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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	ANNEXES to the COMMISSION DELEGATED REGULATION amending Annexes II, III and IV to Regulation (EU) 2019/1009 of the European Parliament and of the Council for the purpose of adding recovered high purity materials as a component material category in EU fertilising products

Delegations will find attached document C(2022) 1422 final, ANNEXES 1 to 3.

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ANNEXES 1 to 3

ANNEXES

to the

COMMISSION DELEGATED REGULATION

amending Annexes II, III and IV to Regulation (EU) 2019/1009 of the European Parliament and of the Council for the purpose of adding recovered high purity materials 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 15: Recovered high purity materials".

(2) Part II is amended as follows:

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

(i) at the end of sub-point (j), the word "or" is deleted;

(ii) in sub-point (k), "." is replaced by ", or";

(iii) the following sub-point (l) is added:

"(l) ammonium salts, sulphate salts, phosphate salts, elemental sulphur, calcium carbonate or calcium oxide, which are recovered from waste within the meaning of Article 3, point 1, of Directive 2008/98/EC."

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

(i) at the end of sub-point (f), the word "or" is deleted;

(ii) in sub-point (g), "." is replaced by ", or";

(iii) the following sub-point (h) is added:

"(h) ammonium salts, sulphate salts, phosphate salts, elemental sulphur, calcium carbonate or calcium oxide, which are recovered from waste within the meaning of Article 3, point 1, of Directive 2008/98/EC."

(c) The following CMC 15 is added:

"CMC 15: RECOVERED HIGH PURITY MATERIALS

(1) An EU fertilising product may contain a recovered high purity material, which is ammonium salt, sulphate salt, phosphate salt, elemental sulphur, calcium carbonate or calcium oxide, or mixtures thereof, of a purity of at least 95 % dry matter of the material.

(2) The high purity material shall be recovered from waste generated from:

(a) a production process that uses as input materials substances and mixtures other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009 (*), or

- (b) a gas purification or emission control process designed to remove nutrients from off-gases derived from one or more of the following input materials and facilities:
 - (i) substances and mixtures, other than waste within the meaning of Article 3, point 1, of Directive 2008/98/EC;
 - (ii) plants or plant parts;
 - (iii) bio-waste within the meaning of Article 3, point 4, of Directive 2008/98/EC, resulting from separate bio-waste collection at source;
 - (iv) urban and domestic waste waters within the meaning of Article 2, points 1 and 2, respectively, of Directive 91/271/EEC (**),;
 - (v) sludge within the meaning of Article 2, point (a), of Directive 86/278/EEC (***), which displays no hazardous properties listed in Annex III to Directive 2008/98/EC;
 - (vi) waste within the meaning of Article 3, point 1, of Directive 2008/98/EC, and fuels input to a waste co-incineration plant as defined in Directive 2010/75/EU of the European Parliament and of the Council (****) and operated according to the conditions of that Directive, on condition that these inputs display no hazardous properties listed in Annex III to Directive 2008/98/EC;
 - (vii) Category 2 or Category 3 materials or derived products thereof, in accordance with the conditions set out in Article 32(1) and (2) and in the measures referred to in Article 32(3) of Regulation (EC) No 1069/2009, provided that the off-gases are derived from a composting or digestion process in accordance with CMCs 3 and 5, respectively, in Annex II to this Regulation;
 - (viii) manure within the meaning of Article 3, point 20, of Regulation (EC) No 1069/2009 or derived products thereof; or
 - (ix) livestock housing facilities.

The input materials referred to in points (i) to (vi) shall not contain animal by-products or derived products within the scope of Regulation (EC) No 1069/2009.

- (3) The high purity material shall have an organic carbon (C_{org}) content of no more than 0,5 % dry matter of the material.
- (4) The high purity material shall contain no more than:
 - (a) 6 mg/kg dry matter of polycyclic aromatic hydrocarbons (PAH_{16}) (*****);
 - (b) 20 ng WHO toxicity equivalents (*****)/kg dry matter of the polychlorinated dibenzo-para-dioxins and dibenzofurans (PCDD/PCDF) (*****).

- (5) An EU fertilising product containing or consisting of high purity materials shall contain no more than:
- (a) 400 mg/kg dry matter of total chromium (Cr); and
 - (b) 2 mg/kg dry matter of thallium (Tl).
- (6) Where compliance with a given requirement laid down in points 4 and 5 (such as absence of a given contaminant) follows certainly and uncontestably from the nature or the recovery process of the high purity material or the manufacturing process of the EU fertilising product, that compliance may be presumed in the conformity assessment procedure without verification (such as testing), under the responsibility of the manufacturer.
- (7) Where for the product function category of an EU fertilising product containing or consisting of high purity materials referred to in point 2(b) no requirements regarding *Salmonella* spp., *Escherichia coli* or *Enterococcaceae* have been laid down in Annex I, those pathogens in the EU fertilising product 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 colony forming units (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.

