to 115,0 mm

— wall thickness: 5,0 mm to 6,5 mm

— length: 1 005 ± 2 mm.

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(e) Bottom plate

— material: steel of good weldable quality

— dimensions: 160 mm × 160 mm

— thickness: 5 mm to 6 mm.

(f) Six lead cylinders

— diameter: 50 ± 1 mm

— height: 100 mm to 101 mm

— materials: soft lead, at least 99,5 % purity.

(g) Steel block

— length: at least 1 000 mm

— width: at least 150 mm

— height: at least 150 mm (alternatively a stack of several beams can be used to achieve this height)

— Mass: at least 300 kg if there is no firm base for the steel block.

(h) Plastic or cardboard cylinder for booster charge

— wall thickness: 1,5 mm to 2,5 mm

— diameter: 92 mm to 96 mm

— height: 64 mm to 67 mm.

(i) Detonator (electric or non-electric) with initiation force 8 to 10

(j) Wooden or plastic disc

— diameter: 92 mm to 96 mm. Diameter to be matched to the internal diameter of the plastic or cardboard cylinder (point (h))

— thickness: 20 mm.

(k) Wooden or plastic rod of same dimensions as detonator (point (i))

(l) Small split pins (maximum length 20 mm)

(m) Split pins (length about 20 mm)

4.4.4. Procedure

4.4.4.1. Preparation of booster charge for insertion into steel tube

Depending on the availability of equipment, the explosive can be initiated in the booster charge either

— by seven-point simultaneous initiation as referred to in point 4.4.4.1.1, or

— by central initiation by a compressed pellet as referred to in point 4.4.4.1.2.

▼B

4.4.4.1.1. Seven-point simultaneous initiation

The booster charge prepared for use is shown in Figure 2.

4.4.4.1.1.1. Drill holes in the wooden or plastic disc (point (j) under point 4.4.3) parallel to the axis of the disc through the centre and through six points symmetrically distributed around a concentric circle 55 mm in diameter. The diameter of the holes shall be 6 mm to 7 mm (see Section A-B in Figure 2), depending on the diameter of the detonating cord used (point (b) under point 4.4.3).

4.4.4.1.1.2. Cut seven lengths of flexible detonating cord (point (b) under point 4.4.3) each 400 mm long, avoiding any loss of explosive at each end by making a clean cut and immediately sealing the end with adhesive. Push each of the seven lengths through each of the seven holes in the wooden or plastic disc (point (j) under point 4.4.3) until their ends project a few centimetres on the other side of the disc. Then insert a small split pin (point (l) under point 4.4.3) transversally into the textile sleeve of each length of cord 5 mm to 6 mm from the end and apply adhesive around the outside of the lengths of cord in a band 2 cm wide adjacent to the pin. Finally, pull the long piece of each cord to bring the pin into contact with the wooden or plastic disc.

4.4.4.1.1.3. Shape the plastic explosive (point (a) under point 4.4.3) to form a cylinder 92 mm to 96 mm in diameter, depending on the diameter of the cylinder (point (h) under point 4.4.3). Stand this cylinder upright on a level surface and insert the shaped explosive. Then insert the wooden or plastic disc ([1]) carrying the seven lengths of detonating cord into the top of the cylinder and press it down onto the explosive. Adjust the height of the cylinder (64 mm to 67 mm) so that its top edge does not extend beyond the level of the wood or plastic. Finally, fix the cylinder to the wooden or plastic disc for instance with staples or small nails, around its entire circumference.

4.4.4.1.1.4. Group the free ends of the seven lengths of detonating cord around the circumference of the wooden or plastic rod (point (k) under point 4.4.3) so that their ends are all level in a plane perpendicular to the rod. Secure them in a bundle around the rod by means of adhesive tape ([2]).

4.4.4.1.2. Central initiation by a compressed pellet

The booster charge prepared for use is shown in Figure 3.

4.4.4.1.2.1. Preparing a compressed pellet

Taking the necessary safety precautions, place maximum 10 g of a secondary explosive (point (c) under point 4.4.3) in a mould with an inside diameter of 19 mm to 21 mm and compress to the correct shape and density (the ratio of diameter: height should be roughly 1:1). In the centre of the bottom of the mould there is a peg, 12 mm in height and 7,0 mm to 7,3 mm in diameter (depending on the diameter of the detonator used), which forms a cylindrical recess in the compressed cartridge for subsequent insertion of the detonator.

