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Subject:	Proposal for a Regulation amending Regulation (EU) 2019/1009 as regards digital labelling of EU fertilising products
	- Letter to the Chair of the European Parliament IMCO Committee

Following the Permanent Representatives Committee meeting of 7/02/2024 which endorsed the final compromise text with a view to agreement, delegations are informed that the Presidency sent the attached letter, together with its Annex, to the Chair of the European Parliament IMCO Committee.

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SGS 24 / D00785

Brussels, 7/02/2024

Ms Anna CAVAZZINI
Chair of the Committee on the Internal Market and Consumer Protection
European Parliament
Rue Wiertz 60
B-1047 BRUSSELS

Subject: Proposal for a Regulation amending Regulation (EU) 2019/1009 as regards digital

labelling of EU fertilising products

Dear Ms CAVAZZINI,

Following the informal negotiations on this proposal between the representatives of the three institutions, today the Permanent Representatives Committee agreed with the final compromise text.

I am therefore now in a position to inform you that, should the European Parliament adopt its position at first reading, in accordance with Article 294(3) TFEU, in the exact form of the text set out in the Annex to this letter (subject to revision by the lawyer-linguists of the two institutions), the Council, in accordance with Article 294(4) TFEU, will approve the European Parliament's position and the act shall be adopted in the wording which corresponds to the position of the European Parliament

On behalf of the Council, I also wish to thank you for your close cooperation which should enable us to reach agreement on this file at first reading.

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Pierre CARTUYVELS
Chair of the Permanent Representatives Committee
(Part 1)

Yours sincerely

Copy: Mr Thierry BRETON - Commissionner for the Internal Market
Ms Maria GRAPINI - Rapporteur of the IMCO Committee of the European Parliament
Mr Dan-Ştefan MOTREANU - Rapporteur of the AGRI Committee of the
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REGULATION (EU) NO .../... OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of

amending Regulation (EU) 2019/1009 as regards the digital labelling of EU fertilising products

(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 Committee¹,

Acting in accordance with the ordinary legislative procedure,

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OJ C , , p. .

Whereas:

- (1) Annex III to Regulation (EU) 2019/1009 lays down the labelling requirements applicable to EU fertilising products. The information referred to in Annex III is to be provided on a label in a physical form attached to that packaging or, for the labelling elements that cannot be provided on the label due to the packaging being too small, in a separate leaflet accompanying that packaging ('physical label'). Products without a packaging are accompanied by a leaflet. The labelling requirements concern various parameters linked to the agronomic efficiency of EU fertilising products (e.g., content of nutrients in a fertiliser) and the content of such products (e.g., quantity). The labelling requirements also cover information needed for the protection of human health and the environment when using EU fertilising products (e.g., information needed for the correct application of Council Directive 91/676/EEC²) and information needed for the correct handling and use of such products after purchase (e.g., information on storage conditions).
- (2) The form in which EU fertilising products are labelled in accordance with Regulation (EU) 2019/1009 should be adapted to technological and societal changes in the field of digitalisation, without compromising the quality and accessibility of information aiming at better information provision, while taking account of the impacts on and benefits for economic operators and end-users.

² Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (OJ L 375, 31.12.1991, p. 1).

(3) Providing information on a label in a digital form ('digital label') has clear benefits. Digital labelling can improve the communication of labelling information both by avoiding overcrowded physical labels and by allowing users to rely on various reading options available only for digital formats, such as increased font, automatic search, loud speakers or translation into other languages. In addition, digital labelling of EU fertilising products contributes to the ongoing progress with regard to the digital and green transformation of the European agricultural sector, reducing packaging waste and facilitating the reporting obligations of farmers regarding the use of such products. Digital labelling can also lead to a more efficient management of the labelling obligations by economic operators, by facilitating the update of labelling information and permitting a more targeted information to users. While the use of digital labels could overcome space limitations compared to physical labels by providing traceability of the information and could reduce fertiliser prices from lower labelling costs, nonetheless irrelevant or unnecessary information should be avoided, so as to ensure best quality of essential information for users. In addition, digital labelling can contribute to reducing labelling costs all along the supply chain, given that the labels of EU fertilising products may be changed following a transaction between economic operators, before reaching end-users,

(4) However, digital labelling can also create new challenges, one of which is the possibility that digital labelling will create problems for the vulnerable population groups, in particular persons with no, or insufficient, digital skills or access to digital devices needed to retrieve the digital labels, and for persons with disabilities. Therefore, digital labelling should be introduced in Regulation (EU) 2019/1009, under certain conditions and should be easily understandable and accessible to vulnerable groups and persons with disabilities. Digital labelling may make more difficult for these groups to easily access essential information on the agronomic efficiency of EU fertilising products, as well as instructions for safe use, protection of human, animal, plant health and environmental *impact, ultimately accentuating* the digital divide. Therefore, digital labelling should be introduced in Regulation (EU) 2019/1009, under certain conditions and should be easily understandable and accessible to vulnerable groups and persons with disabilities, taking into account the need to ensure a high level of protection of human, animal and plant health and the environment, and the digital readiness, without increasing costs excessively. It is vital that user safety is not compromised in the process of making labelling more user-friendly through digital means and that the possibilities and skills of SMEs to digitalise the labels are taken into account.

