Annex I

Annex II to Regulation (EU) No …/2019 is amended as follows:

1. In Part I, the following point is added:

"CMC 12 Precipitated phosphate salts or derivates";

2. Part II is amended as follows:

a) In point 1 of CMC 1:

i. In point (g), "or" is deleted;
ii. In point (h), "." is replaced with ", or";
iii. A new point (i) is added:

"(i) precipitated phosphate salts or derivates,";

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b) In point 1 of CMC 11:

a. In point (c), "or" is deleted;
b. In point (d), "." is replaced with ", or";
c. A new point (e) is added:

"(e) precipitated phosphate salts or derivates,";

c) After CMC11, a new CMC is added with the following content:

"CMC 12 PRECIPITATED PHOSPHATE SALTS OR DERIVATES

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

a) wastewaters and sewage sludge from municipal wastewater treatment plants;
b) derived products referred to in Article 32 of Regulation (EC) No 1069/2009 for which an end-point in the manufacturing chain has been determined in accordance with the third subparagraph of Article 5(2) of that Regulation;
c) animal by-products, the products derived from which are referred to in Article 32 of Regulation (EC) No 1069/2009 and have an end-point in the manufacturing chain determined in accordance with the third subparagraph of Article 5(2) of that Regulation;
d) wastewaters from food processing, pet food, feed, milk and drink industries, unless processing steps involved contact with biocides within the meaning of Regulation (EU) No 528/2012 other than those defined as product type 4 of main group 1 of Annex V thereto;
e) residues from the production of bioethanol and biodiesel as referred to in 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[1];

f) bio-waste within the meaning of Directive 2008/98/EC resulting from separate bio-waste collection at source, other than those materials included in points (b) and (c);

g) living or dead organisms or parts thereof, which are unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which are extracted from air by any means, except:
   i. materials originating from mixed municipal waste,
   ii. sewage sludge, industrial sludge or dredging sludge,
   iii. animal by-products or derived products within the scope of Regulation (EC) No 1069/2009 for which no end-point in the manufacturing chain has been determined in accordance with the third subparagraph of Article 5(2) of that Regulation, and
   iv. materials mentioned in points (a) to (f);

h) substances and mixtures, other than:
   i. those listed under points (a) to (g),
   ii. waste within the meaning of Directive 2008/98/EC,
   iii. 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,
   iv. 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,
   v. non-biodegradable polymers, and
   vi. 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 material listed in points (a)-(h), or combination thereof, processed by manual, mechanical or gravitational means, by solid-liquid fractionation using biodegradable polymers, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, by thermal hydrolysis, by anaerobic digestion or by composting. The temperature of such processes shall not be raised above 275°C.

2. The precipitation process shall take place under controlled conditions in a reactor. The reactor may only process input materials referred to in point 1, which are not contaminated with other material streams, or which have been unintentionally contaminated with other material streams in a one-off incident resulting only in trace levels of exogenous compounds.

In the plant where the precipitation takes place:

(a) the production lines for the processing of input materials referred to in point 1 shall be clearly separated from production lines for the processing of input materials other than those referred to in point 1, and

[1] OJ L 140 5.6.2009, p. 16.

(b) 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 P_2O_5 content of 16% of the dry matter content;
b) a maximum organic carbon 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 point (c).

4. An EU fertilising product may contain derivates from precipitated phosphate salts produced through one or more chemical manufacturing steps that react the precipitated phosphate salts with materials listed under point 1(h) that are consumed in or used for chemical processing.

The precipitated phosphate salts used for the derivates shall comply with points 1 to 3.

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

5. When for the PFC of an EU fertilising product containing or consisting of precipitated phosphate salts and/or derivates there are no requirements regarding *Salmonella* spp., *Escherichia coli* or *Enterococcaceae* in Annex I to this Regulation, these pathogens must not exceed the limits as set out in the following table for such products:

Micro-organisms to be tested	Sampling plans			Limit
	n	c	m	M
Salmonella spp.	5	0	0	Absence in 25 g or 25 ml
Escherichia coli or *Enterococcaceae*	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.

