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Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures - Four-Column table

Delegations will find in the Annex the four-column table of the above proposal, containing the initial positions of the institutions.

In its present version, the second column of the table contains only the amended and the newly added rows by the European Parliament (EP). The empty rows in the second column mean that the EP did not amend the corresponding rows in the Commission proposal.

ANNEX

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures
2022/0432(COD) – COM(2022) 748 final

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Formula				
1	2022/0432 (COD)		2022/0432 (COD)	
Proposal Title				
2	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (Text with EEA relevance)		Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (Text with EEA relevance)	
Formula				
3	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,		THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	

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Citation 1				
4	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114(1) thereof,		Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114(1) thereof,	
Citation 2				
5	Having regard to the proposal from the European Commission,		Having regard to the proposal from the European Commission,	
Citation 3				
6	After transmission of the draft legislative act to the national parliaments,		After transmission of the draft legislative act to the national parliaments,	
Citation 4				
7	Having regard to the opinion of the European Economic and Social Committee[1], _____ 1. OJ C , , p. .		Having regard to the opinion of the European Economic and Social Committee[1], _____ 1. OJ C , , p. .	
Citation 5				

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8	Acting in accordance with the ordinary legislative procedure[1], __________ 1. Position of the European Parliament of xxx and decision of the Council of xxx.		Acting in accordance with the ordinary legislative procedure[1], __________ 1. Position of the European Parliament of xxx and decision of the Council of xxx.	
Formula				
9	Whereas:		Whereas:	
Recital 1				
10	(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	(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	(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	

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	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 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	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*~~***necessary*** to require that there is a supplier established in the Union, which ensures that the 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***, 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*** ~~*would*~~ improve compliance with and enforcement of the Regulation (EC) ~~*No 12727/2008*~~***No 1272/2008*** and thereby ensure a high level of protection of human health and the environment. In order to prevent situations where consumer	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 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**, such as via online market places**. This provision**, together with requirements in Regulation (EU) 2023/988 of the European Parliament and of the Council on General Product Safety, Regulation (EU) 2022/2065 of the European Parliament and of the Council on a Single Market For Digital Services and Regulation (EU) 2019/1020 of the European Parliament and of the Council on Market Surveillance and Compliance of Products,**	

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	substance or the mixture in question meets the requirements set out in that Regulation acts in course of an industrial or professional activity.	becomes ***de jure and de facto*** ~~*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.	would improve compliance with and enforcement of the Regulation (EC) ~~No 12727/2008~~**No 1272/2008** and thereby ensure a high level of protection of human health and the environment. In order to ~~prevent~~ **avoid** situations where consumer becomes ***de jure*** **and** ***de facto*** ~~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.	
Recital 2				
11	(2) From a toxicological point of view, substances with more than one constituent ('multi-constituent substances') are no different from mixtures	(2) ***Substances containing more than one constituent are not intentional mixtures.*** From a toxicological point of view, substances ~~*with*~~***containing*** more	*deleted*	

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	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[1], aimed to limit animal testing, data on multi-constituent substances is to be generated under the same conditions as data on any other substance, while data on individual constituents of a substance is normally not to be generated, except where individual constituents are also substances registered on their own. Where data on individual constituents is available, multi-constituent substances should be evaluated and classified following the same classification rules as mixtures, unless Annex I to Regulation (EC) No 1272/2008 provides for a specific provision for those multi-constituent substances. _____ 1. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning	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[1], aimed to ~~*limit*~~***minimise*** animal testing, data on ~~*multi-constituent substances*~~***substances containing more than one constituent*** is to be generated under the same conditions as data on any other substance, while data on individual constituents of a substance is normally not to be generated, except where individual constituents are also substances registered on their own. Where data on individual constituents ~~*is*~~***are*** available, ~~*multi-constituent substances*~~***substances containing more than one constituent*** should be evaluated and classified following the same classification rules as mixtures~~*, unless Annex I to*~~		

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	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).	~~*Regulation (EC) No 1272/2008 provides for a specific provision for those multi-constituent substances.*~~ . _____ 1. ***[1]*** 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).		
Recital 2a				
11a		***(2a) Scientific evidence on substances containing more than one constituent of***		

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		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.		
Recital 3				
12	(3) It is normally not possible	(3) ~~*It is normally not*~~		

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	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	~~possible~~***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 ~~multi-constituent substance~~***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 ~~multi-constituent substance~~***substance containing more than one constituent*** should therefore normally be used as the basis for hazard identification of those ~~multi-constituent substances~~***substances containing more than one constituent*** or mixtures. However, in certain cases, data on those ~~multi-constituent~~ substances ***containing more than one constituent*** themselves may also be relevant. This is the case in particular where that data	*deleted*	

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	appropriate that data on multi-constituent substances are used in those cases.	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.		
Recital 4				
13	*(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	(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	(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	

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	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.	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.***	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.	
Recital 5				
14	(5) To avoid over-classification		(5) To avoid over-classification	

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	of mixtures which contain substances classified as hazardous solely due to the presence of an impurity, an additive or an individual constituent, and of mixtures which contain other mixtures with such substances, the classification should only be mandatory if such impurity, additive or individual constituent is contained in the mixture or in the final mixture at or above a certain concentration limit as referred to in Annex I to Regulation (EC) No 1272/2008.		of mixtures which contain substances classified as hazardous solely due to the presence of an impurity, an additive or an individual constituent, and of mixtures which contain other mixtures with such substances, the classification should only be mandatory if such impurity, additive or individual constituent is contained in the mixture or in the final mixture at or above a certain concentration limit as referred to in Annex I to Regulation (EC) No 1272/2008.	
Recital 6				
15	(6) Acute toxicity estimates are mainly used to determine the classification for human health acute toxicity of mixtures containing substances classified for acute toxicity. Substances can be classified in one of four acute toxicity hazard categories based on the oral, dermal or inhalation exposure route		(6) Acute toxicity estimates are mainly used to determine the classification for human health acute toxicity of mixtures containing substances classified for acute toxicity. Substances can be classified in one of four acute toxicity hazard categories based on the oral, dermal or inhalation exposure route	

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	according to certain numeric criteria. Acute toxicity values are expressed as (approximate) LD50 (oral, dermal) or LC50 (inhalation) values or as acute toxicity estimates. It is appropriate to specify the meaning of, and further specify, acute toxicity estimates to increase their clarity and consistency. As acute toxicity estimates are part of the harmonised classification and labelling elements of substances classified for acute toxicity they should be included in the proposal, opinion and decision for harmonised classification of a substance for acute toxicity. In the same way as M-factors and concentration limits, acute toxicity estimates should, together with a justification, be notified to the Agency in view of their inclusion in the classification and labelling inventory.		according to certain numeric criteria. Acute toxicity values are expressed as (approximate) LD50 (oral, dermal) or LC50 (inhalation) values or as acute toxicity estimates. It is appropriate to specify the meaning of, and further specify, acute toxicity estimates to increase their clarity and consistency. As acute toxicity estimates are part of the harmonised classification and labelling elements of substances classified for acute toxicity they should be included in the proposal, opinion and decision for harmonised classification of a substance for acute toxicity. In the same way as M-factors and concentration limits, acute toxicity estimates should, together with a justification, be notified to the Agency in view of their inclusion in the classification and labelling inventory.	
Recital 6a				
15a				

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			(6a) In general, substances and mixtures should be classified for any form or physical state. When the available scientific evidence warrants a different classification linked to a specific form or physical state, it should nevertheless be possible for manufacturers, importers, and downstream users in the self-classification process to classify differently depending on the form or physical state. However, if a substance is subject to harmonised classification without being limited to a specific form or physical state, this harmonised classification should apply to all its forms and physical states. If a substance is subject to harmonised classification only for a specific form of that substance, it should be clarified that the classification of the substance for the other forms or physical states is still subject to self-classification.	

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Recital 7				
16	(7) Ammunition qualifying as a substance or a mixture is to bear a label affixed to the surface of the packaging immediately containing the substance or the mixture (inner packaging), which is typically the ammunitions' cartridge. Affixing a label to the cartridge might however cause safety problems for the user, as the label could interfere with the correct functioning of the ammunition and could damage the firearm. Such ammunition should therefore be allowed to bear a label affixed to the next packaging layer instead of the inner packaging. In addition, labelled ammunition, which is exclusively used by national defence forces in combat zones, could, in specific cases, constitute an unacceptable safety or security risk for the cargo, soldiers and staff, if sufficient camouflaging cannot be ensured. For such cases, it is necessary to provide for an		(7) **While the majority of** ammunition ~~qualifying as~~ **is usually considered as an article, in some cases, it may be** a substance or a mixture**. Where ammunition is determined to be a substance or a mixture, it** is to bear a label affixed to the surface of the packaging immediately containing the substance or the mixture (inner packaging)~~,~~ ~~which is typically the ammunitions' cartridge~~. Affixing a label to ~~the cartridge~~**that inner packaging** might however cause safety problems for the user, as the label could interfere with the correct functioning of the ammunition and could damage the firearm. Such ammunition should therefore be allowed to bear a label affixed to the next packaging layer instead of the inner packaging. In addition, labelled ammunition~~, which is exclusively used~~ **that is intended for use** by national	

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	exemption from the labelling requirements and allow for alternative ways of communicating the hazard information.		defence forces ~~in combat zones~~, could, in specific cases, constitute an unacceptable ~~safety or~~ security risk for the cargo, soldiers ~~and~~ **or** staff, if sufficient camouflaging cannot be ensured. For such cases, it is necessary to provide for an exemption from the labelling requirements and allow for alternative ways of communicating the hazard information.	
Recital 8				
17	(8) In order to enhance clarity, all supplemental labelling requirements should be placed together in one Article.		(8) In order to enhance clarity, all supplemental labelling requirements should be placed together in one Article.	
Recital 9				
18	(9) Part 2 of Annex II to Regulation (EC) No 1272/2008 sets out rules for additional hazard statements to be included on the label of certain mixtures listed in Part 2 of that Annex.		(9) Part 2 of Annex II to Regulation (EC) No 1272/2008 sets out rules for additional hazard statements to be included on the label of certain mixtures listed in Part 2 of that Annex.	

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	Given that those statements provide important additional information in specific cases, they should be applied to all mixtures referred to in Part 2 of Annex II, regardless of whether they are classified and whether they contain any classified substance.		Given that those statements provide important additional information in specific cases, they should be applied to all mixtures referred to in Part 2 of Annex II, regardless of whether they are classified and whether they contain any classified substance.	
Recital 10				
19	(10) To increase enforceability of the obligation placed on suppliers to update their labels after a change in the classification and labelling of their substance or mixture, a deadline should be laid down as regards that obligation. A similar obligation placed on registrants is set out in Commission Implementing Regulation (EU) 2020/1435[1]. Where the new hazard class is additional to an existing hazard class or represents a more severe hazard class or category, or where new supplemental labelling elements are required		(10) To increase enforceability of the obligation placed on suppliers to update their labels after a change in the classification ~~and~~ **or** labelling of their substance or mixture, a deadline should be laid down as regards that obligation. A similar obligation placed on registrants is set out in Commission Implementing Regulation (EU) 2020/1435[1]. Where the new hazard class is additional to an existing hazard class or represents a more severe hazard class or category, or where new supplemental labelling elements are required	

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	under Article 25, the deadline to update the labelling information in the case of adaptation of the classification in accordance with the result of a new evaluation should be set at 6 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. In case where a classification is updated to a less severe hazard class or category without triggering classification in an additional hazard class or new supplemental labelling requirements, the deadline for updating the labels should remain at 18 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. It should also be clarified that, in cases of harmonised classification and labelling, the deadlines to update the labelling information should be set at the date of application of the provisions setting out the new or amended classification and		under Article 25, the deadline **for a supplier** to update the labelling information in the case of adaptation of the classification in accordance with the result of a new evaluation should be set at 6 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained **by, or communicated to, that supplier**. In case where a classification is updated to a less severe hazard class or category without triggering classification in an additional hazard class or new supplemental labelling requirements, the deadline for updating the labels should remain at 18 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained **by, or communicated to, that supplier. To ensure that the results of reviewed classifications of substances and mixtures are communicated throughout the**	

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	labelling of the substance concerned, which is usually 18 months from the date of entry into force of those provisions. The same applies in case of changes triggered by other delegated acts adopted in light of the adaptation to technical and scientific progress, for instance as a result of the implementation of new or amended provisions of the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS). _____ 1. Commission Implementing Regulation (EU) 2020/1435 of 9 October 2020 on the duties placed on registrants to update their registrations under Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 331, 12.10.2020, p.24.)		**whole supply chain, suppliers shall cooperate in order to reduce the overall time needed to effectuate any necessary changes in classification, labelling or packaging.** ~~.~~It should also be clarified that, in cases of harmonised classification and labelling, the deadlines to update the labelling information should be set at the date of application of the provisions setting out the new or amended classification and labelling of the substance concerned, which is usually 18 months from the date of entry into force of those provisions. The same applies in case of changes triggered by other delegated acts adopted in light of the adaptation to technical and scientific progress, for instance as a result of the implementation of new or amended provisions of the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS). _____ 1. **[1]** Commission	

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			Implementing Regulation (EU) 2020/1435 of 9 October 2020 on the duties placed on registrants to update their registrations under Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)- (OJ L 331, 12.10.2020, p.24.)	
Recital 11				
20	(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,	(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,	(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 **possibility to use fold-out**	

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	while readability of labels should be ensured by laying down minimum font size and formatting requirements.	while ***durability and good*** readability of ***all*** labels should be ensured***, including*** by laying down minimum font size and formatting requirements.	**labels on a regular basis. It is therefore appropriate to allow labels to be presented in a form** ~~broader use~~ of fold-out labels, ~~while readability of labels should be ensured by laying down minimum font size and formatting requirements~~**applying the general rules on application and formatting to ensure readability and specific requirements for form and design of the front page** .	
Recital 11a				
20a			**(11a) In order to ensure a high level of protection for human health and the environment it is necessary that labels on substances and mixtures are legible. Minimum requirements on important parameters such as font size, distance and colour should therefore be laid down. A flexible approach should however be taken in respect to nuances of those colours so as**	

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			not to hamper the strive for a circular economy through the use of recycled materials for packaging material.	
Recital 12				
21	(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	(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	(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**, such as people with visual impairments, and for** ~~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~~**that the supplier who places a data carrier linking to such a label must satisfy. These technical requirements on the digital label should**	

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	information which is not instrumental for the safety of the user or the protection of the environment.	information which is not instrumental for 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***.	**however not affect the responsibilities of all suppliers to ensure that** labelling **requirements are fulfilled when placing a substance or mixture on the market**. In order to ~~provide for legal certainty,~~ **keep pace with digitalisation** it is appropriate to ~~specify the~~**allow certain** label elements ~~that are allowed~~ **required under this Regulation** 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**, while not affecting the labelling requirements or possibilities for digital labelling laid down in other Union legislation**.	
Recital 13				
22	(13) In order to adapt the label elements allowed to be provided only in a digital format to technical progress or to the level	(13) In order to adapt the label elements allowed to be provided only in a digital format to technical progress or to the level	(13) In order to adapt the label elements allowed to be provided only in a digital format to ~~technical progress or to the level~~	

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	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.	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*** ~~*and a*~~ high level of protection of human health and the environment ***and sufficient information on chemicals that citizens are exposed to***.	~~of digital readiness among all population groups in the Union~~**developments in GHS** , 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 **put on a digital label only, provided that the GHS does not require such labelling elements to be put on the physical label** ~~provided only in a digital format~~, **and** taking into account societal needs and a high level of protection of human health and the environment.	
Recital 14				
23	(14) In order to adjust to technological changes and developments in the field of digitalisation, the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the		(14) In order to adjust to technological changes and developments in the field of digitalisation, the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the	

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	European Union to supplement Regulation (EC) No 1272/2008 by further specifying the technical requirements for the digital labelling.		European Union to supplement Regulation (EC) No 1272/2008 by further specifying the technical requirements for the digital labelling.	
Recital 15				
24	(15) Regulation (EC) No 1272/2008 currently does not lay down any specific rules for labelling and packaging of substances or mixtures supplied to the general public and professional users via refill stations. Considering the increasing trend of selling products, including certain chemicals such as detergents, without packaging to reduce waste and to facilitate more sustainable sales forms, it is appropriate to set out specific rules and conditions for such type of sales, and establish a list of hazard classes and categories prohibiting such refill station sales for substances of mixtures meeting the criteria for classification in those hazard		(15) Regulation (EC) No 1272/2008 currently does not lay down any specific rules for labelling and packaging of substances or mixtures supplied to the general public and professional users via refill stations. Considering the increasing trend of selling products, including certain chemicals such as detergents, without packaging to reduce waste and to facilitate more sustainable sales forms, it is appropriate to set out specific rules and conditions for such type of sales, and establish a list of hazard classes and categories prohibiting such refill station sales for substances of mixtures meeting the criteria for classification in those hazard	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	classes and categories, in order to ensure safety and the protection of human health.		classes and categories, in order to ensure safety and the protection of human health. **Risk mitigation measures should be in place to ensure that refill can be performed safely, for example by preventing overfilling, contamination and operation by children as well as avoiding reaction between substances and mixtures provided through the station, or with residues in refilled packages.**	
Recital 16				
25	(16) Regulation (EC) No 1272/2008 does not lay down rules on the labelling of chemicals supplied to the general public without packaging except for ready mixed cement and concrete in a wet state. In order to enhance legal clarity and ensure a better protection of citizens, it is appropriate to provide for the labelling elements of other chemicals, such as fuels		(16) Regulation (EC) No 1272/2008 does not lay down rules on the labelling of chemicals supplied to the general public without packaging except for ready mixed cement and concrete in a wet state. In order to enhance legal clarity and ensure a better protection of citizens, it is appropriate to provide for the labelling elements of other chemicals, such as fuels**,**	

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	supplied at filling stations and intended to be pumped into receptacles from where they are normally not intended to be removed.		**AdBlue and wind screen fluids,** supplied at filling stations and intended to be pumped into receptacles from where they are normally not intended to be removed. **For the same reason, when it comes to filling vehicle fuels in portable receptacles, there is a need to ensure that labelling information is provided to be available for the user during storage and use.**	
Recital 17				
26	(17) As the new hazard classes and criteria introduced by Commission Delegated Regulation[1] allow for the harmonised classification and labelling of substances of the highest concern with regard to health and environment, they should normally be subject to harmonised classification and labelling and added to the list of hazard classes which includes respiratory sensitisation, germ cell mutagenicity,		(17) As the new hazard classes and criteria introduced by Commission Delegated Regulation[1] allow for the harmonised classification and labelling of substances of the highest concern with regard to health and environment, they should normally be subject to harmonised classification and labelling and added to the list of hazard classes which includes respiratory sensitisation, germ cell mutagenicity,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	carcinogenicity and reproductive toxicity. Sub-categorisation of the hazard class for respiratory sensitisation in sub-category 1A or 1B should be performed where sufficient information to classify in those hazard sub-categories is available, in order to avoid over- or under-classification. In view of the rapid development of scientific knowledge and the long-standing expertise of the European Chemicals Agency (the 'Agency') and the European Food Safety Authority (the 'Authority') on the one hand, and the limited resources of Member States' competent authorities to develop harmonised classification proposals on the other, the Commission should have the right to request the Agency and the Authority to develop a harmonised classification and labelling proposal. _____ 1. [Commission Delegated Regulation amending		carcinogenicity and reproductive toxicity. Sub-categorisation of the hazard class for respiratory sensitisation in sub-category 1A or 1B should be performed where sufficient information to classify in those hazard sub-categories is available, in order to avoid over- or under-classification. In view of the rapid development of scientific knowledge and the long-standing expertise of the European Chemicals Agency (the 'Agency') and the European Food Safety Authority (the 'Authority') on the one hand, and the limited resources of Member States' competent authorities to develop harmonised classification proposals on the other, the Commission should have the right to request the Agency and the Authority to develop a harmonised classification and labelling proposal. _____ 1. [Commission Delegated Regulation amending	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures, OJ XX of XX p XX.]		Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures, OJ XX of XX p XX.]	
Recital 18				
27	(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	(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.	

