

Brussels, 15 December 2023 (OR. en)

Interinstitutional File: 2022/0432(COD)

14625/5/23 REV 5

ENT 224 MI 897 COMPET 1030 CHIMIE 93 IND 556 SAN 612 ENV 1175 CONSOM 380 CODEC 1969

NOTE

From:	General Secretariat of the Council
To:	Delegations
No. Cion doc.:	ST 16258/22 + ADD 1-8 - COM(2022) 748 Final
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
	- Updated and final Four-Column Table

Delegations will find in the Annex the updated four-column table of the above proposal, containing the agreed positions of the institutions after the trilogue meeting on 5 December 2023 and the subsequent adjustments, agreed between the co-legislators.

14625/5/23 REV 5 AT/CDP/RPG/nm 1
COMPET 1

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) LATEST TEXT

15-12-2023

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Formula				
G	1	2022/0432 (COD)	2022/0432 (COD)	2022/0432 (COD)	2022/0432 (COD) Text Origin: Commission Proposal
	Proposal	l Title			
G	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)	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) Text Origin: Commission Proposal
	Formula				

14625/5/23 REV 5

AT/CDP/RPG/nm

COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G	3	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Text Origin: Commission Proposal
	Citation	1			
G	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,	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, Text Origin: Commission Proposal
	Citation	2			
G	5	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission, Text Origin: Commission Proposal
	Citation	3			
G	6	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments,

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm 3

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Commission Proposal
	Citation 4	4			
G	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	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 Text Origin: Commission Proposal
	Citation 5	5			
G	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.	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. Text Origin: Commission Proposal
	Formula				
G	9	Whereas:	Whereas:	Whereas:	Whereas: Text Origin: Commission Proposal
	Recital 1				

14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1

EN

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
6 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 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.	(1) In order to keep pace with globalisation, technological development and new means of sale, such as online sales, it is necessary to adapt Regulation (EC) No 1272/2008 of the European Parliament and of the Council. While under that Regulation it is assumed that all responsible actors in the supply chain are established in the Union, practical experience has shown that economic operators established outside the Union sell chemicals online directly to the general public in the Union. Hence, enforcement authorities are unable to enforce Regulation (EC) No 1272/2008 against economic operators not established in the Union. It is therefore appropriatenecessary 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/xxxx [reference to adopted act to be inserted] on General Product Safety, Regulation (EU)	(1) In order to keep pace with globalisation, technological development and new means of sale, such as online sales, it is necessary to adapt Regulation (EC) No 1272/2008 of the European Parliament and of the Council. While under that Regulation it is assumed that all responsible actors in the supply chain are established in the Union, practical experience has shown that economic operators established outside the Union sell chemicals online directly to the general public in the Union. Hence, enforcement authorities are unable to enforce Regulation (EC) No 1272/2008 against economic operators not established in the Union. It is therefore appropriate to require that there is a supplier established in the Union, which ensures that the 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	(1) In order to keep pace with globalisation, technological development and new means of sale, such as online sales, it is necessary to adapt Regulation (EC) No 1272/2008 of the European Parliament and of the Council. While under that Regulation it is assumed that all responsible actors in the supply chain are established in the Union, practical experience has shown that economic operators established outside the Union sell chemicals online directly to the general public in the Union. Hence, enforcement authorities are unable to enforce Regulation (EC) No 1272/2008 against economic operators not established in the Union. It is therefore appropriatenecessary 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

5 EN 14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	In order to prevent situations where consumer becomes de jure and de facto an importer when buying the substance or the mixture via distance sales from the economic operators established outside the Union, it is necessary to specify that the supplier which ensures that the substance or the mixture in question meets the requirements set out in that Regulation acts in course of an industrial or professional activity.	2022/2065, and Regulation (EU) 2019/1020 should would improve compliance with and enforcement of the Regulation (EC) No 1272/2008 No 1272/2008 and thereby ensure a high level of protection of human health and the environment. In order to prevent situations where consumer 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 substance or the mixture in question meets the requirements set out in that Regulation acts in course of an industrial or professional activity.	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, would improve compliance with and enforcement of the Regulation (EC) No 12727/2008No 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 factode 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.	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, 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 a consumer becomes de jure and de facto de jure and de facto iure and de facto iure and de facto en jure and de facto interest and 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. Text Origin: Council Mandate
Recita	1 2			
G 11				(

14625/5/23 REV 5 AT/CDP/RPG/nm 6
COMPET 1

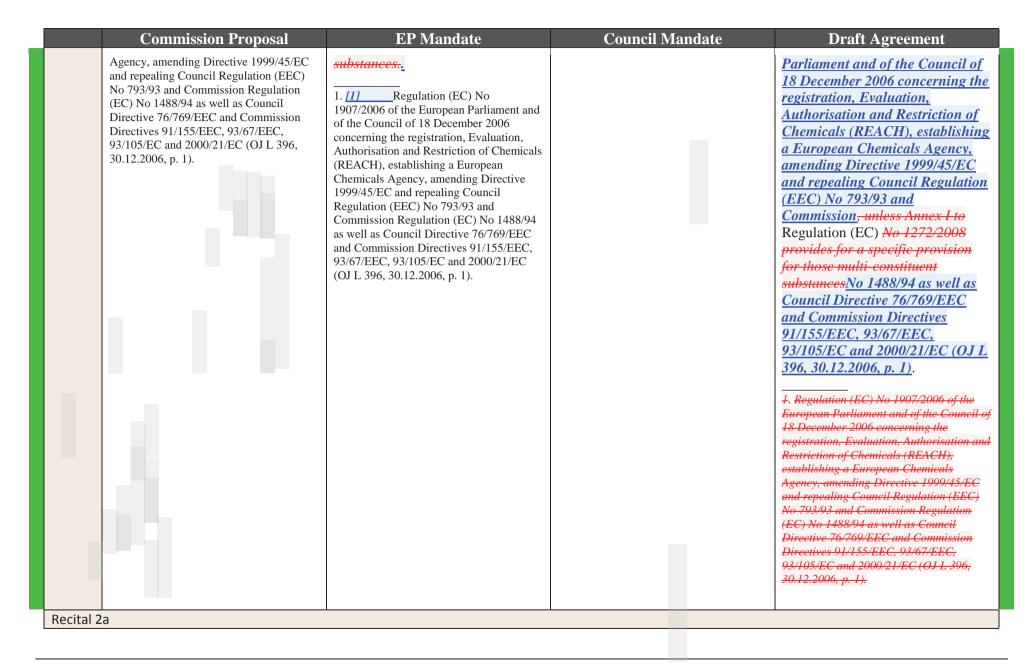
(2) From a toxicological poir view, substances with more the one constituent ('multi-constituent substances') are no different for the constituent ('multi-constituent substances').	tuent intentional mixtures. From a toxicological point of view, substances with containing more	deleted	(2) <u>Substances containing more</u> <u>than one constituent are complex</u> <u>substances.</u> From a toxicological point of view, substances
view, substances with more the one constituent ('multi-consti	tuent intentional mixtures. From a toxicological point of view, substances with containing more	deleted	than one constituent are complex substances. From a toxicological
	rom toxicological point of view, more substances with containing more		
	rom toxicological point of view, more substances with containing more		
mixtures composed of two or	h then one constituent ('multi		withcontaining more than one
substances. In accordance wit	ii titali olie collstituelit mutti-		constituent ('multi-constituent
Article 13 of Regulation (EC)	No constituent substances') are no		substances') are no different from
1907/2006 of the European	different from mixtures composed		mixtures composed of two or more
Parliament and of the Council	of two or more substances. In		substances. In accordance with
aimed to limit animal testing,	data accordance with Article 13 of		Article 13 of Regulation (EC) No
on multi-constituent substance	es is Regulation (EC) No 1907/2006 of		1907/2006 of the European
to be generated under the same	e the European Parliament and of the		Parliament and of the Council ¹ ,
conditions as data on any other	er Council ¹ , aimed to limit minimise		aimed to limitminimise animal
substance, while data on indiv	ridual animal testing, data on multi-		testing, data on multi-constituent
constituents of a substance is	constituent substances substances		substances containing
normally not to be generated,	containing more than one		more than one constituent is to be
except where individual	<i>constituent</i> is to be generated		generated under the same
constituents are also substanc	es under the same conditions as data		conditions as data on any other
registered on their own. When			substance, while data on individual
data on individual constituent	s is on individual constituents of a		constituents of a substance is
available, multi-constituent	substance is normally not to be		normally not to be generated,
substances should be evaluate	7 1		except where individual
classified following the same	constituents are also substances		constituents are also substances
classification rules as mixture	, 6		registered on their own. Where
unless Annex I to Regulation			data on individual constituents
No 1272/2008 provides for a	isare available, multi-constituent		isare available, multi-constituent
specific provision for those m			substances containing more than
constituent substances.	more than one constituent should		one constituent should be
	be evaluated and classified		evaluated and classified following
1. Regulation (EC) No 1907/2006 of			the same classification rules as
European Parliament and of the Cou 18 December 2006 concerning the	rules as illixtures, whiles i to		mixtures.
registration, Evaluation, Authorisation	on and Regulation (EC) No 1272/2008		
Restriction of Chemicals (REACH),	provides for a specific provision		1. Regulation (EC) No
establishing a European Chemicals	for those multi-constituent		1907/2006 of the European

14625/5/23 REV 5

AT/CDP/RPG/nm

COMPET 1

COMPET 1 EN



AT/CDP/RPG/nm 14625/5/23 REV 5 COMPET 1

Commission Pr	oposal EP Mandate	Council Mandate	Draft Agreement
6 11a	(2a) Scientific evidence on substances containing more than one constituent of renewable botanical origin shows that specific constituents considered 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-foss sources). The Commission should review the identification and examination of substances containing more than one constituent of renewable botanic 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.		(2a) Scientific data on certain substances containing more than one constituent extracted from plants has indicated that specific constituents considered in an isolated way can have hazard properties that might not be expressed in the substance as a whole. Therefore, in order to allow time for a scientific evaluation of the suitability for substances containing more than one constituent extracted from plants to follow the rules on classification of substances containing more than one constituent, a derogation from certain rules is introduced for these substances. However, when no relevant information is available on the substance itself, manufacturers, importers or downstream users might apply these classification rules to their substances extracted from plants, in order to maintain the current level of protection and the existing good practice. The Commission should review the rules applicable to the identification and examination of the information on substances containing more than one constituent extracted from

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

9

EN

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				plants within five years from the entry into force of this Regulation and submit, if appropriate, a legislative proposal.
Recital 3	3			
Recital 3	(3) It is normally not possible to sufficiently assess the endocrine disrupting properties for human health and the environment and the persistent, bioaccumulative and mobile properties of a mixture or of a multi-constituent substance on the basis of data on that mixture or substance. The data for the individual substances of the mixture or for the individual constituents of the multi-constituent substance should therefore normally be used as the basis for hazard identification of those multi-constituent substances or mixtures. However, in certain cases, data on those multi-constituent substances themselves may also be relevant. This is the case in particular where that data demonstrates endocrine disrupting properties for human health and the environment, as well as persistent,	(3) It is normally not 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 containing more than one constituent substances containing more than one constituent or	deleted	(3) It is normally not 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 containing more than one constituent or mixtures. However,
	bioaccumulative and mobile properties, or where it supports	mixtures. However, in certain cases, data on those multi-		in certain cases, data on those multi constituent

10 14625/5/23 REV 5 AT/CDP/RPG/nm EN

COMPET 1

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	data on the individual constituents. Therefore, it is appropriate that data on multi-constituent substances are used in those cases.	constituent substances containing more than one constituent themselves may also be relevant. This is the case in particular where that data demonstrates endocrine disrupting properties for human health and the environment, as well as persistent, bioaccumulative and mobile properties, or where it supports data on the individual constituents. Therefore, it is appropriate that data on multiconstituent substances are used in those cases.		more than one constituent themselves may also be relevant. This is the case in particular where that data demonstrates endocrine disrupting properties for human health and the environment, as well as persistent, bioaccumulative and mobile properties, or where it supports data on the individual constituents. Therefore, it is appropriate that data on multiconstituent substances substances containing more than one constituent are used in those cases.
Recital 4				
3 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 bridging principles. It should	(4) In order to improve legal certainty and implementation with regard to the evaluation of hazard information for mixtures where no or inadequate test data are available for the mixture itself, the interaction between the application of the bridging principles and a weight of evidence determination using expert judgement should be clarified. Such clarification should ensure that the weight of evidence determination complements but does not substitute the application of the bridging principles. It should	(4) In order to improve legal certainty and implementation with regard to the evaluation of hazard information for mixtures where no or inadequate test data are available for the mixture itself, the interaction between the application of the bridging principles and a weight of evidence determination using expert judgement should be clarified. Such clarification should ensure that the weight of evidence determination complements but does not substitute the application of the bridging principles. It should	(4) In order to improve legal certainty and implementation with regard to the evaluation of hazard information for mixtures where no or inadequate test data are available for the mixture itself, the interaction between the application of the bridging principles and a weight of evidence determination using expert judgement should be clarified. Such clarification should ensure that the weight of evidence determination complements but does not substitute the application of the bridging principles. It should

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

11

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.	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.	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.	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. Text Origin: Commission Proposal
	Recital 5				
G	14	(5) To avoid over-classification 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	(5) To avoid over-classification 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	(5) To avoid over-classification 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	(5) To avoid over-classification 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

12 14625/5/23 REV 5 AT/CDP/RPG/nm EN

COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.	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.	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.	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. Text Origin: Commission Proposal
	Recital 6				
G	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 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	(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 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	(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 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	(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 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

13 14625/5/23 REV 5 AT/CDP/RPG/nm

COMPET 1 EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.	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.	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.	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. Text Origin: Commission Proposal
	Recital 6	a			
G	15a			(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,	(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

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

14

EN

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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.	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. Text Origin: Council Mandate
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	(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	(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 cartridgethat inner packaging might however cause safety	(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 eartridgethat inner packaging might however cause safety

14625/5/23 REV 5 AT/CDP/RPG/nm 15

EN COMPET 1

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 exemption from the labelling requirements and allow for alternative ways of communicating the hazard information.	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 exemption from the labelling requirements and allow for alternative ways of communicating the hazard information.	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 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.	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 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. Text Origin: Council Mandate
Recita	18			
s 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.	(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. Text Origin: Commission

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

16

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Proposal
	Recital 9				
G	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. 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.	(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. 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.	(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. 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.	(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. 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. Text Origin: Commission Proposal
	Recital 1	0			
G	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	(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	(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	(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

