AMENDMENTS 001-100
by the Committee on the Environment, Public Health and Food Safety

Report
Maria Spyraki **A9-0271/2023**
Classification, labelling and packaging of substances and mixtures

Proposal for a regulation (COM(2022)0748 – C9-0433/2022 – 2022/0432(COD))

Amendment 1

Proposal for a regulation
Recital 1

Text proposed by the Commission	*Amendment*
(1) In order to keep pace with globalisation, technological development and new means of sale, such as online sales, it is necessary to adapt Regulation (EC) No 1272/2008 of the European Parliament and of the Council. While under that Regulation it is assumed that all responsible actors in the supply chain are established in the Union, practical experience has shown that economic operators established outside the Union sell chemicals online directly to the general public in the Union. Hence, enforcement authorities are unable to enforce Regulation (EC) No 1272/2008 against economic operators not established in the Union. It is therefore ***appropriate*** to require that there is a supplier established in the Union, which ensures that the	(1) In order to keep pace with globalisation, technological development and new means of sale, such as online sales, it is necessary to adapt Regulation (EC) No 1272/2008 of the European Parliament and of the Council. While under that Regulation it is assumed that all responsible actors in the supply chain are established in the Union, practical experience has shown that economic operators established outside the Union sell chemicals online directly to the general public in the Union. Hence, enforcement authorities are unable to enforce Regulation (EC) No 1272/2008 against economic operators not established in the Union. It is therefore ***necessary*** to require that there is a supplier established in the Union, which ensures that the substance or

substance or the mixture in question meets the requirements set out in that Regulation when it is being placed on the market, including via distance sales. This provision ***would*** improve compliance with and enforcement of the Regulation (EC) ***No 12727/2008*** and thereby ensure a high level of protection of human health and the environment. In order to prevent situations where consumer becomes de jure and de facto an importer when buying the substance or the mixture via distance sales from the economic operators established outside the Union, it is necessary to specify that the supplier which ensures that the substance or the mixture in question meets the requirements set out in that Regulation acts in course of an industrial or professional activity.

the mixture in question meets the requirements set out in that Regulation when it is being placed on the market, including via distance sales. This provision***, together with the requirements in Regulation (EU) xxx/xxx [reference to adopted act to be inserted] on General Product Safety, Regulation (EU) 2022/2065, and Regulation (EU) 2019/1020 should*** improve compliance with and enforcement of Regulation (EC) ***No 1272/2008*** and thereby ensure a high level of protection of human health and the environment. In order to prevent situations where a consumer becomes *de jure* and *de facto* an importer when buying the substance or the mixture via distance sales from the economic operators established outside the Union, it is necessary to specify that the supplier which ensures that the substance or the mixture in question meets the requirements set out in that Regulation acts in course of an industrial or professional activity.

Amendment 2

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 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	(2) ***Substances containing more than one constituent are not intentional mixtures.*** From a toxicological point of view, substances ***containing*** more than one constituent 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 of the Council[39], aimed to ***minimise*** animal testing, data on substances ***containing more than one constituent*** is to be generated under the same conditions as data on any other

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***.	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 ***are*** available, substances ***containing more than one constituent*** should be evaluated and classified following the same classification rules as mixtures.
[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).	[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).

Amendment 3

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) Scientific evidence on substances containing more than one constituent of renewable botanical origin shows that specific constituents considered in an isolated way can have hazard properties that might not be expressed in the substance as a whole. Substances of renewable botanical origin are substances obtained from living plant algae and fungi organisms, renewable on a human time scale (non-fossil sources). The

	Commission should review the identification and examination of substances containing more than one constituent of renewable botanical origin that are not chemically or genetically modified and are not covered by Regulation (EU) No 1107/2009 or Regulation (EU) No 528/2012. In the context of such review, the Commission should also assess the social and economic impact on micro and small enterprises.

Amendment 4

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 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.	(3) ***Under the current state of science,*** it is ***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 ***containing more than one constituent*** 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 ***containing more than one constituent*** should therefore normally be used as the basis for hazard identification of those substances ***containing more than one constituent*** or mixtures. However, in certain cases, data on those substances ***containing more than one constituent*** 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.

Amendment 5

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 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.	(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. ***Given that the application of criteria on the different hazard classes is not always straightforward and bearing in mind that a specific hazard class may be defined by multiple criteria, manufacturers, importers and downstream users should apply weight of evidence determinations.***

Amendment 6

Proposal for a regulation
Recital 11

Text proposed by the Commission	*Amendment*
(11) Regulation (EC) No 1272/2008 only allows for the use of fold-out labels if the general rules for the application of labels cannot be met due to the shape or form of the packaging or its small size, whilst it does not provide for a minimum font size of labels that would ensure readability. As a result of advancements in labelling technologies, more flexibility should be given to suppliers by providing for a broader use of fold-out labels, while readability of labels should be ensured by laying down minimum font size and formatting requirements.	(11) Regulation (EC) No 1272/2008 only allows for the use of fold-out labels if the general rules for the application of labels cannot be met due to the shape or form of the packaging or its small size, whilst it does not provide for a minimum font size of labels that would ensure readability. As a result of advancements in labelling technologies, more flexibility should be given to suppliers by providing for a broader use of fold-out labels, while ***durability and good*** readability of ***all*** labels should be ensured***, including*** by laying down minimum font size***,*** and formatting requirements.

Amendment 7

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) Regulation (EC) No 1272/2008 needs to be adjusted to technological and societal changes in the field of digitalisation and be prepared for future developments. Digital labelling could improve the efficiency of hazard communication, especially for vulnerable population groups and people who do not speak the national language of a Member State. Therefore, it is necessary to provide for voluntary digital labelling and to lay down technical requirements for such labelling. In order to provide for legal certainty, it is appropriate to specify the label elements that are allowed to be provided in a digital format only. That possibility should only exist for information which is not instrumental for	(12) Regulation (EC) No 1272/2008 needs to be adjusted to technological and societal changes in the field of digitalisation and be prepared for future developments. Digital labelling could improve the efficiency of hazard communication, especially for vulnerable population groups and people who do not speak the national language of a Member State. Therefore, it is necessary to provide for voluntary digital labelling and to lay down technical requirements for such labelling. In order to provide for legal certainty, it is appropriate to specify the label elements that are allowed to be provided in a digital format only. That possibility should only exist for information which is not instrumental for

the safety of the user or the protection of the environment.	the safety of the user or the protection of the environment ***and should be determined taking into account the need for a high level of protection of human health and the environment***. ***The decision as to which information is not relevant for the safety of the user or the protection of the environment needs to be documented transparently. The Unique Formula Identifier, the hazard statement, the precautionary statement, the signal word, and the hazard pictogram should always remain on the on-pack label to ensure they are in sight of consumers.***

Amendment 8

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) In order to adapt the label elements allowed to be provided only in a digital format to technical progress or to the level of digital readiness among all population groups in the Union, the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union to amend the list of label elements allowed to be provided only in a digital format, taking into account societal needs ***and a*** high level of protection of human health and the environment.	(13) In order to adapt the label elements allowed to be provided only in a digital format to technical progress or to the level of digital readiness among all population groups in the Union, the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union to amend the list of label elements allowed to be provided only in a digital format, taking into account societal needs***,*** ***ensuring*** high level of protection of human health and the environment ***and sufficient information on chemicals that citizens are exposed to***.

