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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 6.7.2021 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 thermal oxidation materials and derivates as a component material category in EU fertilising products

Delegations will find attached document C(2021) 4751 final.

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EUROPEAN
COMMISSION

Brussels, 6.7.2021
C(2021) 4751 final

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

of 6.7.2021

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 thermal oxidation materials and derivatives 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 2003/2003² and shall apply from 16 July 2022.

Further, Article 42(2) of Regulation (EU) No 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 Research Center (‘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 thermal oxidation materials and derivatives 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.

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

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.

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 two dozens of contributions received were largely supportive. However, concerns were expressed for some of the requirements for the input materials and their processing methods, as well as some of the requirements for the output material (the thermal oxidation materials and derivatives or the EU fertilising products containing such materials).

On the input materials, one of the concern was that, given the exhaustive list, the opportunity of recovering important waste streams (in particular sludge from agro food industry and industrial sludge) would be missed. On the contrary, some contributions found the list of input materials as being too broad and too vague, and therefore creating the risk of including materials not thoroughly assessed. In addition, 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).

The exhaustive list of input materials has been a key element in determining the safety and agronomic efficiency criteria for thermal oxidation materials and derivatives. This list includes those waste streams for which sufficient information exists on the possible risks and the safety parameters to be checked. This list includes, among others, important waste streams and well known input materials for such processes. It cannot be extended without an additional detailed analysis similar with the one done by JRC for the proposed input 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 permitted in national legislation are not included in the exhaustive list in 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.

Sludge from agro food industry and industrial sludge may be used as input materials for thermal oxidation materials and derivatives.

Regarding the argument about alternative processes that preserve organic matter, 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 in general not part of that assessment. Alternative uses are only assessed when required in order to ascertain that the recovery procedure is compatible with Directive 2008/98/EC of the European Parliament and of the

Council ⁽⁴⁾. Therefore, this delegated act only allows for bio-waste separately collected for recycling incineration as input material if incineration delivers the best environmental outcome.

On the process conditions, it has been mentioned in the public feedback that the reduction of the temperature and minimum time when using animal by-products and derived products could create pathogens risks. However, the purpose of this Regulation is to determine the minimum conditions based on which a process may be considered a thermal oxidation process. Stricter processing requirements may be laid down in the animal by-products rules, when determining the end-point in the manufacturing chain.

On the requirements for the output materials, most of the contributions received concerned the introduction of a limit-value for total chromium and vanadium, either supporting them or contesting them. The main reasons invoked for contesting these limit-values were circumstantial. Thus, it was estimated that as during the negotiations on the Fertilising Products Regulation the limit values for contaminants were set out in the product function categories, no such limits should be set in the component material categories. In addition, it was recalled that during the same negotiations, a decision was taken to include only chromium VI, and not total chromium, among the limit values for product function categories. It was also claimed that vanadium is not a contaminant of concern.

All the requirements in this Regulation have been proposed based on a detailed analysis of the JRC, as included in the report. Indeed, general and established risks are addressed at product function category level in Annex I to the Fertilising Products Regulation, but additional safeguards may well be necessary for products containing materials obtained from iron and steel industries input materials. In the existing component material categories, such input materials are not permitted. Therefore, products containing materials deriving from them could have not been considered when determining the general safety requirements in Annex I. It cannot be assumed that the already determined general safety criteria in Annex I would be enough to ensure that products containing thermal oxidation materials and their derivatives out of input materials from iron and steel industries are also safe.

It is uncontested that there is no benefit to use chromium and vanadium on agricultural soils. Concerns for chromium and vanadium exist due to the potential metal accumulations in soils following long-term fertilising product applications.

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.

⁴ 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).

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

of 6.7.2021

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 thermal oxidation materials and derivatives as a component material category 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⁽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 ash-based products 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 materials do not present a risk to human, animal or plant health, to safety or to the environment, and ensure agronomic efficiency.
- (3) Ash-based products 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 ash-based products in Annex II to Regulation (EU) 2019/1009 only if recovery rules in that Annex ensure that the materials are to be used for specific purposes, that a market or demand exists for them, and that their use will not lead to overall adverse environmental or human health impacts.
- (4) The Commission's Joint Research Center ('JRC') began its assessment of ash-based products 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 thermal oxidation materials, as well as their derivatives.

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).

- (5) JRC's assessment report⁽³⁾ concludes that thermal oxidation materials and derivatives, if produced following the recovery rules suggested in the report, provide plants with 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 thermal oxidation materials and derivatives, and that those materials are likely to be used to provide nutrient inputs to European agriculture. It further concludes that the use of thermal oxidation materials and derivatives produced following the recovery rules suggested in the report does not lead to overall adverse environmental or human health impacts.
- (7) The recovery rules suggested in 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 fertilising products containing thermal oxidation materials and derivatives 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 thermal oxidation materials and derivatives, if produced following the recovery rules suggested in JRC's assessment 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, thermal oxidation materials and derivatives 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 Council⁽⁴⁾ should only be allowed as input materials for thermal oxidation materials and derivatives 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 thermal oxidation materials or derivatives.
- (10) Furthermore, given the fact that thermal oxidation materials and derivatives can be considered to be recovered waste or by-products within the meaning of Directive

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.

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).

2008/98/EC, such materials should be excluded from the 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 thermal oxidation materials and derivatives will follow additional labelling rules and will be 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 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, 6.7.2021

For the Commission
The President
Ursula VON DER LEYEN