17 **EN** 14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1

set out in Commission Implementing Regulation (EU) 2020/1435¹. Where the new hazard class is additional to an existing hazard class or represents a more severe hazard class or category, or where new supplemental labelling elements are required under Article 25, the deadline to update the labelling information in the case of adaptation of the classification in accordance with the result of a new evaluation should be set at 6 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. In case where a classification is updated to a less severe hazard class or category without triggering classification in an additional hazard class or new supplemental labelling requirements, the deadline for updating the labels should remain at 18 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. It should also be clarified that, in cases of harmonised classification and labelling, the deadlines to update the labelling information should be set at the date of

Commission Proposal

set out in Commission Implementing Regulation (EU) 2020/1435¹. Where the new hazard class is additional to an existing hazard class or represents a more severe hazard class or category, or where new supplemental labelling elements are required under Article 25, the deadline to update the labelling information in the case of adaptation of the classification in accordance with the result of a new evaluation should be set at 6 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. In case where a classification is updated to a less severe hazard class or category without triggering classification in an additional hazard class or new supplemental labelling requirements, the deadline for updating the labels should remain at 18 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. It should also be clarified that, in cases of harmonised classification and labelling, the deadlines to update the labelling information should be set at the date of

EP Mandate

registrants is set out in **Commission Implementing** Regulation (EU) 2020/14351. Where the new hazard class is additional to an existing hazard class or represents a more severe hazard class or category, or where new supplemental labelling elements are required under Article 25, the deadline 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

Council Mandate

registrants is set out in Commission Implementing Regulation (EU) 2020/14351. Where the new hazard class is additional to an existing hazard class or represents a more severe hazard class or category, or where new supplemental labelling elements are required under Article 25, the deadline *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

Draft Agreement

14625/5/23 REV 5 AT/CDP/RPG/nm 18
COMPET 1

EN

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

14625/5/23 REV 5 AT/CDP/RPG/nm 19
COMPET 1

COMPET I

(EC) No 1907/2006 of the European

(EC) No 1907/2006 of the European

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 331, 12.10.2020, p.24.)	Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 331, 12.10.2020, p.24.) Text Origin: Council Mandate
	Recital 11			
G	(11) Regulation (EC) No 1272/2008 only allows for the use of fold-out labels if the general rules for the application of labels cannot be met due to the shape or form of the packaging or its small size, whilst it does not provide for a minimum font size of labels that would ensure readability. As a result of advancements in labelling technologies, more flexibility should be given to suppliers by providing for a broader use of fold- out labels, while readability of labels should be ensured by laying down minimum font size and formatting requirements.	(11) Regulation (EC) No 1272/2008 only allows for the use of fold-out labels if the general rules for the application of labels cannot be met due to the shape or form of the packaging or its small size, whilst it does not provide for a minimum font size of labels that would ensure readability. As a result of advancements in labelling technologies, more flexibility should be given to suppliers by providing for a broader use of fold- out labels, while durability and good readability of all labels should be ensured, including by laying down minimum font size and formatting requirements.	(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 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 requirementsapplying the general rules on application and formatting to ensure readability and specific requirements for form and design of the front page	(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 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 good readability and specific requirements for the content of

20 14625/5/23 REV 5 AT/CDP/RPG/nm

EN COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					the front, inner and back pages. Text Origin: Council Mandate
	Recital 1	1a			
G	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 not to hamper the strive for a circular economy through the use of recycled materials for packaging material.	(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 not to hamper the strive for a circular economy through the use of recycled materials for packaging material.
	Recital 1	2			
G	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	(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	(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	(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

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

21

EN

Commission Proposal

efficiency of hazard efficiency of hazard efficiency of hazard efficiency of hazard communication, especially for communication, especially for communication, especially for communication, especially for vulnerable population groups and vulnerable population groups and vulnerable population groups, such vulnerable population groups, such people who do not speak the people who do not speak the as people with visual as people with visual impairments, national language of a Member national language of a Member impairments, and for and people and for and people who do not State. Therefore, it is necessary to State. Therefore, it is necessary to who do not speak the national speak the national language of a Member State. Therefore, it is provide for voluntary digital provide for voluntary digital language of a Member State. labelling and to lay down technical labelling and to lay down technical Therefore, it is necessary to necessary to provide for voluntary requirements for such labelling. In requirements for such labelling. In provide for voluntary digital digital labelling and to lay down order to provide for legal certainty, order to provide for legal certainty, labelling and to lay down technical technical requirements for such it is appropriate to specify the label requirements for such that the it is appropriate to specify the label that the supplier who places a data elements that are allowed to be elements that are allowed to be supplier who places a data carrier linking to such a label provided in a digital format only. provided in a digital format only. carrier linking to such a label must satisfy. These technical That possibility should only exist That possibility should only exist must satisfy. These technical requirements on the digital label for information which is not for information which is not requirements on the digital label should however not affect the responsibilities of all suppliers to instrumental for the safety of the instrumental for the safety of the should however not affect the user or the protection of the user or the protection of the responsibilities of all suppliers to ensure that labelling requirements environment. environment and should be ensure that labelling are fulfilled when placing a determined taking into account requirements are fulfilled when substance or mixture on the the need for a high level of placing a substance or mixture market. In order to provide for legal certainty, keep pace with protection of human health and on the market. In order to provide digitalisation it is appropriate to the environment. The decision as for legal certainty, keep pace with specify theallow certain label to which information is not **digitalisation** it is appropriate to elements that are allowed required specify theallow certain label relevant for the safety of the user elements that are allowed-required under this Regulation to be or the protection of the provided in a digital format only. environment needs to be under this Regulation to be documented transparently. The provided in a digital format only. That possibility should only exist Unique Formula Identifier, the That possibility should only exist for information which is not hazard statement, the for information which is not instrumental for the safety of the precautionary statement, the instrumental for the safety of the user or the protection of the signal word, and the hazard user or the protection of the environment, while not affecting pictogram should always remain environment, while not affecting the labelling requirements or on the on-pack label to ensure the labelling requirements or possibilities for digital labelling they are in sight of consumers. possibilities for digital labelling laid down in other Union

Council Mandate

Draft Agreement

EP Mandate

14625/5/23 REV 5 AT/CDP/RPG/nm 22
COMPET 1

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		·		laid down in other Union legislation.	legislation, and should take into account the need for a high level of protection of human health and the environment. Text Origin: EP Mandate
	Recital 1	3			
G	22	elements allowed to be provided only in a digital format to technical progress or to the level of digital readiness among all population groups in the Union, the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union to amend the list of label elements allowed to be provided only in a digital format, taking into account societal needs and a high level of protection of human health and the environment.	(13) In order to adapt the label elements allowed to be provided only in a digital format to technical progress or to the level of digital readiness among all population groups in the Union, the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union to amend the list of label elements allowed to be provided only in a digital format, taking into account societal needs, ensuring and a high level of protection of human health and the environment and sufficient information on chemicals that citizens are exposed to.	(13) In order to adapt the label elements allowed to be provided only in a digital format to technical progress or to the level of digital readiness among all population groups in the Uniondevelopments 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.	(13) In order to adapt the label elements allowed to be provided only in a digital format to technical progress or to the level of digital readiness among all population groups in the Uniondevelopments 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 only in a digital format, that the GHS does not require such labelling elements to be put on the physical label, and taking into account the level of digital readiness among all population groups in the Union, the societal needs and a high level of protection of human health and the environment.

23 14625/5/23 REV 5 AT/CDP/RPG/nm

COMPET 1 EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Council Mandate
	Recital 1	4			
G	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 European Union to supplement Regulation (EC) No 1272/2008 by further specifying the technical requirements for the digital labelling.	(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 European Union to supplement Regulation (EC) No 1272/2008 by further specifying the technical requirements for the digital labelling.	(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 European Union to supplement Regulation (EC) No 1272/2008 by further specifying the technical requirements for the digital labelling.	(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 European Union to supplement Regulation (EC) No 1272/2008 by further specifying the technical requirements for the digital labelling. Text Origin: Commission Proposal
	Recital 1	5			
G	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,	(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,	(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,	(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,

14625/5/23 REV 5 AT/CDP/RPG/nm 24 EN

COMPET 1

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 classes and categories, in order to ensure safety and the protection of human health.	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 classes and categories, in order to ensure safety and the protection of human health.	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 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.	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 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 especially uncontrolled operation by children as well as avoiding reaction between substances and mixtures provided through the station, or with residues in refilled packages. Text Origin: Council Mandate
Recital	16			
G 25	(16) Regulation (EC) No 1272/2008 does not lay down rules on the labelling of chemicals supplied to the general public	(16) Regulation (EC) No 1272/2008 does not lay down rules on the labelling of chemicals supplied to the general public	(16) Regulation (EC) No 1272/2008 does not lay down rules on the labelling of chemicals supplied to the general public	(16) Regulation (EC) No 1272/2008 does not lay down rules on the labelling of chemicals supplied to the general public

25 14625/5/23 REV 5 AT/CDP/RPG/nm EN

COMPET 1

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 supplied at filling stations and intended to be pumped into receptacles from where they are normally not intended to be removed.	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 supplied at filling stations and intended to be pumped into receptacles from where they are normally not intended to be removed.	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, 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.	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, diesel exhaust fluids, 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. Text Origin: Council Mandate
Recital 1	7	-		
s 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	(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	(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	(17) As the new hazard classes and criteria introduced by Commission Delegated Regulation¹ allow for the harmonised classification and labelling of substances of the highest concern with regard to health and environment, they

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

26

EN

Commission Proposal Council Mandate Draft Agreement EP Mandate should normally be subject to harmonised classification and harmonised classification and harmonised classification and harmonised classification and labelling and added to the list of hazard classes which includes hazard classes which includes hazard classes which includes hazard classes which includes respiratory sensitisation, germ cell respiratory sensitisation, germ cell respiratory sensitisation, germ cell respiratory sensitisation, germ cell mutagenicity, carcinogenicity and mutagenicity, carcinogenicity and mutagenicity, carcinogenicity and mutagenicity, carcinogenicity and reproductive toxicity. Subreproductive toxicity. Subreproductive toxicity. Subreproductive toxicity. Subcategorisation of the hazard class categorisation of the hazard class categorisation of the hazard class categorisation of the hazard class for respiratory sensitisation in subfor respiratory sensitisation in subfor respiratory sensitisation in subfor respiratory sensitisation in subcategory 1A or 1B should be category 1A or 1B should be category 1A or 1B should be category 1A or 1B should be performed where sufficient performed where sufficient performed where sufficient performed where sufficient information to classify in those hazard sub-categories is available, hazard sub-categories is available, hazard sub-categories is available, hazard sub-categories is available. in order to avoid over- or underin order to avoid over- or underin order to avoid over- or underin order to avoid over- or underclassification. In view of the rapid classification. In view of the rapid classification. In view of the rapid classification. In view of the rapid development of scientific development of scientific development of scientific development of scientific knowledge and the long-standing knowledge and the long-standing knowledge and the long-standing knowledge and the long-standing expertise of the European expertise of the European expertise of the European expertise of the European Chemicals Agency (the 'Agency') Chemicals Agency (the 'Agency') Chemicals Agency (the 'Agency') Chemicals Agency (the 'Agency') and the European Food Safety Authority (the 'Authority') on the one hand, and the limited resources of Member States' competent of Member States' competent of Member States' competent of Member States' competent authorities to develop harmonised authorities to develop harmonised authorities to develop harmonised authorities to develop harmonised classification proposals on the classification proposals on the classification proposals on the classification proposals on the other, the Commission should have the right to request the Agency and the Authority to develop a harmonised classification and harmonised classification and harmonised classification and harmonised classification and labelling proposal. labelling proposal. labelling proposal. labelling proposal. 1. [Commission Delegated Regulation 1. [Commission Delegated Regulation 1. [Commission Delegated Regulation 1. [Commission Delegated Regulation amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging the classification, labelling and packaging the classification, labelling and packaging the classification, labelling and packaging

AT/CDP/RPG/nm 14625/5/23 REV 5 27 COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		of substances and mixtures, OJ XX of XX p XX.]	of substances and mixtures, OJ XX of XX p XX.]	of substances and mixtures, OJ XX of XX p XX.]	of substances and mixtures, OJ XX of XX p XX.]
					Text Origin: Commission Proposal
	Recital 1	8	L		
		(18) Harmonised classification and labelling proposals need not necessarily be limited to individual	(18) Harmonised classification and labelling proposals need not necessarily be limited to individual	(18) Harmonised classification and labelling proposals need not necessarily be limited to individual	(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	substances and could cover a group of similar substances, where such similarity <u>based on scientific</u> justification, allows for similar	substances and could cover a group of similar substances, where such similarity allows for similar classification of all substances in	substances and could cover a group of similar substances, where such similarity <u>based on scientific</u> <u>justification</u> , allows for similar
		the group. The purpose of such grouping is to alleviate the burden on manufacturers, importers or downstream users, the Agency and	classification of all substances in the group. The grouping process should be scientifically robust, coherent and transparent for all	the group. The purpose of such grouping is to alleviate the burden on manufacturers, importers or downstream users, the Agency and	classification of all substances in the group. The grouping process should be scientifically robust, coherent and transparent for all
G	27	the Commission in the procedure for harmonisation of classification and labelling of substances. It also avoids testing of substances when	stakeholders. The purpose of such grouping is to alleviate the burden on manufacturers, importers or downstream users, the Agency and	the Commission in the procedure for harmonisation of classification and labelling of substances. It also avoids testing of substances when	stakeholders. The purpose of such grouping is to alleviate the burden on manufacturers, importers or downstream users, the Agency and
		similar substances can be classified as a group.	the Commission in the procedure for harmonisation of classification and labelling of substances. It also	similar substances can be classified as a group.	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		avoids testing of substances when similar substances can be classified
			as a group Where it is scientifically justified and possible, proposals		as a group Where it is scientifically justified and possible, proposals
			for classification should prioritise groups of substances rather than		for classification should prioritise groups of substances rather than
			individual substances. In the event of a proposal for harmonised		individual substances. In the case of a proposal for harmonised

28 **EN** 14625/5/23 REV 5 AT/CDP/RPG/nm

COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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.		classification and labelling of a group of substances, those substances shall be grouped together based on clear scientific reasoning taking into account how the available information 1) supports the grouping of substances and 2) allows the property(ies)s of the substance(s) to be reliably predicted from other substances in the group." Text Origin: EP Mandate
F	ecital 1	9			
G	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 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	(19) To increase transparency and predictability of the proposals submitted to the Agency, the Member States' competent authorities, manufacturers, importers or downstream users should be required to notify the Agency of their intention to submit a proposal for harmonised classification and labelling, while the Commission should be required to notify the Agency of its request to the Agency or to the Authority to prepare such proposal. Furthermore, the Agency should be required to publish information on such intention or request and	(19) To increase transparency and predictability of the proposals submitted to the Agency, the Member States' competent authorities, manufacturers, importers or downstream users should be required to notify the Agency of their intention to submit a proposal for harmonised classification and labelling, while the Commission should be required to notify the Agency of its request to the Agency or to the Authority to prepare such proposal. Furthermore, the Agency should be required to publish information on such intention or request and	(19) To increase transparency and predictability of the proposals submitted to the Agency, the Member States' competent authorities, manufacturers, importers or downstream users should be required to notify the Agency of their intention to submit a proposal for harmonised classification and labelling, while the Commission should be required to notify the Agency of its request to the Agency or to the Authority to prepare such proposal. Furthermore, the Agency should be required to publish information on such intention or request and

