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Circular Economy Package

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

laying down rules on the making available on the market of CE marked fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009

(Text with EEA relevance)

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{SWD(2016) 65 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

1. The proposal aims at addressing important problems currently present on the market, which were first identified in an ex-post evaluation of Regulation (EC) No 2003/2003 ('the existing Fertilisers Regulation') conducted in 2010.[1] It has also been identified as one of the key legislative proposals under the Circular Economy action plan.[2]

The first reason and objective

2. First, innovative fertilising products, often containing nutrients or organic matter recycled from biowaste or other secondary raw materials in line with the circular economy model, have difficulties accessing the internal market due to the existence of diverging national rules and standards.

3. The existing Fertilisers Regulation ensures free movement on the internal market of a class of harmonised products belonging to one of the product-types included in Annex I to that Regulation. Such products are eligible to be labelled 'EC-fertilisers'. Companies wishing to market products of other types as EC-fertilisers must first obtain a new type-approval through a Commission decision amending that Annex. Virtually all product-types currently included in the existing Fertilisers Regulation are conventional, inorganic fertilisers, typically extracted from mines or chemically produced in line with a linear economy model. Also, the chemical processes for producing for example nitrogen-based fertilisers are both energy consuming and CO_2-intensive.

4. Around 50 % of the fertilisers currently on the market, however, are left out of the scope of the Regulation. This is true for a few inorganic fertilisers and for virtually all fertilisers produced from organic materials, such as animal or other agricultural by products, or recycled bio-waste from the food chain. Research, innovation and investment are currently developing rapidly, contributing to the circular economy by creating local jobs and by generating value from secondary, domestically sourced resources which would otherwise have been used directly on land or disposed as landfill waste, causing unnecessary eutrophication and greenhouse gas emissions. There is also a servitization trend in the business, with increasing product customisation based on analysis of the soil where the fertiliser will be used. SMEs and other enterprises throughout Europe are increasingly interested in contributing to this development. However, for customised products containing organic fertilisers, access to the internal market is currently depending on mutual recognition, and therefore often hindered.

5. The problem for innovative fertilisers with the existing regulatory construction is two-fold

6. The first angle of the problem is that inclusion in the existing Fertilisers Regulation of types of products sourced from organic or secondary raw material is challenging. Regulators hesitate because of the relatively variable composition and characteristics of such materials. The existing Fertilisers Regulation is clearly tailored for well

[1] http://ec.europa.eu/smart-regulation/evaluation/search/download.do?documentId=4416

[2] COM(2015) 614/2

characterised, inorganic fertilisers from primary raw materials, and lacks the robust control mechanisms and safeguards necessary for creating trust in products from inherently variable organic or secondary material sources. Furthermore, the links with existing legislation on control of animal by-products and waste are not clear.

7. As a result, fertilisers sourced in line with the circular economy remain non-harmonised. Many Member States have detailed, national rules and standards in place for such non-harmonised fertilisers, with environmental requirements (such as heavy metal contaminant limits) that do not apply to EC-fertilisers. Furthermore, free movement between Member States through mutual recognition has proven extremely difficult. As a result, a producer of fertilisers sourced from organic or secondary raw materials, established in one Member State and seeking to expand its market to the territory of another Member State, is often faced with administrative procedures making the market expansion prohibitively expensive. The resulting lack of critical mass hampers investment in this important sector of the circular economy. The problem is of particular importance for producers established in Member States with a small domestic market compared to the surplus of organic, secondary raw materials (typically manure) of which they dispose.

8. In summary, the playing field in the competition between those fertilisers sourced from domestic organic or secondary raw material in line with the circular economy model and those produced in line with a linear economy model is tilted in favour of the latter. This competition distortion hampers investment in the circular economy.

9. The problem is aggravated by the fact that one of the main fertiliser constituents is phosphate rock, which has been identified by the Commission as a critical raw material. For phosphate fertilisers, the EU is currently highly dependent on import of phosphate rock mined outside of the EU (more than 90% of the phosphate fertilisers used in the EU are imported, mainly from Morocco, Tunisia and Russia). This while domestic waste (in particular sewage sludge) contains large amounts of phosphorus, which – if recycled in line with a circular economy model – could potentially cover about 20-30% of EU's demand of phosphate fertilisers. The related investment potential remains, however, currently largely unexploited, which is partially due to the above-mentioned difficulties to access the internal market.

10. The second angle of the current Fertilisers Regulation's limitations for innovative fertilisers is that, even for new, inorganic fertilisers from primary raw materials, the type-approval procedure is lengthy, and cannot keep up with the innovation cycle of the fertilisers sector. It has therefore been deemed necessary to fundamentally reconsider and modernise the regulatory technique, in order to increase flexibility with regard to product requirements, while maintaining a high level of protection of human, animal, and plant health, safety and the environment. The considerations undertaken in this respect are detailed below in Section 3: *Results of ex-post evaluations, stakeholder consultations and impact assessment*.

11. The main policy objective of the initiative is therefore to incentivise large scale fertiliser production in the EU from domestic organic or secondary raw materials in line with the circular economy model, by transforming waste into nutrients for crops. The proposal will provide a regulatory framework radically easing access to the internal market for such fertilisers, thereby levelling their playing field with that of mined or chemical fertilisers produced in line with a linear economy model. This would contribute to the following circular economy objectives:

- It would allow valorisation of secondary raw materials, hence enabling improved use of raw materials and turning eutrophication and waste management problems into economic opportunities for public and private operators.
- It would increase resource efficiency and decrease import dependency for raw materials essential to European agriculture, in particular phosphorus.
- It would boost investment and innovation in the circular economy, hence creating jobs in the EU.
- It would contribute to relieving the fertilisers industry from its current pressure to reduce CO_2-emissions under ETS, by allowing it to produce fertilisers from less carbon-intensive feedstock.

12. Increased production and trade in innovative fertilisers would also diversify the fertilisers offered to farmers, potentially contributing to making food production more cost- and resource-effective.

The second reason and objective

13. Second, the existing Fertilisers Regulation fails to address environmental concerns arising from contamination by EC-fertilisers of soil, inland waters, sea waters, and ultimately food. A well-recognised issue is the presence of cadmium in inorganic phosphate fertilisers. In the absence of EU limit values, some Member States have imposed unilateral cadmium limits for EC-fertilisers by virtue of Article 114 TFEU, hence creating a certain market fragmentation also in the harmonised field. The presence of contaminants in those fertilisers which are currently subject to national rules (*e.g.* nutrients recycled from sewage sludge) poses similar concerns.

14. A second policy objective is therefore to address this issue and introduce harmonised cadmium limits for phosphate fertilisers. The setting of such limit values, aiming at minimising the negative impact of fertiliser use on the environment and on human health, will contribute to a reduction of cadmium accumulation in soil and of cadmium contamination of food and water. It will also remove the market fragmentation to which the concern currently gives rise in the form of national cadmium limits in some Member States.

- **Consistency with existing policy provisions in the policy area**

15. The proposal will repeal the existing Fertilisers Regulation, but allow already harmonised fertilisers to remain on the market subject to compliance with the new safety and quality requirements. It will define the conditions under which fertilisers produced from waste and animal by-products can leave the controls provided for by 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)[3] and the Directive 2008/98/EC on waste and repealing certain Directives[4] and circulate freely as CE marked fertilisers. It will be complementary to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration,

[3] OJ L 300, 14.11.2009, p. 1.
[4] OJ L 312, 22.11.2008, p. 3.

