Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (Text with EEA relevance)

ANNEX I

Product Function Categories (PFCs) of EU fertilising products

PART I

DESIGNATION OF PFCS

- 1. Fertiliser
- A. Organic fertiliser
- I. Solid organic fertiliser
- II. Liquid organic fertiliser
- B. Organo-mineral fertiliser
- I. Solid organo-mineral fertiliser
- II. Liquid organo-mineral fertiliser
- C. Inorganic fertiliser
- I. Inorganic macronutrient fertiliser
- (a) Solid inorganic macronutrient fertiliser
 - (i) Straight solid inorganic macronutrient fertiliser
 - (A) Straight solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content
 - (ii) Compound solid inorganic macronutrient fertiliser
 - (A) Compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content
- (b) Liquid inorganic macronutrient fertiliser
 - (i) Straight liquid inorganic macronutrient fertiliser
 - (ii) Compound liquid inorganic macronutrient fertiliser
- II. Inorganic micronutrient fertiliser
- (a) Straight inorganic micronutrient fertiliser
- (b) Compound inorganic micronutrient fertiliser
- 2.Liming material

- 3. Soil improver
- A. Organic soil improver
- B. Inorganic soil improver
- 4.Growing medium

- 5. Inhibitor
- A. Nitrification inhibitor
- B. Denitrification inhibitor
- C. Urease inhibitor
- 6. Plant biostimulant
- A. Microbial plant biostimulant
- B. Non-microbial plant biostimulant

7.Fertilising product blend

PART II

REQUIREMENTS RELATED TO PFCS

- 1. This Part sets out the requirements related to the PFCs to which EU fertilising products belong by virtue of their claimed function.
- 2. The requirements laid down in this Annex for a given PFC apply to EU fertilising products in all subcategories of that PFC.
- 3. The claim that an EU fertilising product complies with the function set out in this Annex for the relevant PFC shall be supported by the product's mode of action, the relative content of its various components, or any other relevant parameter.
- 4. Where compliance with a given requirement (such as absence of a given contaminant) follows certainly and uncontestably from the nature or manufacturing process of an EU fertilising product, that compliance can be presumed in the conformity assessment procedure without verification (such as testing), at the responsibility of the manufacturer.
- 5. Where the EU fertilising product contains a substance for which maximum residue limit values for food and feed have been established in accordance with:
- (a) Council Regulation (EEC) No $315/93^{(1)}$,
- (b) Regulation (EC) No 396/2005 of the European Parliament and of the Council⁽²⁾,
- (c) Regulation (EC) No 470/2009 of the European Parliament and of the Council⁽³⁾, or
- (d) Directive 2002/32/EC of the European Parliament and of the Council⁽⁴⁾

the use of the EU fertilising product as specified in the use instructions must not lead to the exceedance of those limit values in food or feed.

- 6. Phosphonates shall not be intentionally added to any EU fertilising product. Unintentional presence of phosphonates shall not exceed 0,5 % by mass.
- 7. The requirements in this Annex are expressed in oxidised form for certain nutrients. Where compliance is assessed based on the presence of the nutrient in question in its elemental form, the following conversion factors shall be used:

phosphorus (P)	=	phosphorus pentoxide (P_2O_5) × 0,436;
potassium (K)	=	potassium oxide (K ₂ O) \times 0,830;
calcium (Ca)	=	calcium oxide (CaO) \times 0,715;
magnesium (Mg)	=	magnesium oxide (MgO) \times 0,603;
sodium (Na)	=	sodium oxide (Na ₂ O) \times 0,742;
sulphur (S)	=	sulphur trioxide $(SO_3) \times 0,400$.

8. The requirements in this Annex are expressed by reference to organic carbon (C_{org}). Where compliance is assessed based on organic matter the following conversion factor applies:

organic carbon (C_{org}) = organic matter × 0,56. PFC 1: FERTILISER

A fertiliser shall be an EU fertilising product the function of which is to provide nutrients to plants or mushrooms.

PFC 1(A): ORGANIC FERTILISER

- 1. An organic fertiliser shall contain:
- organic carbon (C_{org}) and
- nutrients

of solely biological origin.

An organic fertiliser may contain peat, leonardite and lignite, but no other material which is fossilized or embedded in geological formations.

2. Contaminants in an organic fertiliser must not exceed the following limit values:

(a) cadmium (Cd)		1,5 mg/kg dry matter,
(b) hexavalent	:	2 mg/kg dry matter,
chromium (Cr VI)		
(c) mercury (Hg)		1 mg/kg dry matter,
(d) nickel (Ni)		50 mg/kg dry matter,
(e) lead (Pb)	:	120 mg/kg dry matter, and
(f) inorganic	:	40 mg/kg dry matter.
arsenic (As)		

Biuret (C₂H₅N₃O₂) must not be present in an organic fertiliser.

- 3. The copper (Cu) content in an organic fertiliser must not exceed 300 mg/kg dry matter, and the zinc (Zn) content in an organic fertiliser must not exceed 800 mg/kg dry matter.
- 4. Pathogens in an organic fertiliser must not exceed the limits set out in the following table:

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

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU)
2019/1009 of the European Parliament and of the Council. (See end of Document for details)

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,
М	= maximum value of the number of bacteria expressed in CFU.
PFC 1(.	A)(I): SOLID ORGANIC FERTILISER
1.	A solid organic fertiliser shall be in solid form.

2. A solid organic fertiliser shall contain at least one of the following declared primary nutrients: nitrogen (N), phosphorus pentoxide (P_2O_5) or potassium oxide (K_2O).

Where a solid organic fertiliser contains only one declared primary nutrient, that nutrient content shall be at least the following:

- (a) 2,5 % by mass of total nitrogen (N),
- (b) 2 % by mass of total phosphorus pentoxide (P_2O_5), or
- (c) 2% by mass of total potassium oxide (K₂O).

Where a solid organic fertiliser contains more than one declared primary nutrient, those nutrient contents shall be at least the following:

- (a) 1 % by mass of total nitrogen (N),
- (b) 1 % by mass of total phosphorus pentoxide (P_2O_5), or
- (c) 1 % by mass of total potassium oxide (K_2O).

The sum of those nutrient contents shall be at least 4 % by mass.

3. Organic carbon (C_{org}) content in a solid organic fertiliser shall be at least 15 % by mass. PFC 1(A)(II): LIQUID ORGANIC FERTILISER

- 1. A liquid organic fertiliser shall be in liquid form.
- 2. A liquid organic fertiliser shall contain at least one of the following declared primary nutrients: nitrogen (N), phosphorus pentoxide (P_2O_5) or potassium oxide (K_2O).

Where a liquid organic fertiliser contains only one declared primary nutrient, that nutrient content shall be at least the following:

- (a) 2 % by mass of total nitrogen (N),
- (b) 1 % by mass of total phosphorus pentoxide (P_2O_5), or
- (c) 2% by mass of total potassium oxide (K₂O).

Where a liquid organic fertiliser contains more than one declared primary nutrient, those nutrient contents shall be at least the following:

- (a) 1 % by mass of total nitrogen (N),
- (b) 1 % by mass of total phosphorus pentoxide (P_2O_5) , or
- (c) 1 % by mass of total potassium oxide (K_2O).

The sum of those nutrient contents shall be at least 3 % by mass.

3. Organic carbon (C_{org}) content in a liquid organic fertiliser shall be at least 5 % by mass. PFC 1(B): ORGANO-MINERAL FERTILISER

- 1. An organo-mineral fertiliser shall be a co-formulation of:
- (a) one or more inorganic fertilisers, as specified in PFC 1(C), and
- (b) one or more materials containing:
 - organic carbon (C_{org}); and
 - nutrients

of solely biological origin.

An organo-mineral fertiliser may contain peat, leonardite and lignite, but no other material which is fossilized or embedded in geological formations.

- 2. Where one or more of the inorganic fertilisers in the co-formulation is a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content, as specified in PFC 1(C)(I)(a)(i-ii)(A), an organo-mineral fertiliser shall not contain 16 % or more by mass of nitrogen (N) as a result of ammonium nitrate (NH₄NO₃).
- 3. Contaminants in an organo-mineral fertiliser must not exceed the following limit values:
- (a) cadmium (Cd) : (i) where an organo-mineral fertiliser has a total phosphorus (P) content of less than 5 % phosphorus pentoxide (P_2O_5)-equivalent by mass: 3 mg/kg dry matter, or
 - (ii) where an organo-mineral fertiliser has a total phosphorus (P) content of 5 % phosphorus pentoxide (P_2O_5)-equivalent or more by mass ('phosphate fertiliser'): 60 mg/kg phosphorus pentoxide (P_2O_5);

(b)	hexavalent	:	2 mg/kg dry matter;
chromiu	ım (Cr VI)		
(c) merc	cury (Hg)	:	1 mg/kg dry matter;
(d) nick	el (Ni)	:	50 mg/kg dry matter;
(e) lead	(Pb)	:	120 mg/kg dry matter;
		:	40 mg/kg dry matter; and
arsenic	(As)		
(g)	biuret	:	12 g/kg dry matter.
(C_2H_5N)	$_{3}O_{2})$		

- 4. The copper (Cu) content in an organo-mineral fertiliser must not exceed 600 mg/kg dry matter, and the zinc (Zn) content in an organo-mineral fertiliser must not exceed 1 500 mg/kg dry matter. However, these limit values shall not apply where copper (Cu) or zinc (Zn) has been intentionally added to an organo-mineral fertiliser for the purpose of correcting a soil micronutrient deficiency and is declared in accordance with Annex III.
- 5. Pathogens in an organo-mineral fertiliser must not exceed the limits set out in the following table:

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

PFC 1(B)(I): SOLID ORGANO-MINERAL FERTILISER

- 1. A solid organo-mineral fertiliser shall be in solid form.
- 2. A solid organo-mineral fertiliser shall contain at least one of the following declared primary nutrients: nitrogen (N), phosphorus pentoxide (P_2O_5) or potassium oxide (K_2O).

Where a solid organo-mineral fertiliser contains only one declared primary nutrient, that nutrient content shall be at least the following:

- (a) 2,5% by mass of total nitrogen (N), out of which 1 % by mass shall be organic nitrogen (N_{org}),
- (b) 2% by mass of total phosphorus pentoxide (P₂O₅), or
- (c) 2% by mass of total potassium oxide (K₂O).

Where a solid organo-mineral fertiliser contains more than one declared primary nutrient, those nutrient contents shall be at least the following:

- (a) 2% by mass of total nitrogen (N), out of which 0,5% by mass shall be organic nitrogen (N_{org}),
- (b) 2 % by mass of total phosphorus pentoxide (P_2O_5), or
- (c) 2% by mass of total potassium oxide (K₂O).

The sum of those nutrient contents shall be at least 8 % by mass.

- 3. Organic carbon (C_{org}) content in a solid organo-mineral fertiliser shall be at least 7,5 % by mass.
- 4. In a solid organo-mineral fertiliser, each physical unit shall contain organic carbon (C_{org}) and all the nutrients in their declared content. A physical unit refers to one of the component pieces of a product, such as granules or pellets.

PFC 1(B)(II): LIQUID ORGANO-MINERAL FERTILISER

1. A liquid organo-mineral fertiliser shall be in liquid form.

2. A liquid organo-mineral fertiliser shall contain at least one of the following declared primary nutrients: nitrogen (N), phosphorus pentoxide (P_2O_5) or potassium oxide (K_2O).

Where a liquid organo-mineral fertiliser contains only one declared primary nutrient, that nutrient content shall be at least the following:

- (a) 2% by mass of total nitrogen (N), out of which 0,5 % by mass shall be organic nitrogen (N_{org}),
- (b) 2 % by mass of total phosphorus pentoxide (P_2O_5), or
- (c) 2% by mass of total potassium oxide (K₂O).

Where a liquid organo-mineral fertiliser contains more than one declared primary nutrient, those nutrient contents shall be at least the following:

- (a) 2% by mass of total nitrogen (N), out of which 0,5% by mass shall be organic nitrogen (N_{org}),
- (b) 2% by mass of total phosphorus pentoxide (P₂O₅), or
- (c) 2% by mass of total potassium oxide (K₂O).

The sum of those nutrient contents shall be at least 6 % by mass.

3. Organic carbon (C_{org}) content in a liquid organo-mineral fertiliser shall be at least 3 % by mass.

PFC 1(C): INORGANIC FERTILISER

- 1. An inorganic fertiliser shall be a fertiliser containing or releasing nutrients in a mineral form, other than an organic or organo-mineral fertiliser.
- 2. In addition to the requirements of either PFC 1(C)(I) or PFC 1(C)(II), an inorganic fertiliser which contains more than 1 % by mass of organic carbon (C_{org}), other than organic carbon (C_{org}) from:
- chelating or complexing agents referred to in point 3 of component material category (CMC) 1 in Part II of Annex II,
- nitrification inhibitors, denitrification inhibitors or urease inhibitors referred to in point 4 of CMC 1 in Part II of Annex II,
- coating agents referred to in point 1(a) of CMC 9 in Part II of Annex II,
- urea (CH_4N_2O), or
- calcium cyanamide (CaCN₂)

shall meet the requirement that pathogens in an inorganic fertiliser must not exceed the limits set out in the following table:

Micro-	Sampling plans	Limit		
organisms to be tested	n	c	m	М
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 c m M PFC 1(C)(I): INOF	 number of samples to be tested, number of samples where the number of bacteria expressed in CFU is between m and M, threshold value for the number of bacteria expressed in CFU that is considered satisfactory, maximum value of the number of bacteria expressed in CFU. RGANIC MACRONUTRIENT FERTILISER 				
		trient fertiliser shal e following macro		viding plants or mushrooms	
(a) primary r	nacronutrient	s: nitrogen (N), ph	osphorus (P) or p	ootassium (K),	
	b) secondary macronutrients: calcium (Ca), magnesium (Mg), sodium (Na) or sulphur (S).				
2. Contamin limit valu		organic macronutr	ient fertiliser mus	st not exceed the following	
(a) cadmium (Cd)	: (i)		ontent of less than	ent fertiliser has a total a 5 % phosphorus pentoxide kg dry matter, or	
 (b) hexavalent chromium (Cr VI) (c) mercury (Hg) (d) nickel (Ni) (e) lead (Pb) (f) arsenic (As) (g) biuret (C₂H₅N₃O₂) (h) perchlorate 	: 1 mg/kg : 100 mg/ : 120 mg/ : 40 mg/k	phosphorus (P) c equivalent or mor phosphorus pento dry matter, dry matter, kg dry matter, kg dry matter, g dry matter, dry matter,	ontent of 5 % pho re by mass ('phos	ent fertiliser has a total osphorus pentoxide (P ₂ O ₅)- phate fertiliser'): 60 mg/kg	
$(ClO_4-)^{1}$	J				

3. The copper (Cu) content in an inorganic macronutrient fertiliser must not exceed 600 mg/kg dry matter, and the zinc (Zn) content in an inorganic macronutrient fertiliser must not exceed 1 500 mg/kg dry matter. However, these limit values shall not apply where copper (Cu) or zinc (Zn) has been intentionally added to an inorganic macronutrient fertiliser for the purpose of correcting a soil micronutrient deficiency and is declared in accordance with Annex III.

PFC 1(C)(I)(a): SOLID INORGANIC MACRONUTRIENT FERTILISER

A solid inorganic macronutrient fertiliser shall be in solid form. PFC 1(C)(I)(a)(i): STRAIGHT SOLID INORGANIC MACRONUTRIENT FERTILISER

1. A straight solid inorganic macronutrient fertiliser shall have a declared content of:

- (a) only one macronutrient (nitrogen (N), phosphorus (P), potassium (K), calcium (Ca), magnesium (Mg), sodium (Na), sulphur (S)), or
- (b) only one primary macronutrient (nitrogen (N), phosphorus (P), potassium (K)) and one or more secondary macronutrients (calcium (Ca), magnesium (Mg), sodium (Na), sulphur (S)).
- 2. Where a straight solid inorganic macronutrient fertiliser contains only one declared macronutrient (nitrogen (N), phosphorus (P), potassium (K), calcium (Ca), magnesium (Mg), sodium (Na), sulphur (S)), that macronutrient content shall be at least the following:
- (a) 10 % by mass of total nitrogen (N),
- (b) 12 % by mass of total phosphorus pentoxide (P_2O_5) ,
- (c) 6% by mass of total potassium oxide (K₂O),
- (d) 5 % by mass of total magnesium oxide (MgO),
- (e) 12 % by mass of total calcium oxide (CaO),
- (f) 10 % by mass of total sulphur trioxide (SO₃), or
- (g) 1% by mass of total sodium oxide (Na₂O).

However, the total sodium oxide (Na₂O) content shall not exceed 40 % by mass.

Where a straight solid inorganic macronutrient fertiliser contains only one declared primary macronutrient (nitrogen (N), phosphorus (P), potassium (K)) and one or more declared secondary macronutrients (calcium (Ca), magnesium (Mg), sodium (Na), sulphur (S)):

- (a) that primary macronutrient content shall be at least the following:
 - (i) 3 % by mass of total nitrogen (N),
 - (ii) 3 % by mass of total phosphorus pentoxide (P_2O_5) , or
 - (iii) 3% by mass of total potassium oxide (K₂O);
- (b) that or those secondary macronutrient contents shall be at least the following:
 - (i) 1,5 % by mass of total magnesium oxide (MgO),
 - (ii) 1,5 % by mass of total calcium oxide (CaO),
 - (iii) 1,5 % by mass of total sulphur trioxide (SO₃), or
 - (iv) 1 % by mass of total sodium oxide (Na₂O).

However, the total sodium oxide (Na₂O) content shall not exceed 40 % by mass.

The sum of all declared primary and secondary macronutrient contents shall be at least 18 % by mass.

PFC 1(C)(I)(a)(ii): COMPOUND SOLID INORGANIC MACRONUTRIENT FERTILISER

- 1. A compound solid inorganic macronutrient fertiliser shall have a declared content of:
- (a) more than one primary macronutrient (nitrogen (N), phosphorus (P), potassium (K)), or

- (b) more than one secondary macronutrient (calcium (Ca), magnesium (Mg), sodium (Na), sulphur (S)) and no primary macronutrient (nitrogen (N), phosphorus (P), potassium (K)).
- 2. A compound solid inorganic macronutrient fertiliser shall contain more than one of the following declared macronutrients in at least the following contents:
- (a) 3 % by mass of total nitrogen (N),
- (b) 3% by mass of total phosphorus pentoxide (P₂O₅),
- (c) 3% by mass of total potassium oxide (K₂O),
- (d) 1,5 % by mass of total magnesium oxide (MgO),
- (e) 1,5 % by mass of total calcium oxide (CaO),
- (f) 1,5 % by mass of total sulphur trioxide (SO₃), or
- (g) 1% by mass of total sodium oxide (Na₂O).

However, the total sodium oxide (Na₂O) content shall not exceed 40 % by mass.

The sum of all declared macronutrient contents shall be at least 18 % by mass.