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		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***.		
Recital 19				
28	(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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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	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. ~~*receives a proposal for revision of a*~~	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~~	

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	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.	~~harmonised~~***To increase the efficiency of the harmonized*** classification and labelling ~~*submitted by a manufacturer, importer or downstream user*~~***process, the Commission*** 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*~~***adopt a delegated act, no later than 12 months following the publication of the RAC opinion***.	~~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.~~	
Recital 20				
29	(20) The criteria for inclusion of substances in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006 are equivalent to those of certain hazard classes and categories included in Annex I to Regulation (EC) No 1272/2008. In view of the high level of evidence required for		(20) The criteria for inclusion of substances in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006 are equivalent to those of certain hazard classes and categories included in Annex I to Regulation (EC) No 1272/2008. In view of the high level of evidence required for	

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	inclusion in the candidate list, the substances currently on that list should be included in Table 3 in Part 3 of Annex VI to Regulation (EC) No 1272/2008.		inclusion in the candidate list, the substances currently on that list should be included in Table 3 in Part 3 of Annex VI to Regulation (EC) No 1272/2008. **Substances included in the candidate list as having endocrine disrupting properties should be included as endocrine disruption for human health category 1 or endocrine disruption for the environment category 1 in Table 3 in Part 3 of Annex VI to Regulation (EC) No 1272/2008.**	
Recital 21				
30	(21) As the criteria for substances to qualify as endocrine disruptor for human health or the environment included in sections 3.6.5. and 3.8.2. of Annex II to Regulation (EC) No 1107/2009 and in Commission Delegated Regulation (EU) 2017/2100, and those to qualify as endocrine disruptor for human		(21) As the criteria for substances to qualify as endocrine disruptor for human health or the environment included in sections 3.6.5. and 3.8.2. of Annex II to Regulation (EC) No 1107/2009 and in Commission Delegated Regulation (EU) 2017/2100, and those to qualify as endocrine disruptor for human	

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	health or the environment included in Annex I to Regulation (EC) No 1272/2008, are equivalent, substances which qualify as meeting the criteria for endocrine disruptor properties in accordance with Commission Regulation (EU) 2018/605 and Commission Delegated Regulation (EU) 2017/2100 should be included as endocrine disruptors category 1 for human health or endocrine disruptors category 1 for the environment in Table 3 in Part 3 of Annex VI to Regulation (EC) No 1272/2008.		health or the environment included in Annex I to Regulation (EC) No 1272/2008, are equivalent, substances which qualify as meeting the criteria for endocrine disruptor properties in accordance with Commission Regulation (EU) 2018/605 and Commission Delegated Regulation (EU) 2017/2100 should be included as endocrine ~~disruptors category 1~~ **disruption** for human health **category 1** or endocrine ~~disruptors category 1~~ **disruption** for the environment **category 1** in Table 3 in Part 3 of Annex VI to Regulation (EC) No 1272/2008.	
Recital 22				
31	(22) As Article 5(1), point (e), of Regulation (EU) No 528/2012[1] refers to the PBT and vPvB criteria included in Annex XIII to Regulation (EC) No 1907/2006 to identify the PBT and vPvB properties of active		(22) As Article 5(1), point (e), of Regulation (EU) No 528/2012[1] refers to the PBT and vPvB criteria included in Annex XIII to Regulation (EC) No 1907/2006 to identify the PBT and vPvB properties of active	

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	substances and as those criteria are equivalent to those included in Annex I to Regulation (EC) No 1272/2008, the active substances meeting the criteria to qualify as PBT and vPvB under Regulation (EU) No 528/2012 and under Annex XIII to Regulation (EC) No 1907/2006 should be included in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008. As PBT and vPvB properties included in sections 3.7.2. and 3.7.3. of Annex II to Regulation (EC) No 1107/2009 of the European Parliament and of the Council[2] are equivalent to those included in Annex I to Regulation (EC) No 1272/2008, the active substances meeting the criteria to qualify as PBT and vPvB according to those criteria in sections 3.7.2. and 3.7.3. of Annex II to Regulation (EC) No 1107/2009 should be included in Table 3 in Part 3 of Annex VI to Regulation (EC) No 1272/2008. _____ 1. Regulation (EC) No 528/2012		substances and as those criteria are equivalent to those included in Annex I to Regulation (EC) No 1272/2008, the active substances meeting the criteria to qualify as PBT and vPvB under Regulation (EU) No 528/2012 and under Annex XIII to Regulation (EC) No 1907/2006 should be included in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008. As PBT and vPvB properties included in sections 3.7.2. and 3.7.3. of Annex II to Regulation (EC) No 1107/2009 of the European Parliament and of the Council[2] are equivalent to those included in Annex I to Regulation (EC) No 1272/2008, the active substances meeting the criteria to qualify as PBT and vPvB according to those criteria in sections 3.7.2. and 3.7.3. of Annex II to Regulation (EC) No 1107/2009 should be included in Table 3 in Part 3 of Annex VI to Regulation (EC) No 1272/2008. _____	

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	of 22 May 2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 167 of 27.6.2012 p.1). 2. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).		1. **[1]** Regulation (EC) No 528/2012 of 22 May 2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 167 of 27.6.2012 p.1). 2. **[2]** Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).	
Recital 23				
32	(23) As the substances referred to in recitals 30 and 31 have already been assessed by the European Food Safety Authority or the Agency as well as the Commission which has decided upon by them, they should be included in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 by a delegated act, without prior consultation		(23) As the substances referred to in recitals ~~30 and 31~~ **20, 21 and 22** have already been assessed by the European Food Safety Authority or the Agency as well as the Commission which has decided upon by them, they should be included in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 by a delegated act, without prior	

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	of the Agency as provided for in Article 37(4) of Regulation (EC) No 1272/2008.		consultation of the Agency as provided for in Article 37(4) of Regulation (EC) No 1272/2008. **To avoid duplication of ongoing work by authorities under Regulation (EC) No 1272/2008 and Regulation (EC) 1907/2006, Regulation (EC) 1107/2009 and Regulation (EU) 528/2012, delegated acts should also be adopted within an adequate deadline for substances which are foreseen to be added to the candidate list under Article 59 of Regulation (EC) No 1907/2006; substances for which applications for approval or renewal of approval have been submitted in accordance with the relevant provisions of Regulation (EC) No 1107/2009; substances for which the evaluating competent authority has submitted its draft assessment report on the approval or renewal of approval to the Agency in accordance with**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Regulation (EU) No 528/2012, or substances for which the application was submitted for the purpose of Directive 98/8/EC and the Member State's evaluation in accordance with that Directive has been completed by 1 September 2013 but no decision on the approval was adopted before that date, or substances for which the Agency has submitted to the Commission an opinion pursuant to Article 75(1)(g) of Regulation (EU) No 528/2012 concluding that they meet those criteria. **Furthermore, in order to ensure that new dossiers or on-going dossiers still at an early stage of the assessment contain a dossier for harmonised classification and labelling, the transitional provisions should apply for a limited time period.**	
Recital 24				
33				

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	(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.	(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.	(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.	

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	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.	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.***	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.	
Recital 25				
34	(25) In order to enhance	(25) In order to enhance	(25) In order to enhance	

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	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.	transparency of notifications as well as to facilitate the notifiers' duty to come to an agreed notification entry for the same substance, ~~*certain*~~***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.	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.	
Recital 26				
35	(26) Pursuant to Article 45(1)		(26) Pursuant to Article 45(1)	

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	of Regulation (EC) No 1272/2008, appointed bodies in the Member States are to receive relevant information relating to emergency health response submitted by importers and downstream users placing on the market mixtures that are hazardous based on their health or physical effects. Distributors are not required to submit such information. In certain cases of distribution across borders from one Member State to another, or where distributors rebrand or relabel mixtures, the absence of such submission obligation causes information loss for the appointed bodies which may prevent them from providing adequate emergency health response. To address this situation, an obligation to submit information relating to emergency health response should also be introduced for distributors, where they further distribute hazardous mixtures in other Member States or where they rebrand or relabel hazardous mixtures.		of Regulation (EC) No 1272/2008, appointed bodies in the Member States are to receive relevant information relating to emergency health response submitted by importers and downstream users placing on the market mixtures that are hazardous based on their health or physical effects. Distributors are not required to submit such information. In certain cases of distribution across borders from one Member State to another, or where distributors rebrand or relabel mixtures, the absence of such submission obligation causes information loss for the appointed bodies which may prevent them from providing adequate emergency health response. To address this situation, an obligation to submit information relating to emergency health response should also be introduced for distributors, where they further distribute hazardous mixtures in other Member States or where they rebrand or relabel hazardous mixtures.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 27				
36	(27) Pursuant to Article 45(3) of Regulation (EC) No 1272/2008, appointed bodies are to have all the required information available to provide adequate emergency health response. The Agency already set up and maintains a Union level Poison Centres Notification portal, and established, developed and maintains a database containing information relating to emergency health response to assist some Member States in complying with that Regulation. Therefore, the Agency would be in a position to fulfil the task of receiving that information. To reduce administrative burden for Member States and take advantage of economies of scale, Regulation (EC) No 1272/2008 should provide for the option of appointing the Agency as a body responsible for receiving the relevant		(27) Pursuant to Article 45(3) of Regulation (EC) No 1272/2008, appointed bodies are to have all the required information available to provide adequate emergency health response. The Agency already set up and maintains a Union level Poison Centres Notification portal, and established, developed and maintains a database containing information relating to emergency health response to assist some Member States in complying with that Regulation. Therefore, the Agency would be in a position to fulfil the task of receiving that information. To reduce administrative burden for Member States and take advantage of economies of scale, Regulation (EC) No 1272/2008 should provide for the option of appointing the Agency as a body responsible for receiving the relevant	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	information, should a Member State wish to do so.		information, should a Member State wish to do so.	
Recital 28				
37	(28) In addition to the Member States' appointed bodies, the Commission or the Agency should be able to use the information relating to emergency health responses for the purpose of carrying out statistical analysis. That would usefully complement information on the uses of substances submitted as part of registration under Regulation (EC) No 1907/2006, while enabling a better prioritisation of substances to be subject to harmonised classification and labelling under Regulation (EC) No 1272/2008 and feeding into the risk management processes under Regulation (EC) No 1907/2006, and potentially under other Union acts.		(28) In addition to the Member States~~' appointed bodies~~, the Commission or the Agency should be able to use~~ the~~ **statistical** information relating to emergency health responses for the purpose of **identifying where improved risk management measures may be needed**~~ carrying out statistical analysis~~. That would usefully complement information on the uses of substances submitted as part of registration under Regulation (EC) No 1907/2006, while enabling a better prioritisation of substances to be subject to harmonised classification and labelling under Regulation (EC) No 1272/2008 and feeding into the risk management processes under Regulation (EC) No 1907/2006, and potentially under other Union acts.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 29				
38	(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.	(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	(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 **human health**	

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	Therefore, the advertisement should contain the hazard pictogram, the signal word, the hazard class and the hazard statements. The hazard category should not be provided, as it is reflected by the hazard statement.	environment. Therefore, the advertisement should contain the hazard pictogram, the signal word, the hazard class and the hazard statements. The hazard category should not be provided, as it is reflected by the hazard statement.	**and** the environment. Therefore, the advertisement should contain the hazard pictogram, the signal word~~,~~ the hazard ~~class and the hazard~~**statements and supplemental EUH** statements**, with derogations for non-visual advertisement**. The hazard category should not be provided, as it is reflected by the hazard statement.	
Recital 30				
39	(30) Regulation (EC) No 1272/2008 does not explicitly refer to offers, let alone to distance sales offers. Consequently, it does not address specific problems arising from distance sales, such as online sales. Whereas advertisements is understood as being at the pre-stage of offers, notably as information designed to promote messages of a natural or legal person, whether or not against remuneration, offers are understood as invitations by a natural or legal		(30) Regulation (EC) No 1272/2008 does not explicitly refer to offers, let alone to distance sales offers. Consequently, it does not address specific problems arising from distance sales, such as online sales. Whereas advertisements is understood as being at the pre-stage of offers, notably as information designed to promote messages of a natural or legal person, whether or not against remuneration, offers are understood as invitations by a natural or legal	

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	person to conclude a purchase contract. This differentiation should justify the requirement of providing more hazard information in offers than in advertisements. In order to keep pace with technological development and new means of sale, the compliance by design obligations laid down for providers of online marketplaces in Article 31 of Regulation (EU) 2022/2065 of the European Parliament and of the Council[1] should apply for the purpose of labelling information required by Article 17 of Regulation (EC) No 1272/2008. The enforcement of those obligations is subject to the rules laid down in Chapter IV of Regulation (EU) 2022/2065. _____ 1. Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act) (OJ L 277,		person to conclude a purchase contract. This differentiation should justify the requirement of providing more hazard information in offers than in advertisements. In order to keep pace with technological development and new means of sale, **it is necessary to require the labelling elements to be indicated in case of distance sales, including via online market places, in order for** the compliance by design obligations laid down for providers of online marketplaces in Article 31 of Regulation (EU) 2022/2065 of the European Parliament and of the Council[1] ~~should~~ **to** apply **in relation to such** ~~for the purpose of~~ labelling information ~~required by Article 17 of Regulation (EC) No 1272/2008~~. The enforcement of those obligations is subject to the rules laid down in Chapter IV of Regulation (EU) 2022/2065. _____ 1. **[1]** Regulation (EU) 2022/2065 of the European	

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	27.10.2022, p. 1).		Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending- Directive 2000/31/EC (Digital Services Act) (OJ L 277, 27.10.2022, p. 1).	
Recital 31				
40	(31) Apart from providing industry with technical and scientific tools on how to comply with Regulation (EC) No 1272/2008, the Agency should also provide competent authorities with such tools, for example databases, in order to foster implementation. Regulation (EC) No 12727/2008 should more in detail set out the Agency's remit in this regard. Furthermore, the Agency, acting as a body appointed by a Member State competent authority for receiving information for emergency health response, should provide the relevant national appointed body of that Member State		(31) Apart from providing industry with technical and scientific tools on how to comply with Regulation (EC) No 1272/2008, the Agency should also provide competent authorities with such tools, for example databases, in order to foster implementation. Regulation (EC) No 12727/2008 should more in detail set out the Agency's remit in this regard. Furthermore, the Agency, acting as a body appointed by a Member State competent authority for receiving information for emergency health response, should provide the relevant national appointed body of that Member State	

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	access to that information.		access to that information.	
Recital 32				
41	(32) After consultation of the Commission expert group of Competent Authorities for REACH[1] and CLP[2], the Commission regularly adapts the Annexes to Regulation (EC) No 1272/2008 to technical and scientific progress. According to Article 53c of that Regulation, the Commission is to adopt a separate delegated act in respect of each power delegated to it. It has been difficult to apply that provision when amending different parts of Annex VI to Regulation (EC) No 1272/2008 that are subject to different empowerments. In particular in the case of simultaneous introduction of new notes into Part 1 of Annex VI to Regulation (EC) No 1272/2008 pertaining to new entries in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 and the introduction of new		(32) After consultation of the Commission expert group of Competent Authorities for REACH[1] and CLP[2], the Commission regularly adapts the Annexes to Regulation (EC) No 1272/2008 to technical and scientific progress. According to Article 53c of that Regulation, the Commission is to adopt a separate delegated act in respect of each power delegated to it. It has been difficult to apply that provision when amending different parts of Annex VI to Regulation (EC) No 1272/2008 that are subject to different empowerments. In particular in the case of simultaneous introduction of new notes into Part 1 of Annex VI to Regulation (EC) No 1272/2008 pertaining to new entries in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 and the introduction of new	

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	entries themselves in the same Annex, adoption of separated delegated acts has resulted in artificially separating intrinsically related provisions and thereby affecting coherence by requiring simultaneous adoption of two different but related delegated acts. In such cases, it should be possible to adopt a single delegated act in respect of different delegated powers. _____ 1. 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,		entries themselves in the same Annex, adoption of separated delegated acts has resulted in artificially separating intrinsically related provisions and thereby affecting coherence by requiring simultaneous adoption of two different but related delegated acts. In such cases, it should be possible to adopt a single delegated act in respect of different delegated powers. _____ 1. **[**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,	

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	93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1). 2. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).		93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1). 2. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).	
Recital 32a				
41a			**(32a) It is important that the introduction, adjustment, or clarification of the criteria for the classification and labelling of endocrine disruptors for human health, endocrine disruptors for the environment, persistent, bioaccumulative and toxic (PTB), very persistent and very bioaccumulative (vPvB), persistent, mobile and toxic (PMT) and very persistent**	

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			and very mobile (vPvM) substances is promoted in the relevant UN fora. When attending international meetings, the Commission and Member States should cooperate efficiently and be in line with Union positions in accordance with the Treaties.	
Recital 33				
42	(33) In accordance with Directive 2010/63/EU of the European Parliament and of the Council[1], 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	(33) In accordance with Directive 2010/63/EU of the European Parliament and of the Council[1], 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 ~~*alternative test methods*~~***New Approach Methodologies (NAM)***, suitable for the assessment of health and environmental classification of chemicals, wherever possible. In order to speed up the transition	(33) In accordance with Directive 2010/63/EU of the European Parliament and of the Council[1], 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	

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	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. _____ 1. 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).	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 ~~*undue*~~ delay. _____ 1. ***[1]*** 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).	chemical hazard assessments, innovation in the field of non-animal methods should be monitored and systematically evaluated, and the Commission and the Member States **should cooperate efficiently and be in line with Union positions in accordance with the Treaties to** ~~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. _____ 1. 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).	
Recital 34				

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43	(34) Annex VIII to Regulation (EC) No 1272/2008 provides for harmonised information relating to emergency health response and preventative measures to be received by appointed bodies, and sets forth the general requirements, the information to be contained in a submission, the submission format and certain standard formulas. In order to provide legal certainty and clarity on the option for submission of information relating to standardised mixtures and fuels in the context of Annex VIII to Regulation (EC) No 1272/2008, that Regulation should define the term 'composition conforming with a standard formula', the obligation to provide the name and product description of the standard formula in the submission and of the fuel should be introduced, and the option to submit information on components even if they are not always present in certain cases should be provided for.		(34) Annex VIII to Regulation (EC) No 1272/2008 provides for harmonised information relating to emergency health response and preventative measures to be received by appointed bodies, and sets forth the general requirements, the information to be contained in a submission, the submission format and certain standard formulas. In order to provide legal certainty and clarity on the option for submission of information relating to standardised mixtures and fuels in the context of Annex VIII to Regulation (EC) No 1272/2008, that Regulation should define the term 'composition conforming with a standard formula', the obligation to provide the name and product description of the standard formula in the submission and of the fuel should be introduced, and the option to submit information on components even if they are not always present in certain cases should be provided for.	

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Recital 35				
44	(35) In order to provide further legal certainty and clarity of Annex VIII to Regulation (EC) No 1272/2008, that Regulation should further specify when submission updates are required, as well as ways of identifying the mixture, submitter and contact point by means of their product identifier.		(35) In order to provide further legal certainty and clarity of Annex VIII to Regulation (EC) No 1272/2008, that Regulation should further specify when submission updates are required, as well as ways of identifying the mixture, submitter and contact point by means of their product identifier.	
Recital 35a				
44a		***(35a) Where appropriate, the Agency should provide further guidance on the application of the provisions relating to the review of this Regulation.***		
Recital 36				
45	(36) Regulation (EC) No 1272/2008 should therefore be amended accordingly.		(36) Regulation (EC) No 1272/2008 should therefore be amended accordingly.	

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Recital 36a				
45a		***(36a) The amendments introduced by this regulation expand 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.***		
Recital 37				
46	(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 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-	(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-	(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 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-	

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	classified and re-labelled in accordance with this Regulation, to avoid additional burden on suppliers of substances and mixtures.	classified and re-labelled in accordance with this Regulation, to avoid additional burden on suppliers of substances and mixtures.	classified and re-labelled in accordance with this Regulation, to avoid additional burden on suppliers of substances and mixtures.	
Recital 38				
47	(38) In line with the transitional provisions of Regulation (EC) No 1272/2008 which allow the application of the new provisions at an earlier stage on a voluntary basis, suppliers should have the possibility of applying the new classification, labelling and packaging provisions on a voluntary basis before the date of deferred application of this Regulation.		(38) In line with the transitional provisions of Regulation (EC) No 1272/2008 which allow the application of the new provisions at an earlier stage on a voluntary basis, suppliers should have the possibility of applying the new classification, labelling and packaging provisions on a voluntary basis before the date of deferred application of this Regulation.	
Recital 39				
48	(39) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States, because environmental pollution is transboundary and the citizens		(39) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States, because environmental pollution is transboundary and the citizens	

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	of the Union should benefit from an equal protection of their health and environment and because substances and mixtures should circulate freely on the Union market , but can rather, by reason of their scale, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,		of the Union should benefit from an equal protection of their health and environment and because substances and mixtures should circulate freely on the Union market , but can rather, by reason of their scale, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,	
Formula				
49	HAVE ADOPTED THIS REGULATION:		HAVE ADOPTED THIS REGULATION:	
Article 1				
50	Article 1		Article 1	

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Article 1, first paragraph				
51	Regulation (EC) No 1272/2008 is amended as follows:		Regulation (EC) No 1272/2008 is amended as follows:	
Article 1, first paragraph, point (-1)				
51a		***(-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 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:***		

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		(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;"		
Article 1, first paragraph, point (1)				
52	(1) in Article 1(1), the following point (f) is added:		(1) in Article 1(1), the following point (f) is added:	
Article 1, first paragraph, point (1), amending provision, first paragraph				
53	‘ (f) providing an obligation for downstream users, importers and distributors referred to in Article 45(1) to submit information relevant for providing an adequate		‘ (f) providing an obligation for downstream users, importers and distributors referred to in Article ~~45(1)~~**45(1b) and 45(1c)** to submit information relevant for providing an adequate	

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	emergency health response to appointed bodies in accordance with Annex VIII.; ,		emergency health response to appointed bodies in accordance with Annex VIII.**'**; ,	
Article 1, first paragraph, point (2)				
54	(2) Article 2 is amended as follows:		(2) **in** Article 2**, the following points 38 to 41 are added** ~~is amended as follows~~:	
Article 1, first paragraph, point (2)(a)				
55	(a) the following point is inserted:		(a) ~~the following point is inserted:~~	
Article 1, first paragraph, point (2)(a), amending provision, first paragraph				
56	‘ 7a. ‘multi-constituent substance’ means a substance that contains more than one constituent. ,		*deleted*	
Article 1, first paragraph, point (2)(b)				
57	*(b)* the following point is			

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	added:		*deleted*	
Article 1, first paragraph, point (2)(b), amending provision, numbered paragraph (38)				
58	‘ *38.* ‘acute toxicity estimates’ means numeric criteria according to which substances and mixtures are classified in one of four acute toxicity hazard categories based on the oral, dermal or inhalation exposure route.; ’		‘ 38. ‘acute toxicity estimates’ means numeric ~~criteria according to which~~ **values which are used to classify** substances and mixtures ~~are classified~~ in one of four acute toxicity hazard categories based on the oral, dermal or inhalation exposure route.;	
Article 1, first paragraph, point (2)(b), amending provision, numbered paragraph (38a)				
58a		‘ ***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;***		
Article 1, first paragraph, point (2)(b), amending provision, numbered paragraph (38b)				

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58b		***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;*** ,		
Article 1, first paragraph, point (2)(b), amending provision, numbered paragraph (38a)				
58c			**39. 'data carrier' means a linear bar code symbol, a two-dimensional symbol or other automatic identification data capture medium that can be read by a device;**	
Article 1, first paragraph, point (2)(b), amending provision, numbered paragraph (38b)				
58d			**40. 'refill' means an operation by which a consumer or a professional user fills a packaging with a hazardous substance or mixture offered by a supplier in the course of a commercial activity, whether in return for payment or free of charge;**	

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Article 1, first paragraph, point (2)(b), amending provision, numbered paragraph (38c)				
58e			**41. 'refill station' means a place where a supplier offers to consumers or professional users hazardous substances or mixtures that can be acquired through refill, either manually or through automatic or semi-automatic equipment.';** ,	
Article 1, first paragraph, point (2a)				
58f		***(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. Gender differences with regard to the susceptibility to chemicals shall be taken into***		

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		consideration, where relevant."		
Article 1, first paragraph, point (3)				
59	(3) in Article 4, paragraph 10 is replaced by the following:		(3) ~~in~~ Article 4~~, paragraph 10 is replaced by the following~~ **is amended as follows**:	
Article 1, first paragraph, point (3a), first subparagraph				
59a			**(a) paragraph 3 is replaced by the following:**	
Article 1, first paragraph, point (3a), first subparagraph, point (a)				
59b			**'3. If a substance is subject to harmonised classification and labelling in accordance with Title V, through an entry in part 3 of Annex VI, that substance shall be classified in accordance with that entry, and a classification of that substance in accordance with Title II shall not be performed for the hazard classes, differentiations and forms or physical states covered by that entry.**	

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			The harmonised classification of that substance shall apply to all its forms and physical states unless an entry in Part 3 of Annex VI specifies that a harmonised classification applies to a specific form and physical state of that substance. **However, where the substance also falls within one or more hazard classes or differentiations or it is in a form or physical state not covered by an entry in Part 3 of Annex VI, classification under Title II shall be carried out for those hazard classes or, differentiations and forms or physical states.'**	
Article 1, first paragraph, point (3a), second subparagraph				
59c			**(b) the following paragraph 11 is added:**	
Article 1, first paragraph, point (3b)				
59d				