- [5] Economic operators should remain free to choose *whether* to provide a digital or physical label. This will ensure that *they have the* flexibility to opt for the rules most appropriate to their situation. It is particularly important not to create unjustified costs for small and medium-sized enterprises for which , given the reduced volumes or types of EU fertilising products, *digital labelling might be challenging. It is also important to provide support in the form of guidance and training programmes in order to enable such enterprises to develop the adequate skills and capabilities to comply with this Regulation.*
- (6) The choice to provide a digital label lies primarily with manufacturers and importers, who are responsible for fulfilling the labelling requirements set out in Annex III to Regulation (EU) 2019/1009, ensuring they can make informed decisions that are tailored to their product range and intended customers. Nevertheless, to maximise the use of digital labels and thereby improve the communication of information to users, distributors should also have the possibility to digitise the label of EU fertilising products that they make available on the market, based on the information already provided by the manufacturer. The use of digitalised labels should ensure a consistent flow of accurate information throughout the supply chain. The extent of digital labelling should depend on two factors: if the EU fertilising products are made available to economic operators or to end-users and if the products are provided with or without a packaging.

- (7) Economic operators should be allowed to provide all the labelling elements referred to in Annex III of Regulation (EU) 2019/1009 in a digital label only for the EU fertilising products supplied to other economic operators, with or without a packaging. The use of digital labels in such cases can reduce *waste and* the labelling costs in the supply chain. Importers or distributors will have the possibility to affix a physical label to the EU fertilising product directly in the official languages needed for their specific situation. In addition, labelling costs can be avoided in case of blending, packaging or re-packaging of EU fertilising products, since the products can be labelled with a physical label only once, before reaching end-users. As products are supplied to economic operators, the communication of information to end-users is not affected. Where the economic operators choose to provide, in addition to a digital label, a physical label, they should be free to decide which labelling elements to include in that physical label *in accordance with Regulation (EU) 2019/1009*.
- (8) Physical labels remain a preferred way of obtaining key information about the use of EU fertilising products for end-users as by being affixed to packaging such physical labels offer immediate reliable access to information. In addition, the vast majority of EU fertilising products available on the market are used by professional users, such as farmers and agricultural contractors. While professional users are well accustomed with fertilising products and often rely on consultancy for their fertilisation plans, they tend to belong to more advanced age groups, with more reduced digital skills and might encounter difficulties when accessing the digital labels. In addition, less developed rural regions might face fluctuating access to internet in the field or on the farm.

(9)Where economic operators opt for digital labelling of EU fertilising products supplied to end-users in a packaging, they should therefore ensure that a minimum set of key information about the agronomic efficiency and use of the product is also available on the physical label. In this context and with regard to other rules specific to products made available in a packaging, a packaging should contain no more than 1000 kg in coherence with Commission Regulation (EU) No 142/2011³ to ensure that larger quantities, typically used in industrial settings, are treated differently from consumer oriented packages. Products supplied in a packaging exceeding this limit should be considered as being supplied without a packaging for the purpose of Regulation (EU) 2019/1009. This will also address the challenges that vulnerable population groups may face. The specific information that economic operators should be allowed to provide only on a digital label should therefore reflect the current state of the digitalisation of the society and the particular situation of the users of EU fertilising products and acknowledging the diverse user base is crucial. In order to enable all end-users to make informed choices before buying EU fertilising products and to ensure the safe handling and use of such products by all groups of end-users, labelling information concerning safety, the protection of human, *animal, plant* health and the environment as well as minimum information on the agronomic efficiency of the EU fertilising products and on their content and *correct* use, should always be provided on the physical label. *Digital labels could also include* information on greenhouse gas emissions related to the production process, the impact of the fertiliser, including its production process and the agro-ecological efficiency. Regulation (EU) 2019/1009 should clearly indicate which information may be provided only digitally.

Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive, OJ L 54, 26.2.2011, p. 1.

