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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 of the European Parliament and of the Council, as regards simplification of certain requirements and procedures for chemical products

(Text with EEA relevance)

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 analysis provided by the high-level reports of Enrico Letta[1] and Mario Draghi put 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 flagging regulatory obstacles and the administrative burden as their greatest challenge[2].

President von der Leyen in her political guidelines for the European Commission's 2024–2029 mandate[3] 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 the climate and sustainability, and social responsibilities. It also underlined the need to ensure

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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.

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

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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, p. 10.

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.

- **Regulation (EC) No 1223/2009** on cosmetic products[10] ('the Cosmetic Products Regulation', or 'CPR'). 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. The existing derogation procedure from the generic prohibition on the use of substances classified as carcinogenic, mutagenic, or toxic for reproduction (CMR) 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. Furthermore, 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 microorganisms by manufacturers and notified bodies. Another envisaged empowerment would allow the Commission to add further materials safely derived from animal by-products in the Regulation so that they could be used in EU fertilising products. This amendment specifically concerns animal by-products which are safe and out of scope of the Animal By-Products Regulation[12] and which, under the current rules, cannot be included in the Fertilising Products Regulation, since the requirement for the end point to be determined in accordance with the Animal By-Products Regulation cannot be fulfilled. Moreover, the initiative proposes to remove the 'unbundling clause' in Article 43 FPR, 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 Proposal for a Regulation of the European Parliament and of the Council amending Regulations [...] as regards digitalisation and common specifications[13].

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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. 59–209, 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.

12 Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation), OJ L 300, 14.11.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/1069/oj.

13 COM(2025)504.

1.2. Consistency with existing policy provisions in the policy area

The proposal is part of a package of measures concerning simplification, aiming at streamlining certain procedures and reducing administrative burden and costs for industries, 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.

This proposal contains provisions that are intended to reduce the burden for Member States and industry, with the aim of making the three amended pieces of legislation easier to apply and less burdensome.

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 Union legislation.

This proposal follows in the context of a series of Omnibus simplification packages.

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, considering the fact that the recent amendments to Annex I and Annex II were introduced by Regulation (EU) 2024/2865[14] via the ordinary legislative procedure, it is appropriate to use the same procedure for the amendments of these annexes proposed by this initiative.

[14] 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.

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 Annex II, Part II, in order to involve the co-legislators in this important amendment. Moreover, given the 'unbundling clause' in Article 43 of the Fertilising Products Regulation, this amendment, which concerns twelve component material categories, would require the adoption of twelve delegated acts. The amendments to Annexes I and IV are included in this proposal as they are closely related to amendments in the main body of the Regulation.

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 according to the Better Regulation principles to the extent possible.

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[15] 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

[15] 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.

widespread warnings that these changes could drive up packaging waste and force the use of expensive fold-out labels. Numerous participants questioned the necessity of such prescriptive formatting in professional environments – such as B2B[16] transactions – where hazard communication is already effectively handled through Safety Data Sheets (SDS). Calls to "stop the clock" on implementation until a full impact assessment is conducted were repeated throughout the discussion. 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 strong support for exempting B2B advertising altogether, with stakeholders pointing to the adequacy of existing communication tools like SDS for professional audiences.

Beyond these two focal issues, the discussion ranged widely across the CLP regulation. Participants highlighted the need to align definitions of '*placing on the market'* and '*making available'* with terminology used in other EU product legislation, to avoid unnecessary reclassification of stock when new rules become applicable. Participants also flagged the need for better clarity in terminology – particularly around what constitutes '*advertisement*' and '*distance sales*' to ensure consistent compliance across sectors and Member States.

The Poison Centre Notification system came under significant scrutiny, with many citing inconsistent national procedures and high costs. A centralised EU system managed by ECHA was suggested as a possible solution. There were also calls to revise the Unique Formula Identifier requirements for sectors like fuels, where the practicalities of implementation are especially challenging due to the nature of supply chains.

