

Presidency Compromise ST 11824/23	AT, BE, BG, CZ, DE, DK, EE, FR, MT, PT Drafting Suggestions	AT, BE, BG, CZ, DE, DK, EE, FR, MT, PT Comments
		CZ: Czechia generally supports regulation amendment concerning digital labelling. However, we do not agree with the proposed change in the art. 11a (4), regarding formal consent of end-user as it might impose administrative burden. We believe that the possibility to require an alternative form of label constitutes sufficient protection for end-users who do not have access to a digital label. DK: General comments: <u>DK delegation</u> finds that consultation of relevant stakeholders in the industry would be relevant, especially regarding the questions raised in PCY Flash – WK 10056/23. DK would therefore request, that relevant documents are reclassified accordingly, in support of consulting relevant stakeholders in the industry (as minimum WK 10056/23 and 11824/23). <u>DK delegation</u> enters a general scrutiny reservation. <u>DK</u> welcomes the PRES compromise set out in 11824/23. That text introduces a number of useful clarifications.

		<u>DK</u> , nonetheless, considers that a physical labelling containing information on the protection of the human, animal or plant health or the environment, the agronomic properties (content, source) and correct use (timing and to match plant needs, placement, storage), will always be provided to the end-user.
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/

(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.		

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 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 the supply chain, given that the labels of EU fertilising products may be changed following a transaction between economic operators, before reaching end-users,		
<u>(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.</u>		DE: We support this. DK: DK: appreciates the introduction of the clarification provided by recital (3a).

		EE: We support adding of a new recital 3a
(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 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,		FR: The same rules on digitalisation should apply to all EU fertilising products.

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 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 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.		FR: The French authorities (FA) are opposed to the proposal to allow the provision of all labelling elements in a digital label for the EU fertilising products supplied to other economic operators. In case of digitalisation, the most important labelling elements (namely “essential information”) should be kept on a physical label. The same rules on digital labelling should apply to all EU fertilising products (EU fertilising products sold to other economic operators, EU fertilising products sold to an end user, EU fertilising products sold without a packaging, EU fertilising products sold in a packaging) .

(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 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. 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	DK: DK suggestion: (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. 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	FR: The French authorities are opposed to the proposal to allow the provision of all labelling elements in a digital label for the EU fertilising products supplied to other economic operators. In case of digitalisation, the most important labelling elements (namely “essential information”) should be kept on a physical

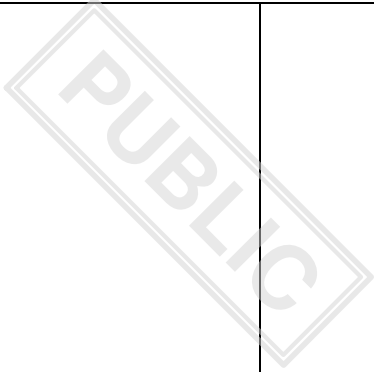
³ Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive, (OJ L 54, 26.2.2011, p. 1).

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. 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 use, should always be provided on the physical label. Regulation (EU) 2019/1009 should clearly indicate which information may be provided only digitally.	in coherence with Commission Regulation (EU) No 142/2011⁴. 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. 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 correct and safe use, should always be provided on the physical label. Regulation (EU) 2019/1009 should clearly indicate which information may be provided only digitally.	label. The same rules on digital labelling should apply to all EU fertilising products (EU fertilising products sold to other economic operators, EU fertilising products sold to an end user, EU fertilising products sold without a packaging, EU fertilising products sold in a packaging)
(10) For EU fertilising products supplied without packaging, the economic operators are to provide the labelling elements in a leaflet.		FR: The French authorities are opposed to the

⁴ 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).

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 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.		proposal to allow the provision of all labelling elements in a digital label for the EU fertilising products supplied to other economic operators. In case of digitalisation, the most important labelling elements (namely “essential information”) should be kept on a physical label. The same rules on digital labelling should apply to all EU fertilising products (EU fertilising products sold to other economic operators, EU fertilising products sold to an end user, EU fertilising products sold without a packaging, EU fertilising products sold in a packaging) .
(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 identify and		

