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PROPOSAL

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	9 July 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 as regards simplification of certain requirements and procedures for chemical products

Delegations will find attached document COM (2025) 531 Final.

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Strasbourg, 8.7.2025
COM(2025) 531 final

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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 as regards simplification of certain requirements and procedures for chemical products

(Text with EEA relevance)

{SWD(2025) 531 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

1.1. Reasons for and objectives of the proposal

The chemical industry is one of the most strategically significant sectors in the European Union, forming the backbone of numerous industrial ecosystems and playing a pivotal role in innovation, employment, and sustainable growth. As the EU advances its twin transition towards climate neutrality and digital leadership, the resilience and global competitiveness of this sector have become even more essential.

Regulatory burdens are one of the two top problems named by businesses operating in the EU when it comes to the investment climate. The high-level reports of Enrico Letta[1] and Mario Draghi placed the reduction of the regulatory burdens and simplification of EU legislation among the top priorities. Overregulation is seen by more than 60% of EU companies as an obstacle to investment, with 55% of SMEs naming regulatory obstacles and the administrative burden as their greatest challenge[2].

In her political guidelines for the European Commission's 2024-2029 mandate[3], President von der Leyen outlined a vision focused on driving sustainable prosperity and strengthening competitiveness across Europe. Central to this vision are efforts to streamline business operations and further integrate the Single Market.

Complementing this, the European Commission's better regulation agenda[4] seeks to enhance the competitiveness of EU businesses by ensuring that legislation achieves its goals efficiently, without placing undue burdens on stakeholders.

The European Commission has reaffirmed its political commitment to lighten the regulatory burden for people, businesses and administrations in the EU to boost prosperity and resilience of the EU in the Competitiveness Compass for the EU that identifies the policy changes that are needed for the EU to step up to the new realities and develop novel ways of working together to increase the speed and quality of decision-making. The Compass, therefore, sets the target of cutting administrative burden by at least 25% for all companies and at least 35% for small and medium-sized enterprises (SMEs) without undermining the respective policy goals[5].

The Single Market strategy, adopted on 21 May 2025, further reiterated the commitment for more simplification and readiness for immediate actions to reduce red tape and make things simple. The strategy highlighted the aim for simplification leading to lower costs, higher productivity, and a better functioning of the Single Market, while maintaining the ambition on

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1 E. Letta, Much more than a market, 2024, available at: https://www.consilium.europa.eu/media/ny3j24sm/much-more-than-a-market-report-by-enrico-letta.pdf.

2 M. Draghi, The future of European competitiveness, 2024, available at: https://commission.europa.eu/topics/eu-competitiveness/draghi-report_en#paragraph_47059, p. 18.

3 Political Guidelines for the next European Commission 2024-2029, available at: https://commission.europa.eu/document/download/e6cd4328-673c-4e7a-8683-f63ffb2cf648_en.

4 Better regulation: Joining forces to make better laws, COM(2021) 219 final, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2021:219:FIN.

5 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, COM(2025) 30 final: A Competitiveness Compass for the EU, available at https://commission.europa.eu/topics/eu-competitiveness/competitiveness-compass_en.

the climate and sustainability, and social responsibilities. It also underlined the need to ensure that rules on labelling balance the need to be clearly understood by consumers with the need to reduce market barriers and burden for industry[6].

Following those commitments, this initiative aims at simplifying and streamlining certain requirements and procedures for chemical products identified as particularly burdensome by industry and authorities. These provisions would benefit from regulatory streamlining and modernisation, which would make chemical legislation more efficient and cost-effective for industry, while at the same time ensuring a high level of protection of human health and the environment. More specifically, this initiative is aiming at simplification of certain provisions and procedures of the following acts:

- **Regulation (EC) No 1272/2008** on classification, labelling and packaging of substances and mixtures[7] ('CLP Regulation'), which requires economic operators to classify, label and package their hazardous chemicals appropriately before placing them on the market. This initiative is seeking to simplify and allow more flexibility for the formatting rules laid down for labelling of hazardous chemicals, including rules on mandatory minimum font sizes and line spacing, as these were identified being particularly burdensome and costly for industry[8]. It also aims at clarifying rules on derogations from labelling requirements for smaller packages and rules on labelling of fuel pumps. In order to alleviate the burden to businesses and to improve the free circulation of substances and mixtures in the internal market without undermining the protection of human health and the environment, this initiative also seeks to reduce the scope of the provisions of Regulation (EC) No 1272/2008 on advertisements and distance sales to products placed on the market for the general public, taking into account the fact that Regulation (EC) No 1907/2006[9] ('REACH') already provides clear obligations on information flows in professional supply chains for substances and mixtures. Furthermore, it seeks to lighten obligations for advertisements of hazardous substances and mixtures, reducing the amount of information to be provided. In addition, it suggests to remove fixed six-month deadline for updating the label, while maintaining the more flexible requirement to ensure the label is updated without undue delay, as the period of six months appeared to be impossible to comply with in the case of complex supply chains. Finally, it

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6 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, COM(2025) 500 final: The Single Market: our European home market in an uncertain world, A Strategy for making the Single Market simple, seamless and strong, available at: https://single-market-economy.ec.europa.eu/publications/single-market-our-european-home-market-uncertain-world_en.

7 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

8 Staff working document accompanying the document proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 of the European Parliament and of the Council as regards simplification of certain requirements and procedures for chemical products, SWD(2025) 531, p. 14.

9 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

proposes to broaden the use of digital labelling, thus allowing more pieces of information to be provided on the digital label only.

- **Regulation (EC) No 1223/2009** on cosmetic products[10] ('the Cosmetic Products Regulation'). The amendments will maintain the high level of safety of cosmetic products made available to consumers on the EU market while setting out in more explicit manner the current requirements and reducing the unnecessary reporting obligations for businesses and the competent authorities. Notably, the procedure for inclusion of colorants, preservatives and UV filters into the relevant Annexes IV, V and VI to Regulation (EC) No 1223/2009 will be established facilitating the process and speeding up the use of new cosmetic ingredients. Article 15 of the Cosmetic Products Regulation establishes that substances which have been classified as Carcinogenic, Mutagenic or Reprotoxic (CMR) in Annex VI to the CLP Regulation are prohibited for use in cosmetic products, unless an exemption has been granted. The existing derogation procedure from the generic prohibition on the use of CMR substances in cosmetic products will be set out in more detail considering the experience gained over more than ten years of practice. Also, the digitalisation of the glossary of common ingredient names will ensure accurate and up-to-date labelling, reduce regulatory risks and compliance errors. Article 13 of the Cosmetic Products Regulation requires businesses to notify to the Commission all cosmetic products before they are placed on the market. In addition, if those products contain nanomaterials, they must comply with additional notification requirements, as information about such products including detailed data on nanomaterials, must be transmitted to the Commission six months before placing them on the market (Article 16 of the Cosmetic Products Regulation). The abolition of pre-notifications of cosmetic products containing nanomaterials, currently required in addition to notification of cosmetic products to the Commission, and of redundant reporting obligation on competent authorities will reduce administrative burden on business and Member States.
- **Regulation (EU) 2019/1009** laying down rules on the making available on the market of EU fertilising products[11] ('Fertilising Products Regulation'). The initiative seeks to remove the specific extended REACH registration requirement set out in the Fertilising Products Regulation, so that 'standard' REACH provisions on chemical safety would also apply to substances used in EU fertilising products. It also seeks to empower the Commission to introduce criteria and a methodology for the assessment of micro-organisms by manufacturers and notified bodies. Moreover, the initiative proposes to remove the 'unbundling clause' in Article 43 of Fertilising Products Regulation, which requires the Commission to adopt separate delegated acts in respect of each component material category. Finally, this initiative would further digitalise the Fertilising Products Regulation, aligning, where appropriate, with the

[10] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (OJ L 342, 22.12.2009, p. 59, ELI: http://data.europa.eu/eli/reg/2009/1223/oj).

[11] 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, ELI: http://data.europa.eu/eli/reg/2019/1009/oj).

Proposal for a Regulation of the European Parliament and of the Council amending Regulations [...] as regards digitalisation and common specifications[12].

1.2. Consistency with existing policy provisions in the policy area

The proposal is part of a package of measures concerning simplification, aiming at reducing administrative burden and costs for industries. Together with the Action Plan that provides a robust business case to address the current challenges facing the chemical industry and drive investments for its long-term growth, and the Proposal postponing the applicability dates of certain requirements for chemicals, this proposal will contribute to improving the competitiveness of the chemicals sector and ensuring a well-functioning Single Market for chemicals, while making sure the same level of protection of human health and of the environment is kept.

The initiative is also in line with the Proposal as regards defence readiness[13] adopted on 17 June 2025, which contains defence-specific simplifications and clarifications of certain chemical legislations, including REACH, CLP Regulation and the Regulation on Biocidal Products[14], and which broadens the conditions for the use of the national exemptions under those Regulations.

Moreover, it takes into account and aligns with, where appropriate, other recent proposals in the area of chemicals legislation, such as the Proposal for a regulation of the European Parliament and of the Council on detergents and surfactants[15].

1.3. Consistency with other Union policies

Under the regulatory fitness and performance programme (REFIT), the Commission ensures that its legislation is fit for purpose, is tailored to the needs of stakeholders and minimises burdens while achieving its objectives. This proposal is therefore part of the REFIT programme, aimed at reducing reporting burdens arising from EU legislation while making sure that the same level of protection of human health and of the environment is kept.

This proposal follows in the context of a series of simplification packages[16].

In keeping high standards of environmental protection and safety, the proposal is also in line with the Commission's commitments in the Clean Industrial Deal[17] to ensure sustainable production in Europe and the Union's overall objective of ensuring the protection of human health and the environment.

This initiative also contributes to the simplification for the agrifood sector, as announced in the Vision on Agriculture and Food[18].

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12 COM(2025) 504.

13 Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 1907/2006, (EC) No 1272/2008, (EU) No 528/2012, (EU) 2019/1021 and (EU) 2021/697 as regards defence readiness and facilitating defence investments and conditions for defence industry, COM(2025) 822 final.

14 Regulation (EU) 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1., ELI: http://data.europa.eu/eli/reg/2012/528/oj).

15 COM(2023)217.

16 COM(2025)80, COM(2025)81, COM(2025)84, COM(2025)87, COM(2025) 236 final, COM(2025)503, COM(2025) 504, COM(2025) 822 final.

17 COM(2025) 85 final.

18 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A Vision for Agriculture and Food Shaping together an attractive farming and agri-food sector for future generations, COM/2025/75 final.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

2.1. Legal basis

This proposal has as its legal basis Article 114 of the Treaty on the Functioning of the European Union in line with the original legal bases for the adoption of the legal acts which this proposal aims to amend.

2.2. Subsidiarity (for non-exclusive competence)

The CLP Regulation, the Cosmetic Products Regulation and Fertilising Products Regulation were adopted at EU level as the objectives of those Regulations could not be sufficiently achieved at Member State level. To solve the same problems, one action at EU level was considered less costly and more efficient than national measures in 27 Member States. Accordingly, amendments to these Regulations need to be made at EU level.

2.3. Proportionality

The initiative does not go beyond what is necessary to achieve the objectives of simplification and burden reduction without lowering the protection of human health and environment.

2.4. Choice of the instrument

This proposal for revision is a legislative proposal, as the CLP Regulation, the Cosmetic Products Regulation and Fertilising Products Regulation were adopted by co-decision/ ordinary legislative procedure and therefore most amendments of those Regulations need to be adopted by ordinary legislative procedure.

Although the Commission is empowered under Article 53 of the CLP Regulation to amend the Annexes to that Regulation in order to adapt them to technical and scientific progress, the amendments to Annex I and Annex II are closely related to the amendments in the main body of this Regulation that could be adopted only via the ordinary legislative procedure. It is therefore appropriate to include the amendments of these Annexes to this initiative.

The Commission is empowered under Article 42(1) of the Fertilising Products Regulation to amend the Regulation's Annexes I, II, III and IV for the purposes of adapting those Annexes to technical progress and of facilitating internal market access and free movement for EU fertilising products. Nevertheless, the Commission opted for the ordinary legislative procedure for the proposed amendment of the Annexes, because most of them are closely related to amendments in the main body of the Regulation. Moreover, given the 'unbundling clause' in Article 43 of the Fertilising Products Regulation, the amendments to the Component Material Categories in Annex II, would require the adoption of twelve delegated acts.

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

3.1. *Ex post* evaluations/fitness checks of existing legislation

This proposal is accompanied by a Commission staff working document that includes a detailed overview of the impact of provisions of chemical legislation that are proposed to be amended. It also provides an analysis of the positive impacts of the proposed measures, based on existing data and information gathered during the various Reality Checks and following the better regulation principles to the extent possible.