Stakeholders expressed strong dissatisfaction with the tight six-month deadline for self-classified substances, advocating instead for alignment with the longer timelines used for harmonised classifications. 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 Reality Check and comments received afterwards also revealed a shared interest among both industry and civil society in improving the harmonised classification and labelling (CLH) process. Suggestions included, amongst others, developing a roadmap for harmonised classification, enabling automatic updates to Annex VI based on scientific assessments and allowing a more pragmatic use of new data and exposure routes.

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

[16] Business-to-business

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. Approx. 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.

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 proposed changes aim notably at setting out in more detail the derogation procedure and streamlining the derogation criteria. 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)[17] 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 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[18] 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.

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

[17] 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

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

Commission six months before placing them on the market (Article 16 of the Cosmetic Products Regulation). This pre-notification requirement for cosmetic products containing nanomaterials has been considered burdensome. Suggestions for improvement included 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.

Article 22 of the Cosmetic Products Regulation requires 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 and made them available to the public. This obligation, according to several competent authorities, places an unnecessary burden on competent authorities as existing tools, such as ICSMS[19], 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, taking place on 7 and 8 May 2025. Approx. 135 stakeholders registered for the meeting and about 95 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 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

[19] 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

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).

Stakeholders in the Reality Check confirmed their interest in the inclusion of additional derived products from animal by-products under the Fertilising Products Regulation. Although the inclusion of derived products within the scope of the ABPR – for which an end point has already been determined or which are currently assessed in a study carried out for the Commission – seemed to be a priority, stakeholders also appreciated the initiative of allowing for the inclusion of materials that are outside the scope of the ABPR, in particular shells, fish sludge, mineralised guano and cat litter.

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 delgated acts would be streamlined.

Multiple 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

The Commission relied on the Reality Checks mentioned above and on the stakeholders’ contributions received before and after the Reality Checks.

3.4. Impact assessment

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 and according to the Better Regulation principles

to the extent possible. Given the urgent need to put forward a proposal to address the identified problems, it has not been possible to prepare a full impact assessment.

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.

3.6. Fundamental rights

The proposal respects the fundamental rights enshrined, and adheres to the principles recognised by the Charter of Fundamental Rights of the European Union[20]. 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. Instead of current requirements for economic operators to indicate their address and telephone number on the label of the packaging of hazardous substance or mixture, the amendment will require providing an address and a digital contact, which could be any up-to-date and accessible online communication channel through which

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

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 be not feasible to comply with due to the complexity of supply chains[21]. In order to create 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 seeks to remove mandatory label formatting rules introduced by Regulation 2024/2865, as they were found to be too costly and restrictive for economic operators[22]. 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 1907/2006, so additional rules would not be proportionate. Furthermore, amendment to Article 48 aims at simplifying information requirement in advertisements aiming 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:

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,

[21] Accompanying Staff Working Document, p. 28.

[22] Detailed analysis of costs associated with new formatting requirements is provided in the accompanying Staff Working Document, p. 10.

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 timelines for submission of the derogation request (nine months after the publication of the Committee for Risk Assessment[23] (RAC opinion) and transitional periods of 12 months for new products, 24 moths for products already available on the market and 36 months for products containing the CMR substance for which a derogation request was submitted and the SCCS opinion was requested. Such longer transitional period, counted from the same starting date as other transitional periods (the entry into application of the harmonised classification) takes into account the time needed for the SCCS assessment.

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

[23] https://echa.europa.eu/about-us/who-we-are/committee-for-risk-assessment

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, CMC 1, point 2, seeks to remove the requirement that all substances incorporated into an EU fertilising products, 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 should 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 should 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.

The empowerment in Article 42(5) is amended to allow the Commission to add derived products within the meaning but outside the scope of Regulation (EC) No 1069/2009 in the component material categories of the Regulation, after an assessment concluding that the derived product meets the requirements for safety and agronomic efficiency laid down in Article 42(1)(b).

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 6-9, 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[24]. More specifically, the proposal includes:

- 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.

24 COM(2025)504.

2025/[…] (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 of the European Parliament and of the Council, 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],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) High quality and safety requirements protect EU citizens and the environment and a fair and sustainable economy. In international competition, the reputation of high-grade products manufactured in the EU can create an advantage for EU companies.

