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Subject:	Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 as regards simplification of certain requirements and procedures for chemical products - Mandate for Negotiations with the European Parliament - Outcome of Proceedings

Delegations will find in the ANNEX the above compromise text of a mandate for starting negotiations with the European Parliament, which was approved at the Permanent Representatives Committee's meeting on 5 November 2025.

ANNEX

2025/0531 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 as regards simplification of certain requirements and procedures for chemical products

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

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

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) High quality and safety requirements for products on the Single Market ensure a high level of protection of human health and the environment and contribute to a fair and sustainable economy. In international competition, the reputation of high-grade products manufactured in the Union can create an advantage for Union companies.

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

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

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

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

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

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

(3) In line with the Commission's objective to promote the 'digital by default' principle to support digital transformations and in order to facilitate communication between ~~economic operators~~***suppliers*** and national authorities ~~responsible for enforcement~~, the indication of a digital contact on the label of hazardous substances and mixtures is necessary to enhance the effectiveness of official controls and enforcement and to expedite the process of detecting substances and mixtures that do not comply with the requirements of Regulation (EC) No 1272/2008. Currently, suppliers are required to indicate their address and telephone number on the label of the packaging of hazardous substances or mixtures, but this is not always sufficient to ensure that authorities responsible for enforcement can establish rapid contact. It is therefore necessary to require suppliers to ***also*** provide a digital contact, which could be any up-to-date and accessible online communication channel with the supplier. ***To reduce required label space, suppliers should be permitted to provide this telephone number on the digital label alone or through the digital contact. For example, where the digital contact is an email address, suppliers should be allowed to provide the telephone number in an auto-response, or where the digital contact is a webpage, suppliers should be allowed to provide the telephone number by clearly stating it on the webpage. To allow suppliers sufficient time to adapt, the requirement to provide a digital contact should first be applied to the placing on the market of substances and mixtures three years after the entry into force of this Regulation. Products placed on the market within the three-year deadline should be permitted to remain on the market without relabelling for a further two years after the passing of the three-year deadline. During the transitional period, the existing rules will continue to apply, including the requirement to use provide a telephone number. Suppliers should also be able to apply the new rules following the entry into force of this Regulation and be allowed to provide the telephone number on digital labels or through the digital contact.***

(3a) ***The digital contact should allow consumers and authorities to contact suppliers directly, and should be accessible free of charge, without the need for providing any personal data, downloading or using additional applications specific to the supplier or the obligation to register solely to contact the supplier. Such digital contact may include, for example, an email address or a contact form on a website. However, it should not be understood as encompassing automatic replies to queries, chatbots, fax numbers, or telephone lines. The term 'digital contact', similarly to the term 'electronic address' in Regulation (EU) 2023/988 of the European Parliament and of the Council, should be interpreted in a technologically neutral manner, capable of evolving with future technological developments, and should cover all forms of direct digital communication.***

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

(5) Regulation (EU) 2024/2865 of the European Parliament and of the Council[6] introduced exemptions from labelling and packaging requirements for packages containing less than 10 ml. ***It introduced a possibility to omit label elements from such inner packaging under certain conditions.*** However, ~~further simplifications are needed with regard to the application of this derogation in cases where these packages are subject to the supplementary hazard statement EUH 208.~~ it is ~~also~~ necessary to ***simplify these provisions and*** clarify ***cases that require labelling elements to be presented on*** the ~~requirements for inner and~~ outer packaging ~~in~~***and*** cases ~~where the 10 ml derogation is applied~~***allowing for these elements to be fully omitted***.

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6 Regulation (EU) 2024/2865 of the European Parliament and of the Council of 23 October 2024 amending Regulation (EC) ~~No~~ ~~1272/2008~~***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).

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

(7) Regulation (EU) 2024/2865 laid down rules on mandatory requirements for label formatting. New information[7] pointed to excessive administrative burden and costs, associated with these requirements. To balance the need for label information to be clearly understood by consumers with the need to reduce market barriers and burden for industry[8], it is necessary to simplify the current formatting obligations without reducing the level of protection of human health and the environment. ~~Economic operators and enforcement authorities~~***Suppliers*** must remain responsible for ensuring that the labels are legible in accordance with the legal requirements.

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

[8] As outlined in the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions The Single Market: our European home market in an uncertain world, A Strategy for making the Single Market simple, seamless and strong, COM(2025) 500 final, p. 10, available at: https://single-market-economy.ec.europa.eu/document/download/d92c78d0-7d47-4a16-b53f-1cead54bcb49_en?filename=Communication%20-%20Single%20Market%20Strategy.pdf.

