



EUROPEAN COMMISSION

132182/EU XXVII.GP
Eingelangt am 27/02/23

Brussels, 22.7.2022
SEC(2023) 99 final

REGULATORY SCRUTINY BOARD OPINION

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

{COM(2023) 98 final}
{SWD(2023) 48 final}
{SWD(2023) 49final}
{SWD(2023) 50 final}



EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB/

Opinion

Title: Impact assessment / Digitalisation of labels on Fertilising Products

Overall opinion: POSITIVE

(A) Policy context

Physical labels of fertilising products are the primary means to communicate essential information to consumers, including hazard and safety information and product use-instructions. However, such labels are overloaded with information, which can contribute to end-user dissatisfaction, confusion and/or non-compliance of economic operators with the applicable legislation. The current legal labelling requirements do not allow the use of digital labelling on its own, nor incentivise it as an addition to existing labelling information.

This impact assessment examines the digitalisation of the labelling of EU fertilising products. Such possibility should improve the readability of the labels of EU fertilising products and facilitate the managing of labels by economic operators.

(B) Summary of findings

The Board notes the additional information provided by the DG and commitments to make changes to the report.

The Board gives a positive opinion. The Board also considers that the report should further improve with respect to the following aspects:

- (1) The baseline is not sufficiently dynamic.**
- (2) The report does not sufficiently assess the risk that the estimated benefits might not fully materialise given the voluntary nature of the initiative.**

(C) What to improve

(1) The report should set out clearly the coherence of the initiative with other initiatives aimed at the digitalisation of the labels or documents accompanying products for construction products and medical devices as well as for the initiatives under preparation concerning batteries, detergents, cosmetics and hazardous chemicals. It should provide the dynamic baseline taking into account likely future developments. It should explain better what prevents Member States from voluntarily adopting the best practices in the near

This opinion concerns a draft impact assessment which may differ from the final version.

Commission européenne, B-1049 Bruxelles - Belgium. Office: BERL 02/352. E-mail: regulatory-scrutiny-board@ec.europa.eu

future under a dynamic baseline scenario and explain how the baseline will evolve and what the uncertainties are.

(2) The report should better explain the risk that the estimated benefits of the preferred option on digital labelling of certain information will not fully, or not at all, materialise given that the analysis shows that the benefits for this option will not outweigh the costs resulting in overall negative net benefits. It should reiterate more clearly the benefits associated with moving certain information to a digital label and highlight the fact that economic operators will opt for digital labelling only if it is economically viable. In this respect, also accounting for the dynamic baseline, the report should provide a range (rather than a single point) for the estimate of the number of businesses that are assumed to choose to provide digital labelling as a result of this initiative. It should also present the level of stakeholder support.

(3) The report should elaborate on the indirect and possible unintended consequences associated with providing certain information digitally instead of providing it on the physical label. It should clarify users' attitude to access effectively and to use digital labelling.

(4) The report should clarify what success would look like and explain to what extent the success criteria of the policy initiative are measurable.

The Board notes the estimated costs and benefits of the preferred option(s) in this initiative, as summarised in the attached quantification tables.

Some more technical comments have been sent directly to the author DG.

(D) Conclusion

The DG may proceed with the initiative.

The DG must take these recommendations into account before launching the interservice consultation.

If there are any changes in the choice or design of the preferred option in the final version of the report, the DG may need to further adjust the attached quantification tables to reflect this.

Full title	Digitalisation of labels on Fertilising Products
Reference number	PLAN/2021/ 10559
Submitted to RSB on	23 June 2022
Date of RSB meeting	Written procedure

ANNEX – Quantification tables extracted from the draft impact assessment report

The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.

If the draft report has been revised in line with the Board's recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.

I. Overview of Benefits (total for all provisions) – Preferred Option

<i>Description</i>	<i>Amount</i>	<i>Comments</i>
Direct benefits		
Reduced administrative costs for businesses (producers, distributors, etc.)	<p>Maximum estimated annual costs savings under PO2a for SMEs is €517, and €4,583 for large enterprises.</p> <p>Maximum estimated annual costs savings under PO3 for SMEs is €6,340 and €58,250 for large enterprises.</p>	<p>Given the voluntary nature of the preferred option, no costs would be imposed on businesses. Businesses would only provide digital labelling if they perceived the potential to enjoy reduced costs (or if they perceived sufficient other business benefits to justify any cost increase). The figures provided show the maximum potential benefits.</p> <p>The figures are based on the baseline costs (except cost of redesigning physical labels, which are based on best estimate based on stakeholder interviews) are mid-point estimates based on the range of cost estimates provided by enterprises responding to the stakeholder survey (total number for respondents 93).</p> <p>Cost savings would arise through reducing the frequency of disposing of and redesigning physical labels. There would also be economies of scale in that more languages could fit on physical labels.</p> <p>All types of firms (SMEs and large enterprises) would be able to benefit from digitalisation. However, large firms may derive more benefits in terms of economies of scale as they can more easily make the necessary one-off, upfront investments in digitalisation.</p>
Users enjoying greater ease of use and increased awareness of key information (e.g. ingredients, safety information).	Non-monetary benefit	<p>Previous research has found that digitalisation of labels can improve hazard communication for consumers (e.g. chemicals used in inorganic fertilisers, storage instructions if any dangers) and workers by solving the problem of consumers being faced with overloaded and unattractive labels and text being too small to read. Non-professional users can also be empowered through better access to more relevant and comprehensible information, enabling more informed decision-making on the purchase and use of fertiliser products.</p> <p>Professional users may also benefit as they would get access to a wider range of technical information digitally than it would be possible to fit onto a physical label under the FPR's labelling requirements.</p>

This opinion concerns a draft impact assessment which may differ from the final version.