Evaluation, Authorisation and Restriction of Chemicals (REACH)[5], which will continue to apply to chemical substances incorporated into fertilising products.

- **Consistency with other Union policies**

16. The initiative supports the Commission's agenda for jobs, growth and investment, by providing the right regulatory environment for investment in the real economy.

17. In particular, the initiative will make an important and concrete contribution to the Commission's Circular Economy Package. It will create a level playing field for all fertilising products and facilitate recourse to domestic, secondary raw materials.

18. Furthermore, the initiative supports the aim to create a deeper and fairer internal market with a strengthened industrial base, by removing existing barriers to free movement of certain innovative fertilisers and facilitating the market surveillance by Member States.

19. The initiative is related to the following policy initiatives:

- The Circular Economy Package: The Fertilisers Regulation revision aims at establishing a regulatory framework enabling production of fertilisers from recycled bio-wastes and other secondary raw materials, in line with the Bioeconomy strategy[6], which encompasses the production of renewable biological resources and the conversion of these resources and waste streams into value added products. This would boost domestic sourcing of plant nutrients which are essential for a sustainable European agriculture, including the critical raw material phosphorus. It would also contribute to a better implementation of the waste hierarchy, by minimising landfilling or energy recovery of bio-wastes, and hence to solving related waste management problems.

- The Single Market Strategy: As described above, a well-known barrier to free movement on the internal market constitutes of heavy and diverging national regulatory frameworks for those fertilisers currently not covered by harmonisation legislation. While economic operators often regard the diverging national rules as a prohibitive obstacle to entering new markets, Member States regard the rules as essential for protecting the food chain and the environment. Because of those concerns relating to health and the environment, mutual recognition has proven exceptionally difficult in the field of non-harmonised fertilisers, and economic operators have asked for the possibility to get access to the entire internal market by complying with harmonised rules addressing those concerns at EU level.

- Horizon 2020: The proposal will have the potential to stimulate relevant research activities launched under Societal Challenges 2 (“Food security, sustainable agriculture and forestry, marine and maritime and inland water research, and the Bioeconomy”) and 5 (“Climate action, environment, resource efficiency and raw materials”), which aim, among other objectives, at providing innovative solutions for a more efficient and safer recovery of resources from waste, wastewater and bio-wastes, and at encouraging researchers to deliver innovative products in compliance with the market needs, the societal needs and the environmental protection policies. The Bio

[5] OJ L 396, 30.12.2006, p. 1.

[6] http://ec.europa.eu/research/bioeconomy/index.cfm

Based Industries Joint Undertaking has identified *i.a.* phosphorus recycling for production of fertilisers as an emerging and economically promising new value chain from (organic) waste.[7] Easy access to the internal market for such fertilizers would be a pre-condition for achieving these goals and bringing results from research to the market.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

20. The aim of the proposal is to improve the functioning of the internal market for fertilising products, hence addressing the issues first identified in the ex-post evaluation of the existing Fertilisers Regulation conducted in 2010. The legal basis is therefore Article 114 of the Treaty on the Functioning of the European Union, which is also the legal basis for the existing Fertilisers Regulation.

• Subsidiarity (for non-exclusive competence)

21. The first objective of the proposed action is to boost investment in production and uptake of effective, safe, innovative fertilisers produced from organic or secondary raw materials in line with the circular economy model and the Bioeconomy strategy, by helping those products reach a critical mass through access to the entire internal market. More efficient recourse to such fertilisers can offer significant environmental benefits, reduced dependency on import of critical raw materials from outside of the EU, as well as an increased variety of high quality fertilising products to farmers. The existing barriers to the free movement of such products, in the form of diverging, national regulatory frameworks, cannot be removed through Member States' unilateral actions. In particular, mutual recognition in this field has proven exceptionally difficult, and becomes an increasingly important obstacle as the interest in producing and trading high-quality fertilisers from organic or secondary raw materials tends to increase. EU action, on the other hand, could ensure the free movement of such fertilisers by establishing harmonised high quality, safety and environmental criteria.

22. The second objective is to address cadmium contamination of soil and food through fertiliser use. Since most of the fertilisers from which the concern originates (*i.e.*, inorganic phosphate fertilisers) are already harmonised, Member States cannot achieve this objective unilaterally. EU-wide maximum limits, on the other hand, can effectively reduce contaminants in harmonised fertilisers to safer levels.

• Proportionality

23. The first objective of the initiative is that of boosting investment in production of effective, safe, innovative fertilisers produced from organic or secondary raw materials in line with the circular economy model, with the related benefits for environmental impact, reduced import dependency, and increased variability of high-quality products on offer. The initiative aims at reaching a critical mass through internal market for such products. Mutual recognition of non-harmonised fertilisers has proven extremely difficult in the past, whereas product harmonisation legislation has been an effective way of securing internal market access for inorganic fertilisers. It is therefore concluded that product harmonisation legislation for fertilisers from organic or secondary raw materials does not go beyond what is necessary for

[7] http://bbi-europe.eu/sites/default/files/documents/BBI_JU_annual_Work_plan_2014.pdf

providing the regulatory certainty required to incentivise large scale investment in the circular economy. The regulatory technique chosen in this proposal leaves economic operators a maximum of flexibility to put new products on the markets without compromising on safety and quality. Furthermore, it leaves Member States free to allow non-harmonised fertilisers to on the market, without depriving those economic operators seeking larger markets of the possibility to opt for the benefits of the harmonised regulatory framework.

24. The form of a Regulation is deemed the most appropriate for harmonisation of products in a field of such technical complexity and potential impact on the food chain and the environment as fertilisers. That conclusion is supported by the fact that the existing harmonisation legislation for fertilisers also has the form of a Regulation.

25. Regarding the second objective, *i.e.*, addressing cadmium contamination of soil and food through use of fertilisers many of which are already harmonised, maximum levels in the product legislation is seen as an effective means of addressing the problem at source. The economic impacts are deemed proportionate to the objective of preventing irrevocable soil contamination affecting current and future generations of farmers and food consumers.

26. The proportionality is further developed in section 4.2.2 of the Impact Assessment.

- **Choice of the instrument**

27. The form of a Regulation is deemed the most appropriate for harmonisation of products in a field of such technical complexity and potential impact on the food chain and the environment as fertilisers. That conclusion is supported by the fact that the existing harmonisation legislation for fertilisers also has the form of a Regulation.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

28. The ex-post evaluation of the existing Fertilisers Regulation conducted in 2010 concluded[8] that the Regulation had been effective in meeting its objective of simplifying and harmonising the regulatory framework in relation to an important part of the fertiliser market.

29. However, the evaluation also concluded that the Regulation could be more effective in promoting innovative fertilisers, and that adjustments would also be needed to better protect the environment. Furthermore, regarding the organic fertilisers currently left out of the scope of the Regulation, the evaluation showed that neither economic operators, nor national authorities considered that mutual recognition was the most appropriate tool for ensuring free movement, since fertilisers are products for which legitimate product quality, environmental, and human health concerns can warrant stringent rules.

