Council of the
European Union

Brussels, 24 June 2021
(OR. en)

10166/21

ENT 110
MI 504
AGRILEG 134
ENV 459
CHIMIE 62
IND 181
DELACT 132

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	23 June 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2021) 4250 final
Subject:	COMMISSION DELEGATED REGULATION (EU) …/... of 23.6.2021 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

Delegations will find attached document C(2021) 4250 final.

Encl.: C(2021) 4250 final

EUROPEAN
COMMISSION

Brussels, 23.6.2021
C(2021) 4250 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 23.6.2021

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

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) 2019/1009 of the European Parliament and of the Council[1] 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 Council[2] 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. Some of these amendments are necessary in order to achieve consistency with other pieces of EU legislation or secure the high level of protection that Regulation (EU) 2019/1009 aims to achieve. Others are necessary to avoid unintended situations in which important categories of fertilising products would inadvertently be excluded from the harmonisation rules for not being able to comply with some technical provisions. By securing the desired level of protection and removing undesired market access barriers, the amendments will thus facilitate internal market access and free movement for agronomically efficient fertilising products which are subject to significant trade on the internal market and which do not present a risk to health, safety or the environment, in accordance with the Commission empowerment in Article 42(1) of Regulation (EU) 2019/1009.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Member States were 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 2016[3] .

Details of these consultations can be found in the minutes of the meetings held on 7 November 2019, 25 June 2020, 24 November 2020 and 23 March 2021, 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

---

[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. 1–194.

[3] OJ L 123, 12.5.2016, p. 1.

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. Over 60 contributions have been submitted, most of them focussing on punctual provisions.

On the amendments to Annex I

On the requirement for pharmacologically active substances with a reference point for action established in accordance with Commission Regulation (EU) 2019/1871[4] not to exceed that reference point, concerns were expressed that it would increase the analytical costs. Such a requirement is however necessary to ensure the safety of the EU fertilising products. It is part of a set of measures replacing the existing provisions on substances with a maximum residues limit (MRL) determined in or based on EU rules[5]. The existing provisions in the Fertilising Products Regulation impose an obligation upon the manufacturer to provide use instructions, which would not lead to the exceedance of those limits in crops. Compared to the major difficulties in complying with the existing obligation, it is reasonable to estimate that the costs of implementing the new obligation would be lowered and the burden of proof considerably facilitated.

The provision on the presence of active substances within the meaning of Regulation (EC) No 1107/2009 of the European Parliament and of the Council[6] in EU fertilising products was found not clear. The text has been redrafted to make it even clearer that while EU fertilising products may include such active substances, it is necessary that the product itself does not have a plant protection function within the meaning of that Regulation. It was also proposed in the public feedback to introduce a maximum concentration for any active substance in EU fertilising products. However, this approach might not lead to satisfactory solutions for all active substances such as copper, for which there are already various maximum limits in the Fertilising Products Regulation depending on the product function category. In addition, the amendment is a mere clarification of the existing provisions in Article 1(1)(b) of the Fertilising Products Regulation stating that this Regulation does not apply to plant protection products, which are products that both contain an active substance and have a plant protection function. It is therefore estimated that a case-by-case analysis to determine if a product

---

4 Commission Regulation (EU) 2019/1871 of 7 November 2019 on reference points for action for non-allowed pharmacologically active substances present in food of animal origin and repealing Decision 2005/34/EC (OJ L 289, 8.11.2019, p. 41).

5 In particular: 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); 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); 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); 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).

6 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

containing an active substance may be an EU fertilising product or a plant protection product remains the most suitable and adaptable solution.

In the public feedback, a proposal was put forward to extend the micronutrient fertiliser typology 'UVCB[7] iron chelates' to other micronutrient chelates. This is coherent with the amendments to Annex II, where the requirement on the pH stability of a chelating agent is adapted precisely to include substances chelating a greater variety of micronutrients.

On the application of the limit-value for nickel to the bioavailable content in growing media out of mineral constituents, most of the contributions welcomed the application of this exception only to nickel, and not to all contaminants. Some were of the view that the growing media out of mineral constituents benefiting from this derogation should not be limited to professional use. However, this proposal could not be taken on board because it is the professional use that considerably increases the recycling of these materials. Furthermore, the text as formulated is aligned with the corresponding provision in Commission Decision (EU) 2015/2099[8].