Amendment 9

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 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.	(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 justification,*** 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. ***Where it is scientifically justified and possible, proposals for classification should prioritise groups of substances rather than individual substances. In the event of a proposal for harmonised classification and labelling of a group of substances, those substances should be grouped together based on clear scientific criteria, including structural similarity and similar evidence-based hazard profiles.***

Amendment 10

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	(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 should share that information with the other competent authorities***.	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 where appropriate.*** 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. ***To increase the efficiency of the harmonized*** classification and labelling ***process, the Commission*** should ***adopt a delegated act, no later than 12 months following the publication of the RAC opinion***.

Amendment 11

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.	(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 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.	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***, without needing to acquire new data or new 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 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. ***Moreover, the Agency should be able to remove incomplete, incorrect or obsolete notifications from the inventory after having informed the notifier.***

Amendment 12

Proposal for a regulation
Recital 25

Text proposed by the Commission	*Amendment*
(25) In order to enhance transparency of notifications as well as to facilitate the notifiers' duty to come to an agreed notification entry for the same substance,	(25) In order to enhance transparency of notifications as well as to facilitate the notifiers' duty to come to an agreed notification entry for the same substance,

certain information notified to the Agency's classification and labelling inventory should be made publicly available, free of charge. Without prejudice to the protection of commercial interests, that information should include the identity of the notifiers as, knowing whom to contact, would facilitate the objective of coming to an agreed entry to be included in that classification and labelling inventory. In the case of notifications by a group of manufacturers or importers, it should suffice to make publicly available the identity of the notifier submitting the information on behalf of the other members of the group.	***all*** information notified to the Agency's classification and labelling inventory should be made publicly available, free of charge. Without prejudice to the protection of commercial interests, that information should include the identity of the notifiers as, knowing whom to contact, would facilitate the objective of coming to an agreed entry to be included in that classification and labelling inventory. In the case of notifications by a group of manufacturers or importers, it should suffice to make publicly available the identity of the notifier submitting the information on behalf of the other members of the group.

Amendment 13

Proposal for a regulation
Recital 29

Text proposed by the Commission	*Amendment*
(29) Regulation (EC) No 1272/2008 regulates advertisement of hazardous substances and mixtures in a general manner and provides that an advertisement for a substance classified as hazardous is to mention the hazard classes or hazard categories concerned, and an advertisement for a mixture classified as hazardous or a mixture containing a classified substance is to mention the types of hazards indicated on the label where such advertisement allows concluding a contract for purchase without first having sight of the label. This obligation should be changed to ensure that the advertisement of hazardous substances and mixtures contains all the information which is most important in terms of safety and protection of the environment. Therefore, the advertisement should contain the hazard pictogram, the signal word, the hazard class and the hazard	(29) Regulation (EC) No 1272/2008 regulates advertisement of hazardous substances and mixtures in a general manner and provides that an advertisement for a substance classified as hazardous is to mention the hazard classes or hazard categories concerned, and an advertisement for a mixture classified as hazardous or a mixture containing a classified substance is to mention the types of hazards indicated on the label where such advertisement allows concluding a contract for purchase without first having sight of the label. This obligation should be changed to ensure that the advertisement of hazardous substances and mixtures contains all the information which is most important in terms of safety and protection of ***health and*** the environment. Therefore, the advertisement should contain the hazard pictogram, the signal word, the hazard class and the

statements. The hazard category should not be provided, as it is reflected by the hazard statement.

hazard statements. The hazard category should not be provided, as it is reflected by the hazard statement.

Amendment 14

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) In accordance with Directive 2010/63/EU of the European Parliament and of the Council[47] , it is necessary to replace, reduce or refine testing on animals. Implementation of Regulation (EC) No 1272/2008 should be based on the use of ***alternative test methods***, suitable for the assessment of health and environmental classification of chemicals, wherever possible. In order to speed up the transition to non-animal methods, with the ultimate goal of fully replacing animal testing, as well as to improve the efficiency of chemical hazard assessments, innovation in the field of non-animal methods should be monitored and systematically evaluated, and the Commission and the Member States acting in the interest of the Union should promote the inclusion of harmonised criteria based on available alternative methods in UN GHS and subsequently include those criteria in Regulation (EC) No 1272/2008 without ***undue*** delay.	(33) In accordance with Directive 2010/63/EU of the European Parliament and of the Council[47], it is necessary to replace, reduce or refine testing on animals***, with a view to phasing out the use of animals for testing as soon as possible***. Implementation of Regulation (EC) No 1272/2008 should be based on the ***promotion and*** use of ***New Approach Methodologies (NAM)***, suitable for the assessment of health and environmental classification of chemicals, wherever possible. In order to speed up the transition to non-animal methods, with the ultimate goal of fully replacing animal testing, as well as to improve the efficiency of chemical hazard assessments, innovation in the field of non-animal methods should be ***promoted,*** monitored and systematically ***and periodically*** evaluated, and the Commission and the Member States acting in the interest of the Union should promote the inclusion of harmonised criteria based on available alternative methods***, including new approach methods,*** in UN GHS and subsequently include those criteria in Regulation (EC) No 1272/2008 without delay.
[47] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L	[47] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L

276, 20.10.2010, p. 33).	276, 20.10.2010, p. 33).

Amendment 15
Proposal for a regulation
Recital 35 a (new)

Text proposed by the Commission	*Amendment*
	(35a) Where appropriate, the Agency should provide further guidance on the application of the provisions relating to the review of this Regulation.

Amendment 16

Proposal for a regulation
Recital 36 a (new)

Text proposed by the Commission	*Amendment*
	(36a) The amendments introduced by this regulation expands the tasks, workload and remit of the Agency. In order to provide adequate expertise, support, and thorough scientific evaluations, appropriate and stable funding for the Agency should be ensured under the framework of the upcoming Regulation establishing the ECHA.

