

II

(Non-legislative acts)

REGULATIONS

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

(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.

⁽¹⁾ OJ L 170, 25.6.2019, p. 1.

- (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 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) No 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 (EC) 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 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

⁽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 (EC) 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).

⁽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).

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 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 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.

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

⁽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).

- (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 Socioeconomic 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 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.

⁽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).

⁽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).

- (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 derivatives), CMC 13 (Thermal oxidation materials and derivatives), as well as CMC 14 (Pyrolysis and gasification materials).
- (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.

⁽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).

- (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.

⁽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).

- (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.

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 June 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

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

(1) point 5 is replaced by the following:

‘5. Residues of a pharmacologically active substance within the meaning of Regulation (EC) No 470/2009 of the European Parliament and of the Council * may be present in an EU fertilising product only if that substance is either:

- included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 **, or
- has had a reference point for action established in accordance with Commission Regulation (EU) 2019/1871 ***, and the substance or its residues are present in the EU fertilising product at a level below that reference point.

* 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).

** 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).

*** 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).;

(2) the following point 5a is inserted:

‘5a. An EU fertilising product may contain an active substance within the meaning of Article 2(2) of Regulation (EC) No 1107/2009 only if that EU fertilising product does not have a plant protection function within the meaning of Article 2(1) of that Regulation.’;

(3) in PFC 1(C)(II)(a), point 2, in the table:

(a) the row concerning the typology ‘Micronutrient salt fertiliser’ is replaced by the following:

‘Micronutrient salt fertiliser	A chemically obtained straight solid inorganic micronutrient fertiliser containing a mineral ion salt as its essential ingredient	10 % by mass of micronutrient salt fertiliser shall consist of a micronutrient’
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(b) the row concerning the typology ‘UVCB iron chelates’ is replaced by the following:

‘UVCB ⁽ⁱ⁾ micronutrient chelates	A water-soluble straight inorganic micronutrient fertiliser in which the declared micronutrient is chemically combined with chelating agent(s) fulfilling the requirements of CMC 1 in Part II of Annex II	— 5 % by mass of UVCB micronutrient chelates shall consist of water-soluble micronutrient, and at least 80 % of the water-soluble micronutrient shall be chelated (chelated fraction) and at least 50 % of the water soluble micronutrient shall be chelated by specific chelating agents fulfilling the requirements of CMC 1 in Part II of Annex II
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⁽ⁱ⁾ UVCB: Substance of unknown or variable composition, complex reaction products or biological materials.’;

(4) in PFC 3(B), the following point 4 is added:

'4. Pathogens in an inorganic soil improver that contains more than 1 % by mass of organic carbon (C_{org}) must not exceed the limits set out in the following table:

Micro-organisms to be tested	Sampling plans			Limit
	n	c	m	M
<i>Salmonella</i> spp.	5	0	0	Absence in 25 g or 25 ml
<i>Escherichia coli</i> or <i>Enterococaceae</i>	5	5	0	1 000 in 1 g or 1 ml

Where:

n = number of samples to be tested,

c = number of samples where the number of bacteria expressed in CFU is between m and M,

m = threshold value for the number of bacteria expressed in CFU that is considered satisfactory,

M = maximum value of the number of bacteria expressed in CFU.;

(5) in PFC 4, the following point 2a is inserted:

'2a. By derogation from point 2(d), the limit value for nickel (Ni) in a growing medium totally composed by mineral constituents and offered for professional use in horticulture, green roofs or green walls, shall apply to the bioavailable content of the contaminant.'

ANNEX II

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

(1) CMC 1 is amended as follows:

(a) point 1(f) is replaced by the following:

‘(f) polymers, other than:

- polymers that are the result of a polymerisation process that has taken place in nature, independently of the extraction process with which they have been extracted and that have not been chemically modified within the meaning of Article 3(40) of Regulation (EC) No 1907/2006,
- biodegradable polymers, or
- polymers with a water-solubility higher than 2 g/L in the following conditions:
 - temperature 20° C
 - pH 7
 - loading: 10 g/1 000 mL
 - test time: 24h;’

(b) in point 3(a), the last sentence is replaced by the following:

‘The EU fertilising product shall remain stable for at least 3 days in a solution having any pH within the range declared as guaranteeing acceptable stability.’;

(2) in CMC 2, the first paragraph is replaced by the following:

‘An EU fertilising product may contain plants, plant parts or plant extracts having undergone no processing other than cutting, grinding, milling, sieving, sifting, centrifugation, pressing, drying, frost treatment, freeze-drying, extraction with water, supercritical CO₂ extraction, or fiberisation at a temperature not higher than 100 °C and without any additives except water.’;

(3) CMC 3 is amended as follows:

(a) point 1(b) is deleted;

