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INFORMATION NOTE

From:	General Secretariat of the Council
To:	Delegations
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 - Offer letter sent to the European Parliament

At its meeting on 26 June 2026, the Permanent Representatives Committee:

a) confirmed the agreement on the compromise text of the above-mentioned draft Regulation, as it was reached between the negotiating parties on 16 June 2026, and as it is contained in the Annex of document 10621/26; and

b) authorised the Presidency to address the habitual offer letter to the European Parliament.

The letter is attached to the Annex, below, together with the text of the agreement, as it was sent to the European Parliament. This information is provided in accordance with point 1 (h) of Note 9493/20 on 'Strengthening legislative transparency.

Council of the European Union

Brussels, 26 June 2026

SGS 26/2376

Ms Anna CAVAZZINI
Chair of the Committee on the Internal Market and Consumer Protection
Mr Pierfrancesco MARAN
Chair of the Committee on the Environment, Climate and Food Safety

European Parliament
Rue Wiertz 60
B-1047 BRUSSELS

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

Dear Ms Anna CAVAZZINI, Mr Pierfrancesco MARAN,

Following the informal negotiations on this proposal between the representatives of the three institutions, today the Permanent Representatives Committee agreed with the final compromise text.

I am, therefore, in a position to inform you that, should the European Parliament adopt its position at first reading, in accordance with Article 294(3) TFEU, in the exact form of the text set out in the Annex to this letter (subject to revision by the lawyer-linguists of the two institutions), the Council, in accordance with Article 294(4) TFEU, will approve the European Parliament's position, and the act shall be adopted in the wording which corresponds to the position of the European Parliament.

On behalf of the Council, I also wish to thank you for your close cooperation which should enable us to reach agreement on this proposal at first reading.

Yours sincerely

Christina RAFTI
Chair of the
Permanent Representatives Committee

Copy:

- Mr Stéphane Séjourné, Executive Vice-President, Prosperity and Industrial Strategy
- Mr Dimitris TSIODRAS, European Parliament Rapporteur, Committee on the Environment, Climate and Food Safety
- Mr Piotr MÜLLER, European Parliament Rapporteur, Committee on the Internal Market and Consumer Protection

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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 ***administrative and*** regulatory burdens should be removed, while maintaining ~~the same~~***a high*** level of ***consumer protection,*** protection of human health and of the environment.

(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 individuals and between 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~~***would contribute to enhancing*** the effectiveness of official controls and enforcement and to expedite the process of ~~detecting~~ ***tracing*** 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~~.

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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).

(3a) The digital contact should allow users and competent authorities to contact suppliers directly, and should be accessible free of charge, without the need to provide any personal data, download or use 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, or any other direct means of digital communication without intermediate steps which allow for traceability of exchanges and should be interpreted in a technologically neutral manner. However, it should not be understood as encompassing automatic replies to queries, chatbots, fax numbers, or telephone lines.

(3b) 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.

(3c) To reduce required label space, suppliers should be permitted to provide the telephone number on the digital label 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.

(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[66] 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 cases ~~where the 10 ml derogation is applied~~***allowing for these elements to be omitted***.

(6) In order to provide ~~the flexibility~~ ***sufficient time*** for suppliers of substances and mixtures, ~~to create equal conditions~~***and in particular*** 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 15 months, while continuing*** to require the labels to be changed without undue delay after new data was obtained by or communicated to a supplier. ***The suppliers should cooperate and ensure the timely communication of the information about the changes in classification and labelling in the supply chain in order for the supply chain actors to meet their respective obligations in this regard.***

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

(7) 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 ***unjustified*** burden for industry[8]***, in particular for small and medium-sized enterprises***, 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~~**,** ***maintaining a high level of consumer protection and ensuring the proper functioning of the internal market. Suppliers*** must remain responsible for ensuring that the labels are legible in accordance with the legal requirements.

(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.

~~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.~~

(7b) To ensure that a label has an appropriate degree of readability, and considering that it is normally the sole source of information readily available to consumers, it is necessary to lay down mandatory font sizes requirements for the labels of substances and mixtures placed on the market for the general public. In particular, the label elements required by the Regulation (EC) No 1272/2008 should use a font size where the x-height is equal to or greater than 1.2 mm with a possibility to use x-height equal to or greater than 0.9 mm for small packaging. This, however, should not apply to label elements required by other EU legislation.