(7a) The label could be the sole source of information readily available to the handler of the chemical, even if some users may have access to more information or may be generally trained to deal with hazardous chemicals. Therefore, it is indispensable that a label is easily readable in normal and under exceptional circumstances such as accidents. For a label to be considered readable a combination of features should be taken into account. Such features could include clear contrast of the text of the label to the background, a suitable typeface, an appropriately large font-size, appropriate line and letter spacing, overall label design and other relevant formatting elements which combined ensures the appropriate degree of readability. The European Chemicals Agency (ECHA) is encouraged to update its guidance on formatting of labels and include clear examples of what constitutes acceptable and unacceptable examples of label formatting. The guidance should consider labelling formats from other relevant Union laws and take account of best practice on "accessible design" and accepted standards for readability, including acceptable as well as unacceptable colour combinations to ensure contrast. It should assist enforcement by relevant national authorities, provide certainty for suppliers, and ensure fair competition on the internal market.

(8) To alleviate the burden on industry and to improve the free circulation of substances and mixtures in the internal market it is appropriate to amend Regulation (EC) No 1272/2008 as regards the rules on advertisements and distance ***sales*** offers, taking advantages of existing provisions in other Union legislation with the same objectives. In this regard, ***certain*** requirements for advertisements and distance ***sales*** offers should be limited to products placed on the market for the general public, as Regulation (EC) No 1907/2006[9] already provides clear obligations on information flows in supply chains for substances and mixtures ***for professional and industrial users through the safety data sheet, which must be provided no later than the date on which the substance or a mixture is first supplied***.

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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).

(8a) ***Professional and industrial users are normally more informed about the hazards associated with a particular substance or mixture prior to use than consumers and therefore it is appropriate to differentiate between the information requirements for consumers as opposed to professional and industrial users of substances and mixtures. When determining whether an advertisement or a distance sales offer is targeted at consumers, national competent authorities should take into account factors such as whether the advertisement or offer clearly states that the substance or mixture is only suitable or only available for professional users. The setting in which the advertisement or distance sales offer is published is also a relevant factor for assessing whether it is directed exclusively at professional users. Such settings may include, for example, trade fairs, trade magazines or web portals addressed to downstream users of chemicals. Similar assessments are made in other areas of Union law, including Regulation (EC) No 1907/2006, Regulation 2019/1148, Regulation (EU) 2022/2065, and Regulation (EU) 2023/988, as well as Regulation (EC) No 1272/2008. To provide greater clarity for enforcement authorities and suppliers, ECHA is encouraged to provide guidance on this point, which takes account of the existing acquis on Union law on advertising, targeting, and distinguishing between consumer and professional use.***

(8b) ***Distance sales offers are often associated with online selling via webshops, online marketplaces or mobile applications. However, the concept of distance sales is broader and also encompasses other sales channels, such as telesales, SMS-based ordering or automatic inventory ordering systems. Owing to the specialist nature of such systems, consumers are unlikely to have access to them. Moreover, providing labelling information in the offer through such other forms of distance sales is often impractical and would impose a disproportionate burden on suppliers and downstream users. This is not the case for online selling, where the information appearing on the label can be made available in the form of an image or as part of the product description. Therefore, except for online distance sales, suppliers should not be required to provide labelling information at the time of sale for distance sales to professional or industrial users, unless the website or mobile application is closed to the general public and only allows professional users to complete purchases. ECHA is encouraged to provide guidance on how to determine when this is the case.***

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

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

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

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

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

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

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

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

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

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

(16a) The assessment of the fulfilment of the derogation criteria requires multiple consultations and deliberations. The assessment of the Scientific Committee on Consumer Safety (SCCS) of the safety of the substance for human health requires a minimum of twelve months, the assessment of the compliance with other derogation criteria require consultations with experts and discussions with the Member States and the industry representatives. Once the draft measure is prepared by the Commission it is subject to notification under the WTO Technical Barriers to Trade (TBT) procedure for a minimum of two months. The draft Commission measure falls under the obligatory scrutiny by the European Parliament and the Council which lasts three months before its final adoption and publication in the Official Journal. The analysis of the fulfilment of the derogation criteria and the obligatory sequential steps which must be followed by the Commission while adopting a regulatory measure require that sufficient time is accorded to the Commission for the adoption of the measure from the submission of the request for derogation.

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

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

(18a) Regarding the assessment of alternatives, the words "similar" and "comparable" means all possible alternatives available, and not only alternatives providing 1:1 substitution. "Technically feasible" highlights that it has to be possible to apply the alternative with technologies and methods generally available. This Regulation does not set out detailed definitions of these terms as their precise interpretation and application may depend on the specific context of the assessment of suitable alternatives. To promote consistency and predictability of the assessment of alternatives, the Commission should be encouraged to develop guidance, in consultation with the SCCS, ECHA, Member States and relevant stakeholders, which could provide further clarification of these concepts. Such guidance should at least explain criteria for economically and technically feasible alternatives, practical examples on alternative technologies and indications of established best practices.

