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From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 23 June 2021

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, for the purpose of adaptation to technical progress, Annexes I, II, III and IV to Regulation (EU) 2019/1009 of the European Parliament and of the Council laying down rules on the making available on the market of EU fertilising products**

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Delegations will find attached document C(2021) 4250 final, ANNEXES 1 - 4.

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Brussels, 23.6.2021  
C(2021) 4250 final

ANNEXES 1 to 4

## ANNEXES

to the

### COMMISSION DELEGATED REGULATION

**amending, for the purpose of adaptation to technical progress, Annexes I, II, III and IV to Regulation (EU) 2019/1009 of the European Parliament and of the Council laying down rules on the making available on the market of EU fertilising products**

## ANNEX I

Annex I, Part II of Regulation (EU) 2019/1009 is amended as follows:

(1) point 5 is replaced by the following:

‘5. Residues of a pharmacologically active substance within the meaning of Regulation (EC) No 470/2009 of the European Parliament and of the Council\* may be present in an EU fertilising product only if that substance is either:

- included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010\*\*, or
- has had a reference point for action established in accordance with Commission Regulation (EU) 2019/1871\*\*\*, and the substance or its residues are present in the EU fertilising product at a level below that reference point.’;

(2) the following point 5a is inserted:

‘5a. An EU fertilising product may contain an active substance within the meaning of Article 2(2) of Regulation (EC) No 1107/2009 only if that EU fertilising product does not have a plant protection function within the meaning of Article 2(1) of that Regulation.’;

(3) in PFC 1(C)(II)(a), point 2, in the table:

(a) the row concerning the typology ‘Micronutrient salt fertiliser’ is replaced by the following:

‘Micronutrient salt fertiliser	A chemically obtained straight solid inorganic micronutrient fertiliser containing a mineral ion salt as its essential ingredient	10 % by mass of micronutrient salt fertiliser shall consist of a micronutrient’
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(b) the row concerning the typology ‘UVCB iron chelates’ is replaced by the following:

‘UVCB <sup>(5)</sup> micronutrient chelates	A water-soluble straight inorganic micronutrient fertiliser in which the declared micronutrient is chemically combined with chelating agent(s) fulfilling the requirements of CMC 1 in Part II of Annex II	— 5 % by mass of UVCB micronutrient chelates shall consist of water-soluble micronutrient, and  at least 80 % of the water-soluble micronutrient shall be chelated (chelated fraction) and  at least 50 % of the water soluble micronutrient shall be chelated by specific chelating agents fulfilling the
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		requirements of CMC 1 in Part II of Annex II
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(5) UVCB: Substance of unknown or variable composition, complex reaction products or biological materials.’;

(4) in PFC 3(B), the following point 4 is added:

‘4. Pathogens in an inorganic soil improver that contains more than 1 % by mass of organic carbon (C<sub>org</sub>) must 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.’;

(5) in PFC 4, the following point 2a is inserted:

‘2a. By derogation from point 2(d), the limit value for nickel (Ni) in a growing medium totally composed by mineral constituents and offered for professional use in horticulture, green roofs or green walls, shall apply to the bioavailable content of the contaminant.’.

\* Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

\*\* Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

\*\*\* Commission Regulation (EU) 2019/1871 of 7 November 2019 on reference points for action for non-allowed pharmacologically active substances present in food of animal origin and repealing Decision 2005/34/EC (OJ L 289, 8.11.2019, p. 41).

## ANNEX II

Annex II, Part II of Regulation (EU) 2019/1009 is amended as follows:

(1) CMC 1 is amended as follows:

(a) point 1(f) is replaced by the following:

‘(f) polymers, other than:

- polymers that are the result of a polymerisation process that has taken place in nature, independently of the extraction process with which they have been extracted and that have not been chemically modified within the meaning of Article 3(40) of Regulation (EC) No 1907/2006,
- biodegradable polymers, or
- polymers with a water-solubility higher than 2 g/L in the following conditions:
  - temperature 20° C
  - pH 7
  - loading: 10 g/1000 mL
  - test time: 24h.’;

(b) in point 3(a), the last sentence is replaced by the following:

‘The EU fertilising product shall remain stable for at least 3 days in a solution having any pH within the range declared as guaranteeing acceptable stability.’;

(2) in CMC 2, the first paragraph is replaced by the following:

‘An EU fertilising product may contain plants, plant parts or plant extracts having undergone no processing other than cutting, grinding, milling, sieving, sifting, centrifugation, pressing, drying, frost treatment, freeze-drying, extraction with water, supercritical CO<sub>2</sub> extraction, or fiberisation at a temperature not higher than 100 °C and without any additives except water.’;

(3) CMC 3 is amended as follows:

(a) point 1(b) is deleted;