- **Stakeholder consultations**

30. Consultation of Member States and other stakeholders has been conducted extensively throughout the preparatory phase starting in 2011, in particular in the

[8] See Section 4, *Conclusions and recommendations.*

context of the Fertilisers Working Group.[9] The public consultation on Circular economy published in May 2015 included questions on this topic.[10] Stake holders were also invited to give feedback to the Roadmap for the revision of the Fertilisers Regulation published on 22 October 2015.[11]

- **Collection and use of expertise**

31. The existing draft Impact Assessment report relies largely on the abovementioned ex-post evaluation of the Fertilisers Regulation of 2010 as well as on the study carried out in 2011 on options to fully harmonise the EU legislation on fertilising materials including technical feasibility, environmental, economic and social impacts[12].

32. Phosphorus recycling has also been addressed by FP7 research projects, the results of which have been analysed during the workshop 'Circular approaches to phosphorus: from research to deployment', held in Berlin on 4 March 2015[13]. One of the identified priorities is to revise the EU Fertiliser Regulation to extend its scope to nutrients from secondary sources (*e.g.* recycled phosphates) and organic sources.

- **Impact assessment**

33. The proposal is supported by an impact assessment, the key documents of which can be found [Once the IAR is published, insert link to the summary sheet and to the positive opinion of the Regulatory Scrutiny Board]. The opinions of the Impact Assessment Board were taken into account by providing better evidence of the divergent national standards as a cause for market fragmentation, by clarifying the content of the various options assessed, and by better justifying the key impacts of the proposal.

34. The impact assessment compared *status quo* (referred to as option 1) with four other policy options (referred to as options 2-5). Under all of the options 2-5, the scope of harmonisation would be extended to fertilisers from organic raw materials and to other fertiliser-related products, and limit values would be introduced for contaminants. The options would build on different control mechanisms: Under option 2, the regulatory technique of the Fertilisers Regulation, *i.e.*, type-approval, would remain un-changed. Under option 3, the type-approval would be replaced by a positive, exhaustive list of materials eligible for intentional incorporation into a fertiliser. Option 4 would achieve the necessary control through the 'New Legislative Framework' ('NLF'), with one conformity assessment procedure applicable across the board. Finally, option 5 would also build on the NLF, but the conformity assessment procedure would vary between material categories. For all four options 2-5, it was also examined whether the harmonisation should be mandatory for all products with a given function, or whether fertilisers could comply with the harmonised legislation

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9 For activity reports of that group's meetings, see http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=1320&NewSearch=1&NewSearch=1

10 http://ec.europa.eu/environment/consultations/closing_the_loop_en.htm?utm_content=buffer68ffa&utm_medium=social&utm_source=twitter.com&utm_campaign=buffer

11 http://ec.europa.eu/smart-regulation/roadmaps/docs/2012_grow_001_fertilisers_en.pdf

12 http://bookshop.europa.eu/en/study-on-options-to-fully-harmonise-the-eu-legislation-on-fertilising-materials-including-technical-feasibility-environmental-economic-and-social-impacts-pbNB0114252/

13 The report of the workshop can be downloaded at http://bookshop.europa.eu/en/circular-approaches-to-phosphorus-pbKI0115204/

on an optional basis, as an alternative to any applicable national legislation and mutual recognition, as is the case under *status quo* for inorganic fertilisers.

35. The final proposal corresponds with option 5, coupled with the variant of optional harmonisation. It was considered to be the best policy choice because it would lead to administrative simplification, in particular for fertilising products from well identified, primary raw materials, and ensure flexibility, while at the same time ensuring that the use of harmonised fertilising products does not pose unacceptable risks to health or the environment.

36. The proposal will mainly affect those producers of innovative fertilisers produced from organic or secondary raw materials in line with the circular economy model, who will be able to reach a critical mass through radically facilitated access to the internal market. Such producers will benefit from the initiative in particular in those Member States which are not providing a sufficiently large home market for new types of fertilisers.

37. It will also affect private and public recovery operators (such as operators of waste water treatment plants, or of waste management plants producing compost or digestate) who will be able to valorise their output, and thus facilitate investments in such infrastructure.

38. Many national authorities will see a decreased workload when national registration or authorisation systems for fertilisers are fully or partially replaced by EU-wide control mechanisms.

39. Finally, farmers and other fertiliser users are likely to see an increase in the product variety offered to them, while the general public will be better protected from contamination of soil, water and food.

- **Regulatory fitness and simplification**

40. The proposal will lead to simplification and reduction of the administrative burden for producers of fertilising products seeking access to more than one national territory on the internal market, since such access will no longer depend on mutual recognition. At the same time, it will avoid banning or restricting market access for producers that do not aim at compliance with EU-level rules, by keeping open the possibility to access national markets subject to any national rules and mutual recognition.

4. BUDGETARY IMPLICATIONS

41. The proposal will have no implications on the EU budget. Human and administrative resources within the European Commission will remain unchanged compared with the implementation and monitoring of the existing Fertilisers Regulation.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

42. The European Commission will assist and monitor Member States' implementation of the Regulation. It will also analyse the need for guidance, standards or schemes proving sustainability of fertilising products, thus allowing sustainability-claims on the product labels.

43. The Commission furthermore intends to include additional component material categories in the Annexes, to keep up with technological progress allowing the production of safe and effective fertilisers from recovered, secondary raw materials, such as biochar, ashes and struvite. Finally, the Commission will keep the requirements in the Annexes under constant review, and revise them wherever necessary to provide an adequate protection of human, animal or plant health, safety or the environment.

- **Detailed explanation of the specific provisions of the proposal**

44. Chapter 1 of the proposed Regulation sets out the subject matter, scope and definitions, as well as the fundamental principles of free movement and marketability of CE marked fertilising products. The provision on product requirements refers to Annexes I and II, which contain the substantive requirements for the categories of end-products in accordance with their intended function (Annex I), as well as for the categories of component materials that can be contained in CE marked fertilising products (Annex II). It also refers to Annex III, which specifies the labelling requirements.

45. Chapter 2 lays down the obligations of economic operators involved in making CE marked fertilising products available on the market.

46. Chapter 3 sets out the general principle for conformity of CE marked fertilising products. It refers to Annex IV, which describes in detail the conformity assessment procedures applicable to CE marked fertilising products, depending on their component material categories and their product function categories. It also refers to Annex V, which sets out the model structure for the EU declaration of conformity.

47. Chapter 4 sets out the provisions on notified bodies, and Chapter 5 sets out the provisions on market surveillance. Chapter 6 sets out the conditions for the Commission's adoption of delegated and implementing acts, and Chapter 7 sets out final provisions.

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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[14],

Acting in accordance with the ordinary legislative procedure,

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[15], 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. 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.

(3) Regulation (EC) No 765/2008 of the European Parliament and of the Council[16] 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

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14 OJ C , , p. .

15 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).

16 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).

Regulation should be applicable to products covered by the scope of 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 health and safety in general, protection of consumers and protection of the environment.

(4) Decision No 768/2008/EC of the European Parliament and of the Council[17] 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 a Regulation drafted to the extent possible in accordance with that Decision.

