

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 (Text with EEA relevance)

REGULATION (EU) 2019/1009 OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL

of 5 June 2019

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(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee⁽¹⁾,

Acting in accordance with the ordinary legislative procedure⁽²⁾,

Whereas:

- (1) The conditions for making fertilisers available on the internal market have been partially harmonised through Regulation (EC) No 2003/2003 of the European Parliament and of the Council⁽³⁾, which almost exclusively covers fertilisers from mined or chemically produced, inorganic materials. There is also a need to make use of recycled or organic materials for fertilising purposes. Harmonised conditions for making fertilisers made from such recycled or organic materials available on the entire internal market should be established in order to provide an important incentive for their further use. Promoting increased use of recycled nutrients would further aid the development of the circular economy and allow a more resource-efficient general use of nutrients, while reducing Union dependency on nutrients from third countries. The scope of the harmonisation should therefore be extended in order to include recycled and organic materials.
- (2) Certain products are being used in combination with fertilisers for the purpose of improving nutrition efficiency, with the beneficial effect of reducing the amount of fertilisers used and hence their environmental impact. In order to facilitate their free movement on the internal market, not only fertilisers, i.e. products intended to provide plants with nutrient, but also products intended to improve plants' nutrition efficiency, should be covered by the harmonisation.

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- (3) Regulation (EC) No 765/2008 of the European Parliament and of the Council⁽⁴⁾ lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking. That Regulation should be applicable to products covered by this Regulation in order to ensure that products benefiting from the free movement of goods within the Union fulfil requirements providing a high level of protection of public interests such as human, animal and plant health, safety and the environment.
- (4) Decision No 768/2008/EC of the European Parliament and of the Council⁽⁵⁾ lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. Regulation (EC) No 2003/2003 should therefore be replaced by this Regulation, drafted to the extent possible in accordance with those common principles and reference provisions.
- (5) Contrary to most other product harmonisation measures in Union law, Regulation (EC) No 2003/2003 does not prevent non-harmonised fertilisers from being made available on the internal market in accordance with national law and the general free movement rules of the Treaty on the Functioning of the European Union (TFEU). In view of the very local nature of certain product markets, this possibility should remain. Compliance with harmonised rules should therefore remain optional, and should be required only for products, intended to provide plants with nutrient or improve plants' nutrition efficiency, which are CE marked when made available on the market. This Regulation should therefore not apply to products which are not CE marked when made available on the market.
- (6) Different product functions warrant different product safety and quality requirements adapted to their different intended uses. EU fertilising products should therefore be divided into different product function categories, which should each be subject to specific safety and quality requirements.
- (7) An EU fertilising product might have more than one of the functions described in the product function categories set out in this Regulation. Where only one of those functions is claimed, it should be sufficient for the EU fertilising product to comply with the requirements of the product function category describing that claimed function. By contrast, where more than one of those functions are claimed, the EU fertilising product should be regarded as a blend of two or more component EU fertilising products, and compliance should be required for each of the component EU fertilising products with respect to its function. A specific product function category should therefore cover such blends.
- (8) A manufacturer using one or more EU fertilising products that have already been subject to a conformity assessment, by that manufacturer or another manufacturer, might wish to rely on that conformity assessment. For the purpose of reducing the administrative burden to a minimum, the resulting EU fertilising product should also be regarded as a blend of two or more component EU fertilising products, and the additional conformity

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requirements for the blend should be limited to the aspects that are warranted by the blending.