(2) Taking into account the findings of the 2024 Draghi report[3] that the increasing number and complexity of rules risks limiting EU businesses' room for manoeuvre, preventing them from flourishing and from remaining competitive, especially in light of fundamental transitions, economic instability and geopolitical tensions, certain procedures and requirements laid down in Regulations (EC) No 1272/2008[4], (EC) No 1223/2009[5] and (EU) 2019/1009[6] should be simplified and unnecessary regulatory burden for industry and authorities be removed.

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

2 OJ C [...], [...], p. [...]

3 2024 report by Mario Draghi on the future of European competitiveness: https://commission.europa.eu/topics/eu-competitiveness/draghi-report_en#paragraph_47059

4 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.

5 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.

6 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 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 are not complying 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 substance or mixture, 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, instead of a telephone number, a digital contact, which could be any up-to-date and accessible online communication channel with supplier.

(4) Regulation (EC) No 1272/2008 of the European Parliament and of the Council lays down the exemptions from labelling and packaging requirements for the 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. In order to simplify those provisions, it would be appropriate to allow the application of the existing exemptions for smaller packages without the need to prove the impossibility of the use of the outer packaging or tie-on tag.

(5) Regulation (EU) 2024/2865[7] introduced exemptions from labelling and packaging requirements for packages containing less than 10 ml. However, further clarification is needed on 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) Regulation (EU) 2024/2865 laid down rules on mandatory requirements for label formatting. New evidence[8] pointed to excessive administrative burden and costs, associated with these requirements. Following the aim of balancing the need for label information to be clearly understood by consumers with the need to reduce market barriers and burden for industry[9], it is necessary simplify the current obligations on formatting without reducing the level of protection of human health and the environment. It should however remain a duty of businesses and enforcement authorities to ensure that the labels are legible in accordance with the legal requirements.

(7) In order to alleviate the burden to businesses 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 EU legislation aiming at achieving the same

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7 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.

8 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 of the European Parliament and of the Council as regards simplification of certain requirements and procedures for chemical products, p. 10.

9 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, available at: https://single-market-economy.ec.europa.eu/document/download/d92c78d0-7d47-4a16-b53f-1cead54bcb49_en?filename=Communication%20-%20Single%20Market%20Strategy.pdf, p.10.

objectives. In this regard, requirements on advertisements and distance offers should be limited to products placed on the market for the general public, as Regulation (EC) No 1907/2006[10] already provides clear obligations on information flows in supply chains for substances and mixtures.

(8) Before amendments introduced by Regulation (EU) 2024/2865, Regulation (EC) No 1272/2008 required the advertisements for hazardous mixtures which allow a member of the general public 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 the advertisements for substances were required 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 a product in question. That Regulation also expanded requirements for advertisements. Taking into account that the advertisements are means of promoting the sale or use of chemical products by various types of media, and considering that 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 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.

(9) As Regulation (EC) No 1107/2009 of the European Parliament and of the Council[11] and Regulation (EU) No 528/2012[12] of the European Parliament and of the Council require the advertisements of plant protection products and biocidal products to use, among other statements, the phrase "Always read the label and product information before use", it would be appropriate to use the same requirement for the advertisements of hazardous substances and mixtures. In cases where advertised hazardous substances and mixtures are also plant protection products or biocidal products, the required phrase would only be used once, thus avoiding duplication.

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

(11) Regulation (EU) 2024/2865 introduced the possibility to include certain labelling elements in the digital label only. In order 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

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10 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.

11 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.

12 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.

the digital contact would also be appropriate where contact details of additional suppliers are provided in the digital label.

(12) Colorants, preservatives and UV filters can only be used in cosmetic products if they are listed in Annexes IV to VI to Regulation (EC) No 1223/2009. Therefore, a procedure should be provided identifying the different steps in this process and conditions under which a substance can be introduced into the respective Annex.