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

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

(21) ~~Often a substance can also be a~~***Article 5 of Regulation (EC) No 1272/2008 provides a specific rule for identification and examination of available information when evaluating the hazardous properties of substances containing more than one*** constituent ***which are extracted from plants or plant parts and which are not chemically modified as defined in Article 3, point (40), of Regulation (EC) No 1907/2006. Such substances, often referred to as '*** ~~of~~ Natural complex substances***', or 'NCS' may contain one or more substances classified as CMR substances*** ~~, for example essential oils. In such cases~~, ***while the overall Natural complex substance is not itself classified as a CMR substance.*** The prohibition of use in cosmetic products under Article 15 of Regulation (EC) No 1223/2009 ~~is relevant~~ only ***applies*** to the substance as it appears in Part 3 of Annex VI to the Regulation (EC) No 1272/2008. ~~This means that~~ Natural complex substances ~~that contain a CMR classified constituent~~ are not subject to the prohibition, except if that Natural complex substance is itself listed as CMR substance of category 1A, 1B or 2 in Part 3 of Annex VI to the Regulation (EC) No 1272/2008. ~~Nevertheless, since the harmonised classification of~~***When*** a constituent ~~may raise concerns as to the safety of the~~***of a*** Natural complex ~~substances when used in cosmetic products~~***substance is classified as a CMR (categories 1A, 1B or 2), this raises concerns about its safe use in cosmetics. In such cases***, the Commission should ~~mandate~~***systematically request*** the SCCS to assess the ~~impact of such constituent on the~~ safety of ~~natural complex substances, if a safety concern arises, and is to follow up with the appropriate~~***such constituents and, where necessary, take*** regulatory ~~measures in accordance with~~***action under*** Article 31(1) of Regulation (EC) No 1223/2009.

(22) When a substance is prohibited or restricted from the use in cosmetic products, the manufacturers, importers, distributors and responsible persons should be given appropriate time to take necessary measures***. To enable manufacturers of cosmetic*** ~~to reformulate and relabel their~~ products ***to secure the suitable alternative substances, to carry out tests as part of reformulation process and to proceed with the safety assessment of the final products and their re-labelling and mandatory notifications, they should be provided with appropriate adjustment period. During this period distributors and retailers continue to receive cosmetic products containing the substance subject to regulatory measures. Therefore, they need additional time to*** withdraw ***such products*** from the distribution ***chain and to*** ~~and~~ destroy the unsold products not complying with the new requirements. ~~Therefore, periods of 12~~***These actions impact the existing contractual arrangements and requires substantial logistical efforts. Accordingly, a period of 6*** months for placing and ~~2~~4***12*** months for making available on the market of cosmetic products containing the substance concerned following the entry into force of the respective amendments to Regulation (EC) No 1223/2009 should be provided.

(23) To reduce compliance and administrative burden on businesses active in the cosmetic sector, ~~only one notification~~ ***notifications*** of the cosmetic products should ***only*** be required before placing them on the Union market. ~~The conditions of such notification should apply in a non-discriminatory way to cosmetic products containing nanomaterials and to those cosmetic products which do not contain them.~~ To maintain vigilance on nanomaterials, ~~it should be required that the~~ specific information on nanomaterials used in a cosmetic product ~~is~~***should continue to be*** provided ~~in the cosmetic~~***by the responsible persons through the existing process before the*** 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~~***is placed on the market.***

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

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

(25) Cosmetics are globally traded goods~~.~~ ***and*** it is therefore ~~important~~***essential*** that the ingredient names present on their labels reflect the current state of scientific and technological development ***in a timely manner***. The use of internationally recognised ***nomenclature, such as the International Nomenclature of*** Cosmetic ~~ingredient' names is an important factor promoting~~***Ingredients (INCI) promotes*** transparency ***for consumers, ensures consistency across jurisdictions, and facilitates*** ~~and facilitating~~ cross-border trade ~~in cosmetics~~***. INCI names are maintained by the Personal Care Products Council (PCPC) as an international industry standard and are widely recognised by regulators and stakeholders worldwide***. This Regulation should enable ***the direct use of*** internationally recognised ~~names~~***nomenclature, such as INCI,*** to be used on the labelling of cosmetic products without ~~any additional~~***further*** regulatory action from the Commission***. Where a common ingredient name is not available in INCI, other generally accepted nomenclature should be used, for example names established in recognised international chemical or pharmacopoeia references, or in other authoritative sources commonly relied upon by industry and regulators. This approach ensures flexibility, avoids unnecessary administrative burden, and guarantees that ingredient names used on cosmetic product labelling remain up to date, internationally coherent, and easily understandable to consumers***. As a glossary of common ingredient names adopted by the Commission would slow down the process of uptake of the new names, the provision requiring the Commission to adopt such a glossary should be abolished. ***The Commission is encouraged to facilitate access to the internationally recognised nomenclature through digital tools, such as the Cosmetic ingredients (CosIng) database.***

(26) In line with the Commission's objective to rationalise and simplify reporting requirements and to promote the 'digital by default' principle to support digital transformations, economic operators dealing with EU fertilising products in accordance with Regulation (EU) 2019/1009 should provide a digital contact through which they can be reached, draw up the EU declaration of conformity in electronic form and make it accessible via an internet address or data carrier, and provide authorities, upon request, with all relevant information and documentation in electronic form. Documents and correspondence to and from notified bodies related to conformity assessments of EU fertilising products should also be provided in electronic form. Where a digital label is used, manufacturers should use the same data carrier used for the digital label to provide access to the EU declaration of conformity, to avoid the presence of multiple data carriers on the same product. Where a Digital Product Passport is required for EU fertilising products under other EU legislation, the digital labelling information and the EU declaration of conformity should be provided in that Digital Product Passport.