Amendment 17

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) To ensure that suppliers of substances and mixtures have time to adapt to rules on classification, labelling and packaging, the application of some provisions of this Regulation should be deferred. Substances and mixtures which	(37) To ensure that suppliers of substances and mixtures have time to adapt to ***new*** rules on classification, labelling and packaging, the application of some provisions of this Regulation should be deferred. Substances and mixtures which

are already placed on the market before the end of that deferral period, should be allowed to continue being placed on the market without being re-classified and re-labelled in accordance with this Regulation, to avoid additional burden on suppliers of substances and mixtures.	are already placed on the market before the end of that deferral period, should be allowed to continue being placed on the market without being re-classified and re-labelled in accordance with this Regulation, to avoid additional burden on suppliers of substances and mixtures.

Amendment 18

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

Present text	*Amendment*
	-1 In Article 1, paragraph 1 is replaced by the following:
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: (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: (i) manufacturers, importers and downstream users to classify substances and mixtures placed on the market; (ii) suppliers to label and package 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;	"The purpose of this Regulation is to ensure a high level of protection of human health and the environment ***including the promotion of alternative methods, for assessment of hazards of substances and mixtures,*** as well as the free movement of substances, mixtures and articles as referred to in Article 4(8) by: (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: (i) manufacturers, importers and downstream users to classify substances and mixtures placed on the market; (ii) suppliers to label and package 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;"

Amendment 19

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 1272/2008
Article 2 – paragraph 1 – point 7a

Text proposed by the Commission	*Amendment*
‘	***deleted***
7a. ‘multi-constituent substance’ means a substance that contains more than one constituent.	

Amendment 20

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 1272/2008
Article 2 – paragraph 1 – point 38 a (new)

Text proposed by the Commission	*Amendment*
	38a. ‘refill’ means an operation through which a consumer or a professional user fills its own container, which fulfils the packaging function, with a hazardous substance or mixture offered by a supplier in the context of a commercial transaction;

Amendment 21

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 1272/2008
Article 2 – paragraph 1 – point 38 b (new)

Text proposed by the Commission	*Amendment*
	38b. ‘refill station’ means a place where a supplier offers to consumers or professional users hazardous substances or mixtures that can be purchased

through refill;

Amendment 22

Proposal for a regulation
Article 1 – paragraph 1 – point 2 a (new)
Regulation (EC) No 1272/2008
Article 3 – paragraph 1

Present text	*Amendment*
	(2a) In Article 3, paragraph 1 is replaced by the following:
A substance or a mixture fulfilling the criteria relating to physical hazards, health hazards or environmental hazards, laid down in Parts 2 to 5 of Annex I is hazardous and shall be classified in relation to the respective hazard classes provided for in that Annex.	"A substance or a mixture fulfilling the criteria relating to physical hazards, health hazards or environmental hazards, laid down in Parts 2 to 5 of Annex I is hazardous and shall be classified in relation to the respective hazard classes provided for in that Annex. ***Gender differences with regard to the susceptibility to chemicals shall be taken into consideration, where relevant.***"

Amendment 23

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 constituents as well as on the substance***, unless Annex I lays down a specific***	A substance containing ***more than*** 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 ***and evaluated*** in accordance with the criteria set out in this paragraph, using the available information on those ***known*** constituents ***above the applicable concentration limit*** as well as on the

provision.	substance ***itself***.

Amendment 24

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 1272/2008
Article 5 – paragraph 3 – subparagraph 2

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 ***these*** substances ***containing more than one constituent*** pursuant to Chapter 2 in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine ***disruption*** for human health' and 'endocrine ***disruption*** for the environment' hazard classes referred to in sections ***3.5., 3.6., 3.7., 3.11. and 4.2***. of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the ***known*** individual constituents***, impurities and additives*** in the substance**,**

Amendment 25

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EC) No 1272/2008
Article 5 – paragraph 3 – subparagraph 3 – 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:	Relevant available information on the substance ***containing more than one constituent*** itself shall be taken into account where one of the following conditions are met:

Amendment 26

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

Text proposed by the Commission	*Amendment*
(a) the information demonstrates germ cell mutagenic, carcinogenic, or toxic to reproduction properties, or endocrine ***disrupting properties*** for human health or the environment;	(a) the information demonstrates germ cell mutagenic, carcinogenic, or toxic to reproduction properties, or endocrine ***disruption*** for human health or the environment;

Amendment 27

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.	Relevant available information on the substance ***containing more than one constituent*** itself showing absence of certain properties or less severe properties shall not override the relevant available information on the constituents in the substance.

Amendment 28

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 'biodegradation, persistence, mobility and bioaccumulation' properties within the 'hazardous to the aquatic	For the evaluation of substances ***containing more than one constituent*** pursuant to Chapter 2 ***of this Title*** in relation to the 'biodegradation, persistence, mobility and bioaccumulation' properties

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.	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 ***known*** constituents***, impurities or additives*** in the substance.

Amendment 29

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:	Relevant available information on the substance ***containing more than one constituent*** itself shall be taken into account where one of the following conditions are met:

Amendment 30

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

Text proposed by the Commission	*Amendment*
(a) the information demonstrates ***biodegradation,*** persistence, mobility and bioaccumulation properties ;	(a) the information demonstrates persistence, mobility and bioaccumulation properties ***or lack of biodegradation***;

Amendment 31

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.	Relevant available information on the substance ***containing more than one constituent*** itself showing absence of ***the*** properties ***referred to in (a)*** or less severe properties shall not override the relevant available information on the constituents in the substance.

Amendment 32

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

Text proposed by the Commission	*Amendment*
	3a. Article 5, paragraph 3 shall not apply to substances containing more than one constituent of renewable botanical origin that are not chemically or genetically modified and are not covered by Regulation (EU) No 1107/2009[1a] or Regulation (EU) No 528/2012[1b].
	[1a] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.
	[1b] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of

biocidal products.

Amendment 33

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

Text proposed by the Commission	*Amendment*
For the evaluation of mixtures 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 only use the relevant available information referred to in paragraph 1 for the substances in the mixture and not for the mixture itself .	For the evaluation of mixtures pursuant to chapter 2 ***of this Title*** 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 only use the relevant available information referred to in paragraph 1 for the substances in the mixture and not for the mixture itself.