- (10)For EU fertilising products supplied without packaging, the economic operators are to provide the labelling elements in a leaflet to secure that even without direct packaging, essential information is still accessible to the user, including those lacking basic literacy skills. The leaflet, contrary to physical labels, has no physical link to the product itself and therefore does not offer immediate access to the information relevant to the product when handling it, but must serve as a bridge between the product and the user, ensuring that vital details are not lost. Providing the same labelling elements in digital format would imply an adjustment of the way the information is retrieved which is justified once the risks to users are properly addressed and mitigated. The digital format should be flexible, harmonised and updated in real-time, ensuring that users can access the most current *information.* Economic operators should therefore be allowed to provide all the labelling elements referred to in Annex III of Regulation (EU) 2019/1009 in a digital label only for the EU fertilising products supplied without packaging. Where the economic operators choose to provide, in addition to a digital label, a physical label, they should be free to decide which labelling elements to include in that physical label.
- (11) To ensure a level playing field among economic operators making available EU fertilising products on the market, and to protect the end-users of such products, *harmonised* requirements for digital labelling should be laid down.

(12)In order to ensure that users receive all the labelling elements on the digital label and will not need to compile the information both from a physical and a digital label, economic operators using a digital label should be required to include all such labelling elements in that label, even if they are also included on the physical label to ensure a one-stop source for all necessary information. The digital label should also contain information allowing end-users to identify and contact the manufacturer and the importer of the EU fertilising products, as this is an essential information since it is necessary to have a direct communication line to enhance trust and transparency and providing it digitally will facilitate the link between the product and the digital label as well as between the manufacturer and the end-user. In addition, given that fertilising products are also placed on the market as non-harmonised products, it is *crucial* to include on the digital label the CE-mark and any corresponding reference to a notified body, so that end-users can deduce only from using the digital label that the product is marketed in accordance with Regulation (EU) 2019/1009. However, to facilitate the update of certain information to be provided by the manufacturers, which changes frequently and is not used on a daily basis by end-users (*specifically*, the batch number and the production date) the manufacturers should have the *option* to provide the information either physically or digitally *based on* flexibility that should lead to more prompt and accurate updates. Similarly, economic operators should have the option not to include the quantity on the digital label if already provided in a physical form, given that this element could change along the supply chain or could vary with each transaction in case of products supplied without a packaging. It is recalled that it is also essential that the end-user has the necessary information referred to in Regulation 2023/988 to be able to identify and contact the responsible person for products placed on the Union market.

(13)Since digital labels, similarly to physical labels, are a means of providing mandatory information on EU fertilising products to users, economic operators should ensure free access to digital labels for a period of 10 years from the moment that EU fertilising product was placed on the market. In addition, and in order to improve the chances that users will in practice retrieve the information, the information provided on the digital label should be easily accessible to end-users in the Union through widely used digital technologies compatible with all major operating systems and browsers, and ensuring that access to the label does not require any password, registration, nor any specific application and taking into account the needs of vulnerable groups. The data carrier should lead directly to the digital label, without the need to register in advance, to browse a website, install applications or to provide a password, and the access to the information should not be conditioned by the geographical area within the territory of the European *Union.* Economic operators should not mix the information required by Regulation (EU) 2019/1009 with other information not requested by Regulation (EU) 2019/1009, such as marketing or commercial statements. Digital space has no space limitations typical for physical labels affixed to the packaging. It is therefore important to keep the labelling elements provided in accordance with Regulation (EU) 2019/1009 concentrated in one place, so that they are not difficult to find among various other information which economic operators might provide. Economic operators should also ensure that digital labels are presented in a way that takes into account the needs of vulnerable population groups, in particular persons with disabilities to further reduce the challenges such groups may face. At the same time, the fact that digital labels do not have space limitations also provides an opportunity to provide additional information regarding the use of the EU fertilising product, such as recommendations and best practises to limit nutrient losses. Economic operators should therefore have the possibility to provide this information in the digital label.

- (14) Taking into account both the interest of users to have access to information about EU fertilising products with a relatively long shelf life and the interest of economic operators to avoid unnecessary costs, economic operators should ensure that the digital label is available for a period of *10* years from the moment *that* EU fertilising product *was* placed on the market.
- (15)In order to reduce any potential risks caused by the unavailability of the digital label to vulnerable population groups, in particular as regards EU fertilising products supplied without packaging to end-users, where all the labelling elements may be provided digitally, economic operators should be responsible for providing the labelling elements by alternative means to end-users, upon request. Potential end-users should have the right irrespective of a purchase to receive information by alternative means in order to take an *informed decision.* Whenever the digital label is temporarily unavailable, the information should be provided even without a request. Additionally, for products supplied to endusers without packaging with a digital label only the labelling information provided in accordance with Annex III to Regulation (EU) 2019/1009 should also be in a visible place at the point of sale on the premises. This will properly inform potential end-users and enable them to make an informed purchase. It would also ensure direct access to information relevant for the protection of human, animal and plant health and the environment, such as information on the content of nitrogen required for the implementation of the national rules transposing the Council Directive 91/676/EEC.