The proposal also takes into account previous analyses, such as the Fitness Check of the most relevant chemicals legislation[19], the impact assessments on fertilising products[20] and for the CLP revision[21] and the evaluation of the Detergents Regulation[22].

3.2. Stakeholder consultations

In preparation of the proposal, the Commission consulted stakeholders in three Reality Checks, one for each Regulation to be amended, and invited participants to send written feedback after these meetings. Furthermore, various suggestions for simplifying or clarifying certain provisions of chemical legislation and removing the excessive administrative burden stemming from these provisions have emerged through stakeholders' proposals for simplification of European chemical legislation[23] and numerous position papers received before and after the Reality Checks. Detailed summaries of these consultation activities and the input received are attached to the Staff Working Document accompanying this proposal.

Regulation (EC) No 1272/2008

On 16 May 2025, the European Commission held a Reality Check, aiming to gather practical feedback on the revised CLP Regulation, which was held online and draw over 570 participants from industry, consumer and environmental groups, legal practitioners, and national authorities. The event focused on identifying simplification opportunities following the adoption of Regulation (EU) 2024/2865, while keeping the same level of protection of human health and of the environment. Stakeholders were invited to share concrete experiences and proposals on how to make the new rules more workable, particularly in operational and multilingual contexts.

A central concern expressed by participants was the impact of new mandatory formatting rules for labels, including prescribed font sizes, line spacing, and the requirement for black text on a white background. Many argued that these rules introduced disproportionate costs, especially for products labelled in multiple languages or sold in small packaging formats. There were widespread warnings that these changes could drive up packaging waste and force the use of expensive fold-out labels. At the same time, stakeholders acknowledged the importance of protecting consumers and workers, noting that any simplification action must ensure legibility and clarity of hazard information.

A second area of contention was the revised rules on advertisements, which require detailed hazard information – including pictograms, signal words, hazard statements and invitation to read label information – to be included in promotional materials. Many participants viewed this approach as excessive and poorly adapted to modern advertising channels, particularly online formats with limited timing and space. Concerns were raised that such requirements might paradoxically reduce public understanding by overwhelming consumers with dense information. The prevailing sentiment was that simpler messaging – such as encouraging users to consult the product label – would be more effective and proportionate. There was also

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19 SWD(2019) 199 final.
20 SWD(2016) 64 final.
21 SWD(2022) 435 final.
22 SWD(2019) 298 final.
23 For example: Cefic, Towards a simpler, faster and more supportive legislative framework to help restore Europe's competitiveness, p. 2, available at https://cefic.org/resources/cefic-views-towards-a-simpler-faster-and-more-supportive-legislative-framework-to-help-restore-europes-competitiveness/; VCI, Omnibus proposal, p. 4, available at https://www.vci.de/ergaenzende-downloads/vci-sectorial-omnibus-chemical-industry.pdf; Business Europe, Reducing regulatory burden to restore EU's competitive edge, p. 12, available at: https://www.businesseurope.eu/wp-content/uploads/2025/02/2025-01-22_businesseurope_mapping_of_regulatory_burden-d55-1.pdf.

strong support for exempting B2B[24] advertising altogether, with stakeholders pointing to the adequacy of existing communication tools like SDS for professional audiences.

Beyond these two focal issues, stakeholders expressed strong dissatisfaction with the tight six-month deadline for self-classified substances. Short implementation windows for label updates and classification changes were seen as wasteful and misaligned with the goals of the Green Deal. Digitalisation emerged as a recurring theme, with many participants urging the Commission to expand the legal basis for digital labelling and allow for more flexible information delivery, particularly in multilingual and industrial contexts.

The event featured three targeted polls, which confirmed many of the views raised during discussions. A large majority of respondents felt the new formatting and advertisement rules were unnecessarily burdensome and ripe for simplification. Stakeholders favoured digital solutions, extended timelines, better regulatory alignment, and more flexible implementation mechanisms. Many also questioned the reliance on online event-based consultations, instead calling for more formal and data-driven processes.

In response and the follow-up of the Reality Check, the Commission received more than 150 detailed position papers from stakeholders, supporting the views expressed during the event and providing additional suggestions, data and costs estimates.

Cosmetic Products Regulation (EC) No 1223/2009

The Reality Check on cosmetics took place on 16 May 2025. Approximately 268 stakeholders registered for the meeting and about 226 eventually joined the online meeting. By 6 June 2025, written feedback was received from 51 stakeholders.

As regards the reduction of administrative and compliance burden which the changes to Article 15 of the Cosmetic Products Regulation would bring, stakeholders broadly welcomed the proposed amendments. Some participants emphasised the need for reassurance that any simplification initiative on cosmetics should not compromise the core policy objectives of the Cosmetic Products Regulation. Specifically, they underlined that the harmonised classification of a substance as a CMR must continue to trigger a ban on its use in cosmetics, and that derogations from this ban should only be granted in exceptional cases. Others stressed that the Cosmetic Products Regulation must continue protecting consumers from the harmful chemicals and cautioned against excessively long transitional periods, warning that they could prolong consumers exposure to hazardous substances.

As regards the proposal for a procedure which would facilitate the addition of colorants, preservatives, and UV filters to Annexes IV–VI, most participants agreed that establishing such a procedure would be beneficial. One stakeholder suggested that, as part of this procedure, the Scientific Committee on Consumer Safety (SCCS)[25] should be tasked with reviewing the safety of all substances in the positive lists every 10 years, like the review process under REACH authorisations.

Commission sought stakeholders' views on the relevance of the glossary of common ingredient names which according to Article 33 of the Cosmetic Products Regulation must be adopted by the Commission and published in the *Official Journal* of the EU, suggesting it could be replaced by a reference in the Cosmetic Products Regulation to the internationally recognised cosmetic ingredient nomenclature. During the discussion, several participants

[24] Business-to-business.

[25] Commission Decision (EU) 2024/1514 of 7 August 2015 on establishing Scientific Committees in the field of public health, consumer safety and the environment (OJ L, 2024/1514, 31.5.2024, ELI: http://data.europa.eu/eli/dec/2024/1514/oj).

expressed a preference for retaining the glossary as a source of legally binding ingredient names but recommended that it be made in an electronic format – integrated into CosIng[26] database – to allow more frequent updates and provide significantly improved user experience.

Some stakeholders, however, argued that the glossary is either no longer necessary or would require substantial improvements to remain useful.

Suggestions for improvement included also simplifying the notification processes by relying on Article 13 of the Cosmetic Products Regulation to avoid notifying a product twice and reduce industry costs without compromising product safety. Vast majority of stakeholders agreed that the pre-notification requirements impose significant and disproportionate burdens and costs on the cosmetic industry.

According to several competent authorities, the obligation under Article 22 of the Cosmetic Products Regulation requiring Member States to periodically review and assess the functioning of their surveillance activities and communicate the results of such review to the other Member States and the Commission, places an unnecessary burden on competent authorities as existing tools, such as ICSMS[27], are already used for reporting and sharing information on market surveillance measures among EU competent authorities. Additionally, PEMSAC – the platform for market surveillance bodies for cosmetics, supports a coherent approach to enforcing the Cosmetic Products Regulation. Some participants cautioned against introducing measures that could weaken EU-level oversight of national market surveillance activities.

Multiple suggestions were made for further simplification of the Cosmetic Products Regulation, going beyond this very targeted simplification exercise. Those aspects could be further investigated in the context of the ongoing evaluation of the Cosmetic Products Regulation.

Fertilising Products Regulation (EU) 2019/1009

The Reality Check for the Fertilising products regulation was held as part of the Commission Expert Group meeting on fertilising products on 7 May 2025. Approximately 135 stakeholders registered for the meeting and 91 eventually attended. By 6 June 2025, written feedback was received from 26 stakeholders.

Most stakeholders confirmed that the extended REACH registration requirement under the Fertilising Products Regulation poses significant challenges for manufacturers of EU fertilising products. Costs for complying with this requirement range between €10 000 and €500 000, depending on whether the substance is registered and to which tonnage band and the extent of additional data required, resulting in a price increase for the substance in question by 40%-540%. This process impedes access to the single market, and some stakeholders may keep placing their products on national markets, facing multiple processes for national registrations or mutual recognition.

Many stakeholders were in favour of applying normal REACH registration requirements, including the gradations according to tonnage, to all or most substances, on their own or in mixtures, in EU fertilising products. However, several stakeholders considered that the extended REACH registration should be maintained, at least for certain very hazardous

[26] https://ec.europa.eu/growth/tools-databases/cosing/

[27] ICSMS (Information and Communication System for Market Surveillance) is the comprehensive communication platform for market surveillance on non-food products and for mutual recognition for goods, https://webgate.ec.europa.eu/single-market-compliance-space/market-surveillance.

substances, such as persistent, bioaccumulative and toxic ones, and for certain unknown, biologically active substances, also considering the specific nature of fertilising product use, i.e. the continued and often large-scale application on soil.

Most stakeholders welcomed the Commission's considerations on introducing a simplified procedure for the assessment of micro-organisms (Component Material Category 7) used in microbial plant biostimulants. They consider the current mechanism for permitting additional strains of micro-organisms in EU fertilising products under the Fertilising Products Regulation as inconsistent with the demands and rapid development pace of the burgeoning plant biostimulant sector. Several stakeholders highlighted that this process impedes market access for microbial plant biostimulants, discouraging innovation and investment, and delaying the availability of these products to farmers.

Many stakeholders participating in the Reality Check were generally in favour of a criteria-based approach, combined with a methodology for manufacturers and notified bodies to assess compliance with the criteria. However, some stakeholders were not convinced of leaving the assessment to manufacturers and notified bodies and several advocated for an assessment by an independent body, such as the European Food Safety Authority (EFSA).

While digitalisation of reporting requirements under the Fertilising Products Regulation did not seem to be the most relevant concern of stakeholders at the Reality Check, several stakeholders, including industry and authorities, underlined in their written submissions that the digitalisation of information requirements can reduce the administrative burden for companies and authorities as electronic management can facilitate the exchange, storage and access to information, reduce errors associated with manual process, and minimise paper usage and the costs linked to the handling of paper documents.

Some concerns were expressed in relation to cyber security, availability and interoperability of digital infrastructure, costs for acquiring necessary technology and, in relation to exports, paper-based systems in third countries. Several stakeholders pointed out that industry and authorities would need 2-3 years to adjust to the new digital requirements, while one suggested 1-2 years.

Stakeholders were not consulted on the deletion of the 'unbundling clause', as this amendment is mainly a simplification of Commission procedures. However, it would also benefit industry and authorities, as necessary amendments via delegated acts could be done more quickly. Moreover, the mandatory consultation in the Commission Expert Group and of the public for delegated acts would be streamlined.

Multiple other suggestions were made for further simplification of the Fertilising Products Regulation, going beyond this very targeted simplification exercise. Some of those aspects could be further investigated in the context of the ongoing evaluation. Others, related to digital labelling, can be considered in the context of the evaluation of the digital labelling rules in accordance with Article 49a of the Fertilising Products Regulation. A few proposals could also be implemented via a delegated act.

3.3. Collection and use of expertise

Different suggestions for clarifying certain provisions of chemical legislation and removing the excessive administrative burden stemming from these provisions have emerged through stakeholders' proposals for simplification of European chemical legislation. Furthermore, in response and the follow-up of the Reality Checks mentioned above, the Commission received more than 150 detailed position papers from stakeholders, supporting the views expressed during the event and providing additional suggestions, data and costs estimates. Detailed

summaries of these consultation activities and the input received are attached to the staff working document accompanying this proposal.

3.4. Impact assessment

Given the need to urgently put forward a proposal to address the identified problems in order to reduce administrative burden and excessive costs for businesses it has not been possible to prepare a full impact assessment.

However, following better regulation principles, this proposal is accompanied by a Commission staff working document that includes an analysis of the impacts of the proposed measures, based on existing data and information gathered during the various Reality Checks, written input received from stakeholders and previous analyses, such as the Fitness Check of the most relevant chemicals legislation, the impact assessments on fertilising products and for the CLP revision, and the evaluation of the Detergents Regulation.

On the basis of the information available, it is expected that the amendments would entail significant cost savings for industry and for authorities. As regards classification, labelling and packaging of chemicals, the saving from the proposed changes to the font size requirements and related typographic rules for the EU chemicals sector were estimated in a conservative way to amount to at least €333 000 000. In addition, lightening obligations for advertisements of hazardous substances and mixtures, and narrowing the scope of obligations to advertisements for the general public, is expected to save the EU chemicals sector at least €30 000 000 annually.

