European Parliament
2024-2029

Committee on the Environment, Climate and Food Safety
Committee on the Internal Market and Consumer Protection

2025/0531(COD)

09.04.2026

COMPROMISE AMENDMENTS 1 - 3

Draft report
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(PE782.180v01-00)

on the 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

Proposal for a regulation
(COM(2025)0531 – C9-0424/2023 – 2025/0531(COD))

Compromise Amendment 1
CLP
Articles 1, 4(1), 5(1-4)
Annex I
Recitals 1-14

Compromise Amendment replacing Amendments: 1-11, 30-46, 81-88, 101-160, 250-340, 497-509, 512-557, 606-607; AGRI 1-2, AGRI 4

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(2) The findings of the 2024 Draghi report[2] indicated that the increasing number and complexity of rules risks limiting room for manoeuvre for Union businesses and preventing them from remaining competitive. Against this background, certain procedures and requirements laid down in Regulations (EC) No 1272/2008[3] , (EC) No 1223/2009[4] and (EU) 2019/1009[5] of the European Parliament and of the Council should be simplified and unnecessary regulatory burdens should be removed, while maintaining ***the same*** level of protection of human health and of the environment.	(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 ***a high*** level of ***consumer protection,*** protection of human health and of the environment.
[2] 2024 report by Mario Draghi on the future of European competitiveness: https://commission.europa.eu/topics/eu-competitiveness/draghi-report_en#paragraph_47059	[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).	[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	[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).

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).

Or. en

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) In line with the Commission's objective to promote the 'digital by default' principle to support digital transformations and in order to facilitate communication between ***economic operators*** and national authorities responsible for enforcement, the indication of a digital contact on the label of hazardous substances and mixtures ***is necessary to enhance*** the effectiveness of official controls and enforcement and to expedite the process of detecting substances and mixtures that do not comply with the requirements of Regulation (EC) No 1272/2008. Currently, suppliers are required to indicate their address and telephone number on the label of the packaging of hazardous substances or mixtures, but this is not always sufficient to ensure that authorities responsible for enforcement can establish rapid contact. It is therefore necessary to require suppliers to provide a digital contact, which ***could*** be any up-to-date ***and*** accessible online communication channel with the supplier.	(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 ***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 ***contributes to enhancing*** the effectiveness of official controls***, traceability, accountability*** and enforcement and to expedite the process of detecting substances and mixtures that do not comply with the requirements of Regulation (EC) No 1272/2008***, as well as to ensure consumers have a quick and direct contact in case of an emergency or accident***. 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 ***should*** be any up-to-date***, easily and freely*** accessible online communication channel with the supplier***, which allows for the storage of information on a durable medium***. ***Where a digital contact is provided, the telephone number can be made directly available through that digital contact.***

Or. en

Proposal for a regulation
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3 a) The digital contact should allow consumers and authorities to contact suppliers directly and swiftly, and should be accessible free of charge, and without the need to provide any personal data, download or use an application or an obligation to register solely for the purpose of contacting the supplier. Such digital contact could include, for example, an email address or a contact form on a website. However, it should not be understood as encompassing automatic replies to queries, chatbots or fax numbers. 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 understood in a technologically neutral manner, capable of evolving with future technological developments, and cover all forms of direct digital communication.

Or. en

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) Regulation (EU) 2024/2865 of the European Parliament and of the Council[6]	(5) Regulation (EU) 2024/2865 of the European Parliament and of the Council[6]

introduced exemptions from labelling and packaging requirements for packages containing less than 10 ml. However, ***further simplifications are needed with regard to the application of this derogation in cases where these packages are subject to the supplementary hazard statement EUH 208.*** It is ***also*** necessary to clarify the ***requirements for inner and*** outer packaging in cases ***where the 10*** ml ***derogation is applied***.

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, it is necessary to ***simplify these provisions and*** clarify ***cases that require labelling elements to be presented on*** the outer packaging in cases ***allowing for these elements to be fully omitted. In addition, the Commission should carry out an assessment on whether further specific reductions of mandatory label elements should apply to packages between 10 and 125*** ml.

[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).

[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).

Or. en

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(6) In order to provide ***the flexibility for*** suppliers of substances and mixtures, ***to create equal conditions*** for small and medium-sized enterprises who often outsource label printing services and to facilitate the preparation and production of fold-out labels, which is significantly longer than the production of the standard labels, it is necessary to ***remove a*** fixed six months relabelling deadline ***and*** to require the labels to be changed without undue delay after new data was obtained by or communicated to a supplier.	(6) ***With regard to the updating of labels in case of new or more severe self-classification, suppliers should inform their direct downstream users about the results of the new evaluation without undue delay.*** In order to provide ***sufficient time for all*** suppliers of substances and mixtures, ***in particular,*** for small and medium-sized enterprises who often outsource label printing services and to facilitate the preparation and ***the*** production of fold-out labels, which is significantly longer than the production of the standard labels, it is necessary to ***extend the*** fixed six months relabelling deadline ***to eighteen months, while***

continuing to require the labels to be changed without undue delay after new data was obtained by or communicated to a supplier.

Or. en

Proposal for a regulation
Recital 7

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

Proposal for a regulation
Recital 7 a (new)

Text proposed by the Commission	*Amendment*
	(7 a) The label serves as a primary and often single source of hazard information and safe-use guidance readily available to consumers, while professional and industrial users are also informed about the hazards associated with a particular substance or mixture prior to use through safety data sheets and safety training. Therefore, it is indispensable that a label is easily readable not only under normal conditions, but also in exceptional circumstances such as accidents.
	Or. en

Proposal for a regulation
Recital 7 b (new)

Text proposed by the Commission	*Amendment*
	(7 b) To ensure that a label has an appropriate degree of readability, it should at least have a clear contrast of the text of the label to the background, a suitable typeface, an appropriately sized font, appropriate line and letter spacing, overall label design and other relevant

formatting elements. In particular, for substances or mixtures made available on the market for the general public, the label elements referred to in Article 17(1) should use a font size where the x-height is equal to or greater than 1.2 mm. However, when the contents of the package do not exceed 125 ml, the label elements referred to in Article 17(1) might use a font size where the x-height is equal to or greater than 0.9 mm. The European Chemicals Agency (ECHA) should update its guidance on formatting of labels and include clear examples of what constitutes acceptable and unacceptable examples of label formatting. The guidance should consider labelling formats from other relevant Union laws and take account of best practice on "accessible design" and accepted standards for readability, including acceptable as well as unacceptable colour combinations to ensure contrast. The guidance should assist enforcement by relevant national authorities, be developed in line with Better Regulation principles and informed by appropriate stakeholder consultation, support competitiveness by reducing unnecessary burdens, provide certainty for suppliers, and ensure fair competition on the internal market.

Or. en

Proposal for a regulation
Recital 8

Text proposed by the Commission	*Amendment*
(8) To alleviate the burden on industry and to improve the free circulation of substances and mixtures in the internal market it is appropriate to amend Regulation (EC) No 1272/2008 as regards the rules on advertisements and distance offers, taking advantages of existing provisions in other Union legislation with the same objectives. In this regard, requirements for advertisements and	(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 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.