PFC 1(C)(I)(a)(i-ii)(A): STRAIGHT OR COMPOUND SOLID INORGANIC MACRONUTRIENT AMMONIUM NITRATE FERTILISER OF HIGH NITROGEN CONTENT

- 1. A straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content shall be ammonium nitrate (NH_4NO_3)-based and contain 28 % or more by mass of nitrogen (N) as a result of ammonium nitrate (NH_4NO_3).
- 2. Any matter other than ammonium nitrate (NH₄NO₃) shall be inert towards ammonium nitrate (NH₄NO₃).
- 3. A straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content shall be made available to the end-user only in packaged form. The package shall be closed in such a way or by such a device that, when it is opened, the fastening, the fastening seal or the package itself is irreparably damaged. Valve sacks may be used.
- 4. The oil retention of a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content, following two thermal cycles as described under point 4.1 in Module A1 in Part II of Annex IV, must not exceed 4 % by mass.
- 5. The detonation resistance of a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content shall be such, that:
- following five thermal cycles as described under point 4.3 in Module A1 in Part II of Annex IV,
- in two detonation resistance tests as described under point 4.4 in Module A1 in Part II of Annex IV,

one or more of the supporting lead cylinders is crushed by less than 5 %.

6. The % by mass of combustible material measured as carbon (C) must not exceed:

- 0,2 % for a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content having a nitrogen (N) content of at least 31,5 % by mass, and
- 0,4 % for a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content having a nitrogen (N) content of at least 28 % but less than 31,5 % by mass.
- 7. A solution of 10 g of a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content in 100 ml of water must have a pH of at least 4,5.
- 8. Not more than 5 % by mass shall pass through a 1 mm mesh sieve, and not more than 3 % by mass shall pass through a 0,5 mm mesh sieve.
- 9. The copper (Cu) content shall not be higher than 10 mg/kg, and the chlorine (Cl) content shall not be higher than 200 mg/kg.

PFC 1(C)(I)(b): LIQUID INORGANIC MACRONUTRIENT FERTILISER

A liquid inorganic macronutrient fertiliser shall be in liquid form. PFC 1(C)(I)(b)(i): STRAIGHT LIQUID INORGANIC MACRONUTRIENT FERTILISER

- 1. A straight liquid inorganic macronutrient fertiliser shall have a declared content of:
- (a) only one macronutrient (nitrogen (N), phosphorus (P), potassium (K), calcium (Ca), magnesium (Mg), sodium (Na), sulphur (S)), or
- (b) only one primary macronutrient (nitrogen (N), phosphorus (P), potassium (K)) and one or more secondary macronutrients (calcium (Ca), magnesium (Mg), sodium (Na), sulphur (S)).
- 2. Where a straight liquid inorganic macronutrient fertiliser contains only one declared macronutrient (nitrogen (N), phosphorus (P), potassium (K), calcium (Ca), magnesium (Mg), sodium (Na), sulphur (S)), that macronutrient content shall be at least the following:
- (a) 5 % by mass of total nitrogen (N),
- (b) 5 % by mass of total phosphorus pentoxide (P_2O_5),
- (c) 3% by mass of total potassium oxide (K₂O),
- (d) 2 % by mass of total magnesium oxide (MgO),
- (e) 6 % by mass of total calcium oxide (CaO),
- (f) 5% by mass of total sulphur trioxide (SO₃), or
- (g) 1 % by mass of total sodium oxide (Na_2O).

However, the total sodium oxide (Na₂O) content shall not exceed 40 % by mass.

Where a straight liquid inorganic macronutrient fertiliser contains only one declared primary macronutrient (nitrogen (N), phosphorus (P), potassium (K)), and one or more declared secondary macronutrients (calcium (Ca), magnesium (Mg), sodium (Na), sulphur (S)):

- (a) that primary macronutrient content shall be at least the following:
 - (i) 1,5 % by mass of total nitrogen (N),

- (ii) 1,5 % by mass of total phosphorus pentoxide (P₂O₅), or
- (iii) 1,5 % by mass of total potassium oxide (K₂O); and
- (b) that or those secondary macronutrient contents shall be at least the following:
 - (i) 0,75 % by mass of total magnesium oxide (MgO),
 - (ii) 0,75 % by mass of total calcium oxide (CaO),
 - (iii) 0,75 % by mass of total sulphur trioxide (SO₃), or
 - (iv) 0,5 % by mass of total sodium oxide (Na₂O).

However, the total sodium oxide (Na₂O) content shall not exceed 20 % by mass.

The sum of all declared primary and secondary macronutrient contents shall be at least 7 % by mass.

PFC 1(C)(I)(b)(ii): COMPOUND LIQUID INORGANIC MACRONUTRIENT FERTILISER

- 1. A compound liquid inorganic macronutrient fertiliser shall have a declared content of:
- (a) more than one primary macronutrient (nitrogen (N), phosphorus (P), potassium (K)), or
- (b) more than one secondary macronutrient (calcium (Ca), magnesium (Mg), sodium (Na), sulphur (S)), and no primary macronutrient (nitrogen (N), phosphorus (P), potassium (K)).
- 2. A compound liquid inorganic macronutrient fertiliser shall contain more than one of the following declared nutrients in at least the following contents:
- (a) 1,5 % by mass of total nitrogen (N),
- (b) 1,5 % by mass of total phosphorus pentoxide (P₂O₅),
- (c) 1,5 % by mass of total potassium oxide (K₂O),
- (d) 0,75 % by mass of total magnesium oxide (MgO),
- (e) 0,75 % by mass of total calcium oxide (CaO),
- (f) 0,75 % by mass of total sulphur trioxide (SO₃), or
- (g) 0,5 % by mass of total sodium oxide (Na₂O).

However, the total sodium oxide (Na₂O) content shall not exceed 20 % by mass.

The sum of all declared nutrient contents shall be at least 7 % by mass. PFC 1(C)(II): INORGANIC MICRONUTRIENT FERTILISER

- 1. An inorganic micronutrient fertiliser shall be an inorganic fertiliser other than an inorganic macronutrient fertiliser aimed at providing plants or mushrooms with one or more of the following micronutrients: boron (B), cobalt (Co), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo) or zinc (Zn).
- 2. Inorganic micronutrient fertilisers shall be made available to the end-user only in packaged form.

3. Contaminants in an inorganic micronutrient fertiliser must not exceed the following limit values:

2019/1009 of the European Parliament and of the Council. (See end of Document for details)

Contaminant	Limit values of contaminants expressed in mg, in relation to the total micronutrient content expressed in kg(mg/kg of total micronutrient content, which means boron (B), cobalt (Co), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo) and zinc (Zn))
Arsenic (As)	1 000
Cadmium (Cd)	200
Lead (Pb)	600
Mercury (Hg)	100
Nickel (Ni)	2 000

PFC 1(C)(II)(a): STRAIGHT INORGANIC MICRONUTRIENT FERTILISER

- 1. A straight inorganic micronutrient fertiliser shall have a declared content of not more than one micronutrient.
- 2. A straight inorganic micronutrient fertiliser shall belong to one of the typologies, and shall comply with the corresponding description and minimum micronutrient content requirements in the following table:

Typology	Description	Minimum micronutrient content
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 water- soluble micronutrient
Micronutrient oxide or hydroxide fertiliser	A chemically obtained straight solid inorganic micronutrient fertiliser containing oxide or hydroxide as its essential ingredient	10 % by mass of a micronutrient oxide or hydroxide fertiliser shall consist of a micronutrient
Micronutrient-based fertiliser	A straight inorganic micronutrient fertiliser combining a micronutrient salt fertiliser with one or more other micronutrient salt fertilisers and/or with a single micronutrient chelate	5 % by mass of a micronutrient-based fertiliser shall consist of a micronutrient
Micronutrient solution fertiliser	An aqueous solution of different forms of a straight	2 % by mass of a micronutrient solution
a UVCB: Substance of unknown or va	ariable composition, complex reaction produ	acts or biological materials.

	inorganic micronutrient fertiliser	fertiliser shall consist of a water-soluble micronutrient
Micronutrient suspension fertiliser	A suspension of different forms of a straight inorganic micronutrient fertiliser	2 % by mass of a micronutrient suspension fertiliser shall consist of a micronutrient
Micronutrient chelate fertiliser	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 a micronutrient chelate fertiliser shall consist of a water-soluble micronutrient, and at least 80 % of the water-soluble micronutrient shall be chelated by a chelating agent fulfilling the requirements of CMC 1 in Part II of Annex II
UVCB ^a iron chelates	A water-soluble straight inorganic micronutrient fertiliser in which the declared iron is chemically combined with chelating agent(s) fulfilling the requirements of CMC 1 in Part II of Annex II	 5 % by mass of UVCB iron chelates shall consist of water-soluble iron, and at least 80 % of the water-soluble iron shall be chelated and at least 50 % of the water soluble iron shall be chelated by a chelating agent fulfilling the requirements of CMC 1 in Part II of Annex II
Micronutrient complex fertiliser	A water-soluble straight inorganic micronutrient fertiliser in which the declared micronutrient is chemically combined with complexing agent(s) fulfilling the requirements of CMC 1 in Part II of Annex II	 5 % by mass of a micronutrient complex fertiliser shall consist of a water-soluble micronutrient, and at least 80 % of the water-soluble micronutrient shall be complexed by a complexing

a UVCB: Substance of unknown or variable composition, complex reaction products or biological materials.

		agent fulfilling the requirements of CMC 1 in Part II of Annex II
	1 .	

a UVCB: Substance of unknown or variable composition, complex reaction products or biological materials.

PFC 1(C)(II)(b): COMPOUND INORGANIC MICRONUTRIENT FERTILISER

- 1. A compound inorganic micronutrient fertiliser shall have a declared content of more than one micronutrient.
- 2. The sum of all declared micronutrient contents in a compound inorganic micronutrient fertiliser shall be at least:
- (a) 2 % by mass for fertilisers in liquid form;

(b) 5 % by mass for fertilisers in solid form.

PFC 2: LIMING MATERIAL

1. A liming material shall be an EU fertilising product the function of which is to correct soil acidity.

A liming material shall contain oxides, hydroxides, carbonates or silicates of the nutrients calcium (Ca) or magnesium (Mg).

2. Contaminants in a liming material must not exceed the following limit values:

(a) cadmium (Cd)		2 mg/kg dry matter,
(b) hexavalent	:	2 mg/kg dry matter,
chromium (Cr VI)		
(c) mercury (Hg)	:	1 mg/kg dry matter,
(d) nickel (Ni)	:	90 mg/kg dry matter,
(e) lead (Pb)	:	120 mg/kg dry matter,
(f) arsenic (As)	:	40 mg/kg dry matter.

- 3. The copper (Cu) content in a liming material must not exceed 300 mg/kg dry matter, and the zinc (Zn) content in a liming material must not exceed 800 mg/kg dry matter.
- 4. The following parameters determined on the basis of the mass of a liming material shall be met:
- (a) minimum neutralising value: 15 (equivalent CaO) or 9 (equivalent HO-),
- (b) minimum reactivity: 10 % (hydrochloric acid test) or 50 % after 6 months (incubation test), and
- (c) minimum grain size: at least 70 % < 1 mm, except for burnt limes, granulated liming material and chalk (at least 70 % of the liming material shall pass through a 1 mm sieve).

PFC 3: SOIL IMPROVER

A soil improver shall be an EU fertilising product the function of which is to maintain, improve or protect the physical or chemical properties, the structure or the biological activity of the soil to which it is added.

PFC 3(A): ORGANIC SOIL IMPROVER

1. An organic soil improver shall consist of material 95 % of which is of solely biological origin.

An organic soil improver may contain peat, leonardite and lignite, but no other material which is fossilized or embedded in geological formations.

2. Contaminants in an organic soil improver must not exceed the following limit values:

(a) cadmium (Cd)	:	2 mg/kg dry matter,
(b) hexavalent	:	2 mg/kg dry matter,
chromium (Cr VI)		
(c) mercury (Hg)	:	1 mg/kg dry matter,
(d) nickel (Ni)		50 mg/kg dry matter,
(e) lead (Pb)	:	120 mg/kg dry matter, and
(f) inorganic	:	40 mg/kg dry matter.
arsenic (As)		

- 3. The copper (Cu) content in an organic soil improver must not exceed 300 mg/kg dry matter, and the zinc (Zn) content in an organic soil improver must not exceed 800 mg/ kg dry matter.
- 4. Pathogens in an organic soil improver must not exceed the limits set out in the following table:

Micro-	Sampling plans			Limit
organisms to be tested	n	c	m	М
Salmonella spp.	5	0	0	Absence in 25 g or 25 ml
<i>Escherichia</i> <i>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,
М	= maximum value of the number of bacteria expressed in CFU.
5.	An organic soil improver shall contain 20 % or more dry matter.

6. Organic carbon (C_{org}) content in an organic soil improver shall be at least 7,5 % by mass.

PFC 3(B): INORGANIC SOIL IMPROVER

- 1. An inorganic soil improver shall be a soil improver other than an organic soil improver.
- 2. Contaminants in an inorganic soil improver must not exceed the following limit values:

(a) cadmium (Cd) : 1,5 mg/kg dry matter,

(b) hexav	alent :	2 mg/kg dry matter,
chromium (Cr	·VI)	
(c) mercury (H	Hg) :	1 mg/kg dry matter,
(d) nickel (Ni)		100 mg/kg dry matter,
(e) lead (Pb)		120 mg/kg dry matter,
(f) inorg	ganic :	40 mg/kg dry matter.
arsenic (As)	-	

3. The copper (Cu) content in an inorganic soil improver must not exceed 300 mg/kg dry matter, and the zinc (Zn) content in an inorganic soil improver must not exceed 800 mg/ kg dry matter.

PFC 4: GROWING MEDIUM

1. A growing medium shall be an EU fertilising product other than soil in situ, the function of which is for plants or mushrooms to grow in.

For the purpose of this point, plants include algae.

2. Contaminants in a growing medium must not exceed the following limit values:

(a) cadmium (Cd)	:	1,5 mg/kg dry matter,
(b) hexavalent	:	2 mg/kg dry matter,
chromium (Cr VI)		
(c) mercury (Hg)		1 mg/kg dry matter,
(d) nickel (Ni)	:	50 mg/kg dry matter,
(e) lead (Pb)	:	120 mg/kg dry matter, and
(f) inorganic	:	40 mg/kg dry matter.
arsenic (As)		

- 3. The copper (Cu) content in a growing medium must not exceed 200 mg/kg dry matter, and the zinc (Zn) content in a growing medium must not exceed 500 mg/kg dry matter.
- 4. Pathogens in a growing medium must not exceed the limits set out in the following table:

Micro-	Sampling pla	Limit		
organisms to be tested	n	c	m	М
Salmonella spp.	5	0	0	Absence in 25 g or 25 ml
<i>Escherichia</i> <i>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,
с	= 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,
М	= maximum value of the number of bacteria expressed in CFU.
PFC 5: INHIBITO	

An inhibitor shall be an EU fertilising product the function of which is to improve the nutrient release patterns of a product providing plants with nutrients by delaying or stopping the activity of specific groups of micro-organisms or enzymes. PFC 5(A): NITRIFICATION INHIBITOR

- 1. A nitrification inhibitor shall inhibit the biological oxidation of ammoniacal nitrogen (NH₃-N) to nitrite nitrogen (NO₂-), thus slowing the formation of nitrate nitrogen (NO₃-).
- 2. The ammoniacal nitrogen (NH₃-N) oxidation rate shall be measured by:
- (a) ammoniacal nitrogen (NH₃-N) disappearance, or
- (b) the sum of nitrite nitrogen (NO_2-) and nitrate nitrogen (NO_3-) production with respect to time.

Compared to a control sample where the nitrification inhibitor has not been added, a soil sample containing the nitrification inhibitor shall show a 20 % reduction in ammoniacal nitrogen (NH₃-N) oxidation rate based on an analysis carried out 14 days after application at the 95 % confidence level.

PFC 5(B): DENITRIFICATION INHIBITOR

- 1. A denitrification inhibitor shall inhibit the formation of nitrous oxide (N_2O) by slowing down or blocking the conversion of nitrate (NO_3-) to dinitrogen (N_2) without influencing the nitrification process as described in PFC 5(A).
- 2. Compared to a control sample where the denitrification inhibitor has not been added, an *in vitro* test containing the denitrification inhibitor shall show a 20 % reduction in rate of the release of nitrous oxide (N_2O) based on an analysis carried out 14 days after application at the 95 % confidence level.

PFC 5(C): **Û**REASE INHIBITOR

- 1. A urease inhibitor shall inhibit hydrolytic action on urea (CH₄N₂O) by the urease enzyme, primarily targeted to reduce ammonia volatilisation.
- 2. Compared to a control sample where the urease inhibitor has not been added, an *in vitro* test containing the urease inhibitor shall show a 20 % reduction in the rate of hydrolysis of urea (CH_4N_2O) based on an analysis carried out 14 days after application at the 95 % confidence level.

PFC 6: PLANT BIOSTIMULANT

- 1. A plant biostimulant shall be an EU fertilising product the function of which is to stimulate plant nutrition processes independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere:
- (a) nutrient use efficiency,
- (b) tolerance to abiotic stress,
- (c) quality traits, or
- (d) availability of confined nutrients in the soil or rhizosphere.
- 2. Contaminants in a plant biostimulant must not exceed the following limit values:

(a) cadmium (Cd) : 1,5 mg/kg dry matter,

(b) hexavalent	:	2 mg/kg dry matter,
chromium (Cr VI)		
(c) lead (Pb)	:	120 mg/kg dry matter,
(d) mercury (Hg)	:	1 mg/kg dry matter,
(e) nickel (Ni)	:	50 mg/kg dry matter, and
(f) inorganic	:	40 mg/kg dry matter.
arsenic (As)		

- 3. The copper (Cu) content in a plant biostimulant must not exceed 600 mg/kg dry matter, and the zinc (Zn) content in a plant biostimulant must not exceed 1 500 mg/kg dry matter.
- 4. The plant biostimulant shall have the effects that are claimed on the label for the plants specified thereon.

PFC 6(A): MICROBIAL PLANT BIOSTIMULANT

- 1. A microbial plant biostimulant shall consist of a micro-organism or a consortium of micro-organisms referred to in CMC 7 in Part II of Annex II.
- 2. Pathogens in a microbial plant biostimulant must not exceed the limits set out in the following table:

Micro-organisms/	Sampling plan	S	Limit
their toxins, metabolites	n	c	
Salmonella spp.	5	0	Absence in 25 g or 25 ml
Escherichia coli	5	0	Absence in 1 g or 1 ml
Listeria monocytogenes	5	0	Absence in 25 g or 25 ml
Vibrio spp.	5	0	Absence in 25 g or 25 ml
Shigella spp.	5	0	Absence in 25 g or 25 ml
Staphylococcus aureus	5	0	Absence in 25 g or 25 ml
Enterococcaceae	5	2	10 CFU/g
Anaerobic plate count unless the microbial plant biostimulant is an aerobic bacterium	5	2	10 ⁵ CFU/g or ml
Yeast and mould count unless the microbial plant biostimulant is a fungus	5	2	1 000 CFU/g or ml

Where:

- n = number of units comprising the sample,
 - = number of sample units giving values over the defined limit.
- 3. When the microbial plant biostimulant is in liquid form, the plant biostimulant shall have a pH optimal for contained micro-organisms and for plants.

PFC 6(B): NON-MICROBIAL PLANT BIOSTIMULANT

- 1. A non-microbial plant biostimulant shall be a plant biostimulant other than a microbial plant biostimulant.
- 2. Pathogens in a non-microbial plant biostimulant must not exceed the limits set out in the following table:

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

Where:

с

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,
М	= maximum value of the number of bacteria expressed in CFU.

