COMMISSION DELEGATED REGULATION (EU) 2022/1519

of 5 May 2022

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ([1]), and in particular Article 42(1) thereof,

Whereas:

(1) A fertilising product, which meets the requirements laid down in Annexes I and II to Regulation (EU) 2019/1009 for the relevant product function category ('PFC') and component material category ('CMC') respectively, is labelled in accordance with Annex III to that Regulation and has successfully passed the conformity assessment procedure laid down in Annex IV to Regulation (EU) 2019/1009, can then be CE marked and can move freely in the internal market as an EU fertilising product.

(2) While preparing for the transition to new harmonisation rules, both Member States and interested stakeholders informed the Commission about the need to adapt some of the technical provisions in the annexes to Regulation (EU) 2019/1009. Those adaptations are necessary to facilitate internal market access for fertilising products that are agronomically efficient, safe and already widely traded on the market. Some of those amendments facilitate the free movement of such products, i.e. safe and agronomically efficient fertilising products, by improving the consistency with other legal acts and policy objectives of the Union. Other amendments are necessary in order to avoid situations in which significant categories of fertilising products would inadvertently be excluded from the harmonisation rules.

(3) Regulation (EU) 2019/1009, as amended by Commission Delegated Regulation (EU) 2021/1768 ([2]), allows manufacturers to use certain types of polymers in EU fertilising products if those are compliant with the conditions laid down for CMC 1 and CMC 11 in Annex II to Regulation (EU) 2019/1009. One of the conditions is that the polymer is registered in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([3]). In the Communication titled 'Chemicals Strategy for Sustainability, towards a Toxic-Free Environment' ([4]), the Commission announced the revision of Regulation (EC) No 1907/2006, extending a registration obligation to certain polymers. Consequently, for reasons of coherence and consistency, the registration obligation of polymers should, as a first step, be regulated under Regulation (EC) No 1907/2006, as the discussions for its revision offer a broader context and the possibility of taking a holistic approach, before becoming applicable under Regulation (EU) 2019/1009.

([1]) OJ L 170, 25.6.2019, p. 1.

([2]) Commission Delegated Regulation (EU) 2021/1768 of 23 June 2021 amending, for the purpose of its adaptation to technical progress, Annexes I, II, III and IV to Regulation (EU) 2019/1009 of the European Parliament and of the Council laying down rules on the making available on the market of EU fertilising products (OJ L 356, 8.10.2021, p. 8).

([3]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

([4]) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Chemicals Strategy for Sustainability, towards a Toxic-Free Environment, COM(2020) 667 final of 14 October 2020.

(4) Regulation (EU) 2019/1009 lays down an obligation for the registration of magnesia in accordance with Regulation (EC) No 1907/2006. However, Regulation (EC) No 1907/2006 exempts magnesia, which is not chemically modified, from the registration obligation, as the registration is deemed inappropriate or unnecessary for that substance and its exemption from the registration obligation does not jeopardise the objectives of that Regulation. Magnesia has a long history of use in fertilisers and has no harmonised classification in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([5]). Taking that into account and in order to facilitate the access to the internal market of fertilisers containing magnesia as EU fertilising products, the registration obligation laid down in Regulation (EU) 2019/1009 should no longer apply to magnesia used in fertilisers.

(5) Regulation (EU) 2019/1009 lays down requirements for inhibitors as EU fertilising products belonging to PFC 5 and for EU fertilising products containing inhibitors as a component material belonging to CMC 1. To avoid any confusions, the terminology used in that Regulation should be amended to reflect the distinction between the two situations. Thus, the term 'inhibiting compound' should be used whenever it concerns a substance or mixture which improves the nutrient release pattern of a nutrient by delaying or stopping the activity of specific groups of micro-organisms or enzyme. The term 'inhibitor' should be used only when it refers to EU fertilising products belonging to PFC 5. This distinction is important as inhibitors may be mixtures containing other substances, like stabilisers, in addition to inhibiting compounds. Correct use of those terms is necessary to facilitate the free movement of EU fertilising products, by clearly laying down the rules applicable in each situation.