- (9) Different component materials warrant different process requirements and control mechanisms adapted to their different potential hazardousness and variability. Component materials for EU fertilising products should therefore be divided into different categories, which should each be subject to specific process requirements and control mechanisms. It should be possible to make available on the market an EU fertilising product composed of several component materials from various component material categories, where each material complies with the requirements of the category to which the material belongs.
- (10) Contaminants in EU fertilising products, such as cadmium, could pose a risk to human, animal or plant health, to safety or to the environment as they accumulate in the environment and enter the food chain. Their content should therefore be limited in such products. Furthermore, impurities in EU fertilising products derived from bio-waste, in particular polymers but also metal and glass, should be either prevented or limited to the extent technically feasible by detection of such impurities in separately collected bio-waste before processing.
- (11) Several Member States have in place national provisions limiting cadmium content in phosphate fertilisers on grounds relating to the protection of human health and of the environment. Should a Member State deem it necessary to maintain such national provisions after the adoption of harmonised limit values under this Regulation, and until those harmonised limit values are equal to or lower than the national limit values already in place, it should notify them to the Commission in accordance with Article 114(4) TFEU. Furthermore, in accordance with Article 114(5) TFEU, if a Member State deems it necessary to introduce new national provisions, such as provisions limiting cadmium content in phosphate fertilisers, based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of this Regulation, it should notify the Commission of the envisaged provisions as well as the grounds for introducing them. In either case, the Commission should verify in accordance with Article 114(6) TFEU whether or not the notified national provisions are a means of arbitrary discrimination, a disguised restriction on trade or an obstacle to the functioning of the internal market.
- (12) In view of the fact that certain Member States have been granted derogations from Article 5 of Regulation (EC) No 2003/2003 in accordance with TFEU relating to cadmium content in fertilisers on the grounds, inter alia, of the protection of human health and the environment in the context of particular soil and climatic conditions prevailing in those Member States, and since the factual circumstances that led to the granting of those derogations by the Commission remain valid, those Member States should be able to continue to apply their national limit values for cadmium content until such time as harmonised limit values for cadmium content in phosphate fertilisers which are equal to or lower than those limit values are applicable at Union level.

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- (13) In order to facilitate the compliance of phosphate fertilisers with the requirements of this Regulation and to boost innovation, sufficient incentives should be provided for the development of relevant technologies, particularly decadmiation technology, and for the management of cadmium-rich hazardous waste in the form of relevant financial resources such as those available under Horizon Europe, the Circular Economy Finance Support Platform or through the European Investment Bank. Those incentives should target cadmium removal solutions that will be economically viable on an industrial scale and allow appropriate treatment of the waste generated.
- (14) An EU fertilising product complying with the requirements of this Regulation should be allowed to move freely on the internal market. Where one or more of the component materials is a derived product within the meaning of Regulation (EC) No 1069/2009 of the European Parliament and of the Council⁽⁶⁾, but has reached a point in the manufacturing chain beyond which it no longer poses any significant risk to human, animal or plant health, to safety or to the environment (the ‘end point in the manufacturing chain’), to continue subjecting the product to the provisions of that Regulation would represent an unnecessary administrative burden. Such fertilising products should therefore be excluded from the requirements of that Regulation. Regulation (EC) No 1069/2009 should therefore be amended accordingly.
- (15) For each component material category which includes derived products within the meaning of Regulation (EC) No 1069/2009, the end point in the manufacturing chain should be determined in accordance with the procedures laid down in that Regulation. Where such an end point is reached before the EU fertilising product is placed on the market but after the manufacturing process regulated under this Regulation has started, the process requirements of both Regulation (EC) No 1069/2009 and this Regulation should apply cumulatively to EU fertilising products, which means application of the stricter requirement in case both Regulations regulate the same parameter.
- (16) Derived products within the meaning of Regulation (EC) No 1069/2009 which are already placed on the market and used in the Union as organic fertilisers and soil improvers in accordance with that Regulation constitute promising raw materials for the production of innovative fertilising products in a circular economy. As soon as an end point in the manufacturing chain has been determined for the respective derived product, the EU fertilising products containing such derived products in accordance with this Regulation should be granted free movement on the internal market without being subject to the requirements of Regulation (EC) No 1069/2009. For this purpose, the Commission should, without undue delay, carry out a first assessment to check whether an end point in the manufacturing chain can be determined.
- (17) In the event of risks to public or animal health from fertilising products derived from animal by-products, recourse to safeguard measures in accordance with Regulation (EC) No 178/2002 of the European Parliament and of the Council⁽⁷⁾ should be possible, as is the case for other categories of products derived from animal by-products.
- (18) The making available on the market of an animal by-product or a derived product within the meaning of Regulation (EC) No 1069/2009 for which no end point in the manufacturing chain has been determined, or for which the determined end point has

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not been reached at the time of making available on the market, is subject to the requirements of that Regulation. Therefore, it would be misleading to provide for the product's CE marking under this Regulation. Any product containing or consisting of such an animal by-product or derived product should therefore be excluded from the scope of this Regulation. Untreated animal by-products should not be subject to this Regulation.