Amendment 34

Proposal for a regulation
Article 1 – paragraph 1 – point 5
Regulation (EC) No 1272/2008
Article 6 – paragraph 3 – subparagraph 2

Text proposed by the Commission	*Amendment*
However, where the available test data on the mixture itself demonstrates germ cell mutagenic, carcinogenic or toxic to reproduction properties, or endocrine disrupting properties for human health or the environment which have not been identified from the relevant available information on the individual substance referred to in the first subparagraph, ***that*** data shall also be taken into account for the	However, ***for the one plant protection product or the one biocidal product for which the approval criteria of Regulation (EC) No 1107/2009 or Regulation (EU) No 528/2012 need to be met, respectively, for the approval of the corresponding active substance, or*** where the available test data on the mixture itself demonstrates germ cell mutagenic, carcinogenic or toxic to reproduction properties, or endocrine

purposes of the evaluation of the mixture referred to in the first subparagraph.	disrupting properties for human health or the environment which have not been identified from the relevant available information on the individual substance referred to in the first subparagraph, data ***on the mixture as a whole*** shall also be taken into account for the purposes of the evaluation of the mixture referred to in the first subparagraph.

Amendment 35

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

Text proposed by the Commission	*Amendment*
4. For the evaluation of mixtures pursuant to Chapter 2 in relation to the 'biodegradation, persistency, 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 only use the relevant available information referred to in paragraph 1 for the substances in the mixture and not for the mixture itself ;	4. For the evaluation of mixtures pursuant to Chapter 2 ***of this Title*** in relation to the 'biodegradation, persistency, 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 only use the relevant available information referred to in paragraph 1 for the substances in the mixture and not for the mixture itself ; ***However, where the available test data on the mixture itself demonstrate a lack of biodegradation, persistency, mobility and bioaccumulation properties that have not been identified from the relevant available information on the individual substance referred to in the first subparagraph, such data shall also be taken into account for the purpose of evaluating the mixture***

referred to in the first subparagraph.

Amendment 36

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

Present text	*Amendment*
	(5 a) Article 7 is replaced by the following:
Article 7	"Article 7
Animal and human testing	***Non-animal,*** 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.
	4. Tests using new approach methodologies shall also be considered."

Amendment 37

Proposal for a regulation
Article 1 – paragraph 1 – point 6 – introductory part

Text proposed by the Commission	*Amendment*
(6) in Article 9, paragraphs 3 ***and 4 are***	(6) in Article 9, paragraphs 3 ***and 4 are***

replaced by the following:

replaced by the following:

Amendment 38

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 available identified information***, or where properties 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 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.

Amendment 39

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	1. A substance or mixture classified as hazardous and contained in packaging shall bear a label including the following

elements:	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**.**
	(ha) where applicable, a link to the digital label where further information can be found.
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.A***	*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.*
	The information in points (h) and (ha) in paragraph 1 may be provided on the inner pages of a fold-out label."

Amendment 40

Proposal for a regulation
Article 1 – paragraph 1 – point 7 b (new)
Regulation (EC) No 1272/2008
Article 18 – paragraph 3 – subparagraph 1– point b

Present text	*Amendment*
	(7b) In Article 18, paragraph 3, point (b) is replaced by the following:
(b) the identity of all substances in the mixture that contribute to the classification of the mixture as regards acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitisation, specific target organ toxicity (STOT) or aspiration hazard.	"(b) the identity of all substances in the mixture that contribute to the classification of the mixture as regards acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, ***endocrine disruption for human health, endocrine disruption for the environment,*** respiratory or skin sensitisation, specific target organ toxicity (STOT) or aspiration hazard***, persistent, bioaccumulative and toxic (PBT), very persistent, very bioaccumulative (vPvB), persistent, mobile and toxic (PMT), very persistent, very mobile (vPvM) properties****."*

Amendment 41

Proposal for a regulation
Article 1 – paragraph 1 – point 8 a (new)
Regulation (EC) No 1272/2008
Article 25 – paragraphs 2 and 3

Present text	*Amendment*
	(8a) In Article 25, paragraphs 2 and 3 are replaced by the following:
2. A statement shall be included in the section for supplemental information on the label where a substance or mixture classified as hazardous falls within the scope of ***Directive 91/414/EEC***. The statement shall be worded in accordance with Part 4 of Annex II and Part 3 of Annex III to this Regulation.	***"***2. A statement shall be included in the section for supplemental information on the label where a substance or mixture classified as hazardous falls within the scope of ***Regulation (EC) No 1107/2009 or Regulation (EU) No 528/2012***. The statement shall be worded in accordance with Part 4 of Annex II and Part 3 of

Annex III to this Regulation.

3. The supplier may include supplemental information in the section for supplemental information on the label other than that referred to in paragraphs 1 ***and 2***, provided that that information does not make it more difficult to identify the label elements referred to in Article 17(1) (a) to (g) and that it provides further details and does not contradict or cast doubt on the validity of the information specified by those elements.	3. The supplier may include supplemental information in the section for supplemental information on the label other than that referred to in paragraphs 1***, 2 and 7***, provided that that information does not make it more difficult to identify the label elements referred to in Article 17(1) (a) to (g) and that it provides further details and does not contradict or cast doubt on the validity of the information specified by those elements.*"*

Amendment 42

Proposal for a regulation
Article 1 – paragraph 1 – point 9
Regulation (EC) No 1272/2008
Article 25 – paragraph 6 – subparagraph 1

Present text	*Amendment*
The specific labelling rules set out in Part 2 of Annex II shall apply to mixtures containing substances referred to in that Annex.	The specific labelling rules set out in Part 2 of Annex II shall apply to mixtures containing substances referred to in that Annex. ***The statements shall be worded in accordance with Part 3 of Annex III and shall be placed in the supplemental information section of the label. The label shall also include the product identifier referred to in Article 18 and the name, address and telephone number of the supplier of the mixture.***

Amendment 43

Proposal for a regulation
Article 1 – paragraph 1 – point 13 – introductory part

Text proposed by the Commission	*Amendment*
(13) in Article ***31(3)***, the following sentence is added:	(13) in Article ***31, paragraph 1***, the following sentence is added:

Amendment 44

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

Present text	*Amendment*
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 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. ***The label may also be presented in a form of a fold out label."***

Amendment 45

Proposal for a regulation
Article 1 – paragraph 1 – point 13
Regulation (EC) 1272/2008
Article 31 – paragraph 3

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

Amendment 46

Proposal for a regulation
Article 1 – paragraph 1 – point 13 a (new)
Regulation (EC) No 1272/2008
Article 32 – paragraph 6

Present text	*Amendment*
	(13a) In Article 32, paragraph 6 is replaced by the following:
6. Label elements ***resulting from the requirements provided for in other Community acts shall be placed in the section for supplemental information on the label*** referred to in Article ***25***.	"***6***. ***Where the*** label elements referred to in Article ***17(1) are provided by means of a fold-out label, the front page shall contain at least the information provided in accordance with Article 17(1)(e), (f) and (g) in all official languages of the Member State where the product is put on the market along with a reference to the additional information provided on the inside page or pages***."