- (8) The compliance of an EU fertilising product containing or consisting of high purity materials referred to in point 2(b) with requirements in point (7), or with the requirements for *Salmonella* spp., *Escherichia coli* or *Enterococcaceae* set out in Annex I for the corresponding PFC of the EU fertilising product shall be verified via testing, in accordance with point 5.1.3.1 in Module D1 – quality assurance of the production process in Part II of Annex IV.

The requirements in point (7) and the requirements for *Salmonella* spp., *Escherichia coli* or *Enterococcaceae* set out in Annex I for the corresponding PFC of an EU fertilising product consisting only of high purity materials referred to in point 2(b) shall not apply, when the high purity materials or all of the biogenic input materials used 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.

The requirements in point (7) and the requirements for *Salmonella* spp., *Escherichia coli* or *Enterococcaceae* set out in Annex I for the corresponding PFC of an EU fertilising product consisting only of high purity materials referred to in point 2(b) shall not apply, where the off-gases derive from an incineration process as defined in Directive 2010/75/EU.

- (9) High purity materials that are stored in a way that does not protect them against precipitation and direct sunlight may be added to an EU fertilising product only if they have been manufactured maximum 36 months before signing the EU declaration of conformity for the respective EU fertilising product.
- (10) The high purity material 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 to 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.

(*) 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).

(**) Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment (OJ L 135, 30.05.1991, p. 40).

(***) Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture (OJ L 181, 4.7.1986, p. 6).

(****) Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17).

(*****) 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.

(*****) 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.

(*****) Sum of 2,3,7,8-TCDD, 1,2,3,7,8-PeCDD; 1,2,3,4,7,8-HxCDD; 1,2,3,6,7,8-HxCDD; 1,2,3,7,8,9-HxCDD; 1,2,3,4,6,7,8-HpCDD; OCDD; 2,3,7,8-TCDF; 1,2,3,7,8-PeCDF; 2,3,4,7,8-PeCDF; 1,2,3,4,7,8-HxCDF; 1,2,3,6,7,8-HxCDF; 1,2,3,7,8,9-HxCDF; 2,3,4,6,7,8-HxCDF; 1,2,3,4,6,7,8-HpCDF; 1,2,3,4,7,8,9-HpCDF; and OCDF.”.

ANNEX II

In Part I of Annex III to Regulation (EU) No 2019/1009, the following point 7b is inserted:

“7b. Where the EU fertilising product contains or consists of high purity materials referred to in Part II, CMC 15, of Annex II and:

- (a) has a selenium (Se) content exceeding 10 mg/kg dry matter, the selenium content shall be indicated;
- (b) has a chloride (Cl-) content exceeding 30 g/kg dry matter, the chloride content shall be indicated, unless the EU fertilising product is produced through a manufacturing process where chloride containing substances or mixtures have been used with the intention of producing or including alkali metal salts or alkaline earth metal salts, and information on these salts is provided in accordance with Annex III.

When the content of selenium or chloride is indicated in accordance with point (a) and (b), it shall be clearly separated from nutrient declaration and it may be expressed as a range of values

Where the fact that such an EU fertilising product contains selenium or chloride below the limit values in points (a) and (b) follows certainly and uncontestably from the nature or recovery operation of the high purity material or the production process of the EU fertilising product containing such a material, as applicable, the label may contain no information on these parameters, without verification (such as testing), at the responsibility of the manufacturer.”.

ANNEX III

In Part II of Annex IV to 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, 12, 13, 14 or 15 as defined in Annex II, a written description and a diagram of the production or recovery process, where each treatment, storage vessel and area is clearly identified.”.

(2) In point 5.1.1.1, the introductory wording is replaced by the following:

“5.1.1.1. For materials belonging to CMCs 3, 5, 12, 13, 14 and 15, 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, 12, 13, 14 and 15, 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, 12, 13, 14 and 15, 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 laid down in CMCs 3, 5, 12, 13, 14 and 15 in Annex II [OR: as defined in Annex II].

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

- the presence of hazardous or damaging substances for the process or for the quality of the final EU fertilising product,
- incompatibility with the specifications laid down in CMCs 3, 5, 12, 13, 14 and 15 in Annex II [OR: as defined 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, 12, 13, 14 and 15, 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 sub-point (fa), the introductory wording is replaced by the following:

“(fa) For materials belonging to CMCs 12, 13, 14 and 15, the output material samples shall be taken with at least the following default frequency, or sooner than scheduled in the case of any significant change that may affect the quality of the EU fertilising product.”.

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

“(fb) For materials belonging to CMCs 12, 13, 14 and 15, 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 sooner, shall be stored in good condition for a period of at least two years.”.

(f) Sub-point (g)(iv) is replaced by the following:

“(iv) for materials belonging to CMCs 12, 13, 14 and 15, 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, 12, 13, 14 and 15, 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 at least contain 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, 12, 13, 14 and 15, 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) In point 6.3.2, the introductory wording is replaced by the following:

“6.3.2. For materials belonging to CMCs 3, 5, 12, 13, 14 and 15, 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:”.