As regards cosmetics, the proposed measures will relieve the cosmetics manufacturers, especially SMEs, from the unnecessary compliance and administrative burden allowing them to shift the financial and human resources from compliance and administrative tasks to R&D and innovation. The changes will allow the EU cosmetic businesses (of which 98% are SMEs) to scale up and be more competitive on the EU and global arena.

As regards EU fertilising products, the obstacle of the costs for complying with the extended REACH registration requirements for substances in EU fertilising products (administrative costs for the whole industry of at least around €200 000 and additional much higher costs for testing, depending on the substance) would be removed. Manufacturers of fertilising products would be encouraged to market their products in the Single Market under the rules of the Fertilising Products Regulation. Like this, they can save fees for national registrations (up to €50 000 per product per Member State) and adaptation costs (at an estimated range of €15 000 to €43 000 per product per Member State).

No detrimental impacts to human health and the environment are expected. The removal of certain obligations under the three pieces of legislation will not compromise the high level of protection ensured by the overall EU legal framework for chemical substances and products. At the same time, certain environmental benefits can be expected from the proposed amendments. The changes to formatting requirements under CLP Regulation will help avoiding massive relabelling and repackaging leading to excessive waste. Moreover, under the Fertilising Products Regulation, the digitalisation of reporting obligations will reduce the use of paper. In addition, the facilitation of the use of micro-organisms in EU fertilising products is expected to have positive impacts on soils. Microbial plant biostimulants enrich microbial biodiversity in soils and have positive effects on the uptake of nutrients present already in soil or offered through the use of fertilisers. Thus they may help farmers to use precision farming schemes, reduce the risk of nutrient surplus and the run-off or leaching of nutrients to aquatic environments. By reducing the use of natural resources and reducing the

creation of waste, the initiative consistent with achieving the EU climate targets of reducing greenhouse gas emissions by 55% by 2030 and by 90% by 2040.

3.5. Regulatory fitness and simplification

This proposal is part of the commitment of the European Commission to lighten the regulatory burden for people, businesses and administrations in the EU to boost prosperity and resilience of the EU. The proposal is therefore aiming at simplifying provisions of chemical legislation, reducing unnecessary burdens and costs for businesses, without undermining the protection of human health and the environment.

3.6. Fundamental rights

The proposal respects the fundamental rights enshrined in the Charter of Fundamental Rights of the European Union[28] and adheres to the principles recognised therein. The reduction of administrative burden on companies should lead to societal gains in terms of wealth creation, employment and innovation. At the same time, the proposal seeks to ensure a high level of protection of human health and of the environment. Furthermore, the proposal is expected to have a positive impact on the environment, as the proposed amendments will reduce the amount of paper-based documentation and decrease the need for relabelling and repackaging, thus also reducing the amount of waste. Therefore, the proposal is also consistent with the fulfilment of the climate neutrality objective as requested by the European Climate Law. It has no impact on gender equality.

4. BUDGETARY IMPLICATIONS

This initiative will not imply any additional costs for the Commission. On the contrary, the new empowerment under Regulation (EU) 2019/1009 which will provide for an assessment of micro-organisms by manufacturers and notified bodies, will save Commission budget which, under the existing empowerment, would need to be spent on a study to support the Commission in the assessment of such micro-organisms. In addition, removing the obligation to adopt a glossary of common ingredient names through a Commission decision will free up Commission human resources for other policy tasks, without requiring additional budget.

5. OTHER ELEMENTS

5.1. Implementation plans and monitoring, evaluation and reporting arrangements

The Commission will monitor the implementation and application of new provisions and compliance with them. Furthermore, the Regulations to be amended by this proposal are subject to regular evaluation of their efficiency, effectiveness in reaching their objectives, relevance, coherence and value added in accordance with better regulation principles. This proposal does not require an implementation plan.

5.2. Detailed explanation of the specific provisions of the proposal

Regarding Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures:

In line with the Commission's general efforts to rationalise and simplify reporting requirements and to promote the 'digital by default' principle to support digital transformations, the definition of 'digital contact' is introduced in Article 2. Instead of current requirements for economic operators to indicate their address and telephone number on the

[28] OJ C 326, 26.10.2012, p. 391, ELI: http://data.europa.eu/eli/treaty/char_2012/oj.

label of the packaging of hazardous substance or mixture, the amendment requires providing an address and a digital contact, which could be any up-to-date and accessible online communication channel through which economic operators can be reached or engaged. This will facilitate communication between suppliers and national authorities responsible for enforcement, and end-users. Once the European Business Wallet is available, the digital address it provides to economic operators could also constitute the 'digital contact'.

The amendments to Article 29(2) and section 1.5.2.4 of Annex I simplify and clarify provisions allowing for derogations from labelling requirements for small packaging, especially for very small containers under 10 ml. The amendment to Article 29(2) will allow economic operators to reduce information required to be provided on the label for packaging containing smaller quantities of chemical substances or mixtures without the need to prove that this packaging is either in such a shape or form or is so small that it is impossible to meet full labelling requirements. The amendment to section 1.5.2.4 of Annex I clarifies derogations from labelling requirements for 10 ml packaging, introduced by Regulation 2024/2865, especially for the ones containing less hazardous substances or mixtures.

The amendment to Article 30(1) removes fixed deadline for the obligation to update the label, as it appeared to not be feasible to comply with due to the complexity of supply chains[29]. In order to provide flexibility for suppliers and create equal conditions for SMEs who often outsource label printing services, and taking into account the fact that preparation and production of fold-out labels is significantly longer that of standard 2D labels, the amendment will require the labels to be changed without undue delay after new data was obtained by or communicated to a supplier.

The amendment to Article 31(3) and section 1.2.1 of Annex I removes mandatory label formatting rules introduced by Regulation 2024/2865, as they were found to be costly and restrictive for economic operators[30]. The new rules ease these requirements, focusing on keeping labels clear and readable rather than enforcing rigid formatting rules.

Articles 48 and 48a on advertisements and online sales are amended to reduce their scope to chemicals sold to the general public. Hazardous substances and mixtures traded between professionals are already subject to information requirements under Regulation (EC) No 1907/2006, so additional rules would not be proportionate. Furthermore, amended Article 48 simplifies information requirement in advertisements aimed at general public. The amended provisions will require advertisements of chemicals to encourage customers to read the label and product information before use.

The amendment to section 1.6 of Annex I broadens the use of digital labelling introduced by Regulation 2024/2865. Suppliers will be able to include extra contact information on digital labels instead of the physical label, saving space on physical labels and making it easier to manage and update product details using digital technology, without, however, compromising health and safety of users. The inclusion of the digital contact would also be appropriate where contact details of additional suppliers are provided in the digital label.

The amendment to Part 5 of Annex II seeks to simplify the labelling requirements for fuelling stations. Some label elements, such as nominal quantity and UFI, will not be required on fuel pumps, helping fuel suppliers meet the requirements without lowering safety standards.

Regarding Regulation (EC) No 1223/2009 on cosmetic products:

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29 Accompanying staff working document, SWD(2025) 531, p. 30.

30 Detailed analysis of costs associated with new formatting requirements is provided in the accompanying staff working document, SWD(2025) 531, p. 14.

The new Article 14a seeks to address the current lack of specific procedure according to which colorants, preservatives, and UV filters could be added to the relevant Annexes IV to VI to the Cosmetic Products Regulation. The new Article specifies different steps of the procedure, outlines the role of the European Commission and reaffirms the responsibility of the SCCS in assessing the safety of any proposed colorant, preservative or UV filter.

The changes to Article 15 do not affect the current approach that the hazard-based harmonised classification of a substance as CMR category 1 or 2 triggers its prohibition in cosmetic products, unless a derogation request is submitted, and the derogation criteria are met. In addition, the amended Cosmetic Products Regulation will continue to uphold the principle that a derogation from the ban is an exception as the substance will have to be assessed and found safe by the SCCS for specific product types and specific use and, for CMR substances category 1A and 1B, the lack of suitable alternatives which could be used instead of the substance in question will have to be demonstrated by the industry. The amendments establish specific timeline for submission of the derogation request (at the latest three months after the date of entry into force of the changes to the CLP Regulation) as well as transitional periods of 12 months for products to be placed on the market and 24 moths for products already available on the market to enable economic operator to adjust to a ban or restriction.

In addition, the changes to Article 15 to the Cosmetic Products Regulation streamline the derogation criteria for substances classified as CMR category 1A or 1B, namely the criterion that the application must be made for a particular use of the product category with a known exposure has been merged with the current criterion (d) requiring the SCCS opinion. The compliance with the food safety requirements will no longer have to be proved for the purpose of receiving a derogation, as food and cosmetics are distinct products and the fact that a product containing a substance is not eatable does not mean that this substance will not be safe when used in a cosmetic formula which is to be applied on the human skin.

Furthermore, the changes to Article 15 clarify that the harmonised classification under the CLP Regulation as a CMR of a constituent of a natural complex substance does not lead to a ban on this natural complex substance. However, in such a case the Commission will have to request the opinion of the SCCS on the safety of such natural complex substance for human health.

Finally, a link between the route of exposure considered for the purpose of the harmonised classification as a CMR category 1A, 1B or 2 and the ban in cosmetics has been established so that if a substance has CMR properties only when it is inhaled or digested, but not if it comes into contact with the human skin (i.e. dermal exposure) is should not be banned from the use in cosmetics on the basis of Article 15.

The amendments to Article 16 of the Cosmetic Products Regulation seek to remove the pre-notification obligation as it is no longer justified. The cosmetic products containing nanomaterials should not be considered less safe than other cosmetic products as they are subject to the appropriate safety assessment under the responsibility of the responsible person. However, to maintain the possibility to address any safety concerns related to the use of nanomaterials, the relevant information will have to be provided in the cosmetic product safety report. Therefore, the deletion of the relevant paragraphs in Article 16 of the Cosmetic Products Regulation will be accompanied with the changes to Annex I to the Cosmetic Products Regulation.

The change in Article 22 aims at releasing the burden on the Member States as they will no longer be required to carry out of the review of their market surveillance activities every four years and report to other Member States and the Commission. This reporting obligation has become redundant with the introduction of the Information and Communication System for

Market Surveillance (ICSMS) which allows information on investigated products (test results, product identification data, economic operator information, accident information, information on measures taken by surveillance authorities etc.) to be quickly and efficiently shared between authorities and the Commission.

The deletion of Article 33 and related changes in Article 19 will enable businesses and competent authorities to rely on the internationally recognised nomenclature for the purpose of labelling of cosmetic products.

Regarding Regulation (EU) 2019/1009 laying down rules on the making available on the market of EU fertilising products:

The amendment to Annex II, Part II, component material category (CMC) 1, point 2, seeks to remove the requirement that all substances incorporated into an EU fertilising product, on their own or in a mixture, except polymers, shall have been registered pursuant to Regulation (EC) No 1907/2006, with a dossier containing: (a) the information provided for by Annexes VI, VII and VIII to Regulation (EC) No 1907/2006; and (b) a chemical safety report pursuant to Article 14 of Regulation (EC) No 1907/2006 covering the use as a fertilising product, unless explicitly covered by one of the registration obligation exemptions provided for by Annex IV to Regulation (EC) No 1907/2006 or by points 6, 7, 8, 9 or 10 (only for magnesia) of Annex V to that Regulation. The other amendments to Annex II, Part II, will remove the references to the provision in CMC 1, point 2, from the requirements for additives and other substances under other component material categories. This means that the generic rules laid down in REACH would apply to all those substances incorporated into an EU fertilising products, either on their own or in a mixture. In particular, the principle set up in Article 1(3) of REACH provides 'that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use […] substances that do not adversely affect human health or the environment'. Furthermore, substances incorporated in EU fertilising products would be subject to the rules laid down in Title II – Registration of substances, especially its Article 5 – 'No data, no market'.

In Article 42, a new paragraph is inserted to empower the Commission to set out criteria and a methodology for the assessment of micro-organisms. Those criteria and the methodology should allow manufacturers and notified bodies to demonstrate and verify that micro-organisms used in a microbial plant biostimulant, other than those listed in CMC 7, do not present a risk to human, animal or plant health, to safety or to the environment, and ensure agronomic efficiency. They should provide for the consideration of certain elements listed in the new Article 42(4a). The existing empowerment in Article 42(4) is maintained, but the word 'only' will be removed, as the Commission will have two parallel empowerments for amending CMC7.

Article 43 is deleted to enable the Commission to adopt delegated acts which amend several component materials at the same time.

