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Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2019/1009 as regards digital labelling of EU fertilising products		
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,		
Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,		
Having regard to the proposal from the European Commission,		
After transmission of the draft legislative act to the national parliaments,		
Having regard to the opinion of the European Economic and Social Committee ¹ ,		
Acting in accordance with the ordinary legislative procedure,		
Whereas:		

¹ NAT/900 – EESC-2023-01740-00-00-AC-TRA (EN) 1/4

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(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 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).

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(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.		
(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 digitalisation of the European agricultural sector and can facilitate 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. In addition, digital labelling can contribute to reducing labelling costs all along		

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the supply chain, given that the labels of EU fertilising products may be changed following a transaction between economic operators, before reaching end-users,		
(3a) — 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.		
[Merged into recital (13)]		
(4) However, digital labelling can also create new challenges for the vulnerable population groups, in particular persons with no, or insufficient, digital skills or persons with disabilities, and thus accentuate the digital divide. Therefore, digital labelling should be introduced in Regulation (EU) 2019/1009, under certain conditions, taking into account the need to ensure a high level of protection of human health and the environment, and the digital readiness.		
(5) Economic operators should remain free		

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to choose if to provide a digital or physical label. This will ensure that such economic operators have 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 digital labelling might be challenging, given the reduced volumes or types of EU fertilising products.		
(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. 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 extent of digital labelling should depend on two factors: if the <u>whether</u> EU fertilising products are made available to economic operators or to end-users and if the products are provided with or without a packaging.		

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(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 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.		
(8) Physical labels remain the preferred way of obtaining information for end-users as by being affixed to packaging such physical labels offer immediate access to information. In addition, the vast majority of EU fertilising products available on the market are used by		

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professional users, such as farmers. 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.		
(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 information is also available on the physical label or in the leaflet, in the case of EU fertilising products supplied without packaging. 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. 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		

³ 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).

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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. 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 the protection of human health and the environment, as well as minimum information on the agronomic efficiency of the EU fertilising products and on their content and <u>correct</u> use, should always be provided on the physical label. Regulation (EU) 2019/1009 should clearly indicate which information may be provided only digitally.		
(10) — For EU fertilising products supplied without packaging, the economic operators are to provide the labelling elements in a leaflet. 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. Providing the same labelling elements in digital format would imply an		

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adjustment of the way the information is retrieved without creating significant risks to users. 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, 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. The digital label should also contain information allowing end-users to		

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identify and contact the manufacturer <u>and the importer</u> of the EU fertilising products, as this is an essential information and providing it digitally will facilitate the link between the product and the digital label. In addition, given that fertilising products are also placed on the market as non-harmonised products, it is important 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 (more precisely, the batch number and the production date) the <u>manufacturers-economic operators</u> should have the choice to provide the information either physically or digitally. <u>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.</u>		
(13) Since digital labels, similarly to physical		

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labels, are a means of providing mandatory information on EU fertilising products to users, economic operators should ensure free access to digital labels. 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. <u>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.</u> 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		

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population groups, to further reduce the challenges such groups may face.		
(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 5 years from the moment the EU fertilising product is 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 <u>and potential end-users</u> , upon request. <u>Potential end-users should have the right irrespective of a purchase to receive information by alternative means in order to take an informed decision.</u> Whenever the digital label is temporarily unavailable, the information should be provided even without a request. <u>In any case, the information in the digital label should also</u>		

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<u>be visibly exposed in brick-and-mortar stores to properly inform potential end-users about the necessary elements to make an informed purchase.</u>		
(16) 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. 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.		
(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		

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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. 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.		
(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		

⁴ OJ L 123, 12.5.2016, p. 1.

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requested by various Union rules in one digital space, so that the users have easy access to all the information needed.		
(19) 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 end-users, 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 health and the environment.		
(20) Regulation (EU) 2019/1009 should therefore be amended accordingly.		
(21) 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.		
(22) The specific objectives of this Regulation, namely to improve the readability of the labels of EU fertilising products and to		

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facilitate the management of such labels by the economic operators <u>in order to guarantee the functioning of the internal market</u>, 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		

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holding not more than 1000 kg;²;		
(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		

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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 and intelligible;		
(c) accessible for inspection purposes when the EU fertilising product is made available on the market.';		
(3) in Article 8, paragraph 4 is replaced by the following:		

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‘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		

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label”); or,		
(b) on a label in a physical form attached to that the packaging or, for the labelling elements that cannot be provided on the label due to the packaging being too small <u>or where the product is made available on the market without a packaging</u> , in a separate leaflet accompanying that packaging product (“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		

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(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:		
(aa) on a leaflet accompanying the EU fertilising product; or		
(a) on a digital label and duplicated on a leaflet; or,		
(b) in a leaflet accompanying the EU fertilising product.		
By way of derogation from point (a), the labelling elements marked with an asterisk in Annex III do not have to be duplicated on the leaflet, or, in the case that there is a formal		

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agreement and the end user has been clearly informed, all information could be provided exclusively on a digital label.		
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 that date has those elements have been provided on the physical label.		

