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2023/0049 (COD)

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

(Text with EEA relevance)

{SEC(2023) 99 final} - {SWD(2023) 48 final} - {SWD(2023) 49 final} - {SWD(2023) 50 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

In 2019, the European Parliament and the Council adopted Regulation (EU) 2019/1009 laying down rules on the making available on the market of EU fertilising products[1]. This Regulation replaces the harmonisation rules on EC fertilisers, as laid down in Regulation (EC) No 2003/2003[2].

Regulation (EU) 2019/1009 introduces labelling requirements that are much more extensive than Regulation (EC) 2003/2003. This reflected new social demands and concerns, as well as the fact that the new rules drastically opened the EU market for products that are innovative and unknown, and therefore require better user information. However, overloaded labels cause two problems: they are both difficult to read by interested persons and difficult to manage for economic operators. Providing a lot of details on a label makes it difficult to identify the essential information and may also need frequent updates, thereby increasing the labelling costs.

This proposal is governed by the same general objectives as Regulation (EU) 2019/1009, namely ensure a high level of protection for human health and the environment and the well-functioning of the internal market. In response to the two problems identified, this proposal follows two specific objectives: improving the readability of labels and facilitating their management by economic operators.

• Consistency with existing rules in the policy area

Fertilising products are part of the food chain and account for a significant portion of the price of agricultural products. In the 2021 Communication on energy prices[3], the Commission acknowledged the economic difficulties faced by the energy-intensive fertiliser industry following the dramatic increase in energy prices as of the autumn of 2021. As explained in the 2022 Communication on food security[4], the war of aggression of Russia against Ukraine exacerbated the economic difficulties already faced by the industry.

The current difficult political and economic context speaks in favour of, firstly, accelerating the existing trend of improving the use efficiency of fertilising products and, secondly, streamlining the costs of bringing fertilising products to the market. This proposal supports both trends in the fertilising products policy.

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1 Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003, OJ L 170, 25.6.2019, p. 1.

2 Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers, OJ L 304, 21.11.2003, p. 1–194.

3 Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions of 13 October 2021 Tackling rising energy prices: a toolbox for action and support, COM/2021/660.

4 Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions of 23 March 2022, Safeguarding food security and reinforcing the resilience of food systems, COM(2022) 133

On the first issue, the more efficient use of, in particular, fertilisers is an important element in the Farm to Fork Strategy[5], which specifies a target of 50% reduction of nutrient losses and aims to reduce fertiliser use by 20% by 2030. The need to increase the use efficiency is reiterated in the 2022 Communication on fertilisers[6]. Use of digital tools is a key enabler in this process, for example in tracking the Gross Nutrient Balance baselines and targets for countries and the collection of data at regional level. In addition, a better communication of product properties by using digital labels is a step towards optimising instructions for use efficiency based on those properties, which will lead to a better communication of the use instructions and avoid over-fertilisation.

On the second issue, laying down rules for the voluntary digitisation of labels will lead to cost reductions for economic operators in the medium and long term. It will further streamline the labelling process, by avoiding unnecessary costs and reducing packaging waste. This will optimise the conditions for bringing fertilisers to the EU market in challenging times.

This proposal feeds into the broader digitalisation process of the agricultural sector, a priority for most Member State who signed a declaration for 'a smart and sustainable digital future for European agriculture and rural areas' on 9 April 2019[7].

- **Consistency with other EU policies**

In the Green Deal[8], the Commission announced its intention to address the twin challenge of the green and digital transitions. Soon after, the COVID-19 pandemic radically changed the role and perception of digitalisation in our societies and economies and accelerated its pace.

The 2021 Digital Compass Communication[9] maps out a clear path towards a common vision and actions for Europe to succeed in the Digital Decade. It puts forward the 'digital by default' principle and outlines a way ahead for the broad-based digitalisation of society.

There is also a general trend towards digitisation of labels and documents accompanying products. Rules are in place for construction products[10] and medical devices[11] or under preparation for batteries[12], detergents[13], cosmetics[14] and hazardous chemicals[15].

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5 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 20 May 2020, A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system, COM/2020/381.

