

COMMISSION DELEGATED REGULATION (EU) 2021/2086**of 5 July 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 ⁽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 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 ⁽²⁾, 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.
- (5) JRC's assessment report ⁽³⁾ 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.

⁽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.

- (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 (*) 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 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.

(*) 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).

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 July 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

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

(1) In Part I, the following point is added:

“CMC 12: Precipitated phosphate salts and derivatives”.

(2) Part II is amended as follows:

(a) In CMC 1, point 1 is amended as follows:

- (i) in sub-point (g), “or” is deleted;
- (ii) in sub-point (h), “.” is replaced by “, or”;
- (iii) the following sub-point (i) is added:

“(i) precipitated phosphate salts or derivatives, which are recovered from waste or are by-products within the meaning of Directive 2008/98/EC.”.

(b) In CMC 11, point 1 is amended as follows:

- (i) in sub-point (c), “or” is deleted;
- (ii) in sub-point (d), “.” is replaced by “, or”;
- (iii) the following sub-point (e) is added:

“(e) precipitated phosphate salts or derivatives, which are recovered from waste or are by-products within the meaning of Directive 2008/98/EC.”.

(c) The following CMC 12 is added:

“CMC 12: PRECIPITATED PHOSPHATE SALTS AND DERIVATES

1. An EU fertilising product may contain precipitated phosphate salts obtained through precipitation exclusively from one or more of the following input materials:

- (a) wastewaters and sewage sludge from municipal wastewater treatment plants, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;
- (b) wastewaters and sludge from processing of foods, beverages, pet foods, animal feeds, or dairy products, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009, unless processing steps involved contact with biocidal products within the meaning of Article 3(1), point (a), of Regulation (EU) No 528/2012 of the European Parliament and of the Council (*) other than those defined as product-type 4 of main group 1 of Annex V to that Regulation;
- (c) bio-waste within the meaning of Article 3, point 4, of Directive 2008/98/EC resulting from separate bio-waste collection at source, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;
- (d) processing residues within the meaning of Article 2, point (t), of Directive 2009/28/EC of the European Parliament and of the Council (**) from the production of bioethanol and biodiesel derived from materials referred to in this point, sub-points (b), (c) and (e);
- (e) living or dead organisms or parts thereof, which are unprocessed or processed only by manual, mechanical or gravitational means, dissolution in water, flotation, extraction with water, steam distillation or heating solely to remove water, or which are extracted from air by any means, except (***):
 - materials originating from mixed municipal waste,
 - sewage sludge, industrial sludge or dredging sludge,
 - animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;

- (f) substances and mixtures, other than (***):
- those referred to in sub-points (a) to (e),
 - waste within the meaning of Article 3, point 1, of Directive 2008/98/EC,
 - substances or mixtures which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC,
 - substances formed from precursors which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC, or mixtures containing such substances,
 - non-biodegradable polymers,
 - animal by-products or derived products within the scope of Regulation (EC) No 1069/2009.

In addition, precipitated phosphate salts shall be obtained through precipitation from any input material referred to in sub-points (a) to (f), or a combination thereof, processed by manual, mechanical or gravitational means, solid-liquid fractionation using biodegradable polymers, dissolution in water, flotation, extraction with water, steam distillation or heating solely to remove water, thermal hydrolysis, anaerobic digestion or composting. The temperature under such processes shall not be raised above 275 °C.

2. The precipitation process shall take place under controlled conditions in a reactor. In addition, only input materials, which are not contaminated with other material streams, or input materials, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009, which have been unintentionally contaminated with other material streams in a one-off incident resulting only in trace levels of exogenous compounds shall be used.

In the plant where the precipitation takes place, physical contacts between input and output materials shall be avoided after the precipitation process, including during storage.

3. The precipitated phosphate salts shall contain:
- (a) a minimum phosphorus pentoxide (P_2O_5) content of 16 % of the dry matter content;
 - (b) a maximum organic carbon (C_{org}) content of 3 % of the dry matter content;
 - (c) no more than 3 g/kg dry matter of macroscopic impurities above 2 mm in any of the following forms: organic matter, glass, stones, metal and plastics;
 - (d) no more than 5 g/kg dry matter of the sum of the macroscopic impurities referred to in sub-point (c).
4. An EU fertilising product may contain derivatives from precipitated phosphate salts produced through one or more chemical manufacturing steps that react the precipitated phosphate salts with materials referred to in sub-point 1(f) that are consumed in or used for chemical processing.

The derivative manufacturing process shall be executed so as to intentionally modify the chemical composition of the precipitated phosphate salts.