(7c) In order to assist enforcement by relevant national authorities and provide certainty for suppliers, the European Chemicals Agency (ECHA) is encouraged to update its guidance on labelling and packaging in accordance with CLP, providing the examples of what constitutes acceptable and unacceptable label formatting.

(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, 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***.

~~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 generally more informed about the hazards associated with a substance or mixture than general public and therefore it is appropriate to differentiate between the information requirements for general public as opposed to professional and industrial users of substances and mixtures. When determining whether an advertisement or a distance sales offer is targeted at general public, national competent authorities should take into account factors such as whether the advertisement or distance sales offer clearly states that the substance or mixture is only intended for professional users, and whether the distance sales offer allows to conclude a purchase of the substance or the mixture by the general public. 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.

(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 ***and to include the applicable pictograms***, ***or signal words but*** ~~but~~ not to duplicate ~~the~~***all*** hazard information from the label. ***This approach ensures that advertisements remain sufficiently informative in alerting potential users to the hazardous nature of the product without imposing requirements that would make advertisements cluttered, difficult to interpret or commercially impractical. 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~~*1* and Regulation (EU) No 528/2012 of the European Parliament and of the Council~~11~~*2* 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 the same ~~requirements~~***statement*** 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.

~~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).~~

(12a) Furthermore, in order to provide labelling flexibility for small packaging that have specific dimension or form constraints due to the technical requirements for their intended function, it is also appropriate to allow all the label elements, except for the hazard pictograms, on the inner packaging, to be provided in a digital label only through a data carrier. In order to maintain a high level of protection of human health and the environment, this possibility should be provided only for the inner packaging, while the outer packing or the tie-on tag should carry all the required label elements and a data carrier in a physical form. In accordance with the requirements laid down in Regulation (EU) 2024/2865, the digital label should contain all the label elements required by Regulation (EC) No 1272/2008.

(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.

(13a) Furthernore, it is also necessary to further defer the obligations introduced by Regulation (EU) 2024/2865 on formatting of labels, relabelling, advertisements, distance sales offers and labelling of fuels supplied at filling stations. Such further deferral would enable economic operators to prepare for changes introduced to those provisions by this Regulation.

(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***, 1B and category 2*** ~~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. ***Timelines related to the procedure for the adoption of the relevant measures for CMR substances category 1 and 2, including the extension of deadlines where a request for derogation is submitted, should be clarified in this Regulation.***

(17) The conditions allowing for exemptions from the ban of use of such substances in cosmetic products should be streamlined ***without lowering the high level of human health and safety and consumer protection***, 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, ***the*** 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 ***any*** alternative substance ~~should result in reduced overall risk to~~ ***is safe for*** human health and ***reduces the overall risk compared to*** ~~the environment and~~ the substance ***it is intended to replace. The alternative*** should provide an equivalent ~~or similar~~ function in ~~a~~***the finished*** cosmetic product~~, be~~ ***together with a comparable level of efficacy and performance and should be technically and economically feasible for businesses, in particular SMEs. To assess economic feasibility, economic aspects, such as reformulation costs and comparative contributions to overall production costs, should be considered. In addition, the assessment should take into account whether the alternative is subject to restrictions under Union legislation that could limit its use in cosmetic products. Market availability should also be assessed, including whether the alternative is*** available ~~on the market in~~ ***at scale and in*** sufficient quantities~~, so that it can be technically feasible and economically viable for businesses and especially for SMEs. In addition~~ ***to meet current and expected demand within a reasonable timeframe, to allow sustained production. In this context, the assessment would also consider whether exclusive rights may unduly restrict*** access to the ~~substance should not be restricted by patents or raw material restrictions. It should also be possible to consider the~~ ***alternative and its effective use by*** 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~~***operators***.