contact the manufacturer 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 manufacturers should have the choice to provide the information either physically or digitally.		
(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. 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. 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, 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.	DK: <u>DK suggestion:</u> (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 10 years from the moment the EU fertilising product is placed on the market. If appropriate, A recital, could be inserted to that effect along the lines: <i>“Whereas this framework should, where appropriate, be aligned to the digital labelling provisions of Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of</i>	DK: Reason: The time period of 5 years is proposed by the Presidency of the Working Party on Technical Harmonisation with the justification, that a 5-year time period is in line with the main Regulation (EU) 2019/1009. <u>DK</u> would line to clarify, that in the main Regulation (EU) 2019/1009, that the 5-year time period does not relate to the labelling information referred to in annex III targeted end users of the products. Instead the 5-year time period mentioned in the main regulation relates only to information that shall be at disposal for the relevant national authorities, namely the technical documentation, EU declaration of conformity and, in case an importer or distributor packages or repackages an EU fertilising product, a specimen of the

	<i>substances and mixture, in particular as regards the period for the availability of digital labelling information.”</i>	original labelling information. The information covered by the 5-year period is to be provided to support market surveillance and does not relate to end users need. Accordingly, DK proposes to align the provisions of 2019/1009 regulation on digital labelling of CE-marked EU fertilizing products to those of regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures. Whilst the two acts have similar scope on the digital labelling requirements, the proposal for the CLP-regulation foresees that the digital labelling information should be available for a period of 10 years. The alignment at a 10 year time period would therefore facilitate end users’ needs. See Article 34b - requirements for digital labelling - Proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (16258/22 - COM (2022) 748 final). This approach would also be in line with recital (18) of the current proposal.
(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. Whenever the digital label is temporarily unavailable, the information should be provided even without a request.		
(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 digital labelling and amending Annex III with regard to which labelling elements economic		FR: The FA have concerns about giving a significant decision-making power to the Commission through the delegate act. Annex III will probably be amended to extend the list of labelling elements allowed to be provided only digitally without taking into account the opinion of the Member States.

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-Making⁵. 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 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,		

⁵ OJ L 123, 12.5.2016, p. 1.

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.		FR: The FA are opposed to the provision of all labelling elements on a digital label. Essential information should be kept on a physical label
(22) 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 <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		EE: We support adding the clarification.

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;’;	DK question for clarification: Regarding the definition of ‘packaging’, fertilising products are often transported for trade in bigbags, which can vary in volume and sealing options. Can the Commission or the Presidency provide DK with some examples regarding which bigbags are considered packaging, and which are not considered packaging, according to this definition?	
(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;’;	EE: (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 widely used device such	EE: Maybe it is reasonable to clarify in the regulation text, that the digital label could be read with the tools that are widely used today, such as e.g. smart phone, to exclude the need to

	as e.g. smart phone	purchase separate devices to open digital label. Changes to the initial Commission proposal are marked in bold. PT: The definition of "data carrier" is the same as in the proposal for the revision of the CLP Regulation. This is relevant because there should be no different concepts when it comes to the labelling rules laid down in the different EU regulatory frameworks.
		BG: A clear distinction between “economic operator” and “end-user” should be drawn. A definition of "end-user" should be added as the use of this term without a definition could cause problems for the application of the Regulation.
(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 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:		
‘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		MT: MT can support the provision of labels in either physical or digital format when concerning Business-to-Business scenarios. On the other hand, MT cannot support the provision of a digital label only in Business-to-Consumer scenarios, regardless of any formal agreement which is being proposed.
		BG: We don’t support the option for only digital label for economic operators. We prefer the same labelling as to end-users. Providing only digital label by manufactures will transfer their obligation for a physical label to either a distributor or to a seller. This will

		cause additional burden to different stakeholders, but won't have a significant effect on simplification and cost reduction. Moreover, the seller will be obliged to print and attach physical label on the product which is not a typical activity for the shops, providing goods to the end-users.
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:		FR: The FAs support this proposal. In case of digitalisation, the most important labelling elements (namely “essential information”) should be kept on a physical label.
<u>(-a) on a leaflet accompanying the EU fertilising product; or</u>		EE: This should be point a. FR: The FAs support this proposal. In case of digitalisation, the most important labelling elements (namely “essential information”) should be kept on a physical