4.4.4.1.2.2. Preparing the booster charge

Place the explosive (point (a) under point 4.4.3) into the cylinder (point (h) under point 4.4.3) standing upright on a level surface, then press it down with a wooden or plastic die to give the explosive a cylindrical shape with a central recess. Insert the compressed pellet into this recess. Cover the cylindrically shaped explosive containing the compressed pellet with a wooden or plastic disc (point (j) under point 4.4.3) having a central hole 7,0 mm to

([1]) The diameter of the disc must always correspond to the inside diameter of the cylinder.
([2]) NB: When the six peripheral lengths of cord are taut after assembly, the central cord must remain slightly slack.

▼B

7,3 mm in diameter for insertion of a detonator. Fix the wooden or plastic disc and the cylinder together with a cross of adhesive tape. Ensure that the hole drilled in the disc and the recess in the compressed pellet are coaxial by inserting the wooden or plastic rod (point (k) under point 4.4.3).

4.4.4.2. Preparing steel tubes for the detonation tests

At one end of the steel tube (point (d) under point 4.4.3), drill two diametrically opposed holes 4 mm in diameter perpendicularly through the side wall at a distance of 4 mm from the edge. Butt weld the bottom plate (point (e) under point 4.4.3) to the opposite end of the tube, completely filling the right angle between the bottom plate and the wall of the tube with weld metal around the entire circumference of the tube.

4.4.4.3. Filling and charging the steel tube

See Figures 2 and 3.

4.4.4.3.1. The test sample, the steel tube and the booster charge shall be conditioned to temperatures of (20 ± 5) °C. About 20 kg of the test sample should be available for two detonation resistance tests.

4.4.4.3.2.1 Place the tube upright with its square bottom plate resting on a firm, flat surface, preferably concrete. Fill the tube to about one-third of its height with the test sample and drop it 10 cm vertically onto the flat surface five times to compact the prills or granules as densely as possible in the tube. To accelerate compaction, vibrate the tube by striking the side wall with a 750 g to 1 000 g hammer between drops for a total of 10 times.

4.4.4.3.2.2. Repeat this charging method with another portion of the test sample. Finally, a further addition shall be made such that, after compaction by raising and dropping the tube 10 times and a total of 20 intermittent hammer blows, the charge fills the tube to a distance of 70 mm from its orifice.

4.4.4.3.2.3 The filling height of the sample shall be adjusted in the steel tube so that the booster charge (referred to in point 4.4.4.1.1 or 4.4.4.1.2) to be inserted later will be in close contact with the sample over its entire surface.

4.4.4.3.3. Insert the booster charge into the tube so that it is in contact with the sample; the top surface of the wooden or plastic disc shall be 6 mm below the end of the tube. Ensure essential close contact between explosive and test sample by taking out the booster charge and adding or removing small quantities of sample. As shown in Figures 2 and 3, split pins should be inserted through the holes near the open end of the tube and their legs opened flat against the tube.

4.4.4.4. Positioning of the steel tube and lead cylinders (see Figure 4)

4.4.4.4.1. Number the bases of the lead cylinders (point (f) under point 4.4.3) 1, 2, 3, 4, 5 and 6. Make six marks 150 mm apart along a line on a steel block (point 4.4.3(g)) lying on a horizontal base, with each mark at least 75 mm from any edge of the block. Place a lead cylinder upright on each of these marks, with the base of each cylinder centred on its mark (see Figure 4).

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4.4.4.4.2. Lay the steel tube prepared according to point 4.4.4.3 horizontally on the lead cylinders so that the axis of the tube is parallel to the centre line of the lead cylinders and the welded end of the tube extends 50 mm beyond lead cylinder No 6. To prevent the tube from rolling, insert small wooden or plastic wedges between the tops of the lead cylinders and the tube wall (one on each side) or place a cross of wood between the tube and the steel block or stack of beams. (see Figure 4).

Note: Make sure that the tube is in contact with all six lead cylinders; a slight curvature of the tube surface can be compensated for by rotating the tube about its longitudinal axis; if any of the lead cylinders is too tall, tap the cylinder in question carefully with a hammer until it is the required height.

4.4.4.5. Preparation for detonation

4.4.4.5.1. Set up the apparatus as described in point 4.4.4.4 in a bunker or suitably prepared underground site or suitable location. Ensure that the temperature of the steel tube is kept at (20 ± 5) °C before detonation.

Note: Detonation can cause steel fragments to be projected with high kinetic energy, therefore, firing shall be carried out at a suitable distance from dwellings or thoroughfares.

4.4.4.5.2. If the booster charge with seven-point initiation is used, ensure that the detonation cords are stretched out as described in the footnote to point 4.4.4.1.1.4 and arranged as horizontally as possible.

4.4.4.5.3. Finally, remove the wooden or plastic rod and replace with the detonator. Do not carry out firing until the danger zone has been evacuated and the test personnel have taken cover.

