Council of the
European Union

Brussels, 6 May 2022
(OR. en)

8838/22
ADD 1

ENT 66
MI 363
COMPET 302
AGRI 176
ENV 404
CHIMIE 42
IND 150
DELACT 78

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	5 May 2022
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2022) 2882 final, ANNEXES 1 to 4
Subject:	ANNEXES to the COMMISSION DELEGATED REGULATION (EU) .../... amending Regulation (EU) 2019/1009 of the European Parliament and of the Council as regards the requirements applicable to EU fertilising products containing inhibiting compounds and the post processing of digestate

Delegations will find attached document C(2022) 2882 final, ANNEXES 1 to 4.

Encl.: C(2022) 2882 final, ANNEXES 1 to 4

EUROPEAN
COMMISSION

Brussels, 5.5.2022
C(2022) 2882 final

ANNEXES 1 to 4

ANNEXES

to the

COMMISSION DELEGATED REGULATION (EU) .../...

amending Regulation (EU) 2019/1009 of the European Parliament and of the Council as regards the requirements applicable to EU fertilising products containing inhibiting compounds and the post processing of digestate

ANNEX I

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

(1) in point 2 of PFC 1(C), the second indent is replaced by the following:

‘- nitrification, denitrification or urease inhibiting compounds referred to in point 4 of CMC 1 in Part II of Annex II,’;

(2) Section ‘PFC 7’ is amended as follows:

(a) the following point 2a is inserted:

‘2a. An inhibiting compound in a blend shall be present in a concentration, which is within the range of concentrations that ensures the achievement of the reduction rates in the conditions referred to in PFC 5 in Part II of this Annex and, respectively, in point 4 of CMC 1 in Part II of Annex II, at the level of the blend.’.

(b) the introductory sentence in point 3 is replaced by the following:

‘The manufacturer of the blend shall assess the conformity of the blend with the requirements set out in points 1, 2 and 2a 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:’.

ANNEX II

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

(1) Section 'CMC 1' is amended as follows:

(a) point 2 is replaced by the following:

'2. All substances incorporated into the EU fertilising product, on their own or in a mixture, except polymers, 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;

(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, 9 or 10 (only for magnesia) of Annex V to that Regulation.';

(b) point 4 is replaced by the following:

'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 a nitrification, a denitrification or a urease inhibiting compound, and the following rules shall apply:

(a) The nitrification inhibiting compound shall inhibit the biological oxidation of ammoniacal nitrogen (NH_3-N) contained in the EU fertilising product to nitrite nitrogen (NO_2^-), thus slowing the formation of nitrate nitrogen (NO_3^-).

The ammoniacal nitrogen (NH_3-N) oxidation rate shall be measured by either of the following:

(i) ammoniacal nitrogen (NH_3-N) disappearance;

(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 inhibiting compound has not been added, a soil sample containing the nitrification inhibiting compound 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.

The nitrification inhibiting compound shall be present in the EU fertilising product in a concentration, which is within the range of concentrations that ensures the achievement of such a reduction.

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 inhibiting compound shall inhibit the formation of nitrous oxide (N_2O) contained in the EU fertilising product 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 inhibiting compound has not been added, an *in vitro* test containing the denitrification inhibiting compound 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.

The denitrification inhibiting compound shall be present in the EU fertilising product in a concentration, which is within the range of concentrations that ensures the achievement of such a reduction.

(c) The urease inhibiting compound shall inhibit hydrolytic action on urea (CH_4N_2O) contained in the EU fertilising product by the urease enzyme, primarily targeted to reduce ammonia volatilisation.

Compared to a control sample where the urease inhibiting compound has not been added, an in vitro test containing the urease inhibiting compound 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.

The urease inhibiting compound shall be present in the EU fertilising product in a concentration, which is within the range of concentrations that ensures the achievement of such a reduction.