(13) The principle that substances classified as CMR substances of categories 1A, 1B or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 should be prohibited from the use in cosmetic products should continue to apply. Nevertheless, due account should be taken of the specific exposure of cosmetic products, which can only be placed in contact with the external parts of human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity and that they cannot be ingested, inhaled, injected or implanted into the human body. Therefore, the scope of the ban directly triggered by the CMR harmonised classification should be limited to substances which CMR properties were established due to the dermal exposure as if their CMR properties are linked to the exposure through oral routes or inhalation their presence in cosmetic products will not put the end-users of such products at risk. However, if the substance used in oral products received the CMR classification due to its oral route of exposure, the Commission should ask the SCCS for its opinion on the safety of the use of such substance in such products and follow up with the appropriate regulatory measures.

(14) Regulation (EC) No 1223/2009 provides the possibility to request an exemption from the ban preventing the use of a CMR classified substance in cosmetic products. The exemption criteria should be streamlined, and their scope should be set out in more detail. In particular, the compliance with food safety requirements does not enhance the safety of cosmetic products as both categories of products are inherently different. Therefore, it is appropriate to abolish this criterion. In addition, the criterion that the application for derogation is made for a particular use of a product category with a known exposure should become one of the conditions for the SCCS assessment, as this scientific committee should be able to assess the safety of the substance when taking due account of its use in particular product category and the exposure. Furthermore, elements to be considered under the availability of suitable alternatives criterion should be indicated. In particular, it should be specified that the alternative substance should not create safety risks for human health but should provide an equivalent function in a cosmetic product, be freely available on the market in sufficient quantities, so that it can be technically feasible and economically viable for the SMEs. The access to this substance should not be restricted by patents or raw material restrictions. The economic aspects, such as costs of reformulation and comparative contribution to overall production costs, can also be considered as relevant factors in the analysis of the suitability of alternatives.

(15) When the substance is banned or restricted from the use in cosmetic products, the cosmetic manufacturers, importers, distributors and responsible persons should be given appropriate time to take necessary measures to reformulate their products, withdraw from the distribution and destroy the unsold products not complying with the new requirements. Although the harmonised classification of a substance does not mean that consumers of cosmetic products would face an immediate risk for human health, the interests of consumers should be carefully considered and the time accorded to business for adjustment should be as short as possible. Therefore, a specific period following the publication of the amendments to respective Annexes to Regulation (EC) No 1223/2009

should be set out considering the situation of new products, products already present at the Union market as well as the derogation process, especially the situation where the SCCS assessment was involved.

(16) It should be set out explicitly that the harmonised classification as a CMR category 1A, 1B or 2 of a substance, which is also a constituent of a natural complex substance, should only trigger a ban based on Article 15 of Regulation (EC) No 1223/2009 on the substance as such, but not on the natural complex substances in which it is one of the many constituents. However, the harmonised classification of such constituent may raise concerns as to the safety of the natural complex substance. In such a case, the Commission should request the opinion of the SCCS and take regulatory measures following the SCCS conclusions. The introduction of this new rule should not impact the current approach according to which the harmonised classification as a CMR category 1A, 1B or 2 of a substance containing more than one constituent, independently from the classification or not of its constituents, should trigger the ban from its use in cosmetic products unless the request for derogation was submitted and derogation criteria are fulfilled.

(17) To reduce compliance and administrative burden on businesses active in cosmetic sector only one notification of the cosmetic products before placing them on the EU market should be required. The conditions of this notification should apply in a non-discriminatory way to cosmetic products containing nanomaterials and to those cosmetics which do not contain them. To maintain the vigilance on the nanomaterials, it should be required that the specific information on nanomaterials present 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.

(18) In accordance with Regulation (EU) 2019/1020[13], 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 to the Commission and other Member States of the review and assessment of their surveillance activities. This reporting obligation should be therefore abolished.

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

(20) 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

[13] 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. 1–44, ELI: http://data.europa.eu/eli/reg/2019/1020/oj.

transformations, economic operators dealing with EU fertilising products in accordance with Regulation (EU) 2019/1009 of the European Parliament and of the Council[14] should provide a digital contact through which they can be reached, draw up the EU declaration of conformity in digital 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 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.

