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

of 17.7.2025

**amending Regulation (EU) 2019/1009 of the European Parliament and of the Council
as regards the conformity assessment procedures for EU fertilising products**

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Annex IV, Part II, of Regulation (EU) 2019/1009 laying down rules on the making available on the market of EU fertilising products¹ sets out conformity assessment procedures for fertilising products as provided for in Decision No 768/2008/EC on a common framework for the marketing of products². In accordance with Article 42(1) of Regulation (EU) 2019/1009, the Commission is empowered to adopt delegated acts in accordance with Article 44 to adapt Annex IV to technical progress and to facilitate internal market access and free movement for EU fertilising products which have a potential to be the subject of significant trade on the internal market and for which there is scientific evidence that they do not present a risk to human, animal or plant health, to safety or to the environment and that they do ensure agronomic efficiency.

Module A1 describes the applicable conformity assessment procedure for ammonium nitrate fertilisers of high nitrogen content. Under the current rules, the required detonation resistance test and prior thermal cycles may be performed by any laboratory chosen by the manufacturer. A notified body with accreditation to perform inspections must supervise the testing. However, considering that ammonium nitrate fertilisers of high nitrogen content are products with explosive potential, it is important that the thermal cycles and detonation resistance tests are performed only in laboratories whose technical capacity has been approved in a reliable manner. This delegated Regulation therefore amends Module A1 in Annex IV to add the requirement that laboratories carrying out the thermal cycles and detonation resistance tests need to be accredited for those activities by an accreditation body established in a Member State operating in accordance with Regulation (EC) No 765/2008³. This new requirement should apply only six months after entry into force of this Regulation, to allow manufacturers to adapt, while ensuring also that they will act within a reasonable period of time to ensure the safety of their products.

Module D1 sets out an audit requirement for recovered component materials. Currently, the frequency of the audits to be performed by notified bodies is linked to the required frequency of the sampling of output material which, depending on the component material category concerned, increases with the volume of annual input or output. For high tonnage manufacturers, this results in a high frequency of audits and, accordingly, a significant burden for manufacturers and notified bodies. To ensure that audits are carried out in a proportionate frequency, this delegated Regulation amends Annex IV as to decouple the frequency of audits from the sampling frequency, and to set out an audit frequency of one audit per year.

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, ELI: <http://data.europa.eu/eli/reg/2019/1009/oj>).

² Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82, ELI: [http://data.europa.eu/eli/dec/2008/768\(1\)/oj](http://data.europa.eu/eli/dec/2008/768(1)/oj)).

³ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93, OJ L 218, 13.8.2008, p. 30, ELI: <http://data.europa.eu/eli/reg/2008/765/oj>.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Member States have been consulted on the draft in the meetings of the Commission expert group on Fertilising Products (E01320)⁴ on 29 November 2023, 15 and 16 April 2024, 26 and 27 November 2024 and 7 and 8 May 2025,⁵ according to the rules of the Interinstitutional Agreement on Better Law-Making of 13 April 2016⁶.

Member States and interested stakeholders were generally in favour of the adoption of this delegated Regulation.

The draft delegated Regulation has been published for feedback on the Better Regulation portal.⁷ The feedback received was overall positive.

With regard to the proposed amendments to Module A1, some stakeholders suggested referring to EN ISO/IEC 17025 for accreditation and/or specifying that laboratories shall be accredited specifically for the thermal cycles and tests for detonation resistance. The Commission took into account the latter suggestion but considers that explicit reference to standard EN ISO/IEC 17025 is not necessary as it is the only eligible standard for laboratories. Some stakeholders proposed limiting the choice of laboratories to laboratories located in the EU. The Commission considers that a geographical limitation is not justified, as accreditation by an EU accreditation body is a proof of the laboratory's technical capacity.

Upon one stakeholder's comment, the Commission clarified in the legal text that the amendment only concerns thermal cycles and tests for detonation resistance, while the requirements for oil retention tests are considered sufficient. Moreover, a citizen suggested requiring periodic reviews of laboratory accreditations. As accreditation bodies are already required to monitor the conformity assessment bodies to which they have issued an accreditation certificate under Regulation (EC) No 765/2008, no change to the draft was made.