		label.
(a) on a digital label <u>and duplicated on a leaflet</u> ; or,		EE: This should be point b. We can support changes. FR: The FAs support this proposal. In case of digitalisation, the most important labelling elements (namely “essential information”) should be kept on a physical label.
(b) in a leaflet accompanying the EU fertilising product.		
<u>By way of derogation from point (ab), 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 agreement and the end-user has been clearly informed, all information could be provided exclusively on a digital label.</u>	AT: EE: 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.	BE: How is formal approval granted? Is an oral agreement sufficient, or is a written, signed document required? More information is needed in practice. BG: We don't support the second part of the paragraph (in the case that there is a formal agreement and the end-user has been clearly informed, all information could be provided exclusively on a digital label). The concept of “formal agreement” is unclear. How, when and with whom an agreement is reached to provide all information digitally and at what point and in what way the end-user is

		informed? This <u>derogation</u> will create unnecessary burden for both economic operators and <u>end-users</u> rather than facilitating the process. EE: We do not support formal agreement requirement. First, the form of the agreement is not clearly defined, secondly as every requirement this need to be controlled by the market surveillance authorities and the administrative burden increases. Thirdly article 11b (4) and article 11c (2) are already sufficiently protect the buyer. So we think, that explanation of the article 11a (4) can be similar to the explanation of the article 11a (3). FR: The FAs are opposed to the provision of all labelling elements on a digital label. Essential information should be kept on a physical label. The same rules on digital labelling should apply to all EU fertilising products (EU fertilising products sold to other economic operators, EU fertilising products sold to an end user, EU fertilising products sold without a packaging, EU fertilising products sold in a packaging) .
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		PT: Our understanding goes against this proposal, because we consider that introducing the requirement for a previous formal agreement would be impractical and would burden economic operators.
	AT: To be added: “On request of an end-user, the distributor shall make the digital information available to the purchaser by other means or in a physical form.”	
Additional question (from PCY Flash – WK 10056/23) <u>Alternative drafting</u> <i>Annex III, part I, point 15 could be replaced by the following:</i> <i>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 following statement: "Information on the agronomic efficiency and the safe handling of the product is</i>	BE: To delete: “and the safe handling”	AT: “supplier” is not defined in the Regulation; but „distributor“. BE: <i>“You can ask your supplier to provide it by other means”.</i> OK with this proposition

available online. **You can ask your supplier to provide it by other means**".

Question: Would delegations prefer to introduce the requirement of having a previous agreement, as in the Presidency's compromise proposal, or would they prefer to introduce this message next to the data carrier? Any other alternative would be also welcome.

To delete: "and the safe handling": this information is necessary for the safety of the user.

OK For this proposition. But previous agreement: More information is needed in practice (see above.)

BG: We would prefer to introduce the alternative drafting "You can ask your supplier to provide it by other means".

DE: The proposal that in the case of a formal agreement between an economic operator and an end-user, physical labelling can be completely dispensed with is rejected. It is not clear how a market surveillance authority can verify that all labelling requirements have been met in such a case (e. g. when a product is in transit from the manufacturer/distributor to the end-user).

We prefer the alternative text proposed by the Presidency to the wording of point 15 in Annex III, Part I

DK:

DK delegation would like to consult relevant national stakeholders. DK would therefore request, that relevant documents are reclassified accordingly, in support of consulting relevant stakeholders in the industry.

		The DK delegation enters a scrutiny reservation. EE: Alternatively, we can support replacement of annex 3 part 1 point 15 with a new text as proposed. At the same time, we are of the opinion that it would be fair, also to inform end-users of the fertilising products that are made available on the market in a packaging, about the same opportunity therefore, we propose to add the similar sentence to the annex 3 part 1 point 14 (please look for the drafting suggestion in the annex 3 part 1 point 14). FR: The FAs supports the proposal introducing a previous agreement of the end users or economics operators who buy a product with a digital label containing non-essential information. MT: As previously stated, MT reiterates its position and alternatively proposes that a physical label or a leaflet label is always made available upon
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		purchase of a fertilising product by a consumer. PT: We agree with this alternative drafting.
5. Where economic operators provide a digital label in accordance with this Article, they <u>, shall ensure a consistent labelling in case of duplication and</u> shall comply with the requirements set out in Articles 11b and 11c.		EE: We support adding the clarification.
	BE: <u>6. Any labelling element foreseen by Regulation (EC) No 1272/2008 shall be provided in a form according to that Regulation.</u>	BE: This new point 6. should be added as Annex III contains elements also covered by the CLP Regulation No 1272/2008, notably: - point (g): <i>“any relevant information on measures recommended to manage risks to human, animal or plant health, to safety or to the environment”</i>: the legal text should be clarified even if the Commission services consider it does not cover elements of the CLP regulation; - new point (i): <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*”</i>. This would resolve ambiguities and contradictions with the current and future provisions on digital labelling in the CLP