On the amendments to Annex II

On the use of certain polymers as component materials in EU fertilising products, based on the public feedback received it has been clarified that water-soluble polymers are to be used as component materials. In addition, some of the contributions insisted that such polymers should not be registered based on Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH Regulation)[9]. While, indeed, there is currently no obligation to register polymers under REACH, such a requirement in the Fertilising Products Regulation is currently deemed appropriate in order to ensure that the safety of the use of such polymers on soils as fertilising products is assessed.

On the inclusion of fiberisation among the exhaustive lists of processes in Component Material Category (CMC) 2, many concerns were expressed concerning the requirements limiting the maximum temperature and the additives to be used. It has been shown that various fiberisation processes of wood would be excluded from CMC 2. The conditions concerning the maximum temperature and the use only of water as additive are however necessary to ensure that the plants or plant parts are not chemically modified. This is essential in CMC 2, where no REACH registration is required and there are no other safety requirements. Materials obtained through fiberisation at higher temperature could be covered by CMC 1, where their safety would be assessed in a REACH registration if they were chemically modified substances.

---

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

8 Commission Decision (EU) 2015/2099 of 18 November 2015 establishing the ecological criteria for the award of the EU Ecolabel for growing media, soil improvers and mulch (OJ L 303, 20.11.2015, p. 75).

9 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).

On the amendments to Annex III

The labelling requirement concerning MRLs has been clarified based on the public feedback received. The situation covered by this provision has two premises: firstly, a component material of an EU fertilising product, if placed on the market as food or feed, would have been subject to the EU rules on MRLs; and, secondly, the said limits are exceeded in the component material. In such cases, the manufacturer of the EU fertilising products will mention on the label the concentration of the said substance in the final product, together with a warning to use it in such a way as not to exceed the limit in crops.

On tolerances, the feedback received was very divergent. On one hand, it was stated that the tolerance rules should not be amended because they can be met with the existent technical capacities. On the other hand, the changes were welcomed and additional changes concerning the tolerances for organic and organo-mineral fertilisers were proposed in particular due to their high content of organic matter leading to higher variations in certain parameters. It was also proposed to include tolerances for quantity varying depending on the size of the packages. The tolerance for the labelling of the quantity of a fertilising product blend was found too complicated. The amendments in this Regulation are however retained as in the draft submitted to the public consultation. They are meant to avoid situations in which certain EU fertilising products would be excluded inadvertently from the single market for not being able to comply with the existing tolerance rules. Depending on the evolution of the standardisation work in support of the Fertilising Products Regulation and the technical progress, the tolerance rules may be adapted in future, if needed.

On the amendments to Annex IV

In the public feedback, concerns were expressed on the possibility of creating a misunderstanding that Modules B+C could no longer be used for plant biostimulants and inhibitors. However, the amendment is clear: Modules B+C may be used for plant biostimulants and inhibitors as long as they are not containing a component material for which Module D1 is mandatory. The draft delegated Regulation has also been notified based on Article 2(9)(2) of the Agreement on Technical Barriers to Trade. No comments have been submitted.

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 23.6.2021 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

(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) Regulation (EU) 2019/1009 empowers the Commission to amend Annexes I (partly), II, III and IV thereto.

(3) 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. Some of those amendments are necessary in order to improve consistency with other pieces of Union legislation, which would facilitate internal market access and the free movement of safe and agronomically efficient fertilising products. Some amendments are necessary to secure the high level of protection that Regulation (EU) 2019/1009 aims to achieve, thereby ensuring that EU fertilising products having access to the internal market by virtue of that Regulation do not present a risk to health, safety or the environment. Other amendments are necessary in order to avoid situations in which significant categories of fertilising products would inadvertently be excluded from the harmonisation rules. Those amendments will secure internal market access for fertilising products that are agronomically efficient, safe, and already widely traded on the market.