6. Pathogens in an EU fertilising product containing or consisting of precipitated phosphate salts obtained from materials listed under point 1(a) and/or derivates from such precipitated phosphate salts shall not exceed the limits set out in the following table:

Micro-organisms to be tested	Sampling plans			Limit
	n	c	m	M
Clostridium perfringens	5	5	0	100 CFU in 1 g or 1 ml
Ascaris sp. 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.

7. The requirements set in points (5) and (6), 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 and/or derivates shall not apply when those precipitated phosphate salts or all of the biogenic input materials used in the precipitation process have undergone the following conditions:

i. 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. 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'); or
ii. processing in a pasteurisation or hygienisation unit that reaches a temperature of 70 °C for at least one hour.

8. Precipitated phosphate salts obtained from materials listed under point 1(a) and derivates out of such precipitated phosphate salts shall have no more than 6 mg/kg dry matter of PAH_{16}[2].

9. The sum of aluminium (Al) and iron (Fe) in precipitated phosphate salts and derivates shall not exceed 10% of the dry matter of the precipitated phosphate salts and the derivates.

10. Precipitated phosphate salts and derivates shall have been registered pursuant to Regulation (EC) No 1907/2006, with a dossier containing:

[2] 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.

(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.

11. For the purpose of points 3, 8 and 9, the dry matter of precipitated phosphate salts and derivates shall be measured using vacuum drying at 40°C until constant weight to avoid the loss of crystal-bound water. ”.

Annex II

Module D1 Quality assurance of the production process in Part II of Annex IV to Regulation (EU) No 2019/1009 is amended as follows:

1. In point 2.2. sub-point (d) is replaced with 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 first sentence in point 5.1.1.1 is replaced with 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 with the following point:

"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 first sentence is replaced with 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-point (b) is replaced with 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. Sub-point (c) is replaced with the following:

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

- the presence of hazardous or damageable substances for the process or for the quality of the final EU fertilising product, or of
- 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.

d. Sub-point (e) is replaced with 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 in Annex I.";

e. The first sentence in sub-point (f) is amended as follows:

"(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:";

f. Two new 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**
≤ 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 to this Regulation, 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 Annex 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.";

g. In sub-point (g)(iii), "." Is replaced with "," and a new 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 the material.";

5. The first sentence in point 5.1.4.1 is replaced with 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.";

6. The first sentence in point 5.1.5.1 is replaced with 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. The first sentence in point 6.3.2 is replaced with 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 the audits shall be carried out with the following frequency:".

Annex I

Annex II to Regulation (EU) No …/2019 is amended as follows:

1. In Part I, the following point is added:

"CMC 13: Thermal oxidation materials or derivates";

2. Part II is amended as follows:

a) In point 1 of CMC 1, a new point (j) is added:

"(j) thermal oxidation materials or derivates, or";

b) In point 1 of CMC 11, a new point (f) is added:

"(f) thermal oxidation materials or derivates, or";

c) After CMC12, a new CMC is added with the following content:

"CMC 13: THERMAL OXIDATION MATERIALS OR DERIVATES

1. An EU fertilising product may contain thermal oxidation materials exclusively obtained through thermochemical conversion under non-oxygen-limiting conditions from one or more of the following input materials:

a) living or dead organisms or parts thereof, which are unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which are extracted from air by any means, except[1]:
   - 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, and
   - materials separately listed under points e) – h);

b) vegetable waste from the food processing industry and fibrous vegetable waste from virgin pulp production and from production of paper from virgin pulp;

c) derived products referred to in Article 32 of Regulation (EC) No 1069/2009 for which an end-point in the manufacturing chain has been determined in accordance with the third subparagraph of Article 5(2) of that Regulation;

d) animal by-products, the products derived from which are referred to in Article 32 of Regulation (EC) No 1069/2009 and have an end-point in the manufacturing chain determined in accordance with the third subparagraph of Article 5(2) of that Regulation;

e) bio-waste within the meaning of Directive 2008/98/EC resulting from separate bio-waste collection at source;

f) materials resulting from a controlled microbial or thermochemical conversion process using exclusively those input materials listed under point (a) - (e) and (i);

g) sewage sludge from municipal wastewater treatment plants;