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2. The information referred to in paragraph 1 shall be provided <u>together</u> in one place and separated from any information not provided under this Regulation.		
3. The digital label shall be:		
(a) accessible free of charge;		
(b) easily and directly accessible <u>and without the</u> 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;		
(e) available for a period of 5 years from the moment the EU fertilising product is 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.		IT: In the case of digital label updates, it should be cleared if the manufacturer has to keep it for 5 years also the previous version.

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Where the digital label is available in more than one language, the choice of languages shall not be dependent on the geographical location.		
4. 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, visibly, legibly and in a way that allows it 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. Upon request by the end-users <u>and independently of a purchase</u> , or without such request where the digital label is temporarily		

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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.		
2a. <u>Where EU fertilising products are made available on the market to end-users, economic operators providing a digital label in accordance with Article 11a(3) shall post the labelling information in a visible place at the point of sale in accordance with Article 11b(1)(c) and except for information referred to in Article 6(5).</u>		
(5) 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		

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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;		
(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;		
(da) <u>ensure that modification of the digital label does not compromise the ability of a market surveillance authorities to verify the content of the label which existed prior to that modification;</u>		
(e) take into account the level of digital readiness among end-users of EU fertilising		

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products.		
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 may provide on a digital label only in accordance with Article 11a(3) point (b), 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 the delegated acts, the Commission shall take into account the need to ensure a high level of protection of human 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		
This Regulation shall enter into force on the twentieth day following that of its publication in the <i>Official Journal of the European Union</i> .		

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It shall apply from [<i>OP: please insert the date = the first day of the month following 30 months after the date of entry onto force of this Regulation</i>].		
This Regulation shall be binding in its entirety and directly applicable in all Member States.		
Done at Brussels,		
For the European Parliament For the Council		
The President The President		
Annexes for Proposal for a		
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL		
amending Regulation (EU) 2019/1009 as regards the digital labelling of EU fertilising products		
ANNEX I		
Annex III to Regulation (EU) 2019/1009 is		

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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;	IT: ‘(d) instructions for intended use concerning application rates, timing and frequency, and target plants or mushrooms*;	IT: EU Regulation 2019/1009 allows the marketing of numerous types of fertilizer in different types of packaging. Depending on the needs of the end user, fertilizers are purchased in big bags or smaller packages. Regarding big bags (typically from 500 to 1000kg) it is possible to provide detailed information in the accompanying documents and leaflets. Unlike for products packaged in small packages (usually in the order of 10, 25 or 40 kg), the physical label has strong space limitations that limit their analysis, especially the ones on the instructions for use. The proposed amendment ensures that the farmer has access to adequate agronomic information and that the fertilizer manufacturer can update it promptly.

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(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;*’;		FR: France requires the removal of asterisk. FRconsiders that the list of ingredients is an essential labelling element and should be provided on the physical label. According to the results of the consultation conducted on digital labelling, professional end users are particularly interested in this information.
(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		

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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.’;		
	IT:(iv bis) the following paragraph is added: IT: When the instructions for use intended for professional users are provided in digital format only, the following sentence must be stated on the physical label: "The product must be used in accordance with the instructions for use provided by the Fertilizer Manufacturer. Before use, please refer to these instructions available in digital format	IT: Given the relevance and high technicality of agronomic information and for better communication of the properties of products using digital labels, the following amendment is suggested, which provides for the addition of a warning next to the QR code of the product. The proposed amendment integrates the previous ones and is aimed at recommending reading the digital label, so that the farmer can have access to all the instructions for use linked to the agronomic efficiency of the product.
(b) the following points are added:		

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'12. Where the EU fertilising product contains peat, its presence shall be indicated on the label.		
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. <u>You can ask your supplier to provide it by other means.</u> " 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 statement "Information		