The amendments to Article 2, Articles 6 to 9, Article 15, Article 16 and Article 41, and those to Annex I, Part II, and Annex IV, Part II, aim to achieve further digitalisation of the information and reporting obligations under the Regulation, aligning the relevant provisions, where appropriate, to the proposal for a Regulation of the European Parliament and of the Council amending Regulations [...] as regards digitalisation and common specifications[31]. More specifically, the proposal includes:

[31] COM(2025)504.

- Specifying that the EU declaration of conformity must be drawn up in electronic form and made accessible through an internet address or data carrier;
- The addition of a ‘digital contact’ as information to be indicated by economic operators on the products which are placed on the market to facilitate communication between economic operators and national authorities. Once the European Business Wallet is available, the digital address it provides to economic operators could constitute the ‘digital contact’;
- The amendment of reporting obligations to national authorities that require a ‘paper or electronic format’ to ‘electronic form’ only;
- Specifying that documents and exchanges between the economic operators and notified bodies related to conformity assessments shall be in electronic form;
- An obligation that, if a digital label is used, the same data carrier providing access to the digital label should also provide access to the EU declaration of conformity;
- An obligation to provide the information contained in the EU declaration of conformity and, if applicable, digital labelling on the digital product passport when the product is subject to other Union legislation that requires the use of such a digital product passport.

2025/0531 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 as regards simplification of certain requirements and procedures for chemical 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) High quality and safety requirements for products on the Single Market ensure a high level of protection of human health and the environment and contribute to a fair and sustainable economy. In international competition, the reputation of high-grade products manufactured in the Union can create an advantage for Union companies.

(2) The findings of the 2024 Draghi report[2] indicated that the increasing number and complexity of rules risks limiting room for manoeuvre for Union businesses and preventing them from remaining competitive. Against this background, certain procedures and requirements laid down in Regulations (EC) No 1272/2008[3], (EC) No 1223/2009[4] and (EU) 2019/1009[5] of the European Parliament and of the Council should be simplified and unnecessary regulatory burdens should be removed, while maintaining the same level of protection of human health and of the environment.

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1 OJ C [...], [...], p. [...].

2 2024 report by Mario Draghi on the future of European competitiveness: https://commission.europa.eu/topics/eu-competitiveness/draghi-report_en#paragraph_47059

3 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

4 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (OJ L 342, 22.12.2009, p. 59, ELI: http://data.europa.eu/eli/reg/2009/1223/oj).

5 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, ELI: http://data.europa.eu/eli/reg/2019/1009/oj).

(3) In line with the Commission's objective to promote the 'digital by default' principle to support digital transformations and in order to facilitate communication between economic operators and national authorities responsible for enforcement, the indication of a digital contact on the label of hazardous substances and mixtures is necessary to enhance the effectiveness of official controls and enforcement and to expedite the process of detecting substances and mixtures that do not comply with the requirements of Regulation (EC) No 1272/2008. Currently, suppliers are required to indicate their address and telephone number on the label of the packaging of hazardous substances or mixtures, but this is not always sufficient to ensure that authorities responsible for enforcement can establish rapid contact. It is therefore necessary to require suppliers to provide a digital contact, which could be any up-to-date and accessible online communication channel with the supplier.

(4) Regulation (EC) No 1272/2008 laid down the exemptions from labelling and packaging requirements for packaging of specific shapes, forms or sizes. Those exemptions can only be triggered if all required label elements do not fit on the outer packaging or on a tie-on tag. To simplify the use of those exemptions, it is appropriate to allow the existing exemptions to be applied to smaller packages without the need to prove the impossibility of using the outer packaging or tie-on tag.

(5) Regulation (EU) 2024/2865 of the European Parliament and of the Council[6] introduced exemptions from labelling and packaging requirements for packages containing less than 10 ml. However, further simplifications are needed with regard to the application of this derogation in cases where these packages are subject to the supplementary hazard statement EUH 208. It is also necessary to clarify the requirements for inner and outer packaging in cases where the 10 ml derogation is applied.

(6) In order to provide the flexibility for suppliers of substances and mixtures, to create equal conditions for small and medium-sized enterprises who often outsource label printing services and to facilitate the preparation and production of fold-out labels, which is significantly longer than the production of the standard labels, it is necessary to remove a fixed six months relabelling deadline and to require the labels to be changed without undue delay after new data was obtained by or communicated to a supplier.

(7) Regulation (EU) 2024/2865 laid down rules on mandatory requirements for label formatting. New information[7] pointed to excessive administrative burden and costs, associated with these requirements. To balance the need for label information to be clearly understood by consumers with the need to reduce market barriers and burden for industry[8], it is necessary to simplify the current formatting obligations without

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6 Regulation (EU) 2024/2865 of the European Parliament and of the Council of 23 October 2024 amending Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (OJ L, 2024/2865, 20.11.2024, ELI: http://data.europa.eu/eli/reg/2024/2865/oj).

7 Detailed analysis of costs associated with new formatting requirements is provided in the Staff Working Document Accompanying the document Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 as regards simplification of certain requirements and procedures for chemical products, SWD(2025) 531, p. 14.

8 As outlined in the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions The Single Market: our European home market in an uncertain world, A Strategy for making the Single Market simple, seamless and strong, COM(2025) 500 final, p. 10, available at:

reducing the level of protection of human health and the environment. Economic operators and enforcement authorities must remain responsible for ensuring that the labels are legible in accordance with the legal requirements.

(8) To alleviate the burden on industry and to improve the free circulation of substances and mixtures in the internal market it is appropriate to amend Regulation (EC) No 1272/2008 as regards the rules on advertisements and distance offers, taking advantages of existing provisions in other Union legislation with the same objectives. In this regard, requirements for advertisements and distance offers should be limited to products placed on the market for the general public, as Regulation (EC) No 1907/2006[9] already provides clear obligations on information flows in supply chains for substances and mixtures.

(9) Before the amendments introduced by Regulation (EU) 2024/2865, Regulation (EC) No 1272/2008 required the advertisements for hazardous mixtures, for which a member of the general public is allowed to conclude a contract for purchase without first having sight of the label, to mention the type or types of hazards indicated on the label, and required advertisements for substances to mention the hazard classes or hazard categories concerned. Regulation (EU) 2024/2865 introduced a new requirement for all distance sales of hazardous substances and mixtures to include all labelling information in the offer, thus ensuring that the buyer is always informed about the hazards before buying the product. That Regulation also expanded requirements for advertisements, requiring them to indicate the hazard pictograms, signal words, hazard statements and supplemental statements and, in addition, to invite general public to follow the information on the product label. Advertisements are means of promoting the sale or use of chemical products, and at the moment of sale the label on the packaging of the substance or mixture or the label information in the distance offer provides full information about the hazards associated with that substance or mixture. It would therefore be appropriate to require advertisements to invite customers to read the label and product information before use, but not to duplicate the hazard information from the label.

(10) As Regulation (EC) No 1107/2009 of the European Parliament and of the Council[10] and Regulation (EU) No 528/2012 of the European Parliament and of the Council[11] require advertisements for authorised plant protection products and biocidal products to use the statement ‘Always read the label and product information before use’, it would be appropriate to use the same requirement for advertisements of hazardous substances and mixtures to ensure consistency, especially in cases where advertised

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https://single-market-economy.ec.europa.eu/document/download/d92c78d0-7d47-4a16-b53f-1cead54bcb49_en?filename=Communication%20-%20Single%20Market%20Strategy.pdf.

9 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

10 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/1107/oj).

11 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj).

hazardous substances and mixtures are also authorised plant protection products or biocidal products.

(11) Regulation (EU) 2024/2865 introduced specific provisions for the labelling of fuels supplied at fuelling stations. To remove unnecessary burdens on businesses, without undermining the protection of human health and the environment, it is necessary to clarify in Annex II of Regulation (EC) No 1272/2008 which of the label elements required by Article 17(1) of that Regulation are not needed on the pump.

(12) Regulation (EU) 2024/2865 introduced the possibility to include certain labelling elements in the digital label only. To ensure broader use of technology and to allow a simpler and more flexible approach to labelling, suppliers should be allowed to place contact details of any additional suppliers on the digital label only. Inclusion of the digital contact would also be appropriate where contact details of additional suppliers are provided in the digital label.

(13) To ensure that suppliers of substances and mixtures have time to adapt to the new rules on classification, labelling and packaging, the application of some provisions of this Regulation should be deferred. Substances and mixtures which are already placed on the market before the end of that deferral period, should not be required to be reclassified or relabelled in accordance with this Regulation, to avoid an additional burden on suppliers of substances and mixtures.

(14) In line with the transitional provisions of Regulation (EC) No 1272/2008, suppliers should have the possibility of applying the new classification, labelling and packaging provisions introduced by this Regulation on a voluntary basis before the date of the deferred application of these provisions.

(15) In accordance with Regulation (EC) No 1223/2009, colorants, preservatives and UV filters may only be used in cosmetic products if they are listed in Annexes IV to VI to that Regulation. To ensure legal certainty for economic operators, a procedure should be provided specifying the different steps in the process for a substance to be included into the respective Annex for the purposes of adapting the Annexes to technical and scientific progress in accordance with Article 31(2) of Regulation (EC) No 1223/2009.

(16) Regulation (EC) No 1223/2009 provides the possibility to use in cosmetic products substances classified as CMR substances of category 1A and 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008 under certain conditions. A request for derogation should be submitted to the Commission at the latest three months after the entry into force of the respective changes to Part 3 of Annex VI to Regulation (EC) No 1272/2008. As the relevant opinion of the Committee for Risk Assessment proposing the substances for the harmonised classification is made publicly available several months before the Commission follows with the regulatory measure, such deadline is sufficient.

(17) The conditions allowing for exemptions from the ban of use of such substances in cosmetic products should be streamlined, and their scope should be set out in more detail. In addition, compliance with food safety requirements is not compatible with the scientific and technical developments that allow the development of new substances for use in cosmetic products that are not used or found in food. The compliance with food safety requirements does not enhance the safety of cosmetic products as both categories of products are inherently different. It is, therefore, appropriate to abolish this condition.

(18) Furthermore, elements to be considered under the availability of suitable alternatives condition should be specified. In particular, it should be provided that the use of alternative substance should result in reduced overall risk to human health and the environment and the substance should provide an equivalent or similar function in a cosmetic product, be available on the market in sufficient quantities, so that it can be technically feasible and economically viable for businesses and especially for SMEs. In addition, access to the substance should not be restricted by patents or raw material restrictions. It should also be possible to consider the economic aspects, such as costs of reformulation and comparative contribution to overall production costs, as relevant factors in the analysis of the suitability of alternatives.

(19) In addition, in order to streamline the derogation procedure, the condition that the derogation request is made for a particular use of a product category with a known exposure should become part of the SCCS assessment criterion. Currently, the scientific committee is already assessing the safety of the substance considering its hazard properties and exposure, (i.e., namely specific use in particular product category), therefore, a separate criterion is redundant.

(20) Due account should be taken of the specific exposure of cosmetic products, which are mainly placed in contact with the external parts of human body (for example epidermis, hair system, nails, external genital organs) and that they are not ingested, inhaled, injected or implanted into the human body. The prohibition triggered by Article 15 of Regulation (EC) No 1223/2009 should cover the substances with CMR harmonised classification under the Regulation (EC) No 1272/2008, where the CMR hazards are not assigned to specific routes of exposure or when they are assigned explicitly to the dermal route of exposure. Where the CMR classification of a substance is only associated with oral or inhalation routes of exposure, its use in cosmetic products does not result in the same level of risk for end-users, since oral and inhalation exposure are incidental (for example, cosmetic products used on lips, teeth or mucous membranes of the oral cavity or cosmetic products used in spray are not intended to be ingested or inhaled). Therefore, such substances should not be subject to a prohibition under Article 15 of Regulation (EC) No 1223/2009. However, the fact that a substance used in oral or sprayable cosmetic products is classified as CMR due to its oral or inhalation route of exposure, may raise concerns for human health. In such cases, the Commission should mandate the SCCS to assess the safety of such substances when used in cosmetic products and is to follow up with the appropriate regulatory measures in accordance with Article 31(1) of Regulation (EC) No 1223/2009.

(21) Often a substance can also be a constituent of natural complex substances, for example essential oils. In such cases, the prohibition of use in cosmetic products under Article 15 of Regulation (EC) No 1223/2009 is relevant only to the substance as it appears in Part 3 of Annex VI to the Regulation (EC) No 1272/2008. This means that natural complex substances that contain a CMR classified constituent are not subject to the prohibition, except if that natural complex substance is itself listed as CMR substance of category 1A, 1B or 2 in Part 3 of Annex VI to the Regulation (EC) No 1272/2008. Nevertheless, since the harmonised classification of a constituent may raise concerns as to the safety of the natural complex substances when used in cosmetic products, the Commission should mandate the SCCS to assess the impact of such constituent on the safety of natural complex substances, if a safety concern arises, and is to follow up with the appropriate regulatory measures in accordance with Article 31(1) of Regulation (EC) No 1223/2009.

