European Parliament
2019-2024

Committee on the Environment, Public Health and Food Safety

2022/0432(COD)

5.4.2023

***I
DRAFT REPORT

on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures
(COM(2022)0748 – C9-0433/2022 – 2022/0432(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Maria Spyraki

Symbols for procedures

*	Consultation procedure
***	Consent procedure
***I	Ordinary legislative procedure (first reading)
***II	Ordinary legislative procedure (second reading)
***III	Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▌ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.
By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (COM(2022)0748 – C9-0433/2022 – 2022/0432(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2022)0748),

– having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0433/2022),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to Rules 59 and 40 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety (A9-0000/2023),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Amendment 1

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(2) ***From a*** toxicological ***point of view,*** substances with ***more than one*** constituent ***('multi-constituent*** substances***') are no*** different from mixtures composed of two or more substances. In accordance with Article 13 of Regulation (EC) No 1907/2006 of the European Parliament and	(2) ***Considering that the bioeconomy contributes to the objectives of the European Green Deal, appropriate classification of bio-sourced substances under the CLP Regulation is necessary to transform the European Union into a modern, resource-efficient and***

of the Council[39] , aimed to limit animal testing, data on ***multi-constituent*** substances is to be generated under the same conditions as data on any other substance, while data on individual constituents of a substance is normally not to be generated, except where individual constituents are also substances registered on their own. Where data on individual constituents ***is*** available, ***multi-constituent*** substances should be evaluated and classified following the same classification rules as mixtures***,*** unless Annex I to Regulation (EC) No 1272/2008 provides for a specific provision for those ***multi-constituent*** substances.

competitive economy. Considering also that there is scientific evidence that in certain cases the toxicological ***effect of*** substances with ***constituents (as an individual*** constituent***, identified impurity or an additive) differs from the known toxicological effects of its constituents, even for those present at high concentrations. Although*** substances ***with constituents are not intentional mixtures from a chemical point of view, they are not*** different from mixtures composed of two or more substances***, but they may differ from a toxicological point of view***. In accordance with Article 13 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[39], aimed to limit animal testing, data on substances ***with constituents*** is to be generated under the same conditions as data on any other substance, while data on individual constituents of a substance is normally not to be generated, except where individual constituents are also substances registered on their own. Where data ***is not available on a substance with constituents and where data*** on individual constituents ***is*** available, substances ***with constituents*** should be evaluated and classified following the same classification rules as mixtures unless Annex I to Regulation (EC) No 1272/2008 provides for a specific provision for those substances.

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[39] 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,

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[39] 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). 30.12.2006, p. 1).

Or. en

Justification

It is of paramount importance to ensure consistency between European policies and ambitions under the EU Green Deal. One of them is the EU's bioeconomy strategy, aiming at shifting the European economy towards a greater and more sustainable use of renewable resources. The definition of multi-constituent substance – a substance that contains more than one constituent – is different from the definition provided on the Guidance for identification and naming of substances under REACH, and this could create confusion. Therefore, we propose to delete the definition of multi-constituent substance. A natural substance (like essential oil, plant extract, etc.) is a "complex substance", generally composed of many different constituents (sometimes several hundreds). The composition of a natural complex substance varies depending on the part of the plant, the geographical origin of the plant, the season and climate conditions, the method of extraction, etc. It is not an intentional addition of ingredients like a real mixture. The mixture approach is not adapted for substances with constituents, such as natural complex substances where the constituents are intrinsically part of the substance and, together, determine the toxicological properties of the substance. Studies have shown that, from a toxicological point of view, a natural complex substance tested as a whole may show different results than one or more of its constituents when tested as single chemicals. The proposed amendments would ensure continued alignment with the approach taken at international level (GHS - Global Harmonised System) and would therefore maintain the competitiveness of the European industry.

Amendment 2

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) ***It is normally not possible*** to sufficiently assess the endocrine disrupting properties for human health and the environment and the persistent, bioaccumulative and mobile properties of a mixture or of a ***multi-constituent*** substance on the basis of data on that mixture or substance. The data for the individual substances of the mixture or for the individual constituents of the ***multi-constituent*** substance should therefore normally be used as the basis for hazard identification of those ***multi-constituent*** substances or mixtures. However, in	(3) ***Under the current state of science, it may be difficult*** to sufficiently assess the endocrine disrupting properties for human health and the environment and the persistent, bioaccumulative and mobile properties of a mixture or of a substance on the basis of data on that mixture or substance. The data for the individual substances of the mixture or for the individual constituents of the substance should therefore normally be used as the basis for hazard identification of those substances or mixtures. However, in certain cases, data on those substances

certain cases, data on those ***multi-constituent*** substances themselves may also be relevant. ***This is the case in particular where that data demonstrates endocrine disrupting properties for human health and the environment, as well as persistent, bioaccumulative and mobile properties, or where it supports data on the individual constituents. Therefore, it is appropriate that data on multi-constituent substances are used in those cases.***

themselves may also be relevant.

Or. en

Justification

The definition of multi-constituent substance – a substance that contains more than one constituent – is different from the definition provided by the Guidance for identification and naming of substances under REACH, and this could create confusion. Therefore, we propose to delete the definition of multi-constituent substance. From a legal standing point we suggest to introduce a more accurate approach at the beginning of the recital "Under the current state of the science (...)" instead of "it is normally not possible to (...)". For the Rapporteur, it seems difficult to define what "normality" is and how to calculate it. Moreover, science is evolving at an accelerated pace on the assessment of new hazard classes (including endocrine disruptors, etc.) and it is therefore legitimate to refer to the current state of the science. The recital specifies that "in certain cases data on the multi- constituent themselves may be relevant". The Rapporteur suggests that this would be sufficient. Science evolves in these areas and validations on the whole substance are relevant from a toxicological point of view, when they show an effect and also when they do not show an effect.

Amendment 3

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) In order to improve legal certainty and implementation with regard to the evaluation of hazard information for mixtures where no or inadequate test data are available for the mixture itself, the interaction between the application of the bridging principles and a weight of evidence determination using expert judgement should be clarified. Such	(4) In order to improve legal certainty and implementation with regard to the evaluation of hazard information for mixtures where no or inadequate test data are available for the mixture itself, the interaction between the application of the bridging principles and a weight of evidence determination using expert judgement should be clarified. Such

clarification should ensure that the weight of evidence determination complements but does not substitute the application of the bridging principles. It should also be clarified that if bridging principles cannot be applied to evaluate a mixture, manufacturers, importers and downstream users should use the calculation method or other methods described in Parts 3 and 4 of Annex I to Regulation (EC) No 1272/2008. It should also be clarified which criteria, when not met, determine when a weight of evidence determination using expert judgment is to be carried out.	clarification should ensure that the weight of evidence determination complements but does not substitute the application of the bridging principles. It should also be clarified that if bridging principles cannot be applied to evaluate a mixture, manufacturers, importers and downstream users should use the calculation method or other methods described in Parts 3 and 4 of Annex I to Regulation (EC) No 1272/2008. It should also be clarified which criteria, when not met, determine when a weight of evidence determination using expert judgment is to be carried out. ***Recognizing that the application of criteria for information on the different hazard classes is not always straightforward and simple, and bearing in mind that a specific hazard class may be defined by multiple criteria, manufacturers, importers and downstream users should apply, as above, weight of evidence determinations involving expert judgement to arrive at adequate results. The weight of evidence should give due consideration to all available information, irrespectively of possibilities for direct comparison with the criteria; it does not mean averaging results, nor it is a worst-case approach. For hazard classes defined by multiple criteria, a single weight of evidence determination should take into account the individual assessments with regard to each of the criteria as well as any interdependencies between the properties defined by these criteria.***

Or. en

Justification

Where more comprehensive and more refined data is available for the assessment of substances, these data should be also used in the hazard classification process to avoid false negative as well as false positive results. Otherwise, safe substances could be considered hazardous and its use banned in Europe under chemicals legislation relying on the CLP Regulation, putting competitiveness of European producers at risk while leading to more imports of finished products from other geographies, jeopardizing European strategic autonomy.

Amendment 4

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(10) To increase enforceability of the obligation placed on suppliers to update their labels after a change in the classification and labelling of their substance or mixture, a deadline should be laid down as regards that obligation. A similar obligation placed on registrants is set out in Commission Implementing Regulation (EU) 2020/1435[40]. ***Where the new hazard class is additional to an existing hazard class or represents a more severe hazard class or category, or where new supplemental labelling elements are required under Article 25, the*** deadline to update the labelling information in the case of adaptation of the classification in accordance with the result of a new evaluation should be set ***at 6 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. In case where a classification is updated to a less severe hazard class or category without triggering classification in an additional hazard class or new supplemental labelling requirements, the deadline for updating the labels should remain*** at 18 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. It should also be clarified that, in cases of harmonised classification and labelling, the deadlines to update the labelling information should be set at the date of application of the provisions setting out the new or amended classification and labelling of the substance concerned, which is usually 18 months from the date of entry into force of those provisions. The same applies in case of	(10) To increase enforceability of the obligation placed on suppliers to update their labels after a change in the classification and labelling of their substance or mixture, a deadline should be laid down as regards that obligation. A similar obligation placed on registrants is set out in Commission Implementing Regulation (EU) 2020/1435[40]. ***The*** deadline to update the labelling information in the case of adaptation of the classification in accordance with the result of a new evaluation should be set at 18 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. It should also be clarified that, in cases of harmonised classification and labelling, the deadlines to update the labelling information should be set at the date of application of the provisions setting out the new or amended classification and labelling of the substance concerned, which is usually 18 months from the date of entry into force of those provisions. The same applies in case of changes triggered by other delegated acts adopted in light of the adaptation to technical and scientific progress, for instance as a result of the implementation of new or amended provisions of the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

changes triggered by other delegated acts adopted in light of the adaptation to technical and scientific progress, for instance as a result of the implementation of new or amended provisions of the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

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[40] Commission Implementing Regulation (EU) 2020/1435 of 9 October 2020 on the duties placed on registrants to update their registrations under Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 331, 12.10.2020, p.24.)

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[40] Commission Implementing Regulation (EU) 2020/1435 of 9 October 2020 on the duties placed on registrants to update their registrations under Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 331, 12.10.2020, p.24.)

Or. en

Justification

The new CLP Regulation proposal requires labels to be updated within 6 months in case a new hazard class or a more severe classification needs to be assigned to a substance or a mixture, or when new supplemental information on the label is required. This timeline is too short, in particular for complex value chains that involve several mixture formulators downstream, and is inconsistent with current practices, which have proven adequate to allow re-design, re-printing of labels and re-labelling of packages, increasing also the burden to adapt for SMEs. Consistently with current rules, the Rapporteur suggests that 18 months should be the timeline for all label updates - that is the usual timeline for ATP's when CLH becomes mandatory for specific substances including when the classification of substance(s) is more severe.