(b) point 1(c) is replaced by the following:

‘(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:

(i) materials originating from mixed municipal waste, ’;

(ii) sewage sludge, industrial sludge or dredging sludge, and

(iii) animal by-products or derived products within the scope of Regulation (EC) No 1069/2009.’;

(c) in point 1(e), the introductory wording is replaced by the following:

‘(e) any material listed in points (a) or (c) or in point 1a which:’;

(d) the following point 1a is inserted:

‘1a. Notwithstanding point 1, an EU fertilising product may contain compost obtained through aerobic composting of 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, alone or mixed with input materials referred to in point 1, provided that:

(a) the end point in the manufacturing chain has been determined in accordance with the third subparagraph of Article 5(2) of Regulation (EC) No 1069/2009, and

(b) the conditions in points 2 and 3 are met.’;

(e) point 2(a) is replaced by the following:

‘(a) in which production lines for the processing of input materials referred to in points 1 and 1a are clearly separated from production lines for the processing of input materials other than those referred to in points 1 and 1a, and’;

(4) CMC 5 is amended as follows:

(a) point 1(b) is deleted;

(b) point 1(c) is replaced by the following:

‘(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:

(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.’;

(c) in point 1(e), the introductory wording is replaced by the following:

‘(e) any material listed in points (a) or (c) or in point 1a which.’;

(d) the following point 1a is inserted:

‘1a. Notwithstanding point 1, an EU fertilising product may contain digestate obtained through anaerobic digestion of 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, alone or mixed with input materials referred to in point 1, provided that:

(a) the end point in the manufacturing chain has been determined in accordance with the third subparagraph of Article 5(2) of Regulation (EC) No 1069/2009, and

(b) the conditions in points 2 and 3 are met.’;

(e) point 2(a) is replaced by the following:

‘(a) in which production lines for the processing of input materials referred to in points 1 and 1a are clearly separated from production lines for the processing of input materials other than those referred to in points 1 and 1a, and’;

(5) in CMC 11, point 1(b) is replaced by the following:

‘(b) polymers, other than:

- polymers that are the result of a polymerisation process that has taken place in nature, independently of the extraction process with which they have been extracted and that have not been chemically modified within the meaning of Article 3(40) of Regulation (EC) No 1907/2006,
- biodegradable polymers, or
- polymers with a water-solubility higher than 2 g/L in the following conditions:
  - temperature 20° C
  - pH 7
  - loading: 10 g/1000 mL
  - test time: 24h,’.



## ANNEX III

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

(1) Part I is amended as follows:

(a) point 1(h) is replaced by the following:

‘(h) a list of all ingredients above 5 % by product weight or volume, or in the case of products in liquid form by dry weight, in descending order of magnitude, including the designations of the relevant CMCs as referred to in Part I of Annex II to this Regulation. Where the ingredient is a substance or a mixture, it shall be identified in accordance with Article 18 of Regulation (EC) No 1272/2008. Naturally occurring substances may be identified by their mineral names.’;

(b) point 3 is replaced by the following:

‘3. Where the EU fertilising product contains a component material which, if placed on the market as food or feed, would have been subject to maximum residue limits established pursuant to Regulation (EC) No 470/2009 or Regulation (EU) No 1831/2003 of the European Parliament and of the Council\*, maximum residue levels set in accordance with Regulation (EC) No 396/2005 of the European Parliament and of the Council\*\*, or maximum levels established pursuant to Council Regulation (EEC) 315/93\*\*\* or Directive 2002/32/EC of the European Parliament and of the Council\*\*\*\*, and that component material contains a substance in exceedance of (one of) the corresponding limit value(s), the maximum concentration of that substance in the EU fertilising product shall be indicated, together with a warning that the EU fertilising product must not be used in such a manner as to risk leading to the exceedance of that limit in food or feed.’;

(c) point 7 is replaced by the following:

‘7. Where the EU fertilising product is a growing medium as referred to in point 2a of PFC 4 in Part II of Annex I, or contains a polymer with the purpose of binding material in the product as referred to in point 1(c) of CMC 9 in Part II of Annex II, the user shall be instructed not to use the product in contact with soil, and in collaboration with the manufacturer, to make sure of a sound disposal of the product after end of use.’;

(2) Part II is amended as follows:

(a) in PFC 1(B), point 5:

(i) sub-point (a) is replaced by the following:

‘(a) indication of the names and chemical symbols of the declared micronutrients, listed in the following order: boron (B), cobalt (Co), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo) and zinc (Zn), followed by the names of their counter-ions when the declared micronutrients are intentionally added.’;

(ii) sub-point (c) is replaced by the following:

‘(c) where the declared micronutrients are chelated by chelating agent(s) or complexed by complexing agent(s):