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Article 1, first paragraph, point (3), amending provision, numbered paragraph (10)				
60	‘ 10. A substance or a mixture shall not be placed on the market unless a supplier has ensured in the course of an industrial or professional activity that the substance or the mixture fulfils the requirements set out in this Regulation.; ’		‘ ~~10~~**11**. **A natural or legal person established outside the Community can place substances and mixtures**~~A substance or a mixture shall not be placed~~ on the market ~~unless~~**only if it ensures that** a supplier ~~has ensured~~**established** in the ~~course of an industrial or professional activity that the substance or the mixture~~ **Community, who shall be indicated on the label, in the course of an industrial or professional activity** fulfils the requirements set out in this Regulation **with regard to the substances and mixtures in question**.**’**; ’	
Article 1, first paragraph, point (4)				
61	(4) in Article 5, the following paragraph 3 is added:		*deleted*	
Article 1, first paragraph, point (4), amending provision, numbered paragraph (3), first subparagraph				

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62	‘ *3.* 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 provision.	‘ 3. A ~~*multi-constituent*~~ substance containing ~~*at least*~~***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 substance~~, unless Annex I lays down a specific provision~~ ***itself***.	*deleted*	
Article 1, first paragraph, point (4), amending provision, numbered paragraph (3), second subparagraph				
63	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	For the evaluation of ~~*multi-constituent*~~***these*** substances ***containing more than one constituent*** pursuant to Chapter 2 in relation to the ‘germ cell mutagenicity’, ‘carcinogenicity’, ‘reproductive	*deleted*	

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	‘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.	toxicity’, ‘endocrine ~~*disrupting property*~~***disruption*** for human health’ and ‘endocrine ~~*disrupting property*~~ ***disruption*** 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*~~***sections3.5., 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~~.~~		
Article 1, first paragraph, point (4), amending provision, numbered paragraph (3), third subparagraph				
64	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 ~~*multi-constituent substance*~~***substance containing more than one constituent*** itself shall be taken into account where one of the following conditions are met:	*deleted*	
Article 1, first paragraph, point (4), amending provision, numbered paragraph (3), third subparagraph, point (a)				

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65	*(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 ~~*disrupting properties*~~***disruption*** for human health or the environment;	*deleted*	
Article 1, first paragraph, point (4), amending provision, numbered paragraph (3), third subparagraph, point (b)				
66	*(b)* the information supports the conclusions based on the relevant available information on the constituents in the substance.		*deleted*	
Article 1, first paragraph, point (4), amending provision, numbered paragraph (3), fourth subparagraph				
67	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 ~~*multi-constituent substance*~~***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.	*deleted*	

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Article 1, first paragraph, point (4), amending provision, numbered paragraph (3), fifth subparagraph				
68	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 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.	For the evaluation of ~~*multi-constituent substances*~~***substances containing more than one constituent*** pursuant to Chapter 2 ***of this Title*** in relation to the 'biodegradation, persistence, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment' 'persistent, bioaccumulative and toxic', 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' and 'very persistent and very mobile' hazard classes referred to in sections 4.1.2.8 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual ***known*** constituents ***, impurities or additives*** in the substance.	*deleted*	

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Article 1, first paragraph, point (4), amending provision, numbered paragraph (3), sixth subparagraph				
69	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*** ~~*multi-constituent substance*~~ itself shall be taken into account where one of the following conditions are met:	*deleted*	
Article 1, first paragraph, point (4), amending provision, numbered paragraph (3), sixth subparagraph, point (a)				
70	*(a)* the information demonstrates biodegradation, persistence, mobility and bioaccumulation properties.	(a) the information demonstrates ~~*biodegradation*~~, persistence, mobility and bioaccumulation properties ***or lack of biodegradation***.	*deleted*	
Article 1, first paragraph, point (4), amending provision, numbered paragraph (3), sixth subparagraph, point (b)				
71	*(b)* the information supports the conclusions based on the relevant available information on the constituents in the substance.		*deleted*	
Article 1, first paragraph, point (4), amending provision, numbered paragraph (3), seventh subparagraph				
72	Relevant available information	Relevant available information		

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	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. ‘	on the ***substance containing more than one constituent*** ~~*multi-constituent substance*~~ itself showing absence of ~~*certain*~~ ***the*** properties ***referred to in (a)*** or less severe properties shall not override the relevant available information on the constituents in the substance.	*deleted*	
Article 1, first paragraph, point (4), amending provision, numbered paragraph (3a)				
72a		***3a. in Article 5, the following paragraph is added:*** ***"3a. Paragraph 3 shall not apply to substances containing more than one constituent of renewable botanical origin that are not chemically or genetically modified without prejudice to the application of Regulation (EU) No 1107/2009[1] or Regulation (EU) No 528/2012.[2] [Am. 106]*** ‘ ***1. Regulation (EC) No 1107/2009 of the European Parliament and of the Council***		

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		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. 2. 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.		
Article 1, first paragraph, point (5)				
73	(5) in Article 6, paragraphs 3 and 4 are replaced by the following:		(5) in Article 6, paragraphs 3 and 4 are replaced by the following:	
Article 1, first paragraph, point (5a)				
73a				
Article 1, first paragraph, point (5), amending provision, numbered paragraph (3), first subparagraph				
74	‘ 3. For the evaluation of mixtures pursuant to chapter 2 in relation to the ‘germ cell mutagenicity’, ‘carcinogenicity’, ‘reproductive	‘ 3. For the evaluation of mixtures pursuant to chapter 2 ***of this Title*** in relation to the ‘germ cell mutagenicity’, ‘carcinogenicity’, ‘reproductive	‘ 3. For the evaluation of mixtures pursuant to Chapter 2 **of this Title** in relation to the ‘germ cell mutagenicity’, ‘carcinogenicity’, ‘reproductive	

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	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 .	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 .	toxicity', 'endocrine ~~disrupting property~~**disruption** for human health' and 'endocrine ~~disrupting property~~**disruption** 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~~.~~	
Article 1, first paragraph, point (5), amending provision, numbered paragraph (3), second subparagraph				
75	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	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	~~However,~~ Where the available test data on the mixture itself demonstrates germ cell mutagenic, carcinogenic or toxic to reproduction properties, or endocrine ~~disrupting properties~~ **disruption** for human health or the environment which have not been identified from the relevant available information on the individual substance	

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	subparagraph, that data shall also be taken into account for the purposes of the evaluation of the mixture referred to in the first subparagraph.	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, ***data on the mixture as a whole*** ~~*that data*~~ shall also be taken into account for the purposes of the evaluation of the mixture referred to in the first subparagraph.	referred to in the first subparagraph, that data shall also be taken into account for the purposes of the evaluation of the mixture referred to in the first subparagraph.	
Article 1, first paragraph, point (5), amending provision, numbered paragraph (4)				
76	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,	~~*4*~~***3a***. 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,	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~~',~~ **or** very persistent and very bioaccumulative	

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	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 ; ,	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 **'**;	**properties**', 'persistent, mobile and toxic~~' and '~~ **or** very persistent and very mobile **properties**' 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~~ **itself.'**;	
Article 1, first paragraph, point (5), amending provision, numbered paragraph (3a), second subparagraph				
76a		***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***		

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		evaluating the mixture referred to in the first subparagraph.		
Article 1, first paragraph, point (5), amending provision, Article				
76b		***Article (5a) Article 7 is replaced by the following: "Article 7 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. 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.***		

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		4. Tests using new approach methodologies shall also be considered." ,		
Article 1, first paragraph, point (5a)				
76c			**5a. in Article 8, the following paragraph 7 is added:**	
Article 1, first paragraph, point (5), amending provision, Article(1)				
76d			**'7. 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.'** ,	
Article 1, first paragraph, point (6)				
77	(6) in Article 9, paragraphs 3 and 4 are replaced by the following:		(6) in Article 9, paragraphs 3 and 4 are replaced by the following:	

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Article 1, first paragraph, point (6), amending provision, numbered paragraph (3)				
78	‘ 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. ’	‘ 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.	
Article 1, first paragraph, point (6), amending provision, numbered paragraph (4), first subparagraph				
79	4. When evaluating hazard information for mixtures, manufacturers, importers and		4. When evaluating hazard information for mixtures, manufacturers, importers and	

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	downstream users shall, where test data for the mixture itself are inadequate or unavailable, apply the bridging principles referred to in section 1.1.3. of Annex I and in each section of Parts 3 and 4 of that Annex for the purposes of the evaluation.		downstream users shall, where test data for the mixture itself are inadequate or unavailable, apply the bridging principles referred to in section 1.1.3. of Annex I and in each section of Parts 3 and 4 of that Annex for the purposes of the evaluation.	
Article 1, first paragraph, point (6), amending provision, numbered paragraph (4), second subparagraph				
80	When applying the bridging principles, manufacturers, importers and downstream users may integrate 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 mixture, and in accordance with section 1.2. of Annex XI to Regulation (EC) No 1907/2006. The rules on bridging principles in section 1.1.3 of Annex I shall remain applicable even in a weight of evidence determination.		**If more than one similar tested mixture is available** when applying the bridging principles, manufacturers, importers and downstream users ~~may integrate~~ **shall apply** 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 mixture, and in accordance with section 1.2. of Annex XI to Regulation (EC) No 1907/2006~~. The rules on bridging principles in section 1.1.3 of Annex I shall remain~~	

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			~~applicable even in a weight of evidence determination~~ **to select the most suitable similar tested mixtures according to Article 6(5) for decision on classification**.	
Article 1, first paragraph, point (6), amending provision, numbered paragraph (4), third subparagraph				
81	When evaluating the hazard information for mixtures, manufacturers, importers and downstream users shall, where that information does not permit the application of the bridging principles in accordance with the first and second subparagraphs, evaluate the information by applying the other method or methods set out in Parts 3 and 4 of Annex I.; ,		When evaluating the hazard information for mixtures, manufacturers, importers and downstream users shall, where that information does not permit the application of the bridging principles in accordance with the first and second subparagraphs, evaluate the information by applying the other method or methods set out in Parts 3 and 4 of Annex I.**'**; ,	
Article 1, first paragraph, point (7)				
82	(7) Article 10 is replaced by the following:		(7) Article 10 is replaced by the following:	

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Article 1, first paragraph, point (7), amending provision, first paragraph				
83	‘ Article 10		‘ Article 10	
Article 1, first paragraph, point (7), amending provision, second paragraph				
84	Concentration limits, M-factors and acute toxicity estimates for classification of substances and mixtures		Concentration limits, M-factors and acute toxicity estimates for classification of substances and mixtures	
Article 1, first paragraph, point (7), amending provision, numbered paragraph (1), first subparagraph				
85	1. Specific concentration limits and generic concentration limits are limits assigned to a substance indicating a threshold at or above which the presence of that substance in another substance or in a mixture as an identified impurity, additive or individual constituent leads to the classification of the substance or mixture as hazardous.		1. Specific concentration limits and generic concentration limits are limits assigned to a substance indicating a threshold at or above which the presence of that substance in another substance or in a mixture as an identified impurity, additive or individual constituent leads to the classification of the substance or mixture as hazardous.	
Article 1, first paragraph, point (7), amending provision, numbered paragraph (1), second subparagraph				
86				

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	Specific concentration limits shall be set by the manufacturer, importer or downstream user where adequate and reliable scientific information shows that the hazard of a substance is evident when the substance is present at a level below the concentrations set for any hazard class in Part 2 of Annex I or below the generic concentration limits set for any hazard class in Parts 3, 4 and 5 of Annex I.		Specific concentration limits shall be set by the manufacturer, importer or downstream user where adequate and reliable scientific information shows that the hazard of a substance is evident when **such a** ~~the~~ substance is present at a level below the concentrations set for any hazard class in Part 2 of Annex I or below the generic concentration limits set for any hazard class in Parts 3, 4 and 5 of Annex I.	
Article 1, first paragraph, point (7), amending provision, numbered paragraph (1), third subparagraph				
87	In exceptional circumstances specific concentration limits may be set by the manufacturer, importer or downstream user where that manufacturer, importer or downstream user has adequate, reliable and conclusive scientific information that a hazard of a substance classified as hazardous is not evident at a level above the concentrations set for the relevant hazard class		~~In exceptional circumstances specific concentration limits may be set by the manufacturer, importer or downstream user where that manufacturer, importer or downstream user has~~ **Manufacturers, importer or downstream users may set a specific concentration limit of a substance in exceptional circumstances where** adequate, reliable and conclusive scientific	

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	in Part 2 of Annex I or above the generic concentration limits set for the relevant hazard class in Parts 3, 4 and 5 of that Annex.		information **shows that the**~~that a~~ hazard of a substance classified as hazardous is not evident at a level above the concentrations set for the relevant hazard class in Part 2 of Annex I or above the generic concentration limits set for the relevant hazard class in Parts 3, 4 and 5 of that Annex.	
Article 1, first paragraph, point (7), amending provision, numbered paragraph (2)				
88	2. M-factors for substances classified as hazardous to the aquatic environment, acute category 1 or chronic category 1, shall be established by manufacturers, importers and downstream users.		2. **Manufacturers, importers and downstream users shall establish** M-factors for substances classified as hazardous to the aquatic environment, acute category 1 or chronic category 1~~, shall be established by manufacturers, importers and downstream users~~.	
Article 1, first paragraph, point (7), amending provision, numbered paragraph (3)				
89	3. Acute toxicity estimates for substances classified as acutely toxic for human health shall be		3. Acute toxicity estimates for substances classified as acutely toxic for human health shall be	

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	established by manufacturers, importers and downstream users.		established by manufacturers, importers and downstream users.	
Article 1, first paragraph, point (7), amending provision, numbered paragraph (4)				
90	4. By way of derogation from paragraph 1, specific concentration limits shall not be set for harmonised hazard classes or differentiations for substances included in Part 3 of Annex VI for which a specific concentration limit is given in that Part.		4. By way of derogation from paragraph 1, **second and third subparagraph,** specific concentration limits shall not be set for harmonised hazard classes or differentiations for substances included in Part 3 of Annex VI ~~for which a specific concentration limit is given in that Part~~.	
Article 1, first paragraph, point (7), amending provision, numbered paragraph (5)				
91	5. By way of derogation from paragraph 2, M-factors shall not be established for harmonised hazard classes or differentiations for substances included in Part 3 of Annex VI for which an M-factor is given in that Part.		5. By way of derogation from paragraph 2, M-factors shall not be established for harmonised hazard classes or differentiations for substances included in Part 3 of Annex VI for which an M-factor is given in that Part. **However, where an M-factor is not given in Part 3 of Annex**	

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			VI for substances classified as hazardous to the aquatic environment, acute category 1 or chronic category 1, an M-factor based on available data for the substance shall be set by the manufacturer, importer or downstream user. When a mixture including the substance is classified by the manufacturer, importer or downstream user using the summation method, this M-factor shall be used.	
Article 1, first paragraph, point (7), amending provision, numbered paragraph (6)				
92	6. By way of derogation from paragraph 3, acute toxicity estimates shall not be established for harmonised hazard classes or differentiations for substances included in Part 3 of Annex VI for which an acute toxicity estimate is given in that Part.		6. By way of derogation from paragraph 3, acute toxicity estimates shall not be established for harmonised hazard classes or differentiations for substances included in Part 3 of Annex VI for which an acute toxicity estimate is given in that Part.	
Article 1, first paragraph, point (7), amending provision, numbered paragraph (7), first subparagraph				

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93	7. When setting the specific concentration limit, M-factor or acute toxicity estimate, manufacturers, importers and downstream users shall take into account any specific concentration limits, M-factors or acute toxicity estimate for that substance which have been included in the classification and labelling inventory.		7. When setting the specific concentration limit, M-factor or acute toxicity estimate, manufacturers, importers and downstream users shall take into account any specific concentration limits, M-factors or acute toxicity estimate for that substance which have been included in the classification and labelling inventory.	
Article 1, first paragraph, point (7), amending provision, numbered paragraph (7), second subparagraph				
94	However, where an M-factor is not given in Part 3 of Annex VI for substances classified as hazardous to the aquatic environment, acute category 1 or chronic category 1, an M-factor based on available data for the substance shall be set by the manufacturer, importer or downstream user. When a mixture including the substance is classified by the manufacturer, importer or downstream user using the summation method, this M-		*deleted*	

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	factor shall be used.			
Article 1, first paragraph, point (7), amending provision, numbered paragraph (8)				
95	*8.* Specific concentration limits set in accordance with paragraph 1 shall take precedence over the concentration limits set out in the relevant sections of Part 2 of Annex I or the generic concentration limits for classification set out in the relevant sections of Parts 3, 4 and 5 of that Annex.		8. Specific concentration limits set in accordance with paragraph 1**, second and third subparagraph,** shall take precedence over the concentration limits set out in the relevant sections of Part 2 of Annex I or the generic concentration limits for classification set out in the relevant sections of Parts 3, 4 and 5 of that Annex.	
Article 1, first paragraph, point (7), amending provision, numbered paragraph (9)				
96	9. The Agency shall provide further guidance for the application of paragraphs 1, 2 and 3.		9. The Agency shall provide further guidance for the application of paragraphs 1, 2 and 3.	
Article 1, first paragraph, point (7), amending provision, numbered paragraph (10)				
97	10. Where a mixture contains a substance which is classified as hazardous solely due to the		10. Where a mixture contains a substance which is classified as hazardous solely due to the	

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	presence of an identified impurity, additive or individual constituent, the concentration limits referred to in paragraph 1 shall apply to the concentration of that identified impurity, additive or individual constituent in the mixture.		presence of an identified impurity, additive or individual constituent, the concentration limits referred to in paragraph 1**, second and third subparagraph,** shall apply to the concentration of that identified impurity, additive or individual constituent in the mixture.	
Article 1, first paragraph, point (7), amending provision, numbered paragraph (11)				
98	11. Where a mixture contains another mixture, the concentration limits referred to in paragraph 1 shall apply to the concentration of the identified impurity, additive or individual constituent referred to in paragraph 10 in the resulting final mixture.; **'**		11. Where a mixture contains another mixture, the concentration limits referred to in paragraph 1**, second and third subparagraph,** shall apply to the concentration of the identified impurity, additive or individual constituent referred to in paragraph 10 in the resulting final mixture.**'**;	
Article 1, first paragraph, point (7a)				
98a			**7a. Article 13 is replaced by the following:**	

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Article 1, first paragraph, point (7a), amending provision, first paragraph				
98b			**" Decision to classify substances and mixtures**	
Article 1, first paragraph, point (7a), amending provision, numbered paragraph (1), first subparagraph				
98c			**If the evaluation undertaken pursuant to Article 9 and Article 12 shows that the hazards associated with the substance or mixture meet the criteria for classification in one or more hazard classes or differentiations in Parts 2 to 5 of Annex I, manufacturers, importers and downstream users shall classify the substance or mixture or, if scientifically justified, specific forms or physical states thereof, in relation to the relevant hazard class or classes or differentiations by assigning the following:**	
Article 1, first paragraph, point (7), amending provision, numbered paragraph (11d)				
98d			**(a) one or more hazard**	

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			categories for each relevant hazard class or differentiation;	
Article 1, first paragraph, point (7), amending provision, numbered paragraph (11e)				
98e			**(b) subject to Article 21, one or more hazard statements corresponding to each hazard category assigned in accordance with (a).** ,	
Article 1, first paragraph, point (7a)				
98f		***(7a) Article 17 is replaced by the following :*** ***"Article 17*** ***General rules*** ***1. A substance or mixture classified as hazardous and contained in packaging shall bear a label including the following elements:*** ***(a) the name, address and telephone number of the supplier(s);*** ***(b) the nominal quantity of the substance or mixture in the***		

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		package made available to the general public, unless this quantity is specified elsewhere on the package; ***(c) product identifiers as specified in Article 18;*** ***(d) where applicable, hazard pictograms in accordance with Article 19;*** ***(e) where applicable, signal words in accordance with Article 20;*** ***(f) where applicable, hazard statements in accordance with Article 21;*** ***(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.*** ***(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***		

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		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.*** ***The information in points (h) and (ha) in paragraph 1 may be provided on the inner pages of a fold-out label."***		
Article 1, first paragraph, point (7b)				
98g		***(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, endocrine disruption for human health, endocrine disruption for the environment, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin***		

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		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."		
Article 1, first paragraph, point (7a)				
98h			**(7b) in Article 18(3), point (b) is replaced by the following:**	
Article 1, first paragraph, point (7a), amending provision, first paragraph				
98i			" **(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),**	

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			aspiration hazard, or endocrine disruption for human health.' "	
Article 1, first paragraph, point (8)				
99	(8) in Article 23, the following point (g) is added:		(8) in Article 23, the following point (g) is added:	
Article 1, first paragraph, point (8), amending provision, first paragraph				
100	‘ (g) ammunition as defined in Article 1(1), point (3), of Directive (EU) 2021/555 of the European Parliament and of the Council* unless it falls within the definition of an article in Article 2, point (9), of this Regulation.		‘ (g) ammunition as defined in Article 1(1), point (3), of Directive (EU) 2021/555 of the European Parliament and of the Council***[1]** unless it ~~falls within the definition of an article~~ **is an article according to the definition** in Article 2, point (9)~~,~~ **and that falls within the scope of Article 4(8)** of this Regulation. _____ **1. Directive (EU) 2021/555 of the European Parliament and of the Council of 24 March 2021 on control of the**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			acquisition and possession of weapons (OJ L 115, 6.4.2021, p. 1).'	
Article 1, first paragraph, point (8a)				
100a			**(8a) In Article 24(2), the second subparagraph is replaced by the following:**	
Article 1, first paragraph, point (8), amending provision, second paragraph				
101	* Directive (EU) 2021/555 of the European Parliament and of the Council of 24 March 2021 on control of the acquisition and possession of weapons (OJ L 115, 6.4.2021, p. 1).; ,		* Directive (EU) 2021/555 of the European Parliament and of the Council of 24 March 2021 on control of the acquisition and possession of weapons (OJ L 115, 6.4.2021, p. 1).; , moved as footnote	
Article 1, first paragraph, point (8a)				
101a		***(8a) In Article 25, paragraphs 2 and 3 are replaced by the following: "2. A statement shall be***		

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		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 , 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."		
Article 1, first paragraph, point (9)				
102				

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	(9) In Article 25, paragraph 6, the first subparagraph is replaced by the following:		(9) ~~In~~ Article 25~~, paragraph 6, the first subparagraph is replaced by the following~~ **is amended as follows**:	
Article 1, first paragraph, point (9a), first subparagraph				
102a			**(x) paragraph 3 is replaced by the following:**	
Article 1, first paragraph, point (8b), second subparagraph, amending provision, first paragraph				
102b			‘ **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 6 to 9, 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.;**	