The requirements for the technical documentation set out in Annex IV to Regulation (EU) 2019/1009 should be adjusted to take into account the introduction of digital labels. *Given the evolving nature of digital platforms and the need for consistent accessibility, these adjustments should be periodically reviewed.* In addition, taking into account the possibility to provide only a digital label for EU fertilising products made available to blenders, to facilitate market surveillance, the technical documentation of fertilising products blends should include a specimen of the information provided under Annex III to Regulation (EU) 2019/1009 on the component EU fertilising products *to ensure that all stakeholders have a clear understanding of the product's components and their respective origins.*

(17)In order to keep Regulation (EU) 2019/1009 up-to-date to technical progress, new scientific evidence and the evolution of the digitalisation of the society, 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 supplementing the requirements for digital labelling and amending Annex III with regard to which labelling elements economic operators making available on the market EU fertilising products in a packaging to end-users may provide on a digital label only. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level, and that those consultations are conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making⁴. It is also of particular importance that the Commission takes into account the views of all stakeholders during its preparatory work. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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⁴ OJ L 123, 12.5.2016, p. 1.

- (18) When setting out more detailed rules for digital labelling, the Commission should pay particular attention to other Union rules on the provision of information about products or substances and mixtures in a digital format. It should be possible to access all the information requested by various Union rules in one digital space, so that the users have easy access to all the information needed. This would simplify the user experience and encourage trust in digital information sources. Furthermore, it would provide a more comprehensive and user-friendly interface, promoting consumer transparency and informed decision-making.
- When deciding which labelling elements may be provided only digitally by economic operators making available on the market EU fertilising products in a packaging to endusers, the Commission should take into account the level of digital readiness among users of EU fertilising products and the need to keep the use of such products safe for human, animal and plant health and the environment, as well as the need to ensure availability of the digital label for a period of 10 years from the moment the EU fertilising product was placed on the market. Additionally, consideration should be given to the evolving digital landscape, ensuring that as technology advances, digital labelling remains accessible and user-friendly. It is crucial to assess the feedback from end-user and stakeholders to ensure that the digital labelling system meets their needs and addresses any emerging concerns.

- (20) Regulation (EU) 2019/1009 should therefore be amended accordingly.
- Given that this Regulation introduces the possibility of providing all or part of the labelling requirements in Annex III only in digital labels, its application should be deferred to provide for enough time for the development of the supplementing requirements concerning the digital labelling.
- The specific objectives of this Regulation, namely to improve the readability of the labels of EU fertilising products and to facilitate the management of such labels by the economic operators *in order to guarantee the functioning of the internal market*, cannot be sufficiently achieved by the Member States. Since they can rather, by reason of their 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, by introducing a possibility to use digital labelling for certain information, this Regulation does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS REGULATION:

Article 1

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

- (1) Article 2 is amended as follows:
 - (a) the following point (10a) is inserted:
 - '(10a) "packaging" means a sealable receptacle holding not more than 1000 kg;;'
 - (b) the following point (16a) is inserted:
 - '(16a) "data carrier" means a linear bar code symbol, a two-dimensional symbol or other automatic identification data capture medium that can be read by a device; ■
- (2) Article 6 is amended as follows:
 - (a) in paragraph 5, the following subparagraph is added:

'The information referred to in the first subparagraph shall be provided either physically on the packaging or the accompanying document, digitally, or both. Where the information is provided digitally, the requirements set out for digital labels in Article 11b and the obligations set out in Article 11c shall apply.;'

- (b) in paragraph 6, the following subparagraph is added:
 - 'The information referred to in the first subparagraph shall be provided physically on the packaging or the accompanying document or both physically on the packaging or the accompanying document and digitally. Where the information is provided digitally, the requirements set out for digital labels in Article 11b and the obligations set out in Article 11c shall apply.;'
- (c) paragraph 7 is replaced by the following:
 - '7. Manufacturers shall ensure that EU fertilising products are accompanied by the labelling elements required under Annex III, provided in the relevant form set out in Article 11a. Those labelling elements shall be:
 - (a) in a language which can be easily understood by end-users, as determined by the Member State concerned;
 - (b) clear, understandable, accurate, intelligible and prominently placed on the packaging;
 - (c) accessible for inspection purposes when the EU fertilising product is made available on the market.;