(5) Contrary to most other product harmonisation measures in Union legislation, 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. 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. CE marked fertilising products should therefore be divided into different product function categories, which should each be subject to specific safety and quality requirements.

(7) Similarly, different component materials warrant different process requirements and control mechanisms adapted to their different potential hazardousness and variability. Component materials for CE marked 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 a CE marked 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.

(8) Contaminants in CE marked fertilising products, such as cadmium, can potentially pose a risk to human and animal health and 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 CE marked 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.

(9) Products complying with all the requirements of this Regulation should be allowed to move freely on the internal market. Where one or more of the component materials in a CE marked fertilising product falls within the scope of Regulation (EC) No 1069/2009 of the European Parliament and of the Council[18], but reaches a point in

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[17] 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).

[18] 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

the manufacturing chain beyond which it no longer poses any significant risk to public or animal health (the 'end point in the manufacturing chain'), it would represent an unnecessary administrative burden to continue subjecting the product to the provisions of that Regulation. Such fertilising products should therefore be excluded from the requirements of that Regulation. Regulation (EC) No 1069/2009 should therefore be amended accordingly.

(10) The end point in the manufacturing chain should be determined for each relevant component material containing animal by-products in accordance with the procedures laid down in Regulation (EC) No 1069/2009. Where a manufacturing process regulated under this Regulation starts already before that end point has been reached, the process requirements of both Regulation (EC) No 1069/2009 and this Regulation should apply cumulatively to CE marked fertilising products, which means application of the stricter requirement in case both Regulations regulate the same parameter.

(11) In the event of risks to public or animal health from CE marked 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[19] should be possible, as is the case for other categories of products derived from animal by-products.

(12) Where one or more of the component materials for a CE marked fertilising product fall within the scope of Regulation (EC) No 1069/2009 and has not reached the end point in the manufacturing chain, it would be misleading to provide for the product's CE marking under this Regulation, since the making available on the market of such a product is subject to the requirements of Regulation (EC) No 1069/2009. Therefore, such products should be excluded from the scope of this Regulation.

(13) For certain recovered wastes within the meaning of Directive 2008/98/EC of the European Parliament and of the Council[20], 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 products does not lead to overall adverse environmental or human health impacts. For CE marked 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.

(14) Certain substances and mixtures, commonly referred to as agronomic additives, improve the nutrient release pattern of a nutrient in a fertiliser. Substances and mixtures made available on the market with the intention of them being added to CE marked fertilising products for that purpose should fulfil certain efficacy criteria at the responsibility of the manufacturer of those substances or mixtures, and should therefore as such be considered as CE marked fertilising products under this Regulation. Furthermore, CE marked fertilising products containing such substances or mixtures should be subject to certain efficacy and safety criteria. Such substances

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consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

19 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).

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

and mixtures should therefore also be regulated as component materials for CE marked fertilising products.

(15) Certain substances, mixtures and micro-organisms, commonly referred to as plant biostimulants, are not as such nutrients, but nevertheless stimulate plants' nutrition processes. Where such products aim solely at improving the plants' nutrient use efficiency, tolerance to abiotic stress, or crop quality traits, they are by nature more similar to fertilising products than to most categories of plant protection products. 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[21]. Regulation (EC) No 1107/2009 should therefore be amended accordingly.

(16) Products with one or more functions, one of which is covered by the scope of Regulation (EC) No 1107/2009, should remain under the control tailored 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 in question. Therefore, such products should be excluded from the scope of this Regulation.

(17) This Regulation should not prevent the application of existing Union legislation relating to aspects of protection of health, safety and the environment not covered by this Regulation. This Regulation should therefore apply without prejudice to Council Directive 86/278/EEC[22], Council Directive 89/391/EEC[23], Regulation (EC) No 1907/2006 of the European Parliament and of the Council[24], Regulation (EC) No 1272/2008 of the European Parliament and of the Council[25], Commission Regulation (EC) No 1881/2006[26], Council Directive 2000/29/EC[27], Regulation (EU) No 98/2013 of the European Parliament and of the Council[28], and Regulation (EU) No 1143/2014 of the European Parliament and of the Council[29].

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21 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).

22 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).

23 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).

24 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) (OJ L 396, 30.12.2006, p. 1).

25 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 (OJ L 353, 31.12.2008, p. 1).

26 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).

27 Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (OJ L 169, 10.7.2000, p. 1).

28 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).

29 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).

(18) Where a CE marked fertilising product contains a substance or mixture within the meaning of Regulation (EC) No 1907/2006, the safety of its constituent substances for the 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 CE marked 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 making available pursuant to this Regulation.

(19) Where the actual quantities of substances in CE marked 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.

(20) A blend of different CE marked fertilising products, each of which has been subject to a successful assessment of conformity with the applicable requirements for that material, can itself be expected to be suitable for use as a CE marked fertilising product, subject only to certain additional requirements warranted by the blending. Therefore, in order to avoid an unnecessary administrative burden, such blends should belong to a separate category, for which the conformity assessment should be limited to the additional requirements warranted by the blending.

(21) Economic operators should be responsible for the compliance of CE marked 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.

(22) 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.

(23) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment of CE marked fertilising products should therefore remain solely the obligation of the manufacturer.

(24) It is necessary to ensure that CE marked 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 fertilising products. Provision should therefore be made for importers to make sure that CE marked fertilising products which they place on the market comply with the requirements of this Regulation and that they do not place on the market CE marked fertilising products which do not comply with such requirements or present a risk to human, animal or plant health, safety or the environment. Provision should also be made for such importers to make sure that conformity assessment procedures have been carried out and that marking of CE marked fertilising products and documentation drawn up by manufacturers are available for inspection by the competent national authorities.

(25) When placing a CE marked fertilising product on the market, the importer should indicate on the packaging of the fertilising product his or her name, registered trade name or registered trade mark and the postal address at which he or she can be contacted, in order to enable market surveillance.

(26) Since the distributor makes a CE marked fertilising product available on the market after it has been placed on the market by the manufacturer or the importer, he or she should act with due care to ensure that his or her handling of the fertilising product does not adversely affect the compliance of that product with this Regulation.

(27) An economic operator who either places a CE marked fertilising product on the market under his or her own name or trade mark or modifies a CE marked fertilising product in such a way that compliance with the provisions of this Regulation may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.

(28) 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 CE marked fertilising product.

(29) Ensuring traceability of a CE marked 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 CE marked 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 a CE marked fertilising product or to whom they have supplied a CE marked fertilising product, since such updated information is normally not available to them.

(30) In order to facilitate the assessment of conformity with safety and quality requirements it is necessary to provide for a presumption of conformity for CE marked 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[30].

(31) Where harmonised standards have not been adopted, or do not with sufficient detail cover all elements of the quality and safety requirements laid down in this Regulation, uniform conditions for implementing those requirements may be needed. The Commission should therefore be empowered to adopt implementing acts setting out those conditions in common specifications. For reasons of legal certainty, it should be clarified that CE marked fertilising products must comply with such specifications even if they are considered to be in conformity with harmonised standards.