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Article 1, first paragraph, point (9), amending provision, Article				
102c			**(a)** **in paragraph 6, the first subparagraph is replaced by the following:** from Commission text, see line 102	
Article 1, first paragraph, point (9), amending provision, first paragraph				
103	‘ 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.’***;	**6.** The ~~specific~~ **special** labelling rules set out in Part 2 of Annex II shall apply to mixtures containing substances referred to in **part 2 of** that Annex.**’**; ’	

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		’		
Article 1, first paragraph, point (10)				
104	(10) In Article 25, the following paragraph is added:		(10) In Article 25, the following paragraph is added:	
Article 1, first paragraph, point (10), amending provision, numbered paragraph (9)				
105	‘ 9. Label elements resulting from requirements set out in other Union acts shall be placed in the section for supplemental information on the label.; ’		‘ 9. Label elements resulting from requirements set out in other Union acts shall be placed in the section for supplemental information on the label.; ’	
Article 1, first paragraph, point (11)				
106	(11) Article 29 is amended as follows:		(11) Article 29 is amended as follows:	
Article 1, first paragraph, point (11)(a)				
107	(a) paragraph 1 is replaced by the following:		(a) paragraph 1 is replaced by the following:	
Article 1, first paragraph, point (11)(a), amending provision, numbered paragraph (1)				

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108	‘ 1. Where the packaging of a substance or a mixture is either in such a shape or form or is so small that it is impossible to meet the requirements laid down in Article 31 for a label or a fold-out label in the languages of the Member State in which the substance or mixture is placed on the market, the label elements set out in Article 17(1), shall be provided in accordance with sections 1.5.1.1. and 1.5.1.2. of Annex I.; ’		‘ 1. Where the packaging of a substance or a mixture is either in such a shape or form or is so small that it is impossible to meet the requirements laid down in Article 31 for a label ~~or a fold-out label~~ in the languages of the Member State in which the substance or mixture is placed on the market, the label elements set out in Article 17(1), shall be provided in accordance with ~~sections 1.5.1.1. and 1.5.1.2~~**section 1.5.1**. of Annex I.**’**; ,	
Article 1, first paragraph, point (11)(b)				
109	(b) paragraph 3 is replaced by the following:		(b) paragraph 3 is replaced by the following:	
Article 1, first paragraph, point (11)(b), amending provision, numbered paragraph (3)				
110	‘ 3. Where a hazardous substance or mixture referred to in Part 5		‘ 3. Where a hazardous substance or mixture referred to in Part 5	

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	of Annex II is supplied to the general public without packaging, the labelling information shall be provided in accordance with the provision referring to that substance or mixture in that Part.; ,		of Annex II is supplied to the general public without packaging, the labelling information shall be provided in accordance with the provision referring to that substance or mixture in that Part.**'**; ,	
Article 1, first paragraph, point (11)(c)				
111	(c) the following paragraphs 4b and 4c are inserted:		(c) the following ~~paragraphs 4b and 4c are~~**paragraph 4b is** inserted:	
Article 1, first paragraph, point (11)(c), amending provision, first paragraph				
112	‘ 4b. By derogation from Article 17(1), the labelling requirement set out in that Article shall not apply to packaging of ammunition that is used by defence forces in combat zones or shipped to such zones where labelling in accordance with that requirement would constitute an unacceptable security risk for the cargo, the soldiers and the		‘ 4b. By derogation from Article 17(1), the labelling requirement set out in that Article shall not apply to packaging of ammunition that is ~~used~~**intended for use** by defence forces ~~in combat zones or shipped to such zones~~ **,** where labelling in accordance with that requirement would constitute an unacceptable	

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	staff, and sufficient camouflaging cannot be ensured.		security risk for the cargo, the soldiers ~~and~~ **or** the staff, and sufficient camouflaging cannot be ensured.	
Article 1, first paragraph, point (11)(c), amending provision, second paragraph				
113	4c. Where paragraph 4b applies, manufactures, importers or downstream users shall provide to the defence force the safety data sheet or a leaflet containing the information referred to in Article 17(1).; ,		4c. ~~Where paragraph 4b applies, manufactures~~ **In this case, manufacturers**, importers or downstream users shall provide to the defence force the safety data sheet or**, if no safety data sheet is required, a copy of the label elements in accordance with** ~~a leaflet containing the information referred to in~~ Article ~~17(1)~~**17.'**; ,	
Article 1, first paragraph, point (12)				
114	(12) Article 30 is replaced by the following:		(12) Article 30 is replaced by the following:	
Article 1, first paragraph, point (12), amending provision, first paragraph				
115	' Article 30		' Article 30	

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Article 1, first paragraph, point (12), amending provision, second paragraph				
116	Updating information on labels		Updating information on labels	
Article 1, first paragraph, point (12), amending provision, numbered paragraph (1)				
117	1. In case of a change regarding the classification and labelling of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in accordance with Article 25, the supplier shall ensure that the label is updated within 6 months after the results of the new evaluation referred to in Article 15(4) were obtained.		1. In case of a change regarding the classification ~~and~~ **or** labelling of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in accordance with Article 25, the supplier **of that substance or that mixture** shall ensure that the label is updated ~~within~~ **without undue delay and no later than** 6 months after the results of the new evaluation referred to in Article 15(4) were obtained **by, or communicated to, that supplier**.	
Article 1, first paragraph, point (12), amending provision, numbered paragraph (2)				
118				

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	2. Where a change regarding the classification and labelling of a substance or a mixture is required other than that referred to in paragraph 1, the supplier shall ensure that the label is updated within 18 months after the results of the new evaluation referred to in Article 15(4) were obtained.		2. Where a change regarding the classification ~~and~~ **or** labelling of a substance or a mixture is required other than that referred to in paragraph 1, the supplier **of that substance or that mixture** shall ensure that the label is updated ~~within~~ **without undue delay and no later than** 18 months after the results of the new evaluation referred to in Article 15(4) were obtained **by, or communicated to, that supplier**.	
Article 1, first paragraph, point (12), amending provision, numbered paragraph (2a)				
118a			**2a. Suppliers shall cooperate in accordance with Article 4(9) to ensure that the results of the new evaluations referred to in Article 15(4) are communicated throughout the supply chain without undue delay in order to fulfil the obligations in paragraphs 1 and 2.**	
Article 1, first paragraph, point (12), amending provision, numbered paragraph (3)				

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119	3. Paragraphs 1 and 2 shall not apply where a change regarding the classification and labelling of a substance or a mixture was triggered by a harmonised classification and labelling of a substance set out in a delegated act adopted pursuant to Article 37(5) or by a provision set out in a delegated act adopted pursuant to Article 53(1). In such cases, the supplier shall ensure that the label is updated by the date set out in the respective delegated act.		3. Paragraphs 1 and 2 shall not apply where a change regarding the classification and labelling of a substance or a mixture was triggered by a harmonised classification and labelling of a substance set out in a delegated act adopted pursuant to Article 37(5) or by a provision set out in a delegated act adopted pursuant to Article 53(1). In such cases, the supplier shall ensure that the label is updated by the date set out in the respective delegated act.	
Article 1, first paragraph, point (12), amending provision, numbered paragraph (4)				
120	4. The supplier of a substance or mixture that falls within the scope of Regulation (EC) No 1107/2009 or Regulation (EU) No 528/2012 shall update the label in accordance with those Regulations; ,		4. The supplier of a substance or mixture that falls within the scope of Regulation (EC) No 1107/2009 or Regulation (EU) No 528/2012 shall update the label in accordance with those Regulations; ,	
Article 1, first paragraph, point (13)				

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121	(13) in Article 31(3), the following sentence is added:	(13) in Article ~~*31(3)*~~***31, paragraph 1***, the following sentence is added:	(13) ~~in~~ Article ~~31(3), the following sentence is added~~**31 is amended as follows**: partly moved to line 49f	
Article 1, first paragraph, point (13a)				
121a			**(a) paragraph 1 is replaced by the following:**	
Article 1, first paragraph, point (13), amending provision, numbered paragraph (-1)				
121b		‘ ***-1. "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."***		
Article 1, first paragraph, point (13), amending provision, numbered paragraph (-1)				
121c			‘	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			-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 be presented in the form of a fold-out-label.	
Article 1, first paragraph, point (13), amending provision, numbered paragraph (-1a)				
121d			**(b) the following paragraph 1a is inserted:**	
Article 1, first paragraph, point (13), amending provision, numbered paragraph (-1b)				
121e			**-1a Where a digital label pursuant to Article 34a(1) is used, a data carrier to that digital label shall be firmly affixed or printed on the physical label or on the packaging next to the label in such a way that it can be processed automatically by digital devices that are widely used.**	

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Article 1, first paragraph, point (13), amending provision, numbered paragraph (-1c)				
121f			**Where label elements pursuant to Article 34a(2) are provided on a digital label only, the data carrier shall be accompanied by the statement "More hazard information available online" or by a similar indication.'**	
Article 1, first paragraph, point (13), amending provision, numbered paragraph (-1d)				
121g			**-1d. paragraph 3 is replaced by the following :**	
Article 1, first paragraph, point (13), amending provision, numbered paragraph (3)				
122	‘ 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~~. 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. They shall be formatted in accordance with section 1.2.1 of Annex I.; ’	

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	’			
Article 1, first paragraph, point (13a)				
122a		***(13a) In Article 32, paragraph 6 is replaced by the following: 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.".***		
Article 1, first paragraph, point (14)				
123	(14) in Article 32, paragraph 6 is deleted;		(14) in Article 32, paragraph 6 is deleted;	
Article 1, first paragraph, point (15)				
124				

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	(15) in Title III, the following Chapter 3 is added:		(15) in Title III, the following Chapter 3 is added:	
Article 1, first paragraph, point (15), amending provision, first paragraph				
125	‘ CHAPTER 3		‘ CHAPTER 3	
Article 1, first paragraph, point (15), amending provision, second paragraph				
126	Formats of the labelling		~~Formats of the labelling~~**Labelling formats**	
Article 1, first paragraph, point (15), amending provision, third paragraph				
127	Article 34a		Article 34a	
Article 1, first paragraph, point (15), amending provision, fourth paragraph				
128	Physical and digital labelling		Physical and digital labelling	
Article 1, first paragraph, point (15), amending provision, numbered paragraph (1)				
129	1. The label elements referred to in Article 17 shall be provided:		1. The label elements **for substances and mixtures** referred to in Article 17 shall be provided~~:~~ **on a label in a**	

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			physical form ('physical label'). In addition to the physical label, the label elements referred to in Article 17 may be provided in a digital form ('digital label').	
Article 1, first paragraph, point (15), amending provision, numbered paragraph (1), point (a)				
130	(a) on a label in a physical form ('physical label'); or		*deleted*	
Article 1, first paragraph, point (15), amending provision, numbered paragraph (1), point (b)				
131	*(b)* both on a physical label and on a label in a digital form ('digital label').		*deleted*	
Article 1, first paragraph, point (15), amending provision, numbered paragraph (2)				
132	*2.* By way of derogation from paragraph 1, the suppliers may provide the label elements set out in section 1.6. of Annex I on a digital label only.		2. By way of derogation from paragraph 1, the suppliers may provide the label elements set out in section 1.6. of Annex I on a digital label only. **Where those label elements are provided on a digital label only, suppliers shall, upon oral or written request or**	

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			when the digital label is temporarily unavailable at the time of purchase of the substance or mixture, provide those label elements by alternative means. Suppliers shall provide those elements independently of a purchase and free of charge.	
Article 1, first paragraph, point (15), amending provision, seventh paragraph				
133	Article 34b		Article 34b	
Article 1, first paragraph, point (15), amending provision, eighth paragraph				
134	Requirements for digital labelling		Requirements for digital labelling	
Article 1, first paragraph, point (15), amending provision, numbered paragraph (1)				
135	1. The digital label for substances and mixtures shall satisfy the following general rules and technical requirements:		1. The **supplier who pursuant to Article 31(1a) places a data carrier linking to a** digital label **shall ensure that the digital label satisfies** ~~for substances and mixtures shall satisfy~~ the following general rules and technical requirements:	

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Article 1, first paragraph, point (15), amending provision, numbered paragraph (1), point (a)				
136	(a) all label elements referred to in Article 17(1) shall be provided in one place and separated from other information;		(a) all label elements referred to in Article 17(1) shall be provided **together** in one place and separated from other information;	
Article 1, first paragraph, point (15), amending provision, numbered paragraph (1), point (b)				
137	(b) the information on the digital label shall be searchable;		(b) the information on the digital label shall be searchable;	
Article 1, first paragraph, point (15), amending provision, numbered paragraph (1), point (c)				
138	(c) the information on the digital label shall be accessible to all users in the Union,		(c) the information on the digital label shall be accessible to all users in the Union~~,~~ **and shall remain accessible for a period of at least 10 years or for a longer period where required by other Union legislation;**	
Article 1, first paragraph, point (15), amending provision, numbered paragraph (1), point (d)				
139	(d) the digital label shall be	‘	(d) the digital label shall be	

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	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; ,	accessible free of charge, without the need to register, download or install applications, or to provide a password;	
Article 1, first paragraph, point (15), amending provision, numbered paragraph (1), point (e)				
140	(e) the information on the digital label shall be presented in a way that also addresses the needs of vulnerable groups and support, as relevant, the necessary adaptations to facilitate access to the information by those groups;		(e) the information on the digital label shall be presented in a way that also addresses the needs of vulnerable groups and support, as relevant, the necessary adaptations to facilitate access to the information by those groups;	
Article 1, first paragraph, point (15), amending provision, numbered paragraph (1), point (f)				
141	(f) the information on the digital label shall be accessible with no more than two clicks;		(f) the information on the digital label shall be accessible with no more than two clicks;	
Article 1, first paragraph, point (15), amending provision, numbered paragraph (1), point (g)				
142	(g) the digital label shall be accessible through digital		(g) the digital label shall be accessible through digital	

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	technologies widely used and compatible with all major operating systems and browsers;		technologies widely used and compatible with all major operating systems and browsers;	
Article 1, first paragraph, point (15), amending provision, numbered paragraph (1), point (h)				
143	(h) when the digital label is available in more than one language, the choice of language shall not be conditioned on the geographical location;		(h) when the **information on the** digital label is ~~available~~ **accessible** in more than one language, the choice of language shall not be conditioned ~~on~~ **by** the geographical location **when accessed**;	
Article 1, first paragraph, point (15), amending provision, numbered paragraph (1), point (i)				
144	(i) the link to the digital label shall be printed or placed physically, visibly and legibly on the product in such a way that it can be processed automatically by digital devices widely used by consumers;		*deleted*	
Article 1, first paragraph, point (15), amending provision, numbered paragraph (1), point (j)				
145	*(j)* the digital label shall remain available for a period of 10		*deleted*	

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	years, including after an insolvency, a liquidation or a cessation of activity in the Union of the supplier that created it, or for such longer period required under other Union legislation covering the information that it contains.			
Article 1, first paragraph, point (15), amending provision, numbered paragraph (2)				
146	*2.* Suppliers shall provide, on oral or written demand or when the digital label is temporarily unavailable at the time of purchase of the substance or mixture, the label elements provided on a digital label only in accordance with Article 34a(2) by alternative means. Suppliers shall provide those elements independently of a purchase and free of charge.		*deleted*	
Article 1, first paragraph, point (15), amending provision, numbered paragraph (3)				
147	*3.* It is prohibited to track, analyse or use any usage information for purposes going		3. It is prohibited to track, analyse or use any usage information for purposes going	

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	beyond what is absolutely necessary for provision of digital labelling; ‘,		beyond what is absolutely necessary for provision of digital labelling; ‘,	
Article 1, first paragraph, point (16)				
148	(16) in Article 35, the following paragraph 2a is added:		(16) in Article 35, the following paragraph 2a is added:	
Article 1, first paragraph, point (16), amending provision, first paragraph				
149	‘ 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.; ‘,		‘ 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.~~;~~	
Article 1, first paragraph, point (16), amending provision, first paragraph a				
149a		‘ ***This paragraph shall not apply to hazardous substances or mixtures supplied to the***		

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		general public without packaging in accordance with Article 29(3). ,		
Article 1, first paragraph, point (16), amending provision, first paragraph a				
149b			**This paragraph shall not apply to hazardous substances or mixtures supplied to the general public without packaging in accordance with Article 29(3).';** ,	
Article 1, first paragraph, point (17)				
150	(17) in Article 36, paragraph 1 is amended as follows:		(17) in Article 36, paragraph 1 is amended as follows:	
Article 1, first paragraph, point (17)(a)				
151	(a) point (a) is replaced by the following:		(a) point (a) is replaced by the following:	
Article 1, first paragraph, point (17)(a), amending provision, first paragraph				
152	‘		‘	

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	(a) respiratory sensitisation, category 1, 1A or 1B (Annex I, section 3.4.); ,		(a) respiratory sensitisation, category 1, 1A or 1B (Annex I, section 3.4.); ,	
Article 1, first paragraph, point (17)(b)				
153	(b) the following points (e) to (j) are added:		(b) the following points (e) to (j) are added:	
Article 1, first paragraph, point (17)(b), amending provision, first paragraph				
154	‘ (e) endocrine disruption for human health, category 1 or 2 (Annex I, section 3.11.);		‘ (e) endocrine disruption for human health, category 1 or 2 (Annex I, section 3.11.);	
Article 1, first paragraph, point (17)(b), amending provision, second paragraph				
155	(f) endocrine disruption for the environment, category 1 or 2 (Annex I, section 4.2.);		(f) endocrine disruption for the environment, category 1 or 2 (Annex I, section 4.2.);	
Article 1, first paragraph, point (17)(b), amending provision, third paragraph				
156	(g) persistent, bioaccumulative and toxic (PBT) (Annex I, section 4.3.);		(g) persistent, bioaccumulative and toxic (~~PBT) (~~Annex I, section 4.3~~.~~);	

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Article 1, first paragraph, point (17)(b), amending provision, fourth paragraph				
157	(h) very persistent, very bioaccumulative (vPvB) (Annex I, section 4.3.);		(h) very persistent, very bioaccumulative (~~vPvB) (~~Annex I, section 4.3~~.~~);	
Article 1, first paragraph, point (17)(b), amending provision, fifth paragraph				
158	(i) persistent, mobile and toxic (PMT) (Annex I, section 4.4.);		(i) persistent, mobile and toxic (~~PMT) (~~Annex I, section 4.4~~.~~);	
Article 1, first paragraph, point (17)(b), amending provision, sixth paragraph				
159	(j) very persistent, very mobile (vPvM) (Annex I, section 4.4).; ,		(j) very persistent, very mobile (~~vPvM) (~~Annex I, section 4.4)~~.~~**’**; ,	
Article 1, first paragraph, point (17)(c)				
160	(c) paragraph 2 is replaced by the following:		(c) paragraph 2 is replaced by the following:	
Article 1, first paragraph, point (17)(c), amending provision, numbered paragraph (2)				
161	‘ 2. Substances that are active		‘ 2. Substances that are active	

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	substances falling within the scope of Regulation (EC) No 1107/2009 or Regulation (EU) 528/2012 shall be subject to harmonised classification and labelling. For such substances, the procedures set out in Article 37(1), (4), (5) and (6) shall apply.; ,		substances falling within the scope of Regulation (EC) No 1107/2009 or Regulation (EU) 528/2012 shall be subject to harmonised classification and labelling. For such substances, the procedures set out in Article 37(1), (4), (5) and (6) shall apply.; ,	
Article 1, first paragraph, point (18)				
162	(18) Article 37 is amended as follows:		(18) Article 37 is amended as follows:	
Article 1, first paragraph, point (18)(a)				
163	(a) paragraph 1 is replaced by the following:		(a) paragraph 1 is replaced by the following:	
Article 1, first paragraph, point (18)(a), amending provision, numbered paragraph (1), first subparagraph				
164	‘ 1. A competent authority may submit to the Agency a proposal for harmonised classification and labelling of substances and, where appropriate, specific	‘ 1. A competent authority may submit to the Agency a proposal for harmonised classification and labelling of ***a substance or a group of*** substances and,	‘ 1. A competent authority may submit to the Agency a proposal for harmonised classification and labelling of substances and, where appropriate, specific	

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	concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof.	where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof.	concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof.	
Article 1, first paragraph, point (18)(a), amending provision, numbered paragraph (1), second subparagraph				
165	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 subsequently submit the proposal to the Agency.	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 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***	The Commission may ~~ask~~ **request** the Agency or the European Food Safety Authority established in accordance with Article 1(2) of Regulation (EC) No 178/2002***[1]** 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 subsequently submit the proposal to the Agency. _____ **1. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law,**	

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		harmonised classification could be necessary to protect human and animal health and the environment.	**establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p.1);**	
Article 1, first paragraph, point (18)(a), amending provision, numbered paragraph (1), third subparagraph				
166	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.	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. ,	
Article 1, first paragraph, point (18)(a), amending provision, numbered paragraph (1), third subparagraph a				
166a		***'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***		

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		individual substances. ,		
Article 1, first paragraph, point (18)(a), amending provision, numbered paragraph (1), fourth subparagraph				
167	* Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p.1); ,			
Article 1, first paragraph, point (18)(b)				
168	(b) in paragraph 2, the first subparagraph is replaced by the following:		(b) in paragraph 2, the first subparagraph is replaced by the following:	
Article 1, first paragraph, point (18)(b), amending provision, numbered paragraph (2)				
169	‘ 2. Manufacturers, importers or downstream users of substances may submit to the Agency a	‘ 2. Manufacturers, importers or downstream users of substances may submit to the Agency a	‘ 2. Manufacturers, importers or downstream users of substances may submit to the Agency a	