(4) Regulation (EU) 2019/1009 lays down rules for EU fertilising products containing a substance with maximum residue limit values for food and feed laid down in

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

accordance with Council Regulation (EEC) No 315/93[2], in Regulation (EC) No 396/2005 of the European Parliament and of the Council[3], in Regulation (EC) No 470/2009 of the European Parliament and of the Council[4], or in Directive 2002/32/EC of the European Parliament and of the Council[5]. The manufacturer is obliged to provide use instructions to ensure that the intended use of the EU fertilising product does not lead to the exceedance of the maximum limit values for food and feed. In addition, the manufacturer is to include in the technical documentation the results of calculations that prove compliance with this requirement. In the discussions on how to implement this obligation, it has become clear that it is impossible for manufacturers to comply therewith, thus preventing agronomically efficient, safe, and already widely traded fertilising products from passing the conformity assessment and accessing the internal market under Regulation (EU) 2019/1009. Those obligations should therefore be replaced by obligations that are more proportionate and implementable in two aspects.

(5) Firstly, the exceedance of those maximum limits or levels in crops can be prevented by providing correct information to the end-user on the label. Consequently, Regulation (EU) 2019/1009 should be amended so as to impose an obligation upon the manufacturer to inform the end-user whenever the EU fertilising product contains a component material which, if placed on the market as food or feed, exceeds the maximum limits or levels set in Regulations (EC) No 470/2009 or (EC) No 396/2005, in accordance with Regulation (EEC) 315/93, or in Directive 2002/32/EC. Furthermore, in order to ensure a high level of protection of human health, animal health and the environment in relation to feed additives, Regulation (EU) No 1831/2003 of the European Parliament and of the Council[6] should be added. In this way, the end-user will be in a position to take all necessary measures to ensure that the crop is compliant with the food and feed rules.

(6) Secondly, additional measures are needed regarding some pharmacologically active substances already covered by Regulation (EC) No 470/2009. The approach should be different depending on whether it is an allowed substance listed in Table 1 in the Annex to Commission Regulation (EU) No 37/2010[7], and for which a maximum residue limit may have been set, or it is a non-allowed substance with a reference point

---

[2] 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).

[3] 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).

[4] 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).

[5] 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).

[6] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

[7] Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

for action laid down in Commission Regulation (EU) 2019/1871[8]. Residues of an allowed substance may be present in an EU fertilising product only if the said substance is listed in Table 1 in the Annex to Regulation (EU) No 37/2010. However, a non-allowed pharmacologically active substance, which is more hazardous to the health of the consumer when present in foodstuff, should not be present above its reference point of action in an EU fertilising product either.

(7) An EU fertilising product may also contain active substances within the meaning of Regulation (EC) No 1107/2009 of the European Parliament and of the Council[9]. As Regulation (EU) 2019/1009 does not cover plant protection products, it should be made clear in the text of that regulation that an EU fertilising product containing an active substance must not have a plant protection function within the meaning of Regulation (EC) No 1107/2009. This clarification is needed to ensure consistency with Regulation (EC) No 1107/2009, which will facilitate the implementation of the harmonisation rules both by economic operators and by national authorities, thereby facilitating access to the internal market based on Regulation (EU) 2019/1009.

(8) Regulation (EU) 2019/1009 contains an exhaustive list of typologies for a straight inorganic micronutrient fertiliser, as well as their corresponding descriptions and minimum micronutrient content. For micronutrient salt fertiliser, 10% by mass of the fertiliser consists of a water-soluble micronutrient. However, there are fertilisers based on carbonate or phosphate salts that have micronutrients that are not water-soluble. This does not affect their performance as fertilisers or the uptake of nutrients in the crop. Such micronutrient salt fertilisers should therefore be allowed access to the internal market by removing the water-soluble condition. For UVCB[10] chelates, only iron chelates are listed. However, other micronutrients may also be UVCB chelates and may be slowly released to plants. Slow release fertilisers are useful in preventing nutrient pollution in soils, by slowly releasing the micronutrients and thus increasing the chances of their absorption by the plants. It is, therefore, appropriate to include such niche products within the scope of the harmonisation rules and promote their free movement on the internal market.