PFC 7: FERTILISING PRODUCT BLEND

- 1. A fertilising product blend shall be an EU fertilising product composed of two or more EU fertilising products of PFC 1 to PFC 6 for which the compliance with the requirements of this Regulation of each component EU fertilising product in the blend has been demonstrated in accordance with the conformity assessment procedure applicable to that component EU fertilising product.
- 2. The blending shall not change the nature of each component EU fertilising product and shall not have an adverse effect on human, animal or plant health, on safety, or on the environment, under reasonably foreseeable conditions of storage or use of the fertilising product blend.
- 3. The manufacturer of the blend shall assess the conformity of the blend with the requirements set out in points 1 and 2 of this PFC, ensure the blend's compliance with the labelling requirements laid down in Annex III, and assume responsibility pursuant to Article 16(4) of this Regulation for the compliance of the blend with the requirements of this Regulation by:
- (a) drawing up an EU declaration of conformity for the fertilising product blend in accordance with Article 6(2) of this Regulation, and
- (b) being in possession of the EU declaration of conformity of each of the component EU fertilising products.

- 4. Economic operators making fertilising product blends available on the market shall respect the following provisions of this Regulation with regard to the EU declaration of conformity of each component EU fertilising product as well as of the blend:
- (a) Article 6(3) (manufacturers' obligation to keep the EU declaration of conformity);
- (b) point (a) of Article 7(2) (authorised representatives' obligation to keep the EU declaration of conformity);
- (c) Article 8(8) (importers' obligation to keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities).

ANNEX II

Component Material Categories (CMCs)

An EU fertilising product shall consist solely of component materials complying with the requirements for one or more of the CMCs listed in this Annex.

The component materials, and the input materials used to produce them, shall not contain any of the substances for which maximum limit values are indicated in Annex I in such quantities as to jeopardise the EU fertilising product's compliance with the applicable requirements of that Annex.

PART I

DESIGNATION OF CMCS

- CMC 1: Virgin material substances and mixtures
- CMC 2: Plants, plant parts or plant extracts

CMC 3: Compost

- CMC 4: Fresh crop digestate
- CMC 5: Digestate other than fresh crop digestate
- CMC 6: Food industry by-products
- CMC 7: Micro-organisms
- CMC 8: Nutrient polymers
- CMC 9: Polymers other than nutrient polymers
- CMC 10: Derived products within the meaning of Regulation (EC) No 1069/2009
- CMC 11: By-products within the meaning of Directive 2008/98/EC

PART II

REQUIREMENTS RELATED TO CMCS

This Part defines the component materials of which EU fertilising products shall solely consist. CMC 1: VIRGIN MATERIAL SUBSTANCES AND MIXTURES

- 1. An EU fertilising product may contain substances and mixtures, except⁽⁵⁾:
- (a) waste within the meaning of Directive 2008/98/EC,
- (b) 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,
- (c) 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,
- (d) by-products within the meaning of Directive 2008/98/EC,
- (e) animal by-products or derived products within the meaning of Regulation (EC) No 1069/2009,
- (f) polymers,
- (g) compost, or
- (h) digestate.
- 2. All substances incorporated into the EU fertilising product, on their own or in a mixture, shall have been registered pursuant to Regulation (EC) No 1907/2006⁽⁶⁾, 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.

- 3. Where the substance or one of the substances in the mixture is intended to enhance the long term availability to plants of micronutrients in the EU fertilising product, that substance shall be either a chelating agent or a complexing agent, and the following rules shall apply:
- (a) The chelating agent shall be an organic substance consisting in a molecule which:
 - (i) has two or more sites that donate electron pairs to a central transition metal cation (zinc (Zn), copper (Cu), iron (Fe), manganese (Mn), magnesium (Mg), calcium (Ca) or cobalt (Co)), and
 - (ii) is large enough to form a five- or six- membered cyclic structure.

The EU fertilising product shall remain stable in standard Hoagland solution at pH 7 and 8 for at least 3 days.

(b) The complexing agent shall be an organic substance forming a flat or steric structure with one di- or tri- valent transition metal cation (zinc (Zn), copper (Cu), iron (Fe), manganese (Mn) or cobalt (Co)).

The EU fertilising product shall remain stable in water solution at pH 6 and 7 for at least 1 day.

- 4. Where the substance or one of the substances in the mixture is intended to improve the EU fertilising product's nutrient release patterns by delaying or stopping the activity of specific groups of micro-organisms or enzymes, that substance shall be an a nitrification inhibitor, a denitrification inhibitor or a urease inhibitor, and the following rules shall apply:
- (a) The nitrification inhibitor shall inhibit the biological oxidation of ammoniacal nitrogen (NH₃-N) to nitrite nitrogen (NO₂-), thus slowing the formation of nitrate nitrogen (NO₃-).

The ammoniacal nitrogen (NH₃-N) oxidation rate shall be measured either by:

- (i) ammoniacal nitrogen (NH₃-N) disappearance, or
- (ii) the sum of nitrite nitrogen (NO_2-) and nitrate nitrogen (NO_3-) production with respect to time.

Compared to a control sample where the nitrification inhibitor has not been added, a soil sample containing the nitrification inhibitor shall show a 20 % reduction in ammoniacal nitrogen (NH_3 -N) oxidation rate based on an analysis carried out 14 days after application at the 95 % confidence level.

At least 50 % of the total nitrogen (N) content of the EU fertilising product shall consist of the nitrogen (N) forms ammonium (NH_4^+) and urea (CH_4N_2O).

(b) The denitrification inhibitor shall inhibit the formation of nitrous oxide (N_2O) by slowing down or blocking the conversion of nitrate (NO_3-) to dinitrogen (N_2) without influencing the nitrification process as described in PFC 5(A).

Compared to a control sample where the denitrification inhibitor has not been added, an *in vitro* test containing the denitrification inhibitor shall show a 20 % reduction in rate of the release of nitrous oxide (N₂O) based on an analysis carried out 14 days after application at the 95 % confidence level.

(c) The urease inhibitor shall inhibit hydrolytic action on urea (CH_4N_2O) by the urease enzyme, primarily targeted to reduce ammonia volatilisation. Compared to a control sample where the urease inhibitor has not been added, an *in vitro* test containing the urease inhibitor shall show a 20% reduction in the rate of hydrolysis of urea (CH_4N_2O) based on an analysis carried out 14 days after application at the 95% confidence level.

At least 50 % of the total nitrogen (N) content of the EU fertilising product shall consist of the nitrogen (N) form urea (CH_4N_2O).

CMC 2: PLANTS, PLANT PARTS OR PLANT EXTRACTS

An EU fertilising product may contain plants, plant parts or plant extracts having undergone no other processing than cutting, grinding, milling, sieving, sifting, centrifugation, pressing, drying, frost treatment, freeze-drying or extraction with water or supercritical CO_2 extraction.

For the purpose of this point, plants include mushrooms and algae and exclude blue-green algae (cyanobacteria).

CMC 3: COMPOST

- 1. An EU fertilising product may contain compost obtained through aerobic composting of exclusively one or more of the following input materials:
- (a) bio-waste within the meaning of Directive 2008/98/EC resulting from separate biowaste collection at source;
- (b) derived products referred to in Article 32 of Regulation (EC) No 1069/2009 for which the end point in the manufacturing chain has been 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:
 - -- the organic fraction of mixed municipal household waste separated through mechanical, physicochemical, biological and/or manual treatment,
 - sewage sludge, industrial sludge or dredging sludge, and
 - animal by-products or derived products falling 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;
- (d) composting additives which are necessary to improve the process performance or the environmental performance of the composting process provided that:
 - (i) the additive is registered pursuant to Regulation (EC) No 1907/2006⁽⁷⁾, with a dossier containing:
 - the information provided for by Annexes VI, VII and VIII to 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 point 6, 7, 8 or 9 of Annex V to that Regulation, and

- (ii) the total concentration of all additives does not exceed 5 % of the total input material weight; or
- (e) any material listed in points (a), (b) or (c) which:
 - (i) has previously been composted or digested, and
 - (ii) contains no more than 6 mg/kg dry matter of $PAH_{16}^{(8)}$.
- 2. The composting shall take place in a plant:
- (a) in which production lines for the processing of input materials referred to in point 1 are clearly separated from production lines for the processing of input materials other than those referred to in point 1, and

- (b) where physical contacts between input and output materials are avoided, including during storage.
- 3. The aerobic composting shall consist of controlled decomposition of biodegradable materials, which is predominantly aerobic and which allows the development of temperatures suitable for thermophilic bacteria as a result of biologically produced heat. All parts of each batch shall be either regularly and thoroughly moved and turned or subject to forced ventilation in order to ensure the correct sanitation and homogeneity of the material. During the composting process, all parts of each batch shall have one of the following temperature-time profiles:
- 70 °C or more for at least 3 days,
- 65 °C or more for at least 5 days,
- 60 °C or more for at least 7 days, or
- 55 °C or more for at least 14 days.
- 4. The compost shall contain:
- (a) no more than 6 mg/kg dry matter of $PAH_{16}^{(9)}$;
- (b) no more than 3 g/kg dry matter of macroscopic impurities above 2 mm in any of the following forms: glass, metal or plastics; and
- (c) no more than 5 g/kg dry matter of the sum of the macroscopic impurities referred to in point (b).

From 16 July 2026, the presence of plastics above 2 mm within the maximum limit value referred to in point (b) shall be no more than 2,5 g/kg dry matter. By 16 July 2029 the limit-value of 2,5 g/kg dry matter for plastics above 2 mm shall be re-assessed in order to take into account the progress made with regards to separate collection of bio-waste.

- 5. The compost shall meet at least one of the following stability criteria:
- (a) Oxygen uptake rate:
 - Definition: an indicator of the extent to which biodegradable organic matter is being broken down within a specified time period. The method is not suitable for material with a content of particle sizes > 10 mm that exceeds 20%,
 - Criterion: maximum 25 mmol O_2 /kg organic matter/h; or
- (b) Self heating factor:
 - Definition: the maximum temperature reached by a compost in standardised conditions as an indicator of the state of its aerobic biological activity,
 - Criterion: minimum Rottegrad III.

CMC 4: FRESH CROP DIGESTATE

- 1. An EU fertilising product may contain digestate obtained through anaerobic digestion of exclusively one or more of the following input materials:
- (a) plants or plant parts grown for the production of biogas. For the purpose of this point, plants include algae and exclude blue-green algae (cyanobacteria);
- (b) digestion additives which are needed to improve the process performance or the environmental performance of the digestion process provided that:

- (i) the additive is registered pursuant to Regulation (EC) No 1907/2006⁽¹⁰⁾, with a dossier containing:
 - the information provided for by Annexes VI, VII and VIII to 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 point 6, 7, 8 or 9 of Annex V to that Regulation, and

- (ii) the total concentration of all additives does not exceed 5 % of the total input material weight; or
- (c) any material referred to in point (a) that has previously been digested.
- 2. The anaerobic digestion shall take place in a plant:
- (a) in which production lines for the processing of input materials referred to in point 1 are clearly separated from production lines for the processing of input materials other than those referred to in point 1, and
- (b) where physical contacts between input and output materials are avoided, including during storage.
- 3. The anaerobic digestion shall consist of controlled decomposition of biodegradable materials, which is predominantly anaerobic and at temperatures suitable for mesophilic or thermophilic bacteria. All parts of each batch shall be regularly and thoroughly moved and turned in order to ensure the correct sanitation and homogeneity of the material. During the digestion process, all parts of each batch shall have one of the following temperature-time profiles:
- (a) thermophilic anaerobic digestion at 55 °C for at least 24 hours followed by a hydraulic retention time of at least 20 days;
- (b) thermophilic anaerobic digestion at 55 °C with a treatment process including pasteurisation as described in point 1 of Section 1 of Chapter I of Annex V to Commission Regulation (EU) No 142/2011⁽¹¹⁾;
- (c) thermophilic anaerobic digestion at 55 °C followed by composting in:
 - 70 °C or more for at least 3 days,
 - 65 °C or more for at least 5 days,
 - 60 °C or more for at least 7 days, or
 - 55 °C or more for at least 14 days;
- (d) mesophilic anaerobic digestion at 37-40 °C with a treatment process including pasteurisation as described in point 1 of Section 1 of Chapter I of Annex V to Regulation (EU) No 142/2011; or
- (e) mesophilic anaerobic digestion at 37-40 °C followed by composting in:
 - 70 °C or more for at least 3 days,
 - 65 °C or more for at least 5 days,
 - 60 °C or more for at least 7 days, or
 - 55 °C or more for at least 14 days.

- 4. Both the solid and the liquid part of the digestate shall meet at least one of the following stability criteria:
- (a) Oxygen uptake rate:
 - Definition: an indicator of the extent to which biodegradable organic matter is being broken down within a specified time period. The method is not suitable for material with a content of particle sizes > 10 mm that exceeds 20 %;
 - Criterion: maximum 25 mmol O₂/kg organic matter/h; or
- (b) Residual biogas potential:
 - Definition: an indicator of the gas released from a digestate in a 28 day period and measured against the volatile solids contained within the sample. The test is run in triplicate, and the average result is used to demonstrate compliance with the criterion. The volatile solids are those solids in a sample of material that are lost on ignition of the dry solids at 550 °C;
- Criterion: maximum 0,25 l biogas/g volatile solids.
- CMC 5: DIGESTATE OTHER THAN FRESH CROP DIGESTATE
- 1. An EU fertilising product may contain digestate obtained through anaerobic digestion of exclusively one or more of the following input materials:
- (a) bio-waste within the meaning of Directive 2008/98/EC resulting from separate biowaste collection at source;
- (b) derived products referred to in Article 32 of Regulation (EC) No 1069/2009 for which the end point in the manufacturing chain has been 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:
 - (i) the organic fraction of mixed municipal household waste separated through mechanical, physicochemical, biological and/or manual treatment,
 - (ii) sewage sludge, industrial sludge or dredging sludge,
 - (iii) animal by-products or derived products falling 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;
- (d) digestion additives which are necessary to improve the process performance or the environmental performance of the digestion process provided that:
 - (i) the additive is registered pursuant to Regulation (EC) No 1907/2006⁽¹²⁾, with a dossier containing:
 - the information provided for by Annexes VI, VII and VIII to 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 point 6, 7, 8 or 9 of Annex V to that Regulation, and

- (ii) the total concentration of all additives does not exceed 5 % of the total input material weight; or
- (e) any material listed in points (a), (b) or (c) which:
 - (i) has previously been composted or digested, and
 - (ii) contains no more than 6 mg/kg dry matter of $PAH_{16}^{(13)}$.
- 2. The anaerobic digestion shall take place in a plant:
- (a) in which production lines for the processing of input materials referred to in point 1 are clearly separated from production lines for the processing of input materials other than those referred to in point 1, and
- (b) where physical contacts between input and output materials are avoided, including during storage.
- 3. The anaerobic digestion shall consist of controlled decomposition of biodegradable materials, which is predominantly anaerobic and at temperatures suitable for mesophilic or thermophilic bacteria. All parts of each batch shall be regularly and thoroughly moved and turned in order to ensure the correct sanitation and homogeneity of the material. During the digestion process, all parts of each batch shall have one of the following temperature-time profiles:
- (a) thermophilic anaerobic digestion at 55 °C for at least 24 hours followed by a hydraulic retention time of at least 20 days;
- (b) thermophilic anaerobic digestion at 55 °C with a treatment process including pasteurisation as described in point 1 of Section 1 of Chapter I of Annex V to Regulation (EU) No 142/2011;
- (c) thermophilic anaerobic digestion at 55 °C followed by composting in:
 - 70 °C or more for at least 3 days,
 - 65 °C or more for at least 5 days,
 - 60 °C or more for at least 7 days, or
 - 55 °C or more for at least 14 days;
- (d) mesophilic anaerobic digestion at 37-40 °C with a treatment process including pasteurisation as described in point 1 of Section 1 of Chapter I of Annex V to Regulation (EU) No 142/2011; or
- (e) mesophilic anaerobic digestion at 37-40 °C followed by composting in:
 - 70 °C or more for at least 3 days,
 - 65 °C or more for at least 5 days,
 - 60 °C or more for at least 7 days, or
 - 55 °C or more for at least 14 days.
- 4. Neither the solid nor the liquid part of the digestate shall contain more than 6 mg/kg dry matter of $PAH_{16}^{(14)}$.

- 5. The digestate shall contain:
- (a) no more than 3 g/kg dry matter of macroscopic impurities above 2 mm in any of the following forms: glass, metal or plastics; and
- (b) no more than 5 g/kg dry matter of the sum of the macroscopic impurities referred to in point (a).

From 16 July 2026, the presence of plastics above 2 mm within the maximum limit value referred to in point (a) shall be no more than 2,5 g/kg dry matter. By 16 July 2029 the limit-value of 2,5 g/kg dry matter for plastics above 2 mm shall be re-assessed in order to take into account the progress made with regards to separate collection of bio-waste.

- 6. Both the solid and the liquid part of the digestate shall meet at least one of the following stability criteria:
- (a) Oxygen uptake rate:
 - Definition: an indicator of the extent to which biodegradable organic matter is being broken down within a specified time period. The method is not suitable for material with a content of particle sizes > 10 mm that exceeds 20 %.
 - Criterion: maximum 25 mmol O₂/kg organic matter/h; or
- (b) Residual biogas potential:
 - Definition: an indicator of the gas released from a digestate in a 28 day period and measured against the volatile solids contained within the sample. The test is run in triplicate, and the average result is used to demonstrate compliance with the criterion. The volatile solids are those solids in a sample of material that are lost on ignition of the dry solids at 550 °C.
 - Criterion: maximum 0,25 l biogas/g volatile solids.
- CMC 6: FOOD INDUSTRY BY-PRODUCTS
- 1. An EU fertilising product may contain component material consisting of one of the following substances:
- (a) food industry factory lime, i.e. a material from the food processing industry obtained by carbonation of organic matter, using exclusively burnt lime from natural sources;
- (b) molasses, i.e. a viscous by-product of the refining of sugarcane or sugar beets into sugar;
- (c) vinasse, i.e. a viscous by-product of the fermentation process of molasses into ethanol, ascorbic acid or other products;
- (d) distillers grains, i.e. by-products resulting from the production of alcoholic beverages;
- (e) plants, plant parts or plant extracts having undergone only heat treatment or heat treatment in addition to processing methods referred to in CMC 2; or
- (f) lime from drinking water production, i.e. residue which is released by production of drinking water from groundwater or surface water and consists, mainly, of calcium carbonate.
- 2. All substances incorporated into the EU fertilising product, on their own or in a mixture, shall have been registered pursuant to Regulation (EC) No 1907/2006⁽¹⁵⁾, 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 point 6, 7, 8, or 9 of Annex V to that Regulation.

CMC 7: MICRO-ORGANISMS

An EU fertilising product belonging to PFC 6(A) may contain micro-organisms, including dead or empty-cell micro-organisms and non-harmful residual elements of the media on which they were produced, which:

- have undergone no other processing than drying or freeze-drying; and
- are listed in the following table:

Azotobacter spp.		
Mycorrhizal fungi		
Rhizobium spp.		
Azospirillum spp.		

CMC 8: NUTRIENT POLYMERS

- 1. An EU fertilising product may contain polymers exclusively made up of monomer substances complying with the criteria set out in points 1 and 2 of CMC 1, where the purpose of the polymerisation is to control the release of nutrients from one or more of the monomer substances.
- 2. At least 60 % of the polymers shall be soluble in a phosphate buffer solution with a pH of 7,5 at 100 °C.
- 3. The final degradation products shall be only ammonia (NH_3) , water and carbon dioxide (CO_2) .