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

(28) In order to accelerate the assessment of micro-organisms and to open the single market for more microbial plant biostimulants, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of Annex II, Part II, component material category (CMC) 7, to Regulation (EU) 2019/1009 to allow the Commission to introduce general criteria and a methodology for the assessment of micro-organisms. Those criteria and the methodology should allow manufacturers ***to demonstrate*** 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. ***This assessment requires special expertise for which conformity assessment bodies will need to be specifically accredited and notified. The national bodies responsible for accreditation and notification should carefully verify the conformity assessment bodies' technical and scientific competence in the assessment of micro-organisms and that they meet the stringent requirements for notified bodies set out by the Regulation, including independence, objectivity, impartiality and professional integrity.*** In order to refine and validate the criteria and methodology to be introduced, it is of particular importance that the Commission ***should invite a scientific body, either EFSA or the JRC, to review and contribute and*** carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[13]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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

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

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

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

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

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

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 1272/2008

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

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

‘42. “digital contact” means any up-to-date and ***freely*** accessible online communication channel ***such as email addresses*** through which a supplier can be ~~reached or engaged~~***contacted*** without the need to register or to download ~~an application~~***or use additional applications specific to the supplier***.;’

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

‘(a) the name, address***,*** and digital contact of the ~~suppliers~~***supplier(s)***;;’

(2a) in Article 17(1), the following point is inserted after point (a):

‘(aa) the telephone number of the supplier(s), unless this telephone number is immediately available through the digital contact;;’

(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***(s)*** of the mixture***, and the telephone number, unless this telephone number is immediately available through the digital contact***.;'

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

'2. ***Where the packaging of a substance or a mixture is either in such a shape or form or is so small that it is impossible to meet the requirements of Article 31 for a label in the languages of the Member State in which the substance or mixture is placed on the market,*** the label ~~elements set out in Article 17(1)~~***information*** may be reduced in accordance with the rules set out in section 1.5.2 of Annex I.~~;~~

2a. For packaging up to and including 10 ml, the label elements set out in Article 17(1) may be reduced in accordance with the rules set out in section 1.5.2.4 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 ***and in any event no later than 12 months*** 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~~***When advertising*** a substance or a mixture classified as hazardous or a mixture containing substances referred to in Part 2 of Annex II***, the advertisement*** shall ~~include the sentence: ‘Always read the label and product information before use.’.~~***only be made if the advertisement includes at least one of any of the following:***

   a) the applicable hazard pictograms;

   b) the relevant signal word in accordance with Article 20, followed by the sentence: ‘Always read the label and product information before use.’; or

   c) the sentence: ‘Always read the label and product information before use. See hazard information at point of purchase.';

2. ~~Any advertisement for~~***When advertising*** a substance or a mixture classified as hazardous***, the advertisement*** shall ***only be made if the advertisement does*** not contain statements that are not ~~allowed~~ to appear on the label or packaging of that substance or mixture in accordance with Article 25(4).~~²~~

;

3. Paragraph 1 shall not apply to advertisements to professional users for substances or mixtures intended for use in the course of their industrial or professional activities, provided that the advertisement is not targeted at consumers.’

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

‘Article 48a

Distance sales offers

1. 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.~~²~~

2. Paragraph 1 also applies to distance sales offers to professional users for substances or mixtures intended for use in the course of their industrial or professional activities, if the offer is made on a website or a mobile application, unless the website or mobile application is closed to the general public and only professional users are able to complete purchases.

;’

(9) Article 61 is amended as follows:

(a) paragraph 8 is replaced by the following:

‘8. Substances and mixtures which have been classified, labelled and packaged in accordance with Article 18(3)***, Article 31(3) and section 1.2.1 of Annex I*** 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.[2]

;’

(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].[2]

;’

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

Article 2

Amendments to Regulation (EC) No 1223/2009

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

(1) The following Article is inserted:

‘Article 14a

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

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

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

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

;’

(2) Article 15 is amended as follows:

(a) paragraph 2 is amended as follows:

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

‘~~2.~~ However, such substances may be used in cosmetic products if a derogation request is submitted to the Commission at the latest three months after at the date of entry into force of the amendments to Part 3 of Annex VI to Regulation (EC) No 1272/2008 classifying the substance as CMR substance of category 1A or 1B~~. The Commission shall grant the derogation~~ ***and*** where all of the following conditions are fulfilled:

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

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

;'

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

'For the purpose of the second subparagraph, point (a), a ***substance, a combination of substances, or where relevant, an alternative technology, that replaces the need for the*** substance shall be considered a suitable alternative if it fulfils all of the following conditions:

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

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

(c) is technically ~~feasible~~ and economically ~~viable~~***feasible***;

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

;'

(iii) the following ~~subparagraph is~~***subparagraphs are*** inserted after the fourth subparagraph:

'The deadline laid down in the fourth subparagraph of this paragraph shall start on the date of entry into ~~application~~***force*** of the relevant amendments to Part 3 of Annex VI to Regulation (EC) No 1272/2008 classifying the substance concerned as CMR substance of category 1A, ***1B, or 2*** ~~or 1B~~.~~;~~

Where a derogation request referred to in the second subparagraph of paragraph 2 has been submitted for CMR substances of category 1A, or 1B, this deadline shall be extended by nine months.