4.4.4.5.4. Detonate the explosive.

4.4.4.6.1. Allow sufficient time for the fumes (gaseous and sometimes toxic decomposition products such as nitrous gases) to disperse, then collect the lead cylinders and measure their heights with a Vernier caliper.

4.4.4.6.2. Record for each of the marked lead cylinders, the degree of crushing expressed as a percentage of the original height of 100 mm. If the cylinders are crushed obliquely, record the highest and the lowest values and calculate the average.

4.4.4.7. Detonation velocity measurement can also be performed.

4.4.4.8. Two detonation tests per sample are to be carried out.

4.4.5. Test report

Values for the following parameters are to be given in the test report for each of the detonation resistance tests:

— the values actually measured for the outside diameter of the steel tube and for the wall thickness,

— the Brinell hardness of the steel tube,

— the temperature of the tube and the sample shortly before firing,

— the packing density (kg/m^3) of the sample in the steel tube,

▼B

— the height of each lead cylinder after firing, specifying the corresponding cylinder number,

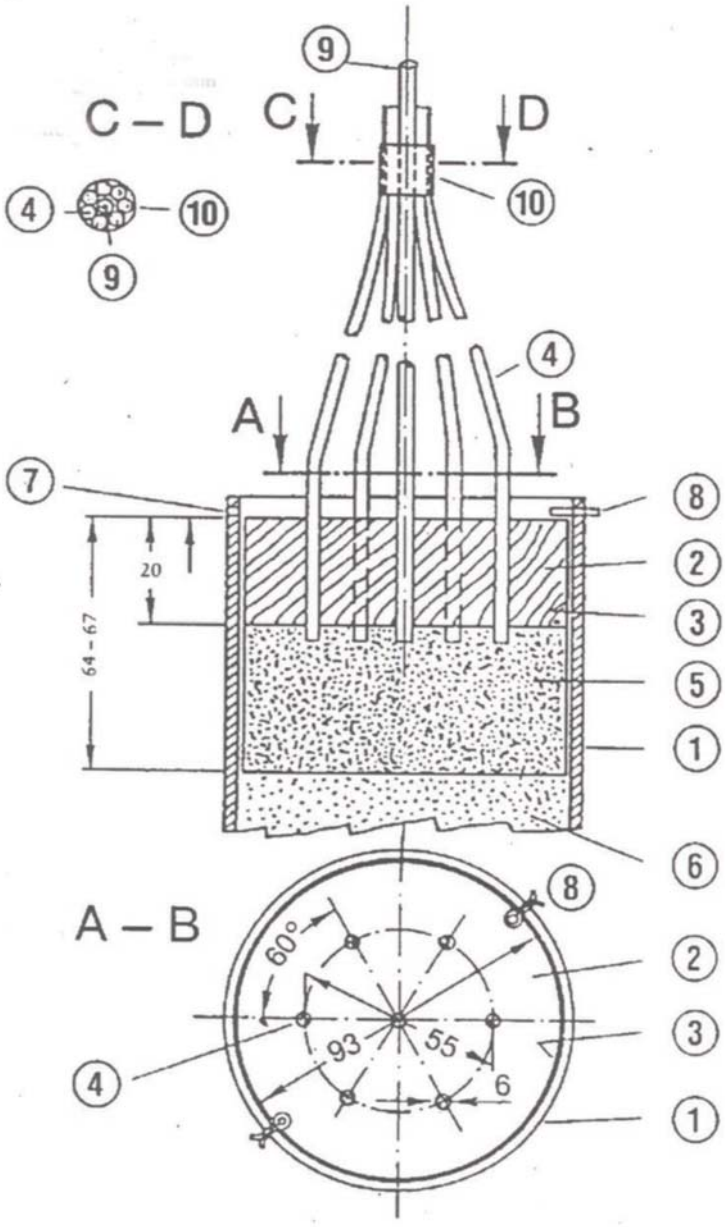
— method of initiation employed for the booster charge.

4.4.6. Evaluation of test results

If, in each firing, the crushing of at least one lead cylinder is less than 5 %, the test shall be considered conclusive and it shall be considered that the sample presented is resistant to detonation.