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	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.; ,	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 case of a proposal for harmonised classification and labelling of a group of substances, those substances shall be grouped together based on clear scientific criteria (as specified in REACH Annex XI (1.5)), including structural similarity and similar evidence-based hazard profiles.*** ,	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.; ,	
Article 1, first paragraph, point (18)(c)				
170	(c) the following paragraph 2a is inserted:		(c) the following paragraph 2a is inserted:	
Article 1, first paragraph, point (18)(c), amending provision, first paragraph, first subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
171	‘ 2a. Before submitting a proposal to the Agency, a competent authority, manufacturer, importer or downstream user shall notify the Agency of its intention to submit a proposal for harmonised classification and labelling and, in the case of the Commission, the request to the Agency or the European Food Safety Authority to prepare such proposal.		‘ 2a. Before submitting a proposal to the Agency, a competent authority, manufacturer, importer or downstream user shall notify the Agency of its intention to submit a proposal for harmonised classification and labelling**. The Commission shall also notify to the Agency of its** ~~and, in the case of the Commission, the~~ request to the Agency or the European Food Safety Authority to prepare such proposal.	
Article 1, first paragraph, point (18)(c), amending provision, first paragraph, second subparagraph				
172	Within one week from receipt of the notification, the Agency shall publish the name and, where relevant, the EC and CAS numbers of the substance(s), the status of the proposal and the name of the submitter. The Agency shall update the information on the status of the proposal after completion of	‘ 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)***, and where relevant***, the status of the proposal and the name of the submitter. The Agency shall	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**, the proposed classification** and the name of the submitter. The Agency shall update the information on the status of the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	each stage of the process referred to in Article 37(4) and (5).	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). ’	proposal after completion of each stage of the process referred to in Article 37(4) and (5).	
Article 1, first paragraph, point (18)(c), amending provision, first paragraph, third subparagraph				
173	Where a competent authority receives a proposal in accordance with paragraph 6, it shall notify the Agency and provide any relevant information on its reason for accepting or refusing the proposal. The Agency shall share that information with the other competent authorities.; ’		Where a competent authority receives a proposal in accordance with paragraph 6, it shall notify the Agency and provide any relevant information on its reason for accepting or refusing the proposal. The Agency shall share that information with the other competent authorities.**’**; ’	
Article 1, first paragraph, point (18)(d)				
174	(d) paragraph 3 is replaced by the following:		(d) paragraph 3 is replaced by the following:	
Article 1, first paragraph, point (18)(d), amending provision, numbered paragraph (3)				
175	‘		‘	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	3. Where the proposal of the manufacturer, importer or downstream user concerns the harmonised classification and labelling of substances in accordance with Article 36(3), it shall be accompanied by the fee determined by the Commission in accordance with the procedure referred to in Article 54(2).; '		3. Where the proposal of the manufacturer, importer or downstream user concerns the harmonised classification and labelling of substances in accordance with Article 36(3), it shall be accompanied by the fee determined by the Commission **by means of implementing act** in accordance with the **examination** procedure referred to in Article 54(2).**'**; '	
Article 1, first paragraph, point (18)(e)				
176	(e) paragraphs 5 and 6 are replaced by the following:		(e) paragraphs 5 and 6 are replaced by the following:	
Article 1, first paragraph, point (18)(e), amending provision, numbered paragraph (5), first subparagraph				
177	‘ 5. 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,	‘ 5. The Commission***, within twelve months of the publication of the opinion of the Committee for Risk Assessment, shall adopt*** ~~*shall adopt without undue delay*~~, delegated acts in accordance	‘ 5. The Commission shall adopt without undue delay, delegated acts in accordance with Article 53a**, where it finds that the harmonisation of the classification and labelling of the substance concerned is**	

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	where appropriate, the specific concentration limits, M-factors or acute toxicity estimates in Table 3 of Part 3 of Annex VI.	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.	**appropriate,** 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.	
Article 1, first paragraph, point (18)(e), amending provision, numbered paragraph (5), second subparagraph				
178	Where, in the case of harmonisation of classification and labelling of substances, imperative grounds of urgency so require, the procedure provided for in Article 53b shall apply to delegated acts adopted pursuant to this paragraph.		Where, in the case of harmonisation of classification and labelling of substances, imperative grounds of urgency so require, the procedure provided for in Article 53b shall apply to delegated acts adopted pursuant to this paragraph.	
Article 1, first paragraph, point (18)(e), amending provision, numbered paragraph (6)				
179	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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.; ,	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.**'**; ,	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.**'**; ,	
Article 1, first paragraph, point (18)(f)				
180	(f) The following paragraphs 7 and 8 are inserted:		(f) the following ~~paragraphs 7 and 8 are~~**paragraph 7 is** inserted:	
Article 1, first paragraph, point (18)(f), amending provision, numbered paragraph (7), first subparagraph				
181	‘ 7. 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	‘ 7. ***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	‘ 7. **In order to avoid duplication of assessment of hazardous properties of substances,** the Commission ~~shall~~ **is empowered to** adopt delegated acts in accordance with Article 53a to amend Table 3 of Part 3 of Annex VI to this Regulation **to:** **- include substances by [OP, please insert the date: 24**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	persistent, bioaccumulative and toxic ~~*or*~~ **,** 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*** ~~*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. ’	**months after the entry into force of this Regulation] in Table 3 of Part 3 of Annex VI as**~~by inclusion of substances as endocrine disruptor category 1 for human health properties,~~ endocrine ~~disruptor category 1 for environment properties~~**disruption for human healthcategory 1, endocrine disruption for the environmentcategory 1**, as persistent, bioaccumulative and toxic**,** or as very persistent ~~and~~ **,** very bioaccumulative**,** together with relevant classification and labelling elements ~~where, on …~~ **on the basis of respective criteria where on** [OP: please insert the date = ~~the date of~~ **6 months after** entry into force of ~~Commission Delegated~~ **this** 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.~~**:**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 1, first paragraph, point (18)(f), amending provision, numbered paragraph (7), first subparagraph, point (a)				
181a			**(a) have been included in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties for human health or the environment, as persistent, bioaccumulative and toxic or as very persistent and very bioaccumulative,**	
Article 1, first paragraph, point (18)(f), amending provision, numbered paragraph (7), second subparagraph				
182	The inclusion of the substances, referred to in the first subparagraph, in Table 3 of Part 3 of Annex VI to this Regulation shall be carried out on the basis of the respective criteria for which those substances have been included in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006.'		*deleted*	
Article 1, first paragraph, point (18)(f), amending provision, numbered paragraph (8), first subparagraph				
183				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	8. The Commission shall adopt delegated acts in accordance with Article 53a to amend Table 3 of Part 3 of Annex VI by inclusion of substances 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. the delegated act on the new hazard classes - reference to be added once adopted] those substances have not been approved, under Regulation (EC) No 1107/2009 or Regulation (EU) No 528/2012 or have been approved with derogation in accordance with the relevant provisions of those Regulations, due to either of the following characteristics:		~~8.~~**(b)** ~~The Commission shall adopt delegated acts~~ **have been identified as having endocrine disrupting properties** in accordance with ~~Article 53a to amend Table 3 of Part 3~~**Section 3.6.5 or Section 3.8.2** of Annex ~~VI by inclusion of substances together with relevant classification and labelling elements where, on … [OP: please insert the date = the date of entry into force of Commission Delegated~~**II to Regulation (EC) No 1107/2009, or persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with Section 3.7.2. or 3.7.3. of Annex II to** Regulation (~~EU~~**EC**) ~~…i.e. the delegated act~~**No 1107/2009 and a decision** on the ~~new hazard classes - reference to be added once adopted]~~ **application for approval or the renewal of approval of** those substances ~~have not been approved,~~ **has been adopted** under Regulation (EC) No 1107/2009	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			~~or Regulation (EU) No 528/2012 or have been approved with derogation in accordance with the relevant provisions of those Regulations, due to either of the following characteristics:~~	
Article 1, first paragraph, point (18)(f), amending provision, numbered paragraph (8), first subparagraph, point (a)				
184	(a) endocrine disruptor in accordance with Section 3.6.5 or Section 3.8.2 of Annex II to Regulation (EC) No 1107/2009;		*deleted*	
Article 1, first paragraph, point (18)(f), amending provision, numbered paragraph (8), first subparagraph, point (b)				
185	*(b)* persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with Section 3.7.2. or 3.7.3. of Annex II to Regulation (EC) No 1107/2009;		*deleted*	
Article 1, first paragraph, point (18)(f), amending provision, numbered paragraph (8), first subparagraph, point (c)				
186	*(c)* endocrine disruptor for human health or for the environment in accordance with		*deleted*	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 1 of Commission Delegated Regulation (EU) 2017/2100*;			
Article 1, first paragraph, point (18)(f), amending provision, numbered paragraph (8), first subparagraph, point (d)				
187	*(d)* persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with Article 5(1), point (e), of Regulation (EU) No 528/2012.		*deleted*	
Article 1, first paragraph, point (18)(f), amending provision, numbered paragraph (8), second subparagraph				
188	The inclusion of the substances, referred to in the first subparagraph, in Table 3 of Part 3 of Annex VI shall be carried out on the basis of the respective criteria that they meet in accordance with the acts referred to in that subparagraph, points (a) to (d).’;		*deleted*	
Article 1, first paragraph, point (18)(f), amending provision, numbered paragraph (8), second subparagraph, point (a)				
188a			**(c) have been identified as having endocrine disrupting**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			properties in accordance with Article 1 of Commission Delegated Regulation (EU) 2017/2100, or persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with Article 5(1), point (e), of Regulation (EU) No 528/2012 and a decision on the application for approval or renewal of approval of those substances has been adopted under Regulation (EU) No 528/2012.	
Article 1, first paragraph, point (18)(f), amending provision, numbered paragraph (8a), first subparagraph				
188b			**- include substances in Table 3 of Part 3 of Annex VI as endocrine disruption for human health category 1, endocrine disruption for the environment category 1 as persistent, bioaccumulative and toxic, or as very persistent, very bioaccumulative, together with relevant classification and labelling elements on the**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			basis of respective criteria where:	
Article 1, first paragraph, point (18)(f), amending provision, numbered paragraph (8a), first subparagraph, point (a)				
188c			**(a) those substances have been included in the candidate list referred to in Article 59 of Regulation (EC) No 1907/2006 before [OP, please insert date – 18 months after the entry into force of this Regulation] as having one of the properties mentioned above and for which a dossier according to Annex XV of Regulation (EC) No 1907/2006 was under assessment by [OP, please insert date – 6 months after entry into force of this Regulation]**	
Article 1, first paragraph, point (18)(f), amending provision, numbered paragraph (8a), first subparagraph, point (b)				
188d			**(b) a decision on the application for approval or the renewal of approval of those substances identified as having one of the properties**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			mentioned above has been adopted under Regulation (EC) No 1107/2009 before [OP, please insert date – 7 years + 6 months after the entry into force of this Regulation] and an application for approval or renewal of approval of those substances in accordance with the relevant provisions of Regulation (EC) No 1107/2009 was submitted before [OP, please insert date – 6 months after entry into force of this Regulation]	
Article 1, first paragraph, point (18)(f), amending provision, numbered paragraph (8a), first subparagraph, point (c)				
188e			**(c) a decision on the application for approval or the renewal of approval of those substances identified as having one of the properties mentioned above has been adopted under Regulation (EU) 528/2012 before [OP, please insert date – 5 years + 6 months after the entry into force of this Regulation] and**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			where, by the date of [OP: please insert the date – 6 months after the entry into force of this Regulation]:	
Article 1, first paragraph, point (18)(f), amending provision, numbered paragraph (8a), first subparagraph, point (c)(i)				
188f			**(i.) the evaluating competent authority has submitted its draft assessment report on the application for approval or renewal of approval to the Agency in accordance with the relevant provisions of Regulation (EU) No 528/2012, or**	
Article 1, first paragraph, point (18)(f), amending provision, numbered paragraph (8a), first subparagraph, point (c)(ii)				
188g			**(ii.) the application was submitted for the purpose of Directive 98/8/EC and the Member State's evaluation in accordance with that Directive has been completed by 1 September 2013, but no decision on the application for approval or renewal of approval was adopted before**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			that date, or	
Article 1, first paragraph, point (18)(f), amending provision, numbered paragraph (8a), first subparagraph, point (c)(iii)				
188h			**(iii.) the Agency has submitted to the Commission an opinion pursuant to Article 75(1)(g) of Regulation (EU) No 528/2012 following a request to establish whether the respective criteria are met.** '	
Article 1, first paragraph, point (18)(f), amending provision, numbered paragraph (8), third subparagraph				
189	* Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301 of 17.11.2017 p.1.; '		this is the footnote to (c) line 186	
Article 1, first paragraph, point (19)				
190				

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	(19) In Article 38(1), point (c) is replaced by the following:		(19) In Article 38(1), point (c) is replaced by the following:	
Article 1, first paragraph, point (19), amending provision, first paragraph				
191	‘ (c) the specific concentration limits, M-factors or acute toxicity estimates, where applicable;; ’		‘ (c) the specific concentration limits, M-factors or acute toxicity estimates, where applicable;; ’	
Article 1, first paragraph, point (20)				
192	(20) Article 40 is amended as follows:		(20) Article 40 is amended as follows:	
Article 1, first paragraph, point (20)(a)				
193	(a) in paragraph 1, the first subparagraph is amended as follows:		(a) in paragraph 1, the first subparagraph is amended as follows:	
Article 1, first paragraph, point (20)(a)(i)				
194	(i) point (e) is replaced by the following:		(i) point (e) is replaced by the following:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 1, first paragraph, point (20)(a)(i), amending provision, first paragraph				
195	‘ (e) specific concentration limits, M-factors or acute toxicity estimates, where applicable, in accordance with Article 10, together with a justification referred to in the relevant parts of sections 1, 2 and 3 of Annex I to Regulation (EC) No 1907/2006; ’		‘ (e) specific concentration limits, M-factors or acute toxicity estimates, where applicable, in accordance with Article 10, together with a justification referred to in the relevant parts of sections 1, 2 and 3 of Annex I to Regulation (EC) No 1907/2006; ’	
Article 1, first paragraph, point (20)(a)(ii)				
196	(ii) points (g) and (h) are added:		(ii) points (g) and (h) are added:	
Article 1, first paragraph, point (20)(a)(ii), amending provision, first paragraph				
197	‘ (g) where applicable, the reason for divergence from the most severe classification per hazard class included in the inventory referred to in Article 42;	‘ (g) where applicable, ***and without needing to acquire new data or new studies being necessary,*** the reason for divergence from the most severe classification per hazard class included in the inventory referred to in Article 42;	‘ (g) where applicable, the reason for divergence from the most severe classification per hazard class included in the inventory referred to in Article 42;	

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Article 1, first paragraph, point (20)(a)(ii), amending provision, second paragraph				
198	(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.***'***; ,	(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.;	
Article 1, first paragraph, point (20)(a)(ii), amending provision, second paragraph a				
198a			**(iii) subparagraph 2 is replaced by the following:**	
Article 1, first paragraph, point (20)(a)(ii), amending provision, fourth subparagraph				
198b			**The information referred to in (a) to (h) shall not be notified, if it has been submitted to the Agency as part of a registration pursuant to Regulation (EC) No 1907/2006, or if it has already been notified by that**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			notifier. ,	
Article 1, first paragraph, point (20)(b)				
199	(b) paragraph 2 is replaced by the following:		(b) paragraph 2 is replaced by the following:	
Article 1, first paragraph, point (20)(ba)				
199a			cell to be deleted, added by mistake	
Article 1, first paragraph, point (20)(b), amending provision, numbered paragraph (2)				
200	‘ 2. The information listed in paragraph 1 shall be notified to the Agency by the notifier(s) concerned at the latest 6 months after a decision to change the classification and labelling of the substance has been taken pursuant to the review referred to in Article 15(1).; ,		‘ 2. The information listed in paragraph 1 shall be notified to the Agency by the notifier(s) concerned at the latest 6 months after a decision to change the classification and labelling of the substance has been taken pursuant to the review referred to in Article 15(1).; ,	
Article 1, first paragraph, point (20a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
200a		***(20a) Article 41 is replaced by the following:*** ***"Article 41*** ***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.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.'"***		
Article 1, first paragraph, point (21)				
201	(21) in Article 42(1), the third subparagraph is replaced by the following:		(21) in Article 42(1), the third subparagraph is replaced by the following:	

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Article 1, first paragraph, point (21), amending provision, first paragraph				
202	‘ 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***:	‘ The following information shall be made publicly available free of charge online:	
Article 1, first paragraph, point (21), amending provision, first paragraph, point (a)				
203	(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)~~, 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)~~, 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~~;	
Article 1, first paragraph, point (21), amending provision, first paragraph, point (b)				
204	(b) in the case of group notifications, the identity of the importer or manufacturer submitting the information on behalf of the other members of the group;		(b) in the case of group notifications, the identity of the importer or manufacturer submitting the information on behalf of the other members of the group;	

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Article 1, first paragraph, point (21), amending provision, first paragraph, point (c)				
205	(c) information in the inventory which corresponds to the information referred to in Article 119(1) of Regulation (EC) No 1907/2006.		(c) information in the inventory which corresponds to the information referred to in Article 119(1) of Regulation (EC) No 1907/2006.	
Article 1, first paragraph, point (21), amending provision, first paragraph, point (d)				
205a			**(d) the date of the latest update of the classification and labelling.**	
Article 1, first paragraph, point (21), amending provision, second paragraph				
206	The Agency shall grant access to the information in the inventory that concerns a substance and is not referred to in the first subparagraph to other parties subject to Article 118 of Regulation (EC) No 1907/2006.; ,		*deleted*	
Article 1, first paragraph, point (21), amending provision, second paragraph a				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
206a			**Information referred to in Article 40(1)(a) shall not be made publicly available where a notifier duly justifies why publication of such information is potentially harmful for its commercial interests or the commercial interests of any other concerned party.';** ,	
Article 1, first paragraph, point (21a)				
206b		***(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."***		
Article 1, first paragraph, point (21b)				
206c		***(21b) The following Article -43***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.***		
Article 1, first paragraph, point (21c)				
206d		***(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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.***		
Article 1, first paragraph, point (22)				
207				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(22) Article 45 is amended as follows:		(22) Article 45 is amended as follows:	
Article 1, first paragraph, point (22)(a)				
208	(a) paragraph 1 is replaced by the following:		(a) paragraph 1 is replaced by the following:	
Article 1, first paragraph, point (22)(a), amending provision, numbered paragraph (1)				
209	‘ 1. Member States shall appoint a body or bodies responsible for receiving the relevant harmonised information relating to emergency health response and preventative measures, in accordance with Annex VIII.; ’		‘ 1. Member States shall appoint a body or bodies responsible for receiving the relevant harmonised information relating to emergency health response and preventative measures, in accordance with Annex VIII.; ’	
Article 1, first paragraph, point (22)(b)				
210	(b) the following paragraphs 1a, 1b and 1c are inserted:		(b) the following paragraphs 1a, 1b and 1c are inserted:	
Article 1, first paragraph, point (22)(b), amending provision, first paragraph				
211	‘		‘	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	1a. Member States may appoint the Agency as the body responsible for receiving information relating to emergency health response and preventative measures referred to in paragraph 1.’;		1a. Member States may appoint the Agency as the body responsible for receiving information relating to emergency health response and preventative measures referred to in paragraph 1.’;	
Article 1, first paragraph, point (22)(b), amending provision, second paragraph				
212	1b. Importers and downstream users placing on the market mixtures that are classified as hazardous on the basis of their health effects or physical effects, shall submit to the body or bodies appointed in accordance with paragraph 1 the harmonised information referred to in Part B of Annex VIII.		1b. Importers and downstream users placing on the market mixtures that are classified as hazardous on the basis of their health ~~effects~~ or physical effects, shall submit to the body or bodies appointed in accordance with paragraph 1 the ~~harmonised~~ information referred to in Part B of Annex VIII.	
Article 1, first paragraph, point (22)(b), amending provision, third paragraph				
213	1c. Distributors placing on the market mixtures that are classified as hazardous on the basis of their health effects or physical effects, shall submit to the appointed body or bodies the		1c. Distributors placing on the market mixtures that are classified as hazardous on the basis of their health ~~effects~~ or physical effects, shall submit to the **body or bodies** appointed	

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	harmonised information referred to in Part B of Annex VIII where they further distribute those mixtures in other Member States, or where they rebrand or relabel the mixtures. This obligation does not apply if the distributors can demonstrate that the appointed body or bodies already received the same information from importers or downstream users.; '		~~body or bodies the harmonised~~ **in accordance with paragraph 1 the** information referred to in Part B of Annex VIII where they further distribute those mixtures in other Member States, or where they rebrand or relabel the mixtures. This obligation does not apply if the distributors can demonstrate that the appointed body or bodies already received the same information from importers or downstream users.**'**; '	
Article 1, first paragraph, point (22)(c)				
214	(c) in paragraph 2, point (b) is replaced by the following:		(c) in paragraph 2, point (b) is replaced by the following:	
Article 1, first paragraph, point (22)(c), amending provision, first paragraph				
215	‘ (b) where requested by a Member State, the Commission or the Agency, to undertake a statistical analysis to identify where improved risk		‘ (b) where requested by ~~a~~**the** Member State, the Commission or the Agency, to undertake a statistical analysis to identify where improved risk	

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	management measures may be needed.; ,		management measures may be needed.**'**; ,	
Article 1, first paragraph, point (22)(d)				
216	(d) paragraph 3 is replaced by the following:		(d) paragraph 3 is replaced by the following:	
Article 1, first paragraph, point (22)(d), amending provision, numbered paragraph (3)				
217	‘ 3. The appointed bodies shall have at their disposal all the information required from importers, downstream users and distributors referred to in paragraph 1c, to carry out the tasks for which they are responsible.; ,		‘ 3. The appointed bodies shall have at their disposal all the information required from importers, downstream users and distributors referred to in paragraph 1c, to carry out the tasks for which they are responsible **in accordance with paragraph 1.'**; ,	
Article 1, first paragraph, point (23)				
218	(23) Article 48 is replaced by the following:		(23) Article 48 is replaced by the following:	
Article 1, first paragraph, point (23), amending provision, first paragraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
219	‘ Article 48		‘ Article 48	
Article 1, first paragraph, point (23), amending provision, second paragraph				
220	Advertisement		Advertisement	
Article 1, first paragraph, point (23), amending provision, numbered paragraph (1)				
221	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.***	1. Any advertisement for a substance classified as hazardous shall indicate the ~~relevant~~ hazard ~~pictogram, the~~ **pictograms,** signal word, ~~the~~ hazard ~~class and the hazard~~**statements and supplemental EUH** statements **set out in Annex II**.	
Article 1, first paragraph, point (23), amending provision, numbered paragraph (2)				
222	2. Any advertisement for a mixture classified as hazardous or covered by Article 25(6) shall	2. Any advertisement for a mixture classified as hazardous or covered by Article 25(6) shall	2. Any advertisement for a mixture classified as hazardous or covered by Article 25(6) shall	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	indicate the hazard pictogram, the signal word, the hazard class and the hazard statements. ‘	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.***	indicate the hazard ~~pictogram~~**pictograms**, ~~the~~ signal word, ~~the~~ hazard ~~class and the hazard~~**statements and supplemental EUH** statements **set out in Annex II**.	
Article 1, first paragraph, point (23), amending provision, numbered paragraph (2a)				
222a		***2a. The use of environmental claims as defined in Article 2, point (o), of Directive 2005/29/EC shall be prohibited for substances and mixtures which are classified as hazardous due to their germ cell mutagenic, carcinogenic, toxic to reproduction, endocrine disruption for human health or the environment, persistent, bioaccumulative and toxic (PBT), very persistent, very bioaccumulative (vPvB), persistent, mobile and toxic (PMT), or very persistent, very mobile (vPvM) properties;***		