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.

[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).

[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).

Or. en

Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8 a) Professional and industrial users are generally better informed about the hazards associated with substances and mixtures than consumers. It is therefore appropriate to differentiate information requirements with respect to advertisement depending on whether products are intended for professional and industrial use or for consumers or directly made available to them. When assessing whether an advertisement is targeted at consumers or made available to them, competent authorities should take into account objective elements, including whether it is clearly indicated that the substance or mixture is intended exclusively for professional use, as well as the context in which the advertisement or

offer is made available, such as trade fairs, trade publications or digital platforms addressed to professional users. Similar provisions already exist under Union law.

Or. en

Proposal for a regulation
Recital 9

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

information from the label.	***or the pictogram*** but not to duplicate ***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.***

Or. en

Proposal for a regulation
Recital 10

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

[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).

Or. en

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(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.	(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. ***In order to ensure the possibility for rapid contact which is essential in certain situation such as in cases of emergency, the presence of a digital contact should not exclude the provision of a telephone number.***

Or. en

Proposal for a regulation
Recital 12 a (new)

Text proposed by the Commission	*Amendment*
	(12 a) Inkjet cartridges (≤150 ml) (supplied in outer packaging and designed to be installed in a printer by a consumer or professional user) have very limited usable surface area for labelling and cannot benefit from the fold out label option enabling multilanguage solutions. In this case suppliers should be permitted to reduce hazard label information under

certain conditions.

Or. en

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(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.	(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 ***and national authorities should encourage them to do so***.

Or. en

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) No 1272/2008
Article 2 – point 42

Text proposed by the Commission	*Amendment*
42. “digital contact” means any up-to-date ***and*** accessible online communication channel through which a supplier can be ***reached or engaged*** without the need to register or to download an application**.**;	42. “digital contact” means any up-to-date ***easily and freely*** accessible online communication channel ***such as email addresses or a weblink*** through which a supplier can be ***contacted*** without the need to register or to download ***or use*** an application;

Or. en

Proposal for a regulation
Article 1 – paragraph 1 – point 1 a (new)
Regulation (EC) No 1272/2008
Article 5 – paragraph 3a (new)

Text proposed by the Commission	*Amendment*

	(1 a) In article 5, the following paragraph is inserted: '3a. By 18 months from the date of the entering into force of this Amending Regulation, the Commission shall carry out an assessment on whether further specific reductions of mandatory label elements should apply to packages between 10 and 125 ml.'

Or. en

Proposal for a regulation
Article 1 – paragraph 1 – point 2 – introductory part
Regulation (EC) No 1272/2008
Article 17 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(2) ***in*** Article 17(1)***,*** point (a) is replaced by the following:	(2) Article 17(1) ***is amended as follows:***
	(a) point (a) is replaced by the following:

Or. en

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 1272/2008
Article 17 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the name, address and digital contact of the ***suppliers*****;;**	(a) the name, address***, telephone number*** and digital contact of the ***supplier***;

Or. en

Proposal for a regulation
Article 1 – paragraph 1 – point 2 a (new)
Regulation (EC) No 1272/2008
Article 17 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	(2 a) in Article 17(1) the following subparagraph is added:

	'The telephone number in point (a) of the first subparagraph may be omitted from the label if such telephone number is directly available through the digital contact.'

Or. en

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 1272/2008
Article 25 – paragraph 6 – subparagraph 3

Text proposed by the Commission	*Amendment*
The label shall also include the product identifier referred to in Article 18 and the name, address ***and*** digital contact of the supplier of the mixture.;	The label shall also include the product identifier referred to in Article 18 and the name, address**,** digital contact of the supplier***(s)*** of the mixture ***and the telephone number, unless this telephone number is directly available through the digital contact. Without prejudice to the deadline established in Article 61(8), the inclusion or change to the digital contact may be added or updated at any time or during the supplier's regular label update cycles***;

Or. en

Proposal for a regulation
Article 1 – paragraph 1 – point 4 – introductory part
Regulation (EC) No 1272/2008
Article 29 – paragraph 2

Text proposed by the Commission	*Amendment*
(4) in Article 29***, paragraph 2 is*** replaced by the following:	(4) in Article 29 ***paragraphs 1 and 2 are*** replaced by the following:

Or. en

Proposal for a regulation
Article 1 – paragraph 1 – point -4a (new)
Regulation (EC) No 1272/2008
Article 29 – paragraph 1

Present text	*Amendment*
Where the packaging of a substance or a mixture is either in such a shape or form or is so small that it is impossible to meet the requirements of Article 31 for a label in the languages of the ***L 353/18 EN Official Journal of the European Union 31.12.2008*** Member State in which the substance or mixture is placed on the market, the label elements in ***accordance with the first subparagraph of*** Article ***17(2)*** shall be provided in accordance with section 1.5.1 of Annex I.	"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.***;***"

Or. en

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 1272/2008
Article 29 – paragraph 2

Text proposed by the Commission	*Amendment*
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.;	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 all the languages of the Member State in which the substance or mixture is placed on the market."***

Or. en

Proposal for a regulation
Article 1 – paragraph 1 – point 4 b (new)
Regulation (EC) No 1272/2008
Article 29 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*

(4 b) In article 29, the following paragraph 2a is inserted:

2a. By way of derogation from Article 17(1) and Article 25(6), the label elements of ink cartridges may be reduced in accordance with the rules set out in 1.5.2.5a of Annex I. For the purpose of this paragraph, 'ink cartridge' means a replaceable unit that holds ink and which must be inserted into a printer during printing.

Or. en

Proposal for a regulation
Article 1 – paragraph 1 – point 5
Regulation (EC) No 1272/2008
Article 30 – paragraph 1

Text proposed by the Commission	*Amendment*
1. In the event of a change regarding the classification or labelling of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in accordance with Article 25, the supplier of that substance or that mixture shall ensure that the label is updated without undue delay after the results of the new evaluation referred to in Article 15(4) are obtained by, or communicated to, that supplier.;	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 eighteen months*** after the results of the new evaluation referred to in Article 15(4) are obtained by, or communicated to, that supplier. ***With a view to complete the changes to the labelling without undue delay, suppliers shall cooperate in accordance with Article 4(9) and inform their direct downstream users about the results of the new evaluation as referred to in subparagraph 1 in accordance with the applicable requirements of Regulation (EC) 1907/2006. Suppliers may apply the new or updated classifications and adapt the labelling accordingly on a voluntary basis before the expiry of the eighteen months period, in order to ensure a high level of protection of human health and***

the environment and to provide sufficient flexibility;

Or. en

Proposal for a regulation
Article 1 – paragraph 1 – point 6
Regulation (EC) No 1272/2008
Article 31 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The label elements referred to in Article 17(1) shall be clearly and indelibly marked. They shall stand out clearly from the background and they shall be of such a size and ***be spaced in such a way*** as to be ***easily*** read.;	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 ***spacing*** as to be ***easy to*** read. ***They shall be formatted in accordance with section 1.2.1 of Annex I.***;

Or. en

Proposal for a regulation
Article 1 – paragraph 1 – point 7
Regulation (EC) No 1272/2008
Article 48 – paragraph 1

Text proposed by the Commission	*Amendment*
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.'.	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 ***always*** include the sentence: 'Always read the label and product information before use.'***, and shall also include one of the following: a) the applicable hazard pictogram(s); or b) the relevant signal word in accordance with Article 20***.