		Regulation
Article 11b Requirements for digital labels		
1. The digital label shall include:		
(a) the information required pursuant to Article 6(6);	BE: (a) (b) the information required pursuant to Article 6(6) and article 8(3); BG: “the information required pursuant to Article 6(6) or 8(3) respectively”;	BE: Without article 8(3) importers do not indicate their name, registered trade name or registered trade mark and the postal address at which they can be contacted. Addition of Article 8(3) of the FPR is necessary to ensure that importers are subject to the same rules as manufacturers. If this proposal is not accepted, please provide a written explanation. BG: Addition of Article 8(3) is necessary to ensure that importers are subject to the same rules as manufacturers.
(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		FR:

date where that date has been provided on the physical label.		The FA consider that all the labelling elements required under Annex III should be provided on a digital label, including the production date. It is not relevant and justified to make an exception of the production
2. The information referred to in paragraph 1 shall be provided in one place and separated from any information not provided under this Regulation.		PT: We have added the word “together” to align with the text of the proposal for revision of the CLP Regulation.
3. The digital label shall be:		
(a) accessible free of charge;		
(b) easily and directly accessible and without the need to register in advance, to download or install applications or to provide a password; accessible to all potential users in the Union;		EE: We support adding the clarification.
(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.	DK: DK suggestion: (e) available for a period of 5 10 years from the moment the EU fertilising product is placed	DK: Reason: See DK comments introduced in the

	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.	context of recital 14.
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, 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		PT: We have added the sentence “Such information shall be provided independently of a purchase” to align with the text of the proposal for revision of the CLP Regulation.

digital label, by alternative means and free of charge.’;		
<u>2a. Economic operators providing a digital label in accordance with Article 11a shall post the labelling information in a visible place at the point of sale.</u>		BG: What is considered as a “point of sale” and where the information should be made available in case when the same product is provided by the manufacturer, for distribution and by the distributors to the end-users - should the information appear in both places? The meaning of “a visible place” is unclear. EE: We do not support adding of point 2a to the article 11c. We are of the opinion, that the same goal is already achieved by the article 11b (4) without increasing economic operator’s administrative burden. MT: With specific reference to the derogation from the duplication of information on a leaflet in cases where an agreement between the economic operator and end-user exists (as per Article 11a(4)), and without prejudice to the comment made with respect to the format of labelling in business-to-end users scenarios (Article 11a), MT would like to request a confirmation on whether ‘posting the labelling information in a visible place at the point of sale’ means that a physical label has to be physically available and visible at the brick-and-mortar store? Moreover, should it also be extended to online stores

		and online sales if it is currently intended solely for brick-and-mortar scenarios?
(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 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;	DK: <u>DK suggestion:</u> (insert a point (da)) <u>(da) ensure that modification of the digital labelling does not compromise the ability of a Member State's market surveillance authority to verify the content of the labelling which existed prior to that modification;</u>	DK: Reason: There exists a requirement on update logs for the digital label. For control purposes, the national market surveillance authority needs to be able to verify when a digital labelling has been altered, and which parts of the labelling have been modified.
(e) take into account the level of digital readiness among end-users of EU fertilising 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.';		FR: The French authorities have concerns about giving a significant decision-making power to the Commission through the delegate act. Annex III will probably be amended to extend the list of labelling elements allowed to be provided only digitally without taking into account the opinion of the Member States.
(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> .		
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 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		

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);*’;		
	BE: point (g) is replaced by the following: (g) any relevant information on measures recommended to manage risks to human, animal or plant health, to safety or to the environment; <u>any information foreseen by Regulation (EC) No 1272/2008 shall be provided in a form according to that Regulation;</u>	BE: As the CLP Regulation No 1272/2008 also foresees labelling elements aiming at managing risks to humans and the environment, the added sentence would resolve contradictions with current and future provisions on digital labelling in the CLP Regulation. The legal text should be clarified even if the Commission services consider that this point does not cover elements of the CLP regulation.
(ii) point (h) is replaced by the following:		FR:

		The French authorities (FA) consider that the list of ingredients is an essential labelling element and should be provided on the physical label.
‘(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: The FA consider 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*’;	BE: ‘(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 <u>provided in a form according to that Regulation;</u>	BE: Next to the addition of the sentence on the application of the form foreseen by the CLP Regulation, it is necessary to delete the asterisk allowing for digital labelling only, which is in contradiction with the current and proposed CLP provisions on digital labelling. EE: We do not support changes.