(21) Under Regulation (EU) 2019/1009, only micro-organisms listed on a positive list in Annex II to the Regulation may be used as component material in microbial plant biostimulants. The Commission is empowered to add strains of micro-organisms to that list after an assessment concluding that the strain does not present 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 additional strains of micro-organism to the positive list is lagging scientific progress. This 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.

(22) 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, CMC 7, 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. 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[15]. 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.

[14] Regulation (EU) No 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.

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

(23) Regulation (EU) 2019/1009 recognises that derived products within the meaning of Regulation (EC) No 1069/2009 of the Parliament and of the Council[16] on animal by products constitute potentially promising raw materials to produce innovative fertilising products in a circular economy. It therefore empowers the Commission to include such products as component materials in EU fertilising products where an end point in the manufacturing chain has been determined in accordance with that Regulation. Regulation (EC) No 1069/2009 does not apply to certain animal by-products listed in Article 2(2) of that Regulation. In line with the objective of Regulation (EU) No 2019/1009 to promote the circular economy, the Commission should also be empowered to add those derived products as component material under Regulation (EU) No 2019/1009, if an assessment has demonstrated that the respective material does not present a risk to human, animal or plant health, to safety or to the environment, and ensures agronomic efficiency.

(24) 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, e.g. 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 the adoption of the respective delegated acts, the Commission should be allowed to amend several component material categories in one delegated act.

(25) 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 volume 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. These extensive information requirements might prevent manufacturers, and in particular small and medium enterprises, from using substances that are not yet registered according to those requirements or force them to place their products 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 follow the requirements, including the relevant gradations, set out in Regulation (EC) No 1907/2006.

[16] Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002, OJ L 300, 14.11.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/1069/oj.

(26) To ensure a smooth and effective transition, to minimize disruptions, and to provide a reasonable timeframe for industries to adjust to the new requirements, amendments to Regulation (EU) 2019/1009 concerning digitalisation should be deferred.

(27) 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 their version applicable before that date.

(28) Regulation (EC) No 1272/2008, Regulation (EC) No 1223/2009 and Regulation (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 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 covered by Article 25(6) 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 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) paragraphs 6 and 7 are replaced by the following:

'7. Substances and mixtures which have been classified, labelled and packaged in accordance with Article 5, Article 6(3) and (4), Article 9(3) and (4), Article 10, Article 25(3), Article 29 and section 1.5.1.2 of Annex I as applicable on 9 December 2024 and which were placed on the market before 1 July 2026 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 July 2028.

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, V or VI, as applicable, 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. That deadline can be extended by the Commission if additional evidence is required.

;

(2) Article 15 is amended as follows:

(a) paragraph 2 is amended as follows:

(a) In paragraph 2, first, second and third subparagraphs are replaced with the paragraph 2 below:

'2. The substances classified as CMR substances of category 1A and 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008 may be used in cosmetic products if a derogation request was submitted to the Commission within nine months following the publication of the relevant opinion of the Committee for Risk Assessment adopted in accordance with Article 37(4) of Regulation (EC) No 1272/2008 and where the following conditions are fulfilled:

(a) there are no suitable alternative substances available;

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

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

(a) complies with the requirements of other applicable Union legislation;

(b) does not increase an overall risk to human health and the environment;

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

(d) is technically feasible and economically viable;

(e) is freely available on the market in sufficient quantities in a sustainable manner.'

;’

(a) The following subparagraph is inserted after the third subparagraph:

‘The deadline laid down in the third subparagraph starts on the date of entry into force of amendments to Part 3 of Annex VI to Regulation (EC) No 1272/2008 classifying the substance concerned as CMR category 1A, 1B or 2. When the Commission receives a request for a derogation in accordance with the first subparagraph, the deadline laid down in the third subparagraph shall not apply.’;

(b) Paragraphs 3 and 4 are deleted;

(c) The following paragraphs 5, 6 and 7 are added:

‘5. Paragraphs 1 and 2 shall not apply where the harmonised classification of a substance under Regulation (EC) No 1272/2008 is based solely on hazards identified via oral or inhalation exposure routes, unless there is scientific evidence demonstrating that such hazards are also relevant via dermal exposure under conditions of cosmetic use.