Amendment 47

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

Amendment 48

Proposal for a regulation
Article 1 – paragraph 1 – point 16
Regulation (EC) No 1272/2008
Article 35 – paragraph 2a

Text proposed by the Commission	*Amendment*
2a. Hazardous substances or mixtures may be supplied to consumers and professional users via refill stations only if, in addition to the requirements set out in Titles III and IV, the conditions laid down	2a. Hazardous substances or mixtures may be supplied to consumers and professional users via refill stations only if, in addition to the requirements set out in Titles III and IV, the conditions laid down

in section 3.4 of Annex II are fulfilled.***;***	in section 3.4 of Annex II are fulfilled. ***This paragraph shall not apply to hazardous substances or mixtures supplied to the general public without packaging in accordance with Article 29(3).***

Amendment 49

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

Text proposed by the Commission	*Amendment*
A competent authority may submit to the Agency a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof.	A competent authority may submit to the Agency a proposal for harmonised classification and labelling ***of a substance or a group*** of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof.

Amendment 50

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

Text proposed by the Commission	*Amendment*
The Commission may ask the Agency or the European Food Safety Authority established in accordance with Article 1(2) of Regulation (EC) No 178/2002* to prepare a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof. The Commission may	The Commission may ask the Agency or the European Food Safety Authority established in accordance with Article 1(2) of Regulation (EC) No 178/2002* to prepare a proposal for harmonised classification and labelling of ***a substance or a group of*** substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof. The

subsequently submit the proposal to the Agency.	Commission may subsequently submit the proposal to the Agency. ***The Agency and the Authority may, on their own initiative, provide scientific advice to the Commission and Member States on substances or a group of substances where a harmonised classification could be necessary to protect human and animal health and the environment.***

Amendment 51

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

Text proposed by the Commission	*Amendment*
The proposals referred to in the first and the second subparagraphs shall follow the format set out in Part 2 of Annex VI and contain the relevant information provided for in Part 1 of Annex VI.	The proposals ***for harmonised classification and labelling of a substance or a group of substances*** referred to in the first and the second subparagraphs shall follow the format set out in Part 2 of Annex VI and contain the relevant information provided for in Part 1 of Annex VI.

Amendment 52

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

Text proposed by the Commission	*Amendment*
	'Whenever considered scientifically justified and possible by a competent authority or the Commission, proposals for harmonised classification and labelling shall prioritise groups of

	substances rather than individual substances.'

Amendment 53

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

Text proposed by the Commission	*Amendment*
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***;***	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. ***In the event of a proposal for harmonised classification and labelling of a group of substances, those substances shall be grouped together based on clear scientific criteria, including structural similarity and similar evidence-based hazard profiles.***

Amendment 54

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	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).	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).

Amendment 55

Proposal for a regulation
Article 1 – paragraph 1 – point 18 – point e
Regulation (EC) No 1272/2008
Article 37 – paragraph 5 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Commission shall adopt ***without undue delay,*** delegated acts in accordance with Article 53a to amend Annex VI by inclusion of substances together with the relevant classification and labelling elements and, where appropriate, the specific concentration limits, M-factors or acute toxicity estimates in Table 3 of Part 3 of Annex VI.	The Commission***, within twelve months of the publication of the opinion of the Committee for Risk Assessment,*** shall adopt delegated acts in accordance with Article 53a to amend Annex VI by inclusion of substances ***or mixtures*** together with the relevant classification and labelling elements and, where appropriate, the specific concentration limits, M-factors or acute toxicity estimates in Table 3 of Part 3 of Annex VI.

Amendment 56

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	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.	placed on the market.

Amendment 57

Proposal for a regulation
Article 1 – paragraph 1 – point 18 – point f
Regulation (EC) No 1272/2008
Article 37 – paragraph 7 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Commission shall adopt delegated acts in accordance with Article 53a to amend Table 3 of Part 3 of Annex VI to this Regulation by inclusion of substances as endocrine disruptor category 1 for human health properties, endocrine disruptor category 1 for environment properties, as persistent, bioaccumulative and toxic ***or*** as very persistent and very bioaccumulative together with relevant classification and labelling elements where, on ***… [OP: please insert the date = the date of entry into force of Commission Delegated Regulation (EU) …i.e. delegated act on the new hazard classes - reference to be added once adopted]***, those substances have been included in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006.	***By 1 January 2026,*** the Commission shall adopt delegated acts in accordance with Article 53a to amend Table 3 of Part 3 of Annex VI to this Regulation by inclusion of substances as endocrine disruptor category 1 for human health properties, endocrine disruptor category 1 for environment properties, as persistent, bioaccumulative and toxic***,*** as very persistent and very bioaccumulative***, as persistent, mobile and toxic, or very persistent and very mobile*** together with relevant classification and labelling elements where, on ***1 January 2025***, those substances have been included in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006.

Amendment 58

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	(g) where applicable***, and without needing to acquire new data or new studies being necessary***, the reason for divergence from the most severe

the inventory referred to in Article 42;	classification per hazard class included in the inventory referred to in Article 42;

Amendment 59

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 without needing to acquire new data or new 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;

Amendment 60

Proposal for a regulation
Article 1 – paragraph 1 – point 20 a (new)
Regulation (EC) No 1272/2008
Article 41

Present text	*Amendment*
	(20a) Article 41 is replaced by the following:
Article 41	"Article 41
Agreed entries	Agreed entries
Where the notification in Article 40(1) results in different entries on the inventory referred to in Article 42 for the same substance, the notifiers and registrants shall make every effort to come to an agreed entry to be included in the inventory. The notifiers shall inform the Agency accordingly.	Where the notification in Article 40(1) results in different entries on the inventory referred to in Article 42 for the same substance, the notifiers and registrants shall make every effort to come to an agreed entry to be included in the inventory. The notifiers shall inform the Agency accordingly. ***In case where notifiers and registrants cannot come to an agreed entry because of divergences about the level of scientific evidence supporting a***

	classification and labelling of the same substance, the most protective classification shall prevail."'

Amendment 61

Proposal for a regulation
Article 1 – paragraph 1 – point 21
Regulation (EC) No 1272/2008
Article 42 – paragraph 1 – subparagraph 3 – introductory part

Text proposed by the Commission	*Amendment*
The following information shall be made publicly available free of charge online:	The following information shall be made publicly available free of charge online ***in a user-friendly format***:

Amendment 62

Proposal for a regulation
Article 1 – paragraph 1 – point 21
Regulation (EC) No 1272/2008
Article 42 – paragraph 1 – subparagraph 3 – point a

Text proposed by the Commission	*Amendment*
(a) information referred to in Article 40(1), point (a)***, except where a notifier duly justifies why such publication is potentially harmful for its commercial interests or the commercial interests of any other concerned party***;	(a) information referred to in Article 40(1), point (a);

Amendment 63

Proposal for a regulation
Article 1 – paragraph 1 – point 21 a (new)
Regulation (EC) No 1272/2008
Article 42 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	(21a) In the Article 42, the following

	paragraph 3a is added:
	"3a. Where the Agency considers that an entry is incomplete, incorrect or obsolete it shall delete the corresponding entry from the inventory after having informed the notifier."