- (19) For certain recovered wastes, such as struvite, biochar and ash-based products, within the meaning of Directive 2008/98/EC of the European Parliament and of the Council⁽⁸⁾, a market demand for their use as fertilising products has been identified. Furthermore, certain requirements are necessary for the waste used as input in the recovery operation and for the treatment processes and techniques, as well as for fertilising products resulting from the recovery operation, in order to ensure that the use of those fertilising products does not lead to overall adverse environmental or human health impacts. For EU fertilising products, those requirements should be laid down in this Regulation. Therefore, as of the moment of compliance with all the requirements of this Regulation, such products should cease to be regarded as waste within the meaning of Directive 2008/98/EC, and it should, therefore, be possible for fertilising products containing or consisting of such recovered waste materials to access the internal market. To ensure legal certainty, take advantage of technical developments, and further stimulate the incentive among producers to make more use of valuable waste streams, the scientific analyses and the setting of recovery requirements at Union level for such products should start immediately after the entry into force of this Regulation. Accordingly, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of defining, without unnecessary delay, larger or additional categories of component materials eligible for use in the production of EU fertilising products.
- (20) Certain by-products within the meaning of Directive 2008/98/EC are currently used by manufacturers as components of fertilising products or can be expected to be used in future emerging markets. For such components, specific requirements should be laid down in a separate component material category in Annex II to this Regulation.
- (21) Certain substances and mixtures, commonly referred to as inhibitors, improve the nutrient release pattern of a nutrient in a fertiliser by delaying or stopping the activity of specific groups of micro-organisms or enzymes. For inhibitors made available on the market with the intention of them being added to fertilising products, the manufacturer should be responsible for ensuring that those inhibitors fulfil certain efficacy criteria. Therefore, those inhibitors should be considered as EU fertilising products under this Regulation. Furthermore, EU fertilising products containing such inhibitors should be subject to certain efficacy, safety and environmental criteria. Such inhibitors should therefore also be regulated as component materials for EU fertilising products.
- (22) Certain substances, mixtures and micro-organisms, referred to as plant biostimulants, are not as such inputs of nutrients, but nevertheless stimulate plants' natural nutrition processes. Where such products aim solely at improving the plants' nutrient use efficiency, tolerance to abiotic stress, quality traits or increasing the availability of

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confined nutrients in the soil or rhizosphere, they are by nature more similar to fertilising products than to most categories of plant protection products. They act in addition to fertilisers, with the aim of optimising the efficiency of those fertilisers and reducing the nutrient application rates. Such products should therefore be eligible for CE marking under this Regulation and excluded from the scope of Regulation (EC) No 1107/2009 of the European Parliament and of the Council⁽⁹⁾. Regulation (EC) No 1107/2009 should therefore be amended accordingly.

