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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	5 July 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 5.7.2021 amending Annexes II and IV to Regulation (EU) 2019/1009 of the European Parliament and of the Council for the purpose of adding precipitated phosphate salts and derivates as a component material category in EU fertilising products

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Delegations will find attached document C(2021) 4743 final.

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Brussels, 5.7.2021  
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**COMMISSION DELEGATED REGULATION (EU) .../...**

**of 5.7.2021**

**amending Annexes II and IV to Regulation (EU) 2019/1009 of the European Parliament  
and of the Council for the purpose of adding precipitated phosphate salts and derivates  
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 <sup>(1)</sup>, 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) No 2019/1009 repeals Regulation (EC) No 2003/2003 <sup>(2)</sup> and shall apply from 16 July 2022.

Further, Article 42(2) of Regulation (EU) No 2019/1009 obliges the Commission to assess struvite, biochar 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 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) No 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 <sup>(3)</sup>. This delegated regulation establishes recovery operations for precipitated phosphate salts 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) No 2019/1009 is fulfilled.

In this context, this delegated regulation amends Annex II to Regulation (EU) No 2019/1009 by adding precipitated phosphate salts and derivatives as a new Component Material Category, and Annex IV to the Regulation by setting up the legal framework for the relevant conformity assessment for EU fertilising products containing precipitated phosphate salts and derivatives.

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<sup>1</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 2003/2003, OJ L 170, 25.6.2019, p. 1–114.

<sup>2</sup> 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).

<sup>3</sup> 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) No 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>4</sup>.

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 dozen 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 precipitated phosphate salts and derivatives or the EU fertilising products containing such materials).

*On the input materials*, the main concern was that, given the exhaustive list, the opportunity of recovering important waste streams (in particular sludge from agro food industry, sludge from wastewater from processing food, wastewater from processing of metals) would be missed.

The exhaustive list of input materials has been a key element in determining the safety and agronomic efficiency criteria for precipitated phosphate salts and derivatives. This list includes those waste streams for which sufficient information exists on the risks which could occur and the safety parameters which should be checked. Therefore, this list cannot be extended to cover sludge from metal industry without an additional detailed analysis similar with the one done by JRC for the proposed input materials.

It is intended to cover the sludge from processing of food, together with the waste water. The text is modified so that to expressly refer to this input material, too.

*On the process conditions*, it has been mentioned in the public feedback that promising technologies would be left outside the material scope of the harmonisation rules (in particular hydrothermal gasification).

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 processes 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.

*On the requirements for the output materials*, various proposals have been submitted, such as to increase the maximum limit for organic carbon content, to reduce the minimum phosphorus pentoxide content, to remove the iron limit-value or refer to *Ascaris* viable eggs (and not to any eggs as the text stands).

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<sup>4</sup> OJ L 123, 12.5.2016, p. 1–14.

All the requirements in this Regulation have been proposed based on the detailed assessment of the JRC, as included in the report. The main objective is to ensure that the precipitated phosphate salts and derivatives do not present a risk to human, animal and plant health, to safety and to the environment.

As regards the reference only to *Ascaris* viable eggs, this is indeed the intention and the text is clarified accordingly. The concern is on the viable stages, and these are typically identified during measurement procedures.

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) No 2019/1009. The legal basis of this delegated act is Article 42(1) of Regulation (EU) No 2019/1009.

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

**of 5.7.2021**

**amending Annexes II and IV to Regulation (EU) 2019/1009 of the European Parliament and of the Council for the purpose of adding precipitated phosphate salts 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<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 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 struvite 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) Struvite 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 that Regulation read in conjunction with Article 6 of Directive 2008/98/EC of the European Parliament and of the Council<sup>(2)</sup>, the Commission may therefore include struvite 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 struvite 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 precipitated phosphate salts, as well as their derivatives.

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

<sup>2</sup> 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<sup>(3)</sup> concludes that precipitated phosphate salts 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 precipitated phosphate salts 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 precipitated phosphate salts 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 the conformity assessment rules applicable to fertilising products containing precipitated phosphate salts and derivatives should include a quality system assessed and approved by a notified body.
- (8) Based on the above, the Commission concludes that precipitated phosphate salts and derivatives, if produced in accordance with 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, precipitated phosphate salts 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<sup>(4)</sup> should only be allowed as input materials for precipitated phosphate salts 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 precipitated phosphate salts or derivatives.
- (10) Furthermore, given the fact that precipitated phosphate salt and derivatives 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

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<sup>3</sup> 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.

<sup>4</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).

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 when fertilising products contain precipitated phosphate salts and derivatives, they are subject to an appropriate conformity assessment procedure including a quality system assessed and approved by a notified body. Therefore, it is necessary to amend Annex IV to Regulation (EU) 2019/1009 to provide for a conformity assessment appropriate for such fertilising products.
- (12) Given that the requirements set out in Annex II 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 IV 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*.

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, 5.7.2021

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