5. The precipitated phosphate salts used for the derivatives shall comply with points 1, 2 and 3.
6. Notwithstanding point 1, an EU fertilising product may contain precipitated phosphate salts obtained through precipitation from Category 2 or Category 3 materials or derived products thereof, in accordance with the conditions set out in Article 32(1) and (2) of Regulation (EC) No 1069/2009 and in the measures referred to in Article 32(3) of that Regulation, alone or mixed with input materials referred to in point 1, provided that both of the following conditions are fulfilled:
- (a) the end point in the manufacturing chain has been determined in accordance with Article 5(2), third subparagraph, of Regulation (EC) No 1069/2009;
 - (b) the conditions in points 2 and 3 are met.

An EU fertilising product may also contain derivatives from such precipitated phosphate salts, obtained in accordance with the conditions set out in point 4.

7. In the plant where the precipitation takes place, the production lines for the processing of input materials allowed for the precipitated phosphate salts and derivatives referred to in points 1, 4 and 6 shall be clearly separated from production lines for the processing of other input materials.
8. Where for the PFC of an EU fertilising product containing or consisting of precipitated phosphate salts or derivatives or both there are no requirements regarding *Salmonella* spp., *Escherichia coli* or *Enterococcaceae* in Annex I, those pathogens shall not exceed the limits set out in the following table:

Micro-organisms to be tested	Sampling plans			Limit
	n	c	m	M
<i>Salmonella</i> spp.	5	0	0	Absence in 25 g or 25 ml
<i>Escherichia coli</i> or <i>Enterococcaceae</i>	5	5	0	1 000 in 1 g or 1 ml

Where:

n = number of samples to be tested,

c = number of samples where the number of bacteria expressed in CFU is between m and M,

m = threshold value for the number of bacteria expressed in CFU that is considered satisfactory,

M = maximum value of the number of bacteria expressed in CFU.

9. Pathogens in an EU fertilising product containing or consisting of precipitated phosphate salts obtained from materials referred to in sub-point 1(a) or derivatives from such precipitated phosphate salts or both shall not exceed the limits set out in the following table:

Micro-organisms to be tested	Sampling plans			Limit
	n	c	m	M
<i>Clostridium perfringens</i>	5	5	0	100 CFU in 1 g or 1 ml
<i>Ascaris</i> sp. viable eggs	5	0	0	Absence in 25 g or 25 ml

Where:

n = number of samples to be tested,

c = number of samples where the number of bacteria expressed in CFU is between m and M,

m = threshold value for the number of bacteria expressed in CFU that is considered satisfactory,

M = maximum value of the number of bacteria expressed in CFU.

10. The requirements set out in points (8) and (9), as well as the requirements for *Salmonella* spp., *Escherichia coli* or *Enterococcaceae* set in the corresponding PFC of an EU fertilising product consisting only of precipitated phosphate salts or derivatives or both shall not apply when those precipitated phosphate salts or all of the biogenic input materials used in the precipitation process have undergone one of the following processes:

- (a) pressure sterilisation through the heating to a core temperature of more than 133 °C for at least 20 minutes at an absolute pressure of at least 3 bars, whereby the pressure must be produced by the evacuation of all air in the sterilisation chamber and the replacement of the air by steam ('saturated steam');

- (b) processing in a pasteurisation or hygienisation unit that reaches a temperature of 70 °C for at least one hour.
11. Precipitated phosphate salts obtained from materials referred to in sub-point 1(a) and derivatives obtained from such precipitated phosphate salts shall have no more than 6 mg/kg dry matter of PAH₁₆ (****)
 12. The sum of aluminium (Al) and iron (Fe) in precipitated phosphate salts or derivatives shall not exceed 10 % of the dry matter of the precipitated phosphate salts or the derivatives.
 13. Precipitated phosphate salts or derivatives shall have been registered pursuant to Regulation (EC) No 1907/2006 with a dossier containing:
 - (a) the information provided for by Annexes VI, VII and VIII of Regulation (EC) No 1907/2006; and
 - (b) a chemical safety report pursuant to Article 14 of Regulation (EC) No 1907/2006 covering the use as a fertilising product, unless explicitly covered by one of the registration obligation exemptions provided for by Annex IV to Regulation (EC) No 1907/2006 or by points 6, 7, 8, or 9 of Annex V to that Regulation.
 14. For the purposes of points 3, 11 and 12, the dry matter of precipitated phosphate salts and derivatives shall be measured using vacuum drying at 40 °C until constant weight to avoid the loss of crystal-bound water.

(*) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

(**) Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC (OJ L 140 5.6.2009, p. 16).

(***) The exclusion of an input material from a sub-point does not prevent it from being an eligible input material by virtue of another sub-point.

(****) 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.”.

ANNEX II

In Annex IV, Part II, of Regulation (EU) 2019/1009, Module D1 (Quality assurance of the production process) is amended as follows:

(1) In point 2.2, sub-point (d) is replaced by the following:

“(d) drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product, and, in relation to materials belonging to CMCs 3, 5 and 12 as defined in Annex II, a written description and a diagram of the production process, where each treatment, storage vessel and area is clearly identified.”.