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on the agronomic efficiency and the safe handling of the product is available online' or by a similar statement.';		
(2) Part II is amended as follows:		
(a) in section 'PFC 1: FERTILISER', point 3(b), (c) and (d) are replaced by the following:		
'(b) the nitrification inhibiting compound content shall be expressed as a % by mass of the total nitrogen (N) present as ammonium nitrogen (NH₄⁺) and urea nitrogen (CH₄N₂O);*		
(c) the denitrification inhibiting compound content shall be expressed as a % by mass of the nitrate (NO₃⁻) present;*		
(d) the urease inhibiting compound content shall be expressed as a % by mass of the total nitrogen (N) present as urea nitrogen (CH₄N₂O).*';		
(b) section 'PFC 1(A): ORGANIC FERTILISER' is amended as follows:		
(i) point (d) is amended as follows:		

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— in point (iv), the second indent is replaced by the following:		
‘ where the soluble content of those nutrients is at least a quarter of the total content of those nutrients;		
(1) as the total content; and		
(2) as the content soluble in water; *’;		
– 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; *’;		
(c) section ‘PFC 1(B): ORGANO-MINERAL FERTILISER’ is amended as		

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follows:		
(i) point 1(d) is amended as follows:		
—— in point (iv), the second indent is replaced by the following:		
‘ where the soluble content of those nutrients is at least a quarter of the total content of those nutrients;		
(1) —— as the total content; and		
(2) —— as the content soluble in water; *’;		
– points (v) and (vi) are replaced by the following:		
‘(v) organic carbon (C _{org});*		
(vi) dry matter; *’;		
(ii) point 5 is amended as follows:		
—— in point (b), the second indent is replaced by the following:		
‘ where the soluble content of those		

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micronutrients is at least a quarter of the total content of those micronutrients;		
(1) — as the total content; and		
(2) — as the content soluble in water; *’;		
— in point (c), the second indent is replaced by the following:		
‘ the amount of chelated/complexed micronutrient(s) as % by mass; *’;		
— point (ca) is replaced by the following:		
‘(ca) where the declared micronutrients are chelated by chelating agent(s), the pH range guaranteeing acceptable stability; *’;		
(d) — in section ‘PFC 1(C)(I): INORGANIC MACRONUTRIENT FERTILISER, point 1(d)(iv), the second indent is replaced by the following:		
‘ where the soluble content of those nutrients is at least a quarter of the total content of those nutrients;		

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(1) — as the total content; and		
(2) — as the content soluble in water;*;		
(e) 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;		

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(-aa) the percentage of fertiliser coated by each coating agent;*’;		
(iii) point 8 is amended as follows:		
—— in point (b), the second indent is replaced by the following:		
‘ where the soluble content of those micronutrients is at least a quarter of the total content of those micronutrients,		
(1) —— as the total content; and		
(2) —— as the content soluble in water;*’;		
—— in point (c), the second indent is replaced by the following:		
‘ the amount of chelated/complexed micronutrient(s) as % by mass;*’;		
– point (ca) is replaced by the following:		
‘(ca) where the declared micronutrients are chelated by chelating agent(s), the pH range guaranteeing acceptable stability;*’;		

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(f) 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) point 6 is amended as follows:		
in point (b), the second indent is replaced by the following:		
'where the soluble content of those micronutrients is at least a quarter of the total content of those micronutrients;		
(1) as the total content; and		
(2) as the content soluble in water;*';		
in point (c), the second indent is replaced by the following:		
'the amount of chelated/complexed micronutrient(s) as % by mass;*';		

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– point (ca) is replaced by the following:		
‘(ca) where the declared micronutrients are chelated by chelating agent(s), the pH range guaranteeing acceptable stability;*’;		
(g) 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) — in point 2, the second indent is replaced		

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by the following:		
‘the amount of chelated/complexed micronutrient(s) as % by mass.*’;		
(iii) 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.*’;		
(h) section ‘PFC 1(C)(II)(a): STRAIGHT INORGANIC MICRONUTRIENT FERTILISER’ is amended as follows:		
(i) 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.*’;		
(ii) in point 2, the second indent is replaced by the following:		
‘where the soluble content of the micronutrient is at least a quarter of the total content of that micronutrient.’		