4.4.7. The test report shall form part of the technical documentation.

Figure 2



Booster charge with seven-point initiation

1: Steel tube

2: Wooden or plastic disc with seven holes

3: Plastic or cardboard cylinder

▼B

4: Detonating cords

5: Plastic explosive

6: Test sample

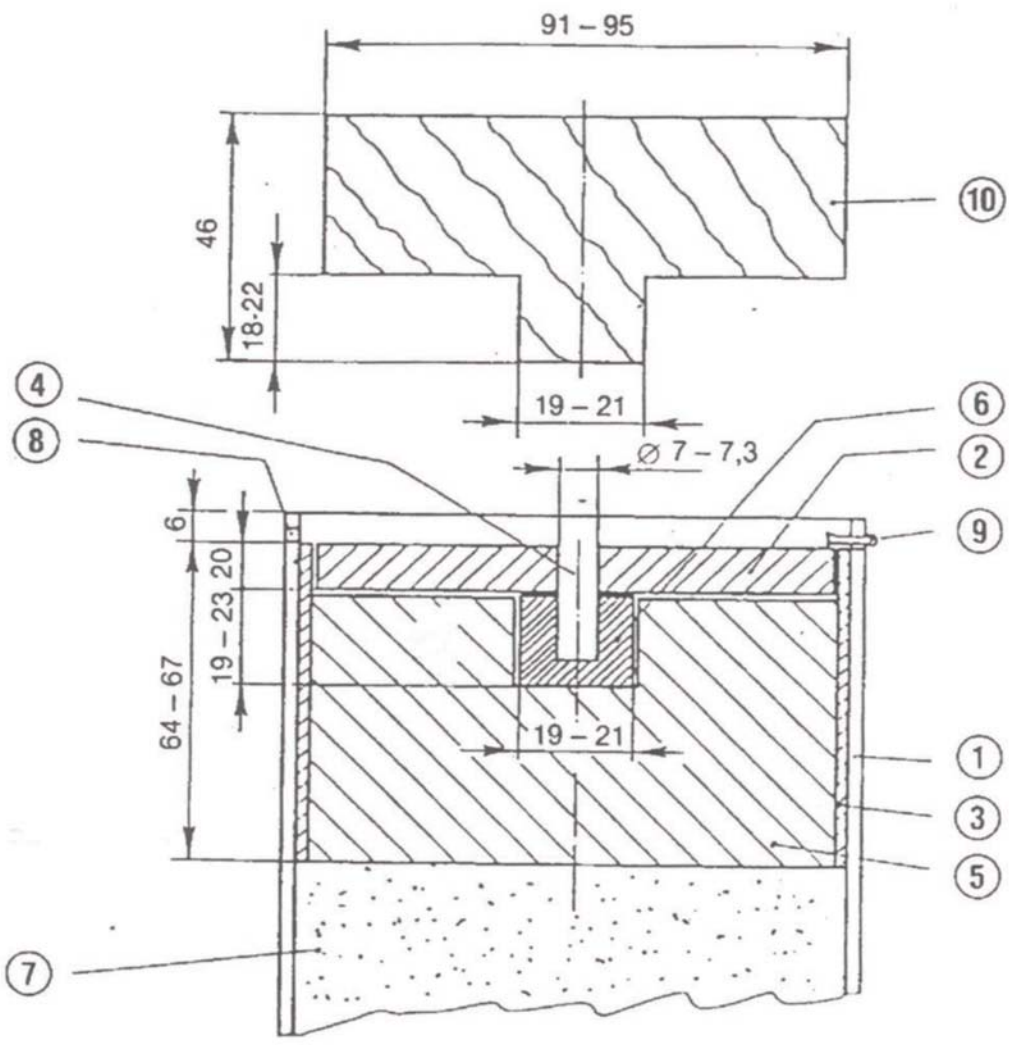
7: 4 mm hole drilled to receive split pin