6 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 9 November 2022, Ensuring availability and affordability of fertilisers, COM/2022/590.

7 Declaration: A smart and sustainable digital future for European agriculture and rural areas (smartagrihubs.eu)

8 Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal, COM/2019/640, 11.12.2019.

9 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 2030 Digital Compass: the European way for the Digital Decade, COM(2021)118, 9.3.2021.

10 Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC, OJ L 88, 4.4.2011, p. 5.

11 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017, p. 1.

12 Proposal for a Regulation of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020, COM(2020)798.

13 Detergents – streamlining and updating the EU rules (europa.eu)

14 EU chemicals strategy for sustainability – Cosmetic Products Regulation (revision) (europa.eu)

The proposal for a Regulation on Ecodesign for Sustainable Products[16] aims to establish a Digital Product Passport (DPP). In the version proposed by the Commission, the passport will introduce the mandatory adoption of digital ways of communicating information about all regulated products, including fertilising products. Such information will not cover labelling requirements. Therefore, this proposal complements the measures already proposed for digitising other information about products.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

This proposal has the same legal base as Regulation (EU) 2019/1009: Article 114 of the Treaty on the functioning of the European Union on the approximation of national rules for the establishment and functioning of the internal market. Although the Commission is empowered to amend the Annexes to Regulation (EU) 2019/1009, all the amendments proposed in this initiative are included in this proposal in order to ease the adoption process as they are linked to each other.

• Subsidiarity

The problems caused by overloaded labels of EU fertilising products have a strong cross-border dimension. Inorganic fertilisers subject to Regulation (EC) 2003/2003 are produced in a few EU Member States[17] and sold all over the EU. Regulation (EU) 2019/1009 aims both to maintain these products within its scope and encompass new products, which have not yet been covered by harmonisation rules, thus increasing their potential on the EU market.

The extensive labelling requirements laid down in Annex III to Regulation (EU) 2019/1009 have to be provided on the physical label. Part of the information required by this Annex is subject to frequent changes and, in accordance with the same Regulation, labels of certain products have to change before reaching the end-users (for instance, the label of a fertilising product blend will contain all the relevant information about the component EU fertilising products expressed in relation to the final blend; so, before the blend reached the end-user, both the component EU fertilising products and the blend itself had a physical label). The Regulation is directly applicable in all Member States. In addition, Member States have the obligation not to impede the free movement of EU fertilising products for reasons linked to their labelling. Therefore, Member States cannot adopt national measures to improve the readability of physical labels or avoid frequent changes to them.

Member States could adopt national rules regarding minimum standards for digitising the labels, when used on a voluntary basis and in addition to physical labels, given that this issue is not yet covered in Regulation (EU) 2019/1009. Such an approach would unavoidably lead to different practices all over the EU and create obstacles in the functioning of the internal market. It could lead to inequalities in terms of potential cost savings and communication of information. It would also increase costs for industry to adapt to divergent digital labelling requirements in different Member States.

By contrast, introducing the conditions for the digital label at EU level has the added value of harmonising the various practices. By creating a level playing field, such an initiative would

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15 Chemicals – simplification and digitalisation of labelling requirements (europa.eu)

16 Proposal for a Regulation of the European Parliament and of the Council establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC, COM/2022/142, 30.03.2022.

17 see footnote 26.

improve the functioning of the internal market, while ensuring the high standard of protection required by Regulation (EU) 2019/1009. In addition, the decision on which labelling elements currently required on the physical label may be provided only digitally can be made only at EU level.

The benefit of EU action also lies in the existence of potential economies of scale in the fertilising products industry. Aligning digital labelling requirements across the EU could facilitate the use of multi-lingual labels and thus support the distribution of products with the same label in more than one Member State.

Therefore, this proposal on the voluntary digitisation of labels for EU fertilising products is necessary and can efficiently tackle the problems identified.

- **Proportionality**

The initiative does not go beyond what is necessary to achieve the objectives sought. It aims to introduce voluntary digital labelling for EU fertilising products. Economic operators will have the choice of whether to provide the labelling elements on a physical or digital label.

If a digital label is provided, this proposal lays down general rules to ensure a high level of protection for users of EU fertilising products.