(2) The introductory wording in point 5.1.1.1 is replaced by the following:

“5.1.1.1. For materials belonging to CMCs 3, 5 and 12, as defined in Annex II, senior management of the manufacturer’s organisation shall.”.

(3) Point 5.1.2.1 is replaced by the following:

“5.1.2.1. For materials belonging to CMCs 3, 5 and 12, as defined in Annex II, the quality system shall ensure compliance with the requirements specified in that Annex.”.

(4) Point 5.1.3.1 is amended as follows:

(a) The introductory wording is replaced by the following:

“5.1.3.1. For materials belonging to CMCs 3, 5 and 12, as defined in Annex II, the examinations and tests shall comprise the following elements:”.

(b) Sub-points (b) and (c) are replaced by the following:

“(b) Qualified staff shall carry out a visual inspection of each consignment of input materials and verify compatibility with the specifications of input materials in CMCs 3, 5 and 12 laid down in Annex II.

(c) The manufacturer shall refuse any consignment of any given input material where visual inspection raises any suspicion of any of the following:

— the presence of hazardous or damageable substances for the process or for the quality of the final EU fertilising product;

— incompatibility with the specifications of CMCs 3, 5 and 12 in Annex II, in particular by presence of plastics leading to exceedance of the limit value for macroscopic impurities.”.

(c) Sub-point (e) is replaced by the following:

“(e) Samples shall be taken on output materials, to verify that they comply with the specifications laid down in CMCs 3, 5 and 12, as defined in Annex II, and that the properties of the output material do not jeopardise the EU fertilising product’s compliance with the relevant requirements laid down in Annex I.”.

(d) In subpoint (f), the introductory wording is replaced by the following:

“(f) For materials belonging to CMCs 3 and 5, the output material samples shall be taken on a regular basis with at least the following frequency:”.

(e) The following sub-points are inserted:

“(fa) For materials belonging to CMC 12, the output material samples shall be taken with at least the following default frequency, or sooner than scheduled if triggered by any significant change that may affect the quality of the EU fertilising product:

Annual output (tonnes)	Samples/year
≤ 3 000	4
3 001 – 10 000	8
10 001 – 20 000	12
20 001 – 40 000	16
40 001 – 60 000	20
60 001 – 80 000	24
80 001 – 100 000	28
100 001 – 120 000	32
120 001 – 140 000	36
140 001 – 160 000	40
160 001 – 180 000	44
> 180 000	48

Manufacturers may reduce the default frequency of testing for contaminants as indicated above by considering the distribution of historical samples. After a minimum monitoring period of one year and a minimum number of 10 samples showing compliance with the requirements in Annex I and II, the manufacturer may reduce the default sampling frequency for that parameter by a factor 2 in case the greatest contaminant level recorded from the last 10 samples is smaller than half of the limit value for that parameter laid down in Annexes I and II.

(fb) For materials belonging to CMC 12, each batch or portion of production shall be assigned a unique code for quality management purposes. At least one sample per 3 000 tonnes of these materials or one sample per two months, whichever occurs soonest, shall be stored in good condition for a period of at least 2 years.”.

(f) In sub-point (g) (iii), “.” is replaced by “,” and the following sub-point (iv) is added:

“(iv) for materials belonging to CMC 12, measure retainer samples referred to in sub-point (fb) and take the necessary corrective actions to prevent possible further transport and use of that material.”.

(5) In point 5.1.4.1, the introductory wording is replaced by the following:

“5.1.4.1. For materials belonging to CMCs 3, 5 and 12, as defined in Annex II, the quality records shall demonstrate effective control of input materials, production, storage and compliance of input and output materials with the relevant requirements of this Regulation. Each document shall be legible and available at its relevant place(s) of use, and any obsolete version shall be promptly removed from all places where it is used, or at least identified as obsolete. The quality management documentation shall contain at least the following information:”.

(6) In point 5.1.5.1, the introductory wording is replaced by the following:

“5.1.5.1. For materials belonging to CMCs 3, 5 and 12, as defined in Annex II, the manufacturer shall establish an annual internal audit program in order to verify the compliance of the quality system, with the following components:”.

(7) Point 6.3.2 is replaced by the following:

“6.3.2. For materials belonging to CMCs 3, 5 and 12, as defined in Annex II, the notified body shall take and analyse output material samples during each audit, and those audits shall be carried out with the following frequency:

- (a) during the notified body's first year of surveillance of the plant in question: the same frequency as the sampling frequency indicated in the tables included in points 5.1.3.1(f) and, respectively, 5.1.3.1(fa); and
 - (b) during the following years of surveillance: half the sampling frequency indicated in the table included in point 5.1.3.1(f) and, respectively, 5.1.3.1(fa).”
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