- in Article 8, paragraph 4 is replaced by the following:
 - '4. Importers shall ensure that EU fertilising products are accompanied by the labelling elements required under Annex III, provided in the relevant form set out in Article 11a. Those labelling elements shall be:
 - (a) in a language which can be easily understood by end-users, as determined by the Member State concerned;
 - (b) accessible for inspection purposes when the EU fertilising product is made available on the market.;'
- (4) the following Articles 11a, 11b and 11c are inserted:

'Article 11a

Forms of labelling

- 1. Where EU fertilising products are made available on the market in a packaging to economic operators, they shall be accompanied by the labelling elements set out in Annex III in the following form:
 - (a) on a label in a digital form ("digital label"); or.
 - (b) on a label in a physical form attached to that packaging or, for the labelling elements that cannot be provided on the label due to the packaging being too small, in a separate leaflet accompanying that packaging ("physical label").

- 2. Where EU fertilising products are made available on the market without packaging to economic operators, they shall be accompanied by the labelling elements set out in Annex III in the following form:
 - (a) on a digital label; or
 - (b) on a leaflet accompanying the EU fertilising product.
- 3. Where EU fertilising products are made available on the market in a packaging to end-users, they shall be accompanied by the labelling elements set out in Annex III in the following form:
 - (a) on a physical label; or
 - (b) on a digital label and duplicated on a physical label.

By way of derogation from point b, the labelling elements marked with an asterisk in Annex III do not have to be duplicated on the physical label.

- 4. Where EU fertilising products are made available on the market without packaging to end-users, they shall be accompanied by the labelling elements set out in Annex III in the following form:
 - (a) on a digital label; or
 - (b) in a leaflet accompanying the EU fertilising product.
- 5. Where economic operators provide a digital label in accordance with this Article, they shall *ensure a consistent labelling in case of duplication and shall* comply with the requirements set out in Articles 11b and 11c.

Article 11b

Requirements for digital labels

- 1. The digital label shall include:
 - (a) the information required pursuant to Article 6(6) and Article 8(3);
 - (b) the CE marking and, where applicable, the identification number of the notified body, in accordance with Articles 17 and 18;

- (c) all the labelling elements required under Annex III, with the exception of the production date *and quantity where those elements have* been provided on the physical label.
- 2. The digital label may include recommendations and best practices for the use of the EU fertilising product.
- 3. The information referred to in paragraph 1 shall be provided *together* in one place and separated *from information under paragraph 2 and* from any information not provided under this Regulation.
- 4. The digital label shall be:
 - (a) accessible free of charge;
 - (b) easily and directly accessible *through all major operating systems and*browsers, without a need to register in advance, to download or install applications or to provide a password; accessible to all potential users in the Union;
 - (c) searchable;
 - (d) presented in a way that also addresses the needs of vulnerable groups and supports, as relevant, the necessary adaptations to facilitate access by those groups, *in particular those made up of persons with disabilities*;

- (e) available for a period of *10* years from the moment *that* EU fertilising product *was* placed on the market, including in case of an insolvency, a liquidation or a cessation of activity in the Union of the economic operator that created it.
 - Where the digital label is available in more than one language, the choice of languages shall not be dependent on the geographical location.
- 5. A data carrier used for a digital label shall be printed or placed physically on the packaging or, where the EU fertilising products are made available on the market without a packaging, on the accompanying document or leaflet, *externally visible*, legibly and in a way that *is accessible to vulnerable groups, including persons with disabilities and that* allows *that data carrier* to be processed automatically by digital devices.

Article 11c

Obligations of economic operators providing a digital label

1. Economic operators providing a digital label shall not track, analyse or use any usage information for purposes other than what is absolutely necessary for providing the relevant information digitally.

- 2. At the request of end-users and independently of a purchase, or without such request where the digital label is temporarily unavailable at the time of purchase, economic operators making available on the market EU fertilising products to such end-users shall provide the information included on the digital label, by alternative means and free of charge

 ;
- 3. Where EU fertilising products are made available on the market with a digital label in accordance with Article 11a(4)(a), the economic operator supplying them to end-users shall post the labelling information referred to in Article 11b(1) in a visible place at the point of sale.'
- in Article 42, the following paragraphs 9 and 10 are added:
 - '9. By [OP: please insert the date = the first day of the month following 30 months after the date of entry into force of this Regulation], the Commission shall adopt delegated acts in accordance with Article 44 to supplement Articles 11b and 11c by laying down specific requirements for the digital labelling of EU fertilising products and conditions for fulfilling the obligations of economic operators providing a digital label. Those requirements shall establish, in particular, the types of electronic technical solutions which economic operators may use for providing the digital label, and the alternative means for providing the information referred to in Article 11c(2). When adopting the delegated acts, the Commission shall:

