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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	23 July 2024
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2024) 5111 final
Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 23.7.2024 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

Delegations will find attached document C(2024) 5111 final.

Encl.: C(2024) 5111 final



EUROPEAN
COMMISSION

Brussels, 23.7.2024
C(2024) 5111 final

COMMISSION DELEGATED REGULATION (EU) .../...

of 23.7.2024

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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

On 5 June 2019, the European Parliament and the Council adopted Regulation (EU) 2019/1009 laying down rules on the making available on the market of EU fertilising products¹. This Regulation repealed Regulation (EC) No 2003/2003 of the European Parliament and of the Council² as of 16 July 2022.

Following developments in the implementation and standardisation work in support of Regulation (EU) 2019/1009, a number of technical adaptations are needed to facilitate the free movement of safe and efficient fertilising products in the internal market.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Member States have been consulted in the Commission expert group on fertilising products (E01320) according to the rules of the Interinstitutional Agreement on Better Law-Making of 13 April 2016³.

Details of these consultations can be found in the minutes of the meetings held on 18-19 April and 27-28 November 2023 and 15-16 April 2024, as well as in the various position papers of interested stakeholders publicly available on the CIRCABC page of the group, at the following link:

<https://circabc.europa.eu/ui/group/36ec94c7-575b-44dc-a6e9-4ace02907f2f/library/b8e01334-4d39-445d-bf4e-589356d55b1f>

Member States and interested stakeholders were largely supportive of the adoption of this delegated Regulation.

The draft delegated Regulation has been published for feedback on the Better Regulation portal together with four other draft delegated Regulations. 49 contributions have been submitted in total.

Based on the contribution from a stakeholder, the reference to '*Enterococcus*' is replaced with a reference to 'enterococci', to better reflect the available testing methods.

One stakeholder opposed the introduction of the possibility to assume compliance without testing in specific cases. No change has been introduced in the draft delegated Regulation. The draft delegated Regulation aims to avoid unnecessary testing when it is clear that the product complies with specific requirements given its manufacturing process or the origin of the input materials. It will ensure coherence with existing provisions in Regulation (EU) 2019/1009, which already sets out such a possibility for similar provisions.

The draft delegated Regulation has also been notified based on Article 2(9)(2) of the Agreement on Technical Barriers to Trade and no comments have been received.

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¹ 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, OJ L 170, 25.6.2019, p. 1.

² Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers, OJ L 304, 21.11.2003, p. 1.

³ OJ L 123, 12.5.2016, p. 1.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated act adapts to technical progress Annexes I, II and III to Regulation (EU) 2019/1009. The legal basis of this delegated act is Article 42(1) of Regulation (EU) 2019/1009.

Commission Delegated Regulation (EU) .../... of 23.7.2024 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 2003/2003¹, 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 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. 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,

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

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.

- (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, 23.7.2024

For the Commission
The President
Ursula VON DER LEYEN