(22) When a substance is prohibited or restricted from the use in cosmetic products, the manufacturers, importers, distributors and responsible persons should be given appropriate time to take necessary measures to reformulate and relabel their products, withdraw from the distribution and destroy the unsold products not complying with the new requirements. Therefore, periods of 12 months for placing and 24 months for making available on the market of cosmetic products containing the substance concerned following the entry into force of the respective amendments to Regulation (EC) No 1223/2009 should be provided.

(23) To reduce compliance and administrative burden on businesses active in the cosmetic sector, only one notification of the cosmetic products should be required before placing them on the Union market. The conditions of such notification should apply in a non-discriminatory way to cosmetic products containing nanomaterials and to those cosmetic products which do not contain them. To maintain vigilance on nanomaterials, it should be required that the specific information on nanomaterials used in a cosmetic product is provided in the cosmetic product safety report so that it can be consulted by the competent authorities where the concerns over the potential risk to human health arise from the use of a particular nanomaterial

(24) In accordance with Regulation (EU) 2019/1020[12], the Commission has developed an information and communication system for the collection, processing and storing of information on issues relating to the enforcement of Union product legislation, including Regulation (EC) No 1223/2009. In practice this system has replaced the reporting obligation laid down in Article 22 of Regulation (EC) No 1223/2009 requiring the Member States to regularly submit the review and assessment of their surveillance activities to the Commission and other Member States. This reporting obligation should therefore be abolished.

(25) Cosmetics are globally traded goods. It is therefore important that the ingredient names present on their labels reflect the current state of scientific and technological development. The use of internationally recognised cosmetic ingredient' names is an important factor promoting transparency and facilitating cross-border trade in cosmetics. This Regulation should enable internationally recognised names to be used on the labelling of cosmetic products without any additional regulatory action from the Commission. As a glossary of common ingredient names adopted by the Commission would slow down the process of uptake of the new names, the provision requiring the Commission to adopt such a glossary should be abolished.

(26) In line with the Commission's objective to rationalise and simplify reporting requirements and to promote the 'digital by default' principle to support digital transformations, economic operators dealing with EU fertilising products in accordance with Regulation (EU) 2019/1009 should provide a digital contact through which they can be reached, draw up the EU declaration of conformity in electronic form and make it accessible via an internet address or data carrier, and provide authorities, upon request, with all relevant information and documentation in electronic form. Documents and correspondence to and from notified bodies related to conformity assessments of EU fertilising products should also be provided in

[12] Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1, ELI: http://data.europa.eu/eli/reg/2019/1020/oj).

electronic form. Where a digital label is used, manufacturers should use the same data carrier used for the digital label to provide access to the EU declaration of conformity, to avoid the presence of multiple data carriers on the same product. Where a Digital Product Passport is required for EU fertilising products under other EU legislation, the digital labelling information and the EU declaration of conformity should be provided in that Digital Product Passport.

(27) Under Regulation (EU) 2019/1009, only micro-organisms listed on a positive list in Annex II to that Regulation may be used as component material in microbial plant biostimulants. The Commission is empowered to add new micro-organisms or strains of micro-organisms to that list after an assessment concluding that none of the strains presents a risk to human, animal or plant health, to safety or to the environment and that it ensures agronomic efficiency. Given the large number of micro-organisms on the market, the assessment and subsequent inclusion of new micro-organisms or strains of micro-organism to the positive list are lagging scientific progress. The current mechanism slows down the development of microbial plant biostimulants and delays farmers' access to those innovative fertilising products which may stimulate plant nutrition processes and thereby reduce the use of traditional fertilisers.

(28) In order to accelerate the assessment of micro-organisms and to open the single market for more microbial plant biostimulants, 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 Annex II, Part II, component material category (CMC) 7, to Regulation (EU) 2019/1009 to allow the Commission to introduce general criteria and a methodology for the assessment of micro-organisms. Those criteria and the methodology should allow manufacturers and notified bodies to demonstrate and verify that micro-organisms used in microbial plant biostimulants, other than those listed in CMC 7, do not present a risk to human, animal or plant health, to safety or to the environment and ensure agronomic efficiency. In order to refine and validate the criteria and methodology to be introduced, it is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[13]. 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.

(29) Where the Commission makes use of its empowerment to amend the component material categories in Annex II to Regulation (EU) 2019/1009, it may currently only do so via separate delegated acts in respect of each component material category. Considering the need to introduce additional materials to the various component material categories in the future and the constant technical and scientific progress in the fertilising product sector, there is a frequent need to amend the different component material categories. In some cases, for instance where a new raw material may be allowed in multiple CMCs, the Commission would introduce the same change in all relevant CMCs, each of them covered by a different delegated act. To speed up

[13] OJ L 123, 12.5.2016, p. 1, ELI: http://data.europa.eu/eli/agree_interinstit/2016/512/oj.

the adoption of the respective delegated acts, the Commission should be allowed to amend several component material categories by one delegated act.

(30) Chemical substances, on their own or in mixtures, if manufactured or imported in quantities above 1 tonne per company per year, need to be registered in accordance with Regulation (EC) No 1907/2006, with information requirements depending on the actual volume. Regulation (EU) 2019/1009, going beyond the requirements of Regulation (EC) No 1907/2006, requires that all substances used in an EU fertilising products, regardless of the quantity in which they are manufactured or imported, are registered, as a minimum, with the information requirements set out by Regulation (EC) No 1907/2006 for substances manufactured or imported in quantities of 10 to 100 tonnes per company per year, together with a chemical safety report covering their use in a fertilising product, in accordance with Article 14 of that Regulation. Those extensive information requirements might prevent manufacturers, especially small and medium-sized enterprises, from using substances that are not yet registered according to those requirements or force them to place their products only on national markets according to national rules. For the sake of proportionality, and considering the general obligation of manufactures and importers of substances and EU fertilising products under Regulation (EC) No 1907/2006 and Regulation (EU) 2019/1009, respectively, to ensure the safety of the products that they place on the market, registration of substances used in EU fertilising products should only follow the requirements, including the relevant gradations, set out in Regulation (EC) No 1907/2006.

(31) To ensure a smooth and effective transition, to minimise disruptions, and to provide a reasonable timeframe for economic operators and authorities to adjust to the new requirements, the application of the amendments to Regulation (EU) 2019/1009 concerning digitalisation should be deferred.

(32) In order to enable economic operators to supply stock of products that have been placed on the market before the date of application of the amendments to Regulation (EU) 2019/1009 concerning digitalisation, it is necessary to provide for reasonable transitional arrangements that do not impede the making available on the market of products that have been placed on the market in accordance with that Regulation in its version applicable before that date.

(33) Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 1272/2008

Regulation (EC) No 1272/2008 is amended as follows:

(1) in Article 2, the following point is added:

‘42. “digital contact” means any up-to-date and accessible online communication channel through which a supplier can be reached or engaged without the need to register or to download an application.’;

(2) in Article 17(1), point (a) is replaced by the following:

‘(a) the name, address and digital contact of the suppliers;’;

(3) in Article 25(6), the third subparagraph is replaced by the following:

'The label shall also include the product identifier referred to in Article 18 and the name, address and digital contact of the supplier of the mixture.';

(4) in Article 29, paragraph 2 is replaced by the following:

'2. The label elements set out in Article 17(1) may be reduced in accordance with the rules set out in section 1.5.2 of Annex I.';

(5) in Article 30, paragraph 1 is replaced by the following:

'1. In the event of a change regarding the classification or labelling of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in accordance with Article 25, the supplier of that substance or that mixture shall ensure that the label is updated without undue delay after the results of the new evaluation referred to in Article 15(4) are obtained by, or communicated to, that supplier.';

(6) in Article 31, paragraph 3 is replaced by the following:

'3. The label elements referred to in Article 17(1) shall be clearly and indelibly marked. They shall stand out clearly from the background and they shall be of such a size and be spaced in such a way as to be easily read.';

(7) Article 48 is replaced by the following:

'Article 48

Advertisement

1. Any advertisement to the general public for a substance or a mixture classified as hazardous or a mixture containing substances referred to in Part 2 of Annex II shall include the sentence: 'Always read the label and product information before use.'.

2. Any advertisement for a substance or a mixture classified as hazardous shall not contain statements that are not allowed to appear on the label or packaging of that substance or mixture in accordance with Article 25(4).'

;

(8) Article 48a is replaced by the following:

'Article 48a

Distance sales offers

When substances or mixtures are placed on the market for the general public through distance sales, the offer shall clearly and visibly indicate the label elements referred to in Article 17.'

;

(9) Article 61 is amended as follows:

(a) paragraph 8 is replaced by the following:

'8. Substances and mixtures which have been classified, labelled and packaged in accordance with Article 18(3) as applicable on 9 December 2024 and which were placed on the market before 1 January 2027 shall not be required to be classified, labelled and packaged in accordance with this Regulation as

amended by Regulation (EU) 2024/2865 of the European Parliament and of the Council until 1 January 2029.'

;

(b) the following paragraph is added:

'9. Substances and mixtures which have been labelled in accordance with Article 17(1), Article 25(6) and section 1.5.1.2 and section 1.6 of Annex I as applicable on [*OP: please insert the date of the day before the date of entry into force of this Regulation*] and which were placed on the market before [*OP: please insert 36 months after entry into force of this Regulation*] shall not be required to be labelled in accordance with this Regulation as amended by [*OP: please add reference to this Regulation*] until [*OP: please insert 60 months after entry into force of this Regulation*].'

;

(10) Annexes I and II are amended in accordance with Annex I to this Regulation.

Article 2

Amendments to Regulation (EC) No 1223/2009

Regulation (EC) No 1223/2009 is amended as follows:

(1) The following Article is inserted:

'Article 14a

Requests for inclusion of substances used as colorants, preservatives or UV-filters in Annexes IV, V or VI

1. A request for a substance to be used as a colorant, preservative or UV-filter to be included in Annex IV, Annex V or Annex VI, as applicable, may be submitted to the Commission. It shall be accompanied by scientific evidence and documentation showing that due to the latest technical and scientific progress, the substance is safe for use in cosmetic products.

2. After receiving the request referred to in paragraph 1, the Commission shall seek an opinion of the SCCS on the safety of the substance for use in cosmetic products without undue delay.

3. The SCCS shall transmit its opinion to the Commission within 12 months after receiving the request from the Commission referred to in paragraph 2. The Commission may extend that deadline if additional evidence is required.'

;

(2) Article 15 is amended as follows:

(a) paragraph 2 is amended as follows:

(i) the second subparagraph is replaced by the following:

'2. However, such substances may be used in cosmetic products if a derogation request is submitted to the Commission at the latest three months after at the date of entry into force of the amendments to Part 3 of Annex VI to Regulation (EC) No 1272/2008 classifying the substance as CMR substance of category 1A or 1B.

The Commission shall grant the derogation where all of the following conditions are fulfilled:

(a) there are no suitable alternative substances available as documented in an analysis of alternatives;

(b) the substances have been evaluated and found safe by the SCCS for a particular use of the cosmetic product category, considering exposure to those products, overall exposure from sources other than cosmetics and of vulnerable population groups.'.

(ii) the third subparagraph is replaced by the following:

'For the purpose of the second subparagraph, point (a), a substance shall be considered a suitable alternative if it fulfils all of the following conditions:

(a) its use in cosmetic products results in reduced overall risk to human health and the environment;

(b) it provides an equivalent function to the classified substance, in a finished cosmetic product with a similar effect and the same level of efficacy;

(c) is technically feasible and economically viable;

(d) it is not restricted, not protected by exclusive rights, and is available on the market at scale, in quantities large enough to meet current and expected demand.'

;

(iii) the following subparagraph is inserted after the fourth subparagraph:

'The deadline laid down in the fourth subparagraph of this paragraph shall start on the date of entry into application of the relevant amendments to Part 3 of Annex VI to Regulation (EC) No 1272/2008 classifying the substance concerned as CMR substance of category 1A, or 1B.';

(b) the following paragraphs 5, 6 and 7 are added:

'5. The prohibition referred to in paragraphs 1 and 2 of this Article shall not apply to a substance where the oral or inhalation route of exposure for CMR harmonised classification has been explicitly indicated in the 'Hazard statement Code(s)' column under the 'Classification' in Part 3 of Annex VI to Regulation (EC) No 1272/2008. If a potential risk to human health arises from cosmetic products containing such substance due to incidental ingestion or inhalation, the Commission shall request an SCCS opinion on the safety of the substance concerned in those specific product types without undue delay.