Amendment 5

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) Harmonised classification and labelling proposals need not necessarily be limited to individual substances and could cover a group of similar substances, where such similarity allows for similar	(18) Harmonised classification and labelling proposals need not necessarily be limited to individual substances and could cover a group of similar substances, where such similarity ***based on scientific***

classification of all substances in the group. The purpose of such grouping is to alleviate the burden on manufacturers, importers or downstream users, the Agency and the Commission in the procedure for harmonisation of classification and labelling of substances. It also avoids testing of substances when similar substances can be classified as a group.	***justification (taking into account all available data on physico-chemical, ecotoxicological and toxicological properties as specified in REACH Annex XI (1.5)) using a weight of evidence approach,*** allows for similar classification of all substances in the group***. The grouping process should be scientifically robust, coherent and transparent for all stakeholders***. The purpose of such grouping is to alleviate the burden on manufacturers, importers or downstream users, the Agency and the Commission in the procedure for harmonisation of classification and labelling of substances. It also avoids testing of substances when similar substances can be classified as a group. ***The similarity of a group of substances should be given for the specific endpoint and the severity of the effect, which results in the same classification for the respective hazard class. To ensure that all submitters of dossiers for harmonised classification and labelling apply the same scientific principles to justify the grouping approach, there is a need for ECHA to develop guidance clarifying the principles from which a harmonised classification for a group of substances can be derived.***

Or. en

Justification

In order to speed up harmonised classification the Commission seeks to move away from a substance-by-substance approach and proposes to classify groups of substances based on 'similar classification'. Due to the fact that structurally similar substances can have different behaviour and effects, the assessment of 'similarity' must be based on a review of all available data, especially based on the substances' physico-chemical, ecotoxicological and toxicological properties, as already has been performed under REACH (Annex XI, part 1.5 on grouping of substances and read-across approach). This review must be in line with well-established scientific practices and include a Weight of Evidence assessment across all relevant criteria for the hazard in question. Such an approach will help avoid over-classifying and over-regulating substances based on 'presumed' adverse effects. For the Rapporteur it is critical to develop clear, transparent criteria for the grouping of chemical substances, and guidance to apply such criteria with a high degree of scientific rigour and robustness, which is a must for legal clarity and certainty. To ensure that all submitters of dossiers for harmonised classification and labelling (e.g., Member States, industry and – new proposal of

the revision – the European Commission) apply the same scientific principles to justify the grouping approach, there is a need for ECHA to develop guidance clarifying the scientific principles from which a harmonised classification for a group of substances can be derived. The development of such a guidance document for the grouping process is also essential to ensure consistency with ongoing processes under REACH, where registrants are developing data to meet REACH requirements for individual substances.

Amendment 6

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(19) To increase transparency and predictability of the proposals submitted to the Agency, the Member States' competent authorities, manufacturers, importers or downstream users should be required to notify the Agency of their intention to submit a proposal for harmonised classification and labelling, while the Commission should be required to notify the Agency of its request to the Agency or to the Authority to prepare such proposal. Furthermore, the Agency should be required to publish information on such intention or request and update the information regarding the submitted proposal at each stage of the procedure for the harmonised classification and labelling of substances. For the same reason, a competent authority that receives a proposal for revision of a harmonised classification and labelling submitted by a manufacturer, importer or downstream user should be required to communicate its decision to accept or refuse the proposal for revision to the Agency, which should share that information with the other competent authorities. ***receives a proposal for revision of a harmonised classification and labelling submitted by a manufacturer, importer or downstream user should be required to communicate its decision to accept or refuse the proposal for revision to the Agency, which***	(19) To increase transparency and predictability of the proposals submitted to the Agency, the Member States' competent authorities, manufacturers, importers or downstream users should be required to notify the Agency of their intention to submit a proposal for harmonised classification and labelling, while the Commission should be required to notify the Agency of its request to the Agency or to the Authority to prepare such proposal. Furthermore, the Agency should be required to publish information on such intention or request and update the information regarding the submitted proposal at each stage of the procedure for the harmonised classification and labelling of substances. ***Interested parties should be given the opportunity to comment, and provide information on the proposal at every stage.*** For the same reason, a competent authority that receives a proposal for revision of a harmonised classification and labelling submitted by a manufacturer, importer or downstream user should be required to communicate its decision to accept or refuse the proposal for revision to the Agency, which should share that information with the other competent authorities.

should share that information with the other competent authorities.

Or. en

Justification

It is important that interested parties that have relevant data are able to provide the relevant information for the proposal of harmonized classification on one substance or on a group of substances at all stages of the process.

Amendment 7

Proposal for a regulation
Recital 24

Text proposed by the Commission	*Amendment*
(24) Manufacturers and importers often notify different information for the same substance to be included in the Agency's inventory for classification and labelling. In some cases, such divergences result from different impurities, physical states or other differentiations and may be justified. In other cases, the divergences are due to differences in data used for classification, or to disagreement between notifiers or registrants in the case of joint submission of data in accordance with Regulation (EC) No 1907/2006, or to obsolete classification entries. As a result, the classification and labelling inventory contains divergent classifications, which makes the inventory less effective as a hazard collection and communication tool and leads to incorrect classifications, ultimately hindering the ability of Regulation (EC) No 1272/2008 to protect human health and the environment. Therefore, the notifiers should be required to provide reasons for divergence from the most severe classification or for introducing a more severe classification per hazard class for the same substance to the Agency. To address divergences between more recent and obsolete classifications, notifiers	(24) Manufacturers and importers often notify different information for the same substance to be included in the Agency's inventory for classification and labelling. In some cases, such divergences result from different impurities, physical states or other differentiations and may be justified. In other cases, the divergences are due to differences in data used for classification, or to disagreement between notifiers or registrants in the case of joint submission of data in accordance with Regulation (EC) No 1907/2006, or to obsolete classification entries. As a result, the classification and labelling inventory contains divergent classifications, which makes the inventory less effective as a hazard collection and communication tool and leads to incorrect classifications, ultimately hindering the ability of Regulation (EC) No 1272/2008 to protect human health and the environment. Therefore, the notifiers should be required ***where applicable and practically achievable, without new data acquiring or studies being necessary,*** to provide reasons for divergence from the most severe classification or for introducing a more severe classification per hazard class for the same substance to the

should be required to update their notifications within 6 months after a decision to change the classification and labelling of a substance has been taken pursuant to a review in Article 15(1) of that Regulation.	Agency. To address divergences between more recent and obsolete classifications, notifiers should be required to update their notifications within 6 months after a decision to change the classification and labelling of a substance has been taken pursuant to a review in Article 15(1) of that Regulation.

Or. en

Justification

As the Classification and Labelling Inventory does not contain any supporting data or study, it is important to bear in mind that the notifier may normally justify only its own classification based on supporting data available to him, but he is generally not able to assess why another notifier concludes a different classification due to lack of access to data from the other notifier(s), unless they have both registered under REACH for the same volume band. Therefore, a justification of divergence from another notification is not always possible, without having access to the supporting data of that notification. In addition, it is unclear whether the notifier bears the responsibility of engaging with other notifier(s) in case of divergence. The concept of lead registrant applies only to REACH, not to CLP. For that reason, the text should clarify that aligning on diverging classifications should only be required when practically achievable, without having to acquire new data nor studies (this would imply costs and such costs would change the outcome on the topic of the Commission's Impact Assessment). Further guidance on when that requirement is applicable and how that requirement should be fulfilled in practice would need to be developed by ECHA.

Amendment 8

Proposal for a regulation
Recital 36 a (new)

Text proposed by the Commission	*Amendment*
	(36a) The revision of this regulation expands the tasks and remit of the Agency. In order to provide adequate expertise, support, and thorough evaluations, the resources of the Agency should be enhanced, under a separate budgetary line.

Or. en

Justification

It is of paramount importance, in order for the Agency to continue performing at high level, that it should be granted sufficient resources to properly navigate the added workload detailed on this regulation. These resources should be provided under a separate budgetary line.

Amendment 9

Proposal for a regulation
Recital 36 b (new)

Text proposed by the Commission	*Amendment*
	(36b) The 'ECHA Founding Regulation' should take account of these needs.

Or. en

Justification

The abovementioned needs, which are the basis of the excessive workload, and that need to be performed for the revision of the current Regulation, should be clearly reflected in the envisaged standalone ECHA Founding Regulation.

Amendment 10

Proposal for a regulation
Recital 37 a (new)

Text proposed by the Commission	*Amendment*
	(37a) To ensure that, for all the direct and indirect costs for producers that result from the adopted provisions in this regulation, the Commission should conduct an assessment on these costs. The assessment should be the basis to establish an EU support scheme, based on the existing financial instruments, that should cover the regulatory compliance costs for the most vulnerable along the production chain of essential oils. The scheme should mainly target micro, small and medium enterprises. The support scheme should aim to reduce the risk of

detriment to EU's competitiveness and should prevent insolvency of producers.

Or. en

Justification

The existing Impact assessment by the Commission does not examine the inevitable costs along the value chain, including on the pre-classification and the information and compliance requirements for registration dossiers. Therefore, the burden on the revenues of the industry is widely unknown. The disproportionate weight on SMEs could easily push them out of business, especially in the context of the recent crises. As a result, local jobs, regional economies and traditional industries are at risk, while the EU opens the door to competitor imports from third countries.

Amendment 11

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

Present text	*Amendment*
	(1a) Article 1 is replaced by the following:
Article 1	‘Article 1
Purpose and Scope	Purpose and Scope
1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment ***as well as*** the free movement of substances, mixtures and articles as referred to in Article 4(8) by:	1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment**,** the free movement of substances, mixtures and articles as referred to in Article 4(8)***, and advance the ultimate goal of fully replacing animal testing,*** by:
(a) harmonising the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures;	(a) harmonising the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures;
(b) providing an obligation for:	(b) providing an obligation for:
(i) manufacturers, importers and downstream users to classify substances and mixtures placed on the market;	(i) manufacturers, importers and downstream users to classify substances and mixtures placed on the market;
(ii) suppliers to label and package	(ii) suppliers to label and package

substances and mixtures placed on the market;	substances and mixtures placed on the market;
(iii) manufacturers, producers of articles and importers to classify those substances not placed on the market that are subject to registration or notification under Regulation (EC) No 1907/2006;	(iii) manufacturers, producers of articles and importers to classify those substances not placed on the market that are subject to registration or notification under Regulation (EC) No 1907/2006;
	(iv) the Commission to ensure, prior to introducing new hazard classes or classification criteria, that such classes or criteria can be fully satisfied with existing data aligned with the EU's goal of fully replacing animal testing.'.