Amendment 64

Proposal for a regulation
Article 1 – paragraph 1 – point 21 b (new)
Regulation (EC) No 1272/2008
Article – 43 (new)

Text proposed by the Commission	*Amendment*
	(21b) The following Article -43 is inserted:
	Article -43
	Right to request action from competent authorities and the Commission
	1. Any natural or legal person, individually or in association, shall be entitled to submit substantiated evidence to competent authorities as referred to in Article 43 or the Commission, such as peer-reviewed studies, human biomonitoring data, or environmental monitoring data, on the hazardous properties of a substance or mixture, or of substances or mixtures, showing that hazardous properties of a substance or mixture or of substances or mixtures may not have been sufficiently considered in the classification or labelling process.
	2. The competent authorities or the Commission shall diligently and impartially assess the information submitted in accordance with paragraph 1, adding the evidence submitted to all other available evidence using a weight of evidence approach.

3. Where the evidence submitted shows non-compliance with one or several of the requirements on the classification, labelling and packaging of substances and mixtures, enforcement measures shall be initiated in accordance with Article 47.

4. Where the assessment has shown that the substance meets the criteria for classification in any of the hazard classes referred to in Article 36(1), the competent authority or the Commission shall initiate a process of harmonised classification and labelling. Where the assessment has shown a wide dispersive use of and/or consumer exposure to the substance or mixture concerned, the competent authority or the Commission shall initiate a risk management process under Article 59, Article 69, or Article 68(2) of Regulation (EU) No 1907/2006. Where the assessment has shown a lack of information on the risk to health or the environment posed by a hazardous substance or mixture, the competent authority or the Commission shall require companies or any other relevant actor to provide more information, with a view to taking risk management measures under Title VI, VII or VIII of Regulation (EU) 1907/2006, where necessary.

5. Where the evidence submitted should have been included in the registration dossier submitted under Regulation (EU) No 1907/2006 but was omitted by the registrant, the enforcement measure shall be initiated under Article 126 of Regulation (EU) No 1907/2006 against registrants the registration of whom is non-compliant.

6. The competent authority or the Commission, shall, within 6 months, inform the natural or legal persons referred to in paragraph 1, of its opinion on the evidence and concerns submitted under paragraph 1, and of any steps it

plans to take to address those concerns, providing the reasons for both the opinion reached and the steps proposed.

7. Competent authorities and the Commission shall publish an annual report on the requests received and how they have been dealt with.

Amendment 65

Proposal for a regulation
Article 1 – paragraph 1 – point 21 c (new)
Regulation (EC) No 1272/2008
Article – 43 a (new)

Text proposed by the Commission	*Amendment*
	(21c) The following Article -43a is added:
	Article -43a
	Access to justice
	1. Any natural or legal person which has submitted a substantiated concern in accordance with Article -43a shall have access to an administrative or judicial procedure to review the procedural and substantive legality of the decisions, acts or omissions of the relevant competent authority under this Regulation.
	2. Member States shall ensure access to administrative or judicial procedures to review their decisions, acts and omissions, in accordance with national law or practice. Decisions, acts and omissions by the Commission shall be subject to review in accordance with Regulation EU (No) 1367/2006.
	3. The procedures referred to in paragraph 2 shall be fair, equitable, timely and not prohibitively expensive while providing adequate and effective remedies, including injunctive relief where necessary. Member States shall ensure that practical information is made

	available to the public on access to administrative and judicial review procedures.

Amendment 66

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 a substance classified as hazardous shall indicate the relevant hazard pictogram, the signal word, the hazard class and the hazard statements. ***Any advertisement for a substance for sale to the general public shall in addition indicate "always read and follow the information on the product label.***

Amendment 67

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 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. ***Any advertisement for sale of mixtures to the general public shall, in addition, indicate "always read and follow the information on the product label.***

Amendment 68

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

Text proposed by the Commission	*Amendment*
	2a. The use of environmental claims, as defined in Article 2, point (o), of Directive 2005/29/EC, is prohibited.

Amendment 69

Proposal for a regulation
Article 1 – paragraph 1 – point 25 – point -a (new)
Regulation (EC) No 1272/2008
Article 50 – paragraph 2 – point a

Present text	*Amendment*
	(-a) in Article 50, paragraph 2, point a is amended as following:
(a) provide industry with technical and scientific guidance and tools where appropriate on how to comply with the obligations laid down by this Regulation;	"(a) provide industry with ***up to date*** technical and scientific guidance and tools where appropriate on how to comply with the obligations laid down by this Regulation;***"***

Amendment 70

Proposal for a regulation
Article 1 – paragraph 1 – point 25 – point a
Regulation (EC) No 1272/2008
Article 50 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) provide competent authorities with technical and scientific guidance and tools on the operation and implementation of this Regulation and provide support to the helpdesks established by Member States	(b) provide competent authorities with ***up to date*** technical and scientific guidance and tools on the operation and implementation of this Regulation and provide support to the helpdesks

under Article 44.***;***	established by Member States under Article 44.

Amendment 71

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

Text proposed by the Commission	*Amendment*
	(ba) the following paragraphs are added:
	"3a. The Agency shall be provided with adequate resources to support its work.
	3b. In order to provide adequate expertise, support, and thorough scientific evaluations, appropriate and stable funding for the Agency shall be ensured."