Or. en

Proposal for a regulation
Article 1 – paragraph 1 – point 7
Regulation (EC) No 1272/2008

Article 48 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. 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 or directly made available to the general public.

Or. en

Proposal for a regulation
Article 1 – paragraph 1 – point 8
Regulation (EC) No 1272/2008
Article 48 a

Text proposed by the Commission	*Amendment*
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.'	***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;'

Or. en

Proposal for a regulation
Article 1 – paragraph 1 – point 9 – point a
Regulation (EC) No 1272/2008
Article 61 – paragraph 8

Text proposed by the Commission	*Amendment*
Substances and mixtures which have been classified, labelled and packaged in accordance with Article 18(3) as applicable	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.'

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. ***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 9 December 2024 and which were placed on the market before 1 January 2028 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 2030.***'

Or. en

Proposal for a regulation
Annex I – paragraph 1 – point 2
Regulation (EC) No 1272/2008
Annex I – section 1.2.1.5

Text proposed by the Commission	*Amendment*
(2) in Annex I, section 1.2.1.5 is ***deleted***;	(2) in Annex I, section 1.2.1.5 is ***replaced by the following: The text on the label shall be legible. For the purpose of this section, a label shall be considered legible if the physical appearance of information, by means of which the information is visually accessible and which is determined by various elements, inter alia, font size, letter spacing, spacing between lines, stroke width, type colour, typeface, width-height ratio of the letters, the surface of the material and significant contrast between the print and the background. It shall have at least the following characteristics: (a) printed in a contrasting colour compared to the background; (b) a single typeface that is easily legible and without serifs shall be used; (c) appropriate letter spacing for the selected typeface to be easily legible; (d)***

appropriate line spacing for the selected typeface to be easily readable and to ensure that lines of text do not overlap; (e) an appropriate font size with regard to the size of the label and the required label elements and the intended user. For substances or mixtures made available on the market for the general public, the label elements referred to in Article 17(1) shall use a font size where the x-height is equal to or greater than 1.2 mm. However, where the contents of the package do not exceed 125 ml, the label elements referred to in Article 17(1) may use a font size where the x-height is equal to or greater than 0.9 mm. These characteristics shall be further clarified in the ECHA guidance on legibility and label presentation to be developed under this Regulation. Compliance with this section shall be assessed on the basis of the overall legibility of the label and applied in a manner compatible with the physical characteristics and technical limitations of the packaging, including size as well as the intended user.

Or. en

Proposal for a regulation
Annex I – paragraph 1 – point 3
Regulation (EC) No 1272/2008
Annex I – section 1.5.1.2

Text proposed by the Commission	*Amendment*
1.5.1.2. Where section 1.5.1.1 applies, the label on any inner packaging shall contain at least the hazard pictograms, the signal words, the product identifier referred to in Article 18(2) for substances or the trade name or designation referred to in Article 18(3), point (a) for mixtures, ***and*** the name ***and*** digital contact of the suppliers of the substance or mixture**.**;	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, the name***, the*** 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***;

Or. en

Proposal for a regulation
Annex I – paragraph 1 – point 5
Regulation (EC) No 1272/2008
Annex I – section 1.5.2.4.1 – point (b)

Text proposed by the Commission	*Amendment*
(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:	(b) the substance or mixture requires labelling in accordance with Part 1 or 2 of Annex II and is not classified in any of the following hazard classes and categories:

Or. en

Proposal for a regulation
Annex I – paragraph 1 – point 7
Regulation (EC) No 1272/2008
Annex I – section 1.5.2.4.3 – point (b)

Text proposed by the Commission	*Amendment*
(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***;	(b) the substance or mixture does not require labelling in accordance with Part 1 or 2 of Annex II;

Or. en

Proposal for a regulation
Annex I – paragraph 1 – point 7 a (new)
Regulation (EC) No 1272/2008
Annex I – section 1.5.2.4.3a (new)

Text proposed by the Commission	*Amendment*
	(7 a) in Annex I, section 1.5.2.4.3a is added: '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';'

Or. en

Proposal for a regulation
Annex I – paragraph 1 – point 7 b (new)
Regulation (EC) No 1272/2008
Annex I – section 1.5.2.5.a (new)

Text proposed by the Commission	*Amendment*
	(7 b) in Annex I, section 1.5.2.5a is added: Labelling of ink cartridges where the contents do not exceed 150 ml.
	1.5.2.5a1: The label elements required by Article 17 may be reduced in accordance with 1.5.2.5a.2 and 1.5.2.5a.3 where:
	(a) the contents of the ink cartridge do not exceed 150 ml
	(b) the outer packaging complies with the provisions laid out in Article 17.; and
	(c) keep the hazard information on the outer packaging is kept with the printer
	1.5.2.5a.2: Where 1.5.2.5a.1 applies the label on the ink cartridge and any intermediate packaging shall contain at least:
	(a) the product identifier in accordance with Article 18(2) for substances and Article 18(3) for mixtures;
	(b) where applicable the pictograms;
	(c) where applicable the unique formula identifier;
	(d) name, registered name or trademark of the supplier; and
	(e) telephone number or digital contact
	1.5.2.5a.3: Where 1.5.2.5a.1 applies and the contents of the ink cartridge do not exceed 30 ml the information required by 1.5.2.5a.1 may be further reduced so that the label on the ink cartridge shall contain at least:
	(a) the product identifier in accordance

with Article 18(2) for substances and Article 18(3)) for mixtures; and

(b) where applicable the following pictograms: GHS01, GHS05, GHS06, GHS08. GHS07, GHS09, Where more than two pictograms are assigned GHS06 and GHS08 may take precedence over GHS01 and GHS05.

Or. en

Proposal for a regulation
Annex I – paragraph 1 – point 8
Regulation (EC) No 1272/2008
Annex I – section 1.6 – point (b a) new

Text proposed by the Commission	*Amendment*
	(b a) The telephone number for the supplier(s) required according to Article 17(1), point (a), and where relevant the third subparagraph of Article 25(6) and section 1.5.1.2 of Annex I';

Or. en

Proposal for a regulation
Annex I – paragraph 1 – point 9
Regulation (EC) No 1272/2008
Annex I – part 5 – point b

Text proposed by the Commission	*Amendment*
(b) For a substance or a mixture supplied at a ***filling*** station ***and directly pumped into a receptacle that forms an integral part of a vehicle and from where the substance or mixture is normally not intended to be removed,*** the copy of the label elements referred to in Article ***17***, points (c) to (h) shall be provided on a visible place on the respective pump**.** The unique formula identifier referred to in Article 25(7) does not need to be provided.	(b) For a substance or a mixture supplied at a ***fuel service*** station the copy of the ***following*** label elements referred to in Article ***17.1***, points (c) to (h) shall be provided on a visible place on ***or next to*** the respective pump***:*** The unique formula identifier referred to in Article 25(7) does not need to be provided.