(9) Regulation (EU) 2019/1009 lays down limit values for contaminants, including nickel, in a growing medium, which is an EU fertilising product other than soil *in situ*, the function of which is for plants or mushrooms to grow in. Regulation (EU) 2019/1009 sets harmonisation rules for this type of fertilising product. There are already numerous kinds of growing media on the market, based on national rules and with very diverse characteristics, which could be candidates for becoming EU fertilising products. However, the limit value for nickel set out in Regulation (EU) 2019/1009 for all types of growing media creates difficulties for some growing media containing solely constituents of mineral origin. Such products are niche products that comply with the principles of the circular economy and already satisfy the EU Ecolabel criteria

---

[8] Commission Regulation (EU) 2019/1871 of 7 November 2019 on reference points for action for non-allowed pharmacologically active substances present in food of animal origin and repealing Decision 2005/34/EC (OJ L 289, 8.11.2019, p. 41).

[9] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

[10] UVCB: Substance of unknown or variable composition, complex reaction products or biological materials.

established for growing media by Commission Decision (EU) 2015/2099[11]. In this Decision, a distinction is made between mineral growing media and other categories of growing media as regards the methods of determining the content of contaminants, including nickel. Thus, for all growing media except mineral growing media, the total content of the contaminant is to be determined, while for mineral growing media only the bioavailable content is to be determined. This distinction is justified by the fact that mineral growing media are usually manufactured at high temperatures, producing a strong chemical bond of contaminants with the structure of the mineral constituents, limiting the extent to which such contaminants are biologically available. However, such a distinction is not made in Regulation (EU) 2019/1009. Based on the information available, while mineral growing media available on the market would comply with the limit value set for nickel in Regulation (EU) 2019/1009 if only the bioavailable content of the contaminant is to be determined, they cannot comply with the same limit if the total content is to be determined, as is currently required. It is therefore important to ensure consistency between the requirements for the CE marking of those products based on Regulation (EU) 2019/1009 and applying the Ecolabel, in order to avoid the unintended situation in which products safe for the environment and therefore having an Ecolabel would be outside the scope of the harmonisation rules. Thus, the limit value for nickel laid down in Annex I to Regulation (EU) 2019/1009 should apply only to the bioavailable content for mineral growing media.

(10) As a safeguard measure, that rule should apply only where the use of those products is limited to professional use in horticultural applications, green roofs or green walls. This would ensure a better handling and a higher recovery rate of the used growing media, with real possibilities of recycling the materials after use. In addition, the manufacturer should also collaborate with the user to ensure the safe disposal of the products once they are no longer in use. Furthermore, the product should not enter into direct contact with the soil, so as not to contribute to the accumulation of contaminants therein.

(11) EU fertilising products may contain only component materials compliant with the requirements laid down for one of the component material categories in Annex II to Regulation (EU) 2019/1009. Fertilising products, in particular fertilisers, often contain polymer-based technical additives, which are important to ensure their efficiency and safe use. Those additives are not covered by any of the existing component material categories. However, fertilisers containing them are covered by the harmonisation rules in Regulation (EC) No 2003/2003 of the European Parliament and of the Council[12]. Such technical additives are, for instance, anti-caking agents preventing the formation of lumps, and anti-dusting agents preventing dust emissions from the fertilising product during its application. Anti-caking agents are essential for the nutrient use efficiency as without such agents, the fertiliser would not spread evenly and therefore the end-user would apply more fertiliser to make sure that it reaches all plants. Anti-dusting agents are also very important for protecting users' health. Polymers that do not cause any environmental concern should therefore be included

[11] Commission Decision (EU) 2015/2099 of 18 November 2015 establishing the ecological criteria for the award of the EU Ecolabel for growing media, soil improvers and mulch (OJ L 303, 20.11.2015, p. 75).

[12] 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).

among the component materials allowed in fertilising products under Regulation (EU) 2019/1009. This would ensure that significant categories of products with an improved agronomic efficiency and safety continue to have access to the internal market.

(12) In order to identify which polymers do not cause any environmental concern, it is appropriate to refer to the scientific opinions issued by the Risk Assessment Committee[13] and the Committee for Socio-economic Analysis of the European Chemical Agency in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council[14], on intentionally added microplastic particles to consumer or professional use products of any kind.