(32) In order to enable the economic operators to demonstrate and the competent authorities to verify that CE marked fertilising products made available on the market comply with the requirements, it is necessary to provide for conformity assessment

[30] 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).

procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, from the least to the most stringent, in proportion to the level 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. However, it is necessary to adapt those modules 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 CE marked fertilising products derived from recovered waste.

(33) In order to ensure that CE marked 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.

(34) To ensure effective access to information for market surveillance purposes, information regarding conformity with all Union acts applicable to CE marked 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, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.

(35) The CE marking, indicating the conformity of a fertilising product, 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 fertilising products should be laid down.

(36) 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.

(37) 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.

(38) 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.

(39) In order to ensure a consistent level of quality in the performance of conformity assessment of CE marked 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.

(40) 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.

(41) Due to the variable nature of certain fertilising product component materials, and the potentially irreversible nature of some of the damages 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 CE marked fertilising products containing such components, should be the only means of demonstrating the technical competence of conformity assessment bodies.

(42) 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 CE marked 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.

(43) 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.

(44) Since the services offered by notified bodies may relate to CE marked 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.

(45) In the interest 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.

(46) 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 CE marked fertilising products covered by this Regulation. This Regulation should not prevent Member States from choosing the competent authorities to carry out those tasks.

(47) CE-marked fertilising products should be placed on the market only if they are sufficiently effective and do not present unacceptable risks to human, animal or plant health, to safety or to the environment when properly stored and used for their intended purpose, and under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour. Therefore, requirements for safety and quality, as well as appropriate control mechanisms, should be established. Furthermore, the intended use of CE marked fertilising products should not lead to food or feed becoming unsafe.

(48) 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.

(49) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to CE marked fertilising products presenting an unacceptable 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 fertilising products.

(50) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, further involvement of the Commission should be required only where non-compliance can be attributed to shortcomings of a harmonised standard, in which case the procedure of formal objection to harmonised standards laid down in Regulation (EU) No 1025/2012 should apply.

(51) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[31].

(52) 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, since such acts do not fall within the ambit of Article 2(2) of Regulation (EU) No 182/2011.

(53) The examination procedure should be used for the adoption of implementing acts with respect to compliant CE marked fertilising products which present an unacceptable risk to human, animal or plant health, to safety or to the environment, since such acts fall within the ambit of Article 2(2) of Regulation (EU) No 182/2011. For the same reason, it should also be used for the adoption, amendment or repeal of common specifications.

(54) The Commission should, by means of implementing acts, determine whether measures taken by Member States in respect of non-compliant CE marked fertilising products are justified or not. Since those acts will relate to the question whether national measures are justified, there is no need for the acts to be subject to control by the Member States.

(55) 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 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of defining larger or additional categories of CE marked fertilising products or component materials eligible for use in the production of such products. For animal by-products, component material categories should be expanded or added only to the extent an end point in the manufacturing chain has been determined in accordance with the procedures laid down in Regulation (EC) No 1069/2009, since animal by-products for which no such end point has been determined are in any event excluded from the scope of this Regulation.

(56) Furthermore, it should be possible to react immediately to new findings regarding the conditions for CE marked fertilising products to be sufficiently effective and to new

[31] 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).

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 of the Treaty should be delegated to the Commission to amend the requirements applicable to various categories of CE marked fertilising products.

(57) In exercising those powers, it is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(58) 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.

(59) 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.

(60) 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.

(61) Since the objective of this Regulation, namely to guarantee the functioning of the internal market while ensuring that CE marked fertilising products on the market fulfil the requirements providing for a high level of protection of human, animal, and plant health, safety and the environment, cannot be sufficiently achieved by the Member States 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:

CHAPTER 1
GENERAL PROVISIONS

Article 1
Scope

1. This Regulation shall apply to CE marked fertilising products.

However, this Regulation shall not apply to the following products:

(a) animal by-products which are subject to the requirements of Regulation (EC) No 1069/2009,

(b) plant protection products covered by the scope of Regulation (EC) No 1107/2009.

2. This Regulation shall not affect the application of the following acts :

(a) Directive 86/278/EEC;

(b) Directive 89/391/EEC;

(c) Regulation (EC) No 1907/2006;

(d) Regulation (EC) No 1272/2008;

(e) Regulation (EC) No 1881/2006;

(f) Directive 2000/29/EC;

(g) Regulation (EU) No 98/2013;

(h) Regulation (EU) No 1143/2014.

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(1) ‘fertilising product’ means a substance, mixture, micro-organism or any other material, applied or intended to be applied, either on its own or mixed with another material, on plants or their rhizosphere for the purpose of providing plants with nutrient or improving their nutrition efficiency;

(2) ‘CE marked fertilising product’ means a fertilising product which is CE marked when made available on the market;

(3) ‘substance’ means a substance within the meaning of Article 3(1) of Regulation (EC) No 1907/2006;

(4) ‘mixture’ means a mixture within the meaning of Article 3(2) of Regulation (EC) No 1907/2006;

(5) 'micro-organism' means a micro-organism within the meaning of Article 3(15) of Regulation (EC) No 1107/2009;

(6) ‘making available on the market’ means any supply of a CE marked fertilising product for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(7) ‘placing on the market’ means the first making available of a CE marked fertilising product on the Union market;

(8) ‘manufacturer’ means a natural or legal person who manufactures a CE marked fertilising product or has a CE marked fertilising product designed or manufactured, and markets that fertilising product under his or her name or trademark;

(9) ‘authorised representative’ means a natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his or her behalf in relation to specified tasks;

(10) ‘importer’ means any natural or legal person established within the Union who places a CE marked fertilising product from a third country on the Union market;

(11) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a CE marked fertilising product available on the market;

(12) ‘economic operators’ means manufacturers, authorised representatives, importers and distributors;

(13) 'technical specification' means a document that prescribes technical requirements to be fulfilled by a CE marked fertilising product;

(14) ‘harmonised standard’ means harmonised standard as defined in Article 2(1)(c) of Regulation (EU) No 1025/2012;

(15) ‘accreditation’ means accreditation as defined in Article 2(10) of Regulation (EC) No 765/2008;

(16) ‘national accreditation body’ means national accreditation body as defined in Article 2(11) of Regulation (EC) No 765/2008;

(17) ‘conformity assessment’ means the process demonstrating whether the requirements provided in this Regulation relating to a CE marked fertilising product have been fulfilled;

(18) ‘conformity assessment body’ means a body that performs conformity assessment activities including testing, certification and inspection;

(19) ‘recall’ means any measure aimed at achieving the return of a CE marked fertilising product that has already been made available to the end-user;

(20) ‘withdrawal’ means any measure aimed at preventing a CE marked fertilising product in the supply chain from being made available on the market;

(21) ‘CE marking’ means a marking by which the manufacturer indicates that the fertilising product is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;

(22) ‘Union harmonisation legislation’ means any Union legislation harmonising the conditions for the marketing of products.

Article 3

Free movement

Member States shall not impede the making available on the market of CE marked fertilising products which comply with this Regulation.

Article 4

Product requirements

1. A CE marked fertilising product shall

(a) meet the requirements set out in Annex I for the relevant product function category;

(b) meet the requirements set out in Annex II for the relevant component material category or categories;

(c) be labelled in accordance with the labelling requirements set out in Annex III.

