

ANNEX II

Component Material Categories (CMCs)

PART II

REQUIREMENTS RELATED TO CMCS

CMC 1: VIRGIN MATERIAL SUBSTANCES AND MIXTURES

1. An EU fertilising product may contain substances and mixtures, except⁽¹⁾:
 - (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⁽²⁾, 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.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2019/1009 of the European Parliament and of the Council, CMC 1: VIRGIN MATERIAL SUBSTANCES AND MIXTURES. (See end of Document for details)

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 ($\text{NH}_3\text{-N}$) to nitrite nitrogen (NO_2^-), thus slowing the formation of nitrate nitrogen (NO_3^-).

The ammoniacal nitrogen ($\text{NH}_3\text{-N}$) oxidation rate shall be measured either by:

- (i) ammoniacal nitrogen ($\text{NH}_3\text{-N}$) 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 ($\text{NH}_3\text{-N}$) 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 ($\text{CH}_4\text{N}_2\text{O}$).

- (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 (N_2O) 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 ($\text{CH}_4\text{N}_2\text{O}$) 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 ($\text{CH}_4\text{N}_2\text{O}$) 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 ($\text{CH}_4\text{N}_2\text{O}$).

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2019/1009 of the European Parliament and of the Council, CMC 1: VIRGIN MATERIAL SUBSTANCES AND MIXTURES. (See end of Document for details)

- (1) 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.
- (2) 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.

Changes to legislation:

There are currently no known outstanding effects for the Regulation (EU) 2019/1009 of the European Parliament and of the Council, CMC 1: VIRGIN MATERIAL SUBSTANCES AND MIXTURES.