(13) By including these categories of polymers in CMC 1 (Virgin material substances and mixtures) and CMC 11 (By-products within the meaning of Directive 2008/98/EC of the European Parliament and of the Council[15]), it is also ensured that those polymers will be registered under Regulation (EC) No 1907/2006 with a dossier including a safety report for their use as a fertilising product. This would ensure that a detailed assessment of any risks from the use of these additives in fertilising products would be carried out, and that the fertilising products granted internal market access under this amendment are thus safe for human health and the environment.

(14) Fertilisers with micronutrients may contain chelating or complexing agents, which are substances intended to enhance the long-term availability of micronutrients to plants.

(15) Regulation (EU) 2019/1009 requires fertilising products containing chelating agents to remain stable in standard Hoagland solution at pH 7 and 8 for at least three days, to ensure that the micronutrients are slowly released to plants. The composition of agricultural soils and variations in pH can disturb the stability of these products. New technical progress allows to assess potential interferences and to establish a pH range where products are stable for agricultural purposes. Based on the above, a product may be stable at a pH range other than pH 7 and 8, and still fulfil its purpose of ensuring long-term availability of micronutrients. Therefore, Regulation (EU) 2019/1009 should be amended to allow such products to be stable within a different pH range. In this way, the harmonisation rules would apply to more products, which slowly release micronutrients to plants and thus reduce the leaching of nutrients in soils. As an additional measure, the pH range in which the EU fertilising products are stable should be indicated on the label to ensure that correct information is provided to the end-user.

(16) Regulation (EU) 2019/1009 requires the declaration of the percentage of each micronutrient chelated by each chelating agent and of each micronutrient complexed by each complexing agent, as applicable. Products with micronutrients may contain a mixture of chelating agents, or complexing agents, or both. In such cases, the analytical methods available cannot support the determination of the exact percentage

---

13 RAC ECHA. 2020. Opinion on an Annex XV dossier proposing restrictions on intentionally added microplastics (ECHA/RAC/RES-O -0000006790-71-01/F).

14 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).

15 Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).

of each micronutrient chelated or complexed by each individual agent. Thus, Regulation (EU) 2019/1009 should be amended in order to allow the manufacturer to comply with these labelling requirements, thereby facilitating their access to the internal market.

(17) Some fertilising products, such as growing media, use peat as a main component. Encouraging the use of alternatives to peat is important in the fight against climate change, especially for the prevention of carbon loss and greenhouse gas emissions, as well as the conservation of fragile ecosystems. Plant fibres could be used to replace partially peat in growing media. However, to upgrade the potential of untreated plant fibres, these have to be transformed into fibres of finer particles as this improves their degree of biodegradability, their interaction with nutrients and water retention. Conditioning of the raw plant fibres using different physical pre-treatments for the purpose of fiberisation should be included in the exhaustive list of treatments in CMC 2 (Plants, plant parts and plant extracts). As a safeguard measure, certain restrictions should be added to the processing methods, such as maximum temperature and the prohibition of additives except water.

(18) CMC 3 (Compost) and CMC 5 (Digestate other than fresh crop digestate) lay down an exhaustive list of input materials that can be used. That list includes derived products referred to in Article 32 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council[16] and animal by-products that can be considered dead organisms, in cases where an end point in the manufacturing chain has been determined in accordance with Article 5(2), the third subparagraph of that Regulation.

(19) Regulation (EU) 2019/1009 lays down for the first time harmonisation rules for compost and digestate as component materials in EU fertilising products. These materials are nevertheless present on the market, based on national rules. Currently, animal by-products that cannot be considered dead organisms (especially unprocessed manure) are frequently used as input materials for compost and digestate. In this way, such materials are transformed into fertilising products with a net economic and environmental added value. The use of composted animal excrement, including poultry manure and composted farmyard manure, as well as digestate containing animal by-products co-digested with material of plant or animal origin is included in the exhaustive list of fertilisers, soil conditioners and nutrients allowed in organic farming in Annex I to Commission Regulation (EC) No 889/2008[17]. It is therefore appropriate to grant access to the internal market to fertilising products containing compost or digestate with such animal by-products as input materials. This would also ensure consistency with the input materials allowed in the recently introduced CMC 12 (Precipitated phosphate salts and derivates), CMC 13 (Thermal oxidation materials and derivates), as well as CMC 14 (Pyrolysis and gasification materials).