8: Split pin

9: Wooden or plastic rod surrounded by 4

10: Adhesive tape for securing 4 around 9

Figure 3



1: Steel tube

2: Wooden of plastic disc

3: Plastic or cardboard cylinder

4: Wooden of plastic rod

5: Plastic explosive

6: Compressed pellet

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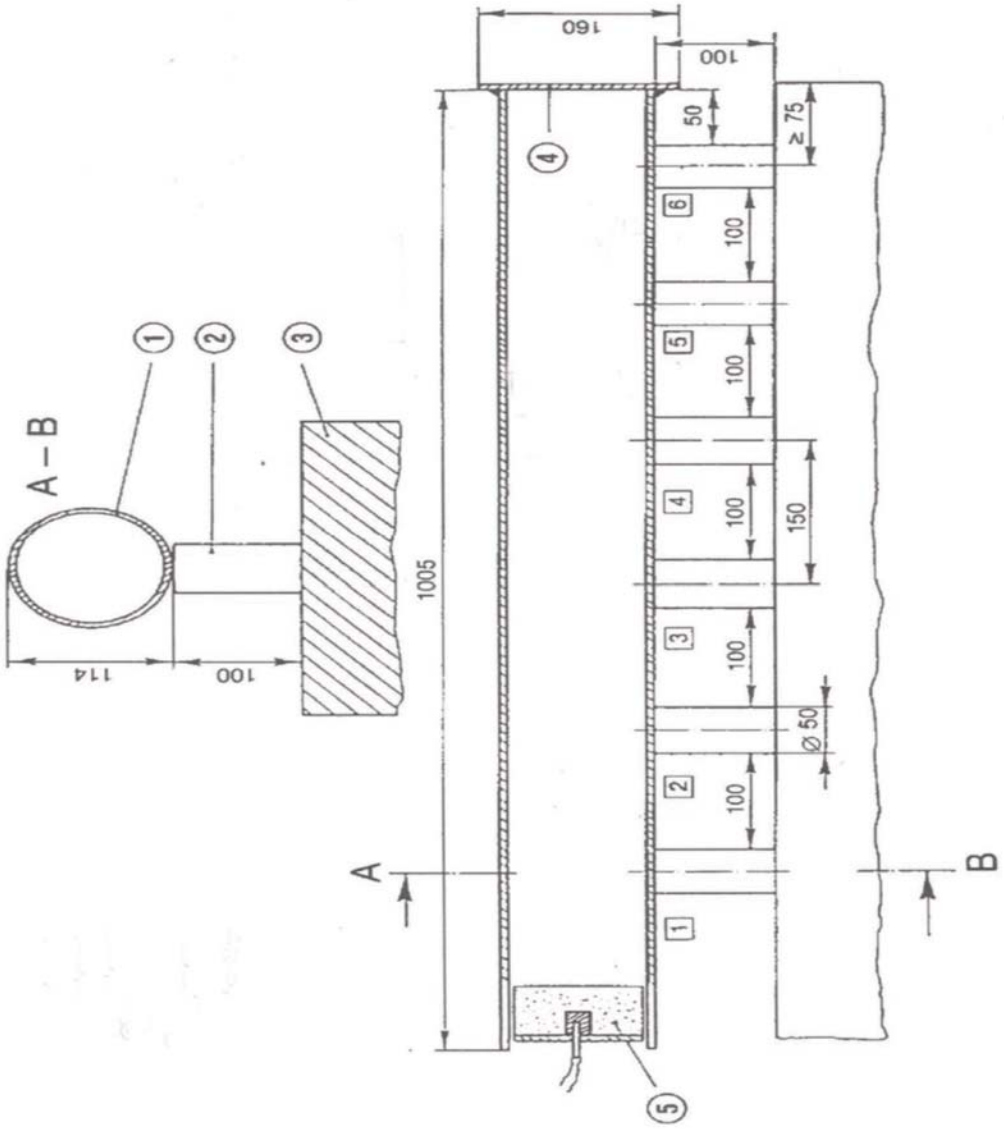
7: Test sample

8: 4 mm hole drilled to receive split pin

9: Split pin

10: Wooden or plastic die for 5

Figure 4



Numbers in circles:

1: Steel tube

2: Lead cylinders

3: Steel block or stack of beams

4: Bottom plate

5: Booster charge

Numbers in squares:

Lead cylinders 1 to 6

▼B

5. CE marking and EU declaration of conformity

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each individual packaging of the EU fertilising product that satisfies the applicable requirements of this Regulation or, where it is supplied without packaging, in a document accompanying the EU fertilising product.

5.2. The manufacturer shall draw up a written EU declaration of conformity for an EU fertilising product type and keep it together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market. The EU declaration of conformity shall identify the EU fertilising product type for which it has been drawn up.

5.3. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. Notified bodies' information and operational obligations

6.1. Each notified body shall, without undue delay, inform its notifying authority and other bodies notified under this Regulation carrying out similar conformity assessment activities covering the same EU fertilising products of the following:

(a) any case where the manufacturer has not complied with the 3-month period for performing the tests required under point 4;

(b) any test results which demonstrate non-conformity with the detonation resistance requirement referred to in point 5 under PFC 1(C)(I)(a)(i-ii)(A) in Annex I.

6.2. In the case referred to in point 6.1(b) the notified body shall request the manufacturer to take the necessary measures in accordance with Article 6(8).

7. Authorised representative

The manufacturer's obligations set out in points 4.4.7 and 5 may be fulfilled by his or her authorised representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.

MODULE B – EU-TYPE EXAMINATION

1. Description of the module

1.1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of an EU fertilising product and verifies and attests that the technical design of the EU fertilising product meets the requirements of this Regulation.

1.2. Assessment of the adequacy of the technical design of the EU fertilising product is carried out through examination of the technical documentation and supporting evidence, plus examination of samples, representative of the production envisaged.

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2. Technical documentation

2.1. The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the EU fertilising product's conformity with the relevant requirements and shall include an adequate analysis and assessment of the risk(s).