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).';

(2) in point 1(d) of Section 'CMC 3', sub-point (i) is replaced by the following:

'(i) the additive complies with the requirement set out in point 2 in CMC 1 and';

(3) Section 'CMC 4' is amended as follows:

(a) in point 1(b), sub-point (i) is replaced by the following:

'(i) the additive complies with the requirement set out in point 2 in CMC 1 and';

(b) the following points 3a, 3b, 3c and 3d are inserted:

'3a. An EU fertilising product may contain a solid or liquid fraction, obtained by mechanical separation of a digestate compliant with points 1 to 3.

3b. An EU fertilising product may contain a digestate compliant with points 1 to 3, or a fraction compliant with point 3a, from which all or part of the soluble ammonium and/or of the phosphate has been removed to recover nitrogen and/or phosphorus, without the intention to otherwise modify the digestate or the fraction.

3c. An EU fertilising product may contain a digestate compliant with points 1 to 3 or point 3b, as well as a fraction compliant with point 3a, which have undergone only physical processing to remove water without the intention to otherwise modify the digestate or the fraction.

3d. Additives needed in the post processing of a digestate or a fraction in accordance with points 3a, 3b and 3c may be used provided that:

(a) the additive complies with the requirement set out in point 2 in CMC 1;

(b) the concentration of the additives needed in each of the processes does not exceed 5% of the weight of the digestate or fraction used as input in the respective process.';

(c) in point 4, the introductory sentence is replaced by the following:

'The digestate or a fraction referred to in points 3a, 3b and 3c shall meet at least one of the following stability criteria:';

(4) Section 'CMC 5' is amended as follows:

(a) in point 1(d), sub-point (i) is replaced by the following:

‘(i) the additive complies with the requirement set out in point 2 in CMC 1 and’;

(b) the following points 3a, 3b, 3c and 3d are inserted:

‘3a. An EU fertilising product may contain a solid or liquid fraction obtained by mechanical separation of a digestate compliant with points 1 to 3.

3b. An EU fertilising product may contain a digestate compliant with points 1 to 3, or a fraction compliant with point 3a, from which all or part of the soluble ammonium and/or of the phosphate has been removed to recover nitrogen and/or phosphorus, without the intention to otherwise modify the digestate or the fraction.

3c. An EU fertilising product may contain a digestate compliant with points 1 to 3 or point 3b, as well as a fraction compliant with point 3a, which have undergone only physical processing to remove water without the intention to otherwise modify the digestate or the fraction.

3d. Additives needed in the post processing of a digestate or a fraction in accordance with points 3a, 3b and 3c may be used provided that:

(a) the additive complies with the requirement set out in point 2 in CMC 1;

(b) the concentration of the additives needed in each of the processes does not exceed 5% of the weight of the digestate or fraction used as input in the respective process.’;

(c) point 4 is replaced by the following:

‘4. The digestate or the fraction referred to in points 3a, 3b and 3c shall not contain more than 6 mg/kg dry matter of PAH_{16} (**).’,

(d) in point 5, the introductory sentence is replaced by the following:

‘The digestate or the fraction referred to in points 3a, 3b and 3c shall contain:’,

(e) in point 6, the introductory sentence is replaced by the following:

‘The digestate or the fraction referred to in points 3a, 3b and 3c shall meet at least one of the following stability criteria:’;

(5) in Section ‘CMC 6’, point 2 is replaced by the following:

‘2. All substances incorporated into the EU fertilising product, on their own or in a mixture, shall comply with the requirement set out in point 2 in CMC 1.’;

(6) in Section ‘CMC 11’, point 2 is replaced by the following:

‘2. The by-products shall comply with the requirement set out in point 2 in CMC 1.’;

(7) in Section ‘CMC 12’, point 13 is replaced by the following:

‘13. The precipitated phosphate salts or derivates shall comply with the requirement set out in point 2 in CMC 1.’;

(8) in Section ‘CMC 13’, point 8 is replaced by the following:

‘8. The thermal oxidation materials or derivates shall comply with the requirement set out in point 2 in CMC 1.’;

(9) Section ‘CMC 14’ is amended as follows:;

(a) point 3(c) is deleted;

(b) point 7 is replaced by the following:

‘7. The pyrolysis and gasification material shall comply with the requirement set out in point 2 in CMC 1.’;

(10) in Section ‘CMC 15’, point 10 is replaced by the following:

‘10. The high purity material shall comply with the requirement set out in point 2 in CMC 1.’.