2. For any aspects not covered by Annex I or II, CE marked fertilising products shall meet the requirement that their use, as specified in the use instructions, does not lead

to food or feed of plant origin becoming unsafe within the meaning of Articles 14 and 15 of Regulation (EC) No 178/2002, respectively.

Article 5
Making available on the market

CE marked fertilising products may be made available on the market only if they satisfy the requirements of the present Regulation.

CHAPTER 2
OBLIGATIONS OF ECONOMIC OPERATORS

Article 6
Obligations of manufacturers

1. When placing CE marked fertilising products on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements set out in Annex I for the relevant product function category and the requirements set out in Annex II for the relevant component material category or categories.

2. Before placing CE marked fertilising products on the market, manufacturers shall draw up the technical documentation and carry out the relevant conformity assessment procedure referred to in Article 14, or have it carried out. Where compliance of such a fertilising product with the applicable requirements laid down in this Regulation has been demonstrated by that procedure, manufacturers shall affix the CE marking, draw up an EU declaration of conformity and ensure that the declaration accompanies the fertilising product when placed on the market.

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the CE marked fertilising product covered by those documents has been placed on the market.

4. Manufacturers shall ensure that procedures are in place for CE marked fertilising products that are part of a series production to remain in conformity with this Regulation. Changes in production method or characteristics of those fertilising products and changes in the harmonised standards, common specifications referred to in Article 13 or other technical specifications by reference to which conformity of a CE marked fertilising product is declared shall be adequately taken into account.

   When deemed appropriate with regard to the performance of, or the risks presented by, a CE marked fertilising product, manufacturers shall carry out sample testing of such fertilising products made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming CE marked fertilising products and recalls of such products, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that the packaging of the CE marked fertilising products which they have placed on the market bears a type, batch or serial number or other element allowing their identification or, where the fertilising products are supplied without packaging, that the required information is provided in a document accompanying each fertilising product.

6. Manufacturers shall indicate their name, registered trade name or registered trade mark and the postal address at which they can be contacted on the packaging of the

CE marked fertilising product or, where the fertilising product is supplied without packaging, in a document accompanying the fertilising product. The postal address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

7. Manufacturers shall ensure that CE marked fertilising products are labelled in accordance with Annex III, or where the fertilising product is supplied without packaging, that the labelling statements are provided in a document accompanying the fertilising product and accessible for inspection purposes when the product is placed on the market. The labelling statement shall be in a language which can be easily understood by end-users, as determined by the Member State concerned, and shall be clear, understandable and intelligible.

8. Manufacturers who consider or have reason to believe that a CE marked fertilising product which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that fertilising product into conformity, to withdraw it or to recall it, if appropriate.

   Furthermore, where manufacturers consider or have reason to believe that CE marked fertilising products which they have placed on the market present an unacceptable risk to human, animal or plant health, to safety or to the environment, they shall immediately inform the competent national authorities of the Member States in which they made the fertilising products available on the market to that effect, giving details, in particular, of any non-compliance and of any corrective measures taken.

9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the CE marked fertilising product with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by CE marked fertilising products which they have placed on the market.

10. The manufacturer shall submit to the competent authority of the Member State of destination a report of the detonation resistance test prescribed in Annex IV for the following CE marked fertilising products:

    (a) straight or compound solid inorganic macronutrient ammonium nitrate fertilisers of high nitrogen content, as specified in product function category 1(C)(I)(a)(i-ii)(A) in Annex I;

    (b) fertilising product blends, as specified in product function category 7 in Annex I, containing a fertiliser referred to in point (a).

    The report shall be submitted at least five days in advance of placing those products on the market.

Article 7

Authorised representative

1. A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 6(1) and the obligation to draw up technical documentation referred to in Article 6(2) shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

(a) keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities for 10 years after the CE marked fertilising product covered by those documents has been placed on the market;

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a CE marked fertilising product;

(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by CE marked fertilising products covered by the authorised representative's mandate.

Article 8

Obligations of importers

1. Importers shall place only compliant CE marked fertilising products on the market.

2. Before placing a CE marked fertilising product on the market importers shall ensure that the appropriate conformity assessment procedure referred to in Article 14 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the CE marked fertilising product is accompanied by the EU declaration of conformity and the required documents, and that the manufacturer has complied with the requirements set out in Article 6(5) and (6). Where an importer considers or has reason to believe that a CE marked fertilising product is not in conformity with the applicable requirements set out in Annex I, Annex II or Annex III, he or she shall not place the fertilising product on the market until it has been brought into conformity. Furthermore, where the CE marked fertilising product presents an unacceptable risk to human, animal or plant health, to safety or to the environment, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3. Importers shall indicate their name, registered trade name or registered trade mark and the postal address at which they can be contacted on the packaging of the CE marked fertilising product or, where the CE marked fertilising product is supplied without packaging, in a document accompanying the fertilising product. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

4. Importers shall ensure that the CE marked fertilising product is labelled in accordance with Annex III in a language which can be easily understood by end-users, as determined by the Member State concerned.

5. Importers shall ensure that, while a CE marked fertilising product is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the safety and quality requirements set out in Annex I or with the labelling requirements set out in Annex III.

6. When deemed appropriate with regard to the performance of or the risks presented by a CE marked fertilising product, importers shall carry out sample testing of such fertilising products made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming CE marked fertilising products and recalls of such products, and shall keep distributors informed of any such monitoring.

7. Importers who consider or have reason to believe that a CE marked fertilising product which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that fertilising product into conformity, to withdraw it or to recall it, if appropriate.

   Furthermore, where importers consider or have reason to believe that CE marked fertilising products which they have placed on the market present an unacceptable risk to human, animal or plant health, to safety or to the environment, they shall immediately inform the competent national authorities of the Member States in which they made the fertilising product available on the market to that effect, giving details, in particular, of any non-compliance and of any corrective measures taken.

8. Importers shall, for 10 years after the CE marked fertilising product has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the CE marked fertilising product in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by CE marked fertilising products which they have placed on the market.

10. The importer shall submit to the competent authority of the Member State of destination a report of the detonation resistance test prescribed in Annex IV for the following CE marked fertilising products:

    (a) straight or compound solid inorganic macronutrient ammonium nitrate fertilisers of high nitrogen content, as specified in product function category 1(C)(I)(a)(i-ii)(A) in Annex I;

    (b) fertilising product blends, as specified in product function category 7 in Annex I, containing a fertiliser referred to in point (a).

    The report shall be submitted at least five days in advance of placing those products on the market.

Article 9

Obligations of distributors

1. When making a CE marked fertilising product available on the market distributors shall act with due care in relation to the requirements of this Regulation.

2. Before making a CE marked fertilising product available on the market distributors shall verify that it is accompanied by the EU declaration of conformity and by the required documents, that it is labelled in accordance with Annex III in a language which can be easily understood by end-users in the Member State in which the CE marked fertilising product is to be made available on the market, and that the

manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3) respectively.

Where a distributor considers or has reason to believe that a CE marked fertilising product is not in conformity with the applicable requirements set out in Annex I, Annex II or Annex III, he or she shall not make the fertilising product available on the market until it has been brought into conformity. Furthermore, where the CE marked fertilising product presents an unacceptable risk to human, animal or plant health, to safety or to the environment, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

3. Distributors shall ensure that, while a CE marked fertilising product is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the safety and quality requirements set out in Annex I or the labelling requirements set out in Annex III.