[1] The exclusion of a material from a lettered item does not prevent it from being an eligible component material by virtue of another lettered item

h) waste within the meaning of Directive 2008/98/EC with the exception[2] of:
   - those listed under points (a) – (g),
   - materials which display one or more of the hazardous properties listed in Annex III of Directive 2008/98/EC,
   - materials originating from mixed municipal waste,
   - bio-waste within the meaning of Directive 2008/98/EC resulting from separate bio-waste collection at source, and
   - animal by-products or derived products within the scope of Regulation (EC) No 1069/2009.

i) auxiliary fuels (natural gas, liquefied gas, natural gas condensate, process gases and components thereof, crude oil, coal, coke as well as their derived materials), when used to process input materials listed under points (a) - (h);

j) substances which are used in production processes of the iron and steel industry; or

k) substances and mixtures, with the exception[3] of:
   - those listed under points a) - j),
   - waste within the meaning 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, and
   - animal by-products or derived products within the scope of Regulation (EC) No 1069/2009.

3. The thermal oxidation shall take place under non-oxygen limiting conditions in such a way that the gas resulting from the thermochemical conversion process is raised, after the last injection of combustion air, in a controlled and homogeneous fashion and even under the most unfavourable conditions to a temperature of at least 850°C for at least two seconds or 1100°C for at least 0.2 seconds. These conditions shall apply to all input materials, with the exemption of those listed under points 1(a), (b) and (i), or materials resulting from a controlled microbial or thermochemical conversion process using exclusively those materials. For the latter exempted materials, a minimum temperature of 450°C for at least 2 seconds shall apply.

3. The thermal oxidation shall take place in an incineration or combustion chamber. The chamber may only process input materials referred to in point 1, which are not contaminated with other material streams, or which have been contaminated with other material streams unintentionally in a one-off incident resulting only in trace levels of exogenous compounds.

In the plant, where the thermal oxidation takes place:

- the production lines for the processing of input materials referred to in point 1 shall be clearly separated from production lines for the processing of input materials other than those referred to in point 1,

[2] The exclusion of a material from a lettered item does not prevent it from being an eligible component material by virtue of another lettered item.

[3] Ibid

- the input material shall be oxidised in such a way that the total organic carbon content of the resulting slags and bottom ashes is less than 3%, and
- physical contact between input and output materials shall be avoided after the thermochemical conversion process, including during storage.

4. The thermal oxidation materials shall have:
- no more than 6 mg/kg dry matter of PAH_{16}[4], and
- no more than 20 ng WHO toxicity equivalents[5] of PCDD/F[6] /kg dry matter.

5. An EU fertilising product may contain derivates from thermal oxidation materials that have been produced from the input materials listed in point 1 and compliant with point 4 and that have been manufactured according to a thermochemical conversion process compliant with points 2 and 3.

The derivate manufacturing process shall be executed so as to intentionally modify the chemical composition of the thermal oxidation material.

The derivate manufacturing process shall be of the following nature:

a) Chemical manufacturing: derivates are produced through one or more chemical manufacturing steps that react thermal oxidation materials with materials listed under point 1(k) that are consumed in or used for chemical processing. Non-biodegradable polymers shall not be used.

b) Thermochemical manufacturing: derivates are produced through one or more manufacturing steps that thermochemically react thermal oxidation materials with reactants listed in point 1 a) – k) that are consumed in or used for chemical processing. Thermochemical process conditions shall be compliant with points 2 and 3, and the derivates shall meet conditions listed in point 4.

Thermal oxidation materials that display one or more of the hazardous properties listed in Annex III of Directive 2008/98/EC shall not be mixed or reacted, either with waste, substances or materials with the intention of reducing hazardous substances to levels below the limit values for the hazardous property as defined in that Directive. Using a mass balance approach, manufacturers that use thermal oxidation materials with hazardous properties must demonstrate the removal or transformation of the contaminants to levels below the limit values as defined in Annex III of Directive 2008/98/EC.

