



2024/2786

31.10.2024

COMMISSION DELEGATED REGULATION (EU) 2024/2786

of 23 July 2024

amending Regulation (EU) 2019/1009 of the European Parliament and of the Council as regards the *Enterococcaceae* and presuming conformity of EU fertilising products without verification

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ⁽¹⁾, and in particular Article 42(1) thereof,

Whereas:

- (1) Regulation (EU) 2019/1009 lays down rules on the making available on the market of EU fertilising products. Following developments in the implementation of the Regulation and the relevant standardization work technical adaptations to Annexes I, II and III to Regulation (EU) 2019/1009 are needed to facilitate the free movement of safe and agronomically efficient EU fertilising products in the internal market.
- (2) Firstly, Annex I to Regulation (EU) 2019/1009 lays down maximum limit values for *Enterococcaceae* for various product function categories and Annex II to that Regulation sets out limit values for the same pathogen for EU fertilising products containing certain component materials. *Enterococcaceae* is a family of bacteria often present in environments rich in nutrients. Out of the various bacteria belonging to this family, enterococci are the most dangerous ones, from a health perspective, as they are often associated with human and animal infections. During the work performed by the European Committee for Standardization (CEN) to develop harmonised standards in support of those requirements in Regulation (EU) 2019/1009, CEN informed the Commission that there are no testing methods to determine the content of *Enterococcaceae*, given the wide variety of bacteria concerned. The existing testing methods determine the content of enterococci. Regulation (EU) 2019/1009 should therefore be amended to lay down requirements which can be tested in practice. That would facilitate the conformity assessment of the products and provide clarity both on the obligations of manufacturers and the way the market surveillance verifications should be performed.
- (3) Secondly, pursuant to Part II, point 4, of Annex I to Regulation (EU) 2019/1009, where compliance with a given requirement in Annex I (such as absence of a given contaminant) follows certainly and uncontestedly 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. A similar provision is laid down for the contaminant limit values in section CMC 15, point (6), for recovered high purity materials. For coherence reasons and to avoid unnecessary administrative burden, similar provisions should be introduced in Part II, sections CMC 3, CMC 5, CMC 12, CMC 13 and CMC 14 of Annex II to Regulation (EU) 2019/1009. Those provisions would facilitate the conformity assessment of EU fertilising products containing such materials and, ultimately, their free movement in the internal market.

⁽¹⁾ OJ L 170, 25.6.2019, p. 1, ELI: <http://data.europa.eu/eli/reg/2019/1009/oj>.

- (4) Thirdly, Part III of Annex III to Regulation (EU) 2019/1009 sets out tolerance rules for various parameters to be included on the label of EU fertilising products. The declared value on the label may deviate from the actual value, only within the limit values set out by that Regulation. As regards the quantity of inorganic fertilisers, two tolerances are set out (1 % and 5 %). It is necessary to identify the situations in which each of the two values apply. Thus, the declared quantity of inorganic macronutrient fertilisers should deviate only with maximum 1 %, given that such products are normally sold in larger packages or bought in bigger quantities. Inorganic micronutrient fertilisers are usually sold in smaller packages and therefore a 5 % tolerance should be complied with.
- (5) Fourthly, Part III of Annex III to Regulation (EU) 2019/1009 sets out a tolerance of 0,3 percentage points in absolute terms for the content of inhibiting compounds exceeding 2 % concentration in inhibitors, the same as the one applicable to fertilisers with inhibiting compounds. According to the coordination group of notified bodies established under Article 36 of Regulation (EU) 2019/1009, that tolerance is very restrictive for inhibitors, as inhibiting compounds are usually present in big concentrations in such products, and not only in small concentrations as for fertilisers. In order to take into account manufacturing deviations and the accuracy of the available testing methods and thus to facilitate the conformity assessment of inhibitors, Regulation (EU) 2019/1009 should be amended to introduce a more permissive tolerance for the content of inhibiting compounds in inhibitors.
- (6) Regulation (EU) 2019/1009 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) 2019/1009 is amended as follows:

- (1) Annex I is amended in accordance with Annex I to this Regulation;
- (2) Annex II is amended in accordance with Annex II to this Regulation;
- (3) Annex III is amended in accordance with Annex III to this Regulation.