4. Distributors who consider or have reason to believe that a CE marked fertilising product which they have made available on the market is not in conformity with this Regulation shall make sure that the corrective measures necessary to bring that fertilising product into conformity, to withdraw it or to recall it, if appropriate, are taken.

Furthermore, where distributors consider or have reason to believe that CE marked fertilising products which they have made available on the market presents an unacceptable risk to human, animal or plant health, to safety or to the environment, they shall immediately inform the competent national authorities of the Member States in which they made the CE marked fertilising product available on the market to that effect, giving details, in particular, of any non-compliance and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the CE marked fertilising product. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by CE marked fertilising products which they have made available on the market.

Article 10

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Regulation, and shall be subject to the obligations of the manufacturer under Article 6, where he or she places a CE marked fertilising product on the market under his or her name or trademark or modifies a CE marked fertilising product already placed on the market in such a way that compliance with this Regulation may be affected.

Article 11

Identification of economic operators

1. Economic operators shall, on request, identify the following to the market surveillance authorities:

(a) any economic operator who has supplied them with a CE marked fertilising product;

(b) any economic operator to whom they have supplied a CE marked fertilising product.

2. The economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the CE marked fertilising product and for 10 years after they have supplied the CE marked fertilising product.

CHAPTER 3
CONFORMITY OF CE MARKED FERTILISING PRODUCTS

Article 12
Presumption of conformity

Without prejudice to the common specifications referred to in Article 13, CE marked fertilising products which are in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the requirements set out in Annexes I, II and III covered by those standards or parts thereof.

Article 13
Common specifications

The Commission may adopt implementing acts laying down common specifications, the compliance with which shall ensure conformity with the requirements set out in Annexes I, II and III covered by those specifications or parts thereof. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 41(3).

Article 14
Conformity assessment procedures

1. Conformity assessment of a CE marked fertilising product with the requirements in this Regulation shall be carried out by applying the conformity assessment procedure specified in Annex IV.

2. Records and correspondence relating to conformity assessment procedures shall be drawn up in the official language(s) of the Member State where the notified body carrying out the conformity assessment procedures is established, or in a language accepted by that body.

Article 15
EU declaration of conformity

1. The EU declaration of conformity shall state that the fulfilment of the requirements set out in Annexes I, II and III has been demonstrated.

2. The EU declaration of conformity shall have the model structure set out in Annex V, shall contain the elements specified in the relevant modules set out in Annex IV and shall be continuously updated. It shall be translated into the language or languages

required by the Member State in which the CE marked fertilising product is placed or made available on the market.

3. Where a CE marked fertilising product is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall state the Union acts concerned and their publication references. It may be a dossier made up of relevant individual declarations of conformity.

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the CE marked fertilising product with the requirements laid down in this Regulation.

Article 16

General principles of CE marking

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

Article 17

Rules and conditions for affixing the CE marking

1. The CE marking shall be affixed visibly, legibly and indelibly to the accompanying documents and, where the CE marked fertilising product is supplied in a packaged form, to the packaging.

2. The CE marking shall be affixed before the CE marked fertilising product is placed on the market.

3. The CE marking shall be followed by the identification number of the notified body involved in the conformity assessment referred to in Annex IV, Module D1.

   The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his or her authorised representative.

4. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

Article 18

End-of-waste status

A CE marked fertilising product that has undergone a recovery operation and complies with the requirements laid down in this Regulation shall be considered to comply with the conditions laid down in Article 6(1) of Directive 2008/98/EC and shall, therefore, be considered as having ceased to be waste.

CHAPTER 4
NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 19
Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Regulation.

Article 20
Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 25.
2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.
3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 21. In addition it shall have arrangements to cover liabilities arising out of its activities.
4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article 21
Requirements relating to notifying authorities

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.
2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.
3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.
4. A notifying authority shall not offer or provide any activities that conformity assessment bodies or consultancy services perform on a commercial or competitive basis.
5. A notifying authority shall safeguard the confidentiality of the information it obtains.
6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Article 22

Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

Article 23

Requirements relating to notified bodies

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2. A conformity assessment body shall be established under the national law of a Member State and have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the CE marked fertilising products it assesses.

   A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, or use of CE marked fertilising products which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, purchaser, owner, or user of fertilising products nor the representative of any of those parties. This shall not preclude the use of fertilising products that are necessary for the operations of the conformity assessment body or the use of fertilising products for personal purposes.

   A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture, marketing, or use of fertilising products or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

   Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annex IV and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of CE marked fertilising products in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out the conformity assessment tasks shall have the following:

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the requirements set out in Annex I, Annex II and Annex III, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation;

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annex IV, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under Article 35 and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 24

Presumption of conformity of notified bodies

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* it shall be presumed to comply with the requirements set out in Article 23 in so far as the applicable harmonised standards cover those requirements.

Article 25

Subsidiaries of and subcontracting by notified bodies

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 23 and shall inform the notifying authority accordingly.
2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.
3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.
4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annex IV.

Article 26

Application for notification

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.
2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the CE marked fertilising product or products for which that body claims to be competent, as well as by an accreditation certificate issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 23.

Article 27

Notification procedure

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 23.

2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and CE marked fertilising product or products concerned and the accreditation certificate referred to in Article 26(2).

4. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification.

   Only such a body shall be considered a notified body for the purposes of this Regulation.

5. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

Article 28

Identification numbers and lists of notified bodies

1. The Commission shall assign an identification number to a notified body.

   It shall assign a single such number even where the body is notified under several Union acts.

2. The Commission shall make publicly available the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified.

   The Commission shall ensure that the list is kept up to date.

Article 29

Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 23 or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Article 30

Challenge of the competence of notified bodies

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requiring the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 41(2).

Article 31

Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annex IV.

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Notified bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the CE marked fertilising product with this Regulation.

3. Where a notified body finds that the requirements set out in Annex I, Annex II or Annex III, or corresponding harmonised standards, common specifications referred to in Article 13 or other technical specifications, have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate.

4. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a CE marked fertilising product no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

Article 32

Appeal against decisions of notified bodies

Member States shall ensure that an appeal procedure against decisions of the notified bodies is available.

Article 33

Information obligation on notified bodies

1. Notified bodies shall inform the notifying authority of the following:

(a) any refusal, restriction, suspension or withdrawal of a certificate;

(b) any circumstances affecting the scope of or conditions for notification;

(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

(d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2. Notified bodies shall provide the other bodies notified under this Regulation carrying out similar conformity assessment activities covering the same CE marked fertilising products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 34

Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

Article 35

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Regulation are put in place and properly operated in the form of a sectoral group of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.

CHAPTER 5
UNION MARKET SURVEILLANCE, CONTROL OF CE MARKED FERTILISING PRODUCTS ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE

Article 36

Union market surveillance and control of CE marked fertilising products entering the Union market

Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to CE marked fertilising products.