29 14625/5/23 REV 5 AT/CDP/RPG/nm

EN COMPET 1

Commission Proposal EP Mandate Council Mandate Draft Agreement update the information regarding update the information regarding update the information regarding update the information regarding the submitted proposal at each stage of the procedure for the harmonised classification and harmonised classification and harmonised classification and harmonised classification and labelling of substances. For the labelling of substances. *Interested* labelling of substances. For the labelling of substances. For the same reason, a competent authority parties should be given the same reason, a competent authority same reason, a competent authority that receives a proposal for opportunity to comment where that receives a proposal for that receives a proposal for revision of a harmonised revision of a harmonised revision of a harmonised appropriate. For the same reason, a classification and labelling competent authority that receives a classification and labelling classification and labelling proposal for revision of a submitted by a manufacturer, submitted by a manufacturer, submitted by a manufacturer, importer or downstream user importer or downstream user importer or downstream user harmonised classification and should be required to communicate labelling submitted by a should be required to communicate should be required to communicate its decision to accept or refuse the manufacturer, importer or its decision to accept or refuse the its decision to accept or refuse the proposal for revision to the downstream user should be proposal for revision to the proposal for revision to the Agency, which should share that Agency, which should share that Agency, which should share that required to communicate its information with the other information with the other decision to accept or refuse the information with the other competent authorities. receives a proposal for revision to the competent authorities. receives a competent authorities. receives a proposal for revision of a Agency, which should share that proposal for revision of a proposal for revision of a harmonised classification and harmonised classification and harmonised classification and information with the other labelling submitted by a labelling submitted by a labelling submitted by a competent authorities, receives a manufacturer, importer or proposal for revision of a manufacturer, importer or manufacturer, importer or downstream user should be harmonised To increase the downstream user should be downstream user should be required to communicate its efficiency of the harmonized required to communicate its required to communicate its classification and labelling decision to accept or refuse the decision to accept or refuse the decision to accept or refuse the proposal for revision to the submitted by a manufacturer, proposal for revision to the proposal for revision to the Agency, which should share that Agency, which should share that importer or downstream Agency, which should share that information with the other user process, the Commission information with the other information with the other competent authorities. should be required to communicate competent authorities. competent authorities The its decision to accept or refuse the Commission should adopt without proposal for revision to the undue delay, and preferably Agency, which should share that before the end of the calendar information with the other vear following the publication of competent authoritiesadopt a the opinion of the Committee for delegated act, no later than 12 Risk Assessment delegated acts.

14625/5/23 REV 5 AT/CDP/RPG/nm 30
COMPET 1

COMPET I

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			months following the publication of the RAC opinion.		Text Origin: EP Mandate
	Recital 2	0			
G	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 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.	(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 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.	(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 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.	(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 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. Text Origin: Council Mandate
	Recital 2	1			

14625/5/23 REV 5 AT/CDP/RPG/nm 31 COMPET 1

EN

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 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 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.	(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 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.	(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 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.	(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 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 I disruption for human health category I or endocrine disruptors category I disruption for the environment category I in Table 3 in Part 3 of Annex VI to Regulation (EC) No 1272/2008. Text Origin: Council Mandate
Recital	22			
g 31				

32 14625/5/23 REV 5 AT/CDP/RPG/nm

EN COMPET 1

(22) As Article 5(1), point (e), of Regulation (EU) No 528/2012¹ 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 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 Council² 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.

Commission Proposal

(22) As Article 5(1), point (e), of Regulation (EU) No 528/2012¹ 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 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 Council² 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.

EP Mandate

(22) As Article 5(1), point (e), of Regulation (EU) No 528/2012¹ 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 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 Council² 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.

Council Mandate

(22) As Article 5(1), point (e), of Regulation (EU) No 528/2012¹ 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 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 Council² 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.

Draft Agreement

AT/CDP/RPG/nm 14625/5/23 REV 5 33 COMPET 1

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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. 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. 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. 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).	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. 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). Text Origin: Commission Proposal
	Recital 2	3			
G	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 of the Agency as provided for in Article 37(4) of Regulation (EC) No 1272/2008.	(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 of the Agency as provided for in Article 37(4) of Regulation (EC) No 1272/2008.	(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 consultation of the Agency as provided for in Article 37(4) of Regulation (EC) No 1272/2008. To avoid duplication of ongoing	(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 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	work by authorities under

34 14625/5/23 REV 5 AT/CDP/RPG/nm EN COMPET 1

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Regulation (EC) No 1272/2008	Regulation (EC) No 1272/2008
		and Regulation (EC) 1907/2006,	and Regulation (EC) 1907/2006,
		Regulation (EC) 1107/2009 and	Regulation (EC) 1107/2009 and
		Regulation (EU) 528/2012,	Regulation (EU) 528/2012,
		delegated acts should also be	delegated acts should also be
		adopted within an adequate	adopted within an adequate
		deadline for substances which	deadline for substances which are
		are foreseen to be added to the	foreseen to be added to the
		candidate list under Article 59 of	candidate list under Article 59 of
		Regulation (EC) No 1907/2006;	Regulation (EC) No 1907/2006;
		substances for which	substances for which applications
		applications for approval or	for approval or renewal of
		renewal of approval have been	approval have been submitted in
		submitted in accordance with the	accordance with the relevant
		relevant provisions of Regulation	provisions of Regulation (EC) No
		(EC) No 1107/2009; substances	1107/2009; substances for which
		for which the evaluating	the evaluating competent
		competent authority has	authority has submitted its draft
		submitted its draft assessment	assessment report on the approval or renewal of approval to the
		report on the approval or renewal of approval to the	Agency in accordance with
		Agency in accordance with	Regulation (EU)
		Regulation (EU)	No 528/2012, or substances for
		No 528/2012, or substances for	which the application was
		which the application was	submitted for the purpose of
		submitted for the purpose of	Directive 98/8/EC and the
		Directive 98/8/EC and the	Member State's evaluation in
		Member State's evaluation in	accordance with that Directive has
		accordance with that Directive	been completed by 1 September
		has been completed by 1	2013 but no decision on the
		September 2013 but no decision	approval was adopted before that
		on the approval was adopted	date, or substances for which the
		before that date, or substances	Agency has submitted to the
		for which the Agency has	Commission an opinion pursuant

14625/5/23 REV 5 AT/CDP/RPG/nm 35

COMPET 1 EN

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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.	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. Text Origin: Council Mandate
Recital 2	4			
33	(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	(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	(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	(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

14625/5/23 REV 5 AT/CDP/RPG/nm 36
COMPET 1
EN

Commission Proposal classification entries. As a result. classification entries. As a result. the classification and labelling the classification and labelling inventory contains divergent inventory contains divergent classifications, which makes the classifications, which makes the inventory less effective as a hazard inventory less effective as a hazard collection and communication tool collection and communication tool and leads to incorrect and leads to incorrect classifications, ultimately classifications, ultimately hindering the ability of Regulation hindering the ability of Regulation (EC) No 1272/2008 to protect (EC) No 1272/2008 to protect human health and the environment. human health and the environment. Therefore, the notifiers should be Therefore, the notifiers should be required to provide reasons for required, without needing to divergence from the most severe acquire new data or new studies classification or for introducing a being necessary, to provide more severe classification per reasons for divergence from the hazard class for the same substance most severe classification or for to the Agency. To address introducing a more severe divergences between more recent classification per hazard class for and obsolete classifications. the same substance to the Agency. notifiers should be required to To address divergences between update their notifications within 6 more recent and obsolete months after a decision to change classifications, notifiers should be the classification and labelling of a required to update their substance has been taken pursuant notifications within 6 months after to a review in Article 15(1) of that a decision to change the Regulation. 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

classification entries. As a result, the classification and labelling inventory contains divergent classifications, which makes the inventory less effective as a hazard collection and communication tool and leads to incorrect classifications, ultimately hindering the ability of Regulation (EC) No 1272/2008 to protect human health and the environment. Therefore, the notifiers should be required to provide reasons for divergence from the most severe classification or for introducing a more severe classification per hazard class for the same substance to the Agency. To address divergences between more recent and obsolete classifications. notifiers should be required to update their notifications within 6 months after a decision to change the classification and labelling of a substance has been taken pursuant to a review in Article 15(1) of that Regulation.

Council Mandate

classification entries. As a result, the classification and labelling inventory contains divergent classifications, which makes the inventory less effective as a hazard collection and communication tool and leads to incorrect classifications, ultimately hindering the ability of Regulation (EC) No 1272/2008 to protect human health and the environment. Therefore, the notifiers should be required, based on the available data that was used for *classification*, 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 require the notifier to rectify an entry that is incomplete, incorrect or obsolete and to notify the Agency thereof.

Draft Agreement

AT/CDP/RPG/nm 14625/5/23 REV 5 37

notifications from the inventory

after having informed the notifier.

EP Mandate

COMPET 1

Recital 24a (24a) Regulation (EC) No 1272/2008 lays down specific rules on packaging that should be fitted with child-resistant packaging and with a tacille warning. It is important to ensure that these provisions ensure a high level of protection of human health. The Commission should therefore within 5 years from the entry into force of this Regulation, assess the effectiveness of these provisions and the need to extend provisions to other hazard classes, in particular to extend requirements for child-resistant fastenings to eve damage category 1, and consult the expert group set up in accordance with Article 53a(4) of the Regulation (EC) No 1272/2008 thereof. If such need is identified, the Commission should adopt a delegated act amending Annex II to that Regulation as soon as possible.		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
(24a) Regulation (EC) No 1272/2008 lays down specific rules on packaging that should be fitted with child-resistant packaging and with a tactile warning. It is important to ensure a high level of protection of human health. The Commission should therefore within 5 years from the entry into force of this Regulation, assess the effectiveness of these provisions and the need to extend provisions to other hazard classes, in particular to extend requirements for child-ratific 4 six of the content of the regulation of the regulation (EC) No 1272/2008 thereof. If such need is identified, the Commission should and alegated act amending Annex II to that Regulation as					Text Origin: EP Mandate
1272/2008 lays down specific rules on packaging that should be fitted with child-resistant packaging and with a tactile warning. It is important to ensure that these provisions ensure a high level of protection of human health. The Commission should therefore within 5 years from the entry into force of this Regulation, assess the effectiveness of these provisions and the need to extend provisions to other hazard classes, in particular to extend requirements for child-resistant fastenings to eye damage category I, and consult the expert group set up in accordant fastenings to the Regulation (EC) No 1272/2008 thereof. If such need is identified, the Commission should adopt a delegated act amending Annex II to that Regulation as	Recital 24a				
Recital 25					1272/2008 lays down specific rules on packaging that should be fitted with child-resistant packaging and with a tactile warning. It is important to ensure that these provisions ensure a high level of protection of human health. The Commission should therefore within 5 years from the entry into force of this Regulation, assess the effectiveness of these provisions and the need to extend provisions to other hazard classes, in particular to extend requirements for child-resistant fastenings to eye damage category 1, and consult the expert group set up in accordance with Article 53a(4) of the Regulation (EC) No 1272/2008 thereof. If such need is identified, the Commission should adopt a delegated act amending Annex II to that Regulation as

14625/5/23 REV 5

AT/CDP/RPG/nm

COMPET 1

EN

38

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G 34	(25) In order to enhance transparency of notifications as well as to facilitate the notifiers' duty to come to an agreed notification entry for the same substance, certain information notified to the Agency's classification and labelling inventory should be made publicly available, free of charge. Without prejudice to the protection of commercial interests, that information should include the identity of the notifiers as, knowing whom to contact, would facilitate the objective of coming to an agreed entry to be included in that classification and labelling inventory. In the case of notifications by a group of manufacturers or importers, it should suffice to make publicly available the identity of the notifier submitting the information on behalf of the other members of the group.	(25) In order to enhance transparency of notifications as well as to facilitate the notifiers' duty to come to an agreed notification entry for the same substance, eertainall 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.	(25) In order to enhance transparency of notifications as well as to facilitate the notifiers' duty to come to an agreed notification entry for the same substance, certain information notified to the Agency's classification and labelling inventory should be made publicly available, free of charge. Without prejudice to the protection of commercial interests, that information should include the identity of the notifiers as, knowing whom to contact, would facilitate the objective of coming to an agreed entry to be included in that classification and labelling inventory. In the case of notifications by a group of manufacturers or importers, it should suffice to make publicly available the identity of the notifier submitting the information on behalf of the other members of the group.	(25) In order to enhance transparency of notifications as well as to facilitate the notifiers' duty to come to an agreed notification entry for the same substance, certainall 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. The Agency should provide for the conditions for notifiers to claim confidentiality and display them in the inventory. It should put in place adequate measures to prevent and identify undue confidentiality claims, in

39 **EN** 14625/5/23 REV 5 AT/CDP/RPG/nm

COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					particular by performing IT screening and spot checks. Text Origin: EP Mandate
	Recital 2	6			
G	35	(26) Pursuant to Article 45(1) 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	(26) Pursuant to Article 45(1) 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	(26) Pursuant to Article 45(1) 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	(26) Pursuant to Article 45(1) 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

14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		hazardous mixtures in other Member States or where they rebrand or relabel hazardous mixtures.	hazardous mixtures in other Member States or where they rebrand or relabel hazardous mixtures.	hazardous mixtures in other Member States or where they rebrand or relabel hazardous mixtures.	hazardous mixtures in other Member States or where they rebrand or relabel hazardous mixtures. Text Origin: Commission Proposal
	Recital 2	7			
G	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	(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	(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	(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

41 14625/5/23 REV 5 AT/CDP/RPG/nm

COMPET 1 EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		receiving the relevant information, should a Member State wish to do so.	receiving the relevant information, should a Member State wish to do so.	receiving the relevant information, should a Member State wish to do so.	receiving the relevant information, should a Member State wish to do so. Text Origin: Commission Proposal
	Recital 2	8			
G	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 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.	(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.

