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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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Delegations will find attached document C(2024) 1309 final.

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Brussels, 4.3.2024  
C(2024) 1309 final

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

**of 4.3.2024**

**amending Regulation (EU) 2019/1009 of the European Parliament and of the Council as regards adding processed manure as a component material in EU fertilising products**

(Text with EEA relevance)

## **EXPLANATORY MEMORANDUM**

### **1. CONTEXT OF THE DELEGATED ACT**

Animal by-products within the meaning of Regulation (EC) No 1069/2009<sup>1</sup> are entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption. Derived products are products obtained from one or more treatments, transformations or steps of processing of animal by-products. Derived products have a long tradition of use as national organic fertilisers and soil improvers, under the conditions laid down in Regulation (EC) No 1069/2009 and the national rules on fertilising products.

Regulation (EU) 2019/1009<sup>2</sup> lays down rules on the making available on the market of EU fertilising products. EU fertilising products are CE-marked and move freely in the internal market. They may contain derived products within the meaning of Regulation (EC) No 1069/2009 having reached the end point in the manufacturing chain as determined in accordance with that Regulation, provided that such derived products are listed in the table in Component Material Category 10 in Annex II to Regulation (EU) 2019/1009.

The end point in the manufacturing chain is the moment as of when the derived products are no longer subject to the veterinary controls set out in Regulation (EC) No 1069/2009. As mentioned in the Communication on the availability and affordability of fertilisers<sup>3</sup>, the definition of such end points constitutes an important step towards promoting green and circular alternatives to natural gas and mined raw materials for fertiliser production.

Pursuant to Article 5 of Regulation (EC) No 1069/2009, the Commission assessed derived products that are already widely used in the Union as organic fertilisers and soil improvers, including processed manure.

The Commission determined the end point in the manufacturing chain for processed manure in Delegated Regulation (EU) 2023/1605<sup>4</sup>.

In accordance with Article 42(5) of Regulation (EU) 2019/1009, the Commission's Joint Research Centre assessed processed manure 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.

This delegated Regulation lists processed manure in the table in Component Material Category 10 and sets out the requirements needed to ensure that EU fertilising products containing this component material are safe and agronomically efficient.

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<sup>1</sup> Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation), OJ L 300, 14.11.2009, p. 1.

<sup>2</sup> 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 2003/2000 OJ L 170, 25.6.2019, p. 1.

<sup>3</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 9 November 2022: Ensuring availability and affordability of fertilisers, COM/2022/590.

<sup>4</sup> Commission Delegated Regulation (EU) 2023/1605 of 22 May 2023 supplementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council as regards the determination of end points in the manufacturing chain of certain organic fertilisers and soil improvers (OJ L 198, 8.8.2023, p. 1).

## 2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Pursuant to Article 44(4) of Regulation (EU) 2019/1009, experts designated by each Member State were 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 2016<sup>5</sup>.

Details of these consultations can be found in the minutes of the meetings held on 8 December 2022, 18-19 April 2023 and 28-29 November 2023, 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. 29 contributions were submitted.

Some of the contributions referred to the oxygen uptake rate criterion. They expressed concerns that fulfilling this requirement is possible only via composting and processed manure is not necessarily composted. The Commission explained that certain stability criteria are needed to ensure that the product maintains its agronomic efficiency during its storage, no viable weed seeds are present in the final product and the ammonia emissions to the environment are reduced. So additional processing to the one needed to reach the end point in the manufacturing chain is needed. The Commission agreed that more flexibility can be introduced as regards the additional processing, as long as the same objectives are reached.

Various comments have been submitted as regards the additional processing of processed manure to improve its agronomic efficiency and the safety of the product. Some contributions concerned the inclusion of various processing methods which are currently in research phase. The Commission is of the view that only processing methods widely used and on which there is sufficient information regarding the safety may be included in the delegated Regulation.

Based on the comments submitted, the processing regarding the recovery of other nutrients, in addition to phosphorus and nitrogen are included.

To ensure more flexibility in performing the conformity assessment, the possibility of assuming compliance with the maximum content of 16 polycyclic aromatic hydrocarbons (PAH<sub>16</sub>)<sup>6</sup> is introduced.