Article 2

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

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

Done at Brussels, 23 July 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Part II of Annex I to Regulation (EU) 2019/1009 is amended as follows:

- (1) in section 'PFC 1(A): ORGANIC FERTILISER', point 4, table, the words '*Escherichia coli* or *Enterococcaceae*', are replaced by '*Escherichia coli* or enterococci';
- (2) in section 'PFC 1(B): ORGANO-MINERAL FERTILISER', point 5, table, the words '*Escherichia coli* or *Enterococcaceae*' are replaced by '*Escherichia coli* or enterococci';
- (3) in section 'PFC 1(C): INORGANIC FERTILISER', point 2, table, the words '*Escherichia coli* or *Enterococcaceae*' are replaced by '*Escherichia coli* or enterococci';
- (4) in section 'PFC 3(A): ORGANIC SOIL IMPROVER', point 4, table, the words '*Escherichia coli* or *Enterococcaceae*' are replaced by '*Escherichia coli* or enterococci';
- (5) in section 'PFC 3(B): INORGANIC SOIL IMPROVER', point 4, table, the words '*Escherichia coli* or *Enterococcaceae*' are replaced by '*Escherichia coli* or enterococci';
- (6) in section 'PFC 4: GROWING MEDIUM', point 4, table, the words '*Escherichia coli* or *Enterococcaceae*' in are replaced by '*Escherichia coli* or enterococci';
- (7) in section 'PFC 6(A): MICROBIAL PLANT BIOSTIMULANT', point 2, table, the word '*Enterococcaceae*' is replaced by 'enterococci';
- (8) in section 'PFC 6(B): NON-MICROBIAL PLANT BIOSTIMULANT', point 2, table, the words '*Escherichia coli* or *Enterococcaceae*' are replaced by '*Escherichia coli* or enterococci'.

ANNEX II

Part II of Annex II to Regulation (EU) 2019/1009 is amended as follows:

(1) in section 'CMC 3: COMPOST', the following point 6 is added:

- '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.';

(2) in section 'CMC 5: DIGESTATE OTHER THAN FRESH CROP DIGESTATE', the following point 7 is added:

- '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.';

(3) section 'CMC 12: PRECIPITATED PHOSPHATE SALTS AND DERIVATES', is amended as follows:

(a) point 8 is amended as follows:

- (i) in the introductory wording, the word '*Enterococcaceae*' is replaced by 'enterococci';
- (ii) in the table, the words '*Escherichia coli* or *Enterococcaceae*' are replaced by '*Escherichia coli* or enterococci';

(b) in point 10, the word '*Enterococcaceae*' is replaced by 'enterococci';

(c) the following point 15 is added:

- '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.';

(4) in section 'CMC 13: THERMAL OXIDATION MATERIALS OR DERIVATES', the following point 9 is added:

- '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.';

(5) in section 'CMC 14: PYROLYSIS AND GASIFICATION MATERIALS', the following point 8 is added:

- '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.';

- (6) section 'CMC 15: RECOVERED HIGH PURITY MATERIALS' is amended as follows:
- (a) point (7) is amended as follows:
 - (i) in the introductory wording, the word '*Enterococcaceae*' is replaced by 'enterococci';
 - (ii) in the table, the words '*Escherichia coli* or *Enterococcaceae*' are replaced by '*Escherichia coli* or enterococci';
 - (b) in point 8, the first, second and third paragraphs, the word '*Enterococcaceae*' is replaced by 'enterococci'.
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ANNEX III

Part III of Annex III to Regulation (EU) 2019/1009 is amended as follows:

(1) section 'PFC 1(C): INORGANIC FERTILISER' is amended as follows:

(a) the entry 'Quantity' is replaced by the following:

'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)
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(b) the last sentence 'Quantity: ± 5 % relative deviation of the declared value' is deleted;

(2) in section 'PFC 5: INHIBITOR', the entry 'Concentration of more than 2 %' is replaced by the following:

'Concentration of more than 2 %'	± 10 % of the declared value up to a maximum of ± 2 % in absolute terms'
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