Or. en

Compromise Amendment 2
Cosmetics
Articles 2, 5(5)
Annexes II & III
Recitals 15-25

Compromise Amendment replacing Amendments: 12-21, 47-63, 89, 161-227, 341-462, 510-511, 558-562, CA 2A

Proposal for a regulation
Recital 17

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

Or. en

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) Furthermore, elements to be considered under the availability of suitable alternatives condition should be ***specified***. In particular, it should be provided that the use of alternative substance ***should result in reduced overall risk*** to human health ***and the environment and the substance*** should provide an	(18) Furthermore, ***the*** elements to be considered under the availability of suitable alternatives condition should be ***outlined***. In particular, it should be provided that the use of ***any*** alternative substance to ***replace the classified substance is safe for*** human health***. The alternative*** should provide an equivalent

equivalent ***or similar*** function ***in a cosmetic product,*** be available on the market in sufficient quantities, ***so that it can*** be technically ***feasible*** and economically ***viable*** for businesses and especially for SMEs***. In addition, access to the substance should not be restricted by patents or raw material restrictions. It should also be possible to consider*** the economic aspects, such as costs of reformulation and comparative contribution to overall production costs, as relevant factors in the analysis of the suitability of alternatives.

function ***and comparable level of efficacy and performance and should*** be available on the market in sufficient quantities, ***or likely to be available in sufficient quantities to meet current demand and has the demonstrated potential to meet expected demands in a reasonable timeframe. Its use should*** be technically and economically ***feasible*** for businesses and especially for SMEs ***to allow sustained production. To assess economic feasibility,*** the economic aspects, such as costs of reformulation and comparative contribution to overall production costs, as relevant factors in the analysis of the suitability of alternatives***, can be considered***.

Or. en

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(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.	(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, (namely specific use in particular product category), therefore, a separate criterion is redundant.

Or. en

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(21) ***Often a substance can also be a*** constituent ***of*** natural complex substances, ***for example essential oils. In such cases,***	(21) ***Substances containing more than one*** constituent ***which are extracted from plants or plant parts and which are not***

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

chemically modified as defined in Article 3, point (40), of Regulation (EC) No 1907/2006, are often referred to as natural complex substances, ***or 'NCS'. They might 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 must apply to such substances and should be based on scientific knowledge and the actual conditions of exposure arising from their use in cosmetic products.*** The prohibition of use in cosmetic products under Article 15 of Regulation (EC) No 1223/2009 only ***applies*** to the substance as it appears in Part 3 of Annex VI to the Regulation (EC) No 1272/2008. Natural complex substances that contain a CMR classified constituent are not subject to the prohibition, except ***where the*** natural complex substance itself ***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 ***raises*** concerns ***about the use and*** safety of the natural complex substances when used in cosmetic products, the Commission should ***without delay*** mandate the SCCS to assess the safety of ***such*** substances ***and, where necessary, take*** appropriate regulatory ***action*** in accordance with Article 31(1) of Regulation (EC) No 1223/2009. ***The assessment of the SCCS should be timely to ensure predictability for the industry.***

Or. en

Proposal for a regulation
Recital 22

Text proposed by the Commission	*Amendment*
(22) When a substance is prohibited or restricted from the use in cosmetic products, the manufacturers, importers, distributors and responsible persons should	(22) When a substance is prohibited or restricted from the use in cosmetic products, the manufacturers, importers, distributors and responsible persons should

be given appropriate time to take necessary measures to reformulate and relabel their products, withdraw from the distribution and destroy the unsold products not complying with the new requirements. ***Therefore, periods of 12*** months for placing and ***24*** months for making available on the market of cosmetic products containing the substance concerned following the entry into force of the respective amendments to Regulation (EC) No 1223/2009 should be provided.

be given appropriate time to take necessary measures to reformulate***, test*** and relabel their products, withdraw from the distribution and destroy the unsold products not complying with the new requirements. ***Accordingly, if no derogation request was submitted, a period of 6*** months for placing and ***15*** 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, those deadlines should be shortened to a period of 3 months for placing and 12 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 request has been refused due to the availability of suitable alternatives, those deadlines should be extended to a period of 24 months for placing and 48 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.***

Or. en

Proposal for a regulation
Recital 23

Text proposed by the Commission	*Amendment*
(23) To reduce compliance and administrative burden on businesses active in the cosmetic sector, ***only one notification*** of the cosmetic products should be required before placing them on the Union market. ***The conditions of such notification should apply in a non-discriminatory way to cosmetic products containing nanomaterials and to those cosmetic products which do not contain them.*** To maintain vigilance on	(23) To reduce compliance and administrative burden on businesses active in the cosmetic sector, ***notifications*** of the cosmetic products ***to the Commission*** should be required before placing them on the Union market. To maintain vigilance on nanomaterials ***in cosmetic products***, it should be required that ***this notification includes the identification of the nanomaterial including its chemical name (IUPAC) and other descriptors as***

nanomaterials, it should be required that ***the*** specific information on nanomaterials used in a cosmetic product is provided in the cosmetic product safety report ***so that it*** can be consulted by the competent authorities where ***the*** concerns over the potential risk to human health arise from the use of a particular nanomaterial

specified in point 2 of the Preamble to Annexes II to VI, and the specification of the nanomaterial including size of particles, physical and chemical properties, intended to be placed on the market per year. This is necessary so that a safety assessment can be requested by the Commission in case of concerns. It should also be explicitly required that specific information on nanomaterials used in a cosmetic product is provided in the Cosmetic ***Products Notification Portal (CPNP) notification and in the cosmetic*** product safety report ***that are both accessible to the competent authorities and*** can be consulted by the competent authorities***,*** where concerns over the potential risk to human health arise from the use of a particular nanomaterial ***in cosmetic products.***

Or. en

Proposal for a regulation
Recital 25

Text proposed by the Commission	*Amendment*
(25) Cosmetics are globally traded goods***.*** It is therefore ***important*** that the ingredient names present on their labels reflect the current state of scientific and technological development. The use of internationally recognised cosmetic ingredient***'*** names is an important factor promoting transparency ***and facilitating*** cross-border trade in cosmetics. This Regulation should enable internationally recognised names to be used on the labelling of cosmetic products without any additional regulatory action from the Commission. As a glossary of common ingredient names adopted by the Commission would slow down the process of uptake of the new names, the provision requiring the Commission to adopt such a glossary should be abolished.	(25) Cosmetics are globally traded goods ***and*** it is therefore ***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 ***(INCI)*** names is an important factor promoting ***Ingredients*** transparency ***for consumers, ensures consistency across jurisdictions, and facilitates*** cross-border trade in cosmetics. ***INCI names are maintained by the Personal Care Products Council (PCPC) as an international industry standard and are widely recognised by regulators and stakeholders worldwide.*** This Regulation should enable ***the direct use of*** internationally recognised names ***nomenclature, such as INCI,*** to be used on the labelling of cosmetic products

without any additional ***further*** regulatory action from the Commission***. Where a common ingredient name is not available in INCI, other generally accepted nomenclature should be used, for example names established in recognised international chemical or pharmacopoeia references, or in other authoritative sources commonly relied upon by industry and regulators. This approach ensures flexibility, avoids unnecessary administrative burden, and guarantees that ingredient names used on cosmetic product labelling remain up to date, internationally coherent, and easily understandable to consumers***. As a glossary of common ingredient names adopted by the Commission would slow down the process of uptake of the new names, the provision requiring the Commission to adopt such a glossary should be abolished.