(18a) To promote consistency and predictability of the assessment of alternatives, the Commission should be encouraged to develop guidance, in consultation with the ECHA, Member States and relevant stakeholders. In that context, and in order to facilitate the assessment of alternatives, the word "Technically feasible" highlights that it has to be possible to apply the alternative with technologies and methods generally available. The precise interpretation of these terms and their application may depend on the specific context of the assessment of suitable alternatives. Such guidance should at least explain criteria for economically and technically feasible alternatives and indications of established best practices.

(18b) In order to support the assessment of suitable alternatives and enhance the transparency of the derogation procedure, the Commission should make publicly available information on substances for which a derogation request has been submitted. Interested parties should be able to provide information on the suitability of alternative substances within a specified period. Such information may contribute to a more comprehensive assessment of the availability of suitable alternatives.

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

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

(21) ~~Often a substance can also be a~~***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, are often referred to a s***~~of~~ natural complex substances, ~~for example essential oils. In such cases~~***or 'NCS'. They may contain one or more constituents classified as CMR substances, while the overall natural complex substance is not itself classified as a CMR substance. A high level of consumer protection should apply to such substances and should be grounded in the latest scientific evidence, while duly taking into account the actual conditions of exposure resulting from their use in cosmetic products.*** 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~~***where the*** natural complex substance ~~is~~ itself ~~listed as~~***is classified as a*** CMR substance of category 1A, 1B or 2 in Part 3 of Annex VI to ~~the~~ Regulation (EC) No 1272/2008. Nevertheless, since the harmonised classification of a constituent ~~may raise~~***raises*** concerns ~~as to the~~ ***about the*** safety of the natural complex substances when used in cosmetic products, the Commission should ***without delay*** mandate the SCCS to assess the ~~impact of such~~***safety of a CMR classified*** constituent ~~on the safety of natural complex substances, if a safety concern arises, and is to follow up with the~~***when present in such NCS and, where necessary, take*** appropriate regulatory ~~measures~~***action*** in accordance with Article 31(1) of Regulation (EC) No 1223/2009. ***The timeline for the assessment of the SCCS should be provided in this Regulation to ensure safety for consumers and predictability for businesses.***

(22) When a substance is prohibited or restricted from the use in cosmetic products, the manufacturers, importers, distributors and responsible persons should be given appropriate time to take necessary measures to reformulate***, test and*** ~~and~~ relabel their products, withdraw from the distribution and destroy the unsold products not complying with the new requirements. ***The length of such transitional*** ~~Therefore,~~ periods ***should reflect the safety considerations. Accordingly, if no derogation request was submitted, a period of 6*** ~~of 12~~ months for placing and ~~24~~ ***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. ***In case a request for derogation has been submitted and the SCCS has found that the substance is not safe when used in cosmetics, those deadlines should be shortened to a period of 3 months for placing and 9 months for making available on the market. In case a request for derogation has been submitted and the SCCS has found that the substance is safe, but the derogation has not been granted due to the availability of suitable alternatives, those deadlines should be extended to 24 months for placing and 36 months for making available on the market, under the condition that an up-to-date Cosmetic Product Safety Report (CPSR) remains available at all times.***

(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 to the Commission 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'~~ ***Ingredients (INCI)***names ~~is an important factor promoting~~ ***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 to be used on~~ ***nomenclature, such as INCI, 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 the 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.***

(25a) In order to ensure a high level of protection of human health, all cosmetic products placed on the Union market, whether offline or online, should be subject to equivalent obligations and effective control. This is particularly important given the growing sale of cosmetic products via online marketplaces Therefore, it is necessary to require certain labelling information referred to in Article 19 to be clearly and visibly indicated in case of distance sales, including via online marketplaces. This requirement will simplify enforcement of Regulation (EC) No 1223/2009 and thereby contribute to fair competition and a high level of protection of human health.

(25b) Fertilising products covered by Regulation (EU) 2019/1009 are subject to regulatory requirements and administrative burdens which, when increased, may widen the gap between agricultural production costs in the Union and those in third countries. The amendments to this Regulation should therefore provide for regulatory simplification that will benefit EU fertilising products manufacturers and EU farmers. Reduced administrative burdens and new opportunities for innovative products to access the single market are expected to result in broader availability of affordable and efficient EU fertilising products across the Single Market. . However, simplification should not undermine a high level of protection of human animal and plant health, safety and the environment nor lower the levels of controls on the products when entering the market.