- the following qualifier as applicable, after the name and chemical identifier of the micronutrient:

‘chelated by [name of the chelating agent(s) or its(their) abbreviation]’ / ‘complexed by [name of the complexing agent(s) or its(their) abbreviation]’ / ‘chelated by [name of the chelating agent(s) or its(their) abbreviation] and complexed by [name of the complexing agent(s) or its (their) abbreviation]’;

- the amount of chelated/complexed micronutrient(s) as % by mass;’;

(iii) the following sub-point (ca) is inserted:

‘(ca) where the declared micronutrients are chelated by chelating agent(s), the pH range guaranteeing acceptable stability;’;

(iv) sub-point (d) is deleted;

- (b) in PFC 1(C)(I)(a):

(i) point 3 is replaced by the following:

‘3. The form of the physical unit of the product shall be indicated with one, or a combination of two or more, of the following mentions:

(a) granules,

(b) pellets,

(c) powder, where at least 90 % by mass of the product can pass through a sieve with a mesh of 1 mm, or

(d) prills;’;

(ii) in point 8:

- sub-point (a) is replaced by the following:

‘(a) indication of the names and chemical symbols of the declared micronutrients, listed in the following order: boron (B), cobalt (Co), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo) and zinc (Zn), followed by the names of their counter-ions when the declared micronutrients are intentionally added;’;

- sub-point (c) is replaced by the following:

‘(c) where the declared micronutrients are chelated by chelating agent(s) or complexed by complexing agent(s):

- the following qualifier, as applicable, after the name and chemical identifier of the micronutrient:

‘chelated by [name of the chelating agent(s) or its(their) abbreviation]’ / ‘complexed by [name of the complexing agent(s) or its(their) abbreviation]’ / ‘chelated by [name of the chelating agent(s) or its(their) abbreviation] and complexed by [name of the complexing agent(s) or its (their) abbreviation]’;

– the amount of chelated/complexed micronutrient(s) as % by mass;’;

– the following sub-point (ca) is inserted:

‘(ca) where the declared micronutrients are chelated by chelating agent(s), the pH range guaranteeing acceptable stability;’;

– sub-point (d) is deleted;

(c) in PFC 1(C)(I)(b), point 6:

(i) sub-point (a) is replaced by the following:

‘(a) indication of the names and chemical symbols of the declared micronutrients, listed in the following order: boron (B), cobalt (Co), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo) and zinc (Zn), followed by the names of their counter-ions when the declared micronutrients are intentionally added;’;

(ii) sub-point (c) is replaced by the following:

‘(c) where the declared micronutrients are chelated by chelating agent(s) or complexed by complexing agent(s):

– the following qualifier, as applicable, after the name and chemical identifier of the micronutrient :

‘chelated by [name of the chelating agent(s) or its(their) abbreviation]’ / ‘complexed by [name of the complexing agent(s) or its(their) abbreviation]’ / ‘chelated by [name of the chelating agent(s) or its(their) abbreviation] and complexed by [name of the complexing agent(s) or its (their) abbreviation]’;

– the amount of chelated/complexed micronutrient(s) as % by mass;’;

(iii) the following sub-point (ca) is inserted:

‘(ca) where the declared micronutrients are chelated by chelating agent(s), the pH range guaranteeing acceptable stability;’;

(iv) sub-point (d) is deleted;

(d) in PFC 1(C)(II):

(i) point 1 is replaced by the following:

‘1. The declared micronutrients in the inorganic micronutrient fertiliser shall be listed by their names and chemical symbols of the declared micronutrients, in the following order: boron (B), cobalt (Co), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo) and zinc (Zn),

followed by the names of their counter-ions when the declared micronutrients are intentionally added.’;

(ii) point 2 is replaced by the following:

‘2. Where the declared micronutrients are chelated by chelating agent(s) and each chelating agent can be identified and quantified and chelates at least 1% water-soluble micronutrient, or the declared micronutrients are complexed by complexing agent(s), the following qualifiers shall be added, as applicable, after the name and chemical identifier of the micronutrient:

- ‘chelated by [name of the chelating agent(s) or its(their) abbreviation]’ / ‘complexed by [name of the complexing agent(s) or its(their) abbreviation]’ / ‘chelated by [name of the chelating agent(s) or its(their) abbreviation] and complexed by [name of the complexing agent(s) or its (their) abbreviation]’,
- the amount of chelated/complexed micronutrient(s) as % by mass;’;

(iii) the following point 2a is inserted:

‘2a. Where the declared micronutrients are chelated by chelating agent(s), the pH range guaranteeing acceptable stability shall be indicated.’;

(iv) point 3 is deleted;

(3) Part III is amended as follows:

(a) in PFC 1(C):