Or. en

Proposal for a regulation
Recital 25 a (new)

Text proposed by the Commission	*Amendment*
	(25 a) In order to ensure a high level of protection of human health, all operators placing cosmetic products on the Union market, whether offline or online, should be subject to equivalent obligations and effective enforcement. This is particularly important given the growing sale of cosmetics via online marketplaces, including products originating from third countries that are not subject to the same health and safety requirements. 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. Furthermore, post-market surveillance should be strengthened, notably for online sales and imports, and cosmetic products identified as non-compliant through the Union rapid alert system (Safety Gate) should not be listed or offered for sale. To this end, online platforms should verify the identity of the responsible person before allowing products to be placed on the Union market, and the online sale, offering for sale and promotion, including via social media, of banned cosmetics, in particular mercury-added products, should be explicitly prohibited.

Or. en

Proposal for a regulation
Article 2 – paragraph 1 – point 1
Regulation (EC) No 1223/2009
Article 14 a – paragraph 2

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

Or. en

Proposal for a regulation
Article 2 – paragraph 1 – point 2 – point a – point i
Regulation (EC) No 1223/2009
Article 15 – paragraph 2 – subparagraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. However, such substances may be used in cosmetic products if a derogation request is submitted to the Commission at the latest three months after at the date of entry into force of the amendments to Part 3 of Annex VI to Regulation (EC) No 1272/2008 classifying the substance as	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

CMR substance of category 1A or 1B. The Commission ***shall*** grant the derogation where all of the following conditions are fulfilled:	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 ***may*** grant the derogation where all of the following conditions are fulfilled:

Or. en

Proposal for a regulation
Article 2 – paragraph 1 – point 2 – point a – point i
Regulation (EC) No 1223/2009
Article 15 – paragraph 2 – subparagraph 2 – point b

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

Or. en

Proposal for a regulation
Article 2 – paragraph 1 – point 2 – point a – point ii
Regulation (EC) No 1223/2009
Article 15 – paragraph 2 – subparagraph 3 – point a

Text proposed by the Commission	*Amendment*
(a) its use in cosmetic products results in ***reduced*** overall risk to human health ***and the environment***;	(a) its use in cosmetic products ***is safe and*** results in ***reduction of*** overall risk to human health***, when assessed against the substance it is intended to replace***;

Or. en

Proposal for a regulation
Article 2 – paragraph 1 – point 2 – point a – point ii
Regulation (EC) No 1223/2009
Article 15 – paragraph 2 – subparagraph 3 – point b

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

Or. en

Proposal for a regulation
Article 2 – paragraph 1 – point 2 – point a – point ii
Regulation (EC) No 1223/2009
Article 15 – paragraph 2 – subparagraph 3 – point c

Text proposed by the Commission	*Amendment*
(c) is technically feasible and economically ***viable***;	(c) is technically feasible and economically ***feasible provided costs and supply conditions allow sustained production***;

Or. en

Proposal for a regulation
Article 2 – paragraph 1 – point 2 – point a – point ii
Regulation (EC) No 1223/2009
Article 15 – paragraph 2 – subparagraph 3 – point d

Text proposed by the Commission	*Amendment*
(d) it is not restricted***, not protected by exclusive rights,*** and is available on the market at scale***,*** in quantities ***large enough*** to meet current ***and*** expected demand.***'***	(d) it is not restricted and is ***either*** available on the market at scale ***and*** in quantities ***sufficient*** to meet current ***demand or has the potential to meet current or*** expected demand ***in a reasonable timeframe***.

Or. en

Proposal for a regulation
Article 2 – paragraph 1 – point 2 – point a – point ii a (new)
Regulation (EC) No 1223/2009
Article 15 – paragraph 2 – subparagraph 3 a (new)

Text proposed by the Commission	*Amendment*

	(ii a) The following subparagraph is inserted after the third subparagraph:
	'The Commission shall consult relevant stakeholders for the purpose of the second subparagraph, point (a) and for the purpose of the third subparagraph.'

Or. en

Proposal for a regulation
Article 2 – paragraph 1 – point 2 – point a – point iii – introductory part
Regulation (EC) No 1223/2009
Article 15 – paragraph 2 – subparagraph 4 a (new)

Text proposed by the Commission	*Amendment*
(iii) the following ***subparagraph is*** inserted after the fourth subparagraph:	(iii) the following ***subparagraphs are*** inserted after the fourth subparagraph:

Or. en

Proposal for a regulation
Article 2 – paragraph 1 – point 2 – point a – point iii
Regulation (EC) No 1223/2009
Article 15 – paragraph 2 – subparagraph 5 a

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

Or. en

Proposal for a regulation
Article 2 – paragraph 1 – point 2 – point b
Regulation (EC) No 1223/2009
Article 15 – paragraph 2 – subparagraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5 a. 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.

Or. en

Proposal for a regulation
Article 2 – paragraph 1 – point 2 – point b
Regulation (EC) No 1223/2009
Article 15 – paragraph 5

Text proposed by the Commission	*Amendment*
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.	***deleted***

Or. en

Proposal for a regulation
Article 2 – paragraph 1 – point 2 – point b
Regulation (EC) No 1223/2009
Article 15 – paragraph 6

Text proposed by the Commission	*Amendment*
The prohibition referred to in paragraphs 1 and 2 of this Article shall not apply to ***a substance*** extracted from plants or plant parts and not chemically modified as defined in Article 3, point (40), of Regulation (EC) No 1907/2006, containing more than one constituent, at least one of	The prohibition referred to in paragraphs 1 and 2 of this Article shall not apply to ***substances*** extracted from plants or plant parts and not chemically modified as defined in Article 3, point (40), of Regulation (EC) No 1907/2006, containing more than one constituent, at least one of

which has been classified as a CMR substance of category 1A, 1B, or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008. ***If*** a potential risk to human health arises from the use of ***such*** substance in ***cosmetic products, the Commission shall seek an opinion of the SCCS on the safety of that substance for its use*** in cosmetic products without undue delay.