Or. en

(https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R1272&from=EN)

Justification

The Union's goal of fully replacing animal testing as articulated in Recital (33) of the Commission's legislative proposal should be reflected and reinforced in Article 1 to translate aspiration into action and accountability. In order for this goal to be achieved, it must be positioned as an overarching priority that guides downstream activity governed under this Regulation, including decisions to introduce new hazard classes, and the classification criteria defined therein, to ensure they can be satisfied without recourse to new animal testing. This amendment is consistent with the Commission's own vision that implementation of the CLP Regulation "should be based on the use of alternative test methods."

Amendment 12

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 1272/2008
Article 5 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
A ***multi-constituent*** substance containing at least one constituent, in the form of an individual constituent, an identified impurity or an additive for which relevant information referred to in paragraph 1 is available, shall be examined in accordance with the criteria set out in this paragraph, using the available information on those	A substance containing at least one constituent ***above the applicable concentration limit***, in the form of an individual constituent, an identified impurity or an additive for which relevant information referred to in paragraph 1 is available, shall be examined ***and evaluated*** in accordance with the criteria set out in

constituents as well as on the substance, unless Annex I lays down a specific provision.	this paragraph ***3***, using the available information on those constituents as well as on the substance ***as a whole***, unless Annex I lays down a ***more*** specific provision.

Or. en

Justification

The Reference to "paragraph 3" should be added simply to clarify that the provision refers to this paragraph (and not to paragraph 1, quoted just before).

Amendment 13

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 1272/2008
Article 5 – paragraph 3 – subparagraph 3

Text proposed by the Commission	*Amendment*
Relevant available information on the ***multi-constituent*** substance itself shall be taken into account where one of the following conditions are met:	***In particular,*** relevant available information on the substance itself shall be taken into account where one of the following conditions are met:

Or. en

Amendment 14

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 1272/2008
Article 5 – paragraph 3 – subparagraph 4

Text proposed by the Commission	*Amendment*
Relevant available information on the multi-constituent substance itself showing absence of certain properties or less severe properties shall not override the relevant available information on the constituents in the substance.	***deleted***

Or. en

Amendment 15

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 1272/2008
Article 5 –paragraph 3 – subparagraph 5

Text proposed by the Commission	*Amendment*
For the evaluation of ***multi-constituent*** substances pursuant to Chapter 2 in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine disrupting property for human health' and 'endocrine disrupting property for the environment' hazard classes referred to in sections ***3.5.3.1, 3.6.3.1, 3.7.3.1, 3.11.3.1. and 4.2.3.1***. of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual constituents in the substance.	For the evaluation of substances pursuant to Chapter 2 in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine disrupting property for human health' and 'endocrine disrupting property for the environment' hazard classes referred to in sections ***3.5., 3.6., 3.7. 3.11. and 4.2***. of Annex I***, where relevant information referred to in paragraph 1 is not available on the substance itself***, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual constituents in the substance.

Or. en

Justification

On the hazard classes referred to in the above sections, it is more appropriate to refer to the titles of the hazard classes (germ cell mutagenicity for example in 3.5) as they apply to both substances and mixtures, and remove the specific numbering (e.g. 3.5.3.1.) that only relates to the mixtures. That is the rational of removing the specific numbering.

Amendment 16

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 1272/2008
Article 5 – paragraph 3 – subparagraph 5

Text proposed by the Commission	*Amendment*
For the evaluation of ***multi-constituent***	For the evaluation of substances pursuant

substances pursuant to Chapter 2 in relation to the 'biodegradation, persistence, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment' 'persistent, bioaccumulative and toxic', 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' and 'very persistent and very mobile' hazard classes referred to in sections 4.1.2.8 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual constituents in the substance.	to Chapter 2 in relation to the 'biodegradation, persistence, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment' 'persistent, bioaccumulative and toxic', 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' and 'very persistent and very mobile' hazard classes referred to in sections 4.1.2.8 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, ***where relevant information referred to in paragraph 1 is not available on the substance itself,*** the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual constituents in the substance.

Or. en

Justification

Where we have information on the natural complex substance as a whole, it is critical to continue being able to use this information as a basis for correct classification. (The over classification expected from a systematic application of the rules of mixtures under CLP and its cascading effects on the perception of natural complex substances and on downstream legislations (cosmetics, flavourings, etc.) would be very detrimental to the maintenance of those natural substances on the market although currently safely used in consumer products.) The proposed amendment would ensure continued alignment with the approach taken at international level (GHS - Global Harmonised System) and would therefore maintain the competitiveness of the European industry.

Amendment 17

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 1272/2008
Article 5 – paragraph 3 – subparagraph 6 – introductory part

Text proposed by the Commission	*Amendment*
Relevant available information on the ***multi-constituent*** substance itself shall be taken into account where one of the following conditions are met:	***In particular,*** relevant available information on the substance itself shall be taken into account where one of the following conditions are met:

Or. en

Amendment 18

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 1272/2008
Article 5 – paragraph 3 – subparagraph 7

Text proposed by the Commission	*Amendment*
Relevant available information on the multi-constituent substance itself showing absence of certain properties or less severe properties shall not override the relevant available information on the constituents in the substance.	***deleted***

Or. en

Justification

Many natural complex substances (lemon, rose, basil, thyme, etc.) may contain constituents which as single substances could be classified. But this does not mean that these natural complex substances "in their totum" and which are commonly used as fragrance ingredients, cosmetic active substances, etc., present safety concerns for the consumers. An incorrect classification of naturals as substances of carcinogenic, mutagenic, toxic for reproduction (CMR) or endocrine disruptor nature would have severe negative consequences on these substances and would lead to their ban in certain consumer products for no safety reason and would have a negative impact on their use in food and daily nutrition.

Amendment 19

Proposal for a regulation
Article 1 – paragraph 1 – point 4 a (new)
Regulation (EC) No 1272/2008
Article 5 – paragraph 3 – subparagraph 7 a (new)

Text proposed by the Commission	*Amendment*
	(4a) in Article 5, paragraph 3, the subparagraph 7a is added:
	'To modify Annex I and in light with all relevant information on substances, the Commission shall use the procedure of Article 53.'.

Or. en

Justification

The procedure for amending Annex I, in light of all relevant information on substances with constituents, is not indicated. Article 53 specifically states that the Commission is empowered to adopt delegated acts in accordance with the amendment of section 1.6. of Annex I in order to adapt the labelling elements referred to in Article 34a(2) to technical progress, but does not mention the procedure for amending Annex I in light of all relevant information on substances with constituents.

Amendment 20

Proposal for a regulation
Article 1 – paragraph 1 – point 5 a (new)
Regulation (EC) No 1272/2008
Article 6 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	(5a) in Article 6, paragraph 4a is added:
	'4a. The Agency shall develop robust and timely guidance to support the abovementioned evaluations. Once the Guidance is adopted, the abovementioned criteria shall begin to apply. The Agency shall be provided with the adequate resources, under a separate budgetary line, to support this work. The 'ECHA Founding Regulation' shall take account of these needs.';

Or. en

Justification

ECHA should be granted sufficient resources on the basis of a separate budget, to properly navigate the added workload to the introduction of new hazard classes, as well as the production of clear and robust guidance to support the evaluation of mixtures. These resources shall be provided under a separate budgetary line. This should be clearly reflected in the envisaged standalone ECHA Founding Regulation.

Amendment 21

Proposal for a regulation
Article 1 – paragraph 1 – point 5 b (new)
Regulation (EC) No 1272/2008
Article 7

Present text	*Amendment*
	(5b) Article 7 is replaced by the following:
Article 7	‘Article 7
Animal and human testing	Animal***, non-animal*** and human testing
1. Where new tests are carried out for the purposes of this Regulation, tests on animals within the meaning of Directive 86/ 609/EEC shall be undertaken only where no other alternatives, which provide adequate reliability and quality of data, are possible.	1. Where new tests are carried out for the purposes of this Regulation, tests on animals within the meaning of Directive 86/ 609/EEC shall be undertaken only where no other alternatives, which provide adequate reliability and quality of data, are possible.
2. Tests on non-human primates shall be prohibited for the purposes of this Regulation.	2. Tests on non-human primates shall be prohibited for the purposes of this Regulation.
3. Tests on humans shall not be performed for the purposes of this Regulation. Data obtained from other sources, such as clinical studies, can however be used for the purposes of this Regulation.	3. Tests on humans shall not be performed for the purposes of this Regulation. Data obtained from other sources, such as clinical studies, can however be used for the purposes of this Regulation.
	3a. All data, including animal test data and non-animal data, shall be evaluated comparably and according to their biological relevance, mechanistic understanding, and ability to provide information suitable for meeting the requirements of this Regulation.’;

Or. en

(https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R1272&from=EN)

Justification

The Commission’s legislative proposal states: “Under the CLP Regulation, the decision to classify a substance or a mixture for environmental and human health hazards is exclusively based on existing information.”. However, the current language of Article 7 clearly allows for

new animal testing. This amendment is therefore necessary to correct this misalignment and bring the CLP Regulation into line with the Commission's stated intent. It is likewise important to ensure that test data are evaluated fairly and without prejudice, as it continues to be the case that non-animal data are held to a more stringent standard than animal data, which leads to a lower level of use and acceptance of non-animal methods for generating information on chemical substances. As noted by several regulators and experts in the field, the robustness of a testing strategy is assessed according to its biological relevance, technical characterization, data integrity and transparency, and independent review. Therefore, the biological relevance of non-animal approaches should focus on their alignment with human biology, mechanistic understanding, and ability to provide information that leads to protective decisions, rather than solely comparing the data generated with those from traditional animal test methods.

Amendment 22

Proposal for a regulation
Article 1 – paragraph 1 – point 6
Regulation (EC) No 1272/2008
Article 9 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where the criteria referred to in paragraph 1 cannot be applied directly to available identified information, manufacturers, importers and downstream users shall carry out an evaluation by applying a weight of evidence determination using expert judgement in accordance with section 1.1.1 of Annex I to this Regulation, weighing all available information having a bearing on the determination of the hazards of the substance or the mixture, and in accordance with section 1.2 of Annex XI to Regulation (EC) No 1907/2006.	3. Where the criteria referred to in paragraph 1 cannot be applied directly to ***all*** available identified information***, or where hazards are defined by multiple criteria***, manufacturers, importers and downstream users shall carry out an evaluation by applying a weight of evidence determination using expert judgement in accordance with section 1.1.1 of Annex I to this Regulation, weighing all available information ***across all individual and relevant criteria*** having a bearing on the determination of the hazards of the substance or the mixture, and in accordance with section 1.2 of Annex XI to Regulation (EC) No 1907/2006.