(i) the first table is replaced by the following:

<b>‘Forms of the declared nutrient and other declared parameters</b>	<b>Permissible tolerance for the declared macronutrient content and other declared parameters</b>
Declared forms of nitrogen (N)	± 25 % relative deviation of the declared value up to a maximum of 2 percentage points in absolute terms
Declared forms of phosphorus pentoxide (P <sub>2</sub> O <sub>5</sub> )	± 25 % relative deviation of the declared value up to a maximum of 2 percentage points in absolute terms
Declared forms of potassium oxide (K <sub>2</sub> O)	± 25 % relative deviation of the declared value up to a maximum of 2 percentage points in absolute terms
Declared forms of nitrogen (N), phosphorus pentoxide (P <sub>2</sub> O <sub>5</sub> ) or potassium oxide (K <sub>2</sub> O) in binary fertilisers	± 1,5 percentage points in absolute terms
Declared forms of nitrogen (N), phosphorus	± 1,9 percentage points in absolute terms

pentoxide (P <sub>2</sub> O <sub>5</sub> ) or potassium oxide (K <sub>2</sub> O) in tertiary fertilisers	
Total and water-soluble magnesium oxide (MgO), calcium oxide (CaO), sulphur trioxide (SO <sub>3</sub> )	-50 and +100 % relative deviation of the declared content of those nutrients up to a maximum of -2 and + 4 percentage points in absolute terms
Total and water soluble sodium oxide (Na <sub>2</sub> O)	- 25 % of the declared content up to a maximum of 0,9 percentage point in absolute terms + 50 % of the declared content up to a maximum of 1,8 percentage points in absolute terms
Granulometry	± 20 % relative deviation of the declared percentage of material passing a specific sieve
Quantity	± 1 % relative deviation of the declared value'

(ii) the second table is replaced by the following:

<b>'Micronutrient</b>	<b>Permissible tolerance for the declared content of forms of micronutrient</b>
Concentration below or equal to 2 %	± 50 % of the declared value
Concentration of more than 2 % and below or equal to 10 %	± 50 % of the declared value up to a maximum of 1,0 percentage point in absolute terms
Concentration of more than 10 %	± 1,0 percentage point in absolute terms'

(b) in PFC 3, the second row which sets out the tolerance for organic carbon is replaced by the following:

'Organic carbon (C <sub>org</sub> )	± 10 % relative deviation of the declared value up to a maximum of 3,0 percentage points in absolute terms'
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(c) the following section is inserted after 'PFC 5: INHIBITOR':

**'PFC 6: PLANT BIOSTIMULANT**

The quantity of a plant biostimulant may deviate by ± 5 %.from the declared value.';

(d) at the beginning of PFC 7, the following table is inserted:

<b>Declared parameter</b>	<b>Permissible tolerance for the declared parameter</b>
Quantity	the tolerance is the sum of the relative proportion of each component EU fertilising product multiplied by the tolerance for the PFC for that fertilising product. If the proportion of each EU fertilising product in the fertilising product blend cannot be determined, the tolerance is that of the PFC with the strictest quantity tolerance value.

\* Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

\*\* Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

\*\*\* Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 37, 13.2.1993, p. 1).

\*\*\*\* Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10).

## ANNEX IV

Annex IV to Regulation 2019/1009/EU is amended as follows:

(1) in Part I, point 3.2 is replaced by the following:

‘3.2 Module B followed by Module C may also be used for a fertilising product blend as specified in PFC 7.’;

(2) Part II is amended as follows:

(a) in Module A, point 2.2:

(i) sub-point (g) is replaced by the following:

‘(g) results of calculations made, examinations carried out, etc.’;

(ii) sub-point (j) is replaced by the following:

‘(j) where the EU fertilising product contains total chromium (Cr) above 200 mg/kg dry matter, information about the maximum quantity and exact source of total chromium (Cr).’;

(b) in Module A1, sub-point 2.2(h) is replaced by the following:

‘(h) results of calculations made, examinations carried out, etc.’;

(c) in Module B, point 2.2:

(i) sub-point (g) is replaced by the following:

‘(g) results of calculations made, examinations carried out, etc.’;

(ii) sub-point (k) is replaced by the following:

‘(k) where the EU fertilising product contains total chromium (Cr) above 200 mg/kg dry matter, information about the maximum quantity and exact source of total chromium (Cr).’;

(d) in Module D1, point 2.2:

(i) sub-point (g) is replaced by the following:

‘(g) results of calculations made, examinations carried out, etc.’;

(ii) sub-point (k) is replaced by the following:

‘(k) where the EU fertilising product contains total chromium (Cr) above 200 mg/kg dry matter, information about the maximum quantity and exact source of total chromium (Cr).’