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COVER NOTE

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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 7.7.2021 amending Annexes II, III and IV to Regulation (EU) No 2019/1009 of the European Parliament and of the Council for the purpose of adding pyrolysis and gasification materials as a component material category in EU fertilising products

Delegations will find attached document C(2021) 4764 final.

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Brussels, 7.7.2021
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COMMISSION DELEGATED REGULATION (EU) .../...

of 7.7.2021

amending Annexes II, III and IV to Regulation (EU) No 2019/1009 of the European Parliament and of the Council for the purpose of adding pyrolysis and gasification materials as a component material category in EU fertilising products

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

According to Article 42(1) of the Fertilising Products Regulation ⁽¹⁾, the Commission is empowered to adopt delegated acts in accordance with Article 44 amending Annex II for the purposes of adapting the Annex to technical progress and of facilitating 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. Regulation (EU) 2019/1009 repeals Regulation (EC) No 2003/2003 ⁽²⁾ and shall apply from 16 July 2022.

Further, Article 42(2) of Regulation (EU) 2019/1009 obliges the Commission to assess STRUvite, Blochar and ASH-based products (hereinafter jointly referred to as ‘STRUBIAS’) without undue delay after the date of entry into force and to adopt delegated acts to include those materials in Annex II if the abovementioned criteria pertaining to scientific evidence are fulfilled.

Such an assessment has been concluded by the Commission based on a report by the Commission’s Joint Research Centre (‘JRC’) on technical and market conditions for a possible legal framework for the manufacturing and placing on the market of specific safe and effective fertilising products derived from STRUBIAS. The report includes technical proposals on eligible input materials and process conditions for STRUBIAS production pathways, quality requirements for STRUBIAS materials, and quality management systems. The report also provides information on the added value that the STRUBIAS materials could provide for food security, food safety, environmental protection, and the EU fertilising and agricultural sector.

In accordance with Article 42(3) of Regulation (EU) 2019/1009, the Commission may only adopt delegated acts pursuant to that Article to include materials in Annex II to the Regulation 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 ⁽³⁾. This delegated regulation establishes recovery operations for pyrolysis and gasification materials, ensuring that they comply with the conditions laid down in Directive 2008/98/EC. Consequently, the requirement set out in Article 42(3) of Regulation (EU) 2019/1009 is fulfilled.

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. 1–114.

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 Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, OJ L 312, 22.11.2008, p. 3–30.

In this context, this delegated regulation amends Annex II to Regulation (EU) 2019/1009 by adding pyrolysis and gasification materials as a new Component Material Category, Annex III by adding labelling requirements to EU fertilising products containing pyrolysis and gasification materials and Annex IV to the Regulation by setting the legal framework for the relevant conformity assessment for such products.

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.

Details of these consultations can be found in the minutes of the meetings held on 7 November 2019 and 24 November 2020, 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. The three dozens of contributions received were largely supportive. However, concerns were expressed for some of the requirements for the input materials and their processing methods.

On the input materials, one recurrent concern was that, given that sewage sludge is not included in the exhaustive list, the opportunity of recovering nutrients from this important waste stream is missed. On the contrary, some contributions welcomed the exclusion of the sewage sludge from the input materials for pyrolysis and gasification materials.

The exhaustive list of input materials has been a key element in determining the safety and agronomic efficiency criteria for pyrolysis and gasification materials. This list includes those waste streams for which sufficient information exists on the possible risks and the safety parameters to be checked. Sewage sludge is and should remain excluded from the list because it is, for the moment, unclear whether contaminants of emerging concern, such as pharmaceuticals, contained therein are completely eliminated following the processing methods for pyrolysis and gasification materials.

Given the optional harmonisation in the field of fertilising products allowing the coexistence of the Fertilising Products Regulation with national rules, it is to be expected that some input materials regulated at national level are not covered by the harmonisation rules and *vice-versa*. The intention with this Regulation is to cover those materials which have the potential to be subject to significant trade on the internal market and for which solid scientific data attests their safety and agronomic efficiency.

In some contributions, it was stated that input materials with biomass should primarily be used in processes that would not destroy the so much needed organic matter (such as composting or digestion). However, the Commission's mandate when adapting the Fertilising Products Regulation to technical progress and facilitate market access for fertilising products is merely to ensure that those products have a significant trade potential and are safe and efficient. The question whether an alternative use of the raw material would be better is not

part of that assessment, in principle. In addition, depending on the process conditions, organic matter can be partially retained in materials covered under this CMC.

On the process conditions, it has been mentioned in the public feedback that the requirement of 180°C for at least 2 seconds is not adequate.

The processing conditions and supplementary requirements (e.g. on H / C_{org} ratio) have been laid down in such a way as to include the majority of the processing methods already existent on the market and make the products safe.

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.