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(1) — as the total content; and		
(2) — as the content soluble in water;*’;		
(i) — in section ‘PFC 1(C)(H)(b): COMPOUND INORGANIC MICRONUTRIENT FERTILISER’, point 3, the second indent is replaced by the following:		
‘— where the soluble content of the micronutrients is at least half of the total content of those micronutrients:		
(1) — as the total content; and		
(2) — as the content soluble in water;*’;		
(j) 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.*’;		
(k) section ‘PFC 3(A): ORGANIC SOIL IMPROVER’ is amended as follows:		

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(i) the first indent is replaced by the following:		
‘– pH;.*’;		
(ii) the third indent is replaced by the following:		
‘– organic carbon (C_{org}) content, expressed as % by mass;.*’;		
(iii) the fifth indent is replaced by the following:		
‘– the ratio of organic carbon to total nitrogen (C _{org} /N).*’;		
(l) 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:		

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‘– nitrogen (N) extractable by CaCl ₂ /DTPA (calcium chloride/ diethylenetriaminepentaacetic acid; ‘CAT-soluble’), if above 150 mg/l;*		
– phosphorus pentoxide (P ₂ O ₅) extractable by CaCl ₂ /DTPA (calcium chloride/ diethylenetriaminepentaacetic acid; ‘CAT-soluble’), if above 20 mg/l;*		
– potassium oxide (K ₂ O) extractable by CaCl ₂ /DTPA (calcium chloride/ diethylenetriaminepentaacetic acid; ‘CAT-soluble’), if above 150 mg/l;*		
– production date*.’;		
(m) section ‘PFC 5: INHIBITOR’ is replaced by the following:	PT: (m) in section ‘PFC 5: INHIBITOR’, points 1 and 3(a) are replaced by the following:	PT: Giving the deletion of points 2 and 3(b), only points 1 and 3(a) must be replaced. In our understanding, the Presidency Compromise Text seems that it applies to the entire section, and the points 2 and 3(b) are removed from de main Regulation.

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'PFC 5: INHIBITOR	PT: 'PFC 5: INHIBITOR	
1. All ingredients shall be declared by product weight or volume in descending order of magnitude.*	PT: '1. All ingredients shall be declared by product weight or volume in descending order of magnitude.*	FR: France requires the removal of asterisk. Fr considers this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label PT: Editorial comment: we suggest putting (‘) in the beginning of the replaced text.
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		

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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 (NH ₄ ⁺) and urea (CH ₄ N ₂ O);*		
(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 (CH ₄ N ₂ O);*	PT: (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 (CH ₄ N ₂ O);*'	PT: Editorial comment: we suggest putting (') in the end of the replaced text.
(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		

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(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 (CH₄N₂O).*’;		
(n) 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;*		
(ba) expiry date;		
(c) application method(s);*		

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(d) effect claimed for each target plant;* and		FR: France requires the removal of asterisk. FR considers this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(e) 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.*’;		
(o) section ‘PFC 6(A): MICROBIAL PLANT BIOSTIMULANT’ is replaced by the following:		
‘PFC 6(A): MICROBIAL PLANT BIOSTIMULANT		
1. All intentionally added micro-organisms shall be indicated.		
2. Where the micro-organism has several strains, the intentionally added strains shall be		

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indicated.		
3. — The concentration of micro-organisms and, where applicable, strains shall be expressed as the number of active units per volume or weight, or in any other manner that is relevant to the micro-organism, e.g. colony forming units per gram (cfu/g).*	PT: 3. The concentration of micro-organisms and, where applicable, strains shall be expressed as the number of active units per volume or weight, or in any other manner that is relevant to the micro-organism, e.g. colony forming units per gram (cfu/g).	PT: According to the Presidency Compromise Text in the beginning of this section: “(o) section ‘PFC 6(A): MICROBIAL PLANT BIOSTIMULANT’ is replaced by the following:”, that, in our understanding, it seems to be applied to the entire section. So the point 3. must remain in this proposal regulation, without (*).
4. The label shall contain the following phrase: ‘Micro-organisms may have the potential to provoke sensitising reactions’.’;		
(p) 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.*’.		FR: France requires the removal of asterisk. FR considers this information to be essential for assessing the agronomic efficacy of the product

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		and should therefore be kept on the physical label.
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		

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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, ’;		

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(3) 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,’;		
(4) in ‘Module D1 – QUALITY ASSURANCE OF THE PRODUCTION PROCESS’, point 2.2. is amended as follows:		

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(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,’.		
		End



Council of the European Union
General Secretariat

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WORKING DOCUMENT

From:	FR, PT, IT Delegations
To:	Working Party on Technical Harmonisation (Dangerous Substances - Fertilisers)
N° Cion doc.:	ST 6896/23 + ADD1-ADD4 - COM (2023)98 final
Subject:	Proposal for a Regulation amending Regulation (EU) 2019/1009 as regards digital labelling of EU fertilising products - Comments by FR, PT, IT