Or. en

Justification

Where more comprehensive and more refined data are available for the assessment of substances, these data should be used in the hazard classification process to avoid false negative as well as false positive results. Otherwise, safe substances could be considered hazardous and banned from the use in Europe under chemicals legislation relying on the CLP

Regulation, putting competitiveness of European producers at risk while leading to more imports of finished products from other geographic areas.

Amendment 23

Proposal for a regulation
Article 1 – paragraph 1 – point 7
Regulation (EC) No 1272/2008
Article 10 – paragraph 9

Text proposed by the Commission	*Amendment*
9. The Agency shall provide further guidance for the application of paragraphs ***1, 2*** and 3.	9. The Agency shall provide further guidance for the application of paragraphs ***1, 2*** and 3. ***The Agency shall be provided with the adequate resources to support this work, under a separate budgetary line. The 'ECHA Founding Regulation' shall take account of these needs.***

Or. en

Justification

ECHA should be granted sufficient resources to produce clear and robust guidance to support this work. These resources shall be provided under a separate budgetary line. This should be clearly reflected in the envisaged standalone ECHA Founding Regulation.

Amendment 24

Proposal for a regulation
Article 1 – paragraph 1 – point 7 a (new)
Regulation (EC) No 1272/2008
Article 17

Present text	*Amendment*
	(7a) Article 17 is replaced by the following:
Article 17	'Article 17
General Rules	General Rules
1. A substance or mixture classified as hazardous and contained in packaging shall bear a label including the following	A substance or mixture classified as hazardous and contained in packaging shall bear a ***label or a fold-out*** label including

elements:	the following elements:
(a) the name, address and telephone number of the supplier(s);	(a) the name, address and telephone number of the supplier(s);
(b) the nominal quantity of the substance or mixture in the package made available to the general public, unless this quantity is specified elsewhere on the package;	(b) the nominal quantity of the substance or mixture in the package made available to the general public, unless this quantity is specified elsewhere on the package;
(c) product identifiers as specified in Article 18;	(c) product identifiers as specified in Article 18;
(d) where applicable, hazard pictograms in accordance with Article 19;	(d) where applicable, hazard pictograms in accordance with Article 19;
(e) where applicable, signal words in accordance with Article 20;	(e) where applicable, signal words in accordance with Article 20;
(f) where applicable, hazard statements in accordance with Article 21;	(f) where applicable, hazard statements in accordance with Article 21;
(g) where applicable, the appropriate precautionary statements in accordance with Article 22;	(g) where applicable, the appropriate precautionary statements in accordance with Article 22;
(h) where applicable, a section for supplemental information in accordance with Article 25.	(h) where applicable, a section for supplemental information in accordance with Article 25.
2. The label shall be written in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.	2. The label shall be written in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.
Suppliers may use more languages on their labels than those required by the Member States, provided that the same details appear in all languages used.	Suppliers may use more languages on their labels ***or fold-out labels*** than those required by the Member States, provided that the same details appear in all languages used.
	The information in paragraph 1 (e), (f), (g) and (h) may be provided on the inner pages of a fold-out label. For multilingual fold-out labels, the languages shall be ordered in a logical way, e.g. alphabetically.'.

Or. en

(https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R1272&from=EN)

Justification

One of the objectives of the Commission proposal is to create more flexibility for the use of fold-out labels (recital (11)) as shown in the amendment to Article 29. To ensure consistency and clarity for economic operators and Member State competent authorities, a corresponding reference to fold-out labels should be included.

Amendment 25

Proposal for a regulation
Article 1 – paragraph 1 – point 11 – point a
Regulation (EC) No 1272/2008
Article 29 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where the packaging of a substance or a mixture is either in such a shape or form or is so small that it is impossible to meet the requirements laid down in Article 31 for a label or a fold-out 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 sections 1.5.1.1. and 1.5.1.2. of Annex I.;	1. Where the packaging of a substance or a mixture is either in such a shape or form or is so small that it is impossible to meet the requirements laid down in Article 31 for a label or a fold-out label in the languages of the Member ***States*** in which the substance or mixture is placed on the market, the label elements set out in Article17(1), shall be provided in accordance with sections 1.5.1.1. and 1.5.1.2. of Annex I.;

Or. en

Amendment 26

Proposal for a regulation
Article 1 – paragraph 1 – point 12
Regulation (EC) No 1272/2008
Article 30 – paragraph 1

Text proposed by the Commission	*Amendment*
1. In case of a change regarding the classification and 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	1. In case of a change regarding the classification and 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

shall ensure that the label is updated within ***6*** months after the results of the new evaluation referred to in Article 15(4) were obtained.	shall ensure that the label is updated within ***18*** months after the results of the new evaluation referred to in Article 15(4) were obtained.

Or. en

Justification

It is critical to grant sufficient time for all actors in the supply chain to update their labels and to sustainably exhaust their stocks. The reason for a label update has absolutely no influence on the efforts required to update label artwork. Downstream users are in the middle of the supply chain and depend on their suppliers for classification information. The proposed six-month transition period is difficult for manufacturers to meet and would create scrappage, product-rework/relabel and unnecessary transport of goods which contradicts the objectives of the Green Deal. This should be aligned with the 18 months given under paragraph 2 and the typical transition period for delegated acts under paragraph 3 for harmonised classification.

Amendment 27

Proposal for a regulation
Article 1 – paragraph 1 – point 13 a (new)
Regulation (EC) No 1272/2008
Article 31

Present text	*Amendment*
	(13a) Article 31 is replaced by the following:
Article 31	‘Article 31
General rules for the application of labels	General rules for the application of labels ***and fold-out labels***
1. Labels shall be firmly affixed to one or more surfaces of the packaging immediately containing the substance or mixture and shall be readable horizontally when the package is set down normally.	***1. Labels and fold-out*** labels shall be firmly affixed to one or more surfaces of the packaging immediately containing the substance or mixture and shall be readable horizontally when the package is set down normally.
2. The colour and presentation of any label shall be such that the hazard pictogram stands out clearly.	2. The colour and presentation of any label shall be such that the hazard pictogram stands out clearly.
3. The label elements referred to in Article 17(1) shall be clearly and indelibly marked. They shall stand out clearly from the	3. The label elements referred to in Article 17(1) shall be clearly and indelibly marked. They shall stand out clearly from

background and be of such size and spacing as to be easily read.	the background and be of such size and spacing as to be easily read.
4. The shape, colour and the size of a hazard pictogram as well as the dimensions of the label shall be as set out in section 1.2.1 of Annex I.	4. The shape, colour and the size of a hazard pictogram as well as the dimensions of the label ***or fold-out label*** shall be as set out in section 1.2.1 of Annex I.
5. A label shall not be required when the label elements referred to in Article 17(1) are shown clearly on the packaging itself. In such cases, the requirements of this Chapter applicable to a label shall be applied to the information shown on the packaging.	5. A label shall not be required when the label elements referred to in Article 17(1) are shown clearly on the packaging itself. In such cases, the requirements of this Chapter applicable to a label shall be applied to the information shown on the packaging.’;

Or. en

(https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R1272&from=EN)

Justification

One of the objectives of the Commission proposal is to create more flexibility for the use of fold-out labels (recital (11)). To ensure consistency and clarity for economic operators and Member State competent authorities, a corresponding reference to fold-out labels as an alternative should be included in Article 31.

Amendment 28

Proposal for a regulation
Article 1 – paragraph 1 – point 13 b (new)
Regulation (EC) No 1272/2008
Article 32 – paragraph 3

Present text	*Amendment*
	(13b) Article 32, paragraph 3, is replaced by the following:
3. Groups of hazard statements and groups of precautionary statements referred to in paragraph 2 shall be located together on the label by language.	‘3. Groups of hazard statements and groups of precautionary statements referred to in paragraph 2 shall be located together on the label ***or the fold-out label*** by language***. The languages shall be ordered in a logical way, e.g. alphabetically***.’;

Or. en

(https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R1272&from=EN)

Justification

One of the objectives of the Commission proposal is to create more flexibility for the use of fold-out labels (recital (11)). To ensure consistency and clarity for economic operators and Member State competent authorities, a corresponding reference to fold-out labels as an alternative should be included in Article 32. This is line with suggested corresponding changes in Article 31. Additionally, to achieve the desired flexibility, the supplier of the substance or mixture should follow ECHA's guidance on language order.

Amendment 29

Proposal for a regulation
Article 1 – paragraph 1 – point 15
Regulation (EC) No 1272/2008
Article 34 b – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) the digital label shall be accessible free of charge, without the need to register, download or install applications, or to provide a password;	(d) the digital label shall be accessible free of charge, without the need to register, download or install ***specific*** applications, or to provide a password;

Or. en

Justification

A general reference not to download or install an application could de facto also prevent the use of a QR code reader application, as some people may need to install it on their mobile.

Amendment 30

Proposal for a regulation
Article 1 – paragraph 1 – point 18 – point b
Regulation (EC) No 1272/2008
Article 37 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Manufacturers, importers or downstream users of substances may submit to the Agency a proposal for harmonised classification and labelling of those substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, provided that there	2. Manufacturers, importers or downstream users of substances may submit to the Agency a proposal for harmonised classification and labelling of those substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, provided that there

is no entry in Part 3 of Annex VI for such substances in relation to the hazard class or differentiation covered by that proposal.***;***	is no entry in Part 3 of Annex VI for such substances in relation to the hazard class or differentiation covered by that proposal. ***In case of a proposal for harmonised classification and labelling of a group of substances, those substances shall be grouped together based on clear and cumulative scientific criteria. These criteria shall include structural similarity and similar evidence-based hazard and risk profiles. The assessment of the hazard and risk profile shall be carried out in a Weight of Evidence manner.***

Or. en

Justification

The grouping of substances going into a harmonised classification of labelling must be based on clear scientific criteria. The allowed grouping criteria should be clearly defined as established under REACH. Chemical structure is the appropriate starting point to consider when grouping substances but cannot be conclusive. All grouping practices must be scientifically robust, coherent and transparent. Similar family name or backbone should not be confused with similar hazard profile. Grouping based merely on structural similarity may lead to inadequate worst-case classification. It must be complemented by an assessment of the hazard properties of the various substances of the group to identify similarities and differences within the group. The assessment of hazard profiles should be carried out in a Weight of Evidence manner in order to give priority to actual robust experimental data.