In the accompanying impact assessment, policy options with various degrees of digitisation have been assessed. The option put forward in this proposal strikes the best balance between the interests of various stakeholders. While it opens the possibility of providing digital labels, it maintains on the physical label of EU fertilising products made available to end-users the most important information, in response to the readiness of such end-users to rely only on digital tools for having access to information. Following the evolution of the society, the number of labelling elements to be provided only digitally could be further increased, which is accounted for in the empowerment laid down in this proposal.

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

- **Stakeholder consultations**

The following consultation activities have been carried out:

Open public consultation

The open public consultation confirmed the interest in digital labels both from the industry and the users' side.

Over half of respondents (52.1%, N=198) would respond positively or moderately positively if some information was removed from the label and could only be obtained digitally. Since 22.7% did not know/could not answer, the percentage is higher (66.9%) among those that answered.

Most respondents (N=93, 72%) would implement digital labelling if it was possible.

The main benefits of a digital label (N=195) include: the possibility to provide more detailed information (14%), being able to provide all the relevant information where the packaging is too small (14%), easy access to information (13%), access to up-to-date information (13%) and information in additional languages (13%); more relevant/targeted information, environmental benefits (19%) and cost savings (8%).

The main challenges of digital labels (N=200) include: difficulty to access information (24%), differences between on-pack and digital information (22%), inequalities for different population groups (22%), and increased costs for industry.

Interviews

Interviews have been organised to collect information on, in particular, (i) what constitutes essential labelling information for various categories of stakeholders, (ii) labels' use patterns, (iii) the benefits and disadvantages of digital labelling and (iv) industry labelling practices. The large number of interviews with industry stakeholders and fertilising product users revealed that input from these groups in relation to specific labelling information (e.g. content of nitrogen) was often divergent, varying according to the Product Function Categories and the types of users in question. Thus, essential information for industry representatives was not the same as for professional and non-professional users.

This proposal takes into account these divergent needs, and gives priority to ensuring the safe use of EU fertilising products and a high level of protection of human health and the environment, by keeping on the physical label of packaged products sold to end-users the most important information.

Targeted survey of stakeholders

The survey targeted users of fertilising products (professional and non-professional), the industry (manufacturers, importers and distributors) as well as conformity assessment bodies and market surveillance authorities from France, Germany, Italy, Lithuania, Poland, Romania, Denmark, and Spain.

Out of the 755 responses received, non-professional users (i.e. hobby gardeners, persons acting outside the scope of an economic activity) constituted the largest response group (43.6%), followed by professional users (33.5%).

The targeted survey also revealed the differences in perception as regards the most important information on the label. While users considered information about safety requirements absolutely essential, for manufacturers what was thought to be essential was agronomic efficiency.

When asked which format they prefer to access label information in, most of the professional and non-professional users selected physical labels. This confirms the need to keep the most important information on the physical label.

Manufacturers had divergent views on whether digitalisation in general would save them money. 48.4% think that it would provide financial savings (N=49).

Focus groups

Eight focus groups were organised with professional and non-professional users from France, Poland, Romania and Spain. Participants welcomed the digitisation of the EU fertilising products labels, which was seen as beneficial and a natural transition. Concerns were expressed about accentuating the negative effects of the digital divide.

This consultation activity showed the differences in perception between professional and non-professional users as regards the importance of various categories of information. Agronomic efficiency information (such as content of nutrients) was considered more important than other types of information by professional users, while after purchase information, such as use instructions or storing conditions, was not that important as 'everybody knew what to do'. Non-professional users, on the contrary, found agronomic efficiency information too technical and thought that after purchase information was more

important. Similarly, professional users were more interested in information on content, such as the list of ingredients, than non-professional users.

Survey experiment

The survey experiment explored the effects of labelling changes on key behaviours among professional and non-professional users of fertilising products. The exercise sought to understand the behaviours users actually exhibit when shown digitised labels, instead of asking participants what they think about digitisation.

The survey experiment showed that professional users are mostly unaffected by changes in the amount of information on the physical label when it comes to product application and storage. Non-professional users are more sensitive to label simplification than their professional counterparts.