(b) point 1(c) is replaced by the following:

‘(c) living or dead organisms or parts thereof, which are unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which are extracted from air by any means, except:

- (i) materials originating from mixed municipal waste;’;
- (ii) sewage sludge, industrial sludge or dredging sludge, and
- (iii) animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;’;

(c) in point 1(e), the introductory wording is replaced by the following:

‘(e) any material listed in points (a) or (c) or in point 1a which;’;

(d) the following point 1a is inserted:

‘1a. Notwithstanding point 1, an EU fertilising product may contain compost obtained through aerobic composting of Category 2 or Category 3 materials or derived products thereof, in accordance with the conditions set out in Article 32(1) and (2) and in the measures referred to in Article 32(3) of Regulation (EC) No 1069/2009, alone or mixed with input materials referred to in point 1, provided that:

- (a) the end point in the manufacturing chain has been determined in accordance with the third subparagraph of Article 5(2) of Regulation (EC) No 1069/2009, and
- (b) the conditions in points 2 and 3 are met;’;

- (e) point 2(a) is replaced by the following:
- ‘(a) in which production lines for the processing of input materials referred to in points 1 and 1a are clearly separated from production lines for the processing of input materials other than those referred to in points 1 and 1a, and’;
- (4) CMC 5 is amended as follows:
- (a) point 1(b) is deleted;
- (b) point 1(c) is replaced by the following:
- ‘(c) living or dead organisms or parts thereof which are unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which are extracted from air by any means, except:
- (i) materials originating from mixed municipal waste.’;
- (ii) sewage sludge, industrial sludge or dredging sludge,
- (iii) animal by-products or derived products within the scope of Regulation (EC) No 1069/2009.’;
- (c) in point 1(e), the introductory wording is replaced by the following:
- ‘(e) any material listed in points (a) or (c) or in point 1a which.’;
- (d) the following point 1a is inserted:
- ‘1a. Notwithstanding point 1, an EU fertilising product may contain digestate obtained through anaerobic digestion of Category 2 or Category 3 materials or derived products thereof, in accordance with the conditions set out in Article 32(1) and (2) and in the measures referred to in Article 32(3) of Regulation (EC) No 1069/2009, alone or mixed with input materials referred to in point 1, provided that:
- (a) the end point in the manufacturing chain has been determined in accordance with the third subparagraph of Article 5(2) of Regulation (EC) No 1069/2009, and
- (b) the conditions in points 2 and 3 are met.’;
- (e) point 2(a) is replaced by the following:
- ‘(a) in which production lines for the processing of input materials referred to in points 1 and 1a are clearly separated from production lines for the processing of input materials other than those referred to in points 1 and 1a, and’;
- (5) in CMC 11, point 1(b) is replaced by the following:
- ‘(b) polymers, other than:
- polymers that are the result of a polymerisation process that has taken place in nature, independently of the extraction process with which they have been extracted and that have not been chemically modified within the meaning of Article 3(40) of Regulation (EC) No 1907/2006,
 - biodegradable polymers, or
 - polymers with a water-solubility higher than 2 g/L in the following conditions:
 - temperature 20° C
 - pH 7
 - loading: 10 g/1 000 mL
 - test time: 24h.’.

ANNEX III

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

(1) Part I is amended as follows:

(a) point 1(h) is replaced by the following:

‘(h) a list of all ingredients above 5 % by product weight or volume, or in the case of products in liquid form by dry weight, in descending order of magnitude, including the designations of the relevant CMCs as referred to in Part I of Annex II to this Regulation. Where the ingredient is a substance or a mixture, it shall be identified in accordance with Article 18 of Regulation (EC) No 1272/2008. Naturally occurring substances may be identified by their mineral names.’;

(b) point 3 is replaced by the following:

‘3. Where the EU fertilising product contains a component material which, if placed on the market as food or feed, would have been subject to maximum residue limits established pursuant to Regulation (EC) No 470/2009 or Regulation (EU) No 1831/2003 of the European Parliament and of the Council *, maximum residue levels set in accordance with Regulation (EC) No 396/2005 of the European Parliament and of the Council **, or maximum levels established pursuant to Council Regulation (EEC) No 315/93 *** or Directive 2002/32/EC of the European Parliament and of the Council ****, and that component material contains a substance in exceedance of (one of) the corresponding limit value(s), the maximum concentration of that substance in the EU fertilising product shall be indicated, together with a warning that the EU fertilising product must not be used in such a manner as to risk leading to the exceedance of that limit in food or feed.

* 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).