Amendment 31

Proposal for a regulation
Article 1 – paragraph 1 – point 18 – point c
Regulation (EC) No 1272/2008
Article 37 – paragraph 2a – subparagraph 1

Text proposed by the Commission	*Amendment*
Before submitting a proposal to the Agency, a competent authority, manufacturer, importer or downstream user shall notify the Agency of its intention to submit a proposal for harmonised classification and labelling and, in the case of the Commission, the request to the Agency or the European Food Safety Authority to prepare such proposal.	Before submitting a proposal to the Agency, a competent authority, manufacturer, importer or downstream user shall notify the Agency of its intention to submit a proposal for harmonised classification and labelling and, in the case of the Commission, the request to the Agency or the European Food Safety Authority to prepare such proposal. ***The***

Agency shall be provided with the adequate resources to support this work, under a separate budgetary line. The 'ECHA Founding Regulation' shall take account of these needs.

Or. en

Justification

This right of initiative will create more work for ECHA therefore should be granted sufficient resources, under separate budgetary line, to carry out these tasks. This should be clearly reflected in the envisaged standalone ECHA Founding Regulation.

Amendment 32

Proposal for a regulation
Article 1 – paragraph 1 – point 18 – point c
Regulation (EC) No 1272/2008
Article 37 – paragraph 2a – subparagraph 2

Text proposed by the Commission	*Amendment*
Within one week from receipt of the notification, the Agency shall publish the name ***and, where relevant***, the EC and CAS numbers of the substance(s), the status of the proposal and the name of the submitter. The Agency shall update the information on the status of the proposal after completion of each stage of the process referred to in Article 37(4) and (5).	Within one week from receipt of the notification, the Agency shall publish the name, the EC and CAS numbers of the substance(s)***, and where relevant***, the status of the proposal and the name of the submitter. The Agency shall update the information on the status of the proposal after completion of each stage of the process referred to in Article 37(4) and (5).

Or. en

Amendment 33

Proposal for a regulation
Article 1 – paragraph 1 – point 18 – point c
Regulation (EC) No 1272/2008
Article 37 – paragraph 2a – subparagraph 3

Text proposed by the Commission	*Amendment*
Where a competent authority receives a	Where a competent authority receives a

proposal in accordance with paragraph 6, it shall notify the Agency and provide any relevant information on its reason for accepting or refusing the proposal. The Agency shall share that information with the other competent authorities.***';***	proposal in accordance with paragraph 6, it shall notify the Agency and provide any relevant information on its reason for accepting or refusing the proposal. The Agency shall share that information with the other competent authorities. ***Any grouping approach in a proposal for harmonised classification and labelling should be justified on the basis of criteria to be developed by the Agency.';***

Or. en

Justification

There is no procedure to propose harmonised classification for a mixture. Therefore, substances with constituents cannot be subject to harmonised classification solely based on the classification criteria for mixtures.

Amendment 34

Proposal for a regulation
Article 1 – paragraph 1 – point 18 – point c a (new)
Regulation (EC) No 1272/2008
Article 37 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	(ca) the following paragraph 2b is inserted:
	'2b. A proposal for harmonised classification of a substance with constituents should be submitted as for any other substance following the procedure described under Article 37 (1) or (2) and cannot be solely based on the application of the classification criteria for mixtures.';

Or. en

Justification

The sole application of the classification criteria for mixtures for the harmonisation procedure for classification and labelling of substances may lead to wrong and/or over-classification of natural complex substances and may trigger negative impacts on their

perception, restrictions or even ban of these ingredients in consumer products through vertical (sectorial) legislations.

Amendment 35

Proposal for a regulation
Article 1 – paragraph 1 – point 18 – point d a (new)
Regulation (EC) No 1272/2008
Article 37 – paragraph 4

Present text	*Amendment*
	(da) paragraph 4 is replaced by the following:
4. The Committee for Risk Assessment of the Agency set up pursuant to Article 76(1)(c) of Regulation (EC) No 1907/2006 shall adopt an opinion on any proposal submitted pursuant to paragraphs 1 or 2 within 18 months of receipt of the proposal, giving the parties concerned the opportunity to comment***. The Agency*** shall forward this opinion and any comments to the Commission.	‘4. The Committee for Risk Assessment of the Agency***,*** set up pursuant to Article 76(1)(c) of Regulation (EC) No 1907/2006 ***and the Committee for Socio-economic Analysis of the Agency set up pursuant to Article 76(1)(d) of Regulation (EC) No 1907/2006, shall check if the submitted proposal conforms with Annex VI Parts 1 and 2. The Committees of the Agency*** shall adopt an opinion on any proposal submitted pursuant to paragraphs 1 or 2 within 18 months of receipt of the proposal, giving the parties concerned the opportunity to comment ***including on the implications of harmonised classification on risk management measures under the Regulation mentioned hereinabove. The Committees shall provide further guidance on how the harmonised classification proposal for group(s) of substances is to be developed, taking into account the complexity of the proposal. The Committees*** shall forward this opinion and any comments to the Commission. ***Where harmonised classification may lead to risk management measures under the Regulation (EC) No 1907/2006, the procedure to submit comments described hereinabove shall be extended by at least 30 days.’;***

Or. en

(https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R1272&from=EN)

Justification

To ensure all CLH dossier submitters (e.g., Member States, industry and – new proposal of the CLP revision – the European Commission) apply the same scientific principles to justify similar classification, there is a need for a formal quality check mechanism, i.e. a conformity check (as applied according to REACH Art 64 (3) for Authorisation and Art 69 (4) for Restriction processes), performed by ECHA Committees and for an ECHA guidance that clarifies the scientific basis from which a harmonised classification for a group of substances can be derived. Introduction of new hazard classes under CLP will increase the workload of authorities, industry and ECHA's committees, in particular RAC. Therefore, sufficient time should be given to allow for a thorough examination of each CLH dossier (including the extended possibility to comment for complex dossiers), ensuring harmonised classifications are assigned where justified based on a comprehensive review of the weight of scientific evidence. As far as potential implications of harmonised classification, recent REACH restriction developments show that there is an increasing reliance on harmonised classifications as a basis to restrict substances in mixtures or/and articles. These restrictions may lead to automatic bans or restrictions in mixtures and/or in articles, even where the concerned substances do not raise concerns for consumers, and where they are important for European competitiveness due to their reduced environmental footprint or market relevance. In addition, the compilation of information on the implications of harmonised classification on risk management measures is expected to be more time-consuming. A longer consultation period would, therefore, be required to ensure sufficient time for the collection of evidence.

Amendment 36

Proposal for a regulation
Article 1 – paragraph 1 – point 18 – point e
Regulation (EC) No 1272/2008
Article 37 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Manufacturers, importers and downstream users who have new information which may lead to ***a*** change of the harmonised classification and labelling elements of substances in Part 3 of Annex VI shall submit a proposal in accordance with paragraph 2, second subparagraph, to the competent authority in one of the Member States in which the substances are placed on the market***;***	6. Manufacturers, importers and downstream users who have new information which may lead to change of the harmonised classification and labelling elements of substances in Part 3 of annex VI shall submit a proposal in accordance with paragraph 2, second subparagraph, to the competent authority in one of the Member States in which the substances are placed on the market ***or, alternatively, directly to the Committee for Risk Assessment of the Agency set up pursuant to Article 76(1)(c) of Regulation (EC) No***

1907/2006, paragraph 4*. *The proposal of the manufacturer, importer or downstream user shall be accompanied by the payment of a fee covering all expected costs.

Or. en

Justification

The classification of substances under the CLP Regulation should be based on the most recent and reliable scientific evidence and research that have resulted from registration and evaluation of substances under the REACH legislation. For many substances classified as hazardous under the CLP, research has evolved to now allow the identification of differing potential health outcomes for different forms of the same basic substance, such as the differences in health risks between soluble and insoluble forms. The dissemination of the correct data according to the form of a substance is fundamental, for example, to allow workers to know more precisely the potential health risks of the substance they are working with rather than general health risks that may or may not apply to the form they are processing. Providing more scientifically accurate classification information will help employers focus on the most relevant necessary controls to best protect their workers. The reclassification process currently foreseen in the CLP Regulation, however, strongly relies on the action of the competent authorities in Member States. Unfortunately, these authorities often do not have the necessary expertise and resources to proceed with the reclassification process of a substance.

Amendment 37

Proposal for a regulation
Article 1 – paragraph 1 – point 20 – point a – point ii
Regulation (EC) No 1272/2008
Article 40 – paragraph 1 – subparagraph 1 – point g

Text proposed by the Commission	*Amendment*
(g) where applicable, the reason for divergence from the most severe classification per hazard class included in the inventory referred to in Article 42;	(g) where applicable ***and practically achievable, without acquiring new data or studies being necessary***, the reason for divergence from the most severe classification per hazard class included in the inventory referred to in Article 42;

Or. en

Justification

As the Classification and Labelling Inventory does not contain any supporting data or study,

it is important to bear in mind that the notifier may normally justify only its own classification based on supporting data available to him/her, but he/she is generally not able to assess why another notifier concludes a different classification due to lack of access to data from the other notifier(s), unless they have both registered under REACH for the same volume band. Therefore, a justification of divergence from another notification is not always possible without having access to the supporting data of that notification. In addition, it is unclear which notifier bears the responsibility of engaging with other notifiers(s) in case of divergence. The concept of lead registrant applies only to REACH, not CLP.

Amendment 38

Proposal for a regulation
Article 1 – paragraph 1 – point 20 – point a – point ii
Regulation (EC) No 1272/2008
Article 40 – paragraph 1 – subparagraph 1 – point h

Text proposed by the Commission	*Amendment*
(h) where applicable, the reason for introducing a more severe classification per hazard class compared to those included in the inventory referred to in Article 42.;	(h) where applicable ***and practically achievable, without acquiring new data or studies being necessary***, the reason for introducing a more severe classification per hazard class compared to those included in the inventory referred to in Article 42.;

Or. en

Justification

As the Classification and Labelling Inventory does not contain any supporting data or study, it is important to bear in mind that the notifier may normally justify only its own classification based on supporting data available to him/her, but he/she is generally not able to assess why another notifier concludes a different classification due to lack of access to data from the other notifier(s), unless they have both registered under REACH for the same volume band. Therefore, a justification of divergence from another notification is not always possible without having access to the supporting data of that notification. In addition, it is unclear which notifier bears the responsibility of engaging with other notifiers(s) in case of divergence. The concept of lead registrant applies only to REACH, not CLP.