- (23) Products with one or more functions, one of which is covered by the scope of Regulation (EC) No 1107/2009, are plant protection products falling within the scope of that Regulation. Those products should remain under the control developed for such products and provided for by that Regulation. Where such products also have the function of a fertilising product, it would be misleading to provide for their CE marking under this Regulation, since the making available on the market of a plant protection product is contingent on a product authorisation valid in the Member State concerned. Therefore, such products should be excluded from the scope of this Regulation.
- (24) This Regulation should not prevent the application of existing Union legislation relating to aspects of protection of human, animal and plant health, of safety and of the environment not covered by this Regulation. This Regulation should therefore apply without prejudice to Council Directive 86/278/EEC⁽¹⁰⁾, Council Directive 89/391/EEC⁽¹¹⁾, Council Directive 91/676/EEC⁽¹²⁾, Directive 2000/60/EC of the European Parliament and of the Council⁽¹³⁾, Directive 2001/18/EC of the European Parliament and of the Council⁽¹⁴⁾, Regulation (EC) No 852/2004 of the European Parliament and of the Council⁽¹⁵⁾, Regulation (EC) No 882/2004 of the European Parliament and of the Council⁽¹⁶⁾, Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁽¹⁷⁾, Commission Regulation (EC) No 1881/2006⁽¹⁸⁾, Council Regulation (EC) No 834/2007⁽¹⁹⁾, Regulation (EC) No 1272/2008 of the European Parliament and of the Council⁽²⁰⁾, Regulation (EU) No 98/2013 of the European Parliament and of the Council⁽²¹⁾, Regulation (EU) No 1143/2014 of the European Parliament and of the Council⁽²²⁾, Regulation (EU) 2016/2031 of the European Parliament and of the Council⁽²³⁾, Directive (EU) 2016/2284 of the European Parliament and of the Council⁽²⁴⁾ and Regulation (EU) 2017/625 of the European Parliament and of the Council⁽²⁵⁾.
- (25) In line with common practice, nitrogen, phosphorus and potassium should be referred to as ‘primary macronutrients’, and calcium, magnesium, sodium and sulphur should be referred to as ‘secondary macronutrients’. Also in line with common practice, fertilisers should be referred to as ‘straight’ when they contain either only one macronutrient – regardless whether it is primary or secondary – or only one primary macronutrient in combination with one or more secondary macronutrients. In line with the same practice, fertilisers should be referred to as ‘compound’ when they contain either more than one primary macronutrient – regardless whether they also contain one or more secondary macronutrients – or contain no primary macronutrient but more than one secondary macronutrient.
- (26) Where an EU fertilising product contains a substance or mixture within the meaning of Regulation (EC) No 1907/2006, the safety of its constituent substances for the

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intended use should be established through registration pursuant to that Regulation. The information requirements should ensure that the safety of the intended use of the EU fertilising product is demonstrated in a manner comparable to that achieved through other regulatory regimes for products intended for use on arable soil or crops, notably Member States' national fertiliser legislation and Regulation (EC) No 1107/2009. Therefore, where the actual quantities placed on the market are lower than 10 tonnes per company per year, the information requirements determined by Regulation (EC) No 1907/2006 for the registration of substances in quantities of 10 to 100 tonnes should exceptionally apply as a condition for use in EU fertilising products. Those information requirements should apply to the actual substances contained in the EU fertilising product, as opposed to the precursors used for the manufacturing of those substances. The precursors themselves, such as sulphuric acid used as a precursor for the production of single superphosphate, should not be regulated as component materials for the purpose of this Regulation, since chemical safety will be better ensured by regulating as component materials the substances formed from the precursors and actually contained in the EU fertilising product. The obligation to comply with all the requirements of a component material category should therefore apply to those substances.

- (27) Where the actual quantities of substances in EU fertilising products regulated by this Regulation are higher than 100 tonnes, the additional information requirements laid down in Regulation (EC) No 1907/2006 should apply directly by virtue of that Regulation. The application of the other provisions of Regulation (EC) No 1907/2006 should also remain unaffected by this Regulation.
- (28) Economic operators should be responsible for the compliance of EU fertilising products with this Regulation, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of the aspects of public interest covered by this Regulation, and also to guarantee fair competition on the internal market. Whenever appropriate, manufacturers and importers should carry out sample testing of the EU fertilising products that they have made available on the market, in order to protect the health and safety of consumers and the environment.
- (29) It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.
- (30) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment of EU fertilising products should therefore remain solely the obligation of the manufacturer.
- (31) It is necessary to ensure that EU fertilising products from third countries that enter the internal market comply with this Regulation, and in particular that the appropriate conformity assessment procedures have been carried out by manufacturers with regard to those EU fertilising products. Provision should therefore be made for importers to make sure that EU fertilising products which they place on the market comply with the requirements of this Regulation and that they do not place on the market EU fertilising products which do not comply with such requirements or present a risk to human, animal or plant health, to safety or to the environment. Provision should also be made for such

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importers to make sure that conformity assessment procedures have been carried out and that marking of EU fertilising products and documentation drawn up by manufacturers are available for inspection by the competent national authorities.