6. Contaminants in an EU fertilising product containing or consisting of thermal oxidation materials or derivates must not exceed the following limit values:
a) total chromium (Cr): 400 mg/kg dry matter, if the thermal oxidation materials or derivates are from input materials listed under point 1(g), (h) or (j);
b) thallium (Tl): 2 mg/kg dry matter, if the thermal oxidation materials or derivates are from input materials listed under point 1(g), (h), (i) or (j); and

[4] 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

[5] van den Berg M., L.S. Birnbaum, M. Denison, M. De Vito, W. Farland, et al. (2006) The 2005 World Health Organization Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds. Toxicological sciences: an official journal of the Society of Toxicology 93:223-241. doi:10.1093/toxsci/kfl055

[6] Polychlorinated dibenzo-p-dioxins and dibenzofurans

The chlorine (Cl^-) content shall not be higher than 30 g/kg of dry matter. However, this limit value shall not apply to EU fertilising products produced through a manufacturing process where a Cl^- - containing compound has been added with the intention of producing alkali metal salts or alkaline earth metal salts, and is declared in accordance with Annex III.

The vanadium (V) content shall not be higher than 600 mg/kg dry matter if the thermal oxidation materials or derivates are from input materials listed under point 1(h) or (j).

7. The thermal oxidation materials or derivates shall have been registered pursuant to Regulation (EC) No 1907/2006, in 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.

Annex II

A new point is added in Annex III, Part I to Regulation (EU) 2019/1009 with the following content:

“7a. Where the EU fertilising product consists or contains thermal oxidation materials or derivates as referred to in CMC 13 in Part II in Annex II and has a manganese (Mn) content above 3.5% by mass, the manganese content shall be declared.”

Annex III

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

1. In point 2.2:
    a. Sub-point (d) is replaced with 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, 12 and 13 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,

    b. a new sub-point (ga) is inserted:

(ga) hazardous waste calculations for EU fertilising products containing or consisting of CMC 13; the testing referred to in point 5 in CMC 13 in Part II of Annex II shall be carried out at least every year, or sooner than scheduled in case of any significant change that may affect the safety or quality of the EU fertilising product (e.g. processing of input material batches of different composition, modification of process conditions). For a representative input material batch that is processed at the plant, the hazardous property identified (cfr. heading 5.1.3.1 (b – bis)) and the total mass shall be measured on the different input materials (1, …, n) and on the output material that will be incorporated in the EU fertilising product. The incorporation rate of the hazardous property into the output material shall then be calculated as:

$$incorporation\ rate\ (\%) = \frac{HPC_{output\ material} \times M_{output\ material}}{\sum_{i=1}^{n}(HPC_{input\ material,\ i} \times M_{input\ material,\ i})}$$

Where:
HPC = the concentration of the hazardous property (mg/kg),
M = the total mass (kg), and
i (1-n) = the different input materials used in the production process.

The removal of the hazardous property during the production process shall be such that the incorporation rate multiplied by the concentration of the hazardous property of each individual input material is below the limit values as defined in Annex III of Directive 2008/98/EC for that hazardous property.

2. The first sentence in point 5.1.1.1 is replaced with the following:

“5.1.1.1. For materials belonging to CMCs 3, 5, 12 and 13, as defined in Annex II, senior management of the manufacturer's organisation shall:”;

3. Point 5.1.2.1 is replaced with the following point:

“5.1.2.1. For materials belonging to CMCs 3, 5, 12 and 13, 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 first sentence is replaced with the following:

“5.1.3.1. For materials belonging to CMCs 3, 5, 12 and 13, as defined in Annex II, the examinations and tests shall comprise the following elements:”;

    b. Sub-point (b) is replaced with 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, 12 and 13 laid down in Annex II.”;

    c. Sub-point (c) is replaced with the following:

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

- the presence of hazardous or damageable substances for the process or for the quality of the final EU fertilising product, or of
- incompatibility with the specifications of CMCs 3, 5, 12 and 13 in Annex II, in particular by presence of plastics leading to exceedance of the limit value for macroscopic impurities.

    d. Sub-point (e) is replaced with the following:

“(e) Samples shall be taken on output materials, to verify that they comply with the specifications laid down in CMCs 3, 5, 12 and 13, 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 in Annex I.”;

    e. The first sentence in sub-point (fa) is amended as follows:

“(fa) For materials belonging to CMCs 12 and 13, the output material samples shall be taken with at least the following default frequency, or sooner than scheduled in case of any significant change that may affect the quality of the EU fertilising product:

    a. Sub-point (fb) is amended as follows:

(fb) for materials belonging to CMCs 12 and 13, 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.”;

    b. Sub-point (g)(iv) is replaced with the following:

“(iv) for materials belonging to CMCs 12 and 13, measure retainer samples referred to in sub-point (fb) and take the necessary corrective actions to prevent possible further transport and use of the material.”;

5. The first sentence in point 5.1.4.1 is replaced with the following:

5.1.4.1. For materials belonging to CMCs 3, 5, 12 and 13, 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.";

6. The first sentence in point 5.1.5.1 is replaced with the following:

5.1.5.1. For materials belonging to CMCs 3, 5, 12 and 13, 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. The first sentence in point 6.3.2 is replaced with the following:

"6.3.2. For materials belonging to CMCs 3, 5, 12 and 13, as defined in Annex II, the notified body shall take and analyse output material samples during each audit, and the audits shall be carried out with the following frequency:".

Annex I

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

1. In Part I, the following point is added:

"CMC 14: Pyrolysis or gasification materials";

2. Part II is amended as follows:

a) In point 1 of CMC 1, a new point (k) is added:

"(k) pyrolysis or gasification materials.";

b) In point 1 of CMC 11, a new point (g) is added:

"(g) pyrolysis or gasification materials.";

c) After CMC 13, a new CMC is added with the following content:

"CMC 14: PYROLYSIS OR GASIFICATION MATERIALS

1. An EU fertilising product may contain materials exclusively obtained through the thermochemical conversion under oxygen-limiting conditions of one or more of the following input materials:

a) derived products referred to in Article 32 of Regulation (EC) No 1069/2009 for which an end-point in the manufacturing chain has been determined in accordance with the third subparagraph of Article 5(2) of that Regulation;
b) animal by-products, the products derived from which are referred to in Article 32 of Regulation (EC) No 1069/2009 and have an end-point in the manufacturing chain determined in accordance with the third subparagraph of Article 5(2) of that Regulation;
c) living or dead organisms or parts thereof, which are unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which are extracted from air by any means, except[1]:
    - materials originating from mixed municipal waste,
    - sewage sludge, industrial sludge or dredging sludge, and
    - animal by-products or derived products within the scope of Regulation (EC) No 1069/2009
    - materials separately listed under points d) – f);
d) vegetable waste from the food processing industry and fibrous vegetable waste from virgin pulp production and from production of paper from virgin pulp;
e) bio-waste within the meaning of Directive 2008/98/EC resulting from separate bio-waste collection at source,
f) processing residues from the production of bioethanol and biodiesel as referred to in Directive 2009/28/EC; or
g) pyrolysis or gasification additives which are necessary to improve the process performance or the environmental performance of the pyrolysis or gasification

[1] The exclusion of a material from a lettered item does not prevent it from being an eligible component material by virtue of another lettered item.

process, provided that the additives are consumed in or used for chemical processing, with the exception[2] of:

- those listed under points (c) to (f),
- waste within the meaning 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, and
- animal by-products or derived products within the scope of Regulation (EC) No 1069/2009.

The total concentration of all additives shall not exceed 25 % of the fresh matter of the total input material.

In addition, an EU fertilising product may contain pyrolysis or gasification materials obtained through thermochemical conversion under oxygen-limiting conditions of any material listed in points (a)-(g), or combination thereof, processed by manual, mechanical or gravitational means, by solid-liquid fractionation using biodegradable polymers, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, by composting or by anaerobic digestion.

2. The thermochemical conversion process of the input materials shall take place under oxygen-limiting conditions in such a way that a temperature of at least 180°C for at least two seconds is reached in the reactor.

The pyrolysis or gasification reactor may only process input materials referred to in point 1, which are not contaminated with material streams, or which have been contaminated with other material streams unintentionally in a one-off incident, resulting only in trace levels of exogenous compounds.

In the plant where the pyrolysis or gasification takes place, the production lines for the processing of input materials referred to in point 1 shall be clearly separated from production lines for the processing of input materials other than those referred to in point 1 and physical contacts between input and output materials shall be avoided after the thermochemical process, including during storage.

3. The pyrolysis or gasification materials shall have:

- a molar ratio of hydrogen (H) to organic carbon (H/C_{org}) of less than 0.7, with testing to be performed in the dry and ash-free fraction for materials that have an organic carbon (C_{org}) content of less than 50%,
- no more than 6 mg/kg dry matter of PAH_{16}[3],

[2] The exclusion of a material from a lettered item does not prevent it from being an eligible component material by virtue of another lettered item.