4. The polymers shall not contain more than 600 ppm of free formaldehyde. CMC 9: POLYMERS OTHER THAN NUTRIENT POLYMERS

- 1. An EU fertilising product may contain polymers other than nutrient polymers only in cases where the purpose of the polymer is:
- (a) to control the water penetration into nutrient particles and thus the release of nutrients (in which case the polymer is commonly referred to as a 'coating agent'),
- (b) to increase the water retention capacity or wettability of the EU fertilising product, or
- (c) to bind material in an EU fertilising product belonging to PFC 4.
- 2. From 16 July 2026, the polymers referred to in point 1(a) and (b) shall comply with the biodegradability criteria established by delegated acts referred to in Article 42(6). In the absence of such criteria, an EU fertilising product placed on the market after that date shall not contain such polymers.
- 3. For the polymers referred to in point 1(a) and (b), neither the polymer, nor its degradation by-products, shall show any overall adverse effect on animal or plant

health, or on the environment, under reasonably foreseeable conditions of use in the EU fertilising product. The polymer shall pass a plant growth acute toxicity test, an earthworm acute toxicity test and a nitrification inhibition test with soil micro-organisms as follows:

(a) In the plant growth acute toxicity test, the germination rate and the plant biomass of the tested plant species grown on the soil exposed to the test material shall be more than 90 % of the germination rate and the plant biomass of the same plant species grown on corresponding blank soil not exposed to the test material.

The results shall be considered to be valid only if in the controls (i.e. blank soil):

- the seedling emergence is at least 70 %;
- the seedlings do not exhibit visible phytotoxic effects (e.g. chlorosis, necrosis, wilting, leaf and stem deformations) and the plants exhibit only normal variation in growth and morphology for that particular species;
- the mean survival of emerged control seedlings is at least 90 % for the duration of the study; and
- environmental conditions for a particular species are identical and growing media contain the same amount of soil matrix, support media, or substrate from the same source.
- (b) In the earthworm acute toxicity test, the observed mortality and the biomass of surviving earthworms in a soil exposed to the test material shall not differ by more than 10 % compared to those from the corresponding blank soil not exposed to the test material. The results shall be considered to be valid, if:
 - the percent mortality observed in the control (i.e. blank soil) is less than 10 %, and
 - the average loss of biomass (mean weight) of the worms in the blank soil does not exceed 20 %.
- (c) In the nitrification inhibition test with soil micro-organisms, the nitrite formation in soil exposed to the test material shall be more than 90 % of those from the corresponding blank soil not exposed to the test material. The results shall be considered to be valid, if the variation between replicate control samples (blank soil) and test samples is less than 20 %.

CMC 10: DERIVED PRODUCTS WITHIN THE MEANING OF REGULATION (EC) NO 1069/2009

An EU fertilising product may contain derived products within the meaning of Regulation (EC) No 1069/2009 having reached the end point in the manufacturing chain as determined in accordance with that Regulation, and which are listed in the following table and as specified therein⁽¹⁶⁾:

CMC 11: BY-PRODUCTS WITHIN THE MEANING OF DIRECTIVE 2008/98/EC

- 1. An EU fertilising product may contain by-products within the meaning of Directive 2008/98/EC, except⁽¹⁷⁾:
- (a) animal by-products or derived products within the meaning of Regulation (EC) No 1069/2009,
- (b) polymers,
- (c) compost, or
- (d) digestate.

- 2. The by-products 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 point 6, 7, 8 or 9 of Annex V to that Regulation.

3. From 16 July 2022, the by-products shall comply with the criteria established by delegated act referred to in Article 42(7). An EU fertilising product placed on the market after that date shall not contain by-products referred to in point 1 which do not comply with such criteria.

ANNEX III

Labelling requirements

This Annex sets out the labelling requirements for EU fertilising products. The requirements laid down in Part II and Part III of this Annex for a given PFC, as specified in Annex I, apply to EU fertilising products in all subcategories of that PFC.

PART I

GENERAL LABELLING REQUIREMENTS

- 1. The following information shall be provided:
- (a) for EU fertilising products in PFC 1 to PFC 6, the designation as indicated in Part I of Annex I of the PFC corresponding to the product's claimed function;
- (b) for EU fertilising products in PFC 7, the designations as indicated in Part I of Annex I of all the PFCs corresponding to the claimed functions of the component EU fertilising products;
- (c) the quantity of the EU fertilising product, indicated by mass or volume;
- (d) instructions for intended use, including application rates, timing and frequency, and target plants or mushrooms;
- (e) recommended storage conditions;
- (f) for products containing a polymer belonging to CMC 9 in Part II of Annex II, the time period following use during which the nutrient release is being controlled or the water retention capacity is being increased (the 'functionality period'), which shall not be longer than the period between two applications in accordance with the use instructions referred to in point (d);

- (g) any relevant information on measures recommended to manage risks to human, animal or plant health, to safety or to the environment; and
- (h) a list of all ingredients above 5 % by product weight in descending order of magnitude by dry weight, 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 as specified in Article 18 of Regulation (EC) No 1272/2008.
- 2. Where the EU fertilising product has functions described in two or more of the PFCs laid down in Annex I, only those functions for which the EU fertilising product has been subject to a successful conformity assessment in accordance with this Regulation may be claimed by using the corresponding PFC designations as indicated in Part I of Annex I.
- 3. Where the EU fertilising product contains a substance for which maximum residue limits for food and feed have been established in accordance with Regulation (EEC) No 315/93, Regulation (EC) No 396/2005, Regulation (EC) No 470/2009 or Directive 2002/32/EC, the instructions referred to in point 1(d) shall ensure that the intended use of the EU fertilising product does not lead to the exceedance of those limits in food or feed.
- 4. Where the EU fertilising product contains derived products within the meaning of Regulation (EC) No 1069/2009 other than manure, the following instruction shall be provided on the label: 'Farmed animals shall not be fed, either directly or by grazing, with herbage from land to which the product has been applied unless the cutting or grazing takes place after the expiry of a waiting period of at least 21 days.'.
- 5. Where the EU fertilising product contains ricin, the following instruction shall be provided on the label: 'Hazardous to animals in case of ingestion'.
- 6. Where the EU fertilising product contains unprocessed or processed cocoa shells, the following instruction shall be provided on the label: 'Toxic to dogs and cats'.
- 7. Where the EU fertilising product 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, make sure of a sound disposal of the products after end of use.
- 8. Information other than the information required under points 1 to 6:
- (a) shall not mislead the user, for example by attributing to the product properties that it does not possess, or by suggesting that the product possesses unique characteristics which similar products also have;
- (b) shall relate to verifiable factors;
- (c) shall not make claims such as 'sustainable' or 'environmentally friendly' unless such claims refer to legislation, or clearly identified guidelines, standards or schemes, with which the EU fertilising product complies; and
- (d) shall not make claims by means of statements or visual representations that the EU fertilising product prevents or treats plant diseases or protects plants against harmful organisms.
- 9. The phrase 'poor in chloride' or similar may only be used if the chloride (Cl-) content is below 30 g/kg of dry matter.

10. Where the nutrient content information requirements in this Annex are expressed in oxidised form, the nutrient content may be expressed in elemental form instead or in addition to the oxidised form in accordance with the following conversion factors:

phosphorus (P)	= phosphorus pentoxide $(P_2O_5) \times 0.436$	5;
potassium (K)	= potassium oxide (K_2O) × 0,830;	
calcium (Ca)	= calcium oxide (CaO) \times 0,715;	
magnesium (Mg)	= magnesium oxide (MgO) \times 0,603;	
sodium (Na)	= sodium oxide (Na ₂ O) \times 0,742;	
sulphur (S)	= sulphur trioxide $(SO_3) \times 0,400$.	

11. Where the information requirements in this Annex refer to organic carbon (C_{org}), the information may refer to organic matter instead of or in addition to organic carbon (C_{org}), in accordance with the following conversion factor: organic carbon (C_{org}) = organic matter × 0,56.

PART II

PRODUCT-SPECIFIC LABELLING REQUIREMENTS

PFC 1: FERTILISER

- 1. The content of nutrients may be declared only where they are present in the EU fertilising product in the minimum quantity specified in Annex I for the relevant PFC.
- 2. If nitrogen (N) or phosphorus (P) are not declared nutrients, the content of nitrogen (N) or phosphorus pentoxide (P_2O_5) shall nevertheless be indicated if above 0,5 % by mass. That indication shall be separate from the nutrient declaration.
- 3. The following rules apply to fertilisers containing inhibitors, as specified in CMC 1 in Part II of Annex II:
- (a) the label shall state the words 'nitrification inhibitor', 'denitrification inhibitor' or 'urease inhibitor', as relevant;
- (b) the nitrification inhibitor content shall be expressed as a % by mass of the total nitrogen (N) present as ammonium nitrogen (NH_4^+) and urea nitrogen (CH_4N_2O);
- (c) the denitrification inhibitor content shall be expressed as a % by mass of the nitrate (NO₃-) present;
- (d) the urease inhibitor content shall be expressed as a % by mass of the total nitrogen (N) present as urea nitrogen (CH_4N_2O).
- 4. The term 'mineral fertiliser' may be used only if the fertiliser belongs to PFC 1(C) and fulfils the following additional conditions:
- (a) the mineral fertiliser must not contain more than 1 % by mass of organic carbon (C_{org}), other than organic carbon from:
 - (i) chelating or complexing agents referred to in point 3 of CMC 1 in Part II of Annex II,

- (ii) nitrification inhibitors, denitrification inhibitors or urease inhibitors referred to in point 4 of CMC 1 in Part II of Annex II,
- (iii) coating agents referred to in point 1(a) of CMC 9 in Part II of Annex II,
- (iv) urea (CH_4N_2O), or
- (v) calcium cyanamide (CaCN₂);
- (b) where phosphorus (P) is a declared nutrient, the declared phosphorus content shall consist only of phosphorus in the phosphatic form, and the mineral fertiliser shall fulfil at least one of the following solubility criteria:
 - (i) water solubility: minimum level 40 % of total phosphorus (P),
 - (ii) solubility in neutral ammonium citrate: minimum level 75 % of total phosphorus (P), or
 - (iii) solubility in formic acid (only for soft rock phosphate): minimum level 55 % of total phosphorus (P);
- (c) where nitrogen (N) is a declared nutrient, the declared nitrogen content shall consist only of the sum of nitric nitrogen, ammoniacal nitrogen, ureic nitrogen, and nitrogen from methylene-urea, from isobutylidenediurea, and from crotonylidenediurea.

PFC 1(A): ORGANIC FERTILISER

The following information shall be provided:

- (a) the declared primary nutrients nitrogen (N), phosphorus (P) or potassium (K), by their chemical symbols in the order N-P-K;
- (b) the declared secondary nutrients calcium (Ca), magnesium (Mg), sodium (Na), or sulphur (S) by their chemical symbols in the order Ca-Mg-Na-S;
- (c) numbers indicating the content of the declared nutrients total nitrogen (N), total phosphorus in the form of phosphorus pentoxide (P_2O_5) or total potassium in the form of potassium oxide (K_2O), followed by numbers in brackets indicating the total content of calcium oxide (CaO), magnesium oxide (MgO), sodium oxide (Na₂O) or sulphur trioxide (SO₃);
- (d) the content of the following declared nutrients and other parameters, in the following order and as % by mass:
 - (i) nitrogen (N):
 - total nitrogen (N);
 - minimum amount of organic nitrogen (N_{org}), followed by a description of the origin of the organic matter used;
 - nitrogen in the form of ammoniacal nitrogen;
 - (ii) total phosphorus pentoxide (P_2O_5) ;
 - (iii) total potassium oxide (K_2O);
 - (iv) calcium oxide (CaO), magnesium oxide (MgO), sodium oxide (Na₂O) and sulphur trioxide (SO₃), expressed:

- where those nutrients are totally soluble in water, only as the content soluble in water;
- where the soluble content of those nutrients is at least a quarter of the total content of those nutrients, as the total content and as the content soluble in water;
- in other cases, as the total content;
- (v) organic carbon (C_{org});
- (vi) dry matter;
- (e) the ratio of organic carbon to total nitrogen (C_{org}/N) ;
- (f) production date;

(g) the form of the physical unit of the product, such as powder or pellets, if applicable. PFC 1(B): ORGANO-MINERAL FERTILISER

- 1. The following information shall be provided:
- (a) the declared primary nutrients nitrogen (N), phosphorus (P) or potassium (K), by their chemical symbols in the order N-P-K;
- (b) where applicable, the declared secondary nutrients calcium (Ca), magnesium (Mg), sodium (Na) or sulphur (S) by their chemical symbols in the order Ca-Mg-Na-S;
- (c) numbers indicating the content of the declared nutrients total nitrogen (N), total phosphorus in the form of phosphorus pentoxide (P₂O₅) or total potassium in the form of potassium oxide (K₂O), followed by numbers in brackets indicating the total content of calcium oxide (CaO), magnesium oxide (MgO), sodium oxide (Na₂O) or sulphur trioxide (SO₃);
- (d) the content of the following declared nutrients and other parameters, in the following order and as % by mass:
 - (i) nitrogen (N):
 - total nitrogen (N);
 - minimum amount of organic nitrogen (N_{org}), followed by a description of the origin of the organic matter used;
 - nitrogen in the form of nitric nitrogen;
 - nitrogen in the form of ammoniacal nitrogen;
 - nitrogen in the form of urea nitrogen;
 - (ii) phosphorus pentoxide (P_2O_5):
 - total phosphorus pentoxide (P_2O_5);
 - water-soluble phosphorus pentoxide (P_2O_5);
 - phosphorus pentoxide (P_2O_5) soluble in neutral ammonium citrate;
 - where soft ground phosphate is present, phosphorus pentoxide (P_2O_5) soluble in formic acid;
 - (iii) potassium oxide (K_2O):
 - total potassium oxide (K₂O);
 - water soluble potassium oxide (K_2O);

- (iv) calcium oxide (CaO), magnesium oxide (MgO), sodium oxide (Na₂O) and sulphur trioxide (SO₃), expressed:
 - where those nutrients are totally soluble in water, only as the content soluble in water;
 - where the soluble content of those nutrients is at least a quarter of the total content of those nutrients, as the total content and as the content soluble in water;
 - in other cases, as the total content;
- (v) organic carbon (C_{org});
- (vi) dry matter,
- (e) where urea (CH_4N_2O) is present, information about the possible air quality impacts of the release of ammonia from the fertiliser use, and an invitation to users to apply appropriate remediation measures.
- 2. Where one or more of the micronutrients boron (B), cobalt (Co), iron (Fe), manganese (Mn) and molybdenum (Mo) are present in the minimum content indicated as % by mass in the following table, they:
- shall be declared if they are intentionally added to an organo-mineral fertiliser, and
 may be declared in other cases:

Micronutrient	Content of micronutrient (% by mass)			
	Solid organo-mine	Liquid organo-		
	Intended for use on crops or grassland	Intended for horticultural use	mineral fertiliser	
Boron (B)	0,01	0,01	0,01	
Cobalt (Co)	0,002	n.a.	0,002	
Iron (Fe)	0,5	0,02	0,02	
Manganese (Mn)	0,1	0,01	0,01	
Molybdenum (Mo)	0,001	0,001	0,001	

3. Where one or both of the micronutrients copper (Cu) and zinc (Zn) are present, without being intentionally added, in the minimum content indicated as % by mass in the following table, they may be declared:

Micronutrient	Content of micronutrient (% by mass)			
	Solid organo-mine	Liquid organo-		
	Intended for use on crops or grassland	Intended for horticultural use	mineral fertiliser	
Copper (Cu)	0,01	0,002	0,002	
Zinc (Zn)	0,01	0,002	0,002	

- 4. Where copper (Cu) or zinc (Zn) is intentionally added to the organo-mineral fertiliser, the total content of copper (Cu) or zinc (Zn) shall be declared.
- 5. The micronutrients referred to in points 2, 3 and 4 shall be declared after the information on macronutrients. The following information shall be provided:
- (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;
- (b) the total micronutrient content expressed as % by mass:
 - where those micronutrients are totally soluble in water, only as the content soluble in water;
 - where the soluble content of those micronutrients is at least a quarter of the total content of those micronutrients, as the total content and as the content soluble in water;
 - in other cases, as the total content;
- (c) where the declared micronutrients are chelated by chelating agents, the following qualifier after the name and the chemical identifier of the micronutrient:
 - 'chelated by ... (name of the chelating agent or its abbreviation)', and the amount of chelated micronutrient as % by mass;
- (d) where the organo-mineral fertiliser contains micronutrients complexed by complexing agents the following qualifier after the name and the chemical identifier of the micronutrient:
 - 'complexed by ... (name of the complexing agent or its abbreviation)', and the amount of complexed micronutrient as % by mass;
- (e) where micronutrients are intentionally added, the following statement: 'To be used only where there is a recognised need. Do not exceed the application rate'.
- 6. Where an organo-mineral fertiliser has a cadmium (Cd) content equal to or lower than 20 mg/kg phosphorus pentoxide (P₂O₅), the statement 'Low cadmium (Cd) content' or similar, or a visual representation to that effect, may be added.

PFC 1(C): INORGANIC FERTILISER

PFC 1(C)(I): INORGANIC MACRONUTRIENT FERTILISER

- 1. The following information shall be provided:
- (a) where applicable, the declared primary nutrients nitrogen (N), phosphorus (P) or potassium (K), by their chemical symbols in the order N-P-K;
- (b) where applicable, the declared secondary nutrients calcium (Ca), magnesium (Mg), sodium (Na) or sulphur (S) by their chemical symbols in the order Ca-Mg-Na-S;
- (c) numbers indicating the content of the declared nutrients total nitrogen (N), total phosphorus in the form of phosphorus pentoxide (P_2O_5) or total potassium in the form of potassium oxide (K_2O), followed by numbers in brackets indicating the total content of calcium oxide (CaO), magnesium oxide (MgO), sodium oxide (Na₂O) or sulphur trioxide (SO₃);
- (d) the content of the following declared nutrients, in the following order and as % by mass:

- (i) nitrogen (N):
 - total nitrogen (N);
 - nitrogen in the form of nitric nitrogen;
 - nitrogen in the form of ammoniacal nitrogen;
 - nitrogen in the form of urea nitrogen;
 - nitrogen from urea formaldehyde, isobutylidenediurea, crotonylidenediurea;
 - nitrogen from cyanamide nitrogen;
- (ii) phosphorus pentoxide (P_2O_5):
 - total phosphorus pentoxide (P_2O_5);
 - water-soluble phosphorus pentoxide (P_2O_5);
 - phosphorus pentoxide (P₂O₅) soluble in neutral ammonium citrate;
 - where soft ground phosphate is present, phosphorus pentoxide (P₂O₅) soluble in formic acid;
- (iii) water soluble potassium oxide (K_2O);
- (iv) calcium oxide (CaO), magnesium oxide (MgO), sodium oxide (Na₂O) and sulphur trioxide (SO₃), expressed:
 - where those nutrients are totally soluble in water, only as the content soluble in water;
 - where the soluble content of those nutrients is at least a quarter of the total content of those nutrients, as the total content and as the content soluble in water;
 - in other cases, as the total content;
- (e) where urea (CH_4N_2O) is present, information about the possible air quality impacts of the release of ammonia from the fertiliser use, and an invitation to users to apply appropriate remediation measures.
- 2. Where an inorganic macronutrient fertiliser has a cadmium (Cd) content equal to or lower than 20 mg/kg phosphorous pentoxide (P₂O₅), the statement 'Low cadmium (Cd) content' or similar, or a visual representation to that effect, may be added.