(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, ***Regulation (EU) 2019/1009 should be aligned, as appropriate, to other pieces of EU product legislation as amended by Regulation (EU) XXXX/XXXX of the European Parliament and of the Council[13].*** 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~~***contacted by competent national authorities and end-users so as to adequately answer any queries from those***, draw up the EU declaration of conformity in electronic form and make it accessible via an internet address or data carrier, and provide ***competent national*** authorities, upon request, with all relevant information and documentation ***in a swift manner*** 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 ***in a swift manner***. 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.

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[13] Regulation (EU) XXXX/XXXX of the European Parliament and of the Council[1] amending Regulations (EU) No 765/2008, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/1230, (EU) 2023/1542 and (EU) 2024/1781 as regards digitalisation and common specifications

(26a) Digitalisation of EU declarations of conformity, technical and documents exchanged between economic operators, competent national authorities and notified bodies is expected to reduce financial and administrative burden for companies, in particular SMEs, and authorities. To ensure effective implementation, due regard should be given to the availablity and interoperability of digital infrastructure and effective and swift enforcement.

(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~~ . ***At the same time, the regulatory framework should ensure that the***use of traditional ***and natural*** fertilisers ***other than microbial plant biostimulants remains a viable and accessible option, recognising their role alongside microbial solutions, so as not to undermine competitiveness or agricultural production within the Union***.

(28) ***The wider use of microbial plant biostimulants can improve nutrient-use efficiency and soil biological activity, thereby fostering the development of sustainable while highly productive agriculture.*** 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 ***microbial strains*** ~~micro-organisms~~. Those criteria and ***methodology should reflect the most recent scientific developments and*** ~~the methodology should~~ allow manufacturers and notified bodies***, to*** ~~to~~ demonstrate and verify that ~~micro-organisms~~ ***each strain*** 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 ***invite a scientific body, such as the European Food Safety Agency, the JRC or ECHA to review and contribute, and also*** carry out appropriate consultations during its preparatory work, including at expert level~~, and that~~***. It is essential that the Commission preserves strong interinstitutional cooperation, while engaging in*** those consultations***, which should*** be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[14]~~. In~~ ***[13].***

~~14~~ ~~OJ L 123, 12.5.2016, p. 1, ELI: http://data.europa.eu/eli/agree_interinstit/2016/512/oj.~~

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. ***This new mechanism should facilitate the timely assessment of new strains, while ensuring that only those meeting Union safety requirements are allowed on the market.***

(28a) In order to ensure that new materials not already covered by existing component material categories in Annex II to Regulation (EU) 2019/1009 can be timely used for the production of EU fertilising products, if safe and agronomically efficient, the Commission should be empowered in accordance with Article 290 of the Treaty on the Functioning of the European Union, Article 42, paragraph 1, of Regulation (EU) 2019/1009, to develop general criteria and a methodology to be used for the assessment of safety and agronomic efficiency by manufacturers and for the subsequent verification by notified bodies. The Commission should aim for criteria and methodology that would allow the assessment of any material. However, if this general approach should not be possible, the Commission should define criteria and a methodology at least for the categories of materials for which safety and agronomic efficiency can be ensured. In that context, the Commission should, as appropriate, develop a new self-standing component material category. In case no criteria and methodology can be established, the Commission should justify why this is not possible.

(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.

(29a) Regulation (EU) 2019/1009 aims to facilitate the placing on the internal market and free movement of safe fertilising products, while supporting the recycling of nutrients and the circular use of materials and ensuring a high level of protection for human, animal and plant health and the environment. The effective application thereof depends, among other things, on the determination of end points for derived products from animal by-products within the meaning of Regulation (EC) No 1069/2009. To allow for the swift uptake of new derived products for which an end point is determined, the timeline and procedure for including such materials as component materials under Regulation (EU) 2019/1009 should be clarified while ensuring a high level of protection for human health and the environment.