- (32) When placing an EU fertilising product on the market, importers should indicate on the packaging of the EU fertilising product their name, registered trade name or registered trade mark and the postal address at which they can be contacted, in order to enable market surveillance.
- (33) Since distributors make an EU fertilising product available on the market after it has been placed on the market by the manufacturer or the importer, they should act with due care to ensure that their handling of the EU fertilising product does not adversely affect the compliance of that EU fertilising product with this Regulation.
- (34) Economic operators who either place an EU fertilising product on the market under their own name or trade mark or modify an EU fertilising product in such a way that compliance with this Regulation may be affected should be considered to be manufacturers and should assume the obligations of manufacturers. In other cases, economic operators who only package or repackage EU fertilising products already placed on the market by other economic operators should be able to prove that compliance with the requirements of this Regulation has not been affected, by indicating their identity on the package and by keeping a copy of the original labelling information.
- (35) Since distributors and importers are close to the market place, they should be involved in market surveillance tasks carried out by competent national authorities, and should be required to participate actively and provide those authorities with all necessary information relating to the EU fertilising product.
- (36) Ensuring traceability of an EU fertilising product throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators who made non-compliant EU fertilising products available on the market. When keeping the information required for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with an EU fertilising product or to whom they have supplied an EU fertilising product, since such updated information is normally not available to them.
- (37) In order to facilitate the assessment of conformity with the requirements of this Regulation it is necessary to provide for a presumption of conformity for EU fertilising products which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council⁽²⁶⁾ or with common specifications adopted in accordance with this Regulation.
- (38) In order to enable economic operators to demonstrate and the competent authorities to verify that EU fertilising products made available on the market comply with the requirements of this Regulation, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, from the least stringent to the most stringent, in proportion to the level

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of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules. It should be possible for manufacturers to choose a more stringent conformity assessment procedure for the assessment of an EU fertilising product eligible for a less stringent procedure, since this might enable the manufacturers to streamline their administration without jeopardising the conformity of the EU fertilising product. Furthermore, it is necessary to adapt the modules established by Decision No 768/2008/EC in order to reflect specific aspects of fertilising products. In particular, it is necessary to reinforce the quality systems and the involvement of notified bodies for the conformity assessment of certain EU fertilising products derived from recovered waste.

- (39) In order to ensure that ammonium nitrate fertilisers of high nitrogen content do not endanger safety, and that such fertilisers are not used for purposes other than those for which they are intended, for example as explosives, such fertilisers should be subject to specific requirements relating to detonation resistance testing and to traceability.
- (40) To ensure effective access to information for market surveillance purposes, information regarding conformity with all Union acts applicable to EU fertilising products should be given in the form of a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, it should be possible for that single EU declaration of conformity to be a dossier made up of relevant individual declarations of conformity.
- (41) The CE marking, indicating the conformity of an EU fertilising product with this Regulation, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking and its relationship to other markings are set out in Regulation (EC) No 765/2008. Specific rules governing the affixing of the CE marking in the case of EU fertilising products should be laid down.
- (42) Certain conformity assessment procedures set out in this Regulation require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.
- (43) It is essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.
- (44) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards it should be presumed to comply with the corresponding requirements set out in this Regulation.
- (45) In order to ensure a consistent level of quality in the performance of conformity assessment of EU fertilising products, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.

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- (46) The system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.
- (47) Due to the variable nature of certain component materials of EU fertilising products, and the potentially irreversible nature of some of the damage to which soil and crop exposure to impurities could lead, transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity of EU fertilising products, should be the only means of demonstrating the technical competence of conformity assessment bodies.
- (48) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for EU fertilising products to be placed on the market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.
- (49) It is necessary to provide for an efficient and transparent notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.
- (50) Since the services offered by notified bodies in a Member State might relate to EU fertilising products made available on the market throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.
- (51) In the interests of easing market access, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.
- (52) In order to ensure legal certainty, it is necessary to clarify that rules on internal market surveillance and control of products entering the internal market provided for in Regulation (EC) No 765/2008 apply to EU fertilising products covered by this Regulation. This Regulation should not prevent Member States from choosing the competent authorities to carry out those tasks.
- (53) EU fertilising products should be placed on the market only if they are sufficiently effective and do not present a risk to human, animal or plant health, to safety or to the environment when properly stored and used for their intended purpose, or under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.