With regards to factors influencing understanding of labels, the ease of interpreting labels (self-reported) is significantly positively related to the age of professional and non-professional users, as well as to their experience of using the fertilising product in question. Less information on labels did not lead to a significant change in how easily information was interpreted on the label in question by either of the two user groups.

Usability testing

The unmoderated usability testing exercise tested the popularity and potential use of various digital technologies that could be implemented on the fertilising product labels. Of the 48 tested individuals, 33 scanned a QR code and 26 accessed a URL, making these the most used options.

Expert Group meeting on options for digitisation of labels

An on-line meeting of the Commission Expert Group on Fertilising Products took place on 15 March 2022. The input received from the Members and Observers in the expert group fed into the development of the policy options. The expert group welcomed the categorisation of the information and the methodology used for building the various policy options.

They expressed divergent views on the need to introduce a distinction between non-professional and professional users. While some pointed to the fact that the two categories of users have different behaviours and different needs in terms of labelling, others drew the attention to the increased complexity such a distinction would add to the rules, and to the difficulties in implementing and market surveillance.

Survey on costs and benefits related to various digitisation options

Following the expert group meeting, an online survey to collect data on costs and benefits related to various options for digitisation was conducted. The survey had 93 valid responses distributed among various stakeholder groups.

Some 56.3% of respondents (manufacturers, N=32) indicated that they already provide some labelling information digitally. Overall, there was strong support for the proposed general rules for digitisation of labels (N=84). When comparing the effects of labels under the different options on economic, environmental and social impacts, the general response was that the higher the level of digitisation, the greater the positive impacts.

- **Collection and use of expertise**

In analysing the results of the consultation activities and the impact of various policy options, the Commission used an external contractor.

- **Impact assessment**

In performing the impact assessment[18], the Commission faced two difficulties. Regulation (EU) 2019/1009 is applicable as of 16 July 2022, so no concrete experience in applying the new rules was available. In addition, the Regulation lays down the optional harmonisation of EU fertilising products. The choice if to apply the Regulation or not is with the manufacturers of the fertilising products. Therefore, it is difficult to estimate how many manufacturers will make such a choice and will maintain it in the coming years.

The impact assessment received a positive opinion from the Regulatory Scrutiny Board on 22 July 2022[19].

The Commission assessed the impacts of three policy options (PO): PO1 - development of a guidance document only, PO2 - information may be provided digitally for EU fertilising products and PO3 - all information is provided digitally for certain categories of products.

As regards PO2, 5 sub-options have been considered (PO2a-PO2e). The level of digitisation varies (ranging from certain information to be provided on the digital label to most of the information to be provided there). In some of the sub-options, a distinction is made between professional and non-professional users. The impacts of PO2a-PO2e are analysed together, as only limited differences have been identified.

The preferred option is PO2a combined with PO3:

– PO2a means the optional digitisation of certain information of the label of EU fertilising products, without making a distinction between professional/non-professional users;

– PO3 means the optional digitisation of all the information for products sold in bulk and products not sold to end-users, but to other economic operators.

While PO2a is the most cautious in terms of the scope of the information to be provided only digitally, combining this option with PO3 ensures the objectives are most effectively addressed, keeping a balanced approach to the different views of stakeholders.

Firstly, option 2a implies keeping all the safety related information, as well as the most important information on agronomic efficiency, content and information relevant after purchase on the physical label. By reducing the other type of information to be included on the physical label, safety information will become more visible thus contributing to the objective of protecting the health and the environment. This option takes most into account the digital divide. Removing all label information, including safety information, under option 3 for sales to economic operators is justified by the particular users concerned, which are not end-users. The economic operators buy the products to make them available on the market, and not to apply them on soils. As regards bulk products, given the nature of the product itself, there is no possibility of providing the information on a physical label affixed to the packaging, which is the direct way of communicating labelling information. Replacing the leaflet with a digital label is not expected to have a significant impact on the availability of the information.

Secondly, this combined option will reduce labelling costs and will create a level playing field between economic operators as regards the use of digital labelling. The labelling costs will be reduced both by including more languages on the physical label and by avoiding frequent changes to it.