Amendment 39

Proposal for a regulation
Article 1 – paragraph 1 – point 20 – point a – point ii a (new)
Regulation (EC) No 1272/2008
Article 40 – paragraph 1 – point h a (new)

Text proposed by the Commission	*Amendment*
	(iia) point (ha) is added as follows:
	'(ha) ECHA should develop guidance on when the requirements specified in (g) and (h) above are applicable and on how those requirements shall be fulfilled.';

Or. en

Justification

The legal text should clarify that aligning on diverging classifications should only be required when practically achievable, without having to acquire new data or studies (this would imply costs and such costs would change the Commission's Impact Assessment). Further guidance on when that requirement is applicable and how that requirement should be fulfilled in practice would need to be developed by ECHA.

Amendment 40

Proposal for a regulation
Article 1 – paragraph 1 – point 22 – point c
Regulation (EC) No 1272/2008
Article 45 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) where requested by a Member State, the Commission or the Agency, to undertake a statistical analysis to identify where improved risk management measures may be needed.	(b) where requested by a Member State, the Commission or the Agency, to undertake a statistical analysis to identify where improved risk management measures may be needed. ***The Agency shall be provided with the adequate resources to support this work, under a separate budgetary line. The 'ECHA Founding Regulation' shall take account of these needs.***

Or. en

Justification

Member States may appoint ECHA as the body responsible for receiving information relating to emergency health response and preventative measures. ECHA therefore should be granted sufficient resources, under a separate budget to carry out these tasks. This should be clearly reflected in the envisaged standalone ECHA Founding Regulation.

Amendment 41

Proposal for a regulation
Article 1 – paragraph 1 – point 23
Regulation (EC) No 1272/2008
Article 48 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Any advertisement for a substance classified as hazardous shall indicate the relevant hazard pictogram, the signal word, the hazard class and the hazard statements.	1. Any advertisement for ***the sale to the general public of*** a substance classified as hazardous shall ***request the user to "always read and follow product label information",*** indicate the relevant hazard pictogram, the signal word, the hazard class and the hazard statements.

Or. en

Justification

The advertisement requirements currently proposed would carry disproportionate burdens, without improving human health and environmental protection. Hazardous substances offered to industrial and professional users must be accompanied by Safety Data Sheets. More specific requirements on advertisement should therefore only be directed to the general public.

Amendment 42

Proposal for a regulation
Article 1 – paragraph 1 – point 23
Regulation (EC) No 1272/2008
Article 48 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Any advertisement for a mixture classified as hazardous or covered by Article 25(6) shall ***indicate the hazard pictogram, the signal word, the hazard class and the hazard statements***.	2. Any advertisement for ***the sale to the general public of*** a mixture classified as hazardous or covered by Article 25(6) shall ***request the user to "always read and follow product label information"***.

Or. en

Justification

For the general public, a request to "always read and follow product label information" is considered a more effective way to draw attention to the hazards and precautionary information on the label. It will also be more straightforward to implement in the context of advertisements, which would otherwise always need to be updated following changes in labels. This is particularly important as "any advertisement" will cover a broad range of advertising materials, including company websites, TV commercials, internet videos, customer presentations, brochures, weekly supermarket circulars and other materials, including updated in case of label changes. Such advertisements are often not made specifically for jurisdictions where CLP is the applicable legislation on hazard communication. Incorporating CLP label elements into a global promotional video will be confusing to non-EU viewers.

Amendment 43

Proposal for a regulation
Article 1 – paragraph 1 – point 24
Regulation (EC) No 1272/2008
Article 48a – paragraph 1

Text proposed by the Commission	*Amendment*
Suppliers placing substances or mixtures on the market through distance sales shall clearly indicate the label elements referred to in Article 17.	Suppliers placing substances or mixtures on the market through distance sales ***to the general public*** shall clearly indicate the label elements referred to in Article 17.

Or. en

Justification

Hazardous substances offered to industrial and professional users must be accompanied by Safety Data Sheets. Including a copy of the CLP label in B2B ordering systems will therefore not improve human health and environmental protection. In such cases, the label would often be visible to a procurement agent who has no relation to the way the purchased hazardous substances and mixtures are used by the employees of the purchasing company. The proposed amendment therefore targets the new requirements to distance sales to the general public.

Amendment 44

Proposal for a regulation
Article 1 – paragraph 1 – point 25 – point b
Regulation (EC) No 1272/2008
Article 50 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where the Agency acts as an appointed body in accordance with Article 45(1a), it shall put in place the tools necessary to provide access to the information to the relevant appointed body or bodies of the appointing Member State to fulfil their tasks with regard to emergency health response and preventative measures.	3. Where the Agency acts as an appointed body in accordance with Article 45(1a), it shall put in place the tools necessary to provide access to the information to the relevant appointed body or bodies of the appointing Member State to fulfil their tasks with regard to emergency health response and preventative measures. ***The Agency shall be provided with the adequate resources to support this work, under a separate budgetary line. The 'ECHA Founding Regulation' shall take account of these needs.***

Or. en

Justification

Article 50 as foreseen provides for the possibility to designate the Agency as the appointed body to receive relevant information for emergency health responses under Article 45. It further tasks the Agency with ensuring the availability of appropriate tools to share information with national appointed authorities so they fulfil their other obligations under Article 45. Therefore, ECHA should be granted adequate resources to carry out these tasks, on a separate budgetary basis.

Amendment 45

Proposal for a regulation
Article 1 – paragraph 1 – point 25 a (new)
Regulation (EC) No 1272/2008
Article 53 – paragraph 1

Present text	*Amendment*
	(25a) In Article 53, paragraph 1, is replaced by the following:
1. The Commission may adjust and adapt Articles 6(5), 11(3), 12, 14, 18(3)(b), 23, 25 to 29 and 35(2) second and third subparagraph and Annexes I to VII to technical and scientific progress, including taking due account of the further development of the GHS, in particular any	'1. The Commission may adjust and adapt Articles 6(5), 11(3), 12, 14, 18(3)(b), 23, 25 to 29 and 35(2) second and third subparagraph and Annexes I to VII to technical and scientific progress, including ***opportunities to promote the inclusion of harmonised criteria based on available***

UN amendments relating to the use of information on similar mixtures, and considering the developments in internationally recognised chemical programmes and of the data from accident databases. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 54(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 54(4).	***non-animal approaches,*** taking due account of the further development of the GHS, in particular any UN amendments relating to the use of information on similar mixtures, and considering the developments in internationally recognised chemical programmes and of the data from accident databases***, and subject to the provisions of Article 1.1(b)(iv)***. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 54(3). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 54(4).’;

Or. en

(https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R1272&from=EN)

Justification

According to the Rapporteur, this amendment is necessary to ensure that the Commission’s powers to introduce delegated acts are guided by the provisions of Article 1, as amended, to ensure alignment with the Union’s goal of fully replacing animal testing.

Amendment 46

Proposal for a regulation
Article 1 – paragraph 1 – point 29
Regulation (EC) No 1272/2008
Article 54 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission shall be assisted by the Committee established by Article 133 of Regulation (EC) No 1907/2006. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011*.***’;**	1. The Commission shall be assisted by the Committee established by Article 133 of Regulation (EC) No 1907/2006. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011*. ***The committee shall be provided with the adequate resources to support this work, under a separate budgetary line. This shall be clearly reflected in the ‘ECHA Founding***

	Regulation'.
_____	_____
* Regulation (EU) No 182/2011 …';	* Regulation (EU) No 182/2011 …';

Or. en

Justification

Article 54 makes reference to the work of the RAC. In order to carry out future tasks, the committee should be provided with adequate resources. These resources shall be provided under a separate budgetary line. This should be clearly reflected in the envisaged standalone ECHA Founding Regulation.

Amendment 47

Proposal for a regulation
Article 1 – paragraph 1 – point 30
Regulation (EC) No 1272/2008
Article 61 – paragraph 7

Text proposed by the Commission	*Amendment*
7. Substances ***and mixtures*** which have been classified, labelled and packaged in accordance with Article 1(1), Article 4(10), Article 5, Article 6(3) and (4), Article 9(3) and (4), Article 25(6) and (9), Articles 29, 30 and 35, Article 40(1) and (2), Article 42(1), third sub-paragraph, Article 48, section 1.2.1. of Annex I, section 1.5.1.2 of Annex I, section 1.5.2.4.1 of Annex I, Parts 3 and 5 of Annex II, Part A, the first sub-paragraph of section 2.4, of Annex VIII, Part B, section 1, of Annex VIII, Part B, the third paragraph of section 3.1, of Annex VIII , Part B, section 3.6, of Annex VIII, Part B, the first row of Table 3 of Section 3.7, of Annex VIII, Part B, the first paragraph of Section 4.1, of Annex VIII, Part C, sections 1.2 and 1.4, of Annex VIII, and Part D, sections 1, 2 and 3, of Annex VIII as applicable on … [OP: please insert the date = the day before the entry into force of this Regulation] and which were placed on the market before [OP: please insert the date =	7. Substances which have been classified, labelled and packaged in accordance with Article 1(1), Article 4(10), Article 5, Article 6(3) and (4), Article 9(3) and (4), Article 25(6) and (9), Articles 29, 30 and 35, Article 40(1) and (2), Article 42(1), third sub-paragraph, Article 48, section 1.2.1. of Annex I, section 1.5.1.2 of Annex I, section 1.5.2.4.1 of Annex I, Parts 3 and 5 of Annex II, Part A, the first sub-paragraph of section 2.4, of Annex VIII, Part B, section 1, of Annex VIII, Part B, the third paragraph of section 3.1, of Annex VIII , Part B, section 3.6, of Annex VIII, Part B, the first row of Table 3 of Section 3.7, of Annex VIII, Part B, the first paragraph of Section 4.1, of Annex VIII, Part C, sections 1.2 and 1.4, of Annex VIII, and Part D, sections 1, 2 and 3, of Annex VIII as applicable on … [OP: please insert the date = the day before the entry into force of this Regulation] and which were placed on the market before [OP: please insert the date = the first day of the month

the first day of the month following 18 months after the date of entry into force of this Regulation] are not required to be classified, labelled and packaged in accordance with this Regulation as amended by Regulation …/… of the European Parliament and of the Council* [OP: please complete the reference in the footnote – it should be the reference to this Regulation] until … [OP: please insert the date = the first day of the month following 42 months after the date of entry into force of this Regulation].	following 18 months after the date of entry into force of this Regulation] are not required to be classified, labelled and packaged in accordance with this Regulation as amended by Regulation …/… of the European Parliament and of the Council* [OP: please complete the reference in the footnote – it should be the reference to this Regulation] until … [OP: please insert the date = the first day of the month following 42 months after the date of entry into force of this Regulation].
_____	_____
* Regulation (EU) .../... of the European Parliament and of the Council of ... on ... (OJ ...).	* Regulation (EU) .../... of the European Parliament and of the Council of ... on ... (OJ ...).