		FR: The FA supports this proposal. The FA consider that the identification of the substance or mixture 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.
(j) the designations of the relevant CMCs as referred to in Part I of Annex II for each ingredient listed in point (h).*’;		FR: The FA consider that the designation of the relevant CMC is an essential labelling element and should be provided on the physical label. The designation of the CMC for each ingredient is an essential labelling element for market surveillance authorities and should therefore be kept on the physical label.
(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:		

‘12. Where the EU fertilising product contains peat, its presence shall be indicated on the label.		DE: From our point of view, the intended labelling of the use of peat should not be deleted. This information should be available to end consumers, otherwise an informed decision to purchase, for example, a peat-free product would not be possible. We are not of the opinion that the labelling of peat is perceived exclusively positively in the sense of a purchase incentive by end consumers. EE: We support the removal of the point 12 from annex 3 part 1, because this information is already being presented according to the annex 3 part 1 point 1h. FR: The FA supports this proposal The peat is part of the list of ingredients required by Annex III and should be provided on a physical label (essential labelling information)
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	BG: “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	BG: No distinction should be made between products in a packaging or without as point 13 refers to the two options - article 11a(1) and (2).

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.	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.”	FR: The same rules should be applied on all EU fertilising products: only non essential labelling elements should be provided digitally. All essential labelling elements should be provided on a physical label.
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 statement ”More comprehensive information on the product is available online” or by a similar statement.	EE: 14. Where economic operators provide a digital label in accordance with Article 11a(3), the data carrier used for that digital label shall be accompanied by the statement: ”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”.	BE: No distinction should be made between packages up to 1000 kg and EU fertilising products without packaging. The same sentence must be added to the leaflet accompanying EU fertilising products without packaging. (See also BE remarks on article 11a.4) EE: The comment is on the page 19.
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		FR:

on the agronomic efficiency and the safe handling of the product is available online' or by a similar statement.”;		The same rules should be applied on all EU fertilising products: All essential labelling elements should be provided on a physical label, in addition to the digital label. PT: According to our comments in respect of Article 11a(4).
(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 (NH ₄ ⁺) and urea nitrogen (CH ₄ N ₂ O);*		(DE: General Remark) We support the deletions of the yellow highlighted "asterixes" in Appendix I. The information should in principle be physically labelled. EE: We do not support changes. FR: The FA supports this proposal. The inhibitor compound content of a fertiliser containing an inhibitor is important for assessing the agronomic efficiency of the

		product. As this is a product for professionals and as the consultation on digital labelling shows that professional end users are particularly interested in information on the agronomic efficiency of products, the FAs consider this element to be essential and this information should be provided on the physical label
(c) the denitrification inhibiting compound content shall be expressed as a % by mass of the nitrate (NO ₃ ⁻) present;*		EE: We do not support changes. FR: The FA supports this proposal. The denitrification inhibitor compound content of a fertiliser containing an inhibitor is important for assessing the agronomic efficiency of the product. As this is a product for professionals and as the consultation on digital labelling shows that professional end users are particularly interested in information on the agronomic efficiency of products, the FAs consider this element to be essential and this information should be provided on the physical label
(d) the urease inhibiting compound content shall be expressed as a % by mass of the total nitrogen (N) present as urea nitrogen (CH ₄ N ₂ O).*		EE:

		We do not support changes. FR: The FA supports this proposal. The urease inhibiting compound content of a fertiliser containing an inhibitor is important for assessing the agronomic efficiency of the product. As this is a product for professionals and as the consultation on digital labelling shows that professional end users are particularly interested in information on the agronomic efficiency of products, the FAs consider this element to be essential and this information should be provided on the physical label
(b) section ‘PFC 1(A): ORGANIC FERTILISER’ is amended as follows:		
(i) point (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,*';		EE: We support changes. FR: The FA supports this proposal. The FAs consider the content soluble in water of nutrients to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
– points (v) and (vi) are replaced by the following:		
'(v) organic carbon (C _{org});*		BE: This amendment means that the indication of the organic carbon (C_{org}) content ratio is optional. To ensure the fertility of an agricultural soil, a sufficient organic carbon content (C_{org}) is necessary. The organic carbon content (C_{org}) of the product gives an indication of the rate/ha to be applied to maintain soil fertility. A product with a high organic carbon (C_{org}) content is applied in smaller quantities. Thus the agronomic value of the organic soil improver is derived from these parameter.