PFC 1(C)(I)(a): SOLID INORGANIC MACRONUTRIENT FERTILISER

- 1. A solid inorganic macronutrient fertiliser may be labelled 'complex' only if each physical unit contains all the declared nutrients in their declared content.
- 2. The granulometry of a solid inorganic macronutrient fertiliser shall be indicated, expressed as % by mass of the product passing through a determined sieve.
- 3. The form of the physical unit of the product shall be indicated with one 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.

- 4. For coated solid inorganic macronutrient fertilisers, the name of the coating agents and the percentage of fertiliser coated by each coating agent shall be indicated and followed by:
- (a) for polymer coated solid inorganic macronutrient fertilisers, the following marking: 'The rate of nutrient releases can vary according to the temperature of the substrate. An adjustment of fertilisation may be necessary'; and
- (b) for sulphur (S) coated solid inorganic macronutrient fertilisers and sulphur (S)/ polymer coated solid inorganic macronutrient fertilisers, the following marking: 'The rate of nutrient release can vary according to the temperature of the substrate and the biological activity. An adjustment of fertilisation may be necessary'.
- 5. Where one or more of the micronutrients boron (B), cobalt (Co), iron (Fe), manganese (Mn) and molybdenum (Mo) are present in the minimum content indicated in the following table as % by mass, they:
- shall be declared if they are intentionally added to the solid inorganic macronutrient fertiliser, and

	may	be	declared	in	other	cases:
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Micronutrient	Content of micronutrients (% by mass)			
	Intended for use on crops or grassland	Intended for horticultural use		
Boron (B)	0,01	0,01		
Cobalt (Co)	0,002	n.a.		
Iron (Fe)	0,5	0,02		
Manganese (Mn)	0,1	0,01		
Molybdenum (Mo)	0,001	0,001		

6. Where one or both of the micronutrients copper (Cu) and zinc (Zn) are present, without being intentionally added, in the minimum content indicated as % by mass in the following table, they may be declared:

Micronutrient	Content of micronutrients (% by mass)			
	Intended for use on crops	Intended for horticultural		
	or grassland	use		
Copper (Cu)	0,01	0,002		
Zinc (Zn)	0,01	0,002		

- 7. Where copper (Cu) or zinc (Zn) is intentionally added to the solid inorganic macronutrient fertiliser the total content of copper (Cu) or zinc (Zn) shall be declared.
- 8. The micronutrients referred to in points 5, 6 and 7 shall be declared after the information on macronutrients. The following information shall be provided:
- (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;

- (b) the total micronutrient content expressed as % by mass:
 - where those micronutrients are totally soluble in water, only as the content soluble in water;
 - where the soluble content of those micronutrients is at least a quarter of the total content of those micronutrients, as the total content and as the content soluble in water;
 - in other cases, as the total content;
- (c) where the declared micronutrients are chelated by chelating agents, the following qualifier after the name and the chemical identifier of the micronutrient:
 - 'chelated by ... (name of the chelating agent or its abbreviation)', and the amount of chelated micronutrient as % by mass;
- (d) where the solid inorganic macronutrient fertiliser contains micronutrients complexed by complexing agents the following qualifier after the name and the chemical identifier of the micronutrient:
 - 'complexed by ... (name of the complexing agent or its abbreviation)', and the amount of complexed micronutrient as % by mass;
- (e) where micronutrients are intentionally added, the following statement: 'To be used only where there is a recognised need. Do not exceed the application rate'.

PFC 1(C)(I)(b): LIQUID INORGANIC MACRONUTRIENT FERTILISER

- 1. The label shall indicate whether the liquid inorganic macronutrient fertiliser is in suspension or in solution.
- 2. The nutrient content may be indicated as % by mass or volume.
- 3. Where one or more of the micronutrients boron (B), cobalt (Co), iron (Fe), manganese (Mn) and molybdenum (Mo) are present in the minimum content indicated in the following table as % by mass, they:
- shall be declared if they are intentionally added to the liquid inorganic macronutrient fertiliser, and
- may be declared in other cases:

Micronutrient	Content of micronutrient (% by mass)
Boron (B)	0,01
Cobalt (Co)	0,002
Iron (Fe)	0,02
Manganese (Mn)	0,01
Molybdenum (Mo)	0,001

- 4. Where one or both of the micronutrients copper (Cu) and zinc (Zn) are present, without being intentionally added, by at least 0,002 % by mass, they may be declared.
- 5. Where copper (Cu) or zinc (Zn) is intentionally added to the liquid inorganic macronutrient fertiliser the total content of copper (Cu) or zinc (Zn) shall be declared.
- 6. The micronutrients referred to in points 3, 4 and 5 shall be declared after the information on macronutrients. The following information shall be provided:

- (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;
- (b) the total micronutrient content expressed as % by mass or volume:
 - where those micronutrients are totally soluble in water, only as the content soluble in water;
 - where the soluble content of those micronutrients is at least a quarter of the total content of those micronutrients, as the total content and as the content soluble in water;
 - in other cases, as the total content;
- (c) where the declared micronutrients are chelated by chelating agents, the following qualifier after the name and the chemical identifier of the micronutrient:
 - 'chelated by ... (name of the chelating agent or its abbreviation)', and the amount of chelated micronutrient as % by mass;
- (d) where the liquid inorganic macronutrient fertiliser contains micronutrients complexed by complexing agents the following qualifier after the name and the chemical identifier of the micronutrient:
 - 'complexed by ... (name of the complexing agent or its abbreviation)', and the amount of complexed micronutrient as % by mass;

 (e) where micronutrients are intentionally added, the following statement: 'To be used only where there is a recognised need. Do not exceed the application rate'.
 PFC 1(C)(II): INORGANIC MICRONUTRIENT FERTILISER

- 1. The declared micronutrients in the inorganic micronutrient fertiliser shall be listed by their names and chemical symbols 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.
- 2. Where the declared micronutrients are chelated by chelating agents, and each chelating agent can be identified and quantified and chelates at least 1 % water-soluble micronutrient, the following qualifier shall be added after the name and the chemical identifier of the micronutrient:
- 'chelated by ... (name of the chelating agent or its abbreviation)', and the amount of chelated micronutrient as % by mass.
- 3. Where the declared micronutrients are complexed by complexing agents, the following qualifier shall be added after the name and the chemical identifier of the micronutrient:
- 'complexed by ... (name of the complexing agent or its abbreviation)', and the amount of complexed micronutrient as % by mass.
- 4. The following statement shall appear: 'To be used only where there is a recognised need. Do not exceed the application rate'.

PFC 1(C)(II)(a): STRAIGHT INORĜANIC MICRONUTRIENT FERTILISER

- 1. The label shall indicate the relevant typology, as referred to in the table under PFC 1(C) (II)(a) in Part II of Annex I.
- 2. The total micronutrient content shall be expressed as % by mass:
- where the micronutrient is totally soluble in water, only as the content soluble in water;

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where the soluble content of the micronutrient is at least a quarter of the total content of that micronutrient, as the total content and as the content soluble in water; in other cases, as the total content.

PFC 1(C)(II)(b): COMPOUND INORGANIC MICRONUTRIENT FERTILISER

Micronutrients may be declared only if they are present in the minimum content 1. indicated in the following table as % by mass:

Micronutrient	Content of micronutrient (% by mass)			
	Non-chelated, non- complexed	Chelated or complexed		
Boron (B)	0,2	n.a.		
Cobalt (Co)	0,02	0,02		
Copper (Cu)	0,5	0,1		
Iron (Fe)	2	0,3		
Manganese (Mn)	0,5	0,1		
Molybdenum (Mo)	0,02	n.a.		
Zinc (Zn)	0,5	0,1		

- 2. If the compound inorganic micronutrient fertiliser is in suspension or in solution, the label shall indicate 'in suspension' or 'in solution', as relevant.
- 3. The total micronutrient content shall be expressed as % by mass:
- where the micronutrients are totally soluble in water, only as the content soluble in water;
- where the soluble content of the micronutrients is at least half of the total content of those micronutrients, as the total content and as the content soluble in water;
- in other cases, as the total content.

PFC 2: LIMING MATERIAL

The following parameters shall be declared in the following order:

- neutralising value;
- granulometry, expressed as % by mass of product passing through a sieve of 1,0 mm;
- total calcium oxide (CaO), expressed as % by mass;
- total magnesium oxide (MgO), expressed as % by mass;
- reactivity and method of determination of reactivity, except for oxide and hydroxide limes.

PFC 3: SOIL IMPROVER

- 1. The dry matter content expressed as % by mass shall be declared.
- 2. The following nutrients expressed as % by mass shall be declared, if exceeding 0.5 %by mass: nitrogen (N), phosphorus pentoxide (P_2O_5) and potassium oxide (K_2O).

PFC 3(A): ORGANIC SOIL IMPROVER

The following parameters shall be declared:

- pH;
- electrical conductivity, given as mS/m;

- organic carbon (C_{org}) content, expressed as % by mass;
- minimum amount of organic nitrogen (N_{org}), expressed as % by mass, followed by a description of the origin of the organic matter used;
- the ratio of organic carbon to total nitrogen (C_{org}/N).
- PFC 4: GROWING MEDIUM

The following parameters shall be declared in the following order:

- electrical conductivity given as mS/m, except for mineral wool;
- рН;
- quantity:
 - for mineral wool, expressed as number of pieces and the three dimensions length, height, and width;
 - for other pre-shaped growing media, expressed as size in at least two dimensions;
 - for other growing media, expressed as total volume;
 - except for pre-shaped growing media, quantity expressed as volume of materials with a particle size greater than 60 mm, when present;
- nitrogen (N) extractable by CaCl₂/DTPA (calcium chloride/ diethylenetriaminepentaacetic acid; 'CAT-soluble'), if above 150 mg/l;
- phosphorus pentoxide (P₂O₅) extractable by CaCl₂/DTPA (calcium chloride/ diethylenetriaminepentaacetic acid; 'CAT-soluble'), if above 20 mg/l;
- $\qquad \mbox{potassium oxide (K_2O) extractable by CaCl_2/DTPA (calcium chloride/diethylenetriaminepentaacetic acid; 'CAT-soluble'), if above 150 mg/l; }$

— production date.

PFC 5: INHIBITOR

All ingredients shall be declared by product weight or volume in descending order of magnitude. PFC 6: PLANT BIOSTIMULANT

The following information shall be provided:

- (a) physical form;
- (b) production and expiry date;
- (c) application method(s);
- (d) effect claimed for each target plant; and
- (e) any relevant instructions related to the efficacy of the product, including soil management practices, chemical fertilisation, incompatibility with plant protection products, recommended spraying nozzles size, sprayer pressure and other anti-drift measures.

PFC 6(A): MICROBIAL PLANT BIOSTIMULANT

All intentionally added micro-organisms shall be indicated. Where the micro-organism has several strains, the intentionally added strains shall be indicated. Their concentration shall be expressed as the number of active units per volume or weight, or in any other manner that is relevant to the micro-organism, e.g. colony forming units per gram (cfu/g).

The label shall contain the following phrase: 'Micro-organisms may have the potential to provoke sensitising reactions'.

PFC 7: FERTILISING PRODUCT BLEND

All the labelling requirements applicable to all component EU fertilising products apply to the fertilising product blend, and shall be expressed in relation to the final fertilising product blend.

Where the fertilising product blend contains one or more plant biostimulants belonging to PFC 6, the concentration of each plant biostimulant in the blend shall be indicated in g/kg or g/l at 20 °C.

PART III

TOLERANCE RULES

- 1. The declared nutrient content or physico-chemical characteristics of an EU fertilising product may deviate from the actual value only in accordance with the tolerances established in this Part for the relevant PFC. The tolerances are intended to allow for deviations in manufacture, in the distribution chain, and during sampling and analysis.
- 2. The tolerances allowed in respect of the declared parameters indicated in this Part are negative and positive values.
- 3. By derogation from point 1, the actual content of a component, in an EU fertilising product, for which a minimum or a maximum content is specified in Annex I or Annex II may never be lower than the minimum content or exceed the maximum content.

PFC 1: FERTILISER

The following tolerance rules apply to fertilisers containing nitrification inhibitors, denitrification inhibitors or urease inhibitors, as specified in CMC 1 in Part II of Annex II:

Inhibitors	Permissible tolerance for the declared content of inhibitors	
Concentration below or equal to 2 %	± 20 % of the declared value	
Concentration of more than 2 %	\pm 0,3 percentage points in absolute terms	

PFC 1(A): ORGANIC FERTILISER

Forms of the declared nutrient and other declared parameters	Permissible tolerance for the declared nutrient content and other declared parameters
Organic carbon (C _{org})	\pm 20 % relative deviation of the declared value up to a maximum of 2,0 percentage points in absolute terms
Dry matter content	\pm 5,0 percentage points in absolute terms
Total nitrogen (N)	\pm 50 % relative deviation of the declared value up to a maximum of 1,0 percentage point in absolute terms
Organic nitrogen (N _{org})	\pm 50 % relative deviation of the declared value up to a maximum of 1,0 percentage point in absolute terms

Total phosphorus pentoxide (P ₂ O ₅)	\pm 50 % relative deviation of the declared value up to a maximum of 1,0 percentage point in absolute terms
Total potassium oxide (K ₂ O)	\pm 50 % relative deviation of the declared value up to a maximum of 1,0 percentage point in absolute terms
Total and water-soluble magnesium oxide (MgO), calcium oxide (CaO), sulphur trioxide(SO ₃) or sodium oxide (Na ₂ O)	± 25 % of the declared content of those nutrients up to a maximum of 1,5 percentage points in absolute terms
Organic carbon (C _{org})/total nitrogen (N)	\pm 20 % relative deviation of the declared value up to a maximum of 2,0 percentage points in absolute terms
Quantity	\pm 1,5 % relative deviation of the declared value

PFC 1(B): ORGANO-MINERAL FERTILISER

Forms of the declared nutrient and other declared parameters	Permissible tolerance for the declared macronutrient content and other declared parameters
Organic carbon (C _{org})	\pm 20 % relative deviation of the declared value up to a maximum of 2,0 percentage points in absolute terms
Dry matter content	\pm 5,0 percentage points in absolute terms
Declared forms of inorganic nitrogen (N)	± 25 % relative deviation of the declared value up to a maximum of 2,0 percentage points in absolute terms
Organic nitrogen (N _{org})	\pm 50 % relative deviation of the declared value up to a maximum of 1,0 percentage point in absolute terms
Declared forms of phosphorus pentoxide (P_2O_5)	\pm 25 % relative deviation of the declared value up to a maximum of 1,5 percentage points in absolute terms
Declared forms of potassium oxide (K ₂ O)	± 25 % relative deviation of the declared value up to a maximum of 1,5 percentage points in absolute terms
Total and water-soluble magnesium oxide (MgO), calcium oxide (CaO), sulphur trioxide (SO ₃)	± 25 % of the declared content of those nutrients up to a maximum of 1,0 percentage point in absolute terms
Total and water-soluble sodium oxide (Na ₂ O)	\pm 25 % of the declared content up to a maximum of 0,9 percentage point in absolute terms
Quantity	\pm 1,5 % relative deviation of the declared value

Micronutrient	Permissible tolerance for the declared content of forms of micronutrient
Concentration below or equal to 2 %	± 20 % of the declared value
Concentration of more than 2 % and below or equal to 10 %	\pm 20 % of the declared value up to a maximum of 1,0 percentage point in absolute terms
Concentration of more than 10 %	\pm 1,0 percentage point in absolute terms

PFC 1(C): INORGANIC FERTILISER

Forms of the declared nutrient and other declared parameters	Permissible tolerance for the declared macronutrient content and other declared parameters
Declared forms of nitrogen (N)	\pm 20 % relative deviation of the declared value up to a maximum of 1,5 percentage points in absolute terms
Declared forms of phosphorus pentoxide (P_2O_5)	\pm 20 % relative deviation of the declared value up to a maximum of 1,5 percentage points in absolute terms
Declared forms of potassium oxide (K ₂ O)	\pm 20 % relative deviation of the declared value up to a maximum of 1,5 percentage points in absolute terms
Declared forms of nitrogen (N), phosphorus pentoxide (P_2O_5) or potassium oxide (K_2O) in binary fertilisers	\pm 1,5 percentage points in absolute terms
Declared forms of nitrogen (N), phosphorus pentoxide (P_2O_5) or potassium oxide (K_2O) in tertiary fertilisers	\pm 1,9 percentage points in absolute terms
Total and water-soluble magnesium oxide (MgO), calcium oxide (CaO), sulphur trioxide (SO ₃)	± 25 % of the declared content of those nutrients up to a maximum of 1,0 percentage point in absolute terms
Total and water soluble sodium oxide (Na ₂ 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	\pm 10 % relative deviation of the declared percentage of material passing a specific sieve
Quantity	\pm 1 % relative deviation of the declared value
Micronutrient	Permissible tolerance for the declared content of forms of micronutrient
Concentration below or equal to 2 %	± 20 % of the declared value

Concentration of more than 2 % and below or equal to 10 %	\pm 20 % of the declared value up to a maximum of 1,0 percentage point in absolute terms
Concentration of more than 10 %	\pm 1,0 percentage point in absolute terms

Quantity: \pm 5 % relative deviation of the declared value PFC 2: LIMING MATERIAL

Forms of the declared nutrient and other declared parameters	Permissible tolerances for the declared parameter
Neutralising value	± 3
Granulometry	\pm 10 % relative deviation of the declared percentage of material passing a specific sieve.
Total calcium oxide (CaO)	\pm 3,0 percentage points in absolute terms
Total magnesium oxide (MgO)	
Concentration below 8 %	\pm 1,0 percentage point in absolute terms
Concentration between 8 to 16 %	\pm 2,0 percentage points in absolute terms
Concentration above or equal to 16 %	\pm 3,0 percentage points in absolute terms
Reactivities (hydrochloric acid test and incubation test)	\pm 5,0 percentage points in absolute terms
Quantity	\pm 1 % relative deviation of the declared value

PFC 3: SOIL IMPROVER

Forms of the declared nutrient and other declared parameters	Permissible tolerances for the declared parameter
pH	\pm 1,0 of the declared value
Organic carbon (C _{org})	\pm 10 % relative deviation of the declared value up to a maximum of 1,0 percentage point in absolute terms
Organic nitrogen (N _{org})	\pm 50 % relative deviation of the declared value up to a maximum of 1,0 percentage point in absolute terms
Total nitrogen (N)	\pm 20 % relative deviation up to a maximum of 1,0 percentage point in absolute terms
Total phosphorus pentoxide (P ₂ O ₅)	\pm 20 % relative deviation up to a maximum of 1,0 percentage point in absolute terms
Total potassium oxide (K ₂ O)	\pm 20 % relative deviation up to a maximum of 1,0 percentage point in absolute terms
Dry matter content	\pm 10 % relative deviation of the declared value

Quantity	\pm 5 % relative deviation of the declared value
Electrical conductivity	\pm 75 % relative deviation of the declared value

PFC 4: GROWING MEDIUM

Forms for the declared nutrient and other declared parameters	Permissible tolerances for the declared parameter
Electrical conductivity	\pm 75 % relative deviation of the declared value
pH	\pm 1,0 of the declared value
Quantity by volume (litres or m ³)	\pm 5 % relative deviation of the declared value
Quantity (volume) determination of materials with particle size greater than 60 mm	\pm 5 % relative deviation of the declared value
Quantity (volume) determination of pre- shaped growing medium	\pm 5 % relative deviation of the declared value
Nitrogen (N) extractable by CaCl ₂ /DTPA (calcium chloride/ diethylenetriaminepentaacetic acid; 'CAT- soluble')	\pm 75 % relative deviation of the declared value
Phosphorus pentoxide (P ₂ O ₅) extractable by CaCl ₂ /DTPA (calcium chloride/ diethylenetriaminepentaacetic acid; 'CAT- soluble')	\pm 75 % relative deviation of the declared value
Potassium oxide (K ₂ O) extractable by CaCl ₂ /DTPA (calcium chloride/ diethylenetriaminepentaacetic acid; 'CAT- soluble')	\pm 75 % relative deviation of the declared value

PFC 5: INHIBITOR

Inhibiting compound	Permissible tolerance for the declared content of inhibiting compound
Concentration below or equal to 2 %	± 20 % of the declared value
Concentration of more than 2 %	\pm 0,3 percentage point in absolute terms

Quantity: \pm 5 % relative deviation of the declared value PFC 6(A): MICROBIAL PLANT BIOSTIMULANT

The actual concentration(s) of micro-organisms may deviate by no more than 15 % from the declared value(s).