(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~~ ***introduced additional registration*** 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~~***for*** substances used in EU fertilising products ~~should only follow the~~***, going beyond those set out in Regulation (EC) No 1907/2006. In order to ensure proportionality while maintaining a high level of protection of human health and the environment, it is appropriate to align the registration*** requirements~~, including the relevant gradations,~~ ***for substances used in EU fertilising products with those*** set out in Regulation (EC) No 1907/2006***, taking into account the relevant tonnage thresholds and information requirements***. ***However, for substances with certain severe hazardous properties, more extensive information should continue to be required where such substances are placed on the market in quantities below 10 tonnes per year, except where they are used in an EU fertilising product in very low concentrations. The information provided should be based on available data, including the use of alternative methods and adaptations in accordance with Regulation (EC) No 1907/2006, and should, wherever relevant and in last resort, avoid unnecessary testing, in particular on vertebrate animals. A chemical safety report should be provided which specifically covers the use of the substance in or as a fertilising product.***

The report may therefore be limited to exposure scenarios related to the agronomic use of fertilising products including their release into the environment. Such an approach ensures a balanced framework that supports innovation and market access, while safeguarding a high level of protection and legal certainty for operators.

(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, ***taking into account the potential costs of introducing and operating new digital systems and the diversity of economic operators and national systems*** 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~~***suppliers*** 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~~ ***paragraphs 1 and 2 are*** replaced by the following:

‘1. 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 laid down in 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) shall be provided in accordance with section 1.5.1 of Annex I.;"

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.~~;~~ ***where:***

a) the content of the packaging of a substance or a mixture does not exceed the quantities indicated in section 1.5.2. of Annex I; and

b)the packaging is either in such a shape or form or is too small in size to allow for a full reference to all the elements referred to in Article 31 in the languages of the Member State in which the substance or mixture is placed on the market.

’

(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 15 months*** after the results of the new evaluation referred to in Article 15(4) are obtained by, or communicated to, that supplier.;’

5a. in Article 30, paragraph 2a is added:

‘2a. For the purpose of paragraphs 1 and 2, suppliers shall cooperate in accordance with Article 4(9) and communicate the information regarding the change of the classification or labelling in the supply chain in accordance with the applicable requirements of Title IV of Regulation (EC) 1907/2006 with a view to complete the changes to the labelling without undue delay.’

(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~~***spacing*** as to be ~~easily~~***easy to*** read. ***They shall be formatted in accordance with section 1.2.1 of Annex I.***;’

(7) Article 48 is replaced by the following:

‘Article 48

Advertisement

1. Any advertisement to the general public for a substance or a mixture classified as hazardous or a mixture containing substances referred to in Part 2 of Annex II shall include the sentence: ‘Always read the label and product information before use.’***, and the applicable hazard pictogram(s) or the signal word***.

~~1a.~~

1a. The first subparagraph 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 the general public.

~~1c.~~

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

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

‘Article 48a

Distance sales offers

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. 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 allows a member of the general public to conclude a distance contract as defined in Article 2, point (7) of Directive 2011/83/EU;’ ’

(9) Article 61 is amended as follows:

(a) paragraph 8 is replaced by the following:

‘8. Substances and mixtures which have been classified, labelled and packaged in accordance with Article 18(3) as applicable on 9 December 2024 and which were placed on the market before 1 January 2027 shall not be required to be classified, labelled and packaged in accordance with this Regulation as amended by Regulation (EU) 2024/2865 of the European Parliament and of the Council until 1 January 2029.~~’~~

8a. Substances and mixtures which have been classified, labelled and packaged in accordance with Article 31(3) and section 1.2.1 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 the date of the last day of the month following 17 months after the date of entry into force of this Regulation] shall not be required to be classified, labelled and packaged in accordance with this Regulation as amended by [OP: please add reference to this Regulation] until [OP: please insert 42 months after the entry into force of this Regulation]. ’

(b) the following paragraph is added:

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

;’

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

Article 2

Amendments to Regulation (EC) No 1223/2009

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

(1) The following Article is inserted:

‘Article 14a

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

1. A request for a substance to be used as a colorant, preservative or UV-filter to be included in Annex IV, Annex V or Annex VI, as applicable, may be submitted to the Commission. It shall be accompanied by scientific evidence and documentation showing that due to the latest technical and scientific progress, the substance is safe for use in cosmetic products.
2. After receiving the request referred to in paragraph 1, the Commission shall ~~seek an opinion of~~***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) Article 15 is amended as follows:

(-a) The following subparagraphs are inserted in the first paragraph of article 15: "The measures laid down in the first subparagraph shall be adopted within the time limits referred to in the fourth, fifth and sixth (5a) subparagraphs of paragraph 2." The evaluation by the SCCS referred to in the first subparagraph shall be triggered by a derogation request submitted to the Commission at the latest three months after the 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 2."