6. Paragraphs 1 and 2 shall not apply to substances 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 if only a substance being its constituent was classified as a CMR substance of categories 1A, 1B or 2.

After a substance that is a constituent of a substance referred to in the first subparagraph has been classified as CMR category 1A, 1B or 2, the Commission shall without undue delay seek an opinion of the SCCS on the safety of that substance for use in cosmetic products.

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 prohibited from use in cosmetic products may be placed on the Union market 12 months after the date of application of amendments to Part 3 of Annex VI to Regulation (EC) No 1272/2008 classifying the substances concerned as CMR category 1A, 1B or 2 and may made available on the Union market 24 months after the date of application of such amendments.

Where a request for a derogation is made in accordance with paragraph 1 or paragraph 2, first subparagraph, and the SCCS was requested to provide its opinion on the safety of the substance classified as CMR category 1A, 1B or 2, but the substance was prohibited or further restricted from use, cosmetic products containing that substance or not compliant with the restriction may be placed on the Union market or made available on the Union market 36 months after the date of application of amendments to Part 3 of Annex VI to Regulation (EC) No 1272/2008 classifying the substance concerned as CMR category 1A, 1B or 2 and in any case during 12 months following the entry into force of the amendments to the relevant Annexes to Regulation (EC) No 1223/2009.’

;

(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 point (g) of paragraph 1 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:

(a) 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.'

(b) 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 amended as follows:

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

(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, paragraph 2(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, 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.’

;

(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:

'2. 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. 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).

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.'

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 an assessment by the manufacturer in accordance with that methodology, may be used as component material in EU fertilising products. The criteria and methodology shall allow for the 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 each of the major antibiotic classes, namely aminoglycoside, macrolide, beta-lactam, tetracycline and fluoroquinolones, with the exception of intrinsic resistance.’

;

(c) paragraph 5 is replaced by the following:

‘5. The Commission may only adopt delegated acts pursuant to paragraph 1 amending Annex II to this Regulation to add derived products within the meaning of Regulation (EC) No 1069/2009 in the component material categories where one of the following conditions is met:

(a) the derived product is obtained from an animal by-product listed in Article 2(2) of Regulation (EC) No 1069/2009;

(b) an end point in the manufacturing chain has been determined for the derived product in a legal act adopted in accordance with Article 5(2) of Regulation (EC) No 1069/2009.

Before adding such derived products to the component material categories, the Commission shall assess whether they meet the criteria in paragraph 1, point (b), of this Article. For the derived products referred to in the first subparagraph, point (b), that assessment shall include relevant aspects not taken into account for the determination of the endpoint. If the assessment concludes that the criteria in paragraph 1, point (b), of this Article are fulfilled, the Commission shall adopt delegated acts pursuant to paragraph 1 of this Article to include those materials in the table in component material category 10 in Part II of Annex II to this Regulation without undue delay after the conclusion of the assessment.

;

(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 provision

1. By way of derogation from Article 29(2), Article 48 of Regulation (EC) No 1272/2008, 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 Article 1, points (4) and (7) of this Regulation and points (4), (5) and (6) 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, 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 (7) 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

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

2. Article 1, points (4) and (5), Article 1, points (7) and (8), points (4), (5), (6) and (8) of Annex I shall apply from 1 July 2026.

3. Article 1, point (6), points (1) and (2) of Annex I shall apply from 1 January 2027.

4. Article 1, points (2) and (3), points (3) and (7) of Annex I shall apply from [*OP: please insert the date of 36 months after the entry into force of this Regulation)*] (digital contact)

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 Brussels,

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 favorable 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;
- Supporting a more circular economy, reducing costs alternatively spent on primary raw materials and waste treatment;
- 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[41]

☐ 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.

1.5.3. Lessons learned from similar experiences in the past

N/A

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

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.[42]	from EFTA countries [43]	from candidate countries and potential candidates [44]	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

[42] Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.
[43] EFTA: European Free Trade Association.
[44] 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[45]							
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**

[45] 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'[46]

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**

[46] 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 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'[47]

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**

[47] 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[48]	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No	Total cost
SPECIFIC OBJECTIVE No 1[49]…																		
- Output																		

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

49 As described in Section 1.3.2. 'Specific objective(s)'

- 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 line [XX.01.YY.YY]	- at Headquarters	0	0	0	0
	- 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	Impact of the proposal/initiative[50]			
		Year **2024**	Year **2025**	Year **2026**	Year **2027**

[50] 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.

	current financial year				
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).