PFC 7: FERTILISING PRODUCT BLEND

Where the fertilising product blend contains one or more plant biostimulants belonging to PFC 6, the following tolerances shall apply for the declared concentration of each plant biostimulant:

Declared concentration in g/kg or g/l at 20 °C	Permissible tolerance
Up to 25	\pm 15 % relative deviation
More than 25 up to 100	\pm 10 % relative deviation
More than 100 up to 250	\pm 6 % relative deviation
More than 250 up to 500	\pm 5 % relative deviation
More than 500	± 25 g/kg or ± 25 g/l

ANNEX IV

Conformity assessment procedures

PART I

APPLICABILITY OF CONFORMITY ASSESSMENT PROCEDURES

This Part sets out the applicability of conformity assessment procedure modules, as specified in Part II of this Annex, to EU fertilising products depending on their CMCs as specified in Annex II, and their PFCs as specified in Annex I.

- 1. APPLICABILITY OF INTERNAL PRODUCTION CONTROL (MODULE A)
- 1.1. Module A may be used for an EU fertilising product composed solely of one or more of the following component materials:
- (a) virgin material substances or mixtures as specified in CMC 1 in Part II of Annex II, except a nitrification inhibitor, a denitrification inhibitor or a urease inhibitor,
- (b) fresh crop digestates as specified in CMC 4 in Part II of Annex II,
- (c) food industry by-products as specified in CMC 6 in Part II of Annex II,
- (d) micro-organisms as specified in CMC 7 in Part II of Annex II,
- (e) nutrient polymers as specified in CMC 8 in Part II of Annex II,
- (f) by-products within the meaning of Directive 2008/98/EC as specified in CMC 11 in Part II of Annex II.
- 1.2. Module A may also be used for a fertilising product blend as specified in PFC 7.
- 1.3. By derogation from points 1.1 and 1.2, Module A must not be used for:
- (a) a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content, as specified in PFC 1(C)(I)(a)(i-ii)(A), or a fertilising product blend as specified in PFC 7 containing 28 % or more by mass of nitrogen (N) from an EU fertilising product belonging to PFC 1(C)(I)(a)(i-ii)(A),
- (b) an inhibitor as specified in PFC 5, or
- (c) a plant biostimulant as specified in PFC 6.

2. APPLICABILITY OF INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT TESTING (MODULE A1)

Module A1 shall be used for a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content, as specified in PFC 1(C)(I)(a)(i-ii)(A), and for a fertilising product blend as specified in PFC 7 containing 28 % or more by mass of nitrogen (N) from an EU fertilising product belonging to PFC 1(C)(I)(a)(i-ii)(A).

- 3. APPLICABILITY OF EU-TYPE EXAMINATION (MODULE B) FOLLOWED BY CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL (MODULE C)
- 3.1. Module B followed by Module C may be used for an EU fertilising product composed solely of one or more of the following component materials:
- (a) nitrification inhibitor, denitrification inhibitor or urease inhibitor as specified in CMC 1 in Part II of Annex II,
- (b) plants, plant parts or plant extracts as specified in CMC 2 in Part II of Annex II,
- (c) polymers other than nutrient polymers as specified in CMC 9 in Part II of Annex II,
- (d) derived products within the meaning of Regulation (EC) No 1069/2009 as specified in CMC 10 in Part II of Annex II,
- (e) CMCs referred to in point 1.1 of this Part.
- 3.2. Module B followed by Module C may also be used for:
- (a) an inhibitor as specified in PFC 5,
- (b) a plant biostimulant as specified in PFC 6, and
- (c) a fertilising product blend as specified in PFC 7.
- 3.3. By derogation from points 3.1 and 3.2, Module B followed by Module C must not be used for a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content, as specified in PFC 1(C)(I)(a)(i-ii)(A), or a fertilising product blend as specified in PFC 7 containing 28 % or more by mass of nitrogen (N) from an EU fertilising product belonging to PFC 1(C)(I)(a)(i-ii)(A).
- 4. APPLICABILITY OF QUALITY ASSURANCE OF THE PRODUCTION PROCESS (MODULE D1)
- 4.1. Module D1 may be used for any EU fertilising product.
- 4.2. By derogation from point 4.1, Module D1 must not be used for a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content, as specified in PFC 1(C)(I)(a)(i-ii)(A), or a fertilising product blend as specified in PFC 7 containing 28 % or more by mass of nitrogen (N) from an EU fertilising product belonging to PFC 1(C)(I)(a)(i-ii)(A).

PART II

DESCRIPTION OF CONFORMITY ASSESSMENT PROCEDURES MODULE A – INTERNAL PRODUCTION CONTROL

1. Description of the module

Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down under points 2, 3 and 4, and ensures and declares on his or her sole responsibility that the EU fertilising products concerned satisfy the requirements of this Regulation that apply to them.

- 2. Technical documentation
- 2.1. The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the EU fertilising product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).
- 2.2. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and intended use of the EU fertilising product. The technical documentation shall contain, where applicable, at least the following elements:
- (a) a general description of the EU fertilising product, the PFC corresponding to the claimed function of the EU fertilising product and description of the intended use,
- (b) a list of component materials used, the CMCs as referred to in Annex II to which they belong and information about their origin or manufacturing process,
- (c) the EU declarations of conformity for the component EU fertilising products of the fertilising product blend,
- (d) drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product,
- (e) a specimen of the label or the leaflet, or both, referred to in Article 6(7)containing the information required in accordance with Annex III,
- (f) a list of the harmonised standards referred to in Article 13, common specifications referred to in Article 14 and/or other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,
- (g) results of calculations made, including the calculations to demonstrate conformity with point 5 of Part II of Annex I, examinations carried out, etc.,
- (h) test reports,
- (i) where the EU fertilising product contains or consists of by-products within the meaning of Directive 2008/98/EC, technical and administrative evidence that the by-products comply with the criteria established by delegated act referred to in Article 42(7) of this Regulation, and with the national measures transposing Article 5(1) of Directive 2008/98/EC and, where applicable, implementing acts referred to in Article 5(2) or national measures adopted under Article 5(3) of that Directive,
- (j) where the EU fertilising product contains total chromium (Cr) above 200 mg/kg, information about the maximum quantity and exact source of total chromium (Cr).
- 3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured EU fertilising products with the technical documentation referred to under point 2 and with the requirements of this Regulation that apply to them.

- 4. CE marking and EU declaration of conformity
- 4.1. The manufacturer shall affix the CE marking to each individual packaging of the EU fertilising product that satisfies the applicable requirements of this Regulation, or, where it is supplied without packaging, in a document accompanying the EU fertilising product.
- 4.2. The manufacturer shall draw up a written EU declaration of conformity for an EU fertilising product or type and keep it together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market. The EU declaration of conformity shall identify the EU fertilising product or type for which it has been drawn up.
- 4.3. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.
- 5. Authorised representative

The manufacturer's obligations set out under point 4 may be fulfilled by his or her authorised representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.

MODULE A1 – INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT TESTING

1. Description of the module

Internal production control plus supervised product testing is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down under points 2, 3, 4, and 5, and ensures and declares on his or her sole responsibility that the EU fertilising products concerned satisfy the requirements of this Regulation that apply to them.

- 2. Technical documentation
- 2.1. The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the EU fertilising product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).
- 2.2. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and intended use of the EU fertilising product. The technical documentation shall contain, where applicable, at least the following elements:
- (a) a general description of the EU fertilising product, the PFC corresponding to the claimed function of the EU fertilising product and description of the intended use,
- (b) a list of component materials used, the CMCs as referred to in Annex II to which they belong and information about their origin or manufacturing process,
- (c) the EU declarations of conformity for the component EU fertilising products of the fertilising product blend,

- (d) drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product,
- (e) a specimen of the label or the leaflet, or both, referred to in Article 6(7) containing the information required in accordance with Annex III,
- (f) the names and addresses of the sites, and of the operators of the sites, at which the product and its principal components were manufactured,
- (g) a list of the harmonised standards referred to in Article 13, common specifications referred to in Article 14 and/or other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,
- (h) results of calculations made, including the calculations to demonstrate conformity with point 5 of Part II of Annex I, examinations carried out, etc.,
- (i) test reports, including the reports from product checks for oil retention and detonation resistance, referred to in point 4 and
- (j) where the EU fertilising product contains or consists of by-products within the meaning of Directive 2008/98/EC, technical and administrative evidence that the by-products comply with the criteria established by delegated acts referred to in Article 42(7) of this Regulation, and with the national measures transposing Article 5(1) of Directive 2008/98/EC and, where applicable, implementing acts referred to in Article 5(2) or national measures adopted under Article 5(3) of that Directive.
- 3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured EU fertilising products with the technical documentation referred to in point 2 and with the requirements of this Regulation that apply to them.

4. Product checks for oil retention and detonation resistance

The thermal cycles and tests referred to in points 4.1 to 4.4 shall be carried out on a representative sample of the EU fertilising product every 3 months on behalf of the manufacturer, in order to verify conformity with:

- (a) the oil retention requirement referred to in point 4 under PFC 1(C)(I)(a)(i-ii)(A) in Annex I, and
- (b) the detonation resistance requirement referred to in point 5 under PFC 1(C)(I)(a)(iii)(A) in Annex I.

The thermal cycles and tests shall be carried out under the responsibility of a notified body chosen by the manufacturer.

- 4.1. Thermal cycles prior to a test for compliance with the oil retention requirement referred to in point 4 under PFC 1(C)(I)(a)(i-ii)(A) in Annex I
- 4.1.1. Principle and definition

In a closed suitable laboratory flask, heat the sample from ambient temperature to 50 °C and maintain at this temperature for a period of two hours (phase at 50 °C). Thereupon cool the sample until a temperature of 25 °C is achieved and maintain at that temperature for two hours

(phase at 25 °C). The combination of the successive phases at 50 °C and 25 °C forms one thermal cycle. After being subjected to two thermal cycles, the test sample is held at a temperature of 20 (\pm 3) °C for the determination of the oil retention value.

4.1.2. Apparatus

Normal laboratory apparatus, in particular:

- water baths or ovens thermostated at 25 ± 1 °C and 50 ± 1 °C respectively, (a)
- (b) suitable laboratory flasks with an individual capacity of 150 ml.
- 4.1.3. Procedure
- 4.1.3.1. Put each test sample of 70 ± 5 g into a suitable laboratory flask which is then closed.
- 4.1.3.2. After attaining the temperature of 50 °C and maintain that temperature for two hours, change the temperature of the flask to the 25 °C bath or oven and proceed as described in 4.1.1.
- 4.1.3.3. If using a water bath maintain the water of each bath at constant temperature and keep in motion by rapid stirring. Ensure the water level comes above the level of the sample. Protect the stopper from condensation by a foam rubber cap.
- 4.2. Oil retention test referred to in point 4 under PFC 1(C)(I)(a)(i-ii)(A) in Annex I

4.2.1. Description

The oil retention of an EU fertilising product shall be the quantity of oil retained by the EU fertilising product determined under the operating conditions specified and expressed as a % by mass.

The test shall be carried out on a representative sample of the EU fertilising product. Before being tested, the whole mass of the sample shall be thermally cycled two times in accordance with point 4.1.

The method is applicable to both prilled and granular fertilisers which do not contain oil soluble materials.

4.2.2. Principle

Total immersion of the test sample in gas oil for a specified period, followed by the draining away of surplus oil under specified conditions. Measurement of the increase in mass of the test portion.

4.2.3. Reagents

Gas oil with the following characteristics:

- (a) viscosity max.: 5 mPas at 40 °C;
- (b) density: 0,8 g/ml to 0,85 g/ml at 20 °C;
- sulphur content: $\leq 1,0 \%$ (m/m); (c)
- (d) ash: $\leq 0,1 \%$ (m/m).
- 4.2.4. Apparatus

Ordinary laboratory apparatus, and:

- (a) balance, capable of weighing to the nearest 0,01 g;
- (b) beakers, of capacity 500 ml;
- (c) funnel, of plastic materials, preferably with a cylindrical wall at the upper end, diameter approximately 200 mm;
- (d) test sieve, aperture 0,5 mm, fitting into the funnel;

Note: The size of the funnel and sieve is such as to ensure that only a few granules lie one above another and the oil is able to drain easily.

- (e) filter paper, rapid filtering grade, creped, soft, mass 150 g/m^2 ;
- (f) absorbent tissue (laboratory grade).
- 4.2.5. Procedure
- 4.2.5.1. Two individual determinations are carried out in quick succession on separate portions of the same test sample.
- 4.2.5.2. Remove particles smaller than 0,5 mm using the test sieve. Weigh to the nearest 0,01 g approximately 50 g of the sample into the beaker. Add sufficient gas oil to cover the prills or granules completely and stir carefully to ensure that the surfaces of all the prills or granules are fully wetted. Cover the beaker with a watch glass and leave to stand for one hour at 25 (\pm 2) °C.
- 4.2.5.3. Filter the entire contents of the beaker through the funnel containing the test sieve. Allow the portion retained by the sieve to remain there for one hour so that most of the excess oil can drain away.
- 4.2.5.4. Lay two sheets of filter paper (about 500 mm x 500 mm) on top of each other on a smooth surface; fold the four edges of both filter papers upwards to a width of about 40 mm to prevent the prills or granules from rolling away. Place two layers of absorbent tissue in the centre of the filter papers. Pour the entire contents of the sieve over the absorbent tissues and spread the prills or granules evenly with a soft, flat brush. After two minutes lift one side of the tissues to transfer the prills or granules to the filter papers beneath and spread them evenly over these with the brush. Lay another sheet of filter paper, similarly with its edges turned upward, on the sample and roll the prills or granules between the filter papers with circular movements while exerting a little pressure. Pause after every eight circular movements to lift the opposite corners of the filter papers and return to the centre the prills or granules that have rolled to the periphery. Keep to the following procedure: make four complete circular movements, first clockwise and then anticlockwise. Then roll the prills or granules back to the centre as described above. This procedure is to be carried out three times (24 circular movements, corners lifted twice). Carefully insert a new sheet of filter paper between the bottom sheet and the one above it and allow the prills or granules to roll onto the new sheet by lifting the edges of the upper sheet. Cover the prills or granules with a new sheet of filter paper and repeat the same procedure as described above. Immediately after rolling, pour the prills or granules into a tared dish and reweigh to the nearest 0,01 g to determine the mass of the quantity of gas oil retained.

4.2.5.5. Repeating the rolling procedure and reweighing

If the quantity of gas oil retained in the portion is found to be greater than 2,00 g, place the portion on a fresh set of filter papers and repeat the rolling procedure, lifting the corners in

accordance with point 4.2.5.4 (two times eight circular movements, lifting once). Then reweigh the portion.

- 4.2.5.6. Two oil retention tests per sample are to be carried out.
- 4.2.6. Test report
- 4.2.6.1. Expression of the results
- 4.2.6.1.1. Method of calculation and formula

The oil retention, from each determination (point 4.2.5.1) expressed as a % by mass of the sieved test portion, is given by the equation: **Oil retention** = $\frac{m_2 - m_1}{m_1} \times 100$

where:

 m_1 is the mass, in grams, of the sieved test portion (point 4.2.5.2),

 m_2 is the mass, in grams, of the test portion according to points 4.2.5.4 and 4.2.5.5 respectively as the result of the last weighing.

- 4.2.6.1.2. Take as the result the arithmetic mean of the two individual determinations.
- 4.2.6.2. The test report shall form part of the technical documentation.
- 4.3. Thermal cycles prior to the detonation resistance test referred to in point 5 under PFC 1(C)(I)(a)(i-ii)(A) in Annex I
- 4.3.1. Principle and definition

In a tight box heat the sample from ambient temperature to 50 °C and maintain at this temperature for a period of one hour (phase at 50 °C). Thereupon cool the sample until a temperature of 25 °C is achieved and maintain at that temperature for one hour (phase at 25 °C). The combination of the successive phases at 50 °C and 25 °C forms one thermal cycle. After being subjected to the required number of thermal cycles, the test sample is held at a temperature of 20 ± 3 °C pending the execution of the detonation resistance test.

4.3.2. Apparatus Method 1

- (a) A water bath, thermostated in a temperature range of 20 to 51 °C with a minimum heating and cooling rate of 10 °C/h, or two water baths, one thermostated at a temperature of 20 °C, the other at 51 °C. The water in the bath(s) is continuously stirred; the volume of the bath shall be large enough to guarantee ample circulation of the water.
- (b) A stainless steel box, watertight all around and provided with a temperature recording device in the centre. The outside width of the box is 45 ± 2 mm and the wall thickness is 1,5 mm (see Figure 1 as an example). The height and length of the box can be chosen to suit the dimensions of the water bath, e.g. length 600 mm, height 400 mm.

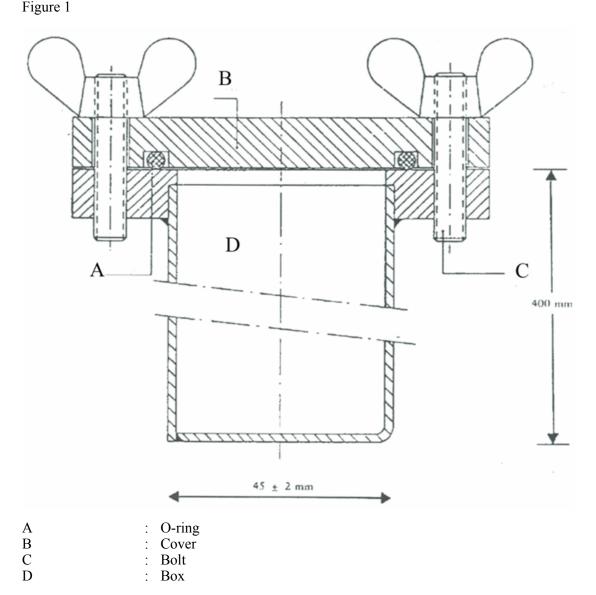
Method 2

- (a) Suitable oven, thermostated in a temperature range of 20 °C to 51 °C with a minimum heating and cooling rate of 10 °C/h.
- (b) Suitable airtight plastics boxes or bags provided with a suitable temperature recording device in the centre of the sample or a stainless steel box as described in point (b) of

method 1 of point 4.3.2. Once filled, the outside thickness of the box or bag shall be maximum 45 mm.

4.3.3. Procedure

Place a quantity of fertilisers sufficient for the detonation resistance test into the boxes or bags and close them. Place the stainless steel boxes in the water bath (method 1) or the boxes or bags in the oven (method 2). Heat the water or oven to 51 °C and measure the temperature in the centre of the fertiliser. One hour after the temperature at the centre has reached 50 °C start cooling. One hour after the temperature at the centre has reached 25 °C start heating for the second cycle. In the case of two water baths or ovens, transfer the boxes or bags to the other bath or oven after each heating/cooling period.