6. The prohibition referred to in paragraphs 1 and 2 of this Article shall not apply to a substance extracted from plants or plant parts and not chemically modified as defined in Article 3, point (40), of Regulation (EC) No 1907/2006, containing more than one constituent, at least one of which has been classified as a CMR substance of category 1A, 1B, or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008. If a potential risk to human health arises from the use of such substance in cosmetic products, the Commission shall seek an opinion of the SCCS on the safety of that substance for its use in cosmetic products without undue delay.

For the purpose of this paragraph, ‘plants’ means living or dead organisms from the kingdoms Plantae and Fungi, and includes algae, lichens and yeasts.

7. Cosmetic products containing a substance classified as a CMR substance of category 1A, 1B, or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 prohibited from use in cosmetic products or such substance not compliant with a restriction may continue to be placed on the market for 12 months and be made available on the market for 24 months after the entry into force of the relevant amendments to the relevant Annexes to this Regulation.’

;

(3) In Article 16, paragraphs 3 and 7 are deleted;

(4) In Article 19, paragraph 6 is replaced by the following:

‘6. The information mentioned in paragraph 1, point (g) shall be expressed by using the common ingredient name in accordance with the internationally recognised nomenclature and in the absence of a common ingredient name, a term as contained in a generally accepted nomenclature shall be used.’

;

(5) In Article 22, fourth subparagraph, the second sentence is deleted;

(6) Article 33 is deleted;

(7) Annex I is amended in accordance with Annex II to this Regulation;

(8) Annexes II to VI are amended in accordance with Annex III this Regulation.

Article 3

Amendments to Regulation (EU) 2019/1009

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

(1) in Article 2, the following point (15a) is inserted:

‘(15a) ‘digital contact’ means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;’

;

(2) Article 6 is amended as follows:

(a) paragraph 2 is amended as follows:

(i) the second subparagraph is replaced by the following:

‘Where compliance of an EU fertilising product with the applicable requirements laid down in this Regulation has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking.’;

(ii) the following subparagraph is added:

‘Manufacturers shall ensure that the EU fertilising product is accompanied by the internet address or data carrier through which the EU declaration of conformity can be accessed.’;

(b) in paragraph 3, the second subparagraph is replaced by the following:

'On request, manufacturers shall make the EU declaration of conformity available to other economic operators in electronic form.';

(c) in paragraph 6, first subparagraph, the first and second sentences are replaced by the following:

'Manufacturers shall indicate on the packaging of the EU fertilising product their name, registered trade name or registered trademark as well as their postal address and digital contact or, where the EU fertilising product is supplied without packaging, in a document accompanying the EU fertilising product. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.'

;

(d) in paragraph 9, the first sentence is replaced by the following:

'Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the EU fertilising product with this Regulation, in a language which can be easily understood by that authority.'

;

(3) in Article 7(2), point (b) is replaced by the following:

'(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of an EU fertilising product;'

;

(4) Article 8 is amended as follows:

(a) in paragraph 2, first subparagraph, the second sentence is replaced by the following:

'They shall ensure that the manufacturer has drawn up the technical documentation, that the EU fertilising product is accompanied by the internet address or data carrier through which the EU declaration of conformity can be accessed and, where appropriate, by other required documents, and that the manufacturer has complied with the requirements set out in Article 6(5) and (6).'

;

(b) in paragraph 3, the first sentence is replaced by the following:

'Importers shall indicate their name, registered trade name or registered trade mark as well as their postal address and digital contact on the packaging of the EU fertilising product or, where the EU fertilising product is supplied without packaging, in a document accompanying the EU fertilising product.'

;

(c) paragraph 8 is replaced by the following:

‘8. Importers shall, for 5 years after the EU fertilising product has been placed on the market, keep the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

On request, importers shall make the EU declaration of conformity available to other economic operators in electronic form.’

;

(d) in paragraph 9, the first sentence is replaced by the following:

‘Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the EU fertilising product with this Regulation in a language which can be easily understood by that authority.’

;

(5) Article 9 is amended as follows:

(a) in paragraph 2, the first subparagraph is replaced by the following:

‘Before making an EU fertilising product available on the market, distributors shall verify that it is accompanied by the internet address or data carrier through which the EU declaration of conformity can be accessed and, where appropriate, by other required documents, including the information referred to in Article 6(7) or Article 8(4) provided in the manner specified therein, in a language which can be easily understood by end-users in the Member State in which the EU fertilising product is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3) respectively.’

;

(b) in paragraph 5, the first sentence is replaced by the following:

‘Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the EU fertilising product with this Regulation.’

;

(6) Article 15 is amended as follows:

(a) paragraph 2 is replaced by the following:

‘2. Records and correspondence relating to the conformity assessment procedures shall be drawn up, in electronic form, in an official language of the Member State where the notified body carrying out the procedures is established or in a language accepted by that body.’

(b) the following paragraph 3 is added:

‘3. The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.’

;

(7) in Article 16, the following paragraphs 5 and 6 are added:

‘5. The EU declaration of conformity shall be provided in a machine-readable and open format as defined in Article 2, points (13) and (14), of Directive (EU) 2019/1024 of the European Parliament and of the Council* and meet the requirements for digital labels set out in Article 11b(4), points (a) to (d).

Where a data carrier is used for providing access to the EU declaration of conformity, it should accompany the product in accordance with Article 11b(5) and be based on one of the electronic technical solutions which economic operators can use for providing the digital label established on the basis of Article 42(9). Economic operators providing the EU declaration of conformity using a data carrier shall not track, analyse or use any usage information for purposes other than what is absolutely necessary for providing the relevant information digitally.

Where a digital label is used in accordance with Article 11a, the data carrier used for the digital label shall also provide access to the EU declaration of conformity.

*Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information, (OJ L 172, 26.06.2019, p. 56, ELI: http://data.europa.eu/eli/dir/2019/1024/oj).’

6. Where other Union legislation applicable to EU fertilising products requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity in a digital product passport, the information set out in Annex V to be included in the EU declaration of conformity and any digital labelling information in accordance with Article 11b, if applicable, shall be provided only in that digital product passport.’

;

(8) in Article 41(1), point (c) is replaced by the following:

‘(c) the EU declaration of conformity has not been drawn up or has not been drawn up correctly, or the EU fertilising product is not accompanied by the internet address or data carrier through which the EU declaration of conformity can be accessed.’

(9) Article 42 is amended as follows:

(a) in paragraph 4, the introductory statement is replaced by the following:

‘The Commission may adopt delegated acts pursuant to paragraph 1 amending Annex II to add new micro-organisms or strains of micro-organisms, or additional processing methods to the component material category for such organisms after having verified which strains of the additional micro-organism fulfil the criteria in paragraph 1, point (b), on the basis of the following data:’

;

(b) the following paragraph 4a is inserted:

‘4a. The Commission may also adopt delegated acts pursuant to paragraph 1 amending Annex II to set out criteria and a methodology for the assessment of micro-organisms other than those listed in Annex II, which, if compliance with those criteria is demonstrated in the conformity assessment of the EU

fertilising product in accordance with that methodology, may be used as component material in EU fertilising products. The criteria and methodology shall allow for verification that the micro-organisms fulfil the criteria in paragraph 1, point (b), and provide, as a minimum, for the consideration of the following elements:

(a) scientific literature reporting about safe production, conservation and use of the micro-organism;

(b) taxonomic relation of the micro-organism to micro-organisms species fulfilling the requirements for a Qualified Presumption of Safety as established by the European Food Safety Authority;

(c) information on the production process of the micro-organism, including, where relevant, the composition of the cultivation medium, processing methods such as spray drying, fluid-bed drying, static drying, centrifugation, deactivation by heat, filtration and grinding;

(d) information on the identity and residue levels of residual intermediates, toxins or microbial metabolites in the component material;

(e) natural occurrence, survival and mobility in the environment;

(f) susceptibility to all relevant antimicrobial agents as defined in the Annex, Introduction to Part B, point (ii)(28), to Commission Regulation (EU) No 283/2013*, with the exception of intrinsic resistance.

*Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 1, ELI: http://data.europa.eu/eli/reg/2013/283/oj).'

;

(10) Article 43 is deleted;

(11) Annexes I, II and IV to Regulation (EU) 2019/1009 are amended in accordance with Annex IV to this Regulation.

Article 4

Transitional provisions

1. By way of derogation from section 1.5.2.4.1 and section 1.5.2.4.2 of Annex I to Regulation (EC) No 1272/2008 as applicable on 9 December 2024 substances and mixtures may until 30 June 2026 be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by points (5), (6) and (7) of Annex I to this Regulation.

By way of derogation from Article 30 and Article 48 of Regulation (EC) No 1272/2008 and Part 5 of Annex II to Regulation (EC) No 1272/2008 as applicable on 9 December 2024, substances and mixtures may until 31 December 2027 be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by Article 1, points (5), (7) and (8) of this Regulation and point (9) of Annex I to this Regulation.

By way of derogation from Article 17(1), Article 25(6) of Regulation (EC) No 1272/2008, section 1.5.1.2 and section 1.6 of Annex I to Regulation (EC) No 1272/2008 as applicable on [*OP: please insert the date of the day before the date*

of entry into force of this Regulation], substances and mixtures may until [*OP: please insert the date of the last day of the month following 35 months after the date of entry into force of this Regulation*] be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by Article 1, points (2) and (3) of this Regulation and points (3) and (8) of Annex I to this Regulation.

2. Member States shall not impede the making available on the market of products which were placed on the market in accordance with Regulation (EU) 2019/1009 before [*OP: please insert 24 months after entry into force of this amending Regulation)*].

Article 5

Entry into force and application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

2. Points (4) to (7) of Annex I shall apply from 1 July 2026.

3. Article 1, points (5) to (8) and points (1), (2) and (9) of Annex I shall apply from 1 January 2028.

4. Article 1, points (1), (2) and (3), points (3) and (8) of Annex I shall apply from [O*P: please insert the date of 36 months after the entry into force of this Regulation)*]

5. Article 2, point (1) to (8) shall apply from [OP: please insert the date of entry into force of this Regulation)]

6. Article 3, point (1) to (8), and Annex IV, point (1) and (3), shall apply from [OP: please insert 24 months after entry into force of this Regulation].

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

Done at Strasbourg,

For the European Parliament	*For the Council*
The President	*The President*
[...]	*[...]*

LEGISLATIVE FINANCIAL AND DIGITAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 of the European Parliament and of the Council, as regards simplification of certain requirements and procedures for chemical products

1.2. Policy area(s) concerned

Better Regulation, Competitiveness

1.3. Objective(s)

1.3.1. General objective(s)

To support the growth and development of companies, thus increasing their competitiveness and contribution to European welfare and prosperity, while at the same time ensuring a high level of protection of human health and the environment.

To promote a favourable business environment and to reduce administrative burdens for companies, thereby enhancing their ability to innovate, create jobs, and contribute to economic growth.

1.3.2. Specific objective(s)

To simplify and streamline certain requirements and procedures for chemical products identified as particularly burdensome by industry and authorities.

To increase the cost-effectiveness and overall competitiveness of the EU chemicals industry and related sectors, while ensuring a high level of protection of human health and the environment.

1.3.3. Expected result(s) and impact

The proposal/initiative is expected to have the following effects on the beneficiaries/groups targeted:

Regulation (EC) No 1272/2008

- Simplifying and allowing more flexibility for the formatting rules for labelling under the Regulation (EC) No 1272/2008, removing excessive costs for industries;
- Alleviating the burden to businesses and improving the free circulation of substance and mixtures, by ligthening obligations for advertisement of hazardous substances and mixtures, and narrowing the scope of obligations to advertisments and distance sales for the genreal public.
- Reducing administrative burden to chemicals supply chain actors by removing prescribed deadlines for relabelling.

– Improving legal clarity, thus contributing to better enforcement, by simplifying the use of derogations for smaller packaging, and adding more flexibility for labelling of fuelling stations.

Regulation (EC) No 1223/2009

– Relieving cosmetics manufacturers, especially SMEs, from the unnecessary compliance and administrative burden allowing them to invest more in R&D and innovation;

– Ensuring that consumers and professionals receive safe cosmetic products which meet their needs and expectations.

Regulation (EU) 2019/1009

– Encouraging manufacturers to market their products as EU fertilising product in the Single Market;

– Paving the way for the use of a larger variety of micro-organisms in the EU, creating economic opportunities in the EU and reducing farmer's use of fertilisers;

– Speeding up the adoption of delegated acts to amend the component material categories in Annex II to the Regulation;

– Reducing adminsitrative burden for companies and authorities linked to the handling of paper documents.