(*) 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.

(**) Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene.

ANNEX III

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

(1) Section 'PFC 1' is amended as follows:

(a) point 3 is replaced by the following:

'3. The following rules apply to fertilisers containing inhibiting compounds, 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 inhibiting compound 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 inhibiting compound content shall be expressed as a % by mass of the nitrate (NO_3^-) present;

(d) the urease inhibiting compound content shall be expressed as a % by mass of the total nitrogen (N) present as urea nitrogen (CH_4N_2O).';

(b) in point 4(a), sub-point (ii) is replaced by the following:

'(ii) nitrification, denitrification or urease inhibiting compounds referred to in point 4 of CMC 1 in Part II of Annex II,';

(2) Section 'PFC 5: INHIBITOR' is replaced by the following:

'PFC 5: INHIBITOR

1. All ingredients shall be declared by product weight or volume in descending order of magnitude.

2. The content of the inhibiting compound(s) as % by mass or volume shall be declared.

3. The use instructions referred to in point 1(d) in Part I of this Annex shall contain information on:

(a) the types of EU fertilising products with which the inhibitor may be mixed, in particular:

(i) for the nitrification inhibitor referred to in PFC 5(A) in Part II of Annex I, an EU fertilising product in which at least 50 % of the total nitrogen (N) content consists of the nitrogen (N) forms ammonium (NH_4^+) and urea (CH_4N_2O);

(ii) for the urease inhibitor referred to in PFC 5(C) in Part II of Annex I, an EU fertilising product in which at least 50 % of the total nitrogen (N) content consists of the nitrogen (N) form urea (CH_4N_2O);

(b) the minimum and maximum recommended concentration of inhibiting compound(s) when mixed with a fertiliser prior to its use:

(i) for the nitrification inhibitor referred to in PFC 5(A) in Part II of Annex I, as a % by mass of the total nitrogen (N) present as ammonium nitrogen (NH_4^+) and urea nitrogen (CH_4N_2O);

(ii) for the denitrification inhibitor referred to in PFC 5(B) in Part II of Annex I, as a % by mass of the nitrate (NO_3^-) present;

(iii) for the urease inhibitor referred to in PFC 5(C) in Part II of Annex I, as a % by mass of the total nitrogen (N) present as urea nitrogen (CH_4N_2O).';

(3) in Section 'PFC 7: FERTILISING PRODUCT BLEND' the following paragraph is added:

'Where the fertilising product blend contains one or more inhibitors belonging to PFC 5, the use instructions referred to in point 3 in PFC 5 in Part II of this Annex shall not be added.'.

In Part III of Annex III, Section 'PFC 1: FERTILISER' is replaced by the following:

'PFC 1: FERTILISER

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

Inhibiting compounds	**Permissible tolerance for the declared content of inhibiting compounds**
Concentration below or equal to 2 %	± 20 % of the declared value
Concentration of more than 2 %	± 0,3 percentage points in absolute terms'

ANNEX IV

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

(1) in point 1.1, sub-point (a) is replaced by the following:

‘(a) virgin material substances or mixtures as specified in CMC 1 in Part II of Annex II, except a nitrification, a denitrification or a urease inhibiting compound,’;

(2) in point 3.1, sub-point (a) is replaced by the following:

‘(a) nitrification, denitrification or urease inhibiting compound as specified in CMC 1 in Part II of Annex II,’.