---

16 Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

17 Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (OJ L 250, 18.9.2008, p. 1).

(20) CMCs 3 and 5 also exclude from their input materials living or dead organisms from the organic fraction of mixed municipal household waste. On the contrary, CMCs 12 , 13 and 14 exclude from their input materials living or dead organisms out of the materials from mixed municipal waste, and not only household waste. The objective of those provisions is to encourage the separate collection of waste in municipalities, by not providing opportunities for the use of mixed waste. The reasoning is the same both if the waste is generated by households or by restaurants or other operators in municipalities. There is no reason to prohibit the use of only household mixed waste as input material in compost and digestate. Therefore, to ensure a coherent and stringent approach towards the recovery of mixed municipal waste and thus to reinforce the protection of the environment, it is necessary to align the provisions in CMCs 3 and 5 with those in the recently introduced CMCs 12, 13 and 14.

(21) Regulation (EU) 2019/1009 sets out an obligation for the manufacturer to list on the label all ingredients above 5% by product weight. However, the element on which the 5% limit is applied should be adapted to the physical characteristics of the fertilising product concerned and thus a declaration of ingredients representing 5% of volume should be allowed. Especially in case of products where the quantity is indicated by volume, listing the ingredients representing 5% of the volume is preferable as the relative ingredients' weight by products weight is not always known. This would facilitate the access of such products to the internal market. As regards the EU fertilising product in liquid form, it is appropriate to label the ingredients above 5 % by dry weight as otherwise there might be situations in which only water would be listed as an ingredient. This would ensure that products have access to the internal market based on Regulation (EU) 2019/1009 only if the users are properly informed about their ingredients, so that they can use the products safely.

(22) The label of an organo-mineral fertiliser, a solid or liquid inorganic macronutrient fertiliser and an inorganic micronutrient fertiliser is to list the names and chemical symbols of the declared micronutrients, followed by the names of their counter-ions. In some cases, the declarable level of micronutrients can be present naturally in the component materials of EU fertilising products. This is particularly the case for fertilisers from mined materials. Because of their natural origin, the names of the counter-ions for those micronutrients cannot always be determined due to analytical or technical limitations. Therefore, the declaration of micronutrients that are not intentionally added to the EU fertilising product should be allowed, even if the corresponding counter-ions cannot be determined. Otherwise, inorganic micronutrient fertilisers from mined materials could not be marketed under Regulation (EU) 2019/1009, as the manufacturer could not comply with this labelling requirement. In addition, declaring the micronutrient content in organo-mineral and inorganic macronutrient fertilisers without the corresponding counter-ions is beneficial both to the end-user, who could adapt a fertilisation plan by taking into account also the micronutrient content, and to the environment, as it could avoid over-fertilisation. The efficiency or safety of the fertiliser is not affected by the exclusion of the counter-ions from the label.

(23) The manufacturer of a solid inorganic macronutrient fertiliser is obliged to mention on the label the form of the physical unit, by reference to one of the four different forms listed in the Regulation, namely powder, granules, prills and pellets. However, in some cases, using only one of the above specific forms is not possible, as the physical form of the product combines two of the four forms. Therefore, to allow the manufacturer to

comply with this labelling requirement, the physical unit description should not be limited to only one possible form, but should also allow the use of a combination of forms. The physical unit definitions should cover all types of fertilisers and should not restrict the placing on the market of products which otherwise comply with the requirements in Regulation (EU) 2019/1009.

(24) Regulation (EU) 2019/1009 sets tolerance rules for each PFC for the different values declared on the label. Regulation (EU) 2019/1009 sets both negative tolerances (the actual value should not go below the declared value reduced by the negative tolerance) and positive tolerances (meaning that the actual value cannot be higher than the declared value increased by the respective tolerance). This is particularly important for the declaration of nutrients where, in order to avoid under- and over-fertilisation, the manufacturer has to ensure that the nutrient content declared is neither below nor above the declared value plus the tolerances.

