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

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ANNEXES 1 to 2

## **ANNEXES**

**to the**

### **COMMISSION DELEGATED REGULATION**

**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**

## 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:
- 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');
  - 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 PAH<sub>16</sub> (\*\*\*\*)
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:
- the information provided for by Annexes VI, VII and VIII of Regulation (EC) No 1907/2006; and;
  - 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) No 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:



<b>Annual output (tonnes)</b>	<b>Samples / year</b>
≤ 3000	4
3001 – 10000	8
10001 – 20000	12
20001 – 40000	16
40001 – 60000	20
60001 – 80000	24
80001 – 100000	28
100001 – 120000	32
120001 – 140000	36
140001 – 160000	40
160001 – 180000	44
> 180000	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 3000 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).”.