Commission Delegated Regulation (EU) .../... of 7.7.2021

amending Annexes II, III and IV to Regulation (EU) No 2019/1009 of the European Parliament and of the Council for the purpose of adding pyrolysis and gasification materials as a component material category in EU fertilising products

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. EU fertilising products contain component materials of one or more of the categories listed in Annex II to that Regulation.
- (2) Article 42(2) of Regulation (EU) 2019/1009 read in conjunction with Article 42(1), first subparagraph, point (b) of that Regulation requires the Commission to assess biochar without undue delay after 15 July 2019, and to include it in Annex II to that Regulation if that assessment concludes that EU fertilising products containing that material do not present a risk to human, animal or plant health, to safety or to the environment, and ensure agronomic efficiency.
- (3) Biochar can be waste, and can in accordance with Article 19 of Regulation (EU) 2019/1009 cease to be waste if it is contained in a compliant EU fertilising product. Pursuant to Article 42(3) of Regulation (EU) 2019/1009 read in conjunction with Article 6 of Directive 2008/98/EC of the European Parliament and of the Council⁽²⁾, the Commission may therefore include biochar in Annex II to Regulation (EU) 2019/1009 only if recovery rules in that Annex ensure that the material is to be used for specific purposes, that a market or demand exists for it, and that its use will not lead to overall adverse environmental or human health impacts.
- (4) The Commission's Joint Research Centre ('JRC') began its assessment of biochar in anticipation of the adoption of Regulation (EU) 2019/1009, and concluded it in 2019. Throughout the assessment, the scope was widened to include the broad spectrum of pyrolysis and gasification materials.
- (5) JRC's assessment report⁽³⁾ concludes that pyrolysis and gasification materials, if produced following the recovery rules suggested in the report, provide plants with

¹ OJ L 170, 25.6.2019, p. 1.

² Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).

³ Huygens D, Saveyn HGM, Tonini D, Eder P, Delgado Sancho L, Technical proposals for selected new fertilising materials under the Fertilising Products Regulation (Regulation (EU) 2019/1009) - Process and quality criteria, and assessment of environmental and market impacts for precipitated phosphate salts & derivatives, thermal oxidation materials & derivatives and pyrolysis & gasification materials, EUR 29841 EN, Publications Office of the European Union, Luxembourg, 2019, ISBN 978-92-76-09888-1, doi:10.2760/186684, JRC117856.

nutrients or improve their nutrition efficiency and therefore ensure agronomic efficiency.

- (6) JRC's assessment report furthermore concludes that there is an existing and growing market demand for pyrolysis and gasification materials, and that those materials are likely to be used to provide nutrient inputs to European agriculture. It further concludes that the use of pyrolysis and gasification materials produced following the recovery rules suggested in the assessment report does not lead to overall adverse environmental or human health impacts.
- (7) The recovery rules suggested in the JRC's assessment report include measures to limit the risks of recycling or producing contaminants, such as creating an exhaustive list of eligible input materials and excluding, for example, mixed municipal waste, and laying down specific processing conditions and product quality requirements. That assessment report also concludes that the fertilising products containing pyrolysis and gasification materials should follow specific labelling rules and that the conformity assessment rules applicable to such products should include a quality system assessed and approved by a notified body.
- (8) Based on the above, the Commission concludes that pyrolysis and gasification materials, if produced following the recovery rules suggested in JRC's report, ensure agronomic efficiency within the meaning of Article 42(1), first subparagraph, point (b)(ii) of Regulation (EU) 2019/1009. Furthermore, they comply with the criteria laid down in Article 6 of Directive 2008/98/EC. Finally, if compliant with the other requirements laid down in Regulation (EU) 2019/1009 in general and in Annex I to that Regulation in particular, they would not present a risk to human, animal or plant health, to safety or to the environment, within the meaning of Article 42(1), first subparagraph, point (b)(i) of Regulation (EU) 2019/1009. Therefore, pyrolysis and gasification materials should be included in Annex II to Regulation (EU) 2019/1009 subject to those recovery rules.
- (9) In particular, animal by-products or derived products within the meaning of Regulation (EC) No 1069/2009 of the European Parliament and of the Council⁴ should only be allowed as input materials for pyrolysis and gasification materials governed by Regulation (EU) 2019/1009, if and when their end points in the manufacturing chain have been determined in accordance with Article 5(2), third subparagraph of Regulation (EC) No 1069/2009 and will be reached at the latest by the end of the production process of the EU fertilising product containing the pyrolysis or gasification materials.
- (10) Furthermore, given the fact that pyrolysis and gasification materials can be considered to be recovered waste or by-products within the meaning of Directive 2008/98/EC, such materials should be excluded from component material categories 1 and 11 of Annex II to Regulation (EU) 2019/1009 pursuant to Article 42(1), third subparagraph of that Regulation.
- (11) It is important to ensure that fertilising products containing pyrolysis and gasification materials follow specific labelling rules and are subject to a conformity assessment procedure including a quality system assessed and approved by a notified body. It is therefore necessary to amend Annex III and Annex IV to Regulation (EU) 2019/1009

⁴ 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).

to provide for labelling requirements and for a conformity assessment appropriate for such fertilising products.

- (12) Given that the requirements set out in Annexes II and III to Regulation (EU) 2019/1009 and the conformity assessment procedures set out in Annex IV to that Regulation are to apply as of 16 July 2022, it is necessary to defer the application of this Regulation to the same date,

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;
- (3) Annex IV 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*.

It shall apply from 16 July 2022.

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

Done at Brussels, 7.7.2021

For the Commission
The President
Ursula VON DER LEYEN