(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 ***exceptionally,*** 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***, and the Commission grants the derogation from the general prohibition laid out in subparagraph 1***. The Commission shall grant the derogation where all of the following conditions are fulfilled:

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

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

;'

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

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

(a) its use in cosmetic products ~~results in reduced~~***is safe and reduces the*** overall risk to human health ~~and the environment;~~***compared to the substituted substance.***

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

(c) is technically ~~feasible~~ and economically ~~viable~~***feasible provided that costs and supply conditions allow sustained production***;

(d) it is not restricted~~, not protected by exclusive rights,~~ and is ***either*** available on the market at scale~~,~~ ***and*** in quantities ~~large enough~~***sufficient*** to meet current ~~and~~***demand or has the potential to meet current or*** expected demand.~~2~~

Within 12 months after the entry into force of this regulation, the Commission shall, in consultation with ECHA, Member States and relevant stakeholders, develop guidance on the analysis of alternatives.

The Commission shall make available on its web-site relevant information with regard to the substances for which a derogation request was received, with a deadline by which information on the suitability of alternative substances may be submitted by third parties.

;'

(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, or 1B.~~;~~

5a. 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 may, where relevant, be extended by twelve 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 substances~~***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~~***presence*** of such ~~substance~~***constituent classified as CMR category 1A, 1B or 2 in such substances*** in cosmetic products, the Commission shall ~~seek~~***without delay request*** an opinion of the SCCS on the safety of that ~~substance~~***constituent*** for its ~~use~~***presence*** in cosmetic products***. The SCCS shall deliver its opinion within 12 months after receiving the request from the Commission. The Commission may extend that deadline by six months if additional evidence is required. The SCCS shall deliver its final opinion within six months of submission of additional data. The opinion of the SCCS shall be made publicly available. Taking into account the opinion of the SCCS, the Commission shall,*** without undue delay***, amend the Annexes to this Regulation***.

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~~***No 1272/2008, for which a derogation request (a) was not submitted in accordance with paragraphs 1 or 2, are prohibited from use in cosmetic products. However, they may continue to be placed and made available on the market for 6 and 12 months, respectively, after the entry into force of the relevant amendments to Annex II to this Regulation. (b) was submitted in accordance with paragraphs 1 or 2, but not granted due to safety concerns by the SCCS, are*** prohibited from use in cosmetic products ~~or such substance not compliant with a restriction~~***. However, they*** may continue to be placed ***and made available*** on the market for ~~12~~ ***3 and 9***months***, respectively, after the entry into force of the relevant amendments to Annex II to this Regulation. Cosmetic products containing a substance classified as a CMR substance of category 1A or1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008 and for which a derogation request was submitted in accordance with paragraph 2 but not granted due to the availability of a suitable alternative, are prohibited from use in cosmetic products. However, they may continue to be placed and*** ~~and be~~ made available on the market for 24 ***and 36*** months***, respectively,*** after the entry into force of the relevant amendments to ~~the relevant Annexes~~ ***Annex II*** to this Regulation.~~’~~ ***In this case, the cosmetic product safety report (CPSR) shall be updated.***

;’

(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.’

(4a) In Article 19, the following paragraph is added:

'6a. When cosmetic products are made available on the market through distance sales, the offer shall clearly and visibly indicate the information referred to in paragraph 1 (a), (b), (d) (f) and (g).’

;’

(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 ***as referred to in Article 16***, in electronic form, and affix the CE marking ***referred to in Article 17***.;’

(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 ***directly*** 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~~***contacted***.’