As regards the proposed amendments to Module D1, one stakeholder suggested a lower audit frequency. The Commission considers that the audit frequency proposed (1 audit per year) is proportionate. Moreover, a citizen proposed to introduce periodic reviews of audit compliance by the Commission. No change was made to the draft as audit compliance is enforced by Member State authorities.

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 were received.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated Regulation amends two technical provisions in Annex IV to Regulation (EU) 2019/1009. The legal basis of this delegated act is Article 42(1) of Regulation (EU) 2019/1009. The Commission is empowered to amend Annex IV for the purpose of facilitating internal market access and free movement for EU fertilising products.

⁴ <https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&groupID=1320>.

⁵ Details of these consultations can be found in the minutes of the meetings on the CIRCABC page of the expert group, at the following link: <https://circabc.europa.eu/ui/group/36ec94c7-575b-44dc-a6e9-4ace02907f2f/library/169df8c3-e093-4738-bd60-c2b7434f4de3>.

⁶ OJ L 123, 12.5.2016, p. 1, ELI: http://data.europa.eu/eli/agree_interinstit/2016/512/oj.

⁷ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14548-Amendment-of-conformity-assessment-procedures-for-EU-fertilising-products_en.

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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. An EU fertilising product may only be made available on the market if it has successfully passed the applicable conformity assessment procedure as set out in Annex IV to that Regulation.
- (2) The applicable conformity assessment procedure for ammonium nitrate fertilisers of high nitrogen content, as described in Module A1 of Annex IV, Part II, includes a detonation resistance test, and prior thermal cycles, which are to be performed by a laboratory chosen by the manufacturer and to be supervised by a notified body. Due to the explosive potential of ammonium nitrate fertilisers, it is important that the thermal cycles and detonation resistance tests results are reliable. Therefore, only laboratories that are accredited for those activities by a national accreditation body should be eligible.
- (3) The conformity assessment procedure described in Module D1 of Annex IV, Part II, of Regulation (EU) 2019/1009 requires notified bodies to carry out periodic audits. For fertilising products containing recovered component materials, the audit frequency is linked to the frequency of the output material sampling as also set out in Annex IV, which results in a high audit density for manufacturers of high tonnages, with up to 48 audits per year. To ensure proportionality of the audit requirement, the frequency of audits should be independent from the sampling frequency, and a general audit frequency of one audit per year should be set out. This will ease the conformity assessment of circular EU fertilising products containing recovered component materials without jeopardising the safety of such materials, as samples would continue to be taken with the same frequency.

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, ELI: <http://data.europa.eu/eli/reg/2019/1009/oj>).

- (4) In order to allow for a period of transition for manufacturers, the amendment of Module A1 should apply to thermal cycles and detonation resistance tests six months after the entry into force of this Regulation.
- (5) Therefore, Regulation (EU) 2019/1009 should be amended accordingly,
- HAS ADOPTED THIS REGULATION:

Article 1

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

- (1) In MODULE A1 - INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT TESTING, point 4, the following paragraph is added :
- ‘The thermal cycles and test referred to in points 4.3 and 4.4 shall be carried out in laboratories that are accredited for those activities by a national accreditation body.’
- (2) In MODULE D1 – QUALITY ASSURANCE OF THE PRODUCTION PROCESS, point 6.3.2, the introductory statement is replaced by the following:
- ‘For materials belonging to CMCs 3, 5, 12, 13, 14 and 15, as defined in Annex II, the notified body shall carry out annual audits. In addition, the notified body shall take and analyse output material samples with the following frequency:’.

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*.

Article 1(1) shall apply from [Publication Office please insert the date = first day of the month following six months after entry into force of this delegated Regulation].

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

Done at Brussels, 17.7.2025

For the Commission
The President
Ursula VON DER LEYEN