Commission européenne, B-1049 Bruxelles - Belgium. Office: BERL 02/352. E-mail: regulatory-scrutiny-board@ec.europa.eu

I. Overview of Benefits (total for all provisions) – Preferred Option

Description	Amount	Comments
Indirect benefits		
Sectoral competitiveness	Not possible to quantify given the available data.	Digital labelling and simplification of physical labels could help enterprises by allowing more space for essential information to be given more prominence on the label and for multiple languages on physical labels. This would allow more cost-effective labelling within the Single Market given the increased costs of producing multiple labels for different export markets. May also facilitate product distribution across the EU and beyond by allowing multilingual labels to be moved digitally.
Reduced risks to health and safety of users	Not possible to quantify given the available data.	Evidence from the consultations highlights that increased awareness about product information on labels and more informed decision-making is likely to reduce risks to health and safety. The number of survey respondents anticipating such benefits increased in line with increased digital labelling: from 19.5% in relation to the policy option 2a to 38.3% in relation to policy option 3.
Administrative cost savings related to the ‘one in, one out’ approach*¹		
Reduced annual administrative costs for businesses (producers, distributors, etc.)	Maximum net recurring benefits accruing to all EU27 enterprise is estimated at: -€2,067,121 under PO2a and; €15,007,812 under PO3. (For both options one off costs are estimated at	The benefits would stem from the digitalisation of some information compared with the current physical-only labelling requirements. Given the voluntary nature of the preferred option, no costs would be imposed on businesses. Businesses would only provide digital labelling if they perceived the potential to enjoy reduced costs (or if they perceived sufficient other business benefits to justify any cost increase). The figures provided show the maximum potential benefits, assuming that all companies will implement the voluntary digital labels (total enterprises 2850, assuming that 56% of enterprises do not yet provide any information about their products in a digital format). Cost savings would arise through reducing the frequency of disposing of and redesigning physical labels. There would also be economies of scale in that more languages could fit on physical labels. All types of firms (SMEs and large enterprises) would be able to benefit from digitalisation.

¹ see Tool #59 cost estimates and the one-in, one-out approach.

I. Overview of Benefits (total for all provisions) – Preferred Option

<i>Description</i>	<i>Amount</i>	<i>Comments</i>
	€5,737,446, and annual ongoing costs are estimated at €3,580,288).	<p>However, large firms may derive more benefits in terms of economies of scale as they can more easily make the necessary one-off, upfront investments in digitalisation.</p> <p>Both SMEs and large firms would benefit. Arguably, medium and large firms proportionately would benefit more from digital labelling as they are more likely to distribute to 5-10 Member States or more so would have cost savings relating to transferring multilingual information to a digital format.</p>

II. Overview of costs – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Action (a)	Direct adjustment costs	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
	Direct administrative costs	Not relevant	Not relevant	*€5.74M	*€3.58M	Not relevant	Not relevant
	Direct regulatory fees and charges	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
	Direct enforcement costs	Not relevant	Not relevant	Not relevant	Not relevant	Possibly purchase of equipment- not quantifiable	Not relevant
	Indirect costs	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
Costs related to the 'one in, one out' approach							
Total	Direct adjustment costs	Not relevant	Not relevant	Not relevant	Not relevant		
	Indirect adjustment costs	Not relevant	Not relevant	Not relevant	Not relevant		
	Administrative costs (for offsetting)	Not relevant	Note relevant	€5.74M	€3.58M ²		

*NB: Given the limited evidence base for the costs, a full extrapolation of costs to EU level is problematic and risks providing a false picture. Nonetheless, a broad indication can be offered.

Further, given the voluntary nature of the preferred option, no costs would be imposed on businesses. Businesses would only incur direct adjustment costs related to digital labelling if they perceived the potential to enjoy reduced costs (or if they perceived sufficient other business benefits to justify any cost increase).

² There are no administrative costs for offsetting as the costs will be offset by benefits. Although the one-off cost is €5.74M, the net recurring annual savings is €9.36M.

This opinion concerns a draft impact assessment which may differ from the final version.

The estimates for direct administrative costs show the maximum potential costs for enterprises assuming that maximum number of companies that might provide digital labelling for the first time is equal to 1,596. Based on the following assumptions:

- That the fertilising products sector features 2,850 enterprises.
- According to the stakeholder survey, 56% of enterprises do not yet provide any information about their products in a digital format (44% are digitalised in some form already).
- If the entirety of these enterprises chose to provide information in digital format, this would amount to 1,596 enterprises.

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. Indeed, given its voluntary nature, enterprises would provide digital labelling if they anticipated that the costs of such provision would be exceeded by the benefits.