- no more than 20 ng WHO toxicity equivalents[4] of PCDD/F[5] /kg dry matter,
- no more than 0.8 mg kg^{-1} dry matter of dl-PCB[6],
- no more than 30 g/kg chlorine (Cl^-) on a dry matter basis, and
- no more than 2 mg/kg dry matter of thallium (Tl), in case more than 5% of pyrolysis or gasification additives relative to the fresh weight of total input material have been applied.

4. The pyrolysis and gasification material shall have been registered pursuant to Regulation (EC) No 1907/2006, in a dossier containing:

(a) the information provided for by Annex 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.

[3] 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

[4] van den Berg M., L.S. Birnbaum, M. Denison, M. De Vito, W. Farland, et al. (2006) The 2005 World Health Organization Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds. Toxicological sciences: an official journal of the Society of Toxicology 93:223-241. doi:10.1093/toxsci/kfl055

[5] Polychlorinated dibenzo-p-dioxins and dibenzofurans

[6] Sum of congeners PCB 28, 52, 101, 138, 153, 180

Annex II

A new point is added in Annex III, Part I to Regulation (EU) 2019/1009 with the following content:

"7a. Where the EU fertilising product consists or contains thermal oxidation materials and derivates as referred to in CMC 13 in Part II in Annex II and/or pyrolysis and gasification materials as referred to in CMC 14 in Part II of that Annex and has a manganese (Mn) content above 3.5% by mass, the manganese content shall be declared."

Annex III

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

1. In point 2.2, sub-point (d) is replaced with 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, 12, 13 and 14 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 first sentence in point 5.1.1.1 is replaced with the following:

“5.1.1.1. For materials belonging to CMCs 3, 5, 12, 13 and 14, as defined in Annex II, senior management of the manufacturer's organisation shall:”;

3. Point 5.1.2.1 is replaced with the following point:

“5.1.2.1. For materials belonging to CMCs 3, 5, 12, 13 and 14, 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 first sentence is replaced with the following:

“5.1.3.1. For materials belonging to CMCs 3, 5, 12, 13 and 14, as defined in Annex II, the examinations and tests shall comprise the following elements:”;

    b. Sub-point (b) is replaced with 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, 12, 13 and 14 laid down in Annex II.”;

    c. Sub-point (c) is replaced with the following:

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

- the presence of hazardous or damageable substances for the process or for the quality of the final EU fertilising product, or of
- incompatibility with the specifications of CMCs 3, 5, 12, 13 and 14 in Annex II, in particular by presence of plastics leading to exceedance of the limit value for macroscopic impurities.

    d. Sub-point (e) is replaced with the following:

"(e) Samples shall be taken on output materials, to verify that they comply with the specifications laid down in CMCs 3, 5, 12, 13 and 14, 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 in Annex I.";

e. The first sentence of sub-points (fa) is amended as follows:

"(fa) For materials belonging to CMCs 12, 13 and 14, the output material samples shall be taken with at least the following default frequency, or sooner than scheduled in case of any significant change that may affect the quality of the EU fertilising product:";

a. Sub-point (fb) is amended as follows:

"(fb) for materials belonging to CMCs 12, 13 and 14, 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.";

b. Sub-point (g)(iv) is replaced with the following:

"(iv) for materials belonging to CMCs 12, 13 and 14, measure retainer samples referred to in sub-point (fb) and take the necessary corrective actions to prevent possible further transport and use of the material.";

5. The first sentence in point 5.1.4.1 is replaced with the following:

5.1.4.1. For materials belonging to CMCs 3, 5, 12, 13 and 14, 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.";

6. The first sentence in point 5.1.5.1 is replaced with the following:

5.1.5.1. For materials belonging to CMCs 3, 5, 12, 13 and 14, 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. The first sentence in point 6.3.2 is replaced with the following:

"6.3.2. For materials belonging to CMCs 3, 5, 12, 13 and 14, as defined in Annex II, the notified body shall take and analyse output material samples during each audit, and the audits shall be carried out with the following frequency:".