42 14625/5/23 REV 5 AT/CDP/RPG/nm

COMPET 1 EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Council Mandate
	Recital 2	9			
G	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. 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	(29) Regulation (EC) No 1272/2008 regulates advertisement of hazardous substances and mixtures in a general manner and provides that an advertisement for a substance classified as hazardous is to mention the hazard classes or hazard categories concerned, and an advertisement for a mixture classified as hazardous or a mixture containing a classified substance is to mention the types of hazards indicated on the label where such advertisement allows concluding a contract for purchase without first having sight of the label. This obligation should be changed to ensure that the advertisement of hazardous substances and mixtures contains all the information which is most important in terms of safety and protection of health and the environment. Therefore, the advertisement should contain the hazard pictogram, the signal word, the hazard class and the hazard statements. The hazard category should not be provided, as it is	(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 and the environment. Therefore, the advertisement should contain the hazard pictogram, the signal word, the hazard elass and the hazardstatements and supplemental EUH statements,	(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 and the environment. Therefore, the advertisement should contain the hazard elass and the hazardstatements and supplemental EUH statements,

14625/5/23 REV 5 AT/CDP/RPG/nm 43 EN

COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		reflected by the hazard statement.	reflected by the hazard statement.	with derogations for non-visual advertisement. The hazard category should not be provided, as it is reflected by the hazard statement.	with derogations for non-visual advertisement. The hazard category should not be provided, as it is reflected by the hazard statement. Text Origin: Council Mandate
	Recital 2	9a			
G	38a				(29a) It is appropriate to clarify that advertisement for a substance or a mixture classified as hazardous should not contain statements such as 'non-toxic', 'non-harmful', 'non-polluting', 'ecological' or other statements indicating that this substance or mixture is not hazardous or any other statements that are inconsistent with its classification, to ensure proper communication of information on the hazards and safe use of the chemicals to consumers and coherence with statements and claims allowed on product labels regarding such claims under this Regulation. This approach, together with other provisions in Union law, would ensure that consumers can make informed purchasing decisions having clear, reliable and non-

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

44

EN

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				misleading information with regard to hazardous substances and mixtures.
Recita	al 30			
6 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 prestage 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 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	(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 prestage 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 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	(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 prestage 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 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	(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 prestage 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 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

45 14625/5/23 REV 5 AT/CDP/RPG/nm

EN COMPET 1

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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, 27.10.2022, p. 1).	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, 27.10.2022, p. 1).	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 Council¹-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 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).	obligations laid down for providers of online marketplaces in Article 31 of Regulation (EU) 2022/2065 of the European Parliament and of the Council¹ 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 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). Text Origin: Council Mandate
Recital 3	31	,		
6 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	(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	(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	(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

46 14625/5/23 REV 5 AT/CDP/RPG/nm

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 access to that information.	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 access to that information.	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 access to that information.	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 access to that information. Text Origin: Commission Proposal
Recit	al 32			
s 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	(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	(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	(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

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

47

EN

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 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.

Commission Proposal

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).

2. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification,

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 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.

EP Mandate

- 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).
- 2. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification,

Council Mandate

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 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, 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,

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 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.

Draft Agreement

- 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).
- 2. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification,

14625/5/23 REV 5 AT/CDP/RPG/nm 48
COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	mixture Directiv and am	g and packaging of substances and ses, amending and repealing wes 67/548/EEC and 1999/45/EC, ending Regulation (EC) No 2006 (OJ L 353, 31.12.2008, p. 1).	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).	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).	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). Text Origin: Commission Proposal
	Recital 32a		-		
G	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 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.	deleted Council drops AM
	Recital 33		l		

14625/5/23 REV 5 AT/CDP/RPG/nm 49 COMPET 1

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		(33) In accordance with Directive	(33) In accordance with Directive	(33) In accordance with Directive	(33) In accordance with Directive
		2010/63/EU of the European	2010/63/EU of the European	2010/63/EU of the European	2010/63/EU of the European
		Parliament and of the Council ¹ , it is	Parliament and of the Council ¹ , it is	Parliament and of the Council ¹ , it is	Parliament and of the Council ¹ , it is
		necessary to replace, reduce or	necessary to replace, reduce or	necessary to replace, reduce or	necessary to replace, reduce or
		refine testing on animals.	refine testing on animals, with a	refine testing on animals.	refine testing on animals, with a
		Implementation of Regulation (EC)	view to phasing out the use of	Implementation of Regulation (EC)	view to phasing out the use of
		No 1272/2008 should be based on	animals for testing as soon as	No 1272/2008 should be based on	animals for testing as soon as
		the use of alternative test methods,	<i>possible</i> . Implementation of	the use of alternative test methods,	scientifically possible.
		suitable for the assessment of	Regulation (EC) No 1272/2008	suitable for the assessment of	Implementation of Regulation (EC)
		health and environmental	should be based on the <i>promotion</i>	health and environmental	No 1272/2008 should be based on
		classification of chemicals,	and use of alternative test	classification of chemicals,	theaim at the promotion and use
		wherever possible. In order to	methods New Approach	wherever possible. In order to	of alternative approaches, in
		speed up the transition to non-	<u>Methodologies (NAM)</u> , suitable for	speed up the transition to non-	particular non-animal test
		animal methods, with the ultimate	the assessment of health and	animal methods, with the ultimate	methods, suitable for the
		goal of fully replacing animal	environmental classification of	goal of fully replacing animal	assessment of health and
G	42	testing, as well as to improve the	chemicals, wherever possible. In	testing, as well as to improve the	environmental classification of
	,-	efficiency of chemical hazard	order to speed up the transition to	efficiency of chemical hazard	chemicals, wherever possible. In
		assessments, innovation in the field	non-animal methods, with the	assessments, innovation in the field	order to speed up the transition to
		of non-animal methods should be	ultimate goal of fully replacing	of non-animal methods should be	non-animal methods, with the
		monitored and systematically	animal testing, as well as to	monitored and systematically	ultimate goal of fully replacing
		evaluated, and the Commission and	improve the efficiency of chemical	evaluated, and the Commission and	animal testing, as well as to
		the Member States acting in the	hazard assessments, innovation in	the Member States should	improve the efficiency of chemical
		interest of the Union should	the field of non-animal methods	cooperate efficiently and be in	hazard assessments, innovation in
		promote the inclusion of	should be <i>promoted</i> , monitored	line with Union positions in	the field of non-animal methods
		harmonised criteria based on	and systematically and	accordance with the Treaties to	should be <i>promoted</i> , monitored
		available alternative methods in	periodically evaluated, and the	acting in the interest of the Union	and systematically regularly
		UN GHS and subsequently include	Commission and the Member	should promote the inclusion of	evaluated, and. The Commission
		those criteria in Regulation (EC)	States acting in the interest of the	harmonised criteria based on	and the Member States acting in
		No 1272/2008 without undue	Union should promote the inclusion of harmonised criteria	available alternative methods in	the interest of the Union
		delay.	based on available alternative	UN GHS and subsequently include	should should cooperate with a
		1. Directive 2010/63/EU of the European		those criteria in Regulation (EC) No 1272/2008 without undue	<u>view to</u> promote the inclusion of harmonised criteria based on
		Parliament and of the Council of 22	methods, in UN GHS and		available alternativeadaptation of
			memous, iii ON GHS and	delay.	ачиниые инетнинуе цииришон о <u>ј</u>

50 14625/5/23 REV 5 AT/CDP/RPG/nm

EN COMPET 1

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).	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).	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).	criteria to alternative approaches, in particular non-animal test 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). Text Origin: EP Mandate
Recital 3	34			
3 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	(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	(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	(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

51 14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1 EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.	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.	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.	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. Text Origin: Commission Proposal
	Recital 3	5			
G	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.	(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. Text Origin: Commission Proposal
	Recital 3	5a			
G	44a		(35a) Where appropriate, the Agency should provide further		(35a) Where appropriate, the Agency should provide further

52 **EN** 14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			guidance on the application of the provisions relating to the review of this Regulation.		guidance on the application of the provisions relating to the review of this Regulation. Text Origin: EP Mandate
	Recital 3	6			
G	45	(36) Regulation (EC) No 1272/2008 should therefore be amended accordingly.	(36) Regulation (EC) No 1272/2008 should therefore be amended accordingly.	(36) Regulation (EC) No 1272/2008 should therefore be amended accordingly.	(36) Regulation (EC) No 1272/2008 should therefore be amended accordingly. Text Origin: Commission Proposal
	Recital 3	6a			
G	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.		(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.
	Recital 3	7			

14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1 EN

53

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G	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-classified and re-labelled in accordance with this Regulation, to avoid additional burden on suppliers of substances and mixtures.	(37) To ensure that suppliers of substances and mixtures have time to adapt to <u>new</u> 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 reclassified and re-labelled in accordance with this Regulation, to avoid additional burden on suppliers of substances and mixtures.	(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-classified and re-labelled in accordance with this Regulation, to avoid additional burden on suppliers of substances and mixtures.	(37) To ensure that suppliers of substances and mixtures have time to adapt to <u>new</u> 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 reclassified and re-labelled in accordance with this Regulation, to avoid additional burden on suppliers of substances and mixtures. Text Origin: EP Mandate
	Recital 3	8			
G	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	(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	(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	(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

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

54

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		deferred application of this Regulation.	deferred application of this Regulation.	deferred application of this Regulation.	deferred application of this Regulation. Text Origin: Commission Proposal
	D :: 10				TIOPODUI
	Recital 3	9			
G	48	(39) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States, because environmental pollution is transboundary and the citizens 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,	(39) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States, because environmental pollution is transboundary and the citizens 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,	(39) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States, because environmental pollution is transboundary and the citizens 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,	(39) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States, because environmental pollution is transboundary and the citizens 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, Text Origin: Commission Proposal

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm 55

EN

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Formula				
s 49	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION: Text Origin: Commission Proposal
Article 1				
50	Article 1	Article 1	Article 1	Article 1 Text Origin: Commission Proposal
Article 1	, first paragraph			
51	Regulation (EC) No 1272/2008 is amended as follows:	Regulation (EC) No 1272/2008 is amended as follows:	Regulation (EC) No 1272/2008 is amended as follows:	Regulation (EC) No 1272/2008 is amended as follows: Text Origin: Commission Proposal
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		EP drops its AM

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

56

EN

		Commission Proposal	EP Mandate	Council N	Mandate	Draft Agreement
			protection of human health and the environment including the promotion of alternative methods, for assessment of hazards of substances and mixtures, as well as the free movement of substances, mixtures and articles as referred to in Article 4(8) by: (a) harmonising the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures; (b) providing an obligation for: (i) manufacturers, importers and downstream users to classify substances and mixtures placed on the market; (ii) suppliers to label and package substances and mixtures placed on the market; (iii) manufacturers, producers of articles and importers to classify those substances not placed on the market that are subject to registration or notification under Regulation (EC) No 1907/2006;"			
	Article 1,	, first paragraph, point (1)				
G	52	(1) in Article 1(1), the following point (f) is added:	(1) in Article 1(1), the following point (f) is added:	(1) in Article 1(1) point (f) is added:	, the following	(1) in Article 1(1), the following point (f) is added:

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

57

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (1), amending	provision, first paragraph		
G	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 emergency health response to appointed bodies in accordance with Annex VIII.;	(f) providing an obligation for downstream users, importers and distributors referred to in Article 45(1) to submit information relevant for providing an adequate emergency health response to appointed bodies in accordance with Annex VIII.;	(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 emergency health response to appointed bodies in accordance with Annex VIII.';	(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 emergency health response to appointed bodies in accordance with Annex VIII.2;
	Article 1,	, first paragraph, point (2)			
G	54	(2) Article 2 is amended as follows:	(2) Article 2 is amended as follows:	(2) in Article 2, the following points 38 to 41 are added is amended as follows:	(2) in Article 2, the following points 38 to 41 are added is amended as follows: Text Origin: Council Mandate
	Article 1,	, first paragraph, point (2)(a)			
G	55	(a) the following point is inserted:	deleted	(a) the following point is inserted:	deleted

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm 58

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 1,	first paragraph, point (2)(a), amendi	ng provision, first paragraph		
G	56	7a. 'multi-constituent substance' means a substance that contains more than one constituent.	deleted	deleted	deleted
	Article 1,	first paragraph, point (2)(b)			
G	57	(b) the following point is added:	(b) the following point is added:	deleted	deleted
	Article 1,	first paragraph, point (2)(b), amendin	ng provision, numbered paragraph (38	3)	
G	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 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 eriteria 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.;	38. 'acute toxicity estimates' means numeric eriteria 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.; Text Origin: Council Mandate
	Article 1,	, first paragraph, point (2)(b), amendi	ng provision, numbered paragraph (38	3a)	
G	58a			39. 'data carrier' means a linear bar code symbol, a two-	39. 'data carrier' means a linear bar code symbol, a two-

59 14625/5/23 REV 5 AT/CDP/RPG/nm EN

COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				dimensional symbol or other automatic identification data capture medium that can be read by a device;	dimensional symbol or other automatic identification data capture medium that can be read by a device; Text Origin: Council Mandate
	Article 1	, first paragraph, point (2)(b), amendi	ng provision, numbered paragraph (38	(b)	
G	58b		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;	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;	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; Text Origin: Council Mandate
	Article 1	, first paragraph, point (2)(b), amendir	ng provision, numbered paragraph (38	Sc)	
G	58c		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;	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.;	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.;

14625/5/23 REV 5 AT/CDP/RPG/nm 60

EN COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Council Mandate
	Article 1,	, first paragraph, point (2)(ba)			
G	58d		(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 consideration, where relevant."		EP drops its AM.
	Article 1,	, first paragraph, point (3)			
G	59	(3) in Article 4, paragraph 10 is replaced by the following:	(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:	(3) in Article 4, paragraph 10 is replaced by the following is amended as follows: Text Origin: Council Mandate
	Article 1	first paragraph, point (3)(a), first sub	naragranh		
G	59a	, mat paragraph, pomt (3)(a), mat aub	paragraph	(a) paragraph 3 is replaced by	(a) paragraph 3 is replaced by the

14625/5/23 REV 5 AT/CDP/RPG/nm 61 COMPET 1

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				the following	following Text Origin: Council Mandate
	Article 1,	first paragraph, point (3)(a), second s	subparagraph		
G	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.	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. Text Origin: Council Mandate
	Article 1,	first paragraph, point (3)(b)			
G	59c			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.	(b) 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 or physical state of that substance.