;'

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

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

‘6. The prohibition referred to in paragraphs 1 and 2 of this Article shall not apply to ~~a substance~~***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, at least one of which has been classified as a CMR substance of category 1A, 1B, or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008. ~~If~~***As*** a potential risk to human health arises from the use ~~of such substance~~ in cosmetic products ***of a substance containing a constituent classified as CMR category 1A, 1B or 2***, the Commission shall ~~seek an opinion of the SCCS on the safety of that substance for its use in cosmetic products~~ without undue delay ***request the SCCS to give its opinion on the safety of the CMR-constituents present in the substance for a particular use of the cosmetic product category, as part of the exposure assessment***.

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

7. Cosmetic products containing a substance classified as a CMR substance of category 1A, 1B, or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 prohibited from use in cosmetic products or such substance not compliant with a restriction may continue to be placed on the market for ~~12~~***6*** months and be made available on the market for ~~24~~***12*** months after the entry into force of the relevant amendments to the relevant Annexes to this Regulation.~~2~~

;’

(3) In Article 16, ~~paragraphs 3 and 7 are deleted~~***paragraph 3 is replaced by the following***;

‘3. In addition to the notification under Article 13, cosmetic products containing nanomaterials shall be notified to the Commission by the responsible person by electronic means prior to being placed on the market.

The first subparagraph shall not apply to cosmetic products containing nanomaterials that are in conformity with the requirements set out in Annex III.

The information notified to the Commission shall contain at least the following:

- ***(a) the identification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes II to VI;***
- ***(b) the specification of the nanomaterial including size of particles, physical and chemical properties;***
- ***(c) an estimate of the quantity of nanomaterial contained in cosmetic products intended to be placed on the market per year;***
- ***(d) the toxicological profile of the nanomaterial;***
- ***(e) the safety data of the nanomaterial relating to the category of cosmetic product, as used in such products;***
- ***(f) the reasonably foreseeable exposure conditions.***

The responsible person may designate another legal or natural person by written mandate for the notification of nanomaterials and shall inform the Commission thereof.

The Commission shall provide a reference number for the submission of the toxicological profile, which may substitute the information to be notified under point (d).

;’

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

‘6. The information mentioned in paragraph 1, point (g) shall be expressed by using the common ingredient name in accordance with the internationally recognised nomenclature and in the absence of a common ingredient name, a term as contained in a generally accepted nomenclature shall be used.~~²~~

;’

(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 ***to*** 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 ***freely*** accessible online communication channel ***such as email addresses*** through which economic operators can be ~~reached or engaged~~***contacted*** without the need to register or to download ~~an application~~***or use additional applications specific to the economic operator***;’

;’

(2) Article 6 is amended as follows:

(a) paragraph 2 is amended as follows:

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

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

(ii) the following subparagraph is added:

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

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

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

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

‘Manufacturers shall indicate on the packaging of the EU fertilising product their name, registered trade name or registered trademark as well as their postal address and digital contact or, where the EU fertilising product is supplied without packaging, in a document accompanying the EU fertilising product. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.²

;’

(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.²

;’

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

‘(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of an EU fertilising product;²

;’

(4) Article 8 is amended as follows:

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

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

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

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

(c) paragraph 8 is replaced by the following:

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

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

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

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

(5) Article 9 is amended as follows:

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

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

;’

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

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

;’

(6) Article 15 is amended as follows:

(a) paragraph 2 is replaced by the following:

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

(b) the following paragraph 3 is added:

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

;’

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

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

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

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

*Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information, (OJ L 172, 26.06.2019, p. 56, ELI: http://data.europa.eu/eli/dir/2019/1024/oj).[2]

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.[2]

;’

(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 ***a manufacturer demonstrates the*** compliance with those criteria~~ is demonstrated~~ in the conformity assessment of the EU fertilising product in accordance with that methodology, may be used as component material in EU fertilising products. The criteria and methodology shall allow ~~for verification~~***a notified body to verify*** that the micro-organisms fulfil the criteria in paragraph 1, point (b), and provide, as a minimum, for the consideration of the following elements:

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

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

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

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

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

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

*Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 1, ELI: http://data.europa.eu/eli/reg/2013/283/oj).~~2~~

;’

(10) ***In*** Article 43***, the following paragraph is added*** ~~is deleted~~;

‘By way of derogation from the first paragraph, the Commission may make changes in respect of several component material categories in Annex II by one delegated act in the following cases:

(a) to introduce or remove the same raw material;

(b) to introduce, amend or remove similar requirements.