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		‘		
Article 1, first paragraph, point (23), amending provision, numbered paragraph (2a)				
222b			**3. By way of derogation from paragraph 1 and 2, the hazard pictograms and signal word may be omitted where the advertisement is non-visual.’;** ‘	
Article 1, first paragraph, point (24)				
223	(24) the following Article 48a is added:			
Article 1, first paragraph, point (24), amending provision, first paragraph				
224	‘ Article 48a		‘ Article 48a	
Article 1, first paragraph, point (24), amending provision, second paragraph				
225	Distance sales offers		Distance sales offers	
Article 1, first paragraph, point (24), amending provision, third paragraph				
226				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Suppliers placing substances or mixtures on the market through distance sales shall clearly indicate the label elements referred to in Article 17.; ,		~~Suppliers placing~~**When** substances or mixtures **are placed** on the market through distance sales**, the offer** shall clearly **and visibly** indicate the label elements referred to in Article 17.**'**; ,	
Article 1, first paragraph, point (25)				
227	(25) Article 50 is amended as follows:		(25) Article 50 is amended as follows:	
Article 1, first paragraph, point (25)(-a)				
227a		***(-a) in Article 50, paragraph 2, point a is amended as following:*** ***"(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;"***		
Article 1, first paragraph, point (25)(a)				
228	(a) in paragraph 2, point (b) is		(a) in paragraph 2, point (b) is	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	replaced by the following:		replaced by the following:	
Article 1, first paragraph, point (25)(a), amending provision, first paragraph				
229	‘ (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 under Article 44.; ’,	‘ (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 established by Member States under Article 44.’; ’,	‘ (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 under Article 44.; ’,	
Article 1, first paragraph, point (25)(b)				
230	(b) the following paragraph 3 is added:		(b) the following paragraph 3 is added:	
Article 1, first paragraph, point (25)(ba)				
230a				
Article 1, first paragraph, point (25)(b), amending provision, numbered paragraph (3)				
231	‘ 3. Where the Agency acts as an		‘ 3. Where the Agency acts as an	

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	appointed body in accordance with Article 45(1a), it shall put in place the tools necessary to provide access to the information to the relevant appointed body or bodies of the appointing Member State to fulfil their tasks with regard to emergency health response and preventative measures. '		appointed body in accordance with Article 45(1a), it shall put in place the tools necessary to provide access to the information to the relevant appointed body or bodies of the appointing Member State to fulfil their tasks with regard to emergency health response and preventative measures.	
Article 1, first paragraph, point (25)(b), amending provision, Article				
231a			**(25a) In Article 52, paragraph 2 is replaced by the following:**	
Article 1, first paragraph, point (25)(b), amending provision, Article(1)				
231b			**'2 Within 60 days of receipt of the information from the Member State, the Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 54(2) either to authorise the**	

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			provisional measure for a time period defined in the decision or to require the Member State to revoke the provisional measure.' ,	
Article 1, first paragraph, point (25)(bb)				
231c		***(bb) 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."***		
Article 1, first paragraph, point (26)				
232	(26) Article 53 is amended as follows:		(26) Article 53 is amended as follows:	
Article 1, first paragraph, point (26)(-a)				
232a		***(-a) In Article 53, paragraph 1***		

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		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 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 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***		

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		54(4)."		
Article 1, first paragraph, point (26)(a)				
233	(a) the following paragraphs 1a to 1b are inserted:		(a) the following paragraphs 1a to 1b are inserted:	
Article 1, first paragraph, point (26)(a), amending provision, first paragraph				
234	‘ 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*** ~~*the societal*~~	‘ 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~~**include** 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~~**that may be put on a digital label only, provided that GHS does not require such labelling elements to appear on the physical label** . When adopting those delegated acts, the Commission shall take into account the societal needs and a high level of protection of	

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		~~*needs and a high level of protection of*~~ human health and the environment ***shall be easily accessible on the label***;	human health and the environment;	
Article 1, first paragraph, point (26)(a), amending provision, second paragraph				
235	1b. In order to adjust to technological changes and (future) developments in the field of digitalisation, the Commission is empowered to adopt delegated acts in accordance with Article 53a to supplement this Regulation by laying down further details on the requirements for the digital labelling referred to in Article 34b. Those requirements shall cover, in particular, the IT solutions which may be used, and the alternative means for providing the information. When adopting those delegated acts, the Commission shall:		1b. In order to adjust to technological changes and ~~(~~future~~)~~ developments in the field of digitalisation, the Commission is empowered to adopt delegated acts in accordance with Article 53a to supplement this Regulation by laying down further details on the requirements for the digital labelling referred to in ~~Article~~**Articles 34a and** 34b. Those requirements shall cover, in particular, the IT solutions which may be used, and the alternative means for providing the information. When adopting ~~those~~ **such** delegated acts, the Commission shall:	
Article 1, first paragraph, point (26)(a), amending provision, second paragraph, point (a)				

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236	(a) ensure coherence with other relevant Union acts;		(a) ensure coherence with other relevant Union acts;	
Article 1, first paragraph, point (26)(a), amending provision, second paragraph, point (b)				
237	(b) encourage innovation;		(b) encourage innovation;	
Article 1, first paragraph, point (26)(a), amending provision, second paragraph, point (c)				
238	(c) ensure technological neutrality by applying no constraints or prescriptions on choices of technology or equipment, within the bounds of compatibility and interference avoidance;		(c) ensure technological neutrality by applying no constraints or prescriptions on choices of technology or equipment, within the bounds of compatibility and interference avoidance;	
Article 1, first paragraph, point (26)(a), amending provision, second paragraph, point (d)				
239	(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***; ‘	(d) take into account the level of digital readiness among all population groups in the Union;	

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Article 1, first paragraph, point (26)(a), amending provision, second paragraph, point (e)				
240	(e) ensure that digitalisation does not compromise the protection of human health and the environment. ‘		(e) ensure that digitalisation does not compromise the protection of human health and the environment. ‘	
Article 1, first paragraph, point (26)(b)				
241	(b) paragraph 2 is replaced by the following:		(b) paragraph 2 is ~~replaced by the following:~~**deleted**	
Article 1, first paragraph, point (26)(b), amending provision, numbered paragraph (2)				
242	‘ 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	‘ 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	*deleted*	

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	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.; '	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.'***; '		
Article 1, first paragraph, point (26)(c)				
243	*(c)* the following paragraph 3 is added:		*deleted*	
Article 1, first paragraph, point (26)(ca)				
243a		***(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***		

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		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."		
Article 1, first paragraph, point (26)(c), amending provision, numbered paragraph (3)				
244	" 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*** ~~*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***, 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***	*deleted*	

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		more than twelve months after non-animal data are included in harmonised criteria for classification and labelling at the level of the UN. "		
Article 1, first paragraph, point (27)				
245	*(27)* Article 53a is amended as follows:		(27) Article 53a is amended as follows:	
Article 1, first paragraph, point (27)(a)				
246	(a) in paragraph 2, the first sentence is replaced by the following:		(a) in paragraph 2, the first sentence is replaced by the following:	
Article 1, first paragraph, point (27)(a), amending provision, first paragraph				
247	‘ 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	‘ 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(~~1b~~ ***3a***) shall be conferred on the Commission for a period of five years from [OP please insert the date = the ***date of entry into***	‘ 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	

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	Regulation] ; ’	***force of this Regulation] ’*** ~~*date of entry into force of this Regulation]*~~ ; ’	Regulation] ; ’	
Article 1, first paragraph, point (27)(b)				
248	(b) in paragraph 3, the first sentence is replaced by the following:		(b) in paragraph 3, the first sentence is replaced by the following:	
Article 1, first paragraph, point (27)(b), amending provision, first paragraph				
249	‘ 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 delegation of power referred to in Articles 37(5), 37(7) and 37(8), 45(4), 53(1), 53(1a) ~~*and 53(1b),*~~ ***, 53(1b), 53(3) and 53(3a)*** may be revoked at any time by the European Parliament or by the Council.***’***; ’	‘ 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.**’**; ’	
Article 1, first paragraph, point (27)(c)				
250	(c) in paragraph 6, the first sentence is replaced by the following:		(c) in paragraph 6, the first sentence is replaced by the following:	

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Article 1, first paragraph, point (27)(c), amending provision, first paragraph				
251	‘ 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 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.; ’	‘ A delegated act adopted pursuant to– Articles 37(5), 37(7), 37(8), 45(4), 53(1), 53(1a) ~~*and 53(1b),*~~ ***, 53(1b), 53(3) or 53(3a)*** shall enter 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.**’**; ,	‘ 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 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.; ’	
Article 1, first paragraph, point (28)				
252	(28) Article 53c is replaced by the following:		(28) Article 53c is replaced by the following:	
Article 1, first paragraph, point (28), amending provision, first paragraph				

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253	‘ Article 53c		‘ Article 53c	
Article 1, first paragraph, point (28), amending provision, second paragraph				
254	Separate delegated acts for different delegated powers		Separate delegated acts for different delegated powers	
Article 1, first paragraph, point (28), amending provision, third paragraph				
255	The Commission shall adopt a separate delegated act in respect of each power delegated to it pursuant to this Regulation, with the exception of amendments to Annex VI, where Parts 1 and 2 of that Annex may be amended together with Part 3 of that Annex in one single act.; ’		The Commission shall adopt a separate delegated act in respect of each power delegated to it pursuant to this Regulation, with the exception of amendments to Annex VI, where Parts 1 and 2 of that Annex may be amended together with Part 3 of that Annex in one single act.; ’	
Article 1, first paragraph, point (29)				
256	(29) Article 54 is replaced by the following:		(29) Article 54 is replaced by the following:	
Article 1, first paragraph, point (29), amending provision, numbered paragraph (1)				

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257	‘ 1. The Commission shall be assisted by the Committee established by Article 133 of Regulation (EC) No 1907/2006. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011*.’;		‘ 1. The Commission shall be assisted by the Committee established by Article 133 of Regulation (EC) No 1907/2006. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011*.’;	
Article 1, first paragraph, point (29), amending provision, numbered paragraph (2)				
258	2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.		2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	
Article 1, first paragraph, point (29), amending provision, third paragraph				
259	* Regulation (EU) 182/2011 …;		* Regulation (EU) 182/2011 …;	
Article 1, first paragraph, point (29a)				
259a		***(29a) the following article is inserted: "Article 54a Review Clause***		

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		No sooner than [insert date six years after the date of entry into force of this Regulation], the Commission shall present a report to the European Parliament and the Council regarding the evaluation and classification of substances of renewable botanical origin containing more than one constituent referred to in Article 5(3a).";		
Article 1, first paragraph, point (30)				
260	(30) in Article 61, the following paragraph 7 is added:			
Article 1, first paragraph, point (30), amending provision, numbered paragraph (7), first subparagraph				
261	‘ 7. Substances and mixtures which have been classified, labelled and packaged in accordance with Article 1(1), Article 4(10), Article 5, Article 6(3) and (4), Article 9(3) and (4), Article 25(6) and (9), Articles 29, 30 and 35, Article	‘ 7. Substances ~~*and mixtures*~~ which have been classified, labelled and packaged in accordance with Article 1(1), Article 4(10), Article 5, Article 6(3) and (4), Article 9(3) and (4), Article 25(6) and (9), Articles 29, 30 and 35, Article	‘ 7. **‘7.** Substances and mixtures which have been classified, labelled and packaged in accordance with ~~Article 1(1), Article 4(10), Article 5,~~ Article 6(3) and (4), Article 9(3) and (4), Article 25(6) ~~and (9)~~,	

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	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	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	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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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].	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]. ,	~~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].~~ [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	

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			insert the date = the first day of the month following 42 months after the date of entry into force of this Regulation].	
Article 1, first paragraph, point (30), amending provision, numbered paragraph (7), second subparagraph				
262	* Regulation (EU) .../... of the European Parliament and of the Council of ... on ... (OJ ...).; ,		* Regulation (EU) .../... of the European Parliament and of the Council of ... on ... (OJ ...).; ,	
Article 1, first paragraph, point (29b), second subparagraph				
262a		***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,***		

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		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		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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]."		
Article 1, first paragraph, point (31)				
263	(31) Annex I is amended as set out in Annex I to this Regulation;		(31) Annex I is amended as set out in Annex I to this Regulation;	
Article 1, first paragraph, point (32)				
264	(32) Annex II is amended as set out in Annex II to this Regulation;		(32) Annex II is amended as set out in Annex II to this Regulation;	
Article 1, first paragraph, point (33)				
265	(33) Annex VIII is amended as set out in Annex III to this Regulation.		(33) Annex VIII is amended as set out in Annex III to this Regulation.	
Article 2				

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266	Article 2		Article 2	
Article 2(1)				
267	1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.		1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	
Article 2(2)				
268	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]:	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]:	
Article 2(2a)				
268a		***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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.		
Article 2(2), point (a)				
269	(a) Article 1, points (1), (4), (5), (6), (7), (10), (11), (12), (15), (16), (20), (21), (23) and (24);		(a) Article 1, points (1), ~~(4),~~ (5), (6), (7), (10), (11), (12), (15), (16), (20), (21), (23)**,** and (24);	
Article 2(2), point (b)				
270	(b) points (2), (3), (7), (9) and (10) of Annex I;		(b) points (2), (3), (7), (9) and (10) of Annex I;	
Article 2(2), point (c)				
271	(c) Annex II;		(c) Annex II;	
Article 2(2), point (d)				
272				

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	(d) points (1)(c), (2), (3) and (4) of Annex III.		(d) points (1)(c), (2), (3) and (4) of Annex III.	
Article 2(3)				
273	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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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:	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 ~~17~~ ***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:	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:	
Article 2(3), point (a)				
274	(a) Article 1, points (1), (4), (5), (6), (7), (10), (11), (12), (16), (20), (21) and (23);		(a) Article 1, points (1), ~~(4),~~ (5), (6), (7), (10), (11), (12), (16), (20), (21) and (23);	
Article 2(3), point (b)				
275	(b) points (2), (3), (7) and (9) of		(b) points (2), (3), (7) and (9) of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Annex I;		Annex I;	
Article 2(3), point (c)				
276	(c) Annex II;		(c) Annex II;	
Article 2(3), point (d)				
277	(d) points (1)(c), (2), (3) and (4) of Annex III.		(d) points (1)(c), (2), (3) and (4) of Annex III.	
Article 2, fourth paragraph				
278	This Regulation shall be binding in its entirety and directly applicable in all Member States.		This Regulation shall be binding in its entirety and directly applicable in all Member States.	
Formula				
279	Done at Brussels,		Done at Brussels,	
Formula				
280	For the European Parliament		For the European Parliament	
Formula				

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281	The President		The President	
Formula				
282	For the Council		For the Council	
Formula				
283	The President		The President	
Annex I				
284	Annex I		Annex I	
Annex I, first paragraph				
285	Part 1 of Annex I to Regulation (EC) No 1272/2008 is amended as follows:		Part 1 of Annex I to Regulation (EC) No 1272/2008 is amended as follows:	
Annex I, second paragraph				
286	(1) Section 1.1.1.3. is replaced by the following:		(1) Section 1.1.1.3. is replaced by the following:	
Annex I, second paragraph, amending provision, first paragraph				

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287	‘ 1.1.1.3. A weight of evidence determination means that all available information bearing on the determination of hazard is considered together, such as the results of suitable in vitro tests, relevant animal data, human experience such as occupational data and data from accident databases, epidemiological and clinical studies and well-documented case reports and observations. For substances, information from the application of the category approach (grouping, read-across) and (Q)SAR results are also considered. The quality and consistency of the data shall be given appropriate weight. Information on substances related to the substance being classified shall be considered, as appropriate. Information on substances or mixtures related to the mixture being classified shall be considered in accordance with Article 9(4). Information on the site of action		‘ 1.1.1.3. A weight of evidence determination means that all available information bearing on the determination of hazard is considered together, such as the results of suitable in vitro tests, relevant animal data, human experience such as occupational data and data from accident databases, epidemiological and clinical studies and well-documented case reports and observations. For substances, information from the application of the category approach (grouping, read-across) and (Q)SAR results are also considered. The quality and consistency of the data shall be given appropriate weight. Information on substances related to the substance being classified shall be considered, as appropriate. Information on substances or mixtures related to the mixture being classified shall be considered in accordance with Article 9(4). Information on the site of action	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	and the mechanism or mode of action study results shall also be considered. Both positive and negative results shall be assembled together in a single weight of evidence determination.; ,		and the mechanism or mode of action study results shall also be considered. Both positive and negative results shall be assembled together in a single weight of evidence determination.'; ,	
Annex I, third paragraph				
288	(2) Section 1.2.1.4. is replaced by the following:		(2) Section 1.2.1.4. is replaced by the following:	
Annex I, third paragraph, amending provision, first paragraph				
289	‘ 1.2.1.4.			
Annex I, third paragraph, amending provision, first paragraph, first subparagraph				
290	1.2.1.4. The dimensions of the label and of each pictogram, and the font size of letters shall be as follows:		‘ 1.2.1.4. The dimensions of the label and of each pictogram, and the font size of letters shall be as follows:	
Annex I, third paragraph, amending provision, first paragraph, second subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
291	Table 1.3		Table 1.3	
Annex I, third paragraph, amending provision, first paragraph, third subparagraph				
292	Minimum dimensions of labels, pictograms and font size		Minimum dimensions of labels, pictograms and font size	
Annex I, third paragraph, amending provision, first paragraph, Table 1, Column 1, Row 1				
293	Capacity of the package		Capacity of the package	
Annex I, third paragraph, amending provision, first paragraph, Table 1, Column 1, Row 2				
294	Not exceeding 3 litres:		Not exceeding 3 litres:	
Annex I, third paragraph, amending provision, first paragraph, Table 1, Column 1, Row 3				
295	Greater than 3 litres but not exceeding 50 litres:		Greater than 3 litres but not exceeding 50 litres:	
Annex I, third paragraph, amending provision, first paragraph, Table 1, Column 1, Row 4				
296	Greater than 50 litres but not exceeding 500 litres:		Greater than 50 litres but not exceeding 500 litres:	
Annex I, third paragraph, amending provision, first paragraph, Table 1, Column 1, Row 5				

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297	Greater than 500 litres:		Greater than 500 litres:	
Annex I, third paragraph, amending provision, first paragraph, Table 1, Column 2, Row 1				
298	Dimensions of the label (in millimetres) for the information required by Article 17		Dimensions of the label (in millimetres) for the information required by Article 17	
Annex I, third paragraph, amending provision, first paragraph, Table 1, Column 2, Row 2				
299	If possible, at least 52x74		If possible, at least 52x74	
Annex I, third paragraph, amending provision, first paragraph, Table 1, Column 2, Row 3				
300	At least 74x105		At least 74x105	
Annex I, third paragraph, amending provision, first paragraph, Table 1, Column 2, Row 4				
301	At least 105x148		At least 105x148	
Annex I, third paragraph, amending provision, first paragraph, Table 1, Column 2, Row 5				
302	At least 148x210		At least 148x210	
Annex I, third paragraph, amending provision, first paragraph, Table 1, Column 3, Row 1				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
303	Dimensions of each pictogram (in millimetres)		Dimensions of each pictogram (in millimetres)	
Annex I, third paragraph, amending provision, first paragraph, Table 1, Column 3, Row 2				
304	Not smaller than 10x10 If possible, at least 16x16		Not smaller than 10x10 If possible, at least 16x16	
Annex I, third paragraph, amending provision, first paragraph, Table 1, Column 3, Row 3				
305	At least 23x23		At least 23x23	
Annex I, third paragraph, amending provision, first paragraph, Table 1, Column 3, Row 4				
306	At least 32x32		At least 32x32	
Annex I, third paragraph, amending provision, first paragraph, Table 1, Column 3, Row 5				
307	At least 46x46		At least 46x46	
Annex I, third paragraph, amending provision, first paragraph, Table 1, Column 4, Row 1				
308	Minimum font-size		Minimum font-size **(x-height in millimeters)**	