[…]

4. DIGITAL DIMENSIONS

4.1. Requirements of digital relevance

Requirement 1:

- Reference: Article 1(1), (2) and (3), Article 3(1), (2)(c), (4)(b) and Annex IV(1) and (3).
- High-level description: Definition of 'digital contact': any up-to-date and accessible online communication channel.
- Stakeholders: Economic Operators, Consumers and other End-users, Member States Authorities.
- High-level processes: Market surveillance verification and monitoring.

Requirement 2:

- Reference: Article 3(2)(a)(ii), (4)(a), (5)(a), (7) and (8).

(1) High-level description: the products must be accompanied by the internet address or data carrier through which the EC declaration of conformity can be accessed.

(2) Stakeholders: Economic Operators, Member States Authorities.

(3) High-level processes: Market surveillance verification and monitoring.

Requirement 3:

- Reference: Article 3(2)(a)(i), Annex IV(3).

(4) High-level description: Definition of EC declaration of conformity, in electronic form.

(5) Stakeholders: Economic Operators, Member States Authorities.

(6) High-level processes: Market surveillance verification and monitoring.

Requirement 4 :

- Reference: Article 3(7).
- High-level description: specifying that the data carrier used for providing access to the EU declaration of conformity shall meet certain requirements for the digital label and be based on the same technological solutionsm and that where a digital label is used, the same data carrier should provide access to the digital label and the EU declaration of conformity.

(7) Stakeholders: Economic Operators, Member States Authorities.

- High-level processes: Market surveillance verification and monitoring.

Requirement 5:

- Reference: Article 3(7).
- High-level description: include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload theEC declaration of conformity or instructions in a digital product passport.
- Stakeholders: Economic Operators, Member States Authorities.
- High-level processes: Market surveillance verification and monitoring.

Requirement 6:

- Reference: Article 3(2)(d), (3)(4)(d), (5)(b), Annex IV(3).
- High-level description: specify that competent authorities, upon receive, all documents necessary to prove conformity in electronic form.
- Stakeholders: Economic Operators, Member States Authorities.
- High-level processes: Conformity assessment procedures.

Requirement 7:

- Reference: Article 3(6).
- High-level description: specify that documents, records and correspondence to and from notified bodies related to the conformity assessment procdure should be in electronic form.
- Stakeholders: Notified Bodies, Economic Operators.
- High-level processes: Conformity assessment procedures.

Requirement 8:

- Reference: Annex I, point (8).
- High-level description: possibility to move certain contact information to the digital label only.
- Stakeholders: Economic Operators, Member States Authorities, Consumers and other End-users.
- High-level processes: Market surveillance verification and monitoring.

4.2. Data

The data in scope is related to assessing and proving the conformity of products and contact details, such as an e-mail address, of economic operators.

4.3. Digital solutions

The 'digital contact'is defined as "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". This could, for instance, be an e-mail address or a webpage with a contact form.

The definition “electronic form” allows plain text files, PDF files, Microsoft Word Documents, Web pages.

The ‘data carrier’ providing access to the EU declaration of conformity or to the digital label can be a linear bar-code symbol, two-dimensional symbol or other automatic identification data capture medium that can be read by a device. 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.

4.4. Interoperability assessment

Digital public service: Market surveillance monitoring/verification/investigations. Certification services.

Legal layer interoperability: Further interoperability can be achieved with the revision of the NLF.

Semantic layer potential barrier: The structure of the digital contact and the EU declaration of conformity and common specifications could be better defined.

Technical interoperability potential barrier: The “electronic form” definition can hinder interoperability because it is possible to use formats which are not interoperable, like websites, unstructured word documents and PDF files, even videos or photos.

4.5. Measures to support digital implementation

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.

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.