;’

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

Article 4

Transitional provisions

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

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

By way of derogation from Article 17(1), Article 25(6) of Regulation (EC) No 1272/2008, section 1.5.1.2 and section 1.6 of Annex I to Regulation (EC) No 1272/2008 as applicable on [OP: please insert the date of the day before the date of entry into force of this Regulation], substances and mixtures may until [OP: please insert the date of the last day of the month following 35 months after the date of entry into force of this Regulation] be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by Article 1, points (2) and (3) of this Regulation and points (3) and (8) of Annex I to this Regulation.

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

Article 5

Entry into force and application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.
2. Points (4) to (7) of Annex I shall apply from 1 July 2026.
3. Article 1, points (5) to (8) and points (1), (2) and (9) of Annex I shall apply from 1 January 2028.
4. Article 1, points (1), (2) and (3), points (3) and (8) of Annex I shall apply from [OP: please insert the date of 36 months after the entry into force of this Regulation)]
5. Article 2, point (1) to (8) shall apply from [OP: please insert the date of entry into force of this Regulation)]
6. Article 3, point (1) to (8), and Annex IV, point (1) and (3), shall apply from [OP: please insert 24 months after entry into force of this Regulation].

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

Done at Strasbourg,

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

ANNEX I

Annexes I and II to Regulation (EC) No 1272/2008 are amended as follows:

(1) in Annex I, section 1.2.1.4 is replaced by the following:

‘1.2.1.4. The dimensions of the label and of each pictogram shall be as follows:

Table 1.3

Minimum dimensions of labels and pictograms

Capacity of the package	Dimensions of the label (in millimetres) for the information required by Article 17	Dimensions of each pictogram (in millimetres)
Not exceeding 3 litres:	If possible, at least 52 × 74	Not smaller than 10 × 10 If possible, at least 16 × 16
Greater than 3 litres but not exceeding 50 litres:	At least 74 × 105	At least 23 × 23
Greater than 50 litres but not exceeding 500 litres:	At least 105 × 148	At least 32×32
Greater than 500 litres:	At least 148 × 210	At least 46×46

’;’

(2) in Annex I, section 1.2.1.5 is ~~deleted;~~***replaced by the following:***

‘1.2.1.5. The text on the label shall be legible. Legibility means the physical appearance of information, by means of which the information is visually accessible and which is determined by various elements, inter alia, font size, letter spacing, spacing between lines, stroke width, type colour, typeface, width-height ratio of the letters, the surface of the material and significant contrast between the print and the background.

It shall have at least the following characteristics:

(a) printed in a contrasting colour compared to the background;

(b) a single typeface that is easily legible and without serifs shall be used;

(c) the letter spacing shall be appropriate for the selected typeface to be easily legible.

(d) the line spacing shall be appropriate for the selected typeface to be easily readable and to ensure that lines of text do not overlap.

(e) an appropriate font size with regard to the size of the label and the required label elements.

;'

(3) in Annex I, section 1.5.1.2 is replaced by the following:

'1.5.1.2. Where section 1.5.1.1 applies, the label on any inner packaging shall contain at least the hazard pictograms, the signal words, the product identifier referred to in Article 18(2) for substances or the trade name or designation referred to in Article 18(3), point (a) for mixtures, and the name and digital contact of the suppliers of the substance or mixture***, and the telephone number, unless this telephone number is immediately available through the digital contact***.;'

(4) the heading of section 1.5.2.4 is replaced by the following:

'1.5.2.4. Labelling of packages where the contents do not exceed 10 ml ;'

(5) in Annex I, section 1.5.2.4.1 is replaced by the following:

'1.5.2.4.1. The label elements set out in Article ~~17~~***17(1)*** may be omitted from the inner packaging where the contents of the inner packaging do not exceed 10 ml, the outer packaging meets the requirements set out in Article ~~17(1)~~***17*** and any of the following applies:

(a) the substance or mixture is placed on the market for scientific research and development or quality control analysis;

(b) the substance or mixture requires labelling in accordance with Part 1 or 2 of Annex II~~, except for section 2.8 of Part 2 of Annex II,~~ and is not classified in any of the following hazard classes and categories:

(a) acute toxicity, any category;

(b) specific target organ toxicity – single exposure, categories 1 and 2;

(c) specific target organ toxicity – repeated exposure, any category;

(d) skin corrosion, category 1, any sub-category;

(e) serious eye damage, category 1;

(f) respiratory sensitisation, any category;

(g) aspiration hazard;

(h) germ cell mutagenicity, any category;

(i) carcinogenicity, any category;

(j) reproductive toxicity, any category;

(k) endocrine disruption for human health, any category.;'

(6) in Annex I, section 1.5.2.4.2 is replaced by the following:

'1.5.2.4.2. Where section 1.5.2.4.1 applies, the label on the inner packaging shall contain the product identifier referred to in Article 18(2) for substances or the trade name or designation referred to in Article 18(3), point (a) for mixtures, and, where applicable, the hazard pictograms 'GHS01', 'GHS05', 'GHS06' or 'GHS08'. Where more than two pictograms are assigned, 'GHS06' and 'GHS08' may take precedence over 'GHS01' and 'GHS05'.';'