4.4. Detonation resistance test referred to in point 5 under PFC 1(C)(I)(a)(i-ii)(A) in Annex I

^{4.4.1.} Description

- 4.4.1.1. The test shall be carried out on a representative sample of the EU fertilising product. Before being tested for resistance to detonation, the whole mass of the sample is to be thermally cycled five times in accordance with point 4.3.
- 4.4.1.2. The EU fertilising product shall be subjected to the detonation resistance test in a horizontal steel tube under the following conditions (the details of the materials are in point 4.4.3):
- (a) seamless steel tube:
 - (i) Tube length: 1 000 mm at least,
 - (ii) Nominal external diameter: 114 mm at least,
 - (iii) Nominal wall thickness: 5 mm at least,
- (b) booster: the type and mass of the booster chosen shall be such as to maximise the detonation pressure applied to the sample in order to determine its susceptibility to the transmission of detonation,
- (c) temperature of the sample: $15 \circ C$ to $25 \circ C$,
- (d) witness lead cylinders for detecting detonation: 50 mm diameter and 100 mm height,
- (e) placed at 150 mm intervals and supporting the tube horizontally.

NOTE: The test is to be carried out twice. The test is deemed conclusive if in both tests one or more of the supporting lead cylinders is crushed by less than 5 %.

4.4.2. Principle

The test sample is confined in a steel tube and subjected to detonation shock from an explosive booster charge. Propagation of the detonation is determined from the degree of crushing of lead cylinders on which the tube rests horizontally during the test.

- 4.4.3. Materials
- (a) Plastic explosive containing 83 % to 86 % penthrite
 - density: $1 500 \text{ kg/m}^3$ to $1 600 \text{ kg/m}^3$
 - detonation velocity: 7 300 m/s to 7 700 m/s
 - mass: (500 ± 1) g;

or any other plastic explosive with similar detonation characteristics.

- (b) Seven lengths of flexible detonating cord with non-metallic sleeve
 - filling mass: 11 g/m to 13 g/m
 - length of each cord: (400 ± 2) mm.
- (c) Compressed pellet of secondary explosive, recessed to receive detonator
 - explosive: hexogen/wax 95/5 or similar secondary explosive, with or without added graphite
 - density: 1 500 kg/m³ to 1 600 kg/m³
 - diameter: 19 mm to 21 mm
 - height: 19 mm to 23 mm
 - mass of the compressed pellet: maximum 10 g

- central recess to receive detonator: maximal diameter 7,0 to 7,3 mm, depth about 12 mm. In case of detonators with large diameters, the diameter of the recess shall be slightly larger (e.g. 0,5 mm) than the diameter of the detonator.
- (d) Seamless steel tube as specified in ISO 65 1981 Heavy Series, with nominal dimensions DN 100 (4")
 - outside diameter: 113,1 mm to 115,0 mm
 - wall thickness: 5,0 mm to 6,5 mm
 - -- length: $1\ 005 \pm 2\ mm$.
- (e) Bottom plate
 - material: steel of good weldable quality
 - dimensions: 160 mm × 160 mm
 - thickness: 5 mm to 6 mm.
- (f) Six lead cylinders
 - diameter: $50 \pm 1 \text{ mm}$
 - height: 100 mm to 101 mm
 - materials: soft lead, at least 99,5 % purity.
- (g) Steel block
 - length: at least 1 000 mm
 - width: at least 150 mm
 - height: at least 150 mm (alternatively a stack of several beams can be used to achieve this height)
 - Mass: at least 300 kg if there is no firm base for the steel block.
- (h) Plastic or cardboard cylinder for booster charge
 - wall thickness: 1,5 mm to 2,5 mm
 - diameter: 92 mm to 96 mm
 - height: 64 mm to 67 mm.
- (i) Detonator (electric or non-electric) with initiation force 8 to 10
- (j) Wooden or plastic disc
 - diameter: 92 mm to 96 mm. Diameter to be matched to the internal diameter of the plastic or cardboard cylinder (point (h))
 - thickness: 20 mm.
- (k) Wooden or plastic rod of same dimensions as detonator (point (i))
- (l) Small split pins (maximum length 20 mm)
- (m) Split pins (length about 20 mm)
- 4.4.4. Procedure
- 4.4.4.1. Preparation of booster charge for insertion into steel tube

Depending on the availability of equipment, the explosive can be initiated in the booster charge either

- by seven-point simultaneous initiation as referred to in point 4.4.4.1.1, or
- by central initiation by a compressed pellet as referred to in point 4.4.4.1.2.

The booster charge prepared for use is shown in Figure 2.

4.4.4.1.1. Drill holes in the wooden or plastic disc (point (j) under point 4.4.3) parallel to the axis of the disc through the centre and through six points symmetrically distributed around a concentric circle 55 mm in diameter. The diameter of the holes shall be 6 mm to 7 mm (see Section A-B in Figure 2), depending on the diameter of the detonating cord used (point (b) under point 4.4.3).

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- 4.4.1.1. Lut seven lengths of flexible detonating cord (point (b) under point 4.4.3) each 400 mm long, avoiding any loss of explosive at each end by making a clean cut and immediately sealing the end with adhesive. Push each of the seven lengths through each of the seven holes in the wooden or plastic disc (point (j) under point 4.4.3) until their ends project a few centimetres on the other side of the disc. Then insert a small split pin (point (l) under point 4.4.3) transversally into the textile sleeve of each length of cord 5 mm to 6 mm from the end and apply adhesive around the outside of the lengths of cord in a band 2 cm wide adjacent to the pin. Finally, pull the long piece of each cord to bring the pin into contact with the wooden or plastic disc.
- 4.4.1.1. Shape the plastic explosive (point (a) under point 4.4.3) to form a cylinder 92 mm to 96 mm in diameter, depending on the diameter of the cylinder (point (h) under point 4.4.3). Stand this cylinder upright on a level surface and insert the shaped explosive. Then insert the wooden or plastic disc⁽¹⁸⁾ carrying the seven lengths of detonating cord into the top of the cylinder and press it down onto the explosive. Adjust the height of the cylinder (64 mm to 67 mm) so that its top edge does not extend beyond the level of the wood or plastic. Finally, fix the cylinder to the wooden or plastic disc for instance with staples or small nails, around its entire circumference.
- 4.4.4.1.1. Group the free ends of the seven lengths of detonating cord around the circumference of the wooden or plastic rod (point (k) under point 4.4.3) so that their ends are all level in a plane perpendicular to the rod. Secure them in a bundle around the rod by means of adhesive tape⁽¹⁹⁾.
- 4.4.4.1.2. Central initiation by a compressed pellet

The booster charge prepared for use is shown in Figure 3.

4.4.4.1.2. Preparing a compressed pellet

Taking the necessary safety precautions, place maximum 10 g of a secondary explosive (point (c) under point 4.4.3) in a mould with an inside diameter of 19 mm to 21 mm and compress to the correct shape and density (the ratio of diameter: height should be roughly 1:1). In the centre of the bottom of the mould there is a peg, 12 mm in height and 7,0 mm to 7,3 mm in diameter (depending on the diameter of the detonator used), which forms a cylindrical recess in the compressed cartridge for subsequent insertion of the detonator.

4.4.4.1.2. **P**reparing the booster charge

Place the explosive (point (a) under point 4.4.3) into the cylinder (point (h) under point 4.4.3) standing upright on a level surface, then press it down with a wooden or plastic die to give the explosive a cylindrical shape with a central recess. Insert the compressed pellet into this recess. Cover the cylindrically shaped explosive containing the compressed pellet with a wooden or plastic disc (point (j) under point 4.4.3) having a central hole 7,0 mm to 7,3 mm in diameter for insertion of a detonator. Fix the wooden or plastic disc and the cylinder together with a cross

of adhesive tape. Ensure that the hole drilled in the disc and the recess in the compressed pellet are coaxial by inserting the wooden or plastic rod (point (k) under point 4.4.3).

4.4.4.2. Preparing steel tubes for the detonation tests

At one end of the steel tube (point (d) under point 4.4.3), drill two diametrically opposed holes 4 mm in diameter perpendicularly through the side wall at a distance of 4 mm from the edge. Butt weld the bottom plate (point (e) under point 4.4.3) to the opposite end of the tube, completely filling the right angle between the bottom plate and the wall of the tube with weld metal around the entire circumference of the tube.

4.4.4.3. Filling and charging the steel tube

See Figures 2 and 3.

- 4.4.3.1. The test sample, the steel tube and the booster charge shall be conditioned to temperatures of (20 ± 5) °C. About 20 kg of the test sample should be available for two detonation resistance tests.
- 4.4.3.2. Place the tube upright with its square bottom plate resting on a firm, flat surface, preferably concrete. Fill the tube to about one-third of its height with the test sample and drop it 10 cm vertically onto the flat surface five times to compact the prills or granules as densely as possible in the tube. To accelerate compaction, vibrate the tube by striking the side wall with a 750 g to 1 000 g hammer between drops for a total of 10 times.
- 4.4.3.2. Repeat this charging method with another portion of the test sample. Finally, a further addition shall be made such that, after compaction by raising and dropping the tube 10 times and a total of 20 intermittent hammer blows, the charge fills the tube to a distance of 70 mm from its orifice.
- 4.4.3.2. The filling height of the sample shall be adjusted in the steel tube so that the booster charge (referred to in point 4.4.4.1.1 or 4.4.4.1.2) to be inserted later will be in close contact with the sample over its entire surface.
- 4.4.3.3. Insert the booster charge into the tube so that it is in contact with the sample; the top surface of the wooden or plastic disc shall be 6 mm below the end of the tube. Ensure essential close contact between explosive and test sample by taking out the booster charge and adding or removing small quantities of sample. As shown in Figures 2 and 3, split pins should be inserted through the holes near the open end of the tube and their legs opened flat against the tube.
- 4.4.4.4. Positioning of the steel tube and lead cylinders (see Figure 4)
- 4.4.4.1. Number the bases of the lead cylinders (point (f) under point 4.4.3) 1, 2, 3, 4, 5 and 6. Make six marks 150 mm apart along a line on a steel block (point 4.4.3(g)) lying on a horizontal base, with each mark at least 75 mm from any edge of the block. Place a lead cylinder upright on each of these marks, with the base of each cylinder centred on its mark (see Figure 4).
- 4.4.4.2. Lay the steel tube prepared according to point 4.4.4.3 horizontally on the lead cylinders so that the axis of the tube is parallel to the centre line of the lead cylinders and the welded end of the tube extends 50 mm beyond lead cylinder No 6. To prevent the tube from rolling, insert small wooden or plastic wedges between the tops of the lead cylinders and the tube wall (one on each side) or place a cross of wood between the tube and the steel block or stack of beams. (see Figure 4).

Note: Make sure that the tube is in contact with all six lead cylinders; a slight curvature of the tube surface can be compensated for by rotating the tube about its longitudinal axis; if any of the lead cylinders is too tall, tap the cylinder in question carefully with a hammer until it is the required height.

- 4.4.4.5. Preparation for detonation
- 4.4.4.5.1.Set up the apparatus as described in point 4.4.4.4 in a bunker or suitably prepared underground site or suitable location. Ensure that the temperature of the steel tube is kept at (20 ± 5) °C before detonation.

Note: Detonation can cause steel fragments to be projected with high kinetic energy, therefore, firing shall be carried out at a suitable distance from dwellings or thoroughfares.

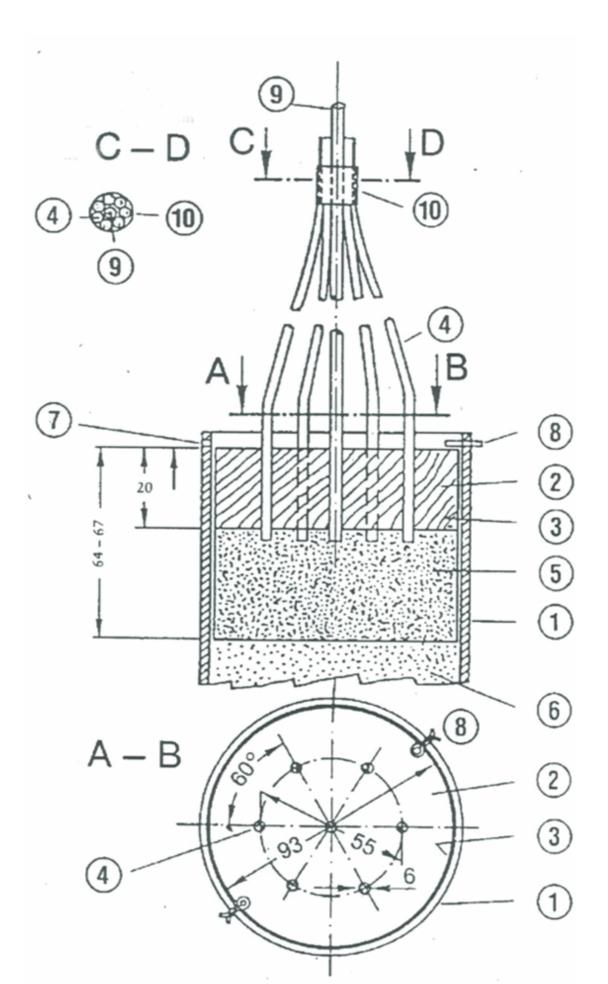
- 4.4.4.5.2. If the booster charge with seven-point initiation is used, ensure that the detonation cords are stretched out as described in the footnote to point 4.4.4.1.1.4 and arranged as horizontally as possible.
- 4.4.4.5.3. Finally, remove the wooden or plastic rod and replace with the detonator. Do not carry out firing until the danger zone has been evacuated and the test personnel have taken cover.
- 4.4.4.5.4. Detonate the explosive.
- 4.4.4.6.1. Allow sufficient time for the fumes (gaseous and sometimes toxic decomposition products such as nitrous gases) to disperse, then collect the lead cylinders and measure their heights with a Vernier caliper.
- 4.4.4.6.2. Record for each of the marked lead cylinders, the degree of crushing expressed as a percentage of the original height of 100 mm. If the cylinders are crushed obliquely, record the highest and the lowest values and calculate the average.
- 4.4.4.7. Detonation velocity measurement can also be performed.
- 4.4.4.8. Two detonation tests per sample are to be carried out.
- 4.4.5. Test report

Values for the following parameters are to be given in the test report for each of the detonation resistance tests:

- the values actually measured for the outside diameter of the steel tube and for the wall thickness,
- the Brinell hardness of the steel tube,
- the temperature of the tube and the sample shortly before firing,
- the packing density (kg/m^3) of the sample in the steel tube,
- the height of each lead cylinder after firing, specifying the corresponding cylinder number,
- method of initiation employed for the booster charge.
- 4.4.6. Evaluation of test results

If, in each firing, the crushing of at least one lead cylinder is less than 5 %, the test shall be considered conclusive and it shall be considered that the sample presented is resistant to detonation.

4.4.7. The test report shall form part of the technical documentation. Figure 2

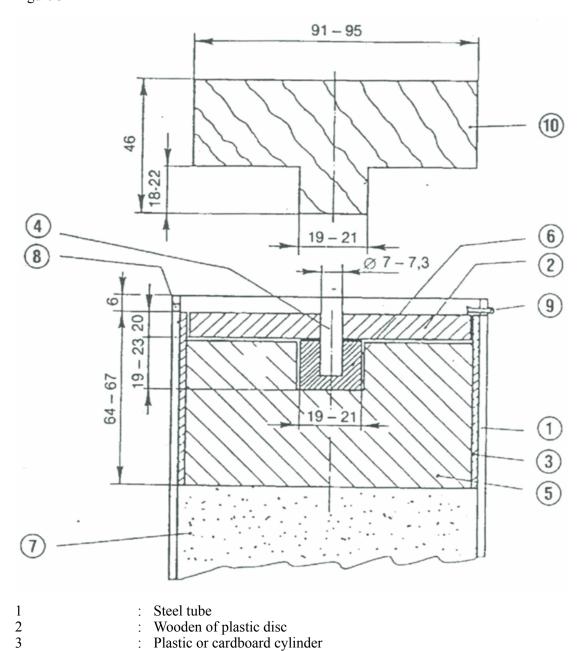


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Booster charge with seven-point initiation

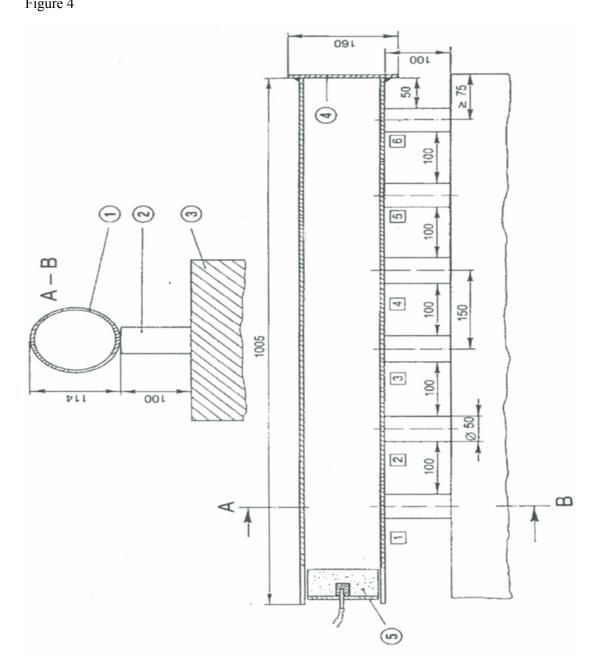
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l	: Steel tube	
2	: Wooden or plastic disc with seven hole	S
3	: Plastic or cardboard cylinder	
4	: Detonating cords	
5	: Plastic explosive	
6	: Test sample	
7	: 4 mm hole drilled to receive split pin	
8	: Split pin	
9	: Wooden or plastic rod surrounded by 4	
10	: Adhesive tape for securing 4 around 9	
Figure 3	· · · · · ·	



Changes to legislation: There a	ire currently no known outst	anding effects for the Regulation (EU)
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4	: Wooden of plastic rod
5	: Plastic explosive
6	: Compressed pellet
7	: Test sample
8	: 4 mm hole drilled to receive split pin
9	: Split pin
10	: Wooden or plastic die for 5
Figure 4	^



Numbers in circles:

1	:	Steel tube
2	:	Lead cylinders

3	:	Steel block or stack of beams
4	:	Bottom plate
5	:	Booster charge

Numbers in squares:

Lead cylinders 1 to 6

- 5. CE marking and EU declaration of conformity
- 5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each individual packaging of the EU fertilising product that satisfies the applicable requirements of this Regulation or, where it is supplied without packaging, in a document accompanying the EU fertilising product.
- 5.2. The manufacturer shall draw up a written EU declaration of conformity for an EU fertilising product type and keep it together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market. The EU declaration of conformity shall identify the EU fertilising product type for which it has been drawn up.
- 5.3. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.
- 6. Notified bodies' information and operational obligations
- 6.1. Each notified body shall, without undue delay, inform its notifying authority and other bodies notified under this Regulation carrying out similar conformity assessment activities covering the same EU fertilising products of the following:
- (a) any case where the manufacturer has not complied with the 3-month period for performing the tests required under point 4;
- (b) any test results which demonstrate non-conformity with the detonation resistance requirement referred to in point 5 under PFC 1(C)(I)(a)(i-ii)(A) in Annex I.
- 6.2. In the case referred to in point 6.1(b) the notified body shall request the manufacturer to take the necessary measures in accordance with Article 6(8).
- 7. Authorised representative

The manufacturer's obligations set out in points 4.4.7 and 5 may be fulfilled by his or her authorised representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.