14625/5/23 REV 5 AT/CDP/RPG/nm 62 COMPET 1

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Council Mandate
	Article 1	first paragraph, point (3)(c)			
G	59d			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.'	(c) 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.' Text Origin: Council Mandate
	Article 1	first paragraph, point (3)(b)			
G	59e			(b) the following paragraph 11 is added:	G
	Article 1	, first paragraph, point (3), amending _I	provision, numbered paragraph (10)		
G	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	of an industrial or professional activity that the substance or the 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	to 1011. 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 unlessonly if it ensures	10. A substance or a mixture shall not be placed on the market unless a supplier, established has ensured in the course of an industrial or professional activity that the substance or the mixture Union,

14625/5/23 REV 5 AT/CDP/RPG/nm 63 EN COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		out in this Regulation.;	out in this Regulation.;	that a supplier has ensuredestablished 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.';	who shall be identified 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; Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (4)			
G	61	(4) in Article 5, the following paragraph 3 is added:	(4) in Article 5, the following paragraph 3 is added:	deleted	(4) in''(4) Article 5, is amended as follows: (a) in paragraph 1 the following point (ca) is added: 'ca) data obtained from new approach methodologies;'; (b) the following paragraph 3 isparagraphs 3 to 8 are added: Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (4), amending	provision, numbered paragraph (3), fi	rst subparagraph	
G	62				C

14625/5/23 REV 5 AT/CDP/RPG/nm EN COMPET 1

64

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 leastmore 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	3. A multi-constituent substance containing at leastmore 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 in accordance with the criteria set out in this paragraphevaluated, using the available information on those known constituents as well as on the substance, unless Annex I lays down a specific provision itself. Text Origin: EP Mandate
Article 6 63	For the evaluation of multiconstituent substances pursuant to Chapter 2 in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine disrupting property for human health' and 'endocrine disrupting property for the environment' hazard classes referred to in sections 3.5.3.1, 3.6.3.1, 3.7.3.1, 3.11.3.1. and 4.2.3.1. of Annex I, the manufacturer, importer or	For the evaluation of multi- constituentthese substances containing more than one constituent pursuant to Chapter 2 in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive 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	cond subparagraph deleted	4. For the evaluation of multiconstituent substances substances containing more than one constituent pursuant to Chapter 2 in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine disrupting propertydisruption for human health' and 'endocrine disrupting propertydisruption 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

14625/5/23 REV 5 AT/CDP/RPG/nm 65
COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual constituents in the substance.	4.2.3.13.5., 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.		4.2.3.13.5., 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 individualknown constituents in the substance. Text Origin: EP Mandate
	Article 1	, first paragraph, point (4), amending	provision, numbered paragraph (3), th	ird subparagraph	
G	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	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: Text Origin: EP Mandate
	Article 1	, first paragraph, point (4), amending	provision, numbered paragraph (3), th	nird subparagraph, point (a)	
G	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 <i>disrupting</i> properties disruption for human health or the environment;	deleted	(a) (a) the information demonstrates germ cell mutagenic, carcinogenic, or toxic to reproduction properties, or endocrine disrupting properties disruption for human health or the environment;

66 14625/5/23 REV 5 AT/CDP/RPG/nm EN

COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: EP Mandate
	Article 1,	, first paragraph, point (4), amending	provision, numbered paragraph (3), th	ird subparagraph, point (b)	
G	66	(b) the information supports the conclusions based on the relevant available information on the constituents in the substance.	(b) the information supports the conclusions based on the relevant available information on the constituents in the substance.	deleted	(b) the information supports the conclusions based on the relevant available information on the constituents in the substance. Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (4), amending	provision, numbered paragraph (3), fo	urth subparagraph	
G	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	_Relevant available information on the <i>multi-constituent substancesubstance containing more than one constituent</i> itself showing absence of <i>certainthe</i> properties <i>referred to in point (a)</i> or less severe properties shall not override the relevant available information on the constituents in the substance.
	Article 1,	, first paragraph, point (4), amending	provision, numbered paragraph (3), fif	th subparagraph	
G	68	For the evaluation of multi- constituent substances pursuant to	For the evaluation of multi- constituent substances substances	deleted	5. For the evaluation of multi-constituent substances substances

14625/5/23 REV 5 AT/CDP/RPG/nm 67
COMPET 1 EN

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.		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 individualknown constituents in the substance. Text Origin: EP Mandate
Article 1	, first paragraph, point (4), amending	provision, numbered paragraph (3), six	xth subparagraph	
⁶ 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 multiconstituent substance itself shall be taken into account where one of the following conditions are met:	deleted	Relevant available information on the <u>substance containing more</u> than one constituent multiconstituent substance itself shall be taken into account where one of the following conditions are met:

68 **EN** 14625/5/23 REV 5 AT/CDP/RPG/nm

COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: EP Mandate
	Article 1,	first paragraph, point (4), amending	provision, numbered paragraph (3), si	xth subparagraph, point (a)	
G	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	(a) the information demonstrates biodegradation, persistence, mobility and bioaccumulation properties or lack of degradation. Text Origin: EP Mandate
	Article 1,	first paragraph, point (4), amending	provision, numbered paragraph (3), si	xth subparagraph, point (b)	
G	71	(b) the information supports the conclusions based on the relevant available information on the constituents in the substance.	(b) the information supports the conclusions based on the relevant available information on the constituents in the substance.	deleted	(b) the information supports the conclusions based on the relevant available information on the constituents in the substance. Text Origin: EP Mandate
	Article 1,	first paragraph, point (4), amending	provision, numbered paragraph (3), se	eventh subparagraph	
G	72	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 <i>substance containing more than one constituent multi-constituent substance</i> itself showing absence of <i>certain the</i> properties <i>referred to in (a)</i> or less severe properties shall not override the relevant available information on the constituents in the substance.	deleted	Relevant available information on the multi-constituent substance substance containing more than one constituent itself showing absence of certainthe properties referred to in point (a) or less severe properties shall not override the relevant available information on the constituents in the substance.

14625/5/23 REV 5 AT/CDP/RPG/nm 69
COMPET 1 EN

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				(5) Article 6 is amended as follows: (a) in paragraph 1 the following point (ca) is added: 'ca) data obtained from new approach methodologies';' (b) paragraphs 3 and 4 are replaced by the following: Text Origin: EP Mandate
Article	1, first paragraph, point (4), amending	provision, numbered paragraph (3), se	eventh subparagraph a	
6 72a		4a. 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 1107/2009¹ or Regulation (EU) No 528/2012.² 1. 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. 2. Regulation (EU) No 528/2012 of the		6. Paragraphs 4 and 5 shall not apply to substances containing more than one constituent which are extracted from plants or plant parts and which are not chemically modified according to Article 3 (40) of Regulation (EC) No 1907/2006. 7. For the purpose of paragraph 6, 'plants' refers to living or dead organisms from the kingdoms Plantae and Fungi. It includes algae, lichens and yeasts. 8. For certain substances containing more than one constituent that are not covered by paragraph 6, where the

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

70

EN

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.		Commission receives evidence that the rules set out in paragraphs 4 or 5 may not be suitable for certain substances containing more than one constituent, the Commission may request the Agency to evaluate the available data. The Commission is empowered to adopt delegated acts in accordance with Article 53a to amend Annex I by creating a new section and by including and modifying, in that section, the derogations from paragraphs 4 or 5 on classification of substances containing more than one constituent. For those delegated acts, the Commission shall take into account scientific evidence, advances in knowledge, and the opinion of the Agency when available, to appropriately classify substances containing more than one constituent provided that a high level of protection of human health and the environment is ensured. Text Origin: EP Mandate
Article 1, first	paragraph, point (5), amending p	provision, numbered paragraph (1ca),	nının subparagraph	

14625/5/23 REV 5 AT/CDP/RPG/nm

COMPET 1 EN

71

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G	72b				deleted
	Article 1,	first paragraph, point (4), amending	provision, numbered paragraph (3), te	nth subparagraph	
G	72c				deleted
	Article 1,	first paragraph, point (5)			
G	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:	(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: Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (5a)			
G	73a				deleted
	Article 1,	first paragraph, point (5a), amending	g provision, numbered paragraph (3), j	irst subparagraph	
G	74	3. For the evaluation of mixtures pursuant to chapter 2 in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine disrupting	3. For the evaluation of mixtures pursuant to chapter 2 of this Title in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine	3. For the evaluation of mixtures pursuant to Chapter 2 of this Title in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine	3. For the evaluation of mixtures pursuant to Chapter 2 of this Title in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine

14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1

EN

72

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.	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.	disrupting propertydisruption for human health' and 'endocrine disrupting propertydisruption 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	disrupting propertydisruption for human health' and 'endocrine disrupting propertydisruption 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. Text Origin: Council Mandate
	Article 1,	, first paragraph, point (5a), amending	 g provision, numbered paragraph (3), s	l second subparagraph	
G	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 subparagraph, that data shall also be taken into account for the purposes of the evaluation of the mixture 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 germ cell mutagenic, carcinogenic or toxic to reproduction properties, or endocrine disrupting properties for human health or the environment	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 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	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 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

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

73

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		subparagraph.	which have not been identified from the relevant available information on the individual substance referred to in the first subparagraph, <i>data on the mixture</i> 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.	subparagraph.	subparagraph. Text Origin: Council Mandate
	Article 1	, first paragraph, point (5a), amending	provision, numbered paragraph (3a),	numbered paragraph (4)	
G	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, mobile and toxic' and 'very persistent and very mobile' hazard classes referred to in sections 4.1.2.8, 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall only use the relevant available information referred to in paragraph 1 for the substances in the mixture and not for the mixture itself;	4. For the evaluation of mixtures pursuant to Chapter 2 of this Title in relation to the 'biodegradation, persistency, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment', 'persistent, bioaccumulative and toxic', 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' and 'very persistent and very mobile' hazard classes referred to in sections 4.1.2.8, 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall only use the relevant available information referred to in paragraph 1 for the substances in the mixture and not	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 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	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 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

74 14625/5/23 REV 5 AT/CDP/RPG/nm EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		· ·	for the mixture itself 2;	paragraph 1— for the substances in the mixture and not for the mixture itself itself.';	paragraph 1—for the substances in the mixture and not for the mixture itself itself.'; It should be point (5) and not (5a) - to be corrected at the consolidated version. Text Origin: Council Mandate
	Article 1,	, first paragraph, point (5a), amending	provision, numbered paragraph (3a),	numbered paragraph (4) a	
G	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 evaluating the mixture referred to in the first subparagraph.		deleted Ok to drop EP AM
	Article 1,	first paragraph, point (5a), amending	provision, -a paragraph		
G	76b		(5a) Article 7 is replaced by the following:		deleted

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

75

EN

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		"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. 4. Tests using new approach methodologies shall also be considered."		
Article 1,	first paragraph, point (5a), amending	g provision, -b paragraph		
c 76c			5a. in Article 8, the following paragraph 7 is added:'7. The Commission shall regularly evaluate the development of alternative test	deleted Council dropped AM

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

76

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				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)			
G	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:	(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: Text Origin: Commission Proposal
	Article 1	, first paragraph, point (6), amending	provision, numbered paragraph (3)		
G	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	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	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	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

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

77

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Annex XI to Regulation (EC) No 1907/2006.	mixture, and in accordance with section 1.2 of Annex XI to Regulation (EC) No 1907/2006.	Annex XI to Regulation (EC) No 1907/2006.	Annex XI to Regulation (EC) No 1907/2006. Text Origin: Commission Proposal
	Article 1,	first paragraph, point (6), amending	provision, numbered paragraph (4), fir	rst subparagraph	
G	79	4. When evaluating hazard information for mixtures, manufacturers, importers and 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.	4. When evaluating hazard information for mixtures, manufacturers, importers and 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.	4. When evaluating hazard information for mixtures, manufacturers, importers and 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.	4. When evaluating hazard information for mixtures, manufacturers, importers and 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. Text Origin: Commission Proposal
	Article 1,	first paragraph, point (6), amending	provision, numbered paragraph (4), se	cond subparagraph	
G	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	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	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	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

78 **EN** 14625/5/23 REV 5 AT/CDP/RPG/nm

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.	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.	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 to select the most suitable similar tested mixtures according to Article 6(5) for decision on classification.	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 to select the most suitable similar tested mixtures according to Article 6(5) for decision on classification. Text Origin: Council Mandate
	Article 1	, first paragraph, point (6), amending	provision, numbered paragraph (4), th	ird subparagraph	
G	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.;	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.;

79 **EN** 14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Commission Proposal
	Article 1,	first paragraph, point (7)			
G	82	(7) Article 10 is replaced by the following:	(7) Article 10 is replaced by the following:	(7) Article 10 is replaced by the following:	(7) Article 10 is replaced by the following: Text Origin: Commission Proposal
	Article 1,	first paragraph, point (7), amending	provision, first paragraph		
G	83	Article 10	Article 10	Article 10	Article 10 Text Origin: Commission Proposal
	Article 1,	first paragraph, point (7), amending	provision, second paragraph		
G	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	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 Text Origin: Commission Proposal
	Article 1,	first paragraph, point (7), amending	provision, numbered paragraph (1), fi	rst subparagraph	
G	85				G

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

80

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.	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. Text Origin: Commission Proposal
	Article 1,	first paragraph, point (7), amending	provision, numbered paragraph (1), se	econd subparagraph	
G	86	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 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.	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. Text Origin: Council Mandate

81 14625/5/23 REV 5 AT/CDP/RPG/nm EN

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 1	L, first paragraph, point (7), amending	provision, numbered paragraph (1), th	ird subparagraph	
c 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 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.	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 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.	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 information shows that thethat 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.	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 information shows that thethat 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. Text Origin: Council Mandate
Article 1	L, first paragraph, point (7), amending	provision, numbered paragraph (2)		
с 88	2. M-factors for substances classified as hazardous to the aquatic environment, acute category 1 or chronic category 1, shall be established by	2. M-factors for substances classified as hazardous to the aquatic environment, acute category 1 or chronic category 1, shall be established by	2. Manufacturers, importers and downstream users shall establish M-factors for substances classified as hazardous to the aquatic environment, acute category 1 or	2. Manufacturers, importers and downstream users shall establish M-factors for substances classified as hazardous to the aquatic environment, acute category 1 or

82 **EN** 14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		manufacturers, importers and downstream users.	manufacturers, importers and downstream users.	chronic category 1 , shall be established by manufacturers, importers and downstream users.	chronic category 1, shall be established by manufacturers, importers and downstream users. Text Origin: Council Mandate
	Article 1,	first paragraph, point (7), amending	provision, numbered paragraph (3)		
G	89	3. Acute toxicity estimates for substances classified as acutely toxic for human health shall be established by manufacturers, importers and downstream users.	3. Acute toxicity estimates for substances classified as acutely toxic for human health shall be established by manufacturers, importers and downstream users.	3. Acute toxicity estimates for substances classified as acutely toxic for human health shall be established by manufacturers, importers and downstream users.	3. Acute toxicity estimates for substances classified as acutely toxic for human health shall be established by manufacturers, importers and downstream users. Text Origin: Commission Proposal
	Article 1,	first paragraph, point (7), amending	provision, numbered paragraph (4)		
G	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, 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.	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. Text Origin: Council Mandate
	Article 1,	first paragraph, point (7), amending	provision, numbered paragraph (5)		