Amendment 72

Proposal for a regulation
Article 1 – paragraph 1 – point 26 – point -a (new)
Regulation (EC) No 1272/2008
Article 53 – paragraph 1

Present text	*Amendment*
	(-a) 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 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	"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 ***the promotion of alternative methods for assessment of hazards of substances and mixtures,*** 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

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).	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).*"*

Amendment 73

Proposal for a regulation
Article 1 – paragraph 1 – point 26 – point a
Regulation (EC) No 1272/2008
Article 53 – paragraph 1a

Text proposed by the Commission	*Amendment*
1a. The Commission is empowered to adopt delegated acts in accordance with Article 53a to amend section 1.6. of Annex I in order to adapt the label elements referred to in Article 34a(2) to technical progress or to the level of digital readiness among all population groups in the Union. When adopting those delegated acts, the Commission shall ***take into account the societal needs and*** a high level of protection of human health and the environment;	1a. The Commission is empowered to adopt delegated acts in accordance with Article 53a to amend section 1.6. of Annex I in order to adapt the label elements referred to in Article 34a(2) to technical progress or to the level of digital readiness among all population groups in the Union. When adopting those delegated acts, the Commission shall ***ensure*** a high level of protection of human health and the environment ***and take into account societal needs. The Commission shall make sure that information which is critical to protect human health and the environment shall be easily accessible on the label***;

Amendment 74

Proposal for a regulation
Article 1 – paragraph 1 – point 26 – point a
Regulation (EC) No 1272/2008
Article 53 – paragraph 1b – point d

Text proposed by the Commission	*Amendment*
(d) take into account the level of digital readiness among all population groups in the Union;	(d) take into account the level of digital readiness among all population groups in the Union***, as well as the readiness of the necessary wireless and other technological infrastructure allowing unrestricted access to the information on chemicals***;

Amendment 75

Proposal for a regulation
Article 1 – paragraph 1 – point 26 – point b
Regulation (EC) No 1272/2008
Article 53 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission or the Member States acting in the interest of the Union shall, in the manner appropriate to their role in the relevant UN fora, promote the harmonisation of the criteria for classification and labelling of endocrine disruptors for human health, endocrine disruptors for the environment, persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances as well as alternative test methods at the level of the UN.;	2. The Commission or the Member States acting in the interest of the Union shall, in the manner appropriate to their role in the relevant UN fora, promote the harmonisation of the criteria for classification and labelling of endocrine disruptors for human health, endocrine disruptors for the environment, persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances as well ***the development of criteria for immunotoxic and neurotoxic substances as well*** as alternative test ***methods, including new approach methods and in particular non-animal*** methods at the level of the UN ***to address existing and emerging hazard classes***.;

Amendment 76

Proposal for a regulation
Article 1 – paragraph 1 – point 26 – point c

Regulation (EC) No 1272/2008
Article 53 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission shall ***regularly*** evaluate the development of alternative test methods referred to in Article 13(1) of Regulation (EC) No 1907/2006 for classification of substances and mixtures.	3. The Commission shall ***promote and*** evaluate the development of alternative test methods referred to in Article 13(1) of Regulation (EC) No 1907/2006 for classification of substances and mixtures***, including new approach methods and in particular non-animal test methods, at least every three years, and adopt delegated acts in accordance with Article 53a, to update Annex I to this Regulation to reflect such technical progress, if relevant. The Commission shall adopt a delegated act in accordance with Article 53a to update Annex I to this Regulation no more than twelve months after non-animal data are included in harmonised criteria for classification and labelling at the level of the UN.***

Amendment 77

Proposal for a regulation
Article 1 – paragraph 1 – point 26 – point c a (new)
Regulation (EC) No 1272/2008
Article 53 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	(ca) In Article 53, paragraph 3a is added as following:
	"3a. The Commission shall assess the introduction of hazard criteria for immunotoxicity and neurotoxicity by 31 December 2025 and, where appropriate, adopt delegated acts in accordance with Article 53a. The Commission shall foster the rapid introduction of those hazard classes at the UNGHS."

Amendment 78

Proposal for a regulation
Article 1 – paragraph 1 – point 27 – point a
Regulation (EC) No 1272/2008
Article 53a – paragraph 2

Text proposed by the Commission	*Amendment*
The power to adopt delegated acts referred to in Articles 37(5), 37(7), 37(8), 45(4) 53(1), 53(1a) and 53(***1b***) shall be conferred on the Commission for a period of five years from [OP please insert the date = the date of entry into force of this Regulation] ***;***	The power to adopt delegated acts referred to in Articles 37(5), 37(7), 37(8), 45(4)***,*** 53(1), 53(1a)***, 53(1b), 53(3)*** and 53(***3a***) shall be conferred on the Commission for a period of five years from [OP please insert the date = the date of entry into force of this Regulation]***.***

Amendment 79

Proposal for a regulation
Article 1 – paragraph 1 – point 27 – point b
Regulation (EC) No 1272/2008
Article 53a – paragraph 3

Text proposed by the Commission	*Amendment*
The delegation of power referred to in Articles 37(5), 37(7) and 37(8), 45(4), 53(1), 53(1a) ***and 53(1b),*** may be revoked at any time by the European Parliament or by the Council.***;***	The delegations of power referred to in Articles 37(5), 37(7) and 37(8), 45(4), 53(1), 53(1a)***, 53(1b), 53(3) and 53(3a)*** may be revoked at any time by the European Parliament or by the Council.

Amendment 80

Proposal for a regulation
Article 1 – paragraph 1 – point 27 – point c
Regulation (EC) No 1272/2008
Article 53 – paragraph 6

Text proposed by the Commission	*Amendment*
A delegated act adopted pursuant to Articles 37(5), 37(7), 37(8), 45(4) 53(1), 53(1a) ***and 53(1b),*** shall enter into force	A delegated act adopted pursuant to ***Article*** Articles 37(5), 37(7), 37(8), 45(4)***,*** 53(1), 53(1a)***, 53(1b), 53(3) or 53(3a)*** shall enter

only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object.;	into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object.;

Amendment 81

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

Text proposed by the Commission	*Amendment*
	(29a) the following article is inserted:
	"Article 54a
	Review Clause
	By ...[insert date four years after the date of entry into force of this Regulation], the Commission shall present a report to the European Parliament and to the Council regarding the identification and examination of substances of renewable botanical origin containing more than one constituent referred to in Article 5.3a. The report shall be accompanied, where appropriate, by a legislative proposal."

Amendment 82

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*
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 = 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].	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 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].

Amendment 83

Proposal for a regulation
Article 1 – paragraph 1 – point 30 – point a (new)

Regulation (EC) No 1272/2008
Article 61 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	a) In Article 61, the following paragraph 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 subparagraph, 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 subparagraph 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] 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]."

Amendment 84

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 and mixtures*** 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]:

Amendment 85

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) points (2), (3), (7), (9) and (10) of Annex I; (c) Annex II; (d) points (1)(c), (2), (3) and (4) of Annex III.