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Annex I, third paragraph, amending provision, first paragraph, Table 1, Column 4, Row 2				
309	8pt		~~8pt~~**1,4**	
Annex I, third paragraph, amending provision, first paragraph, Table 1, Column 4, Row 3				
310	12pt		~~12pt~~**1,8**	
Annex I, third paragraph, amending provision, first paragraph, Table 1, Column 4, Row 4				
311	16pt		~~16pt~~ **2,0**	
Annex I, third paragraph, amending provision, first paragraph, Table 1, Column 4, Row 5				
312	20pt’; ‘		~~20pt~~**2,0**’; ‘	
Annex I, fourth paragraph				
313	(3) the following Section 1.2.1.5. is added:		(3) the following Section 1.2.1.5. is added:	
Annex I, fourth paragraph a				
313a		***In Annex I, part I, the following section is added: Section 1.2.1.5.a***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		For multilingual labels, the languages shall be ordered in a logical way, e.g. alphabetically.		
Annex I, fourth paragraph, amending provision, first paragraph, first subparagraph				
314	‘ 1.2.1.5. The text on the label shall have the following characteristics:		‘ 1.2.1.5. The text on the label shall have the following characteristics:	
Annex I, fourth paragraph, amending provision, first paragraph, first subparagraph, point (a)				
315	(a) the background of the label shall be white;		(a) ~~the background of the label shall be~~**printed in black on a** white **background** ;	
Annex I, fourth paragraph, amending provision, first paragraph, first subparagraph, point (b)				
316	(b) the distance between two lines shall be equal or above 120 % of the font size;		(b) the distance between two lines shall be ~~equal or above 120 % of the font size~~**appropriate for the selected font size to be easily legible**;	
Annex I, fourth paragraph, amending provision, first paragraph, first subparagraph, point (c)				
317				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(c) a single font shall be used that is easily legible and without serifs;		(c) a single font shall be used that is easily legible and without serifs;	
Annex I, fourth paragraph, amending provision, first paragraph, first subparagraph, point (d)				
318	(d) the letter spacing shall be appropriate for the selected font to be comfortably legible.		(d) the letter spacing shall be appropriate for the selected font to be ~~comfortably~~ **easily** legible.	
Annex I, fourth paragraph, amending provision, first paragraph, second subparagraph				
319	For the labelling of inner packaging where the contents do not exceed 10 ml, the font size may be smaller than indicated in Table 1.3, as long as it remains legible for a person with average eyesight, where itis deemed important to place the most critical hazard statement and where the outer packaging meets the requirements of Article 17. '		For the labelling of inner packaging where the contents do not exceed 10 ml, the font size may be smaller than indicated in Table 1.3, as long as it remains legible ~~for a person with average eyesight~~, where ~~itis~~**it is** deemed important to place the most critical **statement, such as** hazard statement **or EUH statement,** and where the outer packaging meets the requirements of Article 17.**'** '	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex I, fourth paragraph a				
319a			**(3a) the following Section 1.2.1.6. is added:**	
Annex I, point 1., first subparagraph				
319b			**1.2.1.6 The front page of the fold-out label shall include at least the following elements:**	
Annex I, point 1., second subparagraph				
319c			**(i) name, address and phone number of supplier(s);**	
Annex I, point 1., third subparagraph				
319d			**(ii) 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;**	
Annex I, point 1., fourth subparagraph				
319e			**(iii) the product identifiers in**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			accordance with Article 18(2) for substances and Article18(3)(a) for mixtures in all languages of the label that are used in the inside pages;	
Annex I, point 1., fifth subparagraph				
319f			**(iv) where applicable, hazard pictograms;**	
Annex I, point 1., sixth subparagraph				
319g			**(v) where applicable, signal words in all languages of the label that are used in the inside pages;**	
Annex I, point 1., seventh subparagraph				
319h			**(vi) where applicable, the unique formula identifier, unless printed or affixed on the inner packaging in accordance with point 5.3, Part A in Annex VIII of this Regulation;**	
Annex I, point 1., eighth subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
319i			**(vii) a reference to the full safety information inside the fold-out label in all languages of the label or a symbol to inform a user that the label can be opened and to illustrate that additional information is available on inside pages;**	
Annex I, point 1., ninth subparagraph				
319j			**(viii) an abbreviation of the language (country code or language code) for all the languages that are used in the inside pages.**	
Annex I, fifth paragraph				
320	(4) the following Section 1.3.7. is added:		(4) the following Section 1.3.7. is added:	
Annex I, fifth paragraph, amending provision, first paragraph, first subparagraph				
321	‘ 1.3.7. Ammunition		‘ 1.3.7. Ammunition	
Annex I, fifth paragraph, amending provision, first paragraph, second subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
322	In the case of ammunition that qualifies as a substance or mixture and that is shot through a firearm, the labelling elements may be provided on the intermediate packaging instead of on the inner packaging, or, if there is no intermediate packaging, on the outer packaging.; ,		In the case of ammunition that ~~qualifies as~~**is** a substance or mixture and that is shot through a firearm, the labelling elements may be provided on the intermediate packaging instead of on the inner packaging, or, if there is no intermediate packaging, on the outer packaging.**'**; ,	
Annex I, sixth paragraph				
323	(5) the heading of Section 1.5.1. is replaced by the following:		(5) the heading of Section 1.5.1. is replaced by the following:	
Annex I, sixth paragraph, amending provision, first paragraph				
324	‘ 1.5.1. Exemptions from Article 31 in accordance with Article 29(1) ,		‘ 1.5.1. ——Exemptions from Article 31 in accordance with Article 29(1)**';** ,	
Annex I, seventh paragraph				
325				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(6) Section 1.5.1.1. is replaced by the following:		(6) Section 1.5.1.1. is replaced by the following:	
Annex I, seventh paragraph, amending provision, first paragraph				
326	‘ 1.5.1.1. Where Article 29(1) applies, the label elements referred to in Article 17 may be provided on a tie-on tag or on an outer packaging.; ’		‘ 1.5.1.1. —Where Article 29(1) applies, the label elements referred to in Article 17 may be provided on a tie-on tag or on an outer packaging.**’**; ’	
Annex I, eighth paragraph				
327	(7) Section 1.5.1.2. is replaced by the following:		(7) Section 1.5.1.2. is replaced by the following:	
Annex I, eighth paragraph, amending provision, first paragraph				
328	‘ 1.5.1.2. Where section 1.5.1.1. applies, the label on any inner packaging shall contain at least hazard pictograms, the signal word, the trade name or the designation of the mixture referred to in Article 18(3), point (a), and the name and		‘ 1.5.1.2. Where section 1.5.1.1. applies, the label on any inner packaging shall contain at least hazard pictograms, the signal word, the ~~trade name or the designation of the mixture~~ **product identifier referred to in Article 18(2) for substances**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	telephone number of the suppliers of the substance or mixture.; ’		**or the trade name or designation** referred to in Article 18(3), point (a) **for mixtures**, and the name and telephone number of the suppliers of the substance or mixture.**’**; ’	
Annex I, ninth paragraph				
329	(8) the heading of Section 1.5.2 is replaced by the following:		(8) the heading of Section 1.5.2 is replaced by the following:	
Annex I, ninth paragraph, amending provision, first paragraph				
330	‘ 1.5.2. Exemptions from Article 17 in accordance with Article 29(2)’; ‘		‘ 1.5.2. Exemptions from Article 17 in accordance with Article 29(2)’; ‘	
Annex I, tenth paragraph				
331	(9) Section 1.5.2.4.1 is replaced by the following:		(9) Section 1.5.2.4.1 is replaced by the following:	
Annex I, tenth paragraph, amending provision, first paragraph				

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332	‘ 1.5.2.4.1. The label elements required by Article 17 may be omitted from the inner packaging where the contents of the inner packaging do not exceed 10 ml and either of the following applies:		‘ 1.5.2.4.1. The label elements required by Article 17 may be omitted from the inner packaging where the contents of the inner packaging do not exceed 10 ml and ~~either~~ **any** of the following applies:	
Annex I, tenth paragraph, amending provision, first paragraph, point (a)				
333	(a) the substance or mixture is placed on the market for supply to a distributor or downstream user for scientific research and development or quality control analysis and the inner packaging is contained within outer packaging that meets the requirements set out in Article 17;		(a) the substance or mixture is placed on the market for supply to a distributor or downstream user for scientific research and development or quality control analysis and the inner packaging is contained within outer packaging that meets the requirements set out in Article 17;	
Annex I, tenth paragraph, amending provision, first paragraph, point (b)				
334	(b) the substance or mixture does not require labelling in accordance with Part 1, 2 or 4 of Annex II and is not classified in		(b) the substance or mixture does not require labelling in accordance with Part 1~~, 2 or 4~~ **or 2** of Annex II	

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	any of the following hazard classes and categories:		and is not classified in any of the following hazard classes and categories:	
Annex I, tenth paragraph, amending provision, first paragraph, point (b)(i)				
335	(i) Acute toxicity, categories 1 to 4;		(i) Acute toxicity, ~~categories 1 to 4~~**any category**;	
Annex I, tenth paragraph, amending provision, first paragraph, point (b)(ii), first subparagraph				
336	(ii) Specific target organ toxicity – Single exposure, categories 1 and		(ii) Specific target organ toxicity – Single exposure, categories 1 and **2;**	
Annex I, tenth paragraph, amending provision, first paragraph, point (b)(ii), second subparagraph				
337	2;			
Annex I, tenth paragraph, amending provision, first paragraph, point (b)(iii), first subparagraph				
338	(iii) Specific target organ toxicity – repeated exposure, categories 1		(iii) Specific target organ toxicity – repeated exposure, ~~categories 1~~**any category;**	
Annex I, tenth paragraph, amending provision, first paragraph, point (b)(iii), second subparagraph				
339				

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	and 2;			
Annex I, tenth paragraph, amending provision, first paragraph, point (b)(iv)				
340	(iv) Skin corrosion/irritation, category 1 (sub-categories 1A, 1B and 1C);		(iv) Skin ~~corrosion/irritation~~**corrosion**, category 1 ~~(sub-categories 1A, 1B and 1C)~~**, any sub-category** ;	
Annex I, tenth paragraph, amending provision, first paragraph, point (b)(iva)				
340a		‘ ***(iva) Serious eye damage category 1/eye irritation, category 2;***		
Annex I, tenth paragraph, amending provision, first paragraph, point (b)(iva)				
340b			**(iv1) Serious Eye Damage, category 1;**	
Annex I, tenth paragraph, amending provision, first paragraph, point (b)(ivb)				
340c			**(iv2) Skin Sensitisation, any category;**	
Annex I, tenth paragraph, amending provision, first paragraph, point (b)(v)				

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341	(v) Respiratory sensitisation, category 1 (sub-categories 1A and 1B);		(v) Respiratory sensitisation, ~~category 1 (sub-categories 1A and 1B)~~**any category** ;	
Annex I, tenth paragraph, amending provision, first paragraph, point (b)(va)				
341a		***(va) Skin sensitisation, category 1 (sub-categories 1A and 1B);*** ,		
Annex I, tenth paragraph, amending provision, first paragraph, point (b)(vi)				
342	(vi) Aspiration hazard;		(vi) Aspiration hazard;	
Annex I, tenth paragraph, amending provision, first paragraph, point (b)(vii)				
343	(vii) Germ cell mutagenicity, any category;		(vii) Germ cell mutagenicity, any category;	
Annex I, tenth paragraph, amending provision, first paragraph, point (b)(viii)				
344	(viii) Carcinogenity, any category;		(viii) Carcinogenity, any category;	
Annex I, tenth paragraph, amending provision, first paragraph, point (b)(ix)				

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345	(ix) Reproductive toxicity, any category;		(ix) Reproductive toxicity, any category;	
Annex I, tenth paragraph, amending provision, first paragraph, point (b)(x)				
346	(x) Flammable solids, categories 1 and 2.;		*deleted*	
Annex I, tenth paragraph, amending provision, first paragraph, point (b)(xi)				
347	*(xi)* Endocrine disruptors for human health, any category;		(xi) Endocrine ~~disruptors~~**disruption** for human health, any category;	
Annex I, tenth paragraph, amending provision, first paragraph, point (c)				
348	(c) the substance or mixture requires labelling in accordance with Part 1, 2 or 4 of Annex II but is not classified in any of the hazard classes and categories referred to in point (b) and has an inner packaging that is contained within outer packaging that meets the requirements set out in Article 17.; ,		(c) the substance or mixture requires labelling in accordance with Part 1~~, 2 or 4~~ **or 2** of Annex II but is not classified in any of the hazard classes and categories referred to in point (b) and has an inner packaging that is contained within outer packaging that meets the requirements set out in Article 17.**'**; ,	

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Annex I, eleventh paragraph				
349	(10) the following Section 1.6. is added:		(10) the following Section 1.6. is added:	
Annex I, eleventh paragraph, amending provision, numbered paragraph (1.6)				
350	‘ 1.6. Label elements that may be provided on a digital label only		‘ 1.6. Label elements that may be provided on a digital label only	
Annex I, eleventh paragraph, amending provision, numbered paragraph (1.6), point (a)				
351	(a) Supplemental information referred to in Article 25(3); ’		(a) Supplemental information referred to in Article 25(3); ’	
Annex II				
352	Annex II		Annex II	
Annex II, first paragraph				
353	Annex II to Regulation (EC) No 1272/2008 is amended as follows:		Annex II to Regulation (EC) No 1272/2008 is amended as follows:	

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Annex II, first paragraph a				
353a		***(-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, or serious eye damage category 1 shall be fitted with child-resistant fastenings".***		
Annex II, second paragraph				
353b		***(-1b) 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 Where substances or mixtures***		

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		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".		
Annex II, second paragraph				
354	(1) in Part 3, the following Section 3.4. is added:		(1) in Part 3, the following Section 3.4. is added:	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), first subparagraph				
355				

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	‘ 3.4. Refill stations		‘ 3.4. **‘3.4. Supply via** refill stations	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph				
356	Hazardous substances or mixtures referred to in Article 35(2a), shall meet the following conditions:		**When** hazardous substances or mixtures ~~referred to in~~**are supplied in accordance with** Article 35(2a), **the supplier** shall ~~meet~~ **ensure that** the following conditions **are met**:	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (a)				
357	(a) the labelling and packaging requirements applicable at the date of placing on the market of the hazardous substance or mixture are fulfilled for every refill station;		(a) the ~~labelling and packaging requirements applicable at the date of placing on the market of the~~ **refill station shall carry labels corresponding to the labels for each** hazardous substance or mixture ~~are fulfilled for every refill~~ **supplied at the** station;	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (b)				
358	(b) a label is firmly affixed on a visible place of the refill station		(b) ~~a label is~~ **the labels on the refill station shall be** firmly	

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	and with a font size that is easily legible and without serifs;		affixed **horizontally** on a visible place **and fulfil the requirements in Article 31 paragraphs 2 to 4 mutatis mutandis** ~~of the refill station and with a font size that is easily legible and without serifs~~;	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (ba)				
358a		‘ ***(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;***		
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (c)				
359	(c) substances and mixtures are only refilled in suitable and clean packaging without any		*deleted*	

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	visible residues, which are cleaned before reuse in case of suspected microbiological or other invisible contamination;			
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (d)				
360	*(d)* the buttons to operate the refill station are out of reach of children and the refill station is not designed in a way to attract the curiosity of children;		*deleted*	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (e)				
361	*(e)* overfilling packaging is technically prevented;		*deleted*	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (f)				
362	*(f)* filling a substance or mixture into unsuitable packaging is technically prevented;		*deleted*	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (fa)				
362a			**(f1) risk mitigation measures**	

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			are applied to ensure that exposure of humans, especially of children, and the environment is avoided as far as possible;	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (g)				
363	(g) at the moment of refill, the supplier is reachable for immediate assistance;		(g) at the moment of refill, the supplier is **available on site for maintenance and** ~~reachable for~~ immediate **assistance, including emergency** assistance;	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (h)				
364	(h) refill stations are not operated outdoors and outside business hours where immediate assistance cannot be provided;		*deleted*	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (i)				
365	*(i)* the substances or mixtures provided through a refill station do not react with each other in a way that could endanger clients or staff;		*deleted*	

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Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (j)				
366	*(j)* staff of the supplier are appropriately trained to minimise safety risks to consumers, professional users and themselves, and follow the necessary hygiene and cleaning protocols;		*deleted*	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (ja)				
366a			**(j1) for every refilled package, the requirements on hazard communication in the form of labelling set out in Title III of this Regulation are fulfilled;**	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (jb)				
366b			**(j2) for every refilled package the requirements on packaging set out in Title IV of this Regulation are fulfilled;**	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (k)				

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367	(k) no substance or mixture provided through a refill station meets the criteria for classification in any of the following hazard classes:		(k) ~~no substance or mixture provided through~~ **hazardous substances or mixtures shall not be provided at** a refill station ~~meets~~ **if** the criteria for classification in any of the following hazard classes **or differentiations are met**:	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (k)(i)				
368	(i) Acute toxicity, categories 1 – 4;		(i) Acute toxicity, ~~categories 1 – 4~~**any category**;	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (k)(ii)				
369	(ii) Specific target organ toxicity – Single exposure, categories 1, 2 and 3;		(ii) Specific target organ toxicity – Single exposure, ~~categories 1, 2 and 3~~**any category**;	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (k)(iii)				
370	(iii) Specific target organ toxicity – repeated exposure, categories 1 and 2;		(iii) Specific target organ toxicity – repeated exposure, ~~categories 1 and 2~~**any category**;	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (k)(iv)				

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371	(iv) Skin corrosion/irritation, category 1 (sub-categories 1A, 1B and 1C);		(iv) Skin ~~corrosion/irritation~~**corrosion**, category 1 ~~(sub-categories 1A, 1B and 1C)~~**, any sub-category** ;	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (k)(iva)				
371a		***(iva) Serious eye damage category 1/eye irritation, category 2;***		
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (k)(iva)				
371b			**(iv1) Serious eye damage, category 1;**	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (k)(v)				
372	(v) Respiratory sensitisation, category 1 (sub-categories 1A and 1B);		(v) Respiratory sensitisation, ~~category 1 (sub-categories 1A and 1B)~~**any category**;	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (k)(va)				
372a		***(va) Skin sensitisation, category 1 (sub-categories 1A and 1B);***		

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		’		
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (k)(va)				
372b			**(v1) Skin sensitisation, any category;**	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (k)(vi)				
373	(vi) Aspiration hazard;		(vi) Aspiration hazard;	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (k)(vii)				
374	(vii) Germ cell mutagenicity, any category;		(vii) Germ cell mutagenicity, any category;	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (k)(viii)				
375	(viii) Carcinogenicity, any category;		(viii) Carcinogenicity, any category;	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (k)(ix)				
376	(ix) Reproductive toxicity, any category;		(ix) Reproductive toxicity, any category;	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (k)(x)				

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377	(x) Flammable gases, categories 1 and 2;		(x) Flammable gases, ~~categories 1 and 2~~**any category**;	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (k)(xi)				
378	(xi) Flammable liquids, categories 1 and 2;		(xi) Flammable liquids, categories 1 and 2;	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (k)(xii)				
379	(xii) Flammable solids, categories 1 and 2.		(xii) Flammable solids, ~~categories 1 and 2.~~**any category;**	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (k)(xiii)				
380	(xiii) [insert: Endocrine disruptor for human health, categories 1 and 2].';		(xiii) ~~[insert:~~ Endocrine ~~disruptor~~**disruption** for human health, ~~categories 1 and 2]~~**any category**.~~[2]~~;	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (k)(xiv)				
381	(xiv) [insert: Endocrine disruptor for the environment, category 1 and 2];		(xiv) ~~[insert:~~ Endocrine ~~disruptor~~**disruption** for the environment, **any** category ~~1 and 2]~~;	

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Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (k)(xv)				
382	(xv) [insert: Persistent, bioaccumulative and toxic (PBT)];		(xv) ~~[insert:~~ Persistent, Bioaccumulative and Toxic ~~(PBT)]~~;	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (k)(xvi)				
383	(xvi) [insert: Very persistent and very bioaccumulative (vPvB)];		(xvi) ~~[insert:~~ Very Persistent and Very Bioaccumulative ~~(vPvB)]~~;	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (k)(xvii)				
384	(xvii) [insert: Persistent, mobile and toxic (PMT)];		(xvii) ~~[insert:~~ Persistent, Mobile and Toxic ~~(PMT)]~~;	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (k)(xviii)				
385	(xviii) [insert Very persistent and very mobile (vPvM)].		(xviii) ~~[insert~~ Very Persistent and Very Mobile ~~(vPvM)]~~.	
Annex II, second paragraph, amending provision, numbered paragraph (3.4), third subparagraph				
386	By way of derogation from point (b), a single label on the		By way of derogation from point ~~(b)~~**(a)**, a single label on	

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	refill station may be used for several substances or mixtures for which the label elements referred to in Article 17(1) are identical, provided that the label clearly indicates the name of each substance or mixture that it applies to.; ’		the refill station may be used for several substances or mixtures for which the label elements referred to in Article 17(1) are identical, provided that the label clearly indicates the name of each substance or mixture that it applies to.**’**; ’	
Annex II, third paragraph				
387	(2) Part 5 is replaced by the following:		(2) Part 5 is replaced by the following:	
Annex II, third paragraph, amending provision, first paragraph				
388	‘ PART 5: HAZARDOUS SUBSTANCES AND MIXTURES TO WHICH ARTICLE 29(3) APPLIES		‘ PART 5: HAZARDOUS SUBSTANCES AND MIXTURES TO WHICH ARTICLE 29(3) APPLIES	
Annex II, third paragraph, amending provision, second paragraph				
389	Ready mixed cement and concrete in the wet state shall be accompanied by a copy of the label elements in accordance		Ready mixed cement and concrete in the wet state shall be accompanied by a copy of the label elements in accordance	

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	with Article 17.		with Article 17.	
Annex II, third paragraph, amending provision, third paragraph				
390	For a substance or a mixture supplied at a filling station and directly pumped into a receptacle that forms an integral part of a vehicle and from where the substance or mixture is normally not intended to be removed, the label elements referred to in Article 17 shall be provided on the respective pump.; ’		For a substance or a mixture supplied at a filling station and directly pumped into a receptacle that forms an integral part of a vehicle and from where the substance or mixture is normally not intended to be removed, the label elements referred to in Article 17 shall be provided on **a visible place on** the respective pump. **When vehicle fuels are supplied at a filling station through pumping into portable receptacles designed to be used for fuels, a physical copy of the label elements referred to in Article 17 shall, in addition to the visible place on the pump, also be provided to be attached on the receptacle.’**; ’	
Annex III				

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391	Annex III		Annex III	
Annex III, first paragraph -a				
391a		***Annex VI is amended as follows:*** ***"ANNEX VI*** ***Harmonised classification and labelling for certain hazardous substances*** ***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.*** ***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***		

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		information may be used. For hazard information which has not been previously submitted to the Agency, a robust study summary shall be included in the dossier. ***A dossier for harmonised classification and labelling shall contain the following:*** ***— Proposal The proposal shall include the identity of the substance or substances concerned and the harmonised classification and labelling proposed;*** ***— Justification for the proposed harmonised classification and labelling.*** ***A comparison of the available information with the criteria contained in Parts 2 to 5, taking into account the general principles in Part 1, of Annex I to this Regulation shall be completed and documented in the format set out in Part B of the Chemical Safety Report in Annex I to Regulation (EC) No 1907/2006.*** ***— Justification for the proposed grouping of***		

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		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. 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."***		

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Annex III, first paragraph				
392	Annex VIII to Regulation (EC) No 1272/2008 is amended as follows:		Annex VIII to Regulation (EC) No 1272/2008 is amended as follows:	
Annex III, second paragraph				
393	(1) Part A is amended as follows:		(1) Part A is amended as follows:	
Annex III, second paragraph, point (a)				
394	(a) Section 1 is replaced by the following:		(a) Section 1 is replaced by the following:	
Annex III, second paragraph, point (a), amending provision, numbered paragraph (1)				
395	‘ 1. Application		‘ 1. Application	
Annex III, second paragraph, point (a), amending provision, numbered paragraph (1), point (1.1)				
396	1.1 Importers, downstream users and distributors referred to in Article 45(1c) placing on the market mixtures for consumer use, within the meaning of		1.1 Importers, downstream users and distributors referred to in Article 45(**1b) and (**1c) placing on the market mixtures for consumer use, within the	

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	Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2021.		meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2021.	
Annex III, second paragraph, point (a), amending provision, numbered paragraph (1), point (1.2)				
397	1.2. Importers, downstream users and distributors referred to in Article 45(1c) placing on the market mixtures for professional use, within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2021.		1.2. Importers, downstream users and distributors referred to in Article 45(**1b) and (**1c) placing on the market mixtures for professional use, within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2021.	
Annex III, second paragraph, point (a), amending provision, numbered paragraph (1), point (1.3)				
398	1.3. Importers, downstream users and distributors referred to in Article 45(1c) placing on the market mixtures for industrial use or mixtures with an end use not subject to notification within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2024.		1.3. Importers, downstream users and distributors referred to in Article 45(**1b) and (**1c) placing on the market mixtures for industrial use or mixtures with an end use not subject to notification within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2024.	