14625/5/23 REV 5 AT/CDP/RPG/nm 83 EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G	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.	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 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.	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 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. Text Origin: Council Mandate
		6. By way of derogation from	6. By way of derogation from	6. By way of derogation from	6. By way of derogation from
G	92	paragraph 3, acute toxicity estimates shall not be established for harmonised hazard classes or	paragraph 3, acute toxicity estimates shall not be established for harmonised hazard classes or	paragraph 3, acute toxicity estimates shall not be established for harmonised hazard classes or	paragraph 3, acute toxicity estimates shall not be established for harmonised hazard classes or

14625/5/23 REV 5 AT/CDP/RPG/nm 84 EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		differentiations for substances included in Part 3 of Annex VI for which an acute toxicity estimate is given in that Part.	differentiations for substances included in Part 3 of Annex VI for which an acute toxicity estimate is given in that Part.	differentiations for substances included in Part 3 of Annex VI for which an acute toxicity estimate is given in that Part.	differentiations for substances included in Part 3 of Annex VI for which an acute toxicity estimate is given in that Part. Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (7), amending	ı provision, numbered paragraph (7), fi	rst subparagraph	
G	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.	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. Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (7), amending	provision, numbered paragraph (7), se	econd subparagraph	
G	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	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	deleted	deleted Text Origin: Commission Proposal

85 14625/5/23 REV 5 AT/CDP/RPG/nm EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.	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 (8)		
G	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 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.	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. Text Origin: Council Mandate
	Article 1,	, first paragraph, point (7), amending	provision, numbered paragraph (9)		
G	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.	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. Text Origin: Commission

14625/5/23 REV 5 AT/CDP/RPG/nm 86 EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Proposal
	Article 1,	, first paragraph, point (7), amending	provision, numbered paragraph (10)		
G	97	10. Where a mixture contains a substance which is classified as hazardous solely due to the 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.	10. Where a mixture contains a substance which is classified as hazardous solely due to the 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.	10. Where a mixture contains a substance which is classified as hazardous solely due to the 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.	10. Where a mixture contains a substance which is classified as hazardous solely due to the 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)		
G	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 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.';	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. 2;

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

87

EN

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Ar	ticle 1, first paragraph, point (7a)			
			(7a) Article 13 is replaced by the	(7a) Article 13 is replaced by the
			following:	following:
			Article 13	Article 13
			Decision to classify substances	Decision to classify substances
			and mixtures	and mixtures
			If the evaluation undertaken	If the evaluation undertaken
			pursuant to Article 9 and Article	pursuant to Article 9 and Article
			12 shows that the hazards associated with the substance or	12 shows that the hazards associated with the substance or
			mixture meet the criteria for	mixture meet the criteria for
			classification in one or more	classification in one or more
			hazard classes or differentiations	hazard classes or differentiations
			in Parts 2 to 5 of Annex I,	in Parts 2 to 5 of Annex I,
			manufacturers, importers and	manufacturers, importers and
G G	98a		downstream users shall classify	downstream users shall classify
			the substance or mixture or, if	the substance or mixture or, if
			scientifically justified, specific	scientifically justified, specific
			forms or physical states thereof,	forms or physical states thereof, in
			in relation to the relevant hazard	relation to the relevant hazard
			class or classes or differentiations	class or classes or differentiations
			by assigning the following:	by assigning the following:
			(a) one or more hazard categories for each relevant	(a) one or more hazard categories for each relevant
			hazard class or differentiation;	hazard class or differentiation;
			(b) subject to Article 21, one or	(b) subject to Article 21, one or
			more hazard statements	more hazard statements
			corresponding to each hazard	corresponding to each hazard
			category assigned in accordance	category assigned in accordance
			with (a).	with (a).

88 14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1

EN

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Council Mandate
Article	1, first paragraph, point (7b)			
s 98b		(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 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;		EP drops the AM here

14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1

EN

89

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			(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 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 (7c)			
G	98c		(7b) In Article 18, paragraph 3, point (b) is replaced by the following:	(7c) in Article 18(3), point (b) is replaced by the following:'(b) the identity of all substances	(7c) in Article 18(3), point (b) is replaced by the following: '(b) the identity of all substances

90 **EN** 14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			"(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 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."	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), aspiration hazard, or endocrine disruption for human health.'	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), aspiration hazard, persistent, bioaccumulative and toxic (PBT), very persistent, very bioaccumulative (vPvB), persistent, mobile and toxic (PMT), very persistent, very mobile (vPvM) properties, or endocrine disruption for human health or the environment.' this provision is 7(c), and not (b) as in the title. to be corrected at the consolidated version.
	Article 1	, first paragraph, point (8)			
G	99	(8) in Article 23, the following point (g) is added:	(8) in Article 23, the following point (g) is added:	(8) in Article 23, the following point (g) is added:	(8) in Article 23, the following point (g) is added: Text Origin: Commission Proposal
	Article 1	, first paragraph, point (8), amending	provision, first paragraph		

14625/5/23 REV 5 AT/CDP/RPG/nm 91 COMPET 1

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G]	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* 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 acquisition and possession of weapons (OJ L 115, 6.4.2021, p. 1).	(g) ammunition as defined in Article 1(1), point (3), of Directive (EU) 2021/555 of the European Parliament and of the Council **I 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 acquisition and possession of weapons (OJ L 115, 6.4.2021, p. 1).' Text Origin: Council Mandate
	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).;	* 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).;	deleted Text Origin: Commission Proposal

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

92

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 1,	first paragraph, point (8a)			
G	101a			(8a) In Article 24(2), the second subparagraph is replaced by the following: 'The level of the fees shall be determined by the Commission by means of implementing act in accordance with the examination procedure referred to in Article 54(2) of this Regulation.'	(8a) In Article 24(2), the second subparagraph is replaced by the following: 'The level of the fees shall be determined by the Commission by means of implementing act in accordance with the examination procedure referred to in Article 54(2) of this Regulation.' Text Origin: Council Mandate
	Article 1	, first paragraph, point (8b)			
G	101b		(8a) In Article 25, paragraphs 2 and 3 are replaced by the following: "2. A statement shall be included in the section for supplemental information on the label where a substance or mixture classified as hazardous falls within the scope of 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		deleted

93 **EN** 14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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)			
G	102	(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:	(9) In-Article 25, paragraph 6, the first subparagraph is replaced by the following is amended as follows:	(9) In Article 25, paragraph 6, the first subparagraph is replaced by the following is amended as follows: Text Origin: Council Mandate
	Article 1,	, first paragraph, point (9)(a)			
G	102a			(x) paragraph 3 is replaced by the following:	(x) paragraph 3 is replaced by the following: Text Origin: Council Mandate
	Article 1,	, first paragraph, point (9)(a), amendir	ng provision, first paragraph		
G	102b			c	c

14625/5/23 REV 5

AT/CDP/RPG/nm

COMPET 1 EN

94

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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.'	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.'
Article 1	, first paragraph, point (9)(b)			
³ 102c			(a) in paragraph 6, the first subparagraph is replaced by the following:	(a) in paragraph 6, the first subparagraph is replaced by the following: Text Origin: Council Mandate
Article 1	, first paragraph, point (9), amending p	provision, first paragraph		
103	The specific labelling rules set out in Part 2 of Annex II shall apply to	6. The specific labelling rules set out in Part 2 of Annex II shall	6. The specific special labelling rules set out in Part 2 of Annex II	The specific special labelling rules set out in Part 2 of Annex II shall

95 14625/5/23 REV 5 AT/CDP/RPG/nm

EN COMPET 1

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	mixtures containing substances referred to in that Annex.;	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.;	shall apply to mixtures containing substances referred to in part 2 of that Annex.';	apply to mixtures containing substances referred to in part 2 of that Annex.2; Text Origin: Council Mandate
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:	(10) In Article 25, the following paragraph is added:	(10) In Article 25, (b) the following paragraph (9) is added: Text Origin: Commission Proposal
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.;	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.;

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

96

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (11)			
G	106	(11) Article 29 is amended as follows:	(11) Article 29 is amended as follows:	(11) Article 29 is amended as follows:	(11) Article 29 is amended as follows: Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (11)(a)			
G	107	(a) paragraph 1 is replaced by the following:	(a) paragraph 1 is replaced by the following:	(a) paragraph 1 is replaced by the following:	(a) paragraph 1 is replaced by the following: Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (11)(a), amend	ing provision, numbered paragraph (1)	
G	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),	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),	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	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

14625/5/23 REV 5
COMPET 1
AT/CDP/RPG/nm
97
EN

					Draft Agreement
		shall be provided in accordance with sections 1.5.1.1. and 1.5.1.2. of Annex I.;	shall be provided in accordance with sections 1.5.1.1. and 1.5.1.2. of Annex I.;	Article 17(1), shall be provided in accordance with sections 1.5.1.1. and 1.5.1.2section 1.5.1. of Annex I.';	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.2; Text Origin: Council Mandate
Α	Article 1,	first paragraph, point (11)(b)			
G	109	(b) paragraph 3 is replaced by the following:	(b) paragraph 3 is replaced by the following:	(b) paragraph 3 is replaced by the following:	(b) paragraph 3 is replaced by the following: Text Origin: Commission Proposal
А	Article 1,	first paragraph, point (11)(b), amend	ing provision, numbered paragraph (3	3)	
G	110	3. Where a hazardous substance or mixture referred to in Part 5 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.;	3. Where a hazardous substance or mixture referred to in Part 5 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.;	3. Where a hazardous substance or mixture referred to in Part 5 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.';	3. Where a hazardous substance or mixture referred to in Part 5 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.; Text Origin: Commission Proposal

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

98

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
O	111	(c) the following paragraphs 4b and 4c are inserted:	(c) the following paragraphs 4b and 4c are inserted:	(c) the following paragraphs 4b and 4c areparagraph 4b is inserted:	(c) the following paragraphs 4b and 4c are paragraph 4b is inserted: Text Origin: Council Mandate
	Article 1,	first paragraph, point (11)(c), amend	ing provision, first paragraph		
G	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 staff, and sufficient camouflaging cannot be ensured.	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 staff, and sufficient camouflaging cannot be ensured.	4b. By derogation from Article 17(1), the labelling requirement set out in that Article shall not apply to packaging of ammunition that is usedintended for use 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 or the staff, and sufficient camouflaging cannot be ensured.	4b. By derogation from Article 17(1), the labelling requirement set out in that Article shall not apply to packaging of ammunition that is usedintended for use 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 or the staff, and sufficient camouflaging cannot be ensured. 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 Article 17.'; Text Origin: Council Mandate

14625/5/23 REV 5 AT/CDP/RPG/nm 99

EN COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 1,	first paragraph, point (11)(c), amend	ing provision, second paragraph		
G	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, 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).;	4e. Where paragraph 4b applies, manufacturers 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.';	deleted Text Origin: Council Mandate
	Article 1,	first paragraph, point (12)			
G	114	(12) Article 30 is replaced by the following:	(12) Article 30 is replaced by the following:	(12) Article 30 is replaced by the following:	(12) Article 30 is replaced by the following: Text Origin: Commission Proposal
	Article 1,	first paragraph, point (12), amending	g provision, first paragraph		
G	115	Article 30	Article 30	Article 30	Article 30 Text Origin: Commission Proposal
	Article 1,	first paragraph, point (12), amending	provision, second paragraph		

14625/5/23 REV 5 AT/CDP/RPG/nm 100

COMPET 1 EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G	116	Updating information on labels	Updating information on labels	Updating information on labels	Updating information on labels Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (12), amending	provision, numbered paragraph (1)		
G	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 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.	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. Text Origin: Council Mandate
	Article 1,	, first paragraph, point (12), amending	provision, numbered paragraph (2)		
G	118	2. Where a change regarding the classification and labelling of a substance or a mixture is required	2. Where a change regarding the classification and labelling of a substance or a mixture is required	2. Where a change regarding the classification and or labelling of a substance or a mixture is required	2. Where a change regarding the classification and or labelling of a substance or a mixture is required

14625/5/23 REV 5 AT/CDP/RPG/nm 101

COMPET 1 EN

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	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. Text Origin: Council Mandate
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.	deleted Council dropped AM.
Article 1	, first paragraph, point (12), amending	provision, numbered paragraph (3)		
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	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	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	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

102 14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.	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.	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.	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. Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (12), amending	provision, numbered paragraph (4)		
G	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;	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; Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (13)			
G	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 added31 is amended as follows:	(13) in Article 31(3), the following sentence is added 31 is amended as follows: Text Origin: Council Mandate

14625/5/23 REV 5 AT/CDP/RPG/nm 103

COMPET 1 EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 1,	, first paragraph, point (13), amending	provision, numbered paragraph (-1)		
G	121a		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."	(a) paragraph 1 is replaced by the following: '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.'	(a) paragraph 1 is replaced by the following: 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.' Text Origin: Council Mandate
	Article 1,	, first paragraph, point (13), amending	provision, numbered paragraph (-1),	point (a), first subparagraph	
G	121b			(b) the following paragraph 1a is inserted:	(b) the following paragraphs 1x and 1a are inserted: Text Origin: Council Mandate
	Article 1,	, first paragraph, point (13), amending	provision, numbered paragraph (-1),	point (a), second subparagraph	
	121c				'Ix. Where the label is presented in the form of a foldout-label, the label elements referred to in Article 17(1) shall

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

104

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					be presented in accordance with Section 1.2.1.6 of Annex I.';
	Article 1,	first paragraph, point (13), amending	provision, numbered paragraph (-1),	point (b)	
G	121d			'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.	'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. Text Origin: Council Mandate
	Article 1,	first paragraph, point (13), amending	provision, numbered paragraph (-1),	point (c)	
G	121e			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.'	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.' Text Origin: Council Mandate
	Article 1,	first paragraph, point (13), amending	provision, numbered paragraph (-1),	point (d)	
G	121f				

14625/5/23 REV 5 AT/CDP/RPG/nm 105

COMPET 1 EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				(c) paragraph 3 is replaced by the following:	(c) paragraph 3 is replaced by the following:
					Text Origin: Council Mandate
	Article 1,	, first paragraph, point (13), amending	g provision, numbered paragraph (3)		
G	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.;	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.; Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (13a)			
G	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		deleted EP dropped its AM

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

106

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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)			
G	123	(14) in Article 32, paragraph 6 is deleted;	(14) in Article 32, paragraph 6 is deleted;	(14) in Article 32, paragraph 6 is deleted;	(14) in Article 32, paragraph 6 is deleted; Text Origin: Commission Proposal
	Article 1,	first paragraph, point (15)			
G	124	(15) in Title III, the following Chapter 3 is added:	(15) in Title III, the following Chapter 3 is added:	(15) in Title III, the following Chapter 3 is added:	(15) in Title III, the following Chapter 3 is added: Text Origin: Commission Proposal
	Article 1,	first paragraph, point (15), amending	provision, first paragraph		
G	125	CHAPTER 3	CHAPTER 3	CHAPTER 3	CHAPTER 3 Text Origin: Commission Proposal
	Article 1,	first paragraph, point (15), amending	provision, second paragraph		

14625/5/23 REV 5 AT/CDP/RPG/nm 107

COMPET 1 EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G	126	Formats of the labelling	Formats of the labelling	Formats of the labelling formats	Formats of the labelling Labelling formats Text Origin: Council Mandate
	Article 1,	first paragraph, point (15), amending	provision, third paragraph		
G	127	Article 34a	Article 34a	Article 34a	Article 34a Text Origin: Commission Proposal
	Article 1,	first paragraph, point (15), amending	provision, fourth paragraph		
G	128	Physical and digital labelling	Physical and digital labelling	Physical and digital labelling	Physical and digital labelling Text Origin: Commission Proposal
	Article 1,	first paragraph, point (15), amending	provision, numbered paragraph (1)		
G	129	1. The label elements referred to in Article 17 shall be provided:	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 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').	1. The label elements for substances and mixtures referred to in Article 17 shall be provided: on a label in a 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').