1.3.4. Indicators of performance

N/A

1.4. The proposal/initiative relates to: None of the below

☐ a new action

☐ a new action following a pilot project / preparatory action[45]

☐ the extension of an existing action

☐ a merger or redirection of one or more actions towards another/a new action

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative

N/A

1.5.2. Added value of EU involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this section 'added value of EU involvement' is the value resulting from EU action, that is additional to the value that would have been otherwise created by Member States alone.

This proposal concerns an act amending EU legislation. It can therefore only be carried out at EU level.

[45] As referred to in Article 58(2), point (a) or (b) of the Financial Regulation.

1.5.3. Lessons learned from similar experiences in the past

N/A

1.5.4. Compatibility with the multiannual financial framework and possible synergies with other appropriate instruments

The proposal does not have budgetary implications

1.5.5. Assessment of the different available financing options, including scope for redeployment

The proposal does not have budgetary implications

1.6. Duration of the proposal/initiative and of its financial impact

☐ **limited duration**

– ☐ in effect from [DD/MM]YYYY to [DD/MM]YYYY

– ☐ financial impact from YYYY to YYYY for commitment appropriations and from YYYY to YYYY for payment appropriations.

☐ **unlimited duration**

– Implementation with a start-up period from YYYY to YYYY,

– followed by full-scale operation.

1.7. Method(s) of budget implementation planned

☐ **Direct management** by the Commission

– ☐ by its departments, including by its staff in the Union delegations;

– ☐ by the executive agencies

☐ **Shared management** with the Member States

☐ **Indirect management** by entrusting budget implementation tasks to:

– ☐ third countries or the bodies they have designated

– ☐ international organisations and their agencies (to be specified)

– ☐ the European Investment Bank and the European Investment Fund

– ☐ bodies referred to in Articles 70 and 71 of the Financial Regulation

– ☐ public law bodies

– ☐ bodies governed by private law with a public service mission to the extent that they are provided with adequate financial guarantees

– ☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that are provided with adequate financial guarantees

– ☐ bodies or persons entrusted with the implementation of specific actions in the common foreign and security policy pursuant to Title V of the Treaty on European Union, and identified in the relevant basic act

– ☐ bodies established in a Member State, governed by the private law of a Member State or Union law and eligible to be entrusted, in accordance with sector-specific rules, with the implementation of Union funds or budgetary guarantees, to the extent that such bodies are controlled by public law bodies or by bodies governed by private law with a public service mission, and are provided with adequate financial guarantees in the form of joint and several liability by the controlling bodies or equivalent financial guarantees and which may be, for each action, limited to the maximum amount of the Union support.

Comments

N/A

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

N/A

2.2. Management and control system(s)

2.2.1. Justification of the budget implementation method(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed

N/A

2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them

N/A

2.2.3. Estimation and justification of the cost-effectiveness of the controls (ratio between the control costs and the value of the related funds managed), and assessment of the expected levels of risk of error (at payment & at closure)

N/A

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures, e.g. from the anti-fraud strategy.

N/A

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff.[46]	from EFTA countries [47]	from candidate countries and potential candidates [48]	From other third countries	other assigned revenue
	N/A	Diff./Non-diff.	YES/NO	YES/NO	YES/NO	YES/NO

- New budget lines requested

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff.	from EFTA countries	from candidate countries and potential candidates	from other third countries	other assigned revenue
	N/A	Diff./Non-diff.	YES/NO	YES/NO	YES/NO	YES/NO

[46] Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.
[47] EFTA: European Free Trade Association.
[48] Candidate countries and, where applicable, potential candidates from the Western Balkans.

3.2. Estimated financial impact of the proposal on appropriations

3.2.1. Summary of estimated impact on operational appropriations

– ✠ The proposal/initiative does not require the use of operational appropriations

– ☐ The proposal/initiative requires the use of operational appropriations, as explained below

3.2.1.1. Appropriations from voted budget

EUR million (to three decimal places)

Heading of multiannual financial framework	Number	

DG: <…….>			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
Operational appropriations							
Budget line	Commitments	(1a)					**0.000**
	Payments	(2a)					**0.000**
Budget line	Commitments	(1b)					**0.000**
	Payments	(2b)					**0.000**
Appropriations of an administrative nature financed from the envelope of specific programmes[49]							
Budget line		(3)					**0.000**
TOTAL appropriations for DG <…….>	Commitments	=1a+1b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=2a+2b+3	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
• TOTAL operational appropriations (all operational headings)	Commitments	(4)	0.000	0.000	0.000	0.000	**0.000**
	Payments	(5)	0.000	0.000	0.000	0.000	**0.000**

[49] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes (all operational headings)		(6)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations Under Heading 1 to 6 of the multiannual financial framework (Reference amount)	Commitments	=4+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
	Payments	=5+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

Heading of multiannual financial framework	**7**	'Administrative expenditure'[50]				
DG: <…….>		Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
• Human resources		0.000	0.000	0.000	0.000	**0.000**
• Other administrative expenditure		0.000	0.000	0.000	0.000	**0.000**
TOTAL DG <…….>	Appropriations	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

DG: <…….>		Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
• Human resources		0.000	0.000	0.000	0.000	**0.000**
• Other administrative expenditure		0.000	0.000	0.000	0.000	**0.000**
TOTAL DG <…….>	Appropriations	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

TOTAL appropriations under HEADING 7 of the multiannual financial framework	(Total commitments = Total payments)	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

[50] The necessary appropriations should be determined using the annual average cost figures available on the appropriate BUDGpedia webpage.

EUR million (to three decimal places)

		Year 2024	Year 2025	Year 2026	Year 2027	TOTAL MFF 2021-2027
TOTAL appropriations under HEADINGS 1 to 7	Commitments	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
of the multiannual financial framework	Payments	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

			Year 2024	Year 2025	Year 2026	Year 2027	TOTAL MFF 2021-2027
TOTAL operational appropriations	Commitments	(4)	0.000	0.000	0.000	0.000	**0.000**
	Payments	(5)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations under HEADING <….>	Commitments	=4+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
of the multiannual financial framework	Payments	=5+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

			Year 2024	Year 2025	Year 2026	Year 2027	TOTAL MFF 2021-2027
TOTAL operational appropriations	Commitments	(4)	0.000	0.000	0.000	0.000	**0.000**
	Payments	(5)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations under HEADING <….>	Commitments	=4+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

of the multiannual financial framework	Payments	=5+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
• TOTAL operational appropriations (all operational headings)	Commitments	(4)	0.000	0.000	0.000	0.000	**0.000**
	Payments	(5)	0.000	0.000	0.000	0.000	**0.000**
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes (all operational headings)		(6)	0.000	0.000	0.000	0.000	**0.000**
TOTAL appropriations under Headings 1 to 6	Commitments	=4+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
of the multiannual financial framework (Reference amount)	Payments	=5+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

Heading of multiannual financial framework	**7**	'Administrative expenditure'[51]

EUR million (to three decimal places)

DG: <…….>		Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
• Human resources		0.000	0.000	0.000	0.000	**0.000**
• Other administrative expenditure		0.000	0.000	0.000	0.000	**0.000**
TOTAL DG <…….>	Appropriations	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

DG: <…….>	Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**

[51] The necessary appropriations should be determined using the annual average cost figures available on the appropriate BUDGpedia webpage.

• Human resources		0.000	0.000	0.000	0.000	**0.000**
• Other administrative expenditure		0.000	0.000	0.000	0.000	**0.000**
TOTAL DG <…….>	Appropriations	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

TOTAL appropriations under HEADING 7 of the multiannual financial framework	(Total commitments = Total payments)	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

EUR million (to three decimal places)

		Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
TOTAL appropriations under HEADINGS 1 to 7	Commitments	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
of the multiannual financial framework	Payments	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

3.2.2. Estimated output funded from operational appropriations (not to be completed for decentralised agencies)

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs ⇩			Year **2024**		Year **2025**		Year **2026**		Year **2027**		Enter as many years as necessary to show the duration of the impact (see Section1.6)						**TOTAL**	
	OUTPUTS																	
	Type[52]	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No	Total cost
SPECIFIC OBJECTIVE No 1[53]…																		

[52] Outputs are products and services to be supplied (e.g. number of student exchanges financed, number of km of roads built, etc.).

[53] As described in Section 1.3.2. 'Specific objective(s)'

- Output																		
- Output																		
- Output																		
Subtotal for specific objective No 1																		
SPECIFIC OBJECTIVE No 2 ...																		
- Output																		
Subtotal for specific objective No 2																		
TOTALS																		

3.2.3. Summary of estimated impact on administrative appropriations

– ✠ The proposal/initiative does not require the use of appropriations of an administrative nature

– ☐ The proposal/initiative requires the use of appropriations of an administrative nature, as explained below

3.2.3.1. Appropriations from voted budget

VOTED APPROPRIATIONS	Year 2024	Year 2025	Year 2026	Year 2027	TOTAL 2021 - 2027
HEADING 7					
Human resources	0.000	0.000	0.000	0.000	**0.000**
Other administrative expenditure	0.000	0.000	0.000	0.000	**0.000**
Subtotal HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
Outside HEADING 7					
Human resources	0.000	0.000	0.000	0.000	**0.000**
Other expenditure of an administrative nature	0.000	0.000	0.000	0.000	**0.000**
Subtotal outside HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
TOTAL	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

The appropriations required for human resources and other expenditure of an administrative nature will be met by appropriations from the DG that are already assigned to management of the action and/or have been redeployed within the DG, together, if necessary, with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

3.2.4. Estimated requirements of human resources

– ✠ The proposal/initiative does not require the use of human resources

– ☐ The proposal/initiative requires the use of human resources, as explained below

3.2.4.1. Financed from voted budget

Estimate to be expressed in full-time equivalent units (FTEs)

VOTED APPROPRIATIONS		Year 2024	Year 2025	Year 2026	Year 2027
• Establishment plan posts (officials and temporary staff)					
20 01 02 01 (Headquarters and Commission's Representation Offices)		0	0	0	0
20 01 02 03 (EU Delegations)		0	0	0	0
01 01 01 01 (Indirect research)		0	0	0	0
01 01 01 11 (Direct research)		0	0	0	0
Other budget lines (specify)		0	0	0	0
• External staff (inFTEs)					
20 02 01 (AC, END from the 'global envelope')		0	0	0	0
20 02 03 (AC, AL, END and JPD in the EU Delegations)		0	0	0	0
Admin. Support	- at Headquarters	0	0	0	0

line [XX.01.YY.YY]	- in EU Delegations	0	0	0	0
01 01 01 02 (AC, END - Indirect research)		0	0	0	0
01 01 01 12 (AC, END - Direct research)		0	0	0	0
Other budget lines (specify) - Heading 7		0	0	0	0
Other budget lines (specify) - Outside Heading 7		0	0	0	0
TOTAL		**0**	**0**	**0**	**0**

The staff required to implement the proposal (in FTEs): N/A

	To be covered by current staff available in the Commission services	**Exceptional additional staff***		
		To be financed under Heading 7 or Research	**To be financed from BA line**	**To be financed from fees**
Establishment plan posts			N/A	
External staff (CA, SNEs, INT)				

Description of tasks to be carried out by:

Officials and temporary staff	
External staff	

3.2.5. Overview of estimated impact on digital technology-related investments

Compulsory: the best estimate of the digital technology-related investments entailed by the proposal/initiative should be included in the table below.

Exceptionally, when required for the implementation of the proposal/initiative, the appropriations under Heading 7 should be presented in the designated line.

The appropriations under Headings 1-6 should be reflected as "Policy IT expenditure on operational programmes". This expenditure refers to the operational budget to be used to re-use/ buy/ develop IT platforms/ tools directly linked to the implementation of the initiative and their associated investments (e.g. licences, studies, data storage etc). The information provided in this table should be consistent with details presented under Section 4 "Digital dimensions".

TOTAL Digital and IT appropriations	Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021 - 2027**
HEADING 7					
IT expenditure (corporate)	0.000	0.000	0.000	0.000	**0.000**
Subtotal HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

Outside HEADING 7					
Policy IT expenditure on operational programmes	0.000	0.000	0.000	0.000	**0.000**
Subtotal outside HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
TOTAL	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

3.2.6. Compatibility with the current multiannual financial framework

The proposal/initiative:

– ☐ can be fully financed through redeployment within the relevant heading of the multiannual financial framework (MFF)

N/A

– ☐ requires use of the unallocated margin under the relevant heading of the MFF and/or use of the special instruments as defined in the MFF Regulation

N/A

– ☐ requires a revision of the MFF

N/A

3.2.7. Third-party contributions

The proposal/initiative:

– ☐ does not provide for co-financing by third parties

– ☐ provides for the co-financing by third parties estimated below:

Appropriations in EUR million (to three decimal places)

	Year **2024**	Year **2025**	Year **2026**	Year **2027**	Total
Specify the co-financing body					
TOTAL appropriations co-financed					

3.3. Estimated impact on revenue

– ✠ The proposal/initiative has no financial impact on revenue.