In the public feedback divergent views were expressed as regards the labelling requirement on the content of aminopyralid or clopyralid. On one hand, some contributors were of the view that this labelling requirement is not justified. In addition, it was explained that the requirement to indicate the content on the label implies performing expensive tests, as, contrary to the pre-existing labelling requirement concerning substances exceeding a maximum residue level, the producer of the fertilising product has no information from the supplier on the content of those substances in manure. On the other hand, other contributors were of the view that the limit value should actually be reduced, and more information should

<sup>5</sup> OJ L 123, 12.5.2016, p. 1–14.

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

be provided to end-users regarding the plants which are sensitive to these substances. Based on these comments, the Commission decided to reduce the administrative burden and compliance costs by no longer indicating on the label the exact content. However, the end-users are to receive more information on the crops known to be sensitive to these substances. Should the manufacturer test the processed manure and determine that the content is below a certain limit value, then no warning is to be included on the label.

A public feedback contribution drawn the attention to the fact that the existing labelling requirements do not ensure that the end-users are informed about the presence of nitrogen out of manure in all cases. As this information is important to ensure the correct application of the national rules transposing Council Directive 91/676/EEC<sup>7</sup>, a specific labelling requirement has been introduced.

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

### **3. LEGAL ELEMENTS OF THE DELEGATED ACT**

The legal act amends Regulation (EU) 2019/1009. The legal basis of this delegated act is Article 42(1) of Regulation (EU) 2019/1009. Article 42(5) of Regulation (EU) 2019/1009 provides further rules for adding derived products in Annex II of that Regulation.

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<sup>7</sup> Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (OJ L 375, 31.12.1991, p. 1).

**Commission Delegated Regulation (EU) .../... of 4.3.2024 amending Regulation (EU) 2019/1009 of the European Parliament and of the Council as regards adding processed manure as a component material in EU fertilising products**

(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<sup>1</sup>, 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. EU fertilising products may contain derived products within the meaning of Regulation (EC) No 1069/2009 of the European Parliament and of the Council<sup>2</sup>. In accordance with Article 5 of Regulation (EC) 1069/2009, the end point in the manufacturing chain for processed manure was determined in Commission Delegated Regulation (EU) 2023/1605<sup>3</sup>.
- (2) In accordance with Article 42(5), second subparagraph, of Regulation (EU) 2019/1009, the Commission's Joint Research Centre (JRC) assessed processed manure with respect to relevant aspects not taken into account for the purpose of determining an end point in the manufacturing chain<sup>4</sup>.
- (3) Processed manure has the potential to be subject to significant trade in the internal market as it is a derived product commonly used in the organic fertilisers and soil improvers. Laying down the requirements for the CE-marking of EU fertilising products containing processed manure would facilitate the trade of such products in the internal market. JRC concluded that the introduction of processed manure in Component Material Category 10 in Annex II to Regulation (EU) 2019/1009 would also facilitate the implementation of Council Directive 91/676/EEC<sup>5</sup> by promoting the

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

<sup>2</sup> Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (OJ L 300, 14.11.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/1069/oj>).

<sup>3</sup> Commission Delegated Regulation (EU) 2023/1605 of 22 May 2023 supplementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council as regards the determination of end points in the manufacturing chain of certain organic fertilisers and soil improvers (OJ L 198, 8.8.2023, p. 1, ELI: [http://data.europa.eu/eli/reg\\_del/2023/1605/oj](http://data.europa.eu/eli/reg_del/2023/1605/oj)).

<sup>4</sup> Huygens, D, Technical proposals for processed manure as a component material for EU Fertilising Products .

<sup>5</sup> Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (OJ L 375, 31.12.1991, p. 1, ELI: <http://data.europa.eu/eli/dir/1991/676/oj>).

transfer of processed manure from regions with a high density of nutrients to those with a low density.