Or. en

Justification

Differentiated dates for substances and mixtures should be introduced in this paragraph, as in paragraph 2 of article 2, allowing 18 months for substances and 24 months for mixtures. This is consistent with the CLP Regulation, and the delegated act for hazard classes.

Amendment 48

Proposal for a regulation
Article 1 – paragraph 1 – point 30 a (new)
Regulation (EC) No 1272/2008
Article 61 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	(30a) in Article 61, the paragraph 7a is added:
	'7a. Mixtures which have been classified, labelled and packaged in accordance with Article 1(1), Article 4(10), Article 5, Article 6(3) and (4), Article 9(3) and (4), Article 25(6) and (9), Articles 29, 30 and 35, Article 40(1) and (2), Article 42(1), third sub-paragraph, Article 48, section 1.2.1. of Annex I, section 1.5.1.2 of Annex I, section

1.5.2.4.1 of Annex I, Parts 3 and 5 of Annex II, Part A, the first sub-paragraph of section 2.4, of Annex VIII, Part B, section 1, of Annex VIII, Part B, the third paragraph of section 3.1, of Annex VIII , Part B, section 3.6, of Annex VIII, Part B, the first row of Table 3 of Section 3.7, of Annex VIII, Part B, the first paragraph of Section 4.1, of Annex VIII, Part C, sections 1.2 and 1.4, of Annex VIII, and Part D, sections 1, 2 and 3, of Annex VIII as applicable on … [OP: please insert the date = the day before the entry into force of this Regulation] and which were placed on the market before [OP: please insert the date = the first day of the month following 24 months [VC1] after the date of entry into force of this Regulation] are not required to be classified, labelled and packaged in accordance with this Regulation as amended by Regulation …/… of the European Parliament and of the Council* [OP: please complete the reference in the footnote – it should be the reference to this Regulation] until … [OP: please insert the date = the first day of the month following 48 months after the date of entry into force of this Regulation].

**** Regulation (EU) .../... of the European Parliament and of the Council of ... on ... (OJ ...).';***

Or. en

Justification

Differentiated dates for substances and mixtures should be introduced in this paragraph, as in 2 of article 2, allowing 18 months for substances and 24 months for mixtures. This is consistent with the CLP Regulation, and the delegated act for hazard classes.

Amendment 49

Proposal for a regulation
Article 2 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. The following provisions shall apply from [OP: please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation]:	2. The following provisions shall apply ***to substances*** from **…** [OP: please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation]:

Or. en

Justification

Currently there is the same application date for substances and mixtures, which makes it very challenging if not impossible for suppliers of mixtures to comply. Given the significance of these changes in the CLP OLP text (first substance, then mixtures), a differentiated timeline should be provided as foreseen in when CLP was first introduced, and as it is also in line with the delegated act on the new hazard classes. A reasonable timeline for application of these provisions would be 18 months for substances and 24 months for mixtures.

Amendment 50

Proposal for a regulation
Article 2 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The following provisions shall apply to mixtures from … [OP: please insert the date = the first day of the month following 24 months after the date of entry into force of this Regulation]:
	(a) Article 1, points (1), (4), (5), (6), (7), (10), (11), (12), (15), (16), (20), (21), (23) and (24);
	(b) Annex I, points (2), (3), (7), (9) and (10);
	(c) Annex II;
	(d) Annex III, points (1)(c), (2), (3) and (4).

Or. en

Justification

Currently there is the same application date for substances and mixtures, which makes it very

challenging if not impossible for suppliers of mixtures to comply. Given the significance of these changes in the CLP OLP text (first substance, then mixtures), a differentiated timeline should be provided as foreseen in when CLP was first introduced, and as it is also in line with the delegated act on the new hazard classes. A reasonable timeline for application of these provisions would be 18 months for substances and 24 months for mixtures.

Amendment 51

Proposal for a regulation
Article 2 – paragraph 3 – introductory part

Text proposed by the Commission	*Amendment*
3. By way of derogation from Article 1(1), Article 4(10), Article 5, Article 6(3) and (4), Article 9(3) and (4), Article 25(6) and (9), Articles 29, 30 and 35, Article 40(1) and (2), Article 42(1), third sub-paragraph, Article 48, section 1.2.1. of Annex I, section 1.5.1.2 of Annex I, section 1.5.2.4.1 of Annex I, Parts 3 and 5 of Annex II, Part A, the first sub-paragraph of section 2.4, of Annex VIII, Part B, section 1, of Annex VIII, Part B, the third paragraph of section 3.1, of Annex VIII , Part B, section 3.6, of Annex VIII, Part B, the first row of Table 3 of Section 3.7, of Annex VIII, Part B, the first paragraph of Section 4.1, of Annex VIII, Part C, sections 1.2 and 1.4, of Annex VIII, and Part D, sections 1, 2 and 3, of Annex VIII to Regulation (EC) No 1272/2008 as applicable on [OP: please insert the date = the day before the date of entry into force of this Regulation], substances and mixtures may until … [OP: please insert the date = the last day of the month following ***17*** months after the date of entry into force of this Regulation] be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by the following provisions of this Regulation:	3. By way of derogation from Article 1(1), Article 4(10), Article 5, Article 6(3) and (4), Article 9(3) and (4), Article 25(6) and (9), Articles 29, 30 and 35, Article 40(1) and (2), Article 42(1), third sub-paragraph, Article 48, section 1.2.1. of Annex I, section 1.5.1.2 of Annex I, section 1.5.2.4.1 of Annex I, Parts 3 and 5 of Annex II, Part A, the first sub-paragraph of section 2.4, of Annex VIII, Part B, section 1, of Annex VIII, Part B, the third paragraph of section 3.1, of Annex VIII , Part B, section 3.6, of Annex VIII, Part B, the first row of Table 3 of Section 3.7, of Annex VIII, Part B, the first paragraph of Section 4.1, of Annex VIII, Part C, sections 1.2 and 1.4, of Annex VIII, and Part D, sections 1, 2 and 3, of Annex VIII to Regulation (EC) No 1272/2008 as applicable on … [OP: please insert the date = the day before the date of entry into force of this Regulation], substances ***may until … [OP: please insert the date = the last day of the month following 17 months after the date of entry into force of this Regulation]*** and mixtures may until … [OP: please insert the date = the last day of the month following ***35*** months after the date of entry into force of this Regulation] be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by the following provisions of this Regulation:

Or. en

Justification

Differentiated dates for substances and mixtures should be introduced in this paragraph, as in paragraph 2 of Article 2, allowing 18 months for substances and 36 months for mixtures. This is consistent with the CLP Regulation, and the delegated act for hazard classes

Amendment 52

Proposal for a regulation
Annex I – paragraph 1 – point 2
Regulation (EC) No 1272/2008
Annex I - part I –section 1.2.1.4 – table 1.3 – row 2

Not exceeding 3 litres:	If possible, at least 52x74	Not smaller than 10x10 If possible, at least 16x16	***8***pt

Not exceeding 3 litres:	If possible, at least 52x74	Not smaller than 10x10 If possible, at least 16x16	***4***pt

Or. en

Amendment 53

Proposal for a regulation
Annex I – paragraph 1 – point 2
Regulation (EC) No 1272/2008
Annex I - part I –section 1.2.1.4 – table 1.3 – row 3

Greater than 3 litres but not exceeding 50 litres:	At least 74x105	At least 23x23	***12***pt

Greater than 3 litres but not exceeding 50 litres:	At least 74x105	At least 23x23	***6***pt

Or. en

Amendment 54

Proposal for a regulation
Annex I – paragraph 1 – point 2
Regulation (EC) No 1272/2008
Annex I - part I –section 1.2.1.4 – table 1.3 – row 4

Greater than 50 litres but not exceeding 500 litres:	At least 105x148	At least 32x32	***16***pt

Greater than 50 litres but not exceeding 500 litres:	At least 105x148	At least 32x32	***8***pt

Or. en

Amendment 55

Proposal for a regulation
Annex I – paragraph 1 – point 2
Regulation (EC) No 1272/2008
Annex I - part I –section 1.2.1.4 – table 1.3 – row 5

Greater than 500 litres:	At least 148x210	At least 46x46	***20***pt’;

Greater than 500 litres:	At least 148x210	At least 46x46	***10***pt’;

Or. en

Amendment 56

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

Text proposed by the Commission	*Amendment*
1.2.1.5. The text on the label shall have the following characteristics:	***deleted***
(a) the background of the label shall be white;	
(b) the distance between two lines shall be equal or above 120 % of the font size;	
(c) a single font shall be used that is easily legible and without serifs;	
(d) the letter spacing shall be appropriate for the selected font to be comfortably legible.	
For the labelling of inner packaging where the contents do not exceed 10 ml, the font size may be smaller than indicated in Table 1.3, as long as it remains legible for a person with average eyesight, where itis deemed important to place the most critical hazard statement and where the outer packaging meets the requirements of Article 17.	

Or. en

Justification

The new rules for formatting labels are too stringent and too specific, particularly those prescribing a minimum font size and spacing requirements. A slight increase in font size would increase legibility, but the proposed increase is unnecessary and impractical: it would make current label sizes unusable for the majority of products and would reduce the number of languages that can be placed on one label and thus, considerably limit flexibility. In addition, companies would need new or updated software's to manage those requirements.

Therefore, we suggest to reach a common ground by maintaining the minimum font size (while increasing it/per category) and eliminating the part 1.2.1.5, as specific formatting rules should be kept in the guidance document. This approach has been underlined also by ECHA Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 Version 4.2 March 2021, according to which: "Readability is determined by the combination of 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.". Overly prescriptive additional requirements regarding font size, distance between two lines and background colour are not justified and severely limit the flexibility of suppliers. It is sufficient if the label or fold-out label is easily readable and clearly stand out from the background. In fact, the additional requirements would hinder the free movement of products in the Single Market, which in turn would entail an adjustment of logistics.