2.2. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and intended use of the EU fertilising product. The technical documentation shall contain, where applicable, at least the following elements:

(a) a general description of the EU fertilising product, the PFC corresponding to the claimed function of the EU fertilising product and description of the intended use,

(b) a list of component materials used, the CMCs as referred to in Annex II to which they belong and information about their origin or manufacturing process,

(c) the EU declarations of conformity for the component EU fertilising products of the fertilising product blend,

(d) drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product,

(e) a specimen of the label or the leaflet, or both, referred to in Article 6(7) containing the information required in accordance with Annex III,

(f) a list of the harmonised standards referred to in Article 13, common specifications referred to in Article 14 and/or other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,

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(g) results of calculations made, examinations carried out, etc.,

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(h) test reports,

(i) where the EU fertilising product contains or consists of derived products within the meaning of Regulation (EC) No 1069/2009, the commercial documents or health certificates required pursuant to that Regulation, and evidence that the derived products have reached the end point in the manufacturing chain within the meaning of that Regulation,

(j) where the EU fertilising product contains or consists of by-products within the meaning of Directive 2008/98/EC, technical and administrative evidence that the by-products comply with the criteria established by delegated act referred to in Article 42(7) of this Regulation, and with the national measures transposing Article 5(1) of Directive 2008/98/EC and, where applicable, implementing acts referred to in Article 5(2) or national measures adopted under Article 5(3) of that Directive, and

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(k) where the EU fertilising product contains total chromium (Cr) above 200 mg/kg dry matter, information about the maximum quantity and exact source of total chromium (Cr).

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3. Application for EU-type examination

3.1. The manufacturer shall lodge an application for EU-type examination with a single notified body of his or her choice.

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3.2. The application shall include:

(a) 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,

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

(c) the technical documentation referred to in point 2,

(d) the samples representative of the production envisaged. The notified body may request further samples if needed for carrying out the test programme,

(e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his or her behalf and under his or her responsibility.

4. Assessment of the adequacy of the technical design

The notified body shall:

(a) examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the EU fertilising product;

(b) verify that the sample(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;

(c) carry out appropriate examinations and tests on the sample(s), or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications, these have been applied correctly;

(d) carry out appropriate examinations and tests on the sample(s), or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, or where relevant harmonised standards or common specifications do not exist, the solutions adopted by the manufacturer meet the corresponding requirements of this Regulation;

(e) agree with the manufacturer on a location where the examinations and tests will be carried out.

5. Evaluation report

The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authority, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. EU-type examination certificate

6.1. Where the type meets the requirements of this Regulation that apply to the EU fertilising product concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the

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conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached.

6.2. The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured EU fertilising products with the examined type to be evaluated.

6.3. Where the type does not satisfy the requirements of this Regulation, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. Changes which may affect the conformity of the EU fertilising product

7.1. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the requirements of this Regulation and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

7.2. The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the EU fertilising product with the requirements of this Regulation or the conditions for validity of the EU-type examination certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

8. Notified bodies' information obligation

8.1. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of EU-type examination certificates and/or any additions thereto refused, suspended or otherwise restricted.

8.2. Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the EU-type examination certificates and/or additions thereto which it has issued.

8.3. The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body.

9. Availability of the EU-type examination certificate

9.1. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the EU-type examination certificate.

9.2. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market.

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10. Authorised representative

The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9.2, provided that they are specified in the mandate.

MODULE C – CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL

1. Description of the module

Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares on his or her sole responsibility that the EU fertilising products concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Regulation that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured EU fertilising products with the approved type described in the EU-type examination certificate and with the requirements of this Regulation that apply to them.

3. CE marking and EU declaration of conformity

3.1 The manufacturer shall affix the CE marking to each individual packaging of the EU fertilising product that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Regulation or, where it is supplied without packaging, in a document accompanying the EU fertilising product.

3.2 The manufacturer shall draw up a written EU declaration of conformity for an EU fertilising product type and keep it together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market. The EU declaration of conformity shall identify the EU fertilising product type for which it has been drawn up.

3.3. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

4. Authorised representative

The manufacturer's obligations set out in point 3 may be fulfilled by his or her authorised representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.

MODULE D1 – QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. Description of the module

Quality assurance of the production process is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 4, and 7, and ensures and declares on his or her sole responsibility that the EU fertilising products concerned satisfy the requirements of this Regulation that apply to them.

2. Technical documentation

2.1. The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the EU fertilising product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).