** 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).

*** 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).

**** 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).’;

(c) point 7 is replaced by the following:

‘7. Where the EU fertilising product is a growing medium as referred to in point 2a of PFC 4 in Part II of Annex I, or contains a polymer with the purpose of binding material in the product as referred to in point 1(c) of CMC 9 in Part II of Annex II, the user shall be instructed not to use the product in contact with soil, and in collaboration with the manufacturer, to make sure of a sound disposal of the product after end of use.’;

(2) Part II is amended as follows:

(a) in PFC 1(B), point 5:

(i) sub-point (a) is replaced by the following:

‘(a) indication of the names and chemical symbols of the declared micronutrients, listed in the following order: boron (B), cobalt (Co), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo) and zinc (Zn), followed by the names of their counter-ions when the declared micronutrients are intentionally added.’;

(ii) sub-point (c) is replaced by the following:

‘(c) where the declared micronutrients are chelated by chelating gent(s) or complexed by complexing agent(s):

— the following qualifier as applicable, after the name and chemical identifier of the micronutrient:

'chelated by [name of the chelating agent(s) or its(their) abbreviation]'/complexed by [name of the complexing agent(s) or its(their) abbreviation]'/chelated by [name of the chelating agent(s) or its(their) abbreviation] and complexed by [name of the complexing agent(s) or its (their) abbreviation]';

— the amount of chelated/complexed micronutrient(s) as % by mass;';

(iii) the following sub-point (ca) is inserted:

'(ca) where the declared micronutrients are chelated by chelating agent(s), the pH range guaranteeing acceptable stability;';

(iv) sub-point (d) is deleted;

(b) in PFC 1(C)(I)(a):

(i) point 3 is replaced by the following:

'3. The form of the physical unit of the product shall be indicated with one, or a combination of two or more, of the following mentions:

(a) granules,

(b) pellets,

(c) powder, where at least 90 % by mass of the product can pass through a sieve with a mesh of 1 mm, or

(d) prills;';

(ii) in point 8:

— sub-point (a) is replaced by the following:

'(a) indication of the names and chemical symbols of the declared micronutrients, listed in the following order: boron (B), cobalt (Co), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo) and zinc (Zn), followed by the names of their counter-ions when the declared micronutrients are intentionally added;';

— sub-point (c) is replaced by the following:

'(c) where the declared micronutrients are chelated by chelating agent(s) or complexed by complexing agent(s):

— the following qualifier, as applicable, after the name and chemical identifier of the micronutrient:

'chelated by [name of the chelating agent(s) or its(their) abbreviation]'/complexed by [name of the complexing agent(s) or its(their) abbreviation]'/chelated by [name of the chelating agent(s) or its(their) abbreviation] and complexed by [name of the complexing agent(s) or its (their) abbreviation]';

— the amount of chelated/complexed micronutrient(s) as % by mass;';

— the following sub-point (ca) is inserted:

'(ca) where the declared micronutrients are chelated by chelating agent(s), the pH range guaranteeing acceptable stability;';

— sub-point (d) is deleted;

(c) in PFC 1(C)(I)(b), point 6:

(i) sub-point (a) is replaced by the following:

'(a) indication of the names and chemical symbols of the declared micronutrients, listed in the following order: boron (B), cobalt (Co), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo) and zinc (Zn), followed by the names of their counter-ions when the declared micronutrients are intentionally added;';

(ii) sub-point (c) is replaced by the following:

'(c) where the declared micronutrients are chelated by chelating agent(s) or complexed by complexing agent(s):

— the following qualifier, as applicable, after the name and chemical identifier of the micronutrient:

'chelated by [name of the chelating agent(s) or its(their) abbreviation]'/complexed by [name of the complexing agent(s) or its(their) abbreviation]'/chelated by [name of the chelating agent(s) or its(their) abbreviation] and complexed by [name of the complexing agent(s) or its (their) abbreviation]';

— the amount of chelated/complexed micronutrient(s) as % by mass;';

(iii) the following sub-point (ca) is inserted:

'(ca) where the declared micronutrients are chelated by chelating agent(s), the pH range guaranteeing acceptable stability;';

(iv) sub-point (d) is deleted;

(d) in PFC 1(C)(II):

(i) point 1 is replaced by the following:

'1. The declared micronutrients in the inorganic micronutrient fertiliser shall be listed by their names and chemical symbols of the declared micronutrients, in the following order: boron (B), cobalt (Co), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo) and zinc (Zn), followed by the names of their counterions when the declared micronutrients are intentionally added.';

(ii) point 2 is replaced by the following:

'2. Where the declared micronutrients are chelated by chelating agent(s) and each chelating agent can be identified and quantified and chelates at least 1 % water-soluble micronutrient, or the declared micronutrients are complexed by complexing agent(s), the following qualifiers shall be added, as applicable, after the name and chemical identifier of the micronutrient:

— 'chelated by [name of the chelating agent(s) or its(their) abbreviation]'/complexed by [name of the complexing agent(s) or its(their) abbreviation]'/chelated by [name of the chelating agent(s) or its(their) abbreviation] and complexed by [name of the complexing agent(s) or its (their) abbreviation]';

— the amount of chelated/complexed micronutrient(s) as % by mass;';

(iii) the following point 2a is inserted:

'2a. Where the declared micronutrients are chelated by chelating agent(s), the pH range guaranteeing acceptable stability shall be indicated.';

(iv) point 3 is deleted;

(3) Part III is amended as follows:

(a) in PFC 1(C):

(i) the first table is replaced by the following:

Forms of the declared nutrient and other declared parameters	Permissible tolerance for the declared macronutrient content and other declared parameters
Declared forms of nitrogen (N)	± 25 % relative deviation of the declared value up to a maximum of 2 percentage points in absolute terms
Declared forms of phosphorus pentoxide (P ₂ O ₅)	± 25 % relative deviation of the declared value up to a maximum of 2 percentage points in absolute terms
Declared forms of potassium oxide (K ₂ O)	± 25 % relative deviation of the declared value up to a maximum of 2 percentage points in absolute terms
Declared forms of nitrogen (N), phosphorus pentoxide (P ₂ O ₅) or potassium oxide (K ₂ O) in binary fertilisers	± 1,5 percentage points in absolute terms
Declared forms of nitrogen (N), phosphorus pentoxide (P ₂ O ₅) or potassium oxide (K ₂ O) in tertiary fertilisers	± 1,9 percentage points in absolute terms

Total and water-soluble magnesium oxide (MgO), calcium oxide (CaO), sulphur trioxide (SO ₃)	-50 and +100 % relative deviation of the declared content of those nutrients up to a maximum of -2 and + 4 percentage points in absolute terms
Total and water soluble sodium oxide (Na ₂ O)	- 25 % of the declared content up to a maximum of 0,9 percentage point in absolute terms + 50 % of the declared content up to a maximum of 1,8 percentage points in absolute terms
Granulometry	± 20 % relative deviation of the declared percentage of material passing a specific sieve
Quantity	± 1 % relative deviation of the declared value'

(ii) the second table is replaced by the following:

'Micronutrient	Permissible tolerance for the declared content of forms of micronutrient
Concentration below or equal to 2 %	± 50 % of the declared value
Concentration of more than 2 % and below or equal to 10 %	± 50 % of the declared value up to a maximum of 1,0 percentage point in absolute terms
Concentration of more than 10 %	± 1,0 percentage point in absolute terms'

(b) in PFC 3, the second row which sets out the tolerance for organic carbon is replaced by the following:

'Organic carbon (C _{org})	± 10 % relative deviation of the declared value up to a maximum of 3,0 percentage points in absolute terms'
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(c) the following section is inserted after 'PFC 5: INHIBITOR':

'PFC 6: PLANT BIOSTIMULANT

The quantity of a plant biostimulant may deviate by ± 5 % from the declared value.;

(d) at the beginning of PFC 7, the following table is inserted:

'Declared parameter	Permissible tolerance for the declared parameter
Quantity	the tolerance is the sum of the relative proportion of each component EU fertilising product multiplied by the tolerance for the PFC for that fertilising product. If the proportion of each EU fertilising product in the fertilising product blend cannot be determined, the tolerance is that of the PFC with the strictest quantity tolerance value.'

ANNEX IV

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

(1) in Part I, point 3.2 is replaced by the following:

‘3.2 Module B followed by Module C may also be used for a fertilising product blend as specified in PFC 7.’;

(2) Part II is amended as follows:

(a) in Module A, point 2.2:

(i) sub-point (g) is replaced by the following:

‘(g) results of calculations made, examinations carried out, etc.’;

(ii) sub-point (j) is replaced by the following:

‘(j) where the EU fertilising product contains total chromium (Cr) above 200 mg/kg dry matter, information about the maximum quantity and exact source of total chromium (Cr).’;

(b) in Module A1, sub-point 2.2(h) is replaced by the following:

‘(h) results of calculations made, examinations carried out, etc.’;

(c) in Module B, point 2.2:

(i) sub-point (g) is replaced by the following:

‘(g) results of calculations made, examinations carried out, etc.’;

(ii) sub-point (k) is replaced by the following:

‘(k) where the EU fertilising product contains total chromium (Cr) above 200 mg/kg dry matter, information about the maximum quantity and exact source of total chromium (Cr).’;

(d) in Module D1, point 2.2:

(i) sub-point (g) is replaced by the following:

‘(g) results of calculations made, examinations carried out, etc.’;

(ii) sub-point (k) is replaced by the following:

‘(k) where the EU fertilising product contains total chromium (Cr) above 200 mg/kg dry matter, information about the maximum quantity and exact source of total chromium (Cr).’