108 14625/5/23 REV 5 AT/CDP/RPG/nm EN COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Council Mandate
	Article 1	, first paragraph, point (15), amending	g provision, numbered paragraph (1), p	point (a)	
G	130	(a) on a label in a physical form ('physical label'); or	(a) on a label in a physical form ('physical label'); or	deleted	deleted
	Article 1,	first paragraph, point (15), amending	g provision, numbered paragraph (1), μ	point (b)	
G	131	(b) both on a physical label and on a label in a digital form ('digital label').	(b) both on a physical label and on a label in a digital form ('digital label').	deleted	deleted
	Article 1,	first paragraph, point (15), amending	provision, numbered paragraph (2)		
G	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.	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 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	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 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.

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

109

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				purchase and free of charge.	Text Origin: Council Mandate
	Article 1,	, first paragraph, point (15), amending	provision, numbered paragraph (2a)		
G	132a			3. Where the information is provided through a digital label, the requirements for digital labels set out in Article 34b shall apply.	3. Where the information is provided through a digital label, the requirements for digital labels set out in Article 34b shall apply. Text Origin: Council Mandate
	Article 1,	, first paragraph, point (15), amending	provision, seventh paragraph		
G	133	Article 34b	Article 34b	Article 34b	Article 34b Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (15), amending	provision, eighth paragraph		
G	134	Requirements for digital labelling	Requirements for digital labelling	Requirements for digital labellinglabels	Requirements for digital labelling Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (15), amending	provision, numbered paragraph (1)		
G	135	1. The digital label for substances and mixtures shall satisfy the following general rules and	1. The digital label for substances and mixtures shall satisfy the following general rules and	1. The supplier who pursuant to Article 31(1a) places a data carrier linking to a digital label	1. The supplier who pursuant to Article 31(1a) places a data carrier linking to a digital label

110 14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1 EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		technical requirements:	technical requirements:	shall ensure that the digital label satisfies for substances and mixtures shall satisfy the following general rules and technical requirements:	shall ensure that the digital label satisfies for substances and mixtures shall satisfy the following general rules and technical requirements: Text Origin: Council Mandate
	Article 1	, first paragraph, point (15), amending	provision, numbered paragraph (1), p	point (a)	
G	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 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;	(a) all label elements referred to in Article 17(1) shall be provided together in one place and separated from other information; Text Origin: Council Mandate
	Article 1	, first paragraph, point (15), amending	g provision, numbered paragraph (1), p	point (b)	
G	137	(b) the information on the digital label shall be searchable;	(b) the information on the digital label shall be searchable;	(b) the information on the digital label shall be searchable;	(b) the information on the digital label shall be searchable; Text Origin: Commission Proposal
	Article 1	, first paragraph, point (15), amending	provision, numbered paragraph (1), p	point (c)	
G	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,	(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	(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

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

111

EN

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			where required by other Union legislation;	where required by other Union legislation;
				Text Origin: Council Mandate
Article	1, first paragraph, point (15), amending	g provision, numbered paragraph (1),	point (d)	
G 139	(d) the digital label shall be accessible free of charge, without the need to register, download or install applications, or to provide a password;	(d) the digital label shall be accessible free of charge, without the need to register, download or install <i>specific</i> applications, or to provide a password;	(d) the digital label shall be accessible free of charge, without the need to register, download or install applications, or to provide a password;	(d) the digital label shall be accessible free of charge, without the need to register, download or install applications, or to provide a password; Text Origin: Council Mandate
Article	1, first paragraph, point (15), amending	g provision, numbered paragraph (1),	point (e)	
c 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;	(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; Text Origin: Commission Proposal
Article	1, first paragraph, point (15), amending	provision, numbered paragraph (1),	point (f)	
6 141	(f) the information on the digital label shall be accessible with no	(f) the information on the digital label shall be accessible with no	(f) the information on the digital label shall be accessible with no	(f) the information on the digital label shall be accessible with no

112 14625/5/23 REV 5 AT/CDP/RPG/nm EN COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		more than two clicks;	more than two clicks;	more than two clicks;	more than two clicks;
					Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (15), amending	provision, numbered paragraph (1), p	point (g)	
G	142	(g) the digital label shall be accessible through digital technologies widely used and compatible with all major operating systems and browsers;	(g) the digital label shall be accessible through digital technologies widely used and compatible with all major operating systems and browsers;	(g) the digital label shall be accessible through digital technologies widely used and compatible with all major operating systems and browsers;	(g) the digital label shall be accessible through digital technologies widely used and compatible with all major operating systems and browsers; Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (15), amending	gprovision, numbered paragraph (1), p	point (h)	
G	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 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;	(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; Text Origin: Council Mandate
	Article 1,	, first paragraph, point (15), amending	g provision, numbered paragraph (1), p	point (i)	
G	144	(i) the link to the digital label shall be printed or placed physically,	(i) the link to the digital label shall be printed or placed physically,	deleted	deleted

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

113

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		visibly and legibly on the product in such a way that it can be processed automatically by digital devices widely used by consumers;	visibly and legibly on the product in such a way that it can be processed automatically by digital devices widely used by consumers;		
	Article 1,	first paragraph, point (15), amending	provision, numbered paragraph (1), p	point (j)	
G	145	(j) the digital label shall remain available for a period of 10 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.	(j) the digital label shall remain available for a period of 10 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.	deleted	deleted
	Article 1,	first paragraph, point (15), amending	provision, numbered paragraph (2)		
G	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.	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	deleted
	Article 1,	first paragraph, point (15), amending	provision, numbered paragraph (3)		

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G	147	3. It is prohibited to track, analyse or use any usage information for purposes going beyond what is absolutely necessary for provision of digital labelling;	3. It is prohibited to track, analyse or use any usage information for purposes going beyond what is absolutely necessary for provision of digital labelling;	3. It is prohibited to track, analyse or use any usage information for purposes going beyond what is absolutely necessary for provision of digital labelling;	3. It is prohibited to track, analyse or use any usage information for purposes going beyond what is absolutely necessary for provision of digital labelling; Text Origin: Commission Proposal
	Article 1	, first paragraph, point (16)			
G	148	(16) in Article 35, the following paragraph 2a is added:	(16) in Article 35, the following paragraph 2a is added:	(16) in Article 35, the following paragraph 2a is added:	(16) in Article 35, the following paragraph 2a is added: Text Origin: Commission Proposal
	Article 1	, first paragraph, point (16), amending	g provision, first paragraph		
G	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.;	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.; Text Origin: Council Mandate

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 1	first paragraph, point (16), amending	provision, first paragraph a		
G	149a		This paragraph shall not apply to hazardous substances or mixtures supplied to the general public without packaging in accordance with Article 29(3).	This paragraph shall not apply to hazardous substances or mixtures supplied to the general public without packaging in accordance with Article 29(3).';	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)			
G	150	(17) in Article 36, paragraph 1 is amended as follows:	(17) in Article 36, paragraph 1 is amended as follows:	(17) in Article 36, paragraph 1 is amended as follows:	(17) in Article 36, paragraph 1 is amended as follows: Text Origin: Commission Proposal
	Article 1,	first paragraph, point (17)(a)			
G	151	(a) point (a) is replaced by the following:	(a) point (a) is replaced by the following:	(a) point (a) is replaced by the following:	(a) point (a) is replaced by the following: Text Origin: Commission Proposal
	Article 1,	first paragraph, point (17)(a), amend	ing provision, first paragraph		
G	152	(a) respiratory sensitisation, category 1, 1A or 1B (Annex I,	(a) respiratory sensitisation, category 1, 1A or 1B (Annex I,	(a) respiratory sensitisation, category 1, 1A or 1B (Annex I,	(a) respiratory sensitisation, category 1, 1A or 1B (Annex I,

116 14625/5/23 REV 5 AT/CDP/RPG/nm EN COMPET 1

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	section 3.4.);	section 3.4.);	section 3.4.);	section 3.4.);
	,	,	,	Text Origin: Commission Proposal
Article	1, first paragraph, point (17)(b)			
G 153	(b) the following points (e) to (j) are added:	(b) the following points (e) to (j) are added:	(b) the following points (e) to (j) are added:	(b) the following points (e) to (j) are added: Text Origin: Commission Proposal
Article	1, first paragraph, point (17)(b), amend	ing provision, first paragraph		
G 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.);	(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.); Text Origin: Commission Proposal
Article	1, first paragraph, point (17)(b), amend	ing provision, second paragraph		
G 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.);	(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.); Text Origin: Commission Proposal

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

117

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 1	, first paragraph, point (17)(b), amend	ing provision, third paragraph	1	
G	156	(g) persistent, bioaccumulative and toxic (PBT) (Annex I, section 4.3.);	(g) persistent, bioaccumulative and toxic (PBT) (Annex I, section 4.3.);	(g) persistent, bioaccumulative and toxic (PBT) (Annex I, section 4.3-);	(g) persistent, bioaccumulative and toxic (<i>PBT</i>) (Annex I, section 4.3,); Text Origin: Council Mandate
	Article 1	, first paragraph, point (17)(b), amend	ling provision, fourth paragraph		
G	157	(h) very persistent, very bioaccumulative (vPvB) (Annex I, section 4.3.);	(h) very persistent, very bioaccumulative (vPvB) (Annex I, section 4.3.);	(h) very persistent, very bioaccumulative (vPvB) (Annex I, section 4.3-);	(h) very persistent, very bioaccumulative (**PvB)*(Annex I, section 4.3.); Text Origin: Council Mandate
	Article 1	, first paragraph, point (17)(b), amend	ing provision, fifth paragraph		
G	158	(i) persistent, mobile and toxic (PMT) (Annex I, section 4.4.);	(i) persistent, mobile and toxic (PMT) (Annex I, section 4.4.);	(i) persistent, mobile and toxic (PMT) (Annex I, section 4.4-);	(i) persistent, mobile and toxic (PMT) (Annex I, section 4.4.); Text Origin: Council Mandate
	Article 1	, first paragraph, point (17)(b), amend	ing provision, sixth paragraph		
G	159	(j) very persistent, very mobile (vPvM) (Annex I, section 4.4).;	(j) very persistent, very mobile (vPvM) (Annex I, section 4.4).;	(j) very persistent, very mobile (vPvM) (Annex I, section 4.4).';	(j) very persistent, very mobile (**PvM)*(Annex I, section 4.4)**.*, Text Origin: Council Mandate

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

118

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 1,	first paragraph, point (17)(c)			
G	160	(c) paragraph 2 is replaced by the following:	(c) paragraph 2 is replaced by the following:	(c) paragraph 2 is replaced by the following:	(c) paragraph 2 is replaced by the following: Text Origin: Commission Proposal
	Article 1,	first paragraph, point (17)(c), amend	ing provision, numbered paragraph (2)	
G	161	2. Substances that are active 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.;	2. Substances that are active 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.;	2. Substances that are active 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.;	2. Substances that are active 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.; Text Origin: Commission Proposal
	Article 1,	first paragraph, point (18)			
G	162	(18) Article 37 is amended as follows:	(18) Article 37 is amended as follows:	(18) Article 37 is amended as follows:	(18) Article 37 is amended as follows: Text Origin: Commission

COMPET 1

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Proposal
Article	1, first paragraph, point (18)(a)			
163	(a) paragraph 1 is replaced by the following:	(a) paragraph 1 is replaced by the following:	(a) paragraph 1 is replaced by the following:	(a) paragraph 1 is replaced by the following: Text Origin: Commission Proposal
Article	1, first paragraph, point (18)(a), amend	ling provision, numbered paragraph (1), first subparagraph	
³ 164	1. A competent authority may submit to the Agency a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof.	1. A competent authority may submit to the Agency a proposal for harmonised classification and labelling of <i>a substance or a group</i> of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof.	1. A competent authority may submit to the Agency a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof.	1. A competent authority may submit to the Agency a proposal for harmonised classification and labelling of <i>a substance or a group of</i> substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof. Text Origin: EP Mandate
Article	1, first paragraph, point (18)(a), amenc	ing 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	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	The Commission may ask request the Agency or the European Food Safety Authority established in accordance with Article 1(2) of Regulation (EC)	The Commission may ask request the Agency or the European Food Safety Authority established in accordance with Article 1(2) of Regulation (EC)

120 14625/5/23 REV 5 AT/CDP/RPG/nm EN COMPET 1

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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 harmonised classification could be necessary to protect human and animal health and the environment.	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, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p.1);	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. 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, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p.1); Text Origin: Council Mandate
Article 1	, first paragraph, point (18)(a), amend	ing provision, numbered paragraph (1), third subparagraph	
⁶ 166	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 <i>for harmonised</i> 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.	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.