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2.2. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and intended use of the EU fertilising product. The technical documentation shall contain, where applicable, at least the following elements:

(a) a general description of the EU fertilising product, the PFC corresponding to the claimed function of the EU fertilising product and description of the intended use,

(b) a list of component materials used, the CMCs as referred to in Annex II, to which they belong and information about their origin or manufacturing process,

(c) the EU declarations of conformity for the component EU fertilising products of the fertilising product blend,

▼M5

(d) drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product, and, in relation to materials belonging to CMCs 3, 5, 12, 13, 14 or 15 as defined in Annex II, a written description and a diagram of the production or recovery process, where each treatment, storage vessel and area is clearly identified,

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(e) a specimen of the label or the leaflet, or both, referred to in Article 6(7) containing the information required in accordance with Annex III,

(f) a list of the harmonised standards referred to in Article 13, common specifications referred to in Article 14 and/or other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,

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(g) results of calculations made, examinations carried out, etc.,

▼M3

(ga) hazardous waste calculations for EU fertilising products containing or consisting of CMC 13; the testing referred to in point 6 in CMC 13 in Part II of Annex II shall be carried out at least every year, or sooner than scheduled in case of any significant change that may affect the safety or quality of the EU fertilising product (for example processing of input material batches of different composition, modification of process conditions). For a representative input material batch that is processed at the plant, the hazardous property identified (in accordance with point 5.1.3.1) and the total mass shall be measured on the different input materials (1, …, n) and on the output material that will be incorporated in the EU fertilising product. The incorporation rate of the hazardous property into the output material shall then be calculated as follows:

$$incorporation\ rate\ (\%) = \frac{HPC_{output\ material} \times M_{output\ material}}{\sum_{i=1}^{n}(HPC_{input\ material,i} \times M_{input\ material,i})}$$

Where:

HPC = the concentration of the hazardous property (mg/kg),

M = the total mass (kg), and

i (1-n) = the different input materials used in the production process.

▼M3

The removal of the hazardous property during the production process shall be such that the incorporation rate multiplied by the concentration of the hazardous property of each individual input material is below the limit values laid down in Annex III to Directive 2008/98/EC for that hazardous property,

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(h) test reports,

(i) where the EU fertilising product contains or consists of derived products within the meaning of Regulation (EC) No 1069/2009, the commercial documents or health certificates required pursuant to that Regulation, and evidence that the derived products have reached the end point in the manufacturing chain within the meaning of that Regulation,

(j) where the EU fertilising product contains or consists of by-products within the meaning of Directive 2008/98/EC, technical and administrative evidence that the by-products comply with the criteria established by delegated act referred to in Article 42(7) of this Regulation, and with the national measures transposing Article 5(1) of Directive 2008/98/EC and, where applicable, implementing acts referred to in Article 5(2) or national measures adopted under Article 5(3) of that Directive, and

▼M1

(k) where the EU fertilising product contains total chromium (Cr) above 200 mg/kg dry matter, information about the maximum quantity and exact source of total chromium (Cr).

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3. Availability of technical documentation

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 5 years after the EU fertilising product has been placed on the market.

4. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the EU fertilising products concerned as specified in point 5, and shall be subject to surveillance as specified in point 6.

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.

▼M5

5.1.1.1. For materials belonging to CMCs 3, 5, 12, 13, 14 and 15, as defined in Annex II, senior management of the manufacturer's organisation shall:

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

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(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.

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5.1.2.1. For materials belonging to CMCs 3, 5, 12, 13, 14 and 15, as defined in Annex II, the quality system shall ensure compliance with the requirements specified in that Annex.

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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.

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5.1.3.1. For materials belonging to CMCs 3, 5, 12, 13, 14 and 15, as defined in Annex II, the examinations and tests shall comprise the following elements:

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(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.

▼M5

(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 CMCs 3, 5, 12, 13, 14 and 15 in Annex II [OR: as defined in Annex II].

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

— the presence of hazardous or damaging substances for the process or for the quality of the final EU fertilising product,

— incompatibility with the specifications laid down in CMCs 3, 5, 12, 13, 14 and 15 in Annex II [OR: as defined in Annex II], in particular by presence of plastics leading to exceedance of the limit value for macroscopic impurities.

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(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.

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(e) Samples shall be taken on output materials, to verify that they comply with the specifications laid down in CMCs 3, 5, 12, 13, 14 and 15, as defined in Annex II, and that the properties of the output material do not jeopardise the EU fertilising product's compliance with the relevant requirements laid down in Annex I.