(25) Some of the tolerances set for inorganic fertilisers are very narrow given the existing technical capacities. This is especially the case for declared nutrients where the content of the nutrient might be relatively low when compared to the whole product. A low nutrient content means that the deviation of its declared value is also small, as it is declared as a percentage of the nutrient content. Thus, the tolerances for some of the requirements for inorganic fertilisers should be widened to ensure a fair balance between the technical capacities of the manufacturer and the need for correct information to be provided to the end-user.

(26) Furthermore, the tolerance in absolute terms for organic carbon content in soil improver should also be widened. Soil improvers may have a significant content of organic carbon, which is not itself problematic, as in fact organic carbon improves the quality of soils by enriching their organic matter content. In such cases, allowing for a deviation in absolute terms of only one percentage point is very restrictive. It is therefore appropriate to allow a bigger deviation in absolute terms while maintaining the existing relative deviation.

(27) Tolerances should be added for the quantity of a plant biostimulant and of a fertilising product blend, as this information is required to be provided on the label. For a fertilising product blend, a distinction should be made between the blend mixing two EU fertilising products, where the proportion of each of them in the blend can be determined and therefore an average of the already set tolerances for each one depending on their proportion in the blend can be calculated and applied to the whole blend and the functional blend, where one and the same material passes the conformity assessment for two EU fertilising products belonging to two different PFCs and it cannot be determined objectively the proportion of each one in the blend. In the latter case, the stricter quantity tolerance of the component PFCs should be applied to the whole blend. Indeed, the manufacturer has to prove compliance with the requirements of each PFC and that includes indicating the quantity of each PFC in accordance with its corresponding tolerance. As each PFC represent 100% of the blend in this particular case, then the blend as a whole will have to respect the stricter tolerance.

(28) Based on Regulation (EU) 2019/1009, there are four conformity assessment procedures applicable to EU fertilising products, with different levels of complexity depending on their CMC(s) and the PFC: Modules A, A1, B+C and D1.

(29) Module D1 has been adapted in order to reflect the specific aspects of EU fertilising products derived from waste. A manufacturer can apply Modules B+C when assessing the conformity of an inhibitor (PFC 5) or a plant biostimulant (PFC 6), irrespective of their component materials. Therefore, as an inadvertent effect of the drafting of Annex IV to Regulation (EU) 2019/1009, nothing may prevent the application of Modules B+C, even in the case of the assessment of an inhibitor or a plant biostimulant that contains component materials for which the stricter Module D1 is mandatory. It is appropriate to apply a strict conformity assessment procedure whenever an EU fertilising product contains component materials deriving from waste, irrespective of its PFC. Therefore, to ensure a high and consistent level of protection, Modules B+C should be allowed for inhibitors and plant biostimulants only when they do not contain such component materials.

(30) When following the conformity assessment procedures, the manufacturer is to provide information in the technical documentation concerning, among other things, the total chromium whenever it is above 200 mg/kg. Regulation (EU) 2019/1009 does not indicate if this limit is to be applied to the dry matter or the fresh matter. This obligation cannot be fulfilled in a uniform manner in the Union if it is not clear how the 200 mg/kg should be calculated. When setting limit values for contaminants, including hexavalent chromium (Cr VI), Regulation (EU) 2019/1009 takes into account the dry matter. Therefore, for coherence reasons, the content of total chromium should be calculated by reference to dry matter.

(31) Consultations on the amendments to Regulation (EU) 2019/1009 have been conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[18]. The Commission expert group on fertilising products has been consulted.

(32) Given that the requirements set out in Annexes I, II, III and IV to Regulation (EU) 2019/1009 are to apply with effect from 16 July 2022, it is necessary to defer the application of this Regulation to the same date,

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.

[18] Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making (OJ L 123, 12.5.2016, p. 1).

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*.

It shall apply from 16 July 2022.

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels, 23.6.2021

For the Commission
The President
Ursula VON DER LEYEN