~~;’~~

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

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

;’

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

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

(4) Article 8 is amended as follows:

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

‘They shall ensure that the manufacturer has drawn up the technical documentation, that the EU fertilising product is accompanied by the internet address or data carrier through which the EU declaration of conformity can be ***directly*** 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 ***directly*** 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)~~***through which it can be directly accessed***.

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

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

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

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

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

'(c) the EU declaration of conformity has not been drawn up or has not been drawn up correctly, or the EU fertilising product is not accompanied by the internet address or data carrier through which the EU declaration of conformity can be ***directly*** 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 ***conformity*** assessment of ***microbial strains*** ~~micro-organisms~~ other than those listed in Annex II~~, which, if~~ ***. The criteria and methodology shall allow manufacturers and notified bodies to assess at strain level whether a micro-organism fulfils the criteria in paragraph 1, point (b). If a manufacturer demonstrates and the notified bodies confirm after verification*** compliance with those criteria ~~is demonstrated~~ in the conformity assessment of the EU-fertilising product in accordance with that methodology, ***this strain*** may be used as component material in EU fertilising products.~~-~~ The criteria and ~~-~~methodology shall allow ~~for verification that the micro-organisms fulfil the criteria in paragraph 1, point (b), and provide~~, as a minimum, for the consideration of the following elements:

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

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

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

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

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

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

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

(ba) The following paragraph 4ab is inserted:

'By [36 months after the date of entry into force of this amending Regulation] the Commission shall adopt a delegated act [pursuant to paragraph 1 of this Article] establishing general criteria and a methodology for the assessment of materials other than those already listed in Annex II, excluding micro-organisms, or, if that should not be possible, criteria and a methodology for categories of such materials, which may be used by a manufacturer of an EU fertilising product to demonstrate that the material fulfils the criteria in paragraph 1, point(b), and, as appropriate, a new component material category. The criteria and methodology shall, as a minimum, provide for the consideration of scientific or technical information supporting safe use of the material in an EU fertilising product and fulfilling the criteria in paragraph 1, point (b). Where the development of general criteria and a methodology for the assessment of materials has not been possible within the deadline referred to in the first sub-paragraph, the Commission shall present within the same deadline a report to the European Parliament and to the Council providing detailed justification, including the reasons why a delegated act establishing general criteria and a methodology for the assessment of materials could not be adopted. In this report, the Commission shall also provide detailed justification why a delegated act establishing criteria and a methodology for categories of materials could neither be adopted.'

(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 an end point in the manufacturing chain has been determined in accordance with Article 5(2) of that Regulation. The Commission shall assess such derived products with respect to relevant aspects not taken into account for the purpose of determining an end point in the manufacturing chain in accordance with Regulation (EC) No 1069/2009, including risks, in particular with regard to protection of soil and water, arising from the application of fertilising products made available in accordance with Regulation 2019/1009 containing the respective materials. That assessment shall, as a rule, be initiated within 12 months from the date on which the end point in the manufacturing chain was determined. If the assessment concludes that the criteria in point (b) of paragraph 1 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. In those delegated acts, the Commission shall lay down requirements that are proportionate and sufficient to ensure a high level of protection of human health and the environment and the efficient use of the derived products as component materials in EU fertilising products.'

~~(b)'~~

(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 component material;

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

;'

(10a) the following Article 49b is inserted:

'Review

The Commission shall periodically review the existing requirements set out in Annexes I, II, III and IV in light of technical progress and scientific evidence, taking into consideration national practices, and the objectives of Regulation (EU) 2019/1009. The first review shall consider the requirements applicable for nutrient polymers covered by CMC 8 and be carried out no later than [OP please insert 7 years after the date of entry of force of this Regulation].'