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. ***As a potential risk to human health arises from the presence of such constituent classified as CMR category 1A, 1B or 2 in such substances in cosmetic products, the Commission shall without delay request an opinion of the SCCS on the safety of that constituent for its presence in cosmetic products. The SCCS shall deliver its opinion within 12 months of the Commission's request. 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, and where*** a potential risk to human health arises from the use of ***a*** substance ***referred to*** in ***the first subparagraph*** in cosmetic products ***containing a constituent classified as CMR category 1A, 1B or 2 for human health, the Commission shall,*** without undue delay***, amend the Annexes to this Regulation***. ***For the purposes of this paragraph, "plants" means living or dead organisms from the kingdoms Plantae and Fungi, including algae, lichens and yeasts.***

Or. en

Proposal for a regulation
Article 2 – paragraph 1 – point 2 – point b
Regulation (EC) No 1223/2009
Article 15 – paragraph 7

Text proposed by the Commission	*Amendment*
Cosmetic products containing a substance classified as a CMR substance of category 1A, 1B, or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 prohibited from use in cosmetic products or such substance not compliant with a restriction may continue to be placed on the market	***Cosmetic products containing a substance classified as a CMR substance of category 1A, 1B, or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 prohibited from use in cosmetic products and for which no derogation request was submitted in accordance with paragraph 2***

for ***12*** months and be made available on the market for ***24*** months after the entry into force of the relevant amendments to the relevant Annexes to this Regulation.**'**	***or such substance is not compliant with a restriction may continue to be placed on the market for 6 months, and be available on the market for 15 months after the entry into force of the relevant amendments to the relevant Annexes to this Regulation. Cosmetic products containing a substance classified as a CMR substance of category 1A, 1B, or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 prohibited from use in cosmetic products and for which a derogation request was submitted in accordance with paragraph 2, but not granted due to safety concerns by the SCCS or such substance not compliant with a restriction may continue to be placed on the market for 3 months, and be available on the market for 12 months after the entry into force of the relevant amendments to the relevant Annexes to this Regulation.*** Cosmetic products containing a substance classified as a CMR substance of category 1A, 1B, or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 prohibited from use in cosmetic products or such substance not compliant with a restriction ***and for which a derogation request was submitted in accordance with paragraph 2, but not granted due to the availability of a suitable alternative,*** may continue to be placed on the market for ***24*** months and be made available on the market for ***48*** months after the entry into force of the relevant amendments to the relevant Annexes to this Regulation***, and where needed updated the cosmetic product safety report (CPSR) remains available***.
	Or. en

Proposal for a regulation
Article 2 – paragraph 1 – point 3
Regulation (EC) No 1223/2009
Article 16 – paragraph 3

Text proposed by the Commission	*Amendment*

(3) In Article 16, paragraphs 3 ***and 7 are deleted;***	(3) In Article 16, paragraphs 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 subparagraphs 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/
	(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, and
	(b) the specification of the nanomaterial including size of particles, physical and chemical properties.
	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, which may substitute the information to be notified in case of the same nanomaterial used in different products.
	Or. en

Proposal for a regulation
Article 2 – paragraph 1 – point 4 a (new)
Regulation (EC) No 1223/2009
Article 19 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	(4 a) In Article 19, paragraph 6a 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.'

Or. en

Proposal for a regulation
Article 2 – paragraph 1 – point 8

Text proposed by the Commission	*Amendment*
(8) Annexes II to VI are amended in accordance with Annex III this Regulation.	***deleted***

Or. en

Compromise Amendment 3
Fertilizers
Articles 3, 4(2)
Annex IV
Recitals 2a, 26-31

Compromise Amendment replacing Amendments: 22-29, 64-80, 90-99, 228-248, 463-494, 563-605; AGRI 3, AGRI 5-14

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2 a) Fertilising products covered by Regulation (EU) 2019/1009 directly affect farmers' production costs, incomes, safety and competitiveness, while regulatory requirements and administrative burdens on producers are transmitted along the supply chain. As competitiveness of the Union depends, inter alia, on its capacity to innovate, the regulatory framework should support innovation and technical progress by remaining proportionate and avoiding unnecessary burdens, while ensuring the objectives of that Regulation are achieved.

Or. en

Proposal for a regulation
Recital 26

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

Or. en

Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission	*Amendment*
	(26 a) Fertiliser 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 revision of this Regulation should therefore provide for regulatory simplification for EU fertiliser producers and benefit EU farmers making it easier for operators to enter the EU market and operate beyond national markets to the benefit of the Single Market. Therefore, it should not undermine a high level of consumer, health, environmental protection and risk management. Furthermore, easing sector-specific requirements for fertilising products should not lower the levels of control on these products when they are entering the market, nor should it raise concerns regarding traceability, safety, and reputational impacts.

Or. en

Proposal for a regulation
Recital 26 b (new)

Text proposed by the Commission	*Amendment*
	(26 b) Digitalisation of declarations of conformity and technical product information may offer certain advantages. Due regard should be given to cybersecurity, effective and swift enforcement oversight, the availability and interoperability of digital infrastructure, the potential costs of introducing and operating such systems and the diversity of economic operators and national systems.

Or. en

Proposal for a regulation
Recital 27

Text proposed by the Commission	*Amendment*

(27) Under Regulation (EU) 2019/1009, only micro-organisms listed on a positive list in Annex II to that Regulation may be used as component material in microbial plant biostimulants. The Commission is empowered to add new micro-organisms or strains of micro-organisms to that list after an assessment concluding that none of the strains presents a risk to human, animal or plant health, to safety or to the environment and that it ensures agronomic efficiency. Given the large number of micro-organisms on the market, the assessment and subsequent inclusion of new micro-organisms or strains of micro-organism to the positive list are lagging scientific progress. The current mechanism slows down the development of microbial plant biostimulants and delays farmers' access to those innovative fertilising products ***which may stimulate plant nutrition processes and thereby reduce*** the use of traditional fertilisers.	(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***. A proactive monitoring of the scientific developments and updating of the list of micro-organisms or strains of micro-organisms, as well as of the relevant criteria and methodology is necessary on a continuous basis. Furthermore, all updates should be implemented swiftly. At the same time, the regulatory framework should ensure that*** the use of traditional ***and natural*** fertilisers ***remains a viable and accessible option, recognising their role alongside microbial solutions, so as not to undermine competitiveness or agricultural production within the Union***.

Or. en

Proposal for a regulation
Recital 27 a (new)

Text proposed by the Commission	*Amendment*
	(27 a) Given the rapid pace of innovation in agricultural biotechnology, it is important that existing regulatory procedures, including the updating of Annexes by the Commission, are applied in a timely and science-based manner,

making full use of the possibilities already provided for under Regulation (EU) 2019/1009. This should facilitate the timely assessment of new strains, while ensuring that only those meeting Union safety requirements are allowed on the market.