(7) in Annex I, section 1.5.2.4.3 is added:

'1.5.2.4.3. The label elements set out in Article 17(1) may be omitted from the package provided that the following conditions are met:

(a) the contents of the package do not exceed 10 ml;

(b) the substance or mixture does not require labelling in accordance with Part 1 or 2 of Annex II~~, except for section 2.8 of Part 2 of Annex II~~;

(c) the substance or mixture is not classified in any of the hazard classes and categories referred to in point (b) of section 1.5.2.4.1.;'

(8) in Annex I, section 1.5.2.4.4 is added:

'1.5.2.4.4. Where section 1.5.2.4.3 applies, the label on the packaging shall contain the product identifier referred to in Article 18(2) for substances or the trade name or designation referred to in Article 18(3), point (a) for mixtures, and, where applicable, the hazard pictograms 'GHS01' or 'GHS05'.';'

~~(8)~~***(9)*** in Annex I, section 1.6 is replaced by the following:

‘1.6. Label elements that may be provided on a digital label only

(a) Supplemental information referred to in Article 25(3);

(b) Where more than one supplier is indicated on the label in accordance with Article 17(1), point (a), the name, address and digital contact of the suppliers may be provided on a digital label only, as long as the supplier referred to in in Article 4(11) is indicated on the physical label.;

(c) The telephone number for the supplier(s) required according to Article 17(1), point (aa), and where relevant the third subparagraph of Article 25(6) and section 1.5.1.2 of Annex I;

;’

~~(9)~~***(10)*** in Annex II, Part 5 is replaced by the following:

‘PART 5: HAZARDOUS SUBSTANCES AND MIXTURES TO WHICH ARTICLE 29(3) APPLIES

(a) Ready mixed cement and concrete in the wet state shall be accompanied by a copy of the label elements in accordance with Article 17.

(b) For a substance or a mixture supplied at a filling station and directly pumped into a receptacle that forms an integral part of a vehicle and from where the substance or mixture is normally not intended to be removed, the copy of the label elements referred to in Article 17, points (c) to (h) shall be provided on a visible place on the respective pump. The unique formula identifier referred to in Article 25(7) does not need to be provided.

(c) When a vehicle fuel is supplied at a filling station through pumping into portable receptacles designed to be used for fuels, a copy of the label elements referred to in Article 17, points (c) to (h), shall be provided to be attached to the receptacle, unless the receptacle is already appropriately labelled. The unique formula identifier referred to in Article 25(7) does not need to be provided.~~.~~’

~~ANNEX II~~

~~In Annex I to Regulation (EC) No 1223/2009 Part A, point 2 is replaced by the following:~~

~~'2. Physical/chemical characteristics and stability of the cosmetic product~~

~~The physical and chemical characteristics of the substances or mixtures, as well as the cosmetic product.~~

~~The stability of the cosmetics product under reasonably foreseeable storage conditions.~~

~~The specification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in point 2 of the preamble to Annexes II to VI, size of particles, physical and chemical properties.~~

~~The safety data of the nanomaterial (including its toxicological profile and exposure conditions) relating to the category of cosmetic product, as used in such products.'~~

ANNEX III

Annexes II to VI to Regulation (EC) No 1223/2009 are amended as follows:

(1) in the preamble to Annexes II to VI, point 2, the fifth indent is replaced by the following:

'- the name included in the internationally recognised nomenclature.;'

(2) in the heading of tables in Annexes III to VI the title 'Name of Common Ingredients Glossary' is replaced by 'Name in the Internationally Recognised Nomenclature'.

ANNEX IV

Annexes I, II and IV to Regulation (EU) 2019/1009 are amended as follows:

(1) in Annex I, Part II, PFC 7: FERTILISING PRODUCT BLEND, point 4(c) is replaced by the following:

'(c) Article 8(8) (importers' obligation to keep the EU declaration of conformity at the disposal of the market surveillance authorities).;'

(2) in Annex II, Part II, is amended as follows:

(a) in CMC 1: VIRGIN MATERIAL SUBSTANCES AND MIXTURES, point 2 is ~~deleted;~~***replaced as follows:***

'a) Substances classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 for the following hazard classes or categories:

- ***Germ cell mutagenicity, category 1A or 1B;***
- ***Carcinogenicity, category 1A or 1B;***
- ***Reproductive toxicity, category 1A or 1B;***
- ***Specific target organ toxicity, repeated exposure, category 1;***
- ***Endocrine disruptor for human health, category 1;***
- ***Endocrine disruptor for the environment, category 1; and***
- ***Persistent, bioaccumulative and toxic or very persistent and very bioaccumulative properties.***

whose actual quantities placed on the market are lower than 10 tonnes per year, incorporated into the EU fertilising product, on their own or in a mixture, shall have been registered pursuant to Regulation (EC) No 1907/2006, with a dossier containing:

(i) the information provided for by Annexes VI, VII and VIII to Regulation (EC) No 1907/2006, and

(ii) 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, or 9 of Annex V to that Regulation.

b) Polymers are exempt from point a).