[18] Link to the summary IA

[19] Link to the opinion

Lastly, this combined option is easier to apply and enforce, as no distinction is made between professional and non-professional users. Such a distinction does not exist in Regulation (EU) 2019/1009 and would have increased the complexity to the rules and made their implementation more difficult.

Given the limited evidence base for the costs, a full extrapolation of costs to EU level is problematic and risks providing a false picture. Maximum EU-level costs for enterprises under PO2 (but also PO3) based on stakeholder survey data would be €0.3m (ranging from €0.1m to €0.6m) for one-off costs, and €0.1m (ranging from €0.06m to €0.4m) for ongoing (annual) costs. In practice, the actual costs would most likely be less than these maximum costs, as a certain proportion of firms would choose not to provide digital labelling.

It should be noted that some costs may additionally be incurred by the economic operator opting for digital labelling, in terms of providing the information by alternative means where necessary. Although such costs could not be quantified, they are expected to be marginal, given that product information would only be supplied to small portions of the target markets. In the longer term, costs would be offset by savings related to updating physical labels, avoiding double labelling and freeing space on the physical label for information in more languages. In addition, PO3 leads to net benefits estimated at 0.8m as it introduces full digitisation of the labelling requirements for products sold in bulk or products which are not sold to end-users.

In terms of direct impacts of PO2a and PO3 on public authorities, despite positive aspects related to the ease of managing and compiling online data, public authorities could require some investment in equipment and training to facilitate access to digital labels.

The estimates for preferred policy option 2a suggest that a mid-range possible one-off net benefits would be negative accruing to all enterprises in EU27 (i.e. €-0.1m, based on the assumption that all enterprises that export would gain from savings associated with reduced physical labelling requirements). Annual maximum recurring benefits for PO2a would be €0.9m accruing to all enterprises (EU27). Under option 3, maximum possible one-off net benefits would also be negative (i.e. €-0.5m based on the same assumptions as for PO2a).[20] However, annual maximum recurring net benefits for PO3 would be €3m accruing to all enterprises[21] (EU27).

The preferred option is expected to have environmental benefits, by reducing packaging waste. Such benefits could not be quantified.

No negative social impact is expected as under PO2a, the information found essential by various categories of users is maintained on the physical label. On the contrary, the readability of the physical label is expected to be improved, by moving various technical details to the digital label. In addition, users will be able to take full advantage of the various possibilities created by digitalisation in terms of accessibility and searching specific information in digital format.

- **Regulatory fitness and simplification**

This proposal aims to simplify the compliance with the labelling requirements under Regulation (EU) 2019/1009 and thus to reduce the burden on economic operators, without

[20] One-off costs are expected to remain the same under PO2 and PO3. Please refer to Annex 4 for a full breakdown of cost and benefit calculations.

[21] Relevant to PO3 14% of all enterprises are assumed to only provide products in bulk or products which are sold to industrial users (e.g. blenders).

jeopardising the main objectives of the Regulation, including the protection of human health and the environment.

This proposal directly contributes to the REFIT scoreboard (Areas 13. Chemicals legislation (other than REACH)), by using digital tools to communicate information on EU fertilising products. Reaping the benefits of the digital age will result in potential burden reduction for SMEs, improved enforcement and compliance, reinforcing cooperation between competent authorities, including customs and market surveillance authorities.

The digitisation of the label remains optional. So, no specific measures are needed for small and medium enterprises, which are free to choose the right moment to do this change, if at all.

5. OTHER ELEMENTS

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

In the evaluation performed in accordance with Article 49 of Regulation (EU) 2019/1009, the Commission will also assess how this specific intervention has performed (or is working), and draw preliminary conclusions. This will be the first opportunity to assess whether there were unintended or unexpected effects.

Subsequently, the Commission will be monitoring if the EU intervention remains fit for its purpose, should be adjusted for greater effectiveness, relevance and coherence, or should simply be repealed.

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

This proposal introduces the voluntary digitisation of the labels of EU fertilising products. The choice is with the manufacturers, importers or distributors of EU fertilising products.