Or. en

Proposal for a regulation
Recital 28

Text proposed by the Commission	*Amendment*
(28) In order to accelerate the assessment of micro-organisms and to open the single market for more microbial plant biostimulants, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of Annex II, Part II, component material category (CMC) 7, to Regulation (EU) 2019/1009 to allow the Commission to introduce general criteria and a methodology for the assessment of micro-organisms. Those criteria ***and the methodology*** should allow manufacturers and notified bodies to demonstrate and verify that micro-organisms used in microbial plant biostimulants, other than those listed in CMC 7, do not present a risk to human, animal or plant health, to safety or to the environment and ensure agronomic efficiency. In order to refine and validate the criteria and methodology to be introduced, it is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level***, and that*** those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making***[13]*** . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as	(28) ***The wider use of microbial plant biostimulants can improve nutrient-use efficiency and soil health, 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 micro-organisms. Those criteria should ***reflect the most recent scientific developments and*** allow manufacturers and notified bodies***,*** to demonstrate and verify that micro-organisms used in microbial plant biostimulants, other than those listed in CMC 7, do not present a risk to human, animal or plant health, to safety or to the environment and ensure agronomic efficiency ***while taking into account EU competitiveness and production. Verifying compliance of micro-organisms with the criteria and methodology set under this Regulation requires specific competences, scientific and technical knowledge from the conformity assessment bodies. Those competences should be therefore***

Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

scrutinized by the national bodies in charge of accreditation and notification, as well as aspects such as 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 ***involves the relevant scientific bodies, in particular the European Food Safety Agency, the JRC and the ECHA, to review and contribute, and also*** carry out appropriate consultations during its preparatory work, including at expert level***. 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. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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

Or. en

Proposal for a regulation
Recital 29 a (new)

Text proposed by the Commission	*Amendment*
	(29 a) 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 raw 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 recognition of end points for constituent materials derived from animal by-products within the meaning of Regulation (EC) No 1069/2009. Delegated Regulation (EU) 2023/1605 has established certain end points for animal by-products intended for fertiliser applications. However, the processing parameters and risk mitigation measures included therein are largely derived from frameworks for feed hygiene and the prevention of feed fraud and do not always reflect the distinct exposure pathways and risk profiles of fertiliser products applied to the soil and water.

Or. en

Proposal for a regulation
Recital 30

Text proposed by the Commission	*Amendment*
(30) ***Chemical*** substances***, on their own or in mixtures, if manufactured or imported in*** quantities ***above 1 tonne per company per year, need to be registered*** in accordance with Regulation (EC) No 1907/2006, ***with information requirements depending on the actual volume***. ***Regulation (EU) 2019/1009, going beyond the requirements of Regulation (EC) No 1907/2006, requires that all substances used in an EU fertilising products, regardless of the quantity in which they are manufactured or imported, are registered, as a minimum, with the information requirements set out by Regulation (EC) No 1907/2006 for substances manufactured or imported in quantities of 10 to 100 tonnes per company per year, together with a*** chemical safety ***report covering their use in a fertilising product, in accordance with Article 14 of that Regulation. Those extensive information requirements might prevent manufacturers, especially small***	(30) ***Regulation (EU) 2019/1009 introduced additional registration requirements for*** substances ***used in EU fertilising products, 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 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. At the same time, for substances with particularly hazardous properties, including those classified under Regulation (EC) No 1272/2008 as carcinogenic, mutagenic, toxic for reproduction, endocrine disrupting or persistent, bioaccumulative and toxic, specific information requirements should apply even where such substances are used in low*** quantities ***in fertilising***

and medium-sized enterprises, from using substances that are not yet registered according to those requirements or force them to place their products only on national markets according to national rules. For the sake of proportionality, and considering the general obligation of manufactures and importers of substances and EU fertilising products ***under Regulation (EC) No 1907/2006 and Regulation (EU) 2019/1009, respectively, to ensure the safety of the products that they place on the*** market***, registration of substances used in EU fertilising products should only follow the requirements, including the relevant gradations, set out in Regulation (EC) No 1907/2006***.

products. This approach ensures that safety-relevant information is available, while avoiding unnecessary burdens for substances presenting lower risks. 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***. Chemical safety ***assessments should be limited to relevant exposure scenarios related to the agronomic use of*** fertilising products ***and 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***.

Or. en

Proposal for a regulation
Article 3 – paragraph 1 – point 1
Regulation (EU) No 2019/1009
Article 2 – paragraph 1 – point 15a

Text proposed by the Commission	*Amendment*
‘digital contact***’*** means any up-to-date and accessible online communication channel through which economic ***operators*** can be ***reached or engaged*** without the need to register ***or to*** download ***an application***;’	***“***digital contact***”*** means any up-to-date and ***freely*** accessible online communication channel through which ***a*** economic ***operator*** can be ***contacted*** without the need to register***,*** download ***or use additional applications specific to the economic operator***;’

Or. en

Proposal for a regulation
Article 3 – paragraph 1 – point 2 – point a – point ii
Regulation (EU) No 2019/1009
Article 6 – paragraph 2 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
Manufacturers shall ensure that the EU	Manufacturers shall ensure that the EU

fertilising product is accompanied by the internet address or data carrier through which the EU declaration of conformity can be accessed.;	fertilising product is accompanied by the internet address or data carrier through which the EU declaration of conformity can be ***directly*** accessed.;

Or. en

Proposal for a regulation
Article 3 – paragraph 1 – point 2 – point c
Regulation (EU) No 2019/1009
Article 6 – paragraph 6 – subparagraph 1

Text proposed by the Commission	*Amendment*
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***.'	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 ***contacted in a swift manner***.'

Or. en

Proposal for a regulation
Article 3 – paragraph 1 – point 4 – point a
Regulation (EU) No 2019/1009
Article 8 – paragraph 2 – subparagraph 1

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

Or. en

Proposal for a regulation
Article 3 – paragraph 1 – point 4 – point c
Regulation (EU) No 2019/1009
Article 8 – paragraph 8 – subparagraph 1

Text proposed by the Commission	*Amendment*
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.	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 ***in a swift manner*** to those authorities, upon request.

Or. en

Proposal for a regulation
Article 3 – paragraph 1 – point 4 – point c
Regulation (EU) No 2019/1009
Article 8 – paragraph 8 – subparagraph 2

Text proposed by the Commission	*Amendment*
On request, importers shall make the EU declaration of conformity available to other economic operators in electronic form.**'**	On request, importers shall make the EU declaration of conformity available to other economic operators in electronic form ***in a swift manner***.

Or. en

Proposal for a regulation
Article 3 – paragraph 1 – point 5 – point a
Regulation (EU) No 2019/1009
Article 9 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
Before making an EU fertilising product available on the market**,** distributors shall verify that it is accompanied by the internet address or data carrier through which the EU declaration of conformity can be accessed and**,** where appropriate, by other	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,

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.**'**

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.

Or. en

Proposal for a regulation
Article 3 – paragraph 1 – point 7
Regulation (EU) No 2019/1009
Article 16 – paragraph 5 – subparagraph 1

Text proposed by the Commission	*Amendment*
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)***.	The EU declaration of conformity shall be provided in a machine-readable format ***through which it can be directly accessed***.