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- (54) Regulation (EC) No 2003/2003 provides for a safeguard procedure allowing the Commission to examine the justification for a measure taken by a Member State against EC fertilisers considered to constitute a risk. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with the view to making it more efficient and drawing on the expertise available in Member States.
- (55) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to EU fertilising products presenting a risk to human, animal or plant health, to safety or to the environment. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an early stage in respect of such EU fertilising products.
- (56) The obligations of market surveillance authorities under this Regulation to require economic operators to take corrective actions should only apply to fertilising products bearing the CE marking when they are made available on the market. Those obligations should therefore be without prejudice to any possibility existing under national law to allow the economic operator to remove the CE marking and to legally place the product on the market as a product not falling within the scope of this Regulation.
- (57) In order to achieve the objectives of this Regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of adaptation to technical progress, in particular in the field of production of fertilising products derived from animal by-products and in the field of waste recovery, as well as in the agricultural sector and the agro-food industry.
- (58) Promising technical progress is being made in the field of recycling of waste, such as phosphorus recycling from sewage sludge, and fertilising product production from animal by-products, such as biochar. It should be possible for products containing or consisting of such materials to access the internal market without unnecessary delay when the manufacturing processes have been scientifically analysed and process requirements have been established at Union level. For that purpose, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of defining and introducing additional component materials eligible for use in the production of EU fertilising products and corresponding contaminant limit values in such products. That empowerment should only apply to the extent justified by technical progress established after the adoption of this Regulation, and not for the purpose of amending any elements of this Regulation in the absence of new evidence of such progress. In order to base the introduction of new contaminant limit values in EU fertilising products on full consideration of the direct and indirect impact on food and feed safety and on the environment, scientific opinions of the European Food Safety Authority, the European Chemicals Agency or the Commission's Joint Research Centre, as relevant, should be taken into account prior to the adoption of new contaminant limit values. For derived products within the meaning of the Regulation (EC) No 1069/2009, component material categories should be expanded or added only to the extent that an end point in the manufacturing chain has been determined in accordance with the

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procedures laid down in that Regulation, since derived products for which no such end point has been determined are in any event excluded from the scope of this Regulation.

- (59) Since micro-organisms are not subject to registration under Regulation (EC) No 1907/2006 or any other horizontal Union legislation requiring manufacturers to demonstrate that the intended use is safe, they should be eligible as component materials for EU fertilising products only to the extent that they have been clearly identified and supported by data demonstrating that their use is safe, and indicated in an exhaustive list adopted on that basis. The power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of adding new micro-organisms to that exhaustive list on the same basis.
- (60) An EU fertilising product can contain polymers other than nutrient polymers. However, this should be limited to cases where the purpose of the polymer is that of controlling the release of nutrients or increasing the water retention capacity or wettability of the EU fertilising product. It should be possible for innovative products containing such polymers to access the internal market. In order to minimise risks to human health, to safety or to the environment that may be posed by polymers other than nutrient polymers, the criteria for their biodegradability, so that they are capable of undergoing physical and biological decomposition, should be established. For that purpose, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of defining the criteria for the conversion of polymeric carbon into carbon dioxide and a related testing method. Polymers which do not comply with those criteria should be prohibited after a transitional period.
- (61) Furthermore, it should be possible to react immediately to new scientific evidence and to new risk assessments regarding human, animal or plant health, safety or the environment. For that purpose, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the requirements applicable to various categories of EU fertilising products.
- (62) When adopting delegated acts under this Regulation, it is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making⁽²⁷⁾. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.
- (63) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers to adopt acts should be conferred on the Commission in order to determine whether measures taken by Member States in respect of non-compliant EU fertilising products are justified or not. Since those acts will relate to the question of whether national measures are justified, such acts should not be subject to control by the Member States.
- (64) In order to further ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be

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exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council⁽²⁸⁾.