- (a) ensure coherence with other relevant Union acts;
- (b) encourage innovation and the use of state-of-the-art technology;
- (c) ensure technological neutrality by not limiting the choice of technology or equipment, within the bounds of compatibility and interference avoidance;
- (d) ensure that the digital labelling does not compromise the safety of the end-user and the environment;
- (e) ensure that modification of the digital label does not compromise the ability of market surveillance authorities to verify the content of the label which existed prior to that modification;
- (f) take into account the level of digital readiness among end-users of EU fertilising products.
- (g) take into account the requirement in this Regulation to provide the information for a period of 10 years from the moment the EU fertilising product was placed on the market;
- (h) take into consideration the enhancement of the free movement of EU fertilising products in the internal market;
- (i) take into consideration the needs and the capacity of SMEs to comply with such requirements;

- 10. The Commission is empowered to adopt delegated acts in accordance with Article 44 to amend Annex III, as regards the labelling information which economic operators *choose to* provide on a digital label only in accordance with *the derogation in* Article 11a(3), *second subparagraph*, in order to adapt that Annex to technical and scientific progress or to the level of digital readiness among end-users of EU fertilising products. When adopting *those* delegated acts, the Commission shall take into account the need to ensure *safety and* a high level of protection of *human*, *animal and plant* health and the environment.
- (6) Annex III is amended in accordance with Annex I to this Regulation;
- (7) Annex IV is amended in accordance with Annex II to this Regulation.

Article 2

By ... [7 years from the entry into force of this Regulation], the Commission shall carry out an evaluation of the digital labelling of EU fertilising products as introduced by Regulation (EU) 2024/... and in particular assess:

- its impact on the proper functioning of the internal market, the level of consumer protection and its impact on businesses, particularly on micro, small and medium-sized enterprises;
- the impact of Article 11a and in particular the extent to which economic operators opted for the use of a digital label. The Commission shall draw up a report on the main findings and submit it to the European Parliament, the Council and the European Economic and Social Committee. Member States shall provide the Commission with the information necessary for the preparation of that report.

The report shall be accompanied, where appropriate, by a legislative proposal.

Article 3

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 [OP: please insert the date = the first day of the month following 30 months after the date of entry onto force of this Regulation].

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

ANNEX I

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

- (1) Part I is amended as follows:
 - (a) point 1 is amended as follows:
 - (i) point (d) is replaced by the following:
 - '(d) instructions for intended use concerning application rates, timing and frequency, and target plants or mushrooms;
 - (da) other instructions for intended use than those listed in point (d);*;'
 - (ii) point (h) is replaced by the following:
 - '(h) a list of all ingredients above 5 % by product weight or volume, or in the case of products in liquid form by dry weight, in descending order of magnitude;*;'

- (iii) the following points (i) and (j) are added:
 - '(i) an identification in accordance with Article 18 of Regulation (EC) No 1272/2008 of any ingredient on the list referred to in point (h) that is a substance or a mixture*;
 - (j) the designations of the relevant CMCs as referred to in Part I of Annex II for each ingredient listed in point (h).*;
- (iv) the following paragraph is added:

'Naturally occurring substances may, in addition to the information requested in point (i), be identified by their mineral names.;'

- (b) the following points are added:
 - 13. Where economic operators provide a digital label in accordance with Article 11a(1) and (2), the data carrier used on that digital label shall be accompanied by the warning: "A physical label must be provided in accordance with Regulation (EU) 2019/1009 before the product is made available on the market to end-users in a packaging of up to 1000 kg" or by a similar warning.
 - 14. Where economic operators provide a digital label in accordance with Article 11a(3) second subparagraph, the data carrier used for that digital label shall be accompanied by the *statements* "More comprehensive information on the product is available online. *You can ask your supplier to provide it by other means.*" or by a similar statement.

- 15. Where economic operators provide a digital label in accordance with Article 11a(4), the data carrier used for that digital label shall be accompanied by the *statements* "Information on the agronomic efficiency and the safe handling of the product is available online. *You can ask your supplier to provide it by other means.*" or by a similar statement.
- (2) Part II is amended as follows:
 - (a) section 'PFC 1(A): ORGANIC FERTILISER' is amended as follows:
 - (i) 'in point (d), sub-points (v) and (vi) are replaced by the following:

 - '(v) organic carbon (C_{org});*
 - (vi) dry matter;*;'
 - (ii) points (e) and (f) are replaced by the following:
 - '(e) the ratio of organic carbon to total nitrogen (C_{org}/N);*
 - (f) production date;*;'