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(f) For materials belonging to CMCs 3 and 5, the output material samples shall be taken on a regular basis with at least the following frequency:

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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

▼M5

(fa) For materials belonging to CMCs 12, 13, 14 and 15, the output material samples shall be taken with at least the following default frequency, or sooner than scheduled in the case of any significant change that may affect the quality of the EU fertilising product:

▼M2

Annual output (tonnes)	Samples/year
≤ 3 000	4
3 001 – 10 000	8
10 001 – 20 000	12
20 001 – 40 000	16
40 001 – 60 000	20
60 001 – 80 000	24
80 001 – 100 000	28
100 001 – 120 000	32
120 001 – 140 000	36
140 001 – 160 000	40
160 001 – 180 000	44
> 180 000	48

Manufacturers may reduce the default frequency of testing for contaminants as indicated above by considering the distribution of historical samples. After a minimum monitoring period of one year and a minimum number of 10 samples showing compliance with the requirements in Annex I and II, the manufacturer may reduce the default sampling frequency for that parameter by a factor 2 in case the greatest contaminant level recorded from the last 10 samples is smaller than half of the limit value for that parameter laid down in Annexes I and II.

▼M5

(fb) For materials belonging to CMCs 12, 13, 14 and 15, each batch or portion of production shall be assigned a unique code for quality management purposes. At least one sample per 3 000 tonnes of these materials or one sample per two months, whichever occurs sooner, shall be stored in good condition for a period of at least two years.

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(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 ►M2 , ◄

▼M5

(iv) for materials belonging to CMCs 12, 13, 14 and 15, measure retainer samples referred to in sub-point (fb) and take the necessary corrective actions to prevent possible further transport and use of that material.

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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.

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5.1.4.1. For materials belonging to CMCs 3, 5, 12, 13, 14 and 15, 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:

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(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.

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5.1.5.1. For materials belonging to CMCs 3, 5, 12, 13, 14 and 15, 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:

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(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;

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(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.

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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.

6. Surveillance under the responsibility of the notified body

6.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

6.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

— the quality system documentation,

— the technical documentation referred to in point 2,

— the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned.

6.3.1. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

▼M12

6.3.2. For materials belonging to CMCs 3, 5, 12, 13, 14 and 15, as defined in Annex II, the notified body shall carry out annual audits. In addition, the notified body shall take and analyse output material samples with the following frequency:

▼M2

(a) during the notified body's first year of surveillance of the plant in question: the same frequency as the sampling frequency indicated in the tables included in points 5.1.3.1(f) and, respectively, 5.1.3.1(fa); and

(b) during the following years of surveillance: half the sampling frequency indicated in the table included in point 5.1.3.1(f) and, respectively, 5.1.3.1(fa).

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6.4 In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

7. CE marking and EU declaration of conformity

7.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 5.2, the latter's identification number to each individual packaging of the EU fertilising product that satisfies the applicable requirements of this Regulation or, where it is supplied without packaging, in a document accompanying the EU fertilising product.

7.2. The manufacturer shall draw up a written EU declaration of conformity for an EU fertilising product or type and keep it, together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market. The EU declaration of conformity shall identify the EU fertilising product or type for which it has been drawn up.

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7.3. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

8. Availability of quality system documentation

The manufacturer shall, for 5 years after the EU fertilising product has been placed on the market, keep at the disposal of the national authorities:

— the documentation referred to in point 5.1.6,

— the information on the changes referred to in points 5.5.1 and 5.5.2, as approved,

— the decisions and reports of the notified body referred to in points 5.5.3, 6.3.1 and 6.4.

9. Notified bodies' information obligation

9.1. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

9.2. Each notified body shall inform the other notified bodies of quality system approvals which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of quality system approvals which it has issued.

10. Authorised representative

The manufacturer's obligations set out in points 3, 5.2, 5.5.1, 7 and 8 may be fulfilled by his or her authorised representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.

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ANNEX V

EU Declaration of conformity (No XXX) ([1])

1. EU fertilising product (product-, batch-, or type- number):

2. Name and address of the manufacturer and, where applicable, its authorised representative:

3. This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

4. Object of the declaration (identification of the EU fertilising product allowing traceability; it may, where necessary for the identification of the EU fertilising product, include an image):

5. The object of the declaration described above is in conformity with:

   — Regulation (EU) 2019/1009 ([2]),

   — other Union harmonisation legislation where applicable:

6. References to the relevant harmonised standards or to the common specifications used or references to the other technical specifications in relation to which conformity is declared:

7. Where applicable, the notified body … (name, number) performed … (description of intervention) and issued the certificate or approval decision … (number):

8. Where applicable, annexed to this EU declaration of conformity are the EU declarations of conformity for the component EU fertilising products of the fertilising product blend.

9. Additional information:

   Signed for and on behalf of:

   (place and date of issue):

   (name, function) (signature):

([1]) It is optional for the manufacturer to assign a number to the EU declaration of conformity.

([2]) Regulation (EU) 2019/1009 of the European parliament and the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1).