Amendment 57

Proposal for a regulation
Annex II a (new)
Regulation (EC) No 1272/2008
Annex VI

Present text	*Amendment*
	ANNEX IIa
	Annex VI is amended as follows:
ANNEX VI	'ANNEX VI
Harmonised classification and labelling for certain hazardous substances	Harmonised classification and labelling for certain hazardous substances
PART 2: DOSSIERS FOR HARMONISED CLASSIFICATION AND LABELLING	PART 2: DOSSIERS FOR HARMONISED CLASSIFICATION AND LABELLING
This Part lays down general principles for preparing dossiers to propose and justify harmonised classification and labelling.	This Part lays down general principles for preparing dossiers to propose and justify harmonised classification and labelling.
The relevant parts of sections 1, 2 and 3 of Annex I to Regulation (EC) No 1907/2006 shall be used for the methodology and format of any dossier.	The relevant parts of sections 1, 2 and 3 of Annex I to Regulation (EC) No 1907/2006 shall be used for the methodology and format of any dossier.
For all dossiers any relevant information from registration dossiers shall be considered and other available information may be used. For hazard information which has not been previously submitted to the Agency, a robust study summary shall be	For all dossiers any relevant information from registration dossiers shall be considered and other available information may be used. For hazard information which has not been previously submitted to the Agency, a robust study summary shall be

included in the dossier.

A dossier for harmonised classification and labelling shall contain the following:

— Proposal The proposal shall include the identity of the substance or substances concerned and the harmonised classification and labelling proposed.

— Justification for the proposed harmonised classification and labelling

A comparison of the available information with the criteria contained in Parts 2 to 5, taking into account the general principles in Part 1, of Annex I to this Regulation shall be completed and documented in the format set out in Part B of the Chemical Safety Report in Annex I to Regulation (EC) No 1907/2006.

— Justification for other effects at Community level

For other effects than carcinogenity, mutagenicity, reprotoxicity and respiratory sensitisation a justification shall be provided that there is a need for action demonstrated at Community level. This does not apply for an active substance in the meaning of Directive 91/414/EEC or Directive 98/8/EC.

included in the dossier.

A dossier for harmonised classification and labelling shall contain the following:

— Proposal The proposal shall include the identity of the substance or substances concerned and the harmonised classification and labelling proposed.

— Justification for the proposed harmonised classification and labelling

A comparison of the available information with the criteria contained in Parts 2 to 5, taking into account the general principles in Part 1, of Annex I to this Regulation shall be completed and documented in the format set out in Part B of the Chemical Safety Report in Annex I to Regulation (EC) No 1907/2006.

— Justification for ***the proposed grouping of substances to harmonized classification and labelling***

Where a harmonised classification and labelling proposal is made for group(s) of substances, the dossier shall include scientific justification (based on assessment of available data on physico-chemical, ecotoxicological and toxicological properties as specified in REACH Annex XI (1.5)) using a weight of evidence approach, for the grouping of substances and for applying a similar classification.

— Justification for other effects at Community level

For other effects than carcinogenity, mutagenicity, reprotoxicity and respiratory sensitisation a justification shall be provided that there is a need for action demonstrated at Community level. This does not apply for an active substance in the meaning of Directive 91/414/EEC or Directive 98/8/EC.'.

Or. en

(https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R1272&from=EN)

Justification

There is a need to develop clear, transparent criteria for the grouping of chemical substances, and guidance to apply such criteria with a high degree of scientific rigour and robustness, which is a must for legal clarity and certainty.

EXPLANATORY STATEMENT

Chemicals are the building blocks of all materials and products we produce and use and are therefore important determinants of their overall safety and sustainability. All European citizens are exposed in their daily life to chemicals, while many also use chemicals at the working environment.

The European Green Deal sets the EU on a course to become a climate neutral, clean and circular economy by 2050. It has also set a goal to step up protection of human health and the environment from hazardous chemicals and to move towards a zero pollution ambition for a toxic-free environment. Towards this end, the Chemicals Strategy for Sustainability is the first step, by defining a 2030 vision and objectives where all chemicals will be produced and used safely and sustainably, so that their negative impacts on health and environment are avoided, while their benefits for the economy and society can be fully exploited.

In this context, the revision of the CLP is an important deliverable of the Chemicals Strategy for Sustainability, which is a key building block of the European Green Deal. Since CLP provides for a horizontal approach to identify and classify the hazards related to chemicals, its revision is a first necessary step for several elements of the further revision of REACH and other sectorial legislation.

The objectives of CLP are to protect human health and the environment from hazardous chemicals and to facilitate the free movement of chemicals in the European market. So far, the Union has overall been successful in creating an efficient single market for chemicals. However, some weaknesses or gaps in the CLP Regulation prevent consumers, companies, and authorities from fully benefiting from protection against the dangers posed by hazardous chemicals.

Although certain chemicals and articles may pose risks to human health or to the environment, their hazards are not always properly identified and communicated. As it has been identified, the main driver behind this issue are inefficiencies in the procedures for assessing and classifying hazards. In addition, there is also a high number of erroneous or obsolete classifications of substances, as well as diverging classifications for the same substance in the European Chemical Agency's classification and labelling inventory ('inventory'), with almost 60% of companies having multiple notified classifications for a single substance.

One of the novelties of the new legislative proposal is the addition of new hazard classes for chemical substances. This initiative was triggered by scientific evidence supporting the fact that harmful substances and mixtures were not fully addressed via the existing criteria. Therefore, as a part of the CLP proposal, a Commission Delegated Act introduces new hazard classes and scientific and technical criteria for classifying substances and mixtures that have endocrine disrupting ('ED'), persistent, bioaccumulative and toxic ('PBT'), very persistent and very bioaccumulative ('vPvB'), persistent, mobile and toxic ('PMT'), or very persistent and very mobile ('vPvM') properties.

This proposal has as its legal basis in Article 114 of the Treaty on the Functioning of the European Union.

The Rapporteur generally supports many elements of the Commission proposal. However, there is certain room for further improvement of the proposal, by keeping some current best practices, aligning better with the needs of the European citizens and industry and providing clarifications where needed.

The grouping process shall be scientifically robust, coherent and transparent for all stakeholders. The Rapporteur considers there is a need to develop clear, transparent criteria for

the grouping of chemical substances, and guidance to apply such criteria with a high degree of scientific rigour and robustness, which is necessary for legal clarity and certainty. In this regard, the development of a guidance document for the grouping process is also essential to ensure consistency with ongoing processes under REACH. In this context, it has to be taken into consideration the Chemicals Strategy for Sustainability objective to move towards 'one substance, one assessment' approach by improving efficiency, effectiveness, coherence and transparency of the delivery of safety assessments of chemicals across all relevant legislation. This approach aims to a simpler and more transparent process and reduce additional bureaucratic burdens.

Grouping based merely on structural similarity may lead to inadequate classification. Therefore, it has to be complemented by an assessment of the hazard properties of the various substances of the group to identify similarities and differences within the group. The assessment of hazard profiles should be carried out in a Weight of Evidence manner in order to give priority to actual robust experimental data.

Regarding the evaluation of hazard information for substances and mixtures, it should be reflected in the proposal that where more comprehensive and more refined data is available for the assessment of substances, these data should be used in the hazard classification process to avoid false results. In addition, the Rapporteur supports that the interested parties that have relevant data should be able to provide the relevant information for the proposal of harmonized classification on one substance or on a group of substances at all stages of the process.

The new CLP proposal seeks to introduce a new definition for multi-constituent substances for clarifying classification rules for substances that contain impurities, additives or individual constituents above certain concentration limit. However, this new definition may create confusion as it is at odds with how multi-constituent substances have been identified under REACH. For that reason, the Rapporteur supports that the classification rules can be clarified without introducing a new definition for multi-constituent substances.

The Rapporteur believes that the legislation should consider, inter alia, the specificities of essential oils, including their character as substances with variable composition and concentration for their classification. Taking into consideration the lack of data particularly, when it comes to the essential oils a derogation is needed. By this derogation will also avoid additional bureucratic burdens, support the local jobs, traditional productions and regional economies of various Member States.

Concerning the reference to animal testing, the Rapporteur considers that the Commission has to ensure, prior to introducing new hazard classes or classification criteria, that such classes or criteria can be fully satisfied with existing data and are aligned with the EU's goal of fully replacing animal testing. This goal should be reflected in the proposal to translate aspiration into action and accountability.

Chemicals' labelling information should be made available before placing on the market, regardless of the means of sale. The new CLP Regulation proposal requires labels to be updated in case a new hazard class or a more severe classification needs to be assigned to a substance or a mixture, or when new supplemental information on the label is required. The Rapporteur considers that 18 months should be the timeline for all label updates, in particular for complex value chains that involve several mixture formulators downstream. This timeline is consistent with current practices, which have proven adequate to allow re-design, re-printing of labels and re-labelling of packages.

One of the objectives of the CLP proposal is to create more flexibility for the use of fold-out labels. To ensure consistency and clarity for economic operators and Member State competent authorities, the Rapporteur has added a corresponding reference to fold-out labels in the relevant articles of the proposal. The Rapporteur would also like to enhance the mandatory use of digital

labelling that will be based on the technological progress and taking into account societal needs and a high level of protection of human health and the environment.
To achieve the objectives of consumer protection and protection of human health and of the environment, the CLP Regulation introduces a requirement that suppliers have to ensure that substances or mixtures, including those sold online via distance sales, meet the requirements of CLP, in particular on classification, labelling and packaging. To ensure that the advertisement requirements, when are directed to the general public, secure the human health and environmental protection, the Rapporteur proposes that in the online offers and advertisements a request to "always read and follow product label information" is considered a more effective way to draw attention to the hazards and precautionary information on the label.
Moreover, the procedure for harmonisation of classification and labelling of substances has to elaborate better the submission of a proposal for harmonised classification of a substance with constituents and take into consideration that the substance(s) subject to regulatory actions must be clearly and individually identified. This is needed for legal certainty and enforcement purposes.
Furthermore, due to the new challenges of the CLP revision, the Rapporteur strongly supports that ECHA should be granted sufficient resources to properly navigate the added workload to the introduction of new hazard classes, as well as the production of clear and robust guidance to support the evaluation of mixtures. These resources have to be provided by a separate budgetary line and have to be clearly reflected in the envisaged standalone ECHA Founding Regulation.

ANNEX: LIST OF ENTITIES OR PERSONS FROM WHOM THE RAPPORTEUR HAS RECEIVED INPUT

The following list is drawn up on a purely voluntary basis under the exclusive responsibility of the rapporteur. The rapporteur has received input from the following entities or persons in the preparation of the draft report:

Entity and/or person
1. CEFIC
2. A.I.S.E. (detergents association)
3. Bayer Crop Science
4. American Chamber of Commerce to the European Union
5. BeST - Beryllium Science & Technology Association
6. L'Oréal group in Europe
7. HACI: Hellenic Association of Chemical Industries
8. AFIRM,
9. ETAD
10. EUCTL
11. BASF
12. IFRA – The International Fragrance Association
13. European Coalition to end Animal Experiments
14. FEICA- Association of the European Adhesive & Sealant Industry