Amendment 86

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	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:	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 = 18months 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:

Amendment 87

Proposal for a regulation
Annex I – paragraph 1 – point 2
Regulation (EC) No 1272/2008
Annex I – Part 1 – 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	***8pt***

Not exceeding 3 litres:	If possible, at least 52x74	Not smaller than 10x10	***1,4 (x-height in millimeters)***

		If possible, at least 16x16	

Amendment 88

Proposal for a regulation
Annex I – paragraph 1 – point 2
Regulation (EC) No 1272/2008
Annex I – Part 1 – 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	***12pt***

Greater than 3 litres but not exceeding 50 litres:	At least 74x105	At least 23x23	***1,8 (x-height in millimeters)***

Amendment 89

Proposal for a regulation
Annex I – paragraph 1 – point 2
Regulation (EC) No 1272/2008
Annex I – Part 1 – 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	***16pt***
Greater than 50 litres but not exceeding 500 litres:	At least 105x148	At least 32x32	***2,4 (x-height in millimeters)***

Amendment 90

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

Greater than 500 litres:	At least 148x210	At least 46x46	***20pt';***
Greater than 500 litres:	At least 148x210	At least 46x46	***3,0 (x-height in millimeters)***

Amendment 91

Proposal for a regulation
Annex I – paragraph 1 – point 3 a (new)
Regulation (EC) No 1272/2008
Annex I – Part 1 – Section 1.2.1.5 a (new))

Text proposed by the Commission	*Amendment*
	(3a) In Annex I, part I, the following section is added:
	Section 1.2.1.5.a
	For multilingual labels, the languages shall be ordered in a logical way, e.g. alphabetically.

Amendment 92

Proposal for a regulation
Annex I – paragraph 1 – point 9
Regulation (EC) No 1272/2008
Annex I – Part 1 – Section 1.5.2.4.1. – point b – point iv a (new)

Text proposed by the Commission	*Amendment*
	(iva) Serious eye damage category 1/eye irritation, category 2;

Amendment 93

Proposal for a regulation
Annex I – paragraph 1 – point -1 (new)
Regulation (EC) No 1272/2008
Annex I – Part 1 – Section 1.5.2.4.1. – point b – point v a (new)

Text proposed by the Commission	*Amendment*
	(va) Skin sensitisation, category 1 (sub-categories 1A and 1B);

Amendment 94

Proposal for a regulation
Annex II – paragraph 1 – point -1 a(new)
Regulation (EC) No 1272/2008
Annex II – Part 3 – Section 3.1.1.1

Present text	*Amendment*
	-1a in Part 3 of Annex II to Regulation (EC) No 1272/2008, point 3.1.1.1. ***is amended as following:***
3.1.1.1.Packaging of whatever capacity containing a substance or mixture supplied to the general public and classified for acute toxicity, categories 1 to 3, STOT — single exposure category 1, STOT — repeated exposure category 1, or skin corrosion category 1 shall be fitted with child-resistant fastenings.	"3.1.1.1. Packaging of whatever capacity containing a substance or mixture supplied to the general public and classified for acute toxicity, categories 1 to 3, STOT — single exposure category 1, STOT — repeated exposure category 1, or skin corrosion category 1***, or serious eye damage category 1*** shall be fitted with child-resistant fastenings.***"***

Amendment 95

Proposal for a regulation
Annex II – paragraph -1 a (new)
Regulation (EC) No 1272/2008
Annex II – Part 3 – section 3.2.1

Present text	*Amendment*
	(-1a) In Part 3 of Annex II, section 3.2.1. is replaced by the following:
3.2.1. Packaging to be fitted with a tactile warning	"3.2.1. Packaging to be fitted with a tactile warning
Where substances or mixtures are supplied to the general public and classified for acute toxicity, skin ***corrosion***, germ cell mutagenicity category 2, carcinogenicity category 2, reproductive toxicity category 2, respiratory ***sensitisation, or Stot***, categories 1 ***and*** 2, aspiration hazard, ***or*** flammable gases, liquids ***and solids in*** categories 1 ***and 2***, the packaging of whatever capacity, shall be fitted with a tactile warning of danger.	Where substances or mixtures are supplied to the general public and classified for acute toxicity, skin ***corrosion/skin irritation, serious eye damage/eye irritation, endocrine disruption for human health category 2, endocrine disruption for the environment category 2***, germ cell mutagenicity category 2, carcinogenicity category 2, reproductive toxicity category 2, respiratory ***or skin sensitization***, ***STOT*** categories 1 ***or*** 2, aspiration hazard, flammable gases, ***flammable*** liquids categories 1 ***or 2, or flammable solids***, the packaging of whatever capacity, shall be fitted with a tactile warning of danger. ***"***

Amendment 96

Proposal for a regulation
Annex II – paragraph 1 – point 1
Regulation (EC) No 1272/2008
Annex II – Part 3 – Section 3.4 – point b

Text proposed by the Commission	*Amendment*
(b) a label is firmly affixed on a visible place of the refill station and ***with a font size that is easily legible and without serifs***;	(b) a label is firmly affixed on a visible place of the refill station and ***fulfils the requirements of Article 31***;

Amendment 97

Proposal for a regulation
Annex II – paragraph 1 – point 1
Regulation (EC) No 1272/2008
Annex II – Part 3 – Section 3.4 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) a label is available at the refill station, free-of-charge for consumers in a self-adhesive sticker form to be affixed on the container used by the consumer. Where refill stations provide several substances or mixtures, labels should easily and clearly identify which substance or mixture provided at the refill station the labels correspond to;

Amendment 98

Proposal for a regulation
Annex II – paragraph 1 – point 1
Regulation (EC) No 1272/2008
Annex II – Part 3 – Section 3.4. – point k – point iv a (new)

Text proposed by the Commission	*Amendment*
	(iva) Serious eye damage category 1/eye irritation, category 2;

Amendment 99

Proposal for a regulation
Annex II – paragraph 1 – point 1
Regulation (EC) No 1272/2008
Annex II – Part 3 – Section 3.4. – point k – point v a (new)

Text proposed by the Commission	*Amendment*
	(va) Skin sensitisation, category 1 (sub-categories 1A and 1B);

Amendment 100

Proposal for a regulation
Annex III – paragraph 1 a (new)

Regulation (EC) No 1272/2008
Annex VI

Present text	*Amendment*
	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 included in the 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 included in the dossier.
A dossier for harmonised classification and labelling shall contain the following:	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;	— 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.	— 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.	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 a group of substances, the dossier shall include a scientific justification.
— Justification for other effects at Community level.	— 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***.	***For effects other than carcinogenity, mutagenicity, reprotoxicity, endocrine disruption for human health and the environment, persistent bioaccumulative and toxic (PBT), very persistent, very bioaccumulative (vPvB), persistent, mobile and toxic (PMT), very persistent, very mobile (vPvM), and respiratory sensitisation, a justification that there is a need for action demonstrated at Union level shall be provided***. This will not apply for an active substance within the meaning of ***Regulation (EU) No 1107/2009 or Regulation (EU) No 528/2012***.*"*