- (65) The advisory procedure should be used for the adoption of implementing acts requiring the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.
- (66) The examination procedure should be used for the adoption of implementing acts laying down in common specifications uniform conditions for implementing the requirements of this Regulation and tests for verifying the conformity of EU fertilising products where harmonised standards have not been adopted, or do not satisfy the requirements of this Regulation, or where there are undue delays in the process of adopting or updating these standards; amending or repealing common specifications where non-compliance of EU fertilising products can be attributed to shortcomings in those common specifications; determining whether a national measure taken in respect of a compliant EU fertilising product that presents a risk to human, animal or plant health, to safety or to the environment is justified or not.
- (67) The Commission should adopt immediately applicable implementing acts determining whether a national measure taken in respect of a compliant EU fertilising product that presents a risk is justified or not where, in duly justified cases relating to the protection of human, animal or plant health, safety or the environment, imperative grounds of urgency so require.
- (68) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.
- (69) In view of the need to ensure a high level of environmental protection and the need to take into account new developments based on scientific facts, the Commission should submit to the European Parliament and to the Council a report which includes a review of the limit values for cadmium content.
- (70) It is necessary to provide for transitional arrangements that allow the making available on the market of EC fertilisers that have been placed on the market in accordance with Regulation (EC) No 2003/2003 before the date of application of this Regulation without those products having to comply with further product requirements. Distributors should therefore be able to supply EC fertilisers that have been placed on the market, namely stock that is already in the distribution chain, before the date of application of this Regulation.
- (71) It is necessary to provide for sufficient time for economic operators to comply with their obligations under this Regulation, and for Member States to set up the administrative infrastructure necessary for its application. The application should therefore be deferred to a date where those preparations can reasonably be finalised.
- (72) Since the objective of this Regulation, namely to guarantee the functioning of the internal market while ensuring that EU fertilising products on the market fulfil the requirements providing for a high level of protection of human, animal, and plant health, of safety and of the environment, cannot be sufficiently achieved by the Member States

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but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS REGULATION:

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- (1) [OJ C 389, 21.10.2016, p. 80.](#)
- (2) Position of the European Parliament of 27 March 2019 (not yet published in the Official Journal) and decision of the Council of 21 May 2019.
- (3) 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.](#))
- (4) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 ([OJ L 218, 13.8.2008, p. 30.](#))
- (5) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC ([OJ L 218, 13.8.2008, p. 82.](#))
- (6) 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.](#))
- (7) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ([OJ L 31, 1.2.2002, p. 1.](#))
- (8) 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.](#))
- (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) Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture ([OJ L 181, 4.7.1986, p. 6.](#))
- (11) Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work ([OJ L 183, 29.6.1989, p. 1.](#))
- (12) Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources ([OJ L 375, 31.12.1991, p. 1.](#))
- (13) Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy ([OJ L 327, 22.12.2000, p. 1.](#))
- (14) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC ([OJ L 106, 17.4.2001, p. 1.](#))
- (15) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs ([OJ L 139, 30.4.2004, p. 1.](#))
- (16) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ([OJ L 165, 30.4.2004, p. 1.](#))
- (17) 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.](#))
- (18) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs ([OJ L 364, 20.12.2006, p. 5.](#))
- (19) Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 ([OJ L 189, 20.7.2007, p. 1.](#))
- (20) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing

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- Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).
- (21) Regulation (EU) No 98/2013 of the European Parliament and of the Council of 15 January 2013 on the marketing and use of explosives precursors (OJ L 39, 9.2.2013, p. 1).
- (22) Regulation (EU) No 1143/2014 of the European Parliament and of the Council of 22 October 2014 on the prevention and management of the introduction and spread of invasive alien species (OJ L 317, 4.11.2014, p. 35).
- (23) Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).
- (24) Directive (EU) 2016/2284 of the European Parliament and of the Council of 14 December 2016 on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/EC (OJ L 344, 17.12.2016, p. 1).
- (25) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).
- (26) Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).
- (27) OJ L 123, 12.5.2016, p. 1.
- (28) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

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