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

Article 3a

Amendments to Regulation (EU) 2024/2865

Article 2 of Regulation (EU) 2024/2865 is amended as follows:

(a) paragraph 3a is replaced by the following:

'3a Article 1, points (14), (15)(c), (26) and (27), points (2) and (3) of Annex I and point (2) of Annex II shall apply from [OP: please insert 18 months after the entry into force of this Regulation];'

(b) paragraph 6 is replaced by the following:

'6. By way of derogation from Article 30, Article 31(3), Article 48 of Regulation (EC) No 1272/2008, section 1.2.1 of Annex I and Part 5 of Annex II to Regulation (EC) No 1272/2008, as applicable on 9 December 2024, substances and mixtures may until [OP: please insert the date of the last day of the month following 17 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 (14), (15)(c) and (26) of this Regulation and points (2) and (3) of Annex I and point (2) of Annex II 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.~~

1 By way of derogation from Article 30***, Article 31(3),*** and Article 48 of Regulation (EC) No 1272/2008***, section 1.2.1 of Annex I*** 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~~***[OP: please insert the date of the last day of the month following 17 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 (5)~~, (7) and~~ ***to*** (8) of this Regulation and ~~point~~***points (1), (2) and*** (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 ***(2a),*** (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~~***30*** 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~~***[OP: please insert [18 months] after the entry into force of this Regulation]***.
4. Article 1, points (1), (2) and (3), points ***(2a),*** (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)~~***points (1) to (4) and points (5)*** to (8) shall apply from [OP: please insert the date of entry into force of this Regulation)]

5a. Article 2, point (4a) shall apply from [OP: please insert the date of 12 months after the 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~~***30*** 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:

'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.Formatting requirements [in accordance with Article 31(3)]***

1.2.1.5.1. The text on the label shall be legible. For the purpose of this section, the legibility should be defined by the physical appearance of information, which enables it to be 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.

1.2.1.5.2. The text on the label shall have at least the following characteristics:

(a) a contrasting colour compared to the background;

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

(c) letter spacing that is appropriate for the selected typeface to be legible;

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

(e) font size that is appropriate with regard to the size of the label, the required label elements and the intended user.

1.2.1.5.3. Where the substance or mixture is placed on the market for the general public, the text of the label elements referred to in Article 17(1) shall be printed in characters using a font size where the x-height is equal to or greater than 1.2 mm.

1.2.1.5.4. By way of derogation from section 1.2.1.5.3., where the contents of the package of the substance or mixture placed on the market for the general public do not exceed 125 ml, the text of the label elements referred to in Article 17(1) may be printed in characters using a font size where the x-height is equal to or greater than 0.9 mm.'

1.2.1.5.5. Sections 1.2.1.5.3 and 1.2.1.5.4 shall not apply to label elements referred to in Article 25(9).

(2a) in Annex I, point (i) of section 1.2.1.6.1 is replaced by the following:

'(i) the name, address, the digital contact and the telephone number of suppliers unless this telephone number is directly available through the digital contact;'

(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***, the*** ~~and~~ digital contact ***and the telephone number*** of the suppliers of the substance or mixture~~.~~ ***unless this telephone number is directly 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.;'

7a in Annex I, section 1.5.2.4.3a is added:

'1.5.2.4.3a. 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) 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 of 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;

(d) Where Section 1.5.1 of Annex I applies, and where the physical dimensions and surface area of the inner packaging are constrained by the technical requirements for its intended function, the applicable label elements referred to in Article 17(1), except for the hazard pictograms, from the inner packaging can be provided on a digital label only. In this case, the data carrier shall be provided on the inner packaging and on the outer packaging or tie-on tag. In such cases, by way of derogation from Article 31(1b) second subparagraph, the statement "More hazard information available online" or a similar indication shall only accompany the data carrier on the outer packaging or tie-on tag.'

(9) 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~~***17(1)***, 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:***

Where a substance, other than a polymer, is included 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, intentionally incorporated into the EU fertilising product, on their own or in a mixture, in a concentration equal to or greater than the cut-off values set out in Article 11(3) of Regulation (EC) No 1272/2008, 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, insofar as relevant and available, Annex VIII to Regulation (EC) No 1907/2006, on the basis of available data, alternative methods pursuant to Article 13 and adaptations pursuant to Annex XI, and conducting new tests on vertebrate animals only as a last resort and where relevant, and

(ii) a chemical safety report pursuant to Article 14 of Regulation (EC) No 1907/2006 strictly limited to the exposure scenarios related to the agronomic use and the environment,

unless explicitly covered by one of the registration obligation exemptions provided for by Article 9 (PPORD) of Regulation (EC) No 1907/2006, used exclusively for scientific research and development, 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.

(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.'