		This information must be indicated on the label. FR: The FAs consider the organic carbon to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(vi) dry matter,*;		FR: The FAs consider the dry matter to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(ii) points (e) and (f) are replaced by the following:		
‘(e) the ratio of organic carbon to total nitrogen (C _{org} /N),*		BE: This change means that the indication of the C_{org}/N ratio is optional. C_{org}/N ratio gives information on the rapidity of action of the fertiliser. If this ratio is less than 10, the fertiliser will act quickly. This information should be indicated on the label.

(f) production date;*’;		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(c) section ‘PFC 1(B): ORGANO-MINERAL FERTILISER’ is amended as follows:		
(i) point 1(d) is amended as follows:		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
– 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;*’;		EE: We support changes.

		FR: The FA supports this proposal The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
– points (v) and (vi) are replaced by the following:		
‘(v) organic carbon (C _{org});*		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(vi) dry matter;*’;		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(ii) point 5 is amended as follows:		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of

		the product and should therefore be kept on the physical label.
– in point (b), the second indent is replaced by the following:		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
‘– where the soluble content of those micronutrients is at least a quarter of the total content of those micronutrients,		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(1) as the total content; and		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(2) as the content soluble in water;*’;		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of

		the product and should therefore be kept on the physical label. PT: As referred in the point 2. of the document “wk10056.en23-Working Party Meeting on technical Harmonisation (Dangerous Substances - Fertilisers) on 27 July 2023” some elements marked with (*) in Annex III were limited, considering that <i>“following the request by some delegations, the Presidency has brought back some information to the physical label that is considered relevant for assessing the <u>agronomic efficiency</u> and <u>for selecting the product at the moment of purchase</u>. For instance, the soluble content of nutrients in fertilisers (PFC1) or Corg in organic soil improvers PFC3”</i>. So, we request the deletion of the (*) in this point.
– in point (c), the second indent is replaced by the following:		
‘– the amount of chelated/complexed micronutrient(s) as % by mass; ² ’		EE: We support changes. FR:

		The FA supports this proposal. The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
– point (ca) is replaced by the following:		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
‘(ca) where the declared micronutrients are chelated by chelating agent(s), the pH range guaranteeing acceptable stability;*’;		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(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,		
(1) as the total content; and		

(2) as the content soluble in water; *;	EE: We support changes. FR: The FAs supports this proposal. The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label. PT: As referred in the point 2. of the document “wk10056.en23-Working Party Meeting on technical Harmonisation (Dangerous Substances - Fertilisers) on 27 July 2023” some elements marked with (*) in Annex III were limited, considering that <i>“following the request by some delegations, the Presidency has brought back some information to the physical label that is considered relevant for assessing the <u>agronomic efficiency</u> and <u>for selecting the product at the moment of purchase</u>. For instance, the soluble content of nutrients in fertilisers (PFC1) or Corg in organic soil improvers PFC3”</i>. So, we request the deletion of the (*) in this point.	

(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.*';		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(ii) point 4 is amended as follows:		
		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
– the introductory sentence is replaced by the following:		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
'For coated solid inorganic macronutrient fertilisers, the following shall be indicated:';		FR:

		The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
– the following points (-a) and (-aa) are inserted:		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
‘(-a) the name of the coating agents;		BE: Language correction (FR) “-a) le nom des agents de revêtement” should be replaced by “ -a) le nom des agents d’enrobage” FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(-aa) the percentage of fertiliser coated by each coating agent;*’;		FR:

		The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(iii) point 8 is amended as follows:		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
– in point (b), the second indent is replaced by the following:		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
‘–where the soluble content of those micronutrients is at least a quarter of the total content of those micronutrients,		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(1) as the total content; and		
(2) as the content soluble in water;*		EE:

		We support changes. FR: The FA supports this proposal. The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
– in point (c), the second indent is replaced by the following:		
‘– the amount of chelated/complexed micronutrient(s) as % by mass;*		EE: We support changes. FR: The FA supports this proposal. The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
– point (ca) is replaced by the following:		
‘(ca) where the declared micronutrients are chelated by chelating agent(s), the pH range		FR:

guaranteeing acceptable stability;*’;		The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(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.*’;		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(ii) point 6 is amended as follows:		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
– 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;*’;		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label. PT: As referred in the point 2. of the document “wk10056.en23-Working Party Meeting on technical Harmonisation (Dangerous Substances - Fertilisers) on 27 July 2023” some elements marked with (*) in Annex III were limited, considering that <i>“following the request by some delegations, the Presidency has brought back some information to the physical label that is considered relevant for assessing the <u>agronomic efficiency</u> and for selecting the product at the moment of purchase. For instance, the soluble content of nutrients in fertilisers (PFC1) or Corg in organic soil improvers PFC3”</i>. So, we request the deletion of the (*) in this point.
– in point (c), the second indent is replaced by the following:		

‘– the amount of chelated/complexed micronutrient(s) as % by mass;*		EE: We support changes. FR: The FA supports this proposal. The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
– point (ca) is replaced by the following:		
‘(ca) where the declared micronutrients are chelated by chelating agent(s), the pH range guaranteeing acceptable stability;*		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(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 by the following:		
‘– the amount of chelated/complexed micronutrient(s) as % by mass.*’;		EE: We support changes. FR: The FAs supports this proposal. The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(iii) point 2a is replaced by the following:		
‘2a. Where the declared micronutrients are chelated by chelating agent(s), the pH range		FR:

guaranteeing acceptable stability shall be indicated.*’;		The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(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.*’;		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(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:		
(1) as the total content; and		
(2) as the content soluble in water;*		EE:

		We support changes. FR: The FAs supports this proposal. The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(i) in section ‘PFC 1(C)(II)(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;*		FR: The FAs supports this proposal. The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
		EE:

		We support changes.
(j) in section ‘PFC 2: LIMING MATERIAL’, the fifth indent is replaced by the following:		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
‘– reactivity and method of determination of reactivity, except for oxide and hydroxide limes.*’;		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(k) section ‘PFC 3(A): ORGANIC SOIL IMPROVER’ is amended as follows:		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(i) the first indent is replaced by the following:		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.

‘– pH,*’;		
	BE: To add: (ii) The second indent is replaced by the following: ‘– electrical conductivity, in ms/m*’	BE: The declaration of electrical conductivity may be optional on the label. To add
(ii) the third indent is replaced by the following:		
‘– organic carbon (C _{org}) content, expressed as % by mass,*’;		EE: We support changes. FR: The FAs supports this proposal. The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(iii) the fifth indent is replaced by the following:	BE: To be deleted	
‘– the ratio of organic carbon to total nitrogen (C _{org} /N).*’;	BE:	BE:

	To be deleted	This amendment means that the indication the Corg/N ratio is optional. The Corg/N ratio gives information on how fast the fertiliser works. For an organic soil improver, the ideal ratio is 10. If this ratio is higher than 20, the product may be phytotoxic to the crop. Soil bacteria need nitrogen to convert the organic carbon in the product into stable organic carbon. If the Corg/N ratio is high, the nitrogen consumed by the bacteria is no longer available to the crop. The plant may be stunted in its growth or die in extreme cases. This information must be indicated on the label.
(l) section ‘PFC 4: GROWING MEDIUM’ is amended as follows:		
(i) the second indent is replaced by the following:		
‘– pH,*’;		FR: The pH is important agronomic information for growing media. Each plant needs a specific pH to express its growth potential (alkaline plant versus acid plant). Thus, it is an essential labelling element and should be kept on a physical label
(ii) the fourth, fifth, sixth and seventh indents		

are replaced by the following:		
‘– nitrogen (N) extractable by CaCl ₂ /DTPA (calcium chloride/diethylenetriaminepentaacetic acid; ‘CAT-soluble’), if above 150 mg/l;*		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
– phosphorus pentoxide (P ₂ O ₅) extractable by CaCl ₂ /DTPA (calcium chloride/diethylenetriaminepentaacetic acid; ‘CAT-soluble’), if above 20 mg/l;*		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
– potassium oxide (K ₂ O) extractable by CaCl ₂ /DTPA (calcium chloride/diethylenetriaminepentaacetic acid; ‘CAT-soluble’), if above 150 mg/l;*		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
– production date*.’;		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.