- (b) section 'PFC 1(B): ORGANO-MINERAL FERTILISER' is amended as follows:
 - (i) in point 1(d) subpoints (v) and (vi) are replaced by the following:
 - '(v) organic carbon (Corg);*
 - (vi) dry matter;*;'
 - (ii) in point 5 subpoint (ca) is replaced by the following:
 - '(ca) where the declared micronutrients are chelated by chelating agent(s), the pH range guaranteeing acceptable stability;*;'
- (c) section 'PFC 1(C)(I)(a): SOLID INORGANIC MACRONUTRIENT FERTILISER' is amended as follows:
 - (i) point 2 is replaced by the following:
 - '2. The granulometry of a solid inorganic macronutrient fertiliser shall be indicated, expressed as % by mass of the product passing through a determined sieve.*;'

- (ii) point 4 is amended as follows:
 - '— the introductory sentence is replaced by the following:
 - 'For coated solid inorganic macronutrient fertilisers, the following shall be indicated:';
 - the following points (-a) and (-aa) are inserted:
 - '(-a) the name of the coating agents;
 - (-aa) the percentage of fertiliser coated by each coating agent;*;'
- (iii) in point 8 subpoint (ca) is replaced by the following:
 - '(ca) where the declared micronutrients are chelated by chelating agent(s), the pH range guaranteeing acceptable stability;*;'
- (d) section 'PFC 1(C)(I)(b): LIQUID INORGANIC MACRONUTRIENT FERTILISER' is amended as follows:
 - (i) point 1 is replaced by the following:

'1. The label shall indicate whether the liquid inorganic macronutrient fertiliser is in suspension or in solution.*;'

- (ii) in point 6 subpoint (ca) is replaced by the following:
 - '(ca) where the declared micronutrients are chelated by chelating agent(s), the pH range guaranteeing acceptable stability;*;'
- (e) section 'PFC 1(C)(II): INORGANIC MICRONUTRIENT FERTILISER' is amended as follows:
 - (i) point 1 is replaced by the following:
 - '1. In the inorganic micronutrient fertiliser, the following shall be indicated:
 - the declared micronutrients listed by their names and chemical symbols of the declared micronutrients, in the following order: boron (B), cobalt (Co), copper (Cu), iron (Fe), manganese (Mn), molybdenum (Mo) and zinc (Zn);
 - the names of their counter-ions when the declared micronutrients are intentionally added.*;'
 - (ii) point 2a is replaced by the following:
 - '2a. Where the declared micronutrients are chelated by chelating agent(s), the pH range guaranteeing acceptable stability shall be indicated.*;'

- (f) *in* section 'PFC 1(C)(II)(a): STRAIGHT INORGANIC MICRONUTRIENT FERTILISER' *point 1 is replaced by the following*:
 - 1. The label shall indicate the relevant typology, as referred to in the table under PFC 1(C)(II)(a) in Part II of Annex I.*;

(g) in section 'PFC 2: LIMING MATERIAL', the fifth indent is replaced by the following:

'- reactivity and method of determination of reactivity, except for oxide and hydroxide limes.*;'

- (h) section 'PFC 3(A): ORGANIC SOIL IMPROVER' is amended as follows:
 - (i) the first indent is replaced by the following:

'- pH;*;'

(iii) the fifth indent is replaced by the following:

'- the ratio of organic carbon to total nitrogen (C_{org}/N).*;'

- (i) section 'PFC 4: GROWING MEDIUM' is amended as follows:
 - (i) the second indent is replaced by the following:

'-pH;*;'

- (ii) the fourth, fifth, sixth and seventh indents are replaced by the following:
 - '- nitrogen (N) extractable by CaCl₂/DTPA (calcium chloride/ diethylenetriaminepentaacetic acid; 'CAT-soluble'), if above 150 mg/l;*
 - phosphorus pentoxide (P₂O₅) extractable by CaCl₂/DTPA (calcium chloride/ diethylenetriaminepentaacetic acid; 'CAT-soluble'), if above 20 mg/l;*
 - potassium oxide (K₂O) extractable by CaCl₂/DTPA (calcium chloride/ diethylenetriaminepentaacetic acid; 'CAT-soluble'), if above 150 mg/l;*
 - production date*.;'

(j) section 'PFC 5: INHIBITOR' is replaced by the following:

'PFC 5: INHIBITOR

- 1. All ingredients shall be declared by product weight or volume in descending order of magnitude.*
- 2. The content of the inhibiting compound(s) as % by mass or volume shall be declared.*
- 3. The use instructions referred to in point 1(da) of Part I of this Annex shall contain information on:
 - (a) the types of EU fertilising products with which the inhibitor may be mixed*, in particular:
 - (i) for the nitrification inhibitor referred to in PFC 5(A) in Part II of Annex I, an EU fertilising product in which at least 50 % of the total nitrogen (N) content consists of the nitrogen (N) forms ammonium (NH₄⁺) and urea (CH₄N₂O);*
 - (ii) for the urease inhibitor referred to in PFC 5(C) in Part II of Annex I, an EU fertilising product in which at least 50 % of the total nitrogen (N) content consists of the nitrogen (N) form urea (CH₄N₂O);*