– ☐ The proposal/initiative has the following financial impact:

  – ☐ on own resources

  – ☐ on other revenue

  – ☐ please indicate, if the revenue is assigned to expenditure lines

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative[54]			
		Year **2024**	Year **2025**	Year **2026**	Year **2027**
Article …….					

For assigned revenue, specify the budget expenditure line(s) affected.

Other remarks (e.g. method/formula used for calculating the impact on revenue or any other information).

[54] As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 20% for collection costs.

4. DIGITAL DIMENSIONS

4.1. Requirements of digital relevance

If the policy initiative is assessed as having no requirement of digital relevance:

Justification of why digital means cannot be used to enhance policy implementation and why the 'digital by default' principle is not applicable

Otherwise:

High-level description of the requirements of digital relevance and related categories (data, process digitalisation & automation, digital solutions and/or digital public services)

Reference to the requirement	**Requirement description**	**Actors affected or concerned by the requirement**	**High-level Processes**	**Categories**
Article 1(3)	The label shall also include the product identifier referred to in Article 18 and the name, address and digital contact of the supplier of the mixture.	Economic Operators Market Surveillance Authorities Consumers	Market Surveillance Verification	Data
Article 1(1), (2) and (3), Article 3(1), (2)(c), (4)(b) Annex I, points (3) and (8), Annex IV, point (3)	'digital contact' means any up-to-date and accessible online communication channel through which supplier can be reached or engaged without the need to register or to download an application.	Economic Operators Member States Authorities Consumers and other End-users	Market surveillance verification and monitoring	Digital Public Service(s) Data
Article 3(2)(a)(i),	Where compliance of an EU fertilising product with the applicable requirements laid down in	Economic Operators	Market surveillance	Digital Public

Annex IV, point (3)	this Regulation has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking.	Member States Authorities	verification and monitoring	Service(s) Data Document Management Digital Solution(s)
Article 3(2)(d), (3)(4)(d), (5)(b), Annex IV, point (3)	Manufacturers, authorised representatives, importers and distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the EU fertilising product with this Regulation in a language which can be easily understood by that authority.	Economic Operators, Member States Authorities	Conformity assessment procedures Market surveillance verification and monitoring	Digital Service(s)
Article 3(2)(a)(ii), (4)(a), (5)(a), and (8)	Economic operators shall ensure that the that the EU fertilising product is accompanied by the internet address or data carrier through which the EU declaration of conformity can be accessed	Economic Operators Notified Bodies Market Surveillance Authorities Consumers	Market surveillance verification and monitoring Conformity assessment procedures	Data Digital Service(s)
Article 3(4)	Importers shall, for 5 years after the EU fertilising product has been placed on the market, keep the electronic EU declaration of conformity at the disposal of the market surveillance authorities	Economic Operators Market Surveillance Authorities Consumers	Market Surveillance Verification	Data

Article 3(6)(a)	Records and correspondence relating to the conformity assessment procedures shall be drawn up, in electronic form, in an official language of the Member State where the notified body carrying out the procedures is established or in a language accepted by that body.	Notified Bodies Economic Operators	Conformity assessment procedures	Digital Service(s) Data
Article 3(6)(b)	The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.	Notified Bodies Economic Operators	Conformity assessment procedures	Digital Service(s) Data
Article 3(7)	Where a data carrier is used for providing access to the EU declaration of conformity, it shall meet the requirements for digital labels set out in Article 11b(4) and (5) and be based on one of the electronic technical solutions which economic operators can use for providing the digital label established in accordance with Article 42(9)	Economic Operators Market Surveillance Authorities Consumers	Market Surveillance Verification	Data
Article 3(7)	Where other Union legislation applicable to EU fertilising products requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity in a digital product passport, the information set out in Annex V to be included in the EU declaration of conformity and any digital labelling information in accordance with Article 11b, if	Economic Operators Member States Authorities Consumers	Market surveillance verification and monitoring	Data

	applicable, shall be provided only in that digital product passport.			
Annex I, point (8)	Label elements that may be provided on a digital label only (a) Supplemental information referred to in Article 25(3); (b) Where more than one supplier is indicated on the label in accordance with Article 17(1), point (a), the name, address and digital contact of the suppliers may be provided on a digital label only, as long as the supplier referred to in in Article 4(11) is indicated on the physical label.’;	Economic Operators Member States Authorities Consumers and other End-users	Market surveillance verification and monitoring	Data

4.2. Data

High-level description of the data in scope

Type of data	**Reference to the requirement(s)**	**Standard and/or specification (if applicable)**
Digital contact	Article 1(1), (2) and (3), Article 3(1), (2)(c), (4)(b) and Annex I, points (3) and (8), Annex IV, point (3)	In accessible formats; free of charge in a clear, comprehensive, user-friendly and easily accessible way, without the need to register or to download an application.
EU declaration of conformity, in electronic form	Article 3(2)(a)(i), Annex IV, point (3)	Machine-readable and open format, as defined in the Directive (EU)2019/1024, Article 2(13)(14) and requirements for digital labels set out in Article

		11b(a)-(d) of Regulation (EU) 2019/1009.
Internet address	Article 3(2)(a)(ii), (4)(a), (5)(a) and (8)	N/A
Data carrier	Article 3(2)(a)(ii), (4)(a), (5)(a), (7) and (8)	Regulation (EU) 2019/1009, electronic technical solutions established on the basis of Article 42(9).
Product technical documentation	Article 3(4), Annex IV, point (3)	N/A
Digital label	Article 3(7)	Regulation (EU) 2019/1009, incl. specifications and electronic technical solutions established on the basis of Article 42(9).
Digital product passport	Article 3(7)	Regulation (EU) 2024/1781
Information and documentation relating to conformity assessment procedures	Article 3(6)	N/A
Label elements that may be provided on a digital label only	Annex I, point (8)	Regulation (EC) No 1272/2008, as amended by Regulation 2024/2865

Alignment with the European Data Strategy

Explanation of how the requirement(s) are aligned with the European Data Strategy

Not applicable

Alignment with the once-only principle

Explanation of how the once-only principle has been considered and how the possibility to reuse existing data has been explored

Not applicable

Explanation of how newly created data is findable, accessible, interoperable and reusable, and meets high-quality standards

Not applicable

Data flows

High-level description of the data flows

Type of data	**Reference(s) to the requirement(s)**	**Actors who provide the data**	**Actors who receive the data**	**Trigger for the data exchange**	**Frequency (if applicable)**
Digital contact	Article 1(1), (2) and (3), Article 3(1), (2)(c), (4)(b) and Annex I, point (3) and (8), Annex IV, point (3)	Economic Operator	Member States Authorities Notified Bodies Consumers and other end users	Product control Conformity assessment procedures	
EU declaration of conformity, in electronic form	Article 3(2)(a)(i), Annex IV, point (3)	Economic Operator	Member States Authorities Notified Bodies	Product control Conformity assessment procedures	
Internet address	Article 3(2)(a)(ii),	Economic Operator	Member States Authorities	Product control Conformity	

	(4)(a), (5)(a) and (8)		Notified Bodies	assessment procedures	
Data carrier	Article 3(2)(a)(ii), (4)(a), (5)(a), (7) and (8)	Economic Operator	Member States Authorities Notified Bodies	Product control Conformity assessment procedures	
Product technical documentation	Article 3(4), Annex IV, point (3)	Economic Operator	Member States Authorities Notified Bodies	Product control Conformity assessment procedures	
Information and documentation relating to conformity assessment procedures	Article 3(6)	Economic Operator	Member States Authorities Notified Bodies	Product control Conformity assessment procedures	
Digital label	Article 3(7)	Economic Operator	Member States Authorities Notified Bodies Consumers and other end users	Product control Conformity assessment procedures	
Digital product passport	Article 3(7)	Economic Operator	Member States Authorities Notified Bodies Consumers and other end users	Product control Conformity assessment procedures	

Label elements that may be provided on a digital label only	Annex I, point (8)	Economic Operator	Member States Authorities Notified Bodies Consumers and end users	Product control	

4.3. Digital solutions

High-level description of digital solutions

Digital solution	Reference(s) to the requirement(s)	Main mandated functionalities	Responsible body	How is accessibility catered for?	How is reusability considered?	Use of AI technologies (if applicable)

For each digital solution, explanation of how the digital solution complies with applicable digital policies and legislative enactments

Digital solution #1

Digital and/or sectorial policy (when these are applicable)	Explanation on how it aligns
AI Act	
EU Cybersecurity framework	
eIDAS	
Single Digital Gateway and IMI	
Others	

Digital solution #2

Digital and/or sectorial policy (when these are applicable)	Explanation on how it aligns
AI Act	
EU Cybersecurity framework	
eIDAS	
Single Digital Gateway and IMI	
Others	

4.4. Interoperability assessment

High-level description of the digital public service(s) affected by the requirements

Digital public service or category of digital public services	**Description**	**Reference(s) to the requirement(s)**	**Interoperable Europe Solution(s)** **(NOT APPLICABLE)**	**Other interoperability solution(s)**
Market surveillance verification and monitoring	Market surveillance authorities check compliance of products, including the EU declaration of conformity accessible via an internet address or data carrier, and other documents that are to be provided by economic operators upon request.	Article 1 Article 3 Annex I Annex IV	//	ICSCMS
Conformity assessment procedures	Notified bodies assess the conformity of products. All information and documentation is to be provided to them in electronic form.	Article 3	//	NANDO

Impact of the requirement(s) as per digital public service on cross-border interoperability

Market surveillance verification and monitoring

Assessment	**Measure(s)**	**Potential remaining barriers (if applicable)**
Alignment with existing digital and	- Proposal for a Regulation of the European Parliament and of the Council	- N/A

sectorial policies **Please list the applicable digital and sectorial policies identified**	amending Regulations [...] as regards digitalisation and common specifications (COM(2025)504) - Regulation (EU) 2024/1781.	
Organisational measures for a smooth cross-border digital public services delivery **Please list the governance measures foreseen**	- Use of commonly agreed open technical specifications and standards (see below)	- In the case of exports, third countries might still require documents to be provided in paper form.
Measures taken to ensure a shared understanding of the data **Please list such measures**	- Use of commonly agreed open technical specifications and standards (see below)	N/A
Use of commonly agreed open technical specifications and standards **Please list such measures**	- Internet address - Digital Label - Digital Product Passport	- Accessibility requirements not defined in detail

Conformity assessment procedure

Assessment	Measure(s)	Potential remaining barriers (if applicable)
Alignment with existing digital and sectorial policies **Please list the applicable digital and sectorial policies identified**	- Proposal for a Regulation of the European Parliament and of the Council amending Regulations [...] as regards digitalisation and common specifications (COM(2025)504) - Regulation (EU) 2024/1781	- N/A

Organisational measures for a smooth cross-border digital public services delivery **Please list the governance measures foreseen**	- Use of commonly agreed open technical specifications and standards (see below)	- In the case of exports, third countries might still require documents to be provided in paper form.
Measures taken to ensure a shared understanding of the data **Please list such measures**	- Use of commonly agreed open technical specifications and standards (see below)	- N/A
Use of commonly agreed open technical specifications and standards **Please list such measures**	- Internet address - Digital Label - Digital Product Passport	- Accessibility requirements not defined in detail.

4.5. Measures to support digital implementation

High-level description of measures supporting digital implementation

Description of the measure	**Reference(s) to the requirement(s)**	**Commission role** (if applicable)	**Actors to be involved** (if applicable)	**Expected timeline** (if applicable)
The Commission will set out the types of electronic technical solutions that can be used for the voluntary digital label by 1 May 2027. Those can then also be used for the data carrier providing access to the EU declaration of conformity.	Article 3(7)	The Commission shall adopt such acts	Economic Operators Notified Bodies Member States Authorities	Q1 2027

			Consumers	
The revision of the NLF and the Digital Product Passport Implementing Acts will take into consideration all digital requirements for further interoperability in all processes in scope of this directive. Particular attention will be paid to the cybersecurity aspects.	Article 3(7)	The Commission shall adopt such acts	Economic Operators Notified Bodies Member States Authorities Consumers	