(m) 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.*		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
2. The content of the inhibiting compound(s) as % by mass or volume shall be declared.*		EE: We do not support changes. FR: The FA supports this proposal. The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label
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:	DK: DK suggestion: to be mandatory mentioned on the physical labelling	DK: Reason: This is vital information regarding agronomic efficiency of the product and for selecting the product at the moment of purchase. FR: It is important to know the type of EU fertilising with which the inhibitor may be mixed for the safety and efficiency of the mixture.
(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);*	DK: DK suggestion: to be mandatory mentioned on the physical labelling	DK: Reason: This is vital information regarding agronomic efficiency of the product and for selecting the product at the moment of purchase. FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the

		physical label.
(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);*	DK: DK suggestion: to be mandatory mentioned on the physical labelling	DK: Reason: This is vital information regarding agronomic efficiency of the product and for selecting the product at the moment of purchase. FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(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 (NH ₄ ⁺) and urea nitrogen (CH ₄ N ₂ O);*		EE: We do not support changes. FR:

		The FAs supports this proposal. The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(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 (NO_3^-) present;*		EE: We do not support changes. FR: The FAs supports this proposal. The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(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 ($\text{CH}_4\text{N}_2\text{O}$).*		EE: We do not support changes. FR: The FAs supports this proposal. The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the

		physical label.
(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;*		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(ba) expiry date;		
(c) application method(s);*	DK: DK suggestion: to be mandatory mentioned on the physical labelling	DK: DK: Reason: This is vital information regarding agronomic efficiency of the product and for selecting the product at the moment of purchase. FR: The FAs consider this information to be

		essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(d) effect claimed for each target plant,* and	BE: To be deleted DK: <u>DK</u> suggestion: to be mandatory mentioned on the physical labelling	BE: Plant biostimulants do not contain nutrients. The effectiveness of the product is indicated in the claims. The user makes his choice based on the claims. This information must be indicated on the label DK: DK: Reason: This is vital information regarding agronomic efficiency of the product and for selecting the product at the moment of purchase. FR: The FAs consider 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.*’;	DK: DK suggestion: to be mandatory mentioned on the physical labelling	DK: DK: Reason: This is vital information regarding agronomic efficiency of the product and for selecting the product at the moment of purchase. FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
(o) section ‘PFC 6(A): MICROBIAL PLANT BIOSTIMULANT’ is replaced by the following:		
‘PFC 6(A): MICROBIAL PLANT BIOSTIMULANT		FR: The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
1. All intentionally added micro-organisms shall be indicated.		

2. Where the micro-organism has several strains, the intentionally added strains shall be 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).*		EE: We support changes. FR: The FAs supports this proposal. The FAs consider this information to be essential for assessing the agronomic efficacy of the product and should therefore be kept on the physical label.
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: The FAs consider this information to be essential for assessing the agronomic efficacy of the product 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,’;		FR: A specimen of the data carrier should be provided even if the manufacturer of the EU fertilising product chooses to provide only some labelling elements in a digital label.
(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,’;		FR: The FA is opposed to the proposal to allow the provision of all labelling information on a digital label. A specimen of the data carrier should be provided even if the manufacturer of the EU fertilising product chooses to provide only some

		labelling elements in a digital label.
(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,’;		FR: The FA is opposed to the proposal to allow the provision of all labelling information on a digital label. A specimen of the data carrier should be provided even if the manufacturer of the EU fertilising product chooses to provide only some labelling elements in a digital label.
(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,’;		FR: The FA is opposed to the proposal to allow the provision of all labelling information on a digital label. A specimen of the data carrier should be provided even if the manufacturer of the EU fertilising product chooses to provide only some labelling elements in a digital label.

(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,’;		FR: The FA is opposed to the proposal to allow the provision of all labelling information on a digital label. A specimen of the data carrier should be provided even if the manufacturer of the EU fertilising product chooses to provide only some labelling elements in a digital label.
(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,’;		FR: The FA is opposed to the proposal to allow the provision of all labelling information on a digital label. A specimen of the data carrier should be provided even if the manufacturer of the EU fertilising product chooses to provide only some labelling elements in a digital label.
(4) 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,’;		FR: The FA is opposed to the proposal to allow the provision of all labelling information on a digital label. A specimen of the data carrier should be provided even if the manufacturer of the EU fertilising product chooses to provide only some labelling elements in a digital label.
(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,’.		FR: The FA is opposed to the proposal to allow the provision of all labelling information on a digital label. A specimen of the data carrier should be provided even if the manufacturer of the EU fertilising product chooses to provide only some labelling elements in a digital label.
		End



Council of the European Union
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WORKING DOCUMENT

From:	Presidency
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 AT, BE, BG, CZ, DE, DK, EE, FR, MT, PT