- (b) the minimum and maximum recommended concentration of inhibiting compound(s) when mixed with a fertiliser prior to its use:
 - (i) for the nitrification inhibitor referred to in PFC 5(A) in Part II of
 Annex I, expressed as a % by mass of the total nitrogen (N) present
 as ammonium nitrogen (NH₄⁺) and urea nitrogen (CH₄N₂O);
 - (ii) for the denitrification inhibitor referred to in PFC 5(B) in Part II of Annex I, expressed as a % by mass of the nitrate (NO₃-) present;
 - (iii) for the urease inhibitor referred to in PFC 5(C) in Part II of Annex I, expressed as a % by mass of the total nitrogen (N) present as urea nitrogen (CH_4N_2O). \blacksquare ;
- (k) section 'PFC 6: PLANT BIOSTIMULANT' is replaced by the following:

'PFC 6: PLANT BIOSTIMULANT

The following information shall be provided:

- (a) physical form;
- (b) production date;*
- (c) expiry date;

(d) application method(s);*

- (e) effect claimed for each target plant;* and
- (f) any relevant instructions related to the efficacy of the product, including soil management practices, chemical fertilisation, incompatibility with plant protection products, recommended spraying nozzles size, sprayer pressure and other anti-drift measures.*;

(l) in section 'PFC 7: FERTILISING PRODUCT BLEND', the second paragraph is replaced by the following:

'Where the fertilising product blend contains one or more plant biostimulants belonging to PFC 6, the concentration of each plant biostimulant in the blend shall be indicated in g/kg or g/l at 20 °C.*.'

ANNEX II

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

- (1) in section 'Module A INTERNAL PRODUCTION CONTROL', point 2.2. is amended as follows:
 - (a) point (c) is replaced by the following:
 - '(c) the EU declarations of conformity for the component EU fertilising products of the fertilising product blend and a specimen of their physical label or leaflet in accordance with Article 11a and, if the information is provided only on a digital label in accordance with that Article, a specimen of the data carrier of the component EU fertilising products,;'
 - (b) point (e) is replaced by the following:
 - '(e) a specimen of the physical label or the leaflet referred to in Article 11a providing the information required in accordance with Annex III and, if the information is provided only on a digital label in accordance with that Article, a specimen of the data carrier,;'

- (2) in section 'Module A1 INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT TESTING', point 2.2. is amended as follows:
 - (a) point (c) is replaced by the following:
 - '(c) the EU declarations of conformity for the component EU fertilising products of the fertilising product blend and a specimen of their physical label or leaflet in accordance with Article 11a and, if the information is provided only on a digital label in accordance with that Article, a specimen of the data carrier of the component EU fertilising products,;'
 - (b) point (e) is replaced by the following:
 - '(e) a specimen of the physical label or the leaflet referred to in Article 11a providing the information required in accordance with Annex III and, if the information is provided only on a digital label in accordance with that Article, a specimen of the data carrier;'

- in section 'Module B EU-TYPE EXAMINATION', point 2.2 is amended as follows:
 - (a) point (c) is replaced by the following:
 - '(c) the EU declarations of conformity for the component EU fertilising products of the fertilising product blend and a specimen of their physical label or leaflet in accordance with Article 11a and, if the information is provided only in a digital label in accordance with that Article, a specimen of the data carrier of the component EU fertilising products,;'
 - (b) point (e) is replaced by the following:
 - '(e) a specimen of the physical label or the leaflet referred to in Article 11a providing the information required in accordance with Annex III, and if the information is provided only on a digital label in accordance with that Article, a specimen of the data carrier,;'

- in 'Module D1 QUALITY ASSURANCE OF THE PRODUCTION PROCESS', point 2.2. is amended as follows:
 - (a) point (c) is replaced by the following:
 - '(c) the EU declarations of conformity for the component EU fertilising products of the fertilising product blend and a specimen of their physical label or leaflet in accordance with Article 11a, and if the information is provided only on a digital label in accordance with that Article, a specimen of the data carrier of the component EU fertilising products,;'
 - (b) point (e) is replaced by the following:
 - '(e) a specimen of the physical label or the leaflet referred to in Article 11a providing the information required in accordance with Annex III, and if the information is provided only on a digital label in accordance with that Article, a specimen of the data carrier,.'