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Annex III, second paragraph, point (a), amending provision, numbered paragraph (1), point (1.4)				
399	1.4. Importers, downstream users and distributors referred to in Article 45(1c) having submitted information relating to hazardous mixtures to a body appointed in accordance with Article 45(1) before the dates of applicability mentioned in Sections 1.1, 1.2 and 1.3 and which are not in accordance with this Annex, shall for those mixtures not be required to comply with this Annex until 1 January 2025.		1.4. Importers, downstream users and distributors referred to in Article 45(**1b) and (**1c) having submitted information relating to hazardous mixtures to a body appointed in accordance with Article 45(1) before the dates of applicability mentioned in Sections 1.1, 1.2 and 1.3 and which are not in accordance with this Annex, shall for those mixtures not be required to comply with this Annex until 1 January 2025.	
Annex III, second paragraph, point (a), amending provision, numbered paragraph (1), point (1.5)				
400	1.5. By way of derogation from Section 1.4, if one of the changes described in Section 4.1 of Part B of this Annex occurs before 1 January 2025, importers, downstream users and distributors referred to in Article 45(1c) shall comply with this Annex before placing that		1.5. By way of derogation from Section 1.4, if one of the changes described in Section 4.1 of Part B of this Annex occurs before 1 January 2025, importers, downstream users and distributors referred to in Article 45(**1b) and (**1c) shall comply with this Annex before	

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	mixture, as changed, on the market.; ,		placing that mixture~~, as changed,~~ on the market.**'**; ,	
Annex III, second paragraph, point (b)				
401	(b) Section 2.1 is replaced by the following:		(b) Section 2.1 is replaced by the following:	
Annex III, second paragraph, point (b), amending provision, numbered paragraph (2.1)				
402	‘ 2.1. This Annex sets out the requirements that importers, downstream users and distributors referred to in Article 45(1c) (‘submitters’) placing mixtures on the market shall fulfil in respect of the submission of information so that appointed bodies have at their disposal the information required to carry out the tasks for which they are responsible under Article 45.; ,		‘ 2.1. This Annex sets out the requirements that importers, downstream users and distributors referred to in Article 45(1c) (‘submitters’) placing mixtures on the market shall fulfil in respect of the submission of information so that appointed bodies have at their disposal the information required to carry out the tasks for which they are responsible under Article 45.**'**; ,	
Annex III, second paragraph, point (c)				
403				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(c) in Section 2.4., first subparagraph, the following point (6) is added:		(c) in Section 2.4., first subparagraph, the following point (6) is added:	
Annex III, second paragraph, point (c), amending provision, numbered paragraph (6)				
404	‘ (6) ‘composition conforming with a standard formula specified in Part D’ means a composition which includes all the components listed in one of the standard formulas referred to in Part D of this Annex, where those components are present in the mixture in concentrations within the ranges specified in that standard formula.; ’		‘ (6) ‘composition conforming with a standard formula specified in Part D’ means a composition which includes all the components listed in one of the standard formulas referred to in Part D of this Annex, where those components are present in the mixture in concentrations within the ranges specified in that standard formula.; ’	
Annex III, third paragraph				
405	(2) Part B is amended as follows:		(2) Part B is amended as follows:	
Annex III, third paragraph, point (a)				
406	(a) the following Section 1.1a.		(a) the following Section 1.1a.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	is inserted:		is inserted:	
Annex III, third paragraph, point (a), amending provision, first paragraph				
407	‘ 1.1a. Name and product description of standard formula or name of fuel		‘ 1.1a. Name and product description of standard formula or name of fuel	
Annex III, third paragraph, point (a), amending provision, second paragraph				
408	For mixtures with a composition conforming with a standard formula specified in Part D, the name and product description of the relevant standard formula as indicated in that Part shall be included in the submission.		For mixtures with a composition conforming with a standard formula specified in Part D, the name and product description of the relevant standard formula as indicated in that Part shall be included in the submission.	
Annex III, third paragraph, point (a), amending provision, third paragraph				
409	For fuels listed in Table 3, the name of the fuel shall be provided as indicated in that table.; ’		For fuels listed in Table 3, the name of the fuel shall be provided as indicated in that table.; ’	
Annex III, third paragraph, point (b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
410	(b) in Section 3.1, the third paragraph is replaced by the following:		(b) in Section 3.1, the third paragraph is replaced by the following:	
Annex III, third paragraph, point (b), amending provision, first paragraph				
411	‘ Components which are not present in a mixture shall not be notified. However, if the components are notified as part of an interchangeable component group in accordance with Section 3.5. or their concentration has been submitted as a range of percentages in accordance with Sections 3.6. or 3.7, they may be notified if it is certain that they will be present in the mixture at some point in time. In addition, for mixtures with a composition conforming with a standard formula specified in Part D for which the composition is notified in accordance with Section 3.6, first indent, components listed in the relevant standard formula		‘ Components which are not present in a mixture shall not be notified. However, if ~~the~~**those** components are notified as part of an interchangeable component group in accordance with Section 3.5. or their concentration has been submitted as a range of percentages in accordance with Sections 3.6. or 3.7, they may be notified if it is certain that they will be present in the mixture at some point in time. In addition, for mixtures with a composition conforming with a standard formula specified in Part D for which the composition is notified in accordance with Section 3.6, first indent, components listed in the relevant standard formula	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	shall be notified even if the component is potentially not, or not permanently, present in cases where the indicated concentration range in Part D includes 0 %.; ,		shall be notified even if the component is potentially not, or not permanently, present in cases where the indicated concentration range in Part D includes 0 %.'; ,	
Annex III, third paragraph, point (c)				
412	(c) the title of Section 3.6. is replaced by the following:		(c) the title of Section 3.6. is replaced by the following:	
Annex III, third paragraph, point (c), amending provision, numbered paragraph (3.6)				
413	‘ 3.6. Mixtures with a composition conforming with a standard formula; ,		‘ 3.6. Mixtures with a composition conforming with a standard formula; ,	
Annex III, third paragraph, point (d)				
414	(d) in Section 3.7., the first row of Table 3 is replaced by the following:		(d) in Section 3.7., the first row of Table 3 is replaced by the following:	
Annex III, third paragraph, point (d), amending provision, first paragraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
415	"			
Annex III, third paragraph, point (d), amending provision, Table 2, Column 1, Row 1				
416	‘Fuel name		" ‘Fuel name	
Annex III, third paragraph, point (d), amending provision, Table 2, Column 2, Row 1				
417	Product description’;		Product description’; "	
Annex III, third paragraph, point (d), amending provision, second paragraph				
418	"			
Annex III, third paragraph, point (e)				
419	(e) in Section 4.1, the first paragraph, the following indent is added; :		(e) in Section 4.1, the first paragraph, the following indent is added; :	
Annex III, third paragraph, point (e), amending provision, first paragraph				
420				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	‘ - when there are other changes to a mixture placed on the market which are relevant for the emergency health response referred to in Article 45; ’		‘ - when there are other changes to a mixture placed on the market which are relevant for the emergency health response referred to in Article 45; ’	
Annex III, fourth paragraph				
421	(3) Part C is amended as follows:		(3) Part C is amended as follows:	
Annex III, fourth paragraph, point (a)				
422	(a) Section 1.2. is replaced by the following:		(a) Section 1.2. is replaced by the following:	
Annex III, fourth paragraph, point (a), amending provision, numbered paragraph (1.2)				
423	‘ 1.2. Identification of the mixture, submitter and contact point		‘ 1.2. Identification of the mixture, submitter and contact point	
Annex III, fourth paragraph, point (a), amending provision, second paragraph				
424	Product identifier		Product identifier	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex III, fourth paragraph, point (a), amending provision, second paragraph, first indent				
425	- Complete trade name(s) of the product including, where relevant, brand name(s), name of the product and variant names as they appear on the label, without abbreviations or non-alphanumerical symbols and enabling specific identification of the product.		- Complete trade name(s) of the product including, where relevant, brand name(s), name of the product and variant names as they appear on the label, without abbreviations or non-alphanumerical symbols and enabling specific identification of the product.	
Annex III, fourth paragraph, point (a), amending provision, second paragraph, second indent				
426	- Unique Formula Identifier(s) (UFI)		- Unique Formula Identifier(s) (UFI)	
Annex III, fourth paragraph, point (a), amending provision, second paragraph, third indent				
427	- Other identifiers (authorisation number, company product codes)		- Other identifiers (authorisation number, company product codes)	
Annex III, fourth paragraph, point (a), amending provision, second paragraph, fourth indent				
428	- In case of group submission, all product identifiers shall be		- In case of group submission, all product identifiers shall be	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	listed.		listed.	
Annex III, fourth paragraph, point (a), amending provision, third paragraph				
429	Name and product description of standard formula or name of fuel		Name and product description of standard formula or name of fuel	
Annex III, fourth paragraph, point (a), amending provision, third paragraph, first indent				
430	- Standard formula name and product description as specified in Part D (where applicable)		- Standard formula name and product description as specified in Part D (where applicable)	
Annex III, fourth paragraph, point (a), amending provision, third paragraph, second indent				
431	- Fuel name as specified in Table 3 of Part B (where applicable)		- Fuel name as specified in Table 3 of Part B (where applicable)	
Annex III, fourth paragraph, point (a), amending provision, fourth paragraph				
432	Contact details of the submitter and contact point		***Contact details of the submitter*****, as defined in section 2.1 of Part A of this Annex, *and contact point*** ~~Contact details of the submitter and contact point~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex III, fourth paragraph, point (a), amending provision, fourth paragraph, first indent				
433	- Name		- Name	
Annex III, fourth paragraph, point (a), amending provision, fourth paragraph, second indent				
434	- Full address		- Full address	
Annex III, fourth paragraph, point (a), amending provision, fourth paragraph, third indent				
435	- Telephone number		- Telephone number	
Annex III, fourth paragraph, point (a), amending provision, fourth paragraph, fourth indent				
436	- E-mail address		- E-mail address	
Annex III, fourth paragraph, point (a), amending provision, fifth paragraph				
437	Contact details for rapid access to additional product information (24 hours/7 days). Only for limited submission.		Contact details for rapid access to additional product information (24 hours/7 days). Only for limited submission.	
Annex III, fourth paragraph, point (a), amending provision, fifth paragraph, first indent				
438				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	- Name		- Name	
Annex III, fourth paragraph, point (a), amending provision, fifth paragraph, second indent				
439	- Telephone number (accessible 24 hours per day, 7 days per week)		- Telephone number (accessible 24 hours per day, 7 days per week)	
Annex III, fourth paragraph, point (a), amending provision, fifth paragraph, third indent				
440	- E-mail address; ,		- E-mail address; ,	
Annex III, fourth paragraph, point (b)				
441	(b) Section 1.4. is replaced by the following:		(b) Section 1.4. is replaced by the following:	
Annex III, fourth paragraph, point (b), amending provision, numbered paragraph (1.4), first subparagraph				
442	‘ 1.4. Information on the mixture components and interchangeable		‘ 1.4. Information on the mixture components and interchangeable	
Annex III, fourth paragraph, point (b), amending provision, numbered paragraph (1.4), second subparagraph				
443				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	component groups		component groups	
Annex III, fourth paragraph, point (b), amending provision, second paragraph				
444	Identification of the mixture components		Identification of the mixture components	
Annex III, fourth paragraph, point (b), amending provision, second paragraph, first indent				
445	- Chemical/trade name of the components		- Chemical/trade name of the components	
Annex III, fourth paragraph, point (b), amending provision, second paragraph, second indent				
446	- CAS number (where applicable)		- CAS number (where applicable)	
Annex III, fourth paragraph, point (b), amending provision, second paragraph, third indent				
447	- EC number (where applicable)		- EC number (where applicable)	
Annex III, fourth paragraph, point (b), amending provision, second paragraph, fourth indent				
448	- UFI (where applicable)		- UFI (where applicable)	
Annex III, fourth paragraph, point (b), amending provision, second paragraph, fifth indent				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
449	- Standard formula name and product description (where applicable)		- Standard formula name and product description (where applicable)	
Annex III, fourth paragraph, point (b), amending provision, second paragraph, sixth indent				
450	- Fuel name (where applicable)’;		- Fuel name (where applicable)’;	
Annex III, fourth paragraph, point (b), amending provision, third paragraph				
451	Name of interchangeable component groups (where applicable)		Name of interchangeable component groups (where applicable)	
Annex III, fourth paragraph, point (b), amending provision, fourth paragraph				
452	Concentration and concentration ranges of the mixture components		Concentration and concentration ranges of the mixture components	
Annex III, fourth paragraph, point (b), amending provision, fourth paragraph, first indent				
453	- Exact concentration or concentration range		- Exact concentration or concentration range	
Annex III, fourth paragraph, point (b), amending provision, fifth paragraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
454	Classification of mixture components		Classification of mixture components	
Annex III, fourth paragraph, point (b), amending provision, fifth paragraph, first indent				
455	- Hazard classification (where applicable)		- Hazard classification (where applicable)	
Annex III, fourth paragraph, point (b), amending provision, fifth paragraph, second indent, first subparagraph				
456	- Additional identifiers (where applicable and relevant for health		- Additional identifiers (where applicable and relevant for health	
Annex III, fourth paragraph, point (b), amending provision, fifth paragraph, second indent, second subparagraph				
457	response)		response)	
Annex III, fourth paragraph, point (b), amending provision, sixth paragraph				
458	List according to Part B, Section 3.1, fifth subparagraph (where applicable) ; ,		List according to Part B, Section 3.1, fifth subparagraph (where applicable) ; ,	
Annex III, fifth paragraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
459	(4) Part D is amended as follows:		(4) Part D is amended as follows:	
Annex III, fifth paragraph, point (a)				
460	(a) In section 1, the first row of the tables with standard formulas for cement are replaced by the following:		(a) In section 1, the first row of the tables with standard formulas for cement are replaced by the following:	
Annex III, fifth paragraph, point (a), amending provision, first paragraph				
461	"			
Annex III, fifth paragraph, point (a), amending provision, Table 3, Column 1, Row 1				
462	‘Standard formula name		" ‘Standard formula name	
Annex III, fifth paragraph, point (a), amending provision, Table 3, Column 2, Row 1				
463	Cement Standard Formula 1’		Cement Standard Formula 1’	
Annex III, fifth paragraph, point (a), amending provision, Table 4, Column 1, Row 1				
464				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	‘Standard formula name		‘Standard formula name	
Annex III, fifth paragraph, point (a), amending provision, Table 4, Column 2, Row 1				
465	Cement Standard Formula 2’		Cement Standard Formula 2’	
Annex III, fifth paragraph, point (a), amending provision, Table 5, Column 1, Row 1				
466	‘Standard formula name		‘Standard formula name	
Annex III, fifth paragraph, point (a), amending provision, Table 5, Column 2, Row 1				
467	Cement Standard Formula 3’		Cement Standard Formula 3’	
Annex III, fifth paragraph, point (a), amending provision, Table 6, Column 1, Row 1				
468	‘Standard formula name		‘Standard formula name	
Annex III, fifth paragraph, point (a), amending provision, Table 6, Column 2, Row 1				
469	Cement Standard Formula 4’		Cement Standard Formula 4’	
Annex III, fifth paragraph, point (a), amending provision, Table 7, Column 1, Row 1				
470	‘Standard formula name		‘Standard formula name	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex III, fifth paragraph, point (a), amending provision, Table 7, Column 2, Row 1				
471	Cement Standard Formula 5’		Cement Standard Formula 5’	
Annex III, fifth paragraph, point (a), amending provision, Table 8, Column 1, Row 1				
472	‘Standard formula name		‘Standard formula name	
Annex III, fifth paragraph, point (a), amending provision, Table 8, Column 2, Row 1				
473	Cement Standard Formula 6’		Cement Standard Formula 6’	
Annex III, fifth paragraph, point (a), amending provision, Table 9, Column 1, Row 1				
474	‘Standard formula name		‘Standard formula name	
Annex III, fifth paragraph, point (a), amending provision, Table 9, Column 2, Row 1				
475	Cement Standard Formula 7’		Cement Standard Formula 7’	
Annex III, fifth paragraph, point (a), amending provision, Table 10, Column 1, Row 1				
476	‘Standard formula name		‘Standard formula name	
Annex III, fifth paragraph, point (a), amending provision, Table 10, Column 2, Row 1				
477				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Cement Standard Formula 8’		Cement Standard Formula 8’	
Annex III, fifth paragraph, point (a), amending provision, Table 11, Column 1, Row 1				
478	‘Standard formula name		‘Standard formula name	
Annex III, fifth paragraph, point (a), amending provision, Table 11, Column 2, Row 1				
479	Cement Standard Formula 9’		Cement Standard Formula 9’	
Annex III, fifth paragraph, point (a), amending provision, Table 12, Column 1, Row 1				
480	‘Standard formula name		‘Standard formula name	
Annex III, fifth paragraph, point (a), amending provision, Table 12, Column 2, Row 1				
481	Cement Standard Formula 10’		Cement Standard Formula 10’	
Annex III, fifth paragraph, point (a), amending provision, Table 13, Column 1, Row 1				
482	‘Standard formula name		‘Standard formula name	
Annex III, fifth paragraph, point (a), amending provision, Table 13, Column 2, Row 1				
483	Cement Standard Formula 11’		Cement Standard Formula 11’	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex III, fifth paragraph, point (a), amending provision, Table 14, Column 1, Row 1				
484	‘Standard formula name		‘Standard formula name	
Annex III, fifth paragraph, point (a), amending provision, Table 14, Column 2, Row 1				
485	Cement Standard Formula 12’;		Cement Standard Formula 12’;	
Annex III, fifth paragraph, point (a), amending provision, Table 15, Column 1, Row 1				
486	‘Standard formula name		‘Standard formula name	
Annex III, fifth paragraph, point (a), amending provision, Table 15, Column 2, Row 1				
487	Cement Standard Formula 13’		Cement Standard Formula 13’	
Annex III, fifth paragraph, point (a), amending provision, Table 16, Column 1, Row 1				
488	‘Standard formula name		‘Standard formula name	
Annex III, fifth paragraph, point (a), amending provision, Table 16, Column 2, Row 1				
489	Cement Standard Formula 14’		Cement Standard Formula 14’	
Annex III, fifth paragraph, point (a), amending provision, Table 17, Column 1, Row 1				
490				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	‘Standard formula name		‘Standard formula name	
Annex III, fifth paragraph, point (a), amending provision, Table 17, Column 2, Row 1				
491	Cement Standard Formula 15’		Cement Standard Formula 15’	
Annex III, fifth paragraph, point (a), amending provision, Table 18, Column 1, Row 1				
492	‘Standard formula name		‘Standard formula name	
Annex III, fifth paragraph, point (a), amending provision, Table 18, Column 2, Row 1				
493	Cement Standard Formula 16’		Cement Standard Formula 16’	
Annex III, fifth paragraph, point (a), amending provision, Table 19, Column 1, Row 1				
494	‘Standard formula name		‘Standard formula name	
Annex III, fifth paragraph, point (a), amending provision, Table 19, Column 2, Row 1				
495	Cement Standard Formula 17’		Cement Standard Formula 17’	
Annex III, fifth paragraph, point (a), amending provision, Table 20, Column 1, Row 1				
496	‘Standard formula name		‘Standard formula name	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex III, fifth paragraph, point (a), amending provision, Table 20, Column 2, Row 1				
497	Cement Standard Formula 18’		Cement Standard Formula 18’	
Annex III, fifth paragraph, point (a), amending provision, Table 21, Column 1, Row 1				
498	‘Standard formula name		‘Standard formula name	
Annex III, fifth paragraph, point (a), amending provision, Table 21, Column 2, Row 1				
499	Cement Standard Formula 19’		Cement Standard Formula 19’	
Annex III, fifth paragraph, point (a), amending provision, Table 22, Column 1, Row 1				
500	‘Standard formula name		‘Standard formula name	
Annex III, fifth paragraph, point (a), amending provision, Table 22, Column 2, Row 1				
501	Cement Standard Formula 20’;		Cement Standard Formula 20’; "	
Annex III, fifth paragraph, point (a), amending provision, second paragraph				
502	"			
Annex III, fifth paragraph, point (b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
503	(b) In section 2, the two first rows of the table with standard formula for gypsum is replaced by the following:		(b) In section 2, the ~~two~~ first ~~rows~~**row** of the table with standard formula for gypsum is replaced by the following **two rows**:	
Annex III, fifth paragraph, point (b), amending provision, first paragraph				
504	"			
Annex III, fifth paragraph, point (b), amending provision, Table 23, Column 1, Row 1				
505	‘Standard formula name		" ‘Standard formula name	
Annex III, fifth paragraph, point (b), amending provision, Table 23, Column 1, Row 2				
506	Product description		Product description	
Annex III, fifth paragraph, point (b), amending provision, Table 23, Column 2, Row 1				
507	— Gypsum binder Standard Formula		— Gypsum binder Standard Formula	
Annex III, fifth paragraph, point (b), amending provision, Table 23, Column 2, Row 2				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
508	Gypsum binder’;		Gypsum binder’; "	
Annex III, fifth paragraph, point (b), amending provision, second paragraph				
509	"			
Annex III, fifth paragraph, point (c)				
510	(c) In section 3, the two first rows of the tables with standard formulas for ready mixed concrete are replaced by the following:		~~(c)~~**(a) (c)** In section 3, the ~~two~~ first ~~rows~~**row** of the tables with standard formulas for ready mixed concrete are replaced by the following:	
Annex III, fifth paragraph, point (c), amending provision, first paragraph				
511	"			
Annex III, fifth paragraph, point (c), amending provision, Table 24, Column 1, Row 1				
512	‘Standard formula name		" ‘Standard formula name	
Annex III, fifth paragraph, point (c), amending provision, Table 24, Column 1, Row 2				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
513	Product description		Product description	
Annex III, fifth paragraph, point (c), amending provision, Table 24, Column 2, Row 1				
514	— Ready mixed concrete Standard Formula 1		— Ready mixed concrete Standard Formula 1	
Annex III, fifth paragraph, point (c), amending provision, Table 24, Column 2, Row 2				
515	— Ready mixed concrete with concrete strength classes C8/10, C12/15, C16/20, C20/25, C25/30, C28/35, C32/40, C35/45, C40/50, C45/55, C50/60, LC8/9, LC12/13, LC16/18, LC20/22, LC25/28, LC30/33, LC35/38, LC40/44, LC45/50, LC50/55, LC55/60’;		—Ready mixed concrete with concrete strength classes C8/10, C12/15, C16/20, C20/25, C25/30, C28/35, C32/40, C35/45, C40/50, C45/55, C50/60, LC8/9, LC12/13, LC16/18, LC20/22, LC25/28, LC30/33, LC35/38, LC40/44, LC45/50, LC50/55, LC55/60’;	
Annex III, fifth paragraph, point (c), amending provision, Table 25, Column 1, Row 1				
516	‘Standard formula name		‘Standard formula name	
Annex III, fifth paragraph, point (c), amending provision, Table 25, Column 1, Row 2				
517	Product description		Product description	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex III, fifth paragraph, point (c), amending provision, Table 25, Column 2, Row 1				
518	— Ready mixed concrete Standard Formula 2		— Ready mixed concrete Standard Formula 2	
Annex III, fifth paragraph, point (c), amending provision, Table 25, Column 2, Row 2				
519	— Ready mixed concrete with concrete strength classes C55/67, C60/75, C70/85, C80/95, C90/105, C100/105, LC 60/66, LC70/77, LC80/88’.		—Ready mixed concrete with concrete strength classes C55/67, C60/75, C70/85, C80/95, C90/105, C100/105, LC 60/66, LC70/77, LC80/88’. "	
Annex III, fifth paragraph, point (c), amending provision, second paragraph				
520	"			