MODULE B – EU-TYPE EXAMINATION

- 1. Description of the module
- 1.1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of an EU fertilising product and verifies and attests that the technical design of the EU fertilising product meets the requirements of this Regulation.
- 1.2. Assessment of the adequacy of the technical design of the EU fertilising product is carried out through examination of the technical documentation and supporting evidence, plus examination of samples, representative of the production envisaged.

- 2. Technical documentation
- 2.1. The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the EU fertilising product's conformity with the relevant requirements and shall include an adequate analysis and assessment of the risk(s).
- 2.2. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and intended use of the EU fertilising product. The technical documentation shall contain, where applicable, at least the following elements:
- (a) a general description of the EU fertilising product, the PFC corresponding to the claimed function of the EU fertilising product and description of the intended use,
- (b) a list of component materials used, the CMCs as referred to in Annex II to which they belong and information about their origin or manufacturing process,
- (c) the EU declarations of conformity for the component EU fertilising products of the fertilising product blend,
- (d) drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product,
- (e) a specimen of the label or the leaflet, or both, referred to in Article 6(7) containing the information required in accordance with Annex III,
- (f) a list of the harmonised standards referred to in Article 13, common specifications referred to in Article 14 and/or other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,
- (g) results of calculations made, including the calculations to demonstrate conformity with point 5 of Part II of Annex I, examinations carried out, etc.,
- (h) test reports,
- (i) where the EU fertilising product contains or consists of derived products within the meaning of Regulation (EC) No 1069/2009, the commercial documents or health certificates required pursuant to that Regulation, and evidence that the derived products have reached the end point in the manufacturing chain within the meaning of that Regulation,
- (j) where the EU fertilising product contains or consists of by-products within the meaning of Directive 2008/98/EC, technical and administrative evidence that the by-products comply with the criteria established by delegated act referred to in Article 42(7) of this Regulation, and with the national measures transposing Article 5(1) of Directive 2008/98/EC and, where applicable, implementing acts referred to in Article 5(2) or national measures adopted under Article 5(3) of that Directive, and
- (k) where the EU fertilising product contains total chromium (Cr) above 200 mg/kg, information about the maximum quantity and exact source of total chromium (Cr).
- 3. Application for EU-type examination

- 3.1. The manufacturer shall lodge an application for EU-type examination with a single notified body of his or her choice.
- 3.2. The application shall include:
- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his or her name and address as well,
- (b) a written declaration that the same application has not been lodged with any other notified body,
- (c) the technical documentation referred to in point 2,
- (d) the samples representative of the production envisaged. The notified body may request further samples if needed for carrying out the test programme,
- (e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his or her behalf and under his or her responsibility.
- 4. Assessment of the adequacy of the technical design

The notified body shall:

- (a) examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the EU fertilising product;
- (b) verify that the sample(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;
- (c) carry out appropriate examinations and tests on the sample(s), or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications, these have been applied correctly;
- (d) carry out appropriate examinations and tests on the sample(s), or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, or where relevant harmonised standards or common specifications do not exist, the solutions adopted by the manufacturer meet the corresponding requirements of this Regulation;
- (e) agree with the manufacturer on a location where the examinations and tests will be carried out.
- 5. Evaluation report

The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authority, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

- 6. EU-type examination certificate
- 6.1. Where the type meets the requirements of this Regulation that apply to the EU fertilising product concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached.
- 6.2. The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured EU fertilising products with the examined type to be evaluated.
- 6.3. Where the type does not satisfy the requirements of this Regulation, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.
- 7. Changes which may affect the conformity of the EU fertilising product
- 7.1. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the requirements of this Regulation and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.
- 7.2. The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the EU fertilising product with the requirements of this Regulation or the conditions for validity of the EU-type examination certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.
- 8. Notified bodies' information obligation
- 8.1. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of EU-type examination certificates and/or any additions thereto refused, suspended or otherwise restricted.
- 8.2. Each notified body shall inform the other notified bodies concerning the EUtype examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the EUtype examination certificates and/or additions thereto which it has issued.
- 8.3. The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body.
- 9. Availability of the EU-type examination certificate
- 9.1. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the EU-type examination certificate.

9.2. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market.

10. Authorised representative

The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9.2, provided that they are specified in the mandate.

MODULE C – CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL

1. Description of the module

Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares on his or her sole responsibility that the EU fertilising products concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Regulation that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured EU fertilising products with the approved type described in the EU-type examination certificate and with the requirements of this Regulation that apply to them.

- 3. CE marking and EU declaration of conformity
- 3.1 The manufacturer shall affix the CE marking to each individual packaging of the EU fertilising product that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Regulation or, where it is supplied without packaging, in a document accompanying the EU fertilising product.
- 3.2 The manufacturer shall draw up a written EU declaration of conformity for an EU fertilising product type and keep it together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market. The EU declaration of conformity shall identify the EU fertilising product type for which it has been drawn up.
- 3.3. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.
- 4. Authorised representative

The manufacturer's obligations set out in point 3 may be fulfilled by his or her authorised representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.

MODULE D1 – QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. Description of the module

Quality assurance of the production process is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 4, and 7, and ensures and declares on his or her sole responsibility that the EU fertilising products concerned satisfy the requirements of this Regulation that apply to them.

- 2. Technical documentation
- 2.1. The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the EU fertilising product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).
- 2.2. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and intended use of the EU fertilising product. The technical documentation shall contain, where applicable, at least the following elements:
- (a) a general description of the EU fertilising product, the PFC corresponding to the claimed function of the EU fertilising product and description of the intended use,
- (b) a list of component materials used, the CMCs as referred to in Annex II, to which they belong and information about their origin or manufacturing process,
- (c) the EU declarations of conformity for the component EU fertilising products of the fertilising product blend,
- (d) drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product, and, in relation to compost belonging to CMC 3 or digestate belonging to CMC 5, 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,
- (e) a specimen of the label or the leaflet, or both, referred to in Article 6(7) containing the information required in accordance with Annex III,
- (f) a list of the harmonised standards referred to in Article 13, common specifications referred to in Article 14 and/or other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,
- (g) results of calculations made, including the calculations to demonstrate conformity with point 5 of Part II of Annex I, examinations carried out, etc.,
- (h) test reports,
- (i) where the EU fertilising product contains or consists of derived products within the meaning of Regulation (EC) No 1069/2009, the commercial documents or health certificates required pursuant to that Regulation, and evidence that the derived products have reached the end point in the manufacturing chain within the meaning of that Regulation,
- (j) where the EU fertilising product contains or consists of by-products within the meaning of Directive 2008/98/EC, technical and administrative evidence that the by-products comply with the criteria established by delegated act referred to in Article 42(7) of this Regulation, and with the national measures transposing Article 5(1) of Directive 2008/98/EC and, where applicable, implementing acts referred to in Article 5(2) or national measures adopted under Article 5(3) of that Directive, and
- (k) where the EU fertilising product contains total chromium (Cr) above 200 mg/kg, information about the maximum quantity and exact source of total chromium (Cr).

3. Availability of technical documentation

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 5 years after the EU fertilising product has been placed on the market.

4. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the EU fertilising products concerned as specified in point 5, and shall be subject to surveillance as specified in point 6.

- 5. Quality system
- 5.1. The manufacturer shall implement a quality system which shall ensure compliance of the EU fertilising products with the requirements of this Regulation that apply to them.
- 5.1.1. The quality system shall cover the quality objectives and the organisational structure with responsibilities and powers of the management with regard to product quality.
- 5.1.1.1. For compost belonging to CMC 3 and digestate belonging to CMC 5, as defined in Annex II, senior management of the manufacturer's organisation shall:
- (a) ensure that sufficient resources (people, infrastructure, equipment) are available to create and implement the quality system;
- (b) appoint a member of the organisation's management who shall be responsible for:
 - ensuring that quality management processes are established, approved, implemented and maintained;
 - reporting to senior management of the manufacturer on the performance of the quality management and any need for improvement;
 - ensuring the promotion of awareness of customer needs and legal requirements throughout the manufacturer's organisation, and for making the personnel aware of the relevance and importance of the quality management requirements to meet the legal requirements of this Regulation;
 ensuring that each person whose duties affect the product quality is
 - ensuring that each person whose duties affect the product quality is sufficiently trained and instructed; and
 - ensuring the classification of the quality management documents mentioned under point 5.1.4;
- (c) conduct an internal audit every year, or sooner than scheduled if triggered by any significant change that may affect the quality of the EU fertilising product; and
- (d) ensure that appropriate communication processes are established within and outside the organisation and that communication take place regarding the effectiveness of the quality management.
- 5.1.2. The quality system shall cover the manufacturing, quality control and quality assurance techniques, processes and systematic actions.
- 5.1.2.1. For compost belonging to CMC 3 and digestate belonging to CMC 5, as defined in Annex II, the quality system shall ensure compliance with the composting and digestion process criteria specified in that Annex.
- 5.1.3. The quality system shall cover the examinations and tests to be carried out before, during and after manufacture with a specified frequency.

- 5.1.3.1. For compost belonging to CMC 3 and digestate belonging to CMC 5, as defined in Annex II, the examinations and tests shall comprise the following elements:
- (a) The following information shall be recorded for each batch of input materials:
 - (i) date of delivery;
 - (ii) amount by weight (or estimation based on the volume and density);
 - (iii) identity of the input material supplier;
 - (iv) input material type;
 - (v) identification of each batch and delivery location on site. A unique identification code shall be assigned throughout the production process for quality management purposes; and
 - (vi) in case of refusal, the reasons for the rejection of the batch and where it was sent.
- (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 CMC 3 and CMC 5 in Annex II.
- (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 composting or digestion process or for the quality of the final EU fertilising product, or
 - incompatibility with the specifications laid down in CMC 3 and CMC 5 in Annex II, in particular by presence of plastics leading to exceedence of the limit value for macroscopic impurities.
- (d) The staff shall be trained on:
 - potential hazardous properties that may be associated with input materials, and
 - features that allow hazardous properties and the presence of plastics to be recognised.
- (e) Samples shall be taken on output materials, to verify that they comply with the component material specifications for compost and digestate laid down in CMC 3 and CMC 5 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.
- (f) The output material samples shall be taken on a regular basis with at least the following frequency:

Annual input(tonnes)	Samples / year	
\leq 3 000	1	
3 001 - 10 000	2	
10 001 - 20 000	3	
20 001 - 40 000	4	
40 001 - 60 000	5	

60 001 - 80 000	6
80 001 - 100 000	7
100 001 - 120 000	8
120 001 - 140 000	9
140 001 - 160 000	10
160 001 - 180 000	11
> 180 000	12

- (g) If any tested output material sample fails one or more of the applicable limits specified in the relevant sections of Annexes I and II, the person responsible for quality management referred to in point 5.1.1.1(b) shall:
 - (i) clearly identify the non-conforming output materials and their storage place,
 - (ii) analyse the reasons of the non-conformity and take any necessary action to avoid its repetition,
 - (iii) record in the quality records referred to in point 5.1.4 if reprocessing takes place, or if the output material is eliminated.
- 5.1.4. The quality system shall cover the manufacturer's quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.
- 5.1.4.1. For compost belonging to CMC 3 and digestate belonging to CMC 5, 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:
- (a) a title,
- (b) a version number,
- (c) a date of issue,
- (d) the name of the person who issued it,
- (e) records about the effective control of input materials,
- (f) records about the effective control of the production process,
- (g) records about the effective control of the output materials,
- (h) records of non-conformities,
- (i) reports on all accidents and incidents that occur to the site, their known or suspected causes and actions taken,
- (j) records of the complaints expressed by third parties and how they have been addressed,
- (k) a record of the date, type and topic of training followed by the persons responsible for the quality of the product,

- (l) results of internal audit and actions taken, and
- (m) results of external audit review and actions taken.
- 5.1.5. The quality system shall cover the means of monitoring the achievement of the required product quality and the effective operation of the quality system.
- 5.1.5.1. For compost belonging to CMC 3 and digestate belonging to CMC 5, 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:
- (a) a procedure that defines the responsibilities and requirements for planning and conducting internal audits, establishing records and reporting results shall be established and documented. A report identifying the non-conformities to the quality scheme shall be prepared and all corrective actions shall be reported. The records of the internal audit shall be annexed to the quality management documentation;
- (b) priority shall be given to non-conformities identified by external audits;
- (c) each auditor shall not audit his or her own work;
- (d) the management responsible for the area audited shall ensure that the necessary corrective actions are taken without undue delay;
- (e) internal audit realised in the frame of another quality management system can be taken into account provided that it is completed by an audit of the requirements to this quality system.
- 5.1.6. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of all the quality management elements set out in points 5.1.1 to 5.1.5.
- 5.2. The manufacturer shall lodge an application for assessment of his or her quality system with the notified body of his or her choice, for the EU fertilising products concerned. The application shall include:
- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his or her name and address as well,
- a written declaration that the same application has not been lodged with any other notified body,
- all relevant information for the EU fertilising product category envisaged,
- the documentation concerning the quality system containing all the elements set out in point 5.1,
- the technical documentation referred to in point 2.
- 5.3.1. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 5.1.
- 5.3.2. It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.
- 5.3.3. In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and

product technology concerned, and knowledge of the applicable requirements of this Regulation. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 2 in order to verify the manufacturer's ability to identify the relevant requirements of this Regulation and to carry out the necessary examinations with a view to ensuring compliance of the EU fertilising product with those requirements.

- 5.3.4. The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.
- 5.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- 5.5.1. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.
- 5.5.2. The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 5.1 or whether reassessment is necessary.
- 5.5.3. It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.
- 6. Surveillance under the responsibility of the notified body
- 6.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 6.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:
- the quality system documentation,
- the technical documentation referred to in point 2,
- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned.
- 6.3.1. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.
- 6.3.2. For compost belonging to CMC 3 and digestate belonging to CMC 5, 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:
- (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 table included in point 5.1.3.1(f); and
- (b) during the following years of surveillance: half the sampling frequency indicated in the table included in point 5.1.3.1(f).
- 6.4 In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

- 7. CE marking and EU declaration of conformity
- 7.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 5.2, the latter's identification number to each individual packaging of the EU fertilising product that satisfies the applicable requirements of this Regulation or, where it is supplied without packaging, in a document accompanying the EU fertilising product.
- 7.2. The manufacturer shall draw up a written EU declaration of conformity for an EU fertilising product or type and keep it, together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market. The EU declaration of conformity shall identify the EU fertilising product or type for which it has been drawn up.
- 7.3. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.
- 8. Availability of quality system documentation

The manufacturer shall, for 5 years after the EU fertilising product has been placed on the market, keep at the disposal of the national authorities:

- the documentation referred to in point 5.1.6,
- the information on the changes referred to in points 5.5.1 and 5.5.2, as approved,
- the decisions and reports of the notified body referred to in points 5.5.3, 6.3.1 and 6.4.
- 9. Notified bodies' information obligation
- 9.1. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.
- 9.2. Each notified body shall inform the other notified bodies of quality system approvals which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of quality system approvals which it has issued.
- 10. Authorised representative

The manufacturer's obligations set out in points 3, 5.2, 5.5.1, 7 and 8 may be fulfilled by his or her authorised representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.

ANNEX V

EU Declaration of conformity (No XXX)⁽²⁰⁾

- 1. EU fertilising product (product-, batch-, or type- number):
- 2. Name and address of the manufacturer and, where applicable, its authorised representative:
- 3. This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

- 4. Object of the declaration (identification of the EU fertilising product allowing traceability; it may, where necessary for the identification of the EU fertilising product, include an image):
- 5. The object of the declaration described above is in conformity with:
- Regulation (EU) $2019/1009^{(21)}$,
- other Union harmonisation legislation where applicable:
- 6. References to the relevant harmonised standards or to the common specifications used or references to the other technical specifications in relation to which conformity is declared:
- 7. Where applicable, the notified body ... (name, number) performed ... (description of intervention) and issued the certificate or approval decision ... (number):
- 8. Where applicable, annexed to this EU declaration of conformity are the EU declarations of conformity for the component EU fertilising products of the fertilising product blend.
- 9. Additional information:

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature):

- (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).
- (2) 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).
- (3) 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).
- (4) 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).
- (5) The exclusion of a material from CMC 1 does not prevent it from being an eligible component material by virtue of another CMC stipulating different requirements. See, for instance, CMC 3 on compost, CMCs 4 and 5 on digestate, CMCs 8 and 9 on polymers, CMC 10 on derived products within the meaning of Regulation (EC) No 1069/2009 or CMC 11 on by-products within the meaning of Directive 2008/98/EC.
- (6) In the case of a substance recovered in the European Union, this condition is fulfilled if the substance is the same, within the meaning of point (d)(i) of Article 2(7) of Regulation (EC) No 1907/2006, as a substance registered with a dossier containing the information here indicated, and if information is available to the fertilising product manufacturer within the meaning of point (d)(ii) of Article 2(7) of Regulation (EC) No 1907/2006.
- (7) In the case of an additive recovered in the European Union, this condition is fulfilled if the additive is the same, within the meaning of point (d)(i) of Article 2(7) of Regulation (EC) No 1907/2006, as a substance registered with a dossier containing the information here indicated, and if information is available to the fertilising product manufacturer within the meaning of point (d)(ii) of Article 2(7) of Regulation (EC) No 1907/2006.
- (8) 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.
- (9) 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.
- (10) In the case of an additive recovered in the European Union, this condition is fulfilled if the additive is the same, within the meaning of point (d)(i) of Article 2(7) of Regulation (EC) No 1907/2006, as a substance registered with a dossier containing the information here indicated, and if information is available to the fertilising product manufacturer within the meaning of point (d)(ii) of Article 2(7) of Regulation (EC) No 1907/2006.
- (11) Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).
- (12) In the case of an additive recovered in the European Union, this condition is fulfilled if the additive is the same, within the meaning of point (d)(i) of Article 2(7) of Regulation (EC) No 1907/2006, as a substance registered with a dossier containing the information here indicated, and if information is available to the fertilising product manufacturer within the meaning of point (d)(ii) of Article 2(7) of Regulation (EC) No 1907/2006.
- (13) 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.
- (14) 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

- (15) In the case of a substance recovered in the European Union, this condition is fulfilled if the substance is the same, within the meaning of point (d)(i) of Article 2(7) of Regulation (EC) No 1907/2006, as a substance registered with a dossier containing the information here indicated, and if information is available to the fertilising product manufacturer within the meaning of point (d)(ii) of Article 2(7) of Regulation (EC) No 1907/2006.
- (16) The table will be established by delegated acts referred to in Article 42(5).
- (17) The exclusion of a material from CMC 11 does not prevent it from being an eligible component material by virtue of another CMC stipulating different requirements. See, for instance, CMC 3 on compost, CMCs 4 and 5 on digestate, CMCs 8 and 9 on polymers or CMC 10 on derived products within the meaning of Regulation (EC) No 1069/2009.
- (18) The diameter of the disc must always correspond to the inside diameter of the cylinder.
- (19) NB: When the six peripheral lengths of cord are taut after assembly, the central cord must remain slightly slack.
- (20) It is optional for the manufacturer to assign a number to the EU declaration of conformity.
- (21) Regulation (EU) 2019/1009 of the European parliament and the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1).

Changes to legislation:

There are currently no known outstanding effects for the Regulation (EU) 2019/1009 of the European Parliament and of the Council.