;'

(b) in CMC 3: COMPOST, point 1(d) is replaced by the following:

'(d) composting additives which are necessary to improve the process performance or the environmental performance of the composting process, provided that the total concentration of all additives does not exceed 5% of the total input material weight; or;'

(c) CMC 4: FRESH CROP DIGESTATE is amended as follows:

(i) point 1(b) is replaced by the following:

'(b) digestion additives which are needed to improve the process performance or the environmental performance of the digestion process, provided that the total concentration of all additives does not exceed 5% of the total input material weight; or;'

(ii) point 3d is replaced by the following:

'3d. Additives needed in the post processing of a digestate or a fraction in accordance with points 3a, 3b and 3c may be used provided that the concentration of the additives needed in each of the processes does not exceed 5 % of the weight of the digestate or fraction used as input in the respective process.;'

(d) CMC 5: DIGESTATE OTHER THAN FRESH CROP DIGESTATE is amended as follows:

(i) point 1(d) is replaced by the following:

'(d) digestion additives which are necessary to improve the process performance or the environmental performance of the digestion process, provided that the total concentration of all additives does not exceed 5% of the total input material weight; or;'

(ii) point 3d is replaced by the following:

'3d. Additives needed in the post processing of a digestate or a fraction in accordance with points 3a, 3b and 3c may be used, provided that the concentration of the additives needed in each of the processes does not exceed 5% of the weight of the digestate or fraction used as input in the respective process.;'

(e) in CMC 6: FOOD INDUSTRY BY-PRODUCTS, point 2 is deleted;

(f) in CMC 8: NUTRIENT POLYMERS, point 1 is replaced by the following:

‘1. An EU fertilising product may contain polymers exclusively made up of monomer substances complying with the criteria set out in point 1 of CMC 1, where the purpose of the polymerisation is to control the release of nutrients from one or more of the monomer substances.;’

(g) in CMC 10: DERIVED PRODUCTS WITHIN THE MEANING OF REGULATION (EC) No 1069/2009, the table, point 1.3 is replaced by the following:

‘1.3. Additives needed in the processing referred to in points 1.1 and 1.2 may be used, provided that the concentration of the additives needed in each of the processes does not exceed 5% of the weight of the processed manure or fraction used as input in the respective process.;’

(h) in CMC 11: BY-PRODUCTS WITHIN THE MEANING OF DIRECTIVE 2008/98/EC, point 2 is deleted;

(i) in CMC 12: PRECIPITATED PHOSPHATE SALTS AND DERIVATES, point 13 is deleted;

(j) in CMC 13: THERMAL OXIDATION MATERIALS OR DERIVATES, point 8 is deleted;

(k) in CMC 14: PYROLYSIS AND GASIFICATION MATERIALS, point 7 is deleted;

(l) in CMC 15: RECOVERED HIGH PURITY MATERIALS, point 10 is deleted;

(3) in Annex IV, Part II is amended as follows:

(a) MODULE A – INTERNAL PRODUCTION CONTROL is amended as follows:

(i) in point 4.2, the first sentence is replaced by the following:

‘The manufacturer shall draw up an EU declaration of conformity for an EU fertilising product or type in electronic form and keep it together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market.;’

(ii) point 4.3. is replaced by the following:

‘4.3. The manufacturer 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.;’

(b) MODULE A1 - INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT TESTING is amended as follows:

(i) point 2.2.(f) is replaced by the following:

‘(f) the names, postal addresses and digital contacts of the sites, and of the operators of the sites, at which the product and its principal components were manufactured,;’

(ii) in point 5.2., the first sentence is replaced by the following:

‘The manufacturer shall draw up an EU declaration of conformity for an EU fertilising product type in electronic form and keep it together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market.;’

(iii) point 5.3. is replaced by the following:

‘5.3. The manufacturer 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.;’

(c) MODULE B – EU-TYPE EXAMINATION is amended as follows:

(i) point 3.2.(a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his or her name, postal address and digital contact as well,;’

(ii) in point 6.1., the second sentence is replaced by the following:

‘The certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.;’

(d) MODULE C – CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL is amended as follows:

(i) in point 3.2., the first sentence is replaced by the following:

'The manufacturer shall draw up an EU declaration of conformity for an EU fertilising product type in electronic form and keep it together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market.;'

(ii) point 3.3. is replaced by the following:

'3.3. The manufacturer 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.;'

(e) MODULE D1 - QUALITY ASSURANCE OF THE PRODUCTION PROCESS is amended as follows:

(i) in point 5.2., the first indent is replaced by the following:

'the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his or her name, postal address and digital contact as well,;'

(ii) in point 7.2., the first sentence is replaced by the following:

'The manufacturer shall draw up an EU declaration of conformity for an EU fertilising product or type in electronic form and keep it together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market.;'

(iii) point 7.3. is replaced by the following:

'The manufacturer 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.'