It is proposed to allow economic operators to provide all the labelling elements required under Annex III to Regulation (EU) 2019/1009 only in a digital format in the following two situations: the EU fertilising products are sold without a packaging, or the EU fertilising products are sold to economic operators (which are not end-users of the products).

The economic operators opting for the digital labelling of EU fertilising products supplied to end-users in packaging will have to provide also a physical label, containing the most important information. The physical label will contain all the information concerning the protection of human health and the environment, as well as the most important information on the agronomic efficiency and content of the product, or information used after purchase.

Once economic operators choose to provide digital labels, the proposal lays down the general rules regarding the digitisation of labels. In particular, the economic operators will have to ensure that the digital label can be accessed free of charge and is easily accessible all over the EU, and they will have to take into account the needs of vulnerable population groups. The information on digital labels is also to be provided by alternative means, where needed.

The proposal contains a Commission empowerment to supplement the general digital labelling requirements and further adapt Annex III by deciding which labelling elements could be provided digitally when EU fertilising products are made available to end-users in packaging, depending on the evolution of the society.

2023/0049 (COD)

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee[1],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Annex III to Regulation (EU) 2019/1009 lays down the labelling requirements applicable to EU fertilising products. The information referred to in Annex III is to be provided on a label in a physical form attached to that packaging or, for the labelling elements that cannot be provided on the label due to the packaging being too small, in a separate leaflet accompanying that packaging ('physical label'). Products without a packaging are accompanied by a leaflet. The labelling requirements concern various parameters linked to the agronomic efficiency of EU fertilising products (e.g., content of nutrients in a fertiliser) and the content of such products (e.g., quantity). The labelling requirements also cover information needed for the protection of human health and the environment when using EU fertilising products (e.g., information needed for the correct application of Council Directive 91/676/EEC[2]) 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.

(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

[1] OJ C , , p. .

[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).

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,

(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, 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.

(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 142/2011[3]. 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 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 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 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

[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.

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.

(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 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-Making[4]. 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, 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 facilitate the management of such labels by the economic operators, cannot be sufficiently achieved by the Member States. Since they can rather, by reason of their scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, by introducing a possibility to use digital labelling for certain information, this Regulation does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS REGULATION:

Article 1

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

(1) Article 2 is amended as follows:

(a) the following point (10a) is inserted:

‘(10a) “packaging” means a sealable receptacle holding not more than 1000 kg;’;

(b) the following point (16a) is inserted:

‘(16a) “data carrier” means a linear bar code symbol, a two-dimensional symbol or other automatic identification data capture medium that can be read by a device;’;

[4] OJ L 123, 12.5.2016, p. 1.

(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

1. Where EU fertilising products are made available on the market in a packaging to economic operators, they shall be accompanied by the labelling elements set out in Annex III in the following form:

(a) on a label in a digital form ("digital label"); or.

(b) on a label in a physical form attached to that packaging or, for the labelling elements that cannot be provided on the label due to the packaging being too small, in a separate leaflet accompanying that packaging ("physical label").

2. Where EU fertilising products are made available on the market without packaging to economic operators, they shall be accompanied by the labelling elements set out in Annex III in the following form:

   (a) on a digital label; or

   (b) on a leaflet accompanying the EU fertilising product.

3. Where EU fertilising products are made available on the market in a packaging to end-users, they shall be accompanied by the labelling elements set out in Annex III in the following form:

   (a) on a physical label; or

   (b) on a digital label and duplicated on a physical label.

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

4. Where EU fertilising products are made available on the market without packaging to end-users, they shall be accompanied by the labelling elements set out in Annex III in the following form:

   (a) on a digital label; or

   (b) in a leaflet accompanying the EU fertilising product.

5. Where economic operators provide a digital label in accordance with this Article, they shall 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);

   (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 where that date has been provided on the physical label.

2. The information referred to in paragraph 1 shall be provided 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, without a need to register in advance, to download or install applications or to provide a password;accessible to all potential users in the Union;

   (c) searchable;

   (d) presented in a way that also addresses the needs of vulnerable groups and supports, as relevant, the necessary adaptations to facilitate access by those groups;

(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.

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 digital label, by alternative means and free of charge.';

(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;

(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.';

(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 *Official Journal of the European Union*.

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

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

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*