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COVER NOTE

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

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To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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Subject: COMMISSION DELEGATED REGULATION (EU) .../... of 5.5.2022 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

Delegations will find attached document C(2022) 2882 final.

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Brussels, 5.5.2022
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COMMISSION DELEGATED REGULATION (EU) .../...

of 5.5.2022

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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) 2019/1009 of the European Parliament and of the Council¹ lays down rules on the making available on the market of EU fertilising products. It repeals Regulation (EC) No 2003/2003 of the European Parliament and of the Council² as of 16 July 2022.

Regulation (EU) 2019/1009 lays down harmonisation rules for various categories of fertilising products. This Regulation lays down radically different harmonisation rules for inorganic fertilisers already regulated under varied types of EC fertilisers in Regulation (EC) No 2003/2003. It also lays down harmonisation rules for extensive categories of products, which are not yet subject to harmonisation rules, such as organic and organo-mineral fertilisers, soil improvers or growing media.

While preparing the transition to the new harmonisation rules, both Member States and interested stakeholders informed the Commission on the need to adapt some technical provisions in the annexes to Regulation (EU) 2019/1009. Part of these adaptations have already been introduced by Commission Delegated Regulation (EU) 2021/1768³.

Certain 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, 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.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Member States have been consulted in the Commission expert group on Fertilising Products (E01320) according to the rules of the Interinstitutional Agreement on Better Law-Making of 13 April 2016⁴.

Details of these consultations can be found in the minutes of the meetings held on 22-23 November 2021 and 25 March 2022, as well as in the various position papers of interested stakeholders publicly available on the CIRCABC page of the group, at the following link:

<https://circabc.europa.eu/ui/group/36ec94c7-575b-44dc-a6e9-4ace02907f2f/library/b8e01334-4d39-445d-bf4e-589356d55b1f>

Member States and interested stakeholders were largely supportive of the adoption of this delegated Regulation.

The draft delegated Regulation has been published for feedback on the Better Regulation portal. 25 technical contributions have been received, which were largely supportive.

¹ 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, OJ L 170, 25.6.2019, p. 1.

² Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers, OJ L 304, 21.11.2003, p. 1.

³ 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.

⁴ OJ L 123, 12.5.2016, p. 1.

On the amendments concerning inhibitors, based on the questions raised in the public feedback regarding the testing of products with inhibiting compounds, the delegated Regulation has been further clarified so that not to request additional tests comparing to those already requested in Regulation (EU) 2019/1009. Thus, while the testing of the efficiency of the inhibiting compound does not change, the delegated Regulation sets out a requirement that the final product will have to contain inhibiting compounds in such a concentration as to ensure that the product itself is also efficient. More precisely, the proportion nutrient/inhibiting compound used for the testing of the efficiency of the inhibiting compound will have to be the same in the product itself, too.

On the amendments concerning the post processing of digestate, following the feedback received, several changes have been introduced: (1) to further facilitate the recovery of nutrients, the digestate after the recovery of phosphorus by precipitation will be eligible as component material in EU fertilising products; (2) additives needed for any of the post processes expressly mentioned therein have to comply with specific conditions regarding the REACH registration and the concentration.

As regards the REACH registration, to ensure coherence, any references to the REACH registration similar to point 2 in CMC 1 in any of the other CMCs is replaced by a cross reference to that provision in CMC 1.

The draft delegated Regulation has also been notified based on Article 2(9)(2) of the Agreement on Technical Barriers to Trade and no comments have been received.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated act amends technical provisions in Annexes I, II, III and IV to Regulation (EU) 2019/1009. The legal basis of this delegated act is Article 42(1) of Regulation (EU) 2019/1009.

**COMMISSION DELEGATED REGULATION (EU) .../...of 5.5.2022 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 2003/2003¹, 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) 2021/1768², 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 Council³. In the Communication titled 'Chemicals Strategy for

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

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.

- (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 Council⁵. 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

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.

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

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 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

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.

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

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 Council¹⁰, 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*.

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

Done at Brussels, 5.5.2022

For the Commission
The President
Ursula VON DER LEYEN

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).