(6) Regulation (EU) 2019/1009 includes requirements ensuring that the inhibiting compounds are efficient, but does not lay down requirements on the efficiency of the fertiliser or the blend containing such an inhibiting compound. The use of efficient products containing such substances helps avoiding the environmental pollution caused by the leaching of nitrogen. Commission Communications titled 'Pathway to a Healthy Planet for All EU Action Plan: "Towards Zero Pollution for Air, Water and Soil"' ([6]) and 'A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system' ([7]) mention the environmental concerns and the ambitious targets to reduce nutrient losses by 50 % by 2030. It is therefore important to ensure that the EU fertilising products, which contain inhibiting compounds, are efficient. Therefore, Regulation (EU) 2019/1009 should be amended to include a requirement that inhibiting compounds are present in fertilisers (PFC 1) or in fertilising product blend (PFC 7) in a concentration, which is within the range of concentrations that ensures the efficiency of the inhibiting compound. Furthermore, additional labelling requirements should ensure that the manufacturers of inhibitors referred to in PFC 5 provide clear instructions on how to mix such products with a fertiliser to ensure their efficiency.

(7) Regulation (EU) 2019/1009 lays down rules on the use of fresh crop digestate and on digestate other than fresh crop digestate, hereafter commonly referred to as 'digestate', as component materials in EU fertilising products. That Regulation lays down rules for the digestion processes. However, it does not provide for any other rules for post processing of the digestate.

(8) The Joint Research Centre (JRC) report titled 'End-of-waste criteria for biodegradable waste subjected to biological treatment (compost & digestate): Technical proposals' ([8]) states that digestate is often used in agriculture, either as a whole or following separation in a solid and liquid fraction. That separation facilitates the storing of materials and their long-distance transport, which is especially important for a CE marked product. The mechanical separation of a digestate in the solid and liquid fractions is a commonly used method in some Member States and seems to be a well-established method according to a recent study titled 'Digestate and compost as fertilisers: Risk assessment and

([5]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

([6]) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Pathway to a Healthy Planet for All EU Action Plan: 'Towards Zero Pollution for Air, Water and Soil', COM(2021) 400 final of 12 May 2021.

([7]) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system, COM(2020) 381 final of 20 May 2020.

([8]) Saveyn H, Eder P. End-of-waste criteria for biodegradable waste subjected to biological treatment (compost and digestate): Technical proposals, EUR 26425, Publications Office of the European Union, 2013. JRC87124.

risk management options' ([9]). The separation of a digestate in the solid and liquid fractions could pose limited risks if conditions regarding the post digestion process and the additives to be used are laid down. Therefore, Regulation (EU) 2019/1009 should be amended to include this post digestion process, under the conditions that the additives used do not exceed a certain concentration and are registered in accordance with Regulation (EC) No 1907/2006. Allowing these processes in Regulation (EU) 2019/1009 is necessary in order to facilitate the access to the internal market for EU fertilising products containing digestate and to adapt the requirements laid down for these component material categories to technical progress. It will also create new opportunities for the recovery of bio-waste, which is in line with the overall ambitious plans for a circular economy.

(9) Besides the mechanical separation of a digestate in the solid and liquid fractions, other processes are commonly used to remove water from a digestate or its fractions. Regulation (EU) 2019/1009 should allow manufacturers to further process the digestate or its fractions in order to extract water, without the intention to otherwise chemically modify the component materials. Furthermore, nitrogen or phosphorus may be recovered out of a digestate via stripping or precipitation. To close the loop, it is important not only to create the possibility for the recovery of these nutrients out of digestate, but also to allow for the use of the remaining digestate in EU fertilising products, given that it contains various other nutrients and organic matter. In addition, requirements for the use of additives needed for such processes should be laid down.

(10) Regulation (EU) 2019/1009 applies without prejudice to Regulation (EU) 2019/1021 of the European Parliament and of the Council ([10]), which lays down general rules applicable to persistent organic pollutants. Regulation (EU) 2019/1009 lays down a limit value of 0,8 mg/kg dry matter of ndl-PCB for pyrolysis and gasification materials belonging to CMC 14. However, in accordance with Regulation (EU) 2019/2021, PCB are not to be present in substances or mixtures placed on the EU market. To ensure coherence with Regulation (EU) 2019/1021 and clarity as to the fact that no ndl-PCB is to be contained in EU fertilising products with pyrolysis or gasification materials, that limit value in Regulation (EU) 2019/1009 should be deleted.

(11) Regulation (EU) 2019/1009 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

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

(1) Annex I is amended in accordance with Annex I to this Regulation;

(2) Annex II is amended in accordance with Annex II to this Regulation;

(3) Annex III is amended in accordance with Annex III to this Regulation;

(4) Annex IV is amended in accordance with Annex IV to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

([9]) Digestate and compost as fertilisers: Risk assessment and risk management options, 2019, 40039CL003i3.

([10]) Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 5 May 2022.

For the Commission
The President
Ursula VON DER LEYEN

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.

(*) 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.';

(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} (**).

(**) 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.';

(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.'.

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,'.