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)

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.

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;

(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.

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.

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 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).

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.

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.

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.

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.

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 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.

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.

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.

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.

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.

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.

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.

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.

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.

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).

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

(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;

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.

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.

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.;

(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[(1)].

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.

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:

(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;

(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.

Done at Brussels, 5 June 2019.

For the European Parliament

The President

A. TAJANI

For the Council

The President

G. CIAMBA

(**1**) OJ L 123, 12.5.2016, p. 1.’

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