- (4) Processed manure contains organic matter and nutrients, in particular, nitrogen and phosphorus, two of the three primary macronutrients set out in Regulation (EU) 2019/1009. It has proven its agronomic value during a long history of use.
- (5) To ensure that an EU fertilising product containing processed manure maintains its content of nutrients over time, that its content of viable weed seeds or plant propagules is limited and that emissions of nutrients to the environment during storage are reduced, it is necessary to require processing in addition to the one needed to reach the end point in the manufacturing chain. Thus, the processed manure should be further processed to pass through a sieve with a mesh smaller to the known weed seeds dimensions, or be granulated or pelletised in certain conditions which ensure that weed seeds are no longer viable. Any other processing could also be used as long as it ensures that the content of viable weed seeds is limited. As an alternative, the processed manure could also be further processed to comply with one of the stability criteria laid down for Component Material Category 3, compost. This would ensure that the resulting material is stable, that decomposition would not continue after the product is placed on the market and that the weed seeds would no longer be viable after the composting process.
- (6) An additional safety criterion should be laid down to limit the content of 16 polycyclic aromatic hydrocarbons (PAH<sub>16</sub>)<sup>6</sup> which may be generated during the processing of manure. Regulation (EU) 2019/1021 of the European Parliament and of the Council<sup>7</sup> lays down release reduction requirements for PAH<sub>16</sub> as unintentionally produced substances during manufacturing processes, but does not introduce a limit value in such cases. Given the high risks generated by the presence of such pollutants in fertilising products, it is appropriate to introduce more stringent requirements than those laid down in Regulation (EU) 2019/1021. Such a limit value should be laid down at component material level, to ensure coherence with Regulation (EU) 2019/1021 and should apply in addition to the safety criteria laid down in Annex I to Regulation (EU) 2019/1009 for the corresponding product function category. To facilitate the conformity assessment procedure and avoid unnecessary costs, the possibility to assume compliance with this requirement without testing should be introduced, when it is clear from the manufacturing process that this limit value is met.
- (7) Processed manure may undergo additional processing to further improve its agronomic value or its safety. The processing methods which are currently widely used, such as solid-liquid separation, drying, pelletising, and recovery of nutrients, should be included in Component Material Category 10 in Annex II to Regulation (EU) 2019/1009. However, the manure processing steps should not include thermochemical conversion processes at high temperatures or pressures, such as liquefaction, hydrothermal carbonisation, pyrolysis, gasification or combustion, as such processes are covered under other component material categories due to the specific nature of the material transformation process.

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

<sup>7</sup> Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45, ELI: <http://data.europa.eu/eli/reg/2019/1021/oj>).

- (8) As an additional safety measure, the additives needed in the processing of manure should be registered based on Regulation (EC) No 1907/2006 of the European Parliament and of the Council<sup>8</sup>, in the extensive conditions already laid down in Regulation (EU) 2019/1009 for additives in other component material categories. That would ensure that the manufacturers take into account the use of the additives in a fertilising product when performing the risk assessment under Regulation (EC) No 1907/2006 and that the registration is done also for low tonnage materials.
- (9) Furthermore, processed manure may be available on local markets in quantities that exceed demand. To ensure that its long-term storage under suboptimal conditions does not lead to adverse environmental impacts, it is appropriate to limit the time during which it can be used as a component material for EU fertilising products.
- (10) A general labelling requirement should be introduced for EU fertilising products containing processed manure to inform end-users about the potential air quality impacts of the release of ammonia from the use of processed manure and to invite them to apply appropriate measures to reduce such impacts.
- (11) Processed manure may contain aminopyralid or clopyralid, substances for which maximum residue levels for food and feed are set in accordance with Regulation (EC) 396/2005. Users of EU fertilising products containing such processed manure should therefore be fully informed as regards the presence of those substances, so that they take the necessary measures to ensure that the resulting crop complies with the maximum residue levels.
- (12) 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 II is amended in accordance with Annex I to this Regulation;
- (2) Annex III is amended in accordance with Annex II 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*.

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<sup>8</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1, ELI: <http://data.europa.eu/eli/reg/2006/1907/oj>).



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

Done at Brussels, 4.3.2024

*For the Commission*  
*The President*  
*Ursula VON DER LEYEN*