Article 37

Procedure for dealing with CE marked fertilising products presenting a risk at national level

1. Where the market surveillance authorities of one Member State have sufficient reason to believe that a CE marked fertilising product presents an unacceptable risk to human, animal or plant health, to safety or to the environment, they shall carry out an evaluation in relation to the fertilising product concerned covering the requirements laid down in this Regulation. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

Where, in the course of the evaluation, the market surveillance authorities find that the CE market fertilising product does not comply with the requirements laid down in this Regulation, they shall without delay require the economic operator to take all appropriate corrective actions within a reasonable period to bring the fertilising product into compliance with those requirements, to withdraw the fertilising product from the market, to recall it, or to remove the CE marking.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the CE marked fertilising products concerned that it has made available on the market throughout the Union.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the CE marked fertilising product being made available on their national market, to withdraw the fertilising product from that market or to recall it.

   The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant CE marked fertilising product, the origin of that fertilising product, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:

   (a) failure of the CE marked fertilising product to meet the requirements set out in Annexes I, II or III

   (b) shortcomings in the harmonised standards referred to in Article 12 conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the CE marked fertilising product concerned, and, in the event of disagreement with the adopted national measure, of their objections.

7. Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8. Member States shall ensure that appropriate restrictive measures, such as withdrawal, are taken without delay in respect of the CE marked fertilising product concerned.

Article 38
Union safeguard procedure

1. Where, on completion of the procedure set out in Article 37(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act in the form of a decision determining whether the national measure is justified or not.

   If the national measure is considered justified, the decision shall order all Member States to take the necessary measures to ensure that the non-compliant CE marked fertilising product is withdrawn from their market, and to inform the Commission accordingly.

   If the national measure is considered unjustified, the decision shall order the Member State concerned to withdraw that measure.

   The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2. Where the national measure is considered justified and the non-compliance of the CE marked fertilising product is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 37(5), the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

Article 39
Compliant CE marked fertilising products which present a risk

1. Where, having carried out an evaluation under Article 37(1), a Member State finds that although a CE marked fertilising product is in compliance with this Regulation it presents an unacceptable risk to human, animal or plant health, to safety or to the environment, it shall require the relevant economic operator to take all appropriate measures within a reasonable period to ensure that the fertilising product concerned, when placed on the market, no longer presents that risk, to withdraw the fertilising product from the market or to recall it.

2. The economic operator shall ensure that corrective action is taken in respect of all the CE marked fertilising products concerned that he or she has made available on the market throughout the Union.

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the CE marked fertilising product concerned, the origin and the supply chain of that fertilising product, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall

adopt an implementing act in the form of a decision determining whether the national measure is justified or not, and where necessary, ordering appropriate measures.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 41(3).

On duly justified imperative grounds of urgency relating to the protection of human, animal or plant health, safety or the environment, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 41(4).

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

Article 40
Formal non-compliance

1. Without prejudice to Article 37, where a Member State makes one of the following findings on a CE marked fertilising product, it shall require the relevant economic operator to put an end to the non-compliance concerned:

   (a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 17 of this Regulation;

   (b) the identification number of the notified body has been affixed in violation of Article 17 or has not been affixed, where required by Article 17;

   (c) the EU declaration of conformity does not accompany the CE marked fertilising product;

   (d) the EU declaration of conformity has not been drawn up correctly;

   (e) technical documentation is either not available or not complete;

   (f) the information referred to in Article 6(6) or Article 8(3) is absent, false or incomplete;

   (g) any other administrative requirement provided for in Article 6 or Article 8 is not fulfilled.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the CE marked fertilising product being made available on the market or ensure that it is recalled or withdrawn from the market or that the CE marking is removed.

CHAPTER 6
COMMITTEE AND DELEGATED ACTS

Article 41
Committee procedure

1. The Commission shall be assisted by the Committee on Fertilising products. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

Article 42
Amendments of Annexes

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 43 to amend Annexes I to IV for the purposes of adapting them to technical progress and facilitating internal market access and free movement for CE marked fertilising products

   (a) which are likely to be subject of significant trade on the internal market, and

   (b) for which there is scientific evidence that the they do not present an unacceptable risk to human, animal or plant health, to safety or to the environment, and that they are sufficiently effective.

2. Where the Commission amends Annex II in order to add new micro-organisms to the component material category for such organisms pursuant to paragraph 1, it shall do so on the basis of the following data:

   (a) name of the micro-organism;

   (b) taxonomic classification of the micro-organism;

   (c) historical data of safe production and use of the micro-organism

   (d) taxonomic relation to micro-organism species fulfilling the requirements for a Qualified Presumption of Safety as established by the European Food Safety Agency;

   (e) information on residue levels of toxins;

   (f) information on the production process; and

   (g) information on the identity of residual intermediates or microbial metabolites in the component material.

3. When adopting delegated acts in accordance with paragraph 1, the Commission may amend the component material categories set out in Annex II in order to add animal by-products within the meaning of Regulation (EC) No 1069/2009 only where an end point in the manufacturing chain has been determined for such products in accordance with the procedures laid down in that Regulation.

4. The Commission shall also be empowered to adopt delegated acts in accordance with Article 43 to amend Annexes I to IV in the light of new scientific evidence. The Commission shall use this empowerment where, based on a risk assessment, an amendment proves necessary to ensure that any CE marked fertilising product complying with the requirements of this Regulation does not, under normal conditions of use, present an unacceptable risk to human, animal, or plant health, to safety or to the environment.

Article 43

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 42 shall be conferred on the Commission for five years from [Publications office, please insert the date of entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 42 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 42 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

CHAPTER 7
TRANSITIONAL AND FINAL PROVISIONS

Article 44

Penalties

Member States shall lay down rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, without delay, notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.

Article 45

Amendments to Regulation (EC) No 1069/2009

In Regulation (EC) No 1069/2009, Article 5 is amended as follows:

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

"For derived products referred to in Articles 32, 35 and 36 which no longer pose any significant risk to public or animal health, an end point in the

manufacturing chain may be determined, beyond which they are no longer subject to the requirements of this Regulation.";

(2) paragraph 3 is replaced by the following:

"3. In the event of risks to public or animal health, Articles 53 and 54 of Regulation (EC) No 178/2002 concerning emergency health measures shall apply mutatis mutandis to the derived products referred to in Articles 32, 33 and 36 of this Regulation."

Article 46

Amendments to Regulation (EC) No 1107/2009

Regulation (EC) No 1107/2009 is amended as follows:

(1) Article 2(1) (b) is replaced by the following:

"(b) influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient or a plant biostimulant;"

(2) in Article 3, the following point is added:

(3) "34. "plant biostimulant" means a product stimulating plant nutrition processes independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant:

(a) nutrient use efficiency;

(b) tolerance to abiotic stress;

(c) crop quality traits."

Article 47

Repeal of Regulation (EC) No 2003/2003

Regulation (EC) No 2003/2003 is repealed with effect from the date referred to in the second paragraph of Article 49.

References to the repealed Regulation shall be construed as references to this Regulation.

Article 48

Transitional provisions

Member States shall not impede the making available on the market of products which were placed on the market as fertilisers designated "EC fertiliser" in conformity with Regulation (EC) No 2003/2003 before [Publications office, please insert the date of application of this Regulation]. However, Chapter 5 shall apply *mutatis mutandis* to such products.

Article 49

Entry into force and application

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 1 January 2018.

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President