Or. en

Article 3 – paragraph 1 – point 9 – point b
Regulation (EU) No 2019/1009
Article 42 – paragraph 4a – introductory part

Text proposed by the Commission	*Amendment*
The Commission may also adopt delegated acts pursuant to paragraph 1 amending Annex II to set out criteria and a methodology for the assessment of micro-organisms other than those listed in Annex II, which, if compliance with those criteria ***is demonstrated*** in the conformity assessment of the EU fertilising product in accordance with that methodology, may be used as component material in EU	The Commission may also adopt delegated acts pursuant to paragraph 1 amending Annex II to set out criteria and a methodology for the assessment of micro-organisms other than those listed in Annex II, which, if ***a manufacturer demonstrates and the notifying bodies verify the*** compliance with those criteria in the conformity assessment of the EU fertilising product in accordance with that

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

Or. en

Proposal for a regulation
Article 3 – paragraph 1 – point 9 – point b
Regulation (EU) No 2019/1009
Article 42 – paragraph 4 aa (new)

Text proposed by the Commission	*Amendment*
	The following paragraph 4aa is inserted:
	‘4aa. The Commission may also adopt delegated acts pursuant to paragraph 1 amending Annex II to establish general criteria and a methodology for the assessment of materials and processing methods other than those already listed in Annex II, excluding micro-organisms, which may be used as component materials in EU fertilising products where compliance with those criteria is demonstrated in the conformity assessment. The criteria and methodology shall, as a minimum, provide for the consideration of scientific or technical information supporting safe sourcing, processing and use of the material.’

Or. en

Proposal for a regulation
Article 3 – paragraph 1 – point 9 – point b
Regulation (EU) No 2019/1009
Article 42 – paragraph 4 ab (new)

Text proposed by the Commission	*Amendment*
	The following paragraph 4 ab is inserted:

	4 ab. By [12 months after the date of entry into force of this amending Regulation] the Commission shall adopt a delegated act to establish the criteria and methodology and upon assessment to create a corresponding new category for materials and processing methods other than those already listed in Annex II, excluding micro-organisms, which may be used as component materials in EU fertilising products provided that compliance with those criteria is demonstrated in the conformity assessment. The criteria and methodology shall aim to ensure safe sourcing, processing and use of the material. This new category shall be established without prejudice to the application of other component material categories set out in Annex II.'

Or. en

Proposal for a regulation
Article 3 – paragraph 1 – point 9 – point b a (new)
Regulation (EU) No 2019/1009
Article 42 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	(b a) The following paragraph is inserted
	'5a. For the purposes of this Regulation, products derived from animal by-products that are used solely as component materials in EU fertilising products may be made available on the market only where they originate from animal by-products or derived products that have reached an end point in the manufacturing chain in accordance with Article 5(2) of Regulation (EC) No 1069/2009. When determining such end points for derived products intended for use in EU fertilising products, the Commission shall ensure that: a) the processing and safety criteria, as well as any necessary risk-mitigation measures,

are proportionate and sufficient to ensure a high level of protection for human health and the environment, specifically relevant to fertilising uses; b) those criteria and measures are appropriate to the risks arising from the application of fertilising products to soil and water; and c) those criteria and measures are aligned with the requirements set out in Article 42(5) of this Regulation. Where existing delegated or implementing acts adopted under Regulation (EC) No 1069/2009 do not meet those conditions, the Commission shall, where appropriate and in accordance with the procedures laid down in that Regulation, review them and, where necessary, amend them to ensure such consistency. For that purpose, the Commission shall, where relevant, request scientific opinions from the European Food Safety Authority to assess risks specific to fertilising uses, taking into account exposure pathways that are distinct from those associated with feed or other uses.'

Or. en

Proposal for a regulation
Article 3 – paragraph 1 – point 9 – point b b (new)
Regulation (EU) No 2019/1009
Article 42 – paragraph 8 a (new)

Text proposed by the Commission	*Amendment*
	(b b) The following paragraph is added: '8a. The Commission shall adopt the first delegated act pursuant to paragraph 4a by ... [18 months after the entry into force of this Regulation].'

Or. en

Proposal for a regulation
Article 3 – paragraph 1 – point 9 – point b c (new)
Regulation (EU) No 2019/1009
Article 49 a (new)

Text proposed by the Commission	*Amendment*
	(b c) 'Article 49a
	Review
	The Commission shall periodically assess whether the requirements governing the treatment of materials intended for use in fertilising products remain appropriate and, where necessary, adapt them in light of scientific and technical advances, taking into account national practices, and the objectives of Regulation (EU) 2019/1009. This review shall be carried out for the first time no later than two years after the date of application of this amending Regulation.'

Or. en

Proposal for a regulation
Article 3 – paragraph 1 – point 9 – point b d (new)
Regulation (EU) No 2019/1009
Article 49 aa (new)

Text proposed by the Commission	*Amendment*
	(b d) By [insert date: 12 months after entry into force], the Commission shall submit a report to the European Parliament and the Council assessing the requirements for fertilising product blends where the primary component is one or more growing media belonging to PFC 4.
	The report shall, in particular, evaluate the conditions for adjusting nutrient content, pH value or biological activity, updated labelling requirements, and appropriate conformity assessment procedures for such blends and it may accompany, where appropriate, amendments to this Regulation.

Or. en

Proposal for a regulation

Annex IV – paragraph 1 – point 2 – point a
Regulation (EU) No 2019/1009
ANNEX II – Part II – VIRGIN MATERIAL SUBSTANCES AND MIXTURES

Text proposed by the Commission	*Amendment*
(a) in CMC 1: VIRGIN MATERIAL SUBSTANCES AND MIXTURES, point 2 is ***deleted***;	(a) in CMC 1: VIRGIN MATERIAL SUBSTANCES AND MIXTURES, point 2 is ***replaced as follows:***
	a) Substances classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 for the following hazard classes or categories:
	- Germ cell mutagenicity, category 1A or 1B;
	- Carcinogenicity, category 1A or 1B;
	- Reproductive toxicity, category 1A or 1B;
	- Specific target organ toxicity, repeated exposure, category 1
	- Endocrine disruptor for human health, category 1;
	- Endocrine disruptor for the environment, category 1; and
	- Persistent, bioaccumulative and toxic or very persistent and very bioaccumulative properties
	whose actual quantities placed on the market are lower than 10 tonnes per year, intentionally incorporated into the EU fertilising product, on their own or in a mixture, in a concentration equal or lower than the generic 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 9 (only for magnesia) of Annex V to that Regulation.
	b) Polymers are exempt from point a).;

Or. en

Proposal for a regulation
Annex IV – paragraph 1 – point 2 – point f
Regulation (EU) No 2019/1009
Annex II – Part II – CMC 8: NUTRIENT POLYMERS

Text proposed by the Commission	*Amendment*
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.;	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. ***The polymer may additionally perform other functions, provided that this does not alter the safety characteristics of the product nor compromise the controlled-release function*** ;

Or. en