121 14625/5/23 REV 5 AT/CDP/RPG/nm EN COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: EP Mandate
	Article 1,	first paragraph, point (18)(a), amend	ing provision, numbered paragraph (1	a)	
G	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 individual substances.'		Ia. 'Whenever considered scientifically justified and possible by a competent authority or the Commission, proposals for harmonised classification and labelling shall aim toprioritise groups of substances rather than individual substances.' Text Origin: EP Mandate
	Article 1,	first paragraph, point (18)(a), amend	ing provision, numbered paragraph (1), third subparagraph a	
	166b				Ib. The Agency and the European Food Safety Authority may, on their own initiative, provide scientific advice to the Commission and the competent authorities indicating that a harmonised classification and labelling of a substance or a group of substances would be appropriate.
	Article 1,	first paragraph, point (18)(a), amend	ing provision, numbered paragraph (1	.), fourth subparagraph	

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

122

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G	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);	* 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);		* 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); Text Origin: Commission Proposal
	Article 1,	first paragraph, point (18)(b)			
G	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:	(b) in paragraph 2, the first subparagraph is replaced by the following:	(b) in paragraph 2, the first subparagraph is replaced by the following: Text Origin: Commission Proposal
	Article 1,	first paragraph, point (18)(b), amend	ing provision, numbered paragraph (2	2)	
G	169	2. Manufacturers, importers or downstream users of substances may submit to the Agency a proposal for harmonised classification and labelling of those substances and, where appropriate, specific concentration limits, M-	2. Manufacturers, importers or downstream users of substances may submit to the Agency a proposal for harmonised classification and labelling of those substances and, where appropriate, specific concentration limits, M-	2. Manufacturers, importers or downstream users of substances may submit to the Agency a proposal for harmonised classification and labelling of those substances and, where appropriate, specific concentration limits, M-	2. Manufacturers, importers or downstream users of substances may submit to the Agency a proposal for harmonised classification and labelling of those substances and, where appropriate, specific concentration limits, M-

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.;	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.	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.;	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.; Text Origin: Commission Proposal
	Article 1,	first paragraph, point (18)(c)			
G	170	(c) the following paragraph 2a is inserted:	(c) the following paragraph 2a is inserted:	(c) the following paragraph 2a is inserted:	(c) the following paragraph 2a is inserted: Text Origin: Commission Proposal
	Article 1,	first paragraph, point (18)(c), amend	ing provision, first paragraph, first sub	paragraph	
G	171	2a. Before submitting a proposal to the Agency, a competent authority, manufacturer, importer or downstream user shall notify the	2a. Before submitting a proposal to the Agency, a competent authority, manufacturer, importer or downstream user shall notify the	2a. Before submitting a proposal to the Agency, a competent authority, manufacturer, importer or downstream user shall notify the	2a. Before submitting a proposal to the Agency, a competent authority, manufacturer, importer or downstream user shall notify the

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.	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.	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.	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. Text Origin: Council Mandate
	Article 1,	, first paragraph, point (18)(c), amend	ing provision, first paragraph, first sub	paragraph a	
G	171a				2b. "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 reasoning taking into account how the available information 1) supports the grouping of substances and 2) allows the property(ies)s of the substance(s) to be reliably predicted from other substances in the group." this shall be independent paragraph 10 in article 37, to be transversal to all. to adapt formatting in TTE later. also include this wording in row 391a
	Article 1,	, first paragraph, point (18)(c), amend	ing provision, first paragraph, second	subparagraph	

		-			
	72	Within one week from receipt of the notification, the Agency shall publish the name and, where relevant, the EC and CAS numbers of the substance(s), the status of the proposal and the name of the submitter. The Agency shall update the information on the status of the proposal after completion of each stage of the process referred to in Article 37(4) and (5).	Within one week from receipt of the notification, the Agency shall publish the name 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 update the information on the status of the proposal after completion of each stage of the process referred to in Article 37(4) and (5).	Within one week from receipt of the notification, the Agency shall publish the name 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 proposal after completion of each stage of the process referred to in Article 37(4) and (5).	Within one week from receipt of the notification, the Agency shall publish the name and, where relevant, the EC and CAS numbers of the substance(s), the status of the proposal and the name of the submitter. The Agency shall update the information on the status of the proposal after completion of each stage of the process referred to in Article 37(4) and (5). Text Origin: Commission Proposal
Arti	icle 1,	first paragraph, point (18)(c), amendi	ing provision, first paragraph, third su	bparagraph	
	73	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.;	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.; Text Origin: Commission Proposal

COMPET 1

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
174	(d) paragraph 3 is replaced by the following:	(d) paragraph 3 is replaced by the following:	(d) paragraph 3 is replaced by the following:	(d) paragraph 3 is replaced by the following: Text Origin: Commission Proposal
Article	e 1, first paragraph, point (18)(d), amend	ling provision, numbered paragraph (3	3)	
s 175	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 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).';	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).2; Text Origin: Council Mandate
Article	e 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:	(e) paragraphs 5 and 6 are replaced by the following:	(e) paragraphs 5 and 6 are replaced by the following: Text Origin: Commission Proposal

127 14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 1,	, first paragraph, point (18)(e), amend	ing provision, numbered paragraph (5), first subparagraph	
O	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, where appropriate, the specific concentration limits, M-factors or acute toxicity estimates in Table 3 of Part 3 of Annex VI.	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 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.	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 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.	5. The Commission shall adopt without undue delay, and preferably before the end of the calendar year following the publication of the opinion of the Committee for Risk Assessment, delegated acts in accordance with Article 53a and, where it finds that the harmonisation of the classification and labelling of the substance concerned is 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. Text Origin: EP Mandate
	Article 1,	, first paragraph, point (18)(e), amend	ing provision, numbered paragraph (5), second subparagraph	
G	178	Where, in the case of harmonisation of classification and labelling of substances, imperative grounds of urgency so require, the	Where, in the case of harmonisation of classification and labelling of substances, imperative grounds of urgency so require, the	Where, in the case of harmonisation of classification and labelling of substances, imperative grounds of urgency so require, the	Where, in the case of harmonisation of classification and labelling of substances, imperative grounds of urgency so require, the

COMPET 1

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	procedure provided for in Article 53b shall apply to delegated acts adopted pursuant to this paragraph.	procedure provided for in Article 53b shall apply to delegated acts adopted pursuant to this paragraph.	procedure provided for in Article 53b shall apply to delegated acts adopted pursuant to this paragraph.	procedure provided for in Article 53b shall apply to delegated acts adopted pursuant to this paragraph. Text Origin: Commission Proposal
Article	 1, first paragraph, point (18)(e), amend	 ing provision, numbered paragraph (6	j)	
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 in Part 3 of Annex VI shall submit a proposal in accordance with paragraph 2, second subparagraph, to the competent authority in one of the Member States in which the substances are placed on the market.;	6. Manufacturers, importers and downstream users who have new information which may lead to—a change of the harmonised classification and labelling elements of substances in Part 3 of Annex VI shall submit a proposal in accordance with paragraph 2, second subparagraph, to the competent authority in one of the Member States in which the substances are placed on the market. 2;	6. Manufacturers, importers and downstream users who have new information which may lead to a change of the harmonised classification and labelling elements of substances in Part 3 of Annex VI shall submit a proposal in accordance with paragraph 2, second subparagraph, to the competent authority in one of the Member States in which the substances are placed on the market.';	6. Manufacturers, importers and downstream users who have new information which may lead to a change of the harmonised classification and labelling elements of substances in Part 3 of Annex VI shall submit a proposal in accordance with paragraph 2, second subparagraph, to the competent authority in one of the Member States in which the substances are placed on the market.;
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 inserted:	(f) the following paragraphs 7 and 8 areparagraph 7 is inserted:	(f) the following paragraphs 7 and 8 areparagraph 7 is inserted: Text Origin: Council Mandate

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 1	first paragraph, point (18)(f), amendi	ng provision, numbered paragraph (7) first suhnaragranh	
	/ II ticic 1,		ing provision, nambered paragraph (7	, mst subparagraph	
		6	6	6	
		7. The Commission shall adout	7 Po 1 Income 2026 the	7 In and an to avail develoption	7 In andone to mucid development on of
		7. The Commission shall adopt delegated acts in accordance with	7. By 1 January 2026, the Commission shall adopt delegated	7. In order to avoid duplication of assessment of hazardous	7. <u>In order to avoid duplication of</u> assessment of hazardous
		Article 53a to amend Table 3 of	acts in accordance with Article 53a	properties of substances, the	
		Part 3 of Annex VI to this	to amend Table 3 of Part 3 of	Commission shall is empowered	properties of substances, the Commission shall is empowered to
		Regulation by inclusion of	Annex VI to this Regulation by	to adopt delegated acts in	adopt delegated acts in accordance
		substances as endocrine disruptor	inclusion of substances—as	accordance with Article 53a to	with Article 53a to amend Table 3
		category 1 for human health	endocrine disruptor category 1 for	amend Table 3 of Part 3 of Annex	of Part 3 of Annex VI to this
		properties, endocrine disruptor	human health properties, endocrine	VI to this Regulation to:	Regulation to:
		category 1 for environment	disruptor category 1 for	- include substances by [OP,	- include substances by [OP,
		properties, as persistent,	environment properties, as	please insert the date: 24 months	please insert the date: 18 months
		bioaccumulative and toxic or as	persistent, bioaccumulative and	after the entry into force of this	after the entry into force of this
		very persistent and very	toxic or , as very persistent and	Regulation] in Table 3 of Part 3	Regulation in Table 3 of Part 3 of
		bioaccumulative together with	very bioaccumulative, as	of Annex VI asby inclusion of	Annex VI as by inclusion of
G	181	relevant classification and labelling	persistent, mobile and toxic, or	substances as endocrine disruptor	substances as endocrine disruptor
	101	elements where, on [OP: please	very persistent and very mobile	category 1 for human health	category 1 for human health
		insert the date = the date of entry	together with relevant	properties, endocrine disruptor	properties, endocrine disruptor
		into force of Commission	classification and labelling	category 1 for environment	category 1 for environment
		Delegated Regulation (EU)i.e.	elements where, on 1 January	properties disruption for human	properties disruption for human
		delegated act on the new hazard	2025 together with relevant	healthcategory 1, endocrine	healthcategory 1, endocrine
		classes - reference to be added	classification and labelling	disruption for the	disruption for the
		once adopted], those substances	elements where, on [OP: please	environmentcategory 1, as	environmentcategory 1, as
		have been included in the	<i>insert the date = the date of entry</i>	persistent, bioaccumulative and	persistent, bioaccumulative and
		candidate list referred to in Article	into force of Commission	toxic, or as very persistent and,	toxic, or as very persistent and,
		59(1) of Regulation (EC) No	Delegated Regulation (EU)i.e.	very bioaccumulative, together	very bioaccumulative, together
		1907/2006.	delegated act on the new hazard	with relevant classification and	with relevant classification and
			classes - reference to be added	labelling elements on the basis of	labelling elements on the basis of
			once adopted], those substances	respective criteria where, on	respective criteria where, on on
			have been included in the	on [OP: please insert the date = 6	[OP: please insert the date = <u>6</u>
			candidate list referred to in Article	months after the date of entry into	months after the date of entry into

COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			59(1) of Regulation (EC) No 1907/2006.	force of Commission Delegated this Regulation (EU)i.e. delegated act on the new hazard elasses—reference to be added once adopted], those substances: (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,	force of Commission Delegated this Regulation (EU)i.e. delegated act on the new hazard classes reference to be added once adopted], those substances: (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. Text Origin: Council Mandate
	Article 1,	first paragraph, point (18)(f), amendi	ng provision, numbered paragraph (7)), second subparagraph	
G	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.'	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	deleted
	Article 1,	first paragraph, point (18)(f), amend	ng provision, numbered paragraph (7), second subparagraph a	

COMPET 1

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
c 182a			(c) have been identified as having endocrine disrupting 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.	(c) have been identified as having endocrine disrupting 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. Text Origin: Council Mandate
Article 1	, first paragraph, point (18)(f), amendi	ing provision, numbered paragraph (7), second subparagraph a, point (a)	
s 182b			- 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 basis of respective criteria where:	- 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 basis of respective criteria where:

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm 132

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Council Mandate
	Article 1,	first paragraph, point (18)(f), amendi	ng provision, numbered paragraph (7), second subparagraph a, point (b)	
G	182c			(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]	(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] Text Origin: Council Mandate
	Article 1,	first paragraph, point (18)(f), amendi	ng provision, numbered paragraph (7)), second subparagraph a, point (c)	
G	182d			(b) 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 (EC) No 1107/2009 before [OP, please	(b) 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 (EC) No 1107/2009 before [OP, please

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm 133

EN

Artic				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	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]	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] Text Origin: Council Mandate
s 182	icle 1, f	first paragraph, point (18)(f), amendi	ng provision, numbered paragraph (7	a)	
Artio				(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 where, by the date of [OP: please insert the date – 6 months after the entry into force of this Regulation]:	(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 where, by the date of [OP: please insert the date – 6 months after the entry into force of this Regulation]:

14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1

EN

134

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
3 182f			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	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 Text Origin: Council Mandate
Article 1	, first paragraph, point (18)(f), amendi	ing provision, numbered paragraph (7	a), point (b)	
3 182g			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 that date, or	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 that date, or Text Origin: Council Mandate
Article 1	, first paragraph, point (18)(f), amendi	ng provision, numbered paragraph (7	a), point (c)	
182h			iii. the Agency has submitted to the Commission an opinion pursuant to Article 75(1)(g) of	iii. the Agency has submitted to the Commission an opinion pursuant to Article 75(1)(g) of

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm 135

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Regulation (EU) No 528/2012 following a request to establish whether the respective criteria are met.	Regulation (EU) No 528/2012 following a request to establish whether the respective criteria are met. Text Origin: Council Mandate
	Article 1,	first paragraph, point (18)(f), amendi	ng provision, numbered paragraph (8), b.	
G	183	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. 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 3Section 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 (EUEC)i.e. the delegated actNo 1107/2009 and a decision on the new hazard classes—reference to be added once adopted] application for approval or the	8b. 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 3Section 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 (EUEC)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

136 14625/5/23 REV 5 AT/CDP/RPG/nm EN COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				renewal of approval of those substances have not been approved, has been adopted 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:	renewal of approval of those substances have not been approved, has been adopted 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:
	Article 1,	first paragraph, point (18)(f), amendi	ng provision, numbered paragraph (8), b., point (a)	
G	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;	(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	deleted
	Article 1,	first paragraph, point (18)(f), amendi	ng provision, numbered paragraph (8), b., point (b)	
G	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;	(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	deleted
	Article 1,	first paragraph, point (18)(f), amendi	ng provision, numbered paragraph (8), b., point (c)	

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G	186	(c) endocrine disruptor for human health or for the environment in accordance with Article 1 of Commission Delegated Regulation (EU) 2017/2100*;	(c) endocrine disruptor for human health or for the environment in accordance with Article 1 of Commission Delegated Regulation (EU) 2017/2100*;	deleted	deleted
	Article 1,	first paragraph, point (18)(f), amend	ing provision, numbered paragraph (8)), b., point (d)	
G	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.	(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	deleted
	Article 1,	first paragraph, point (18)(f), amend	ng provision, numbered paragraph (8,), second subparagraph	
G	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).';	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	deleted
	Article 1,	first paragraph, point (18)(f), amend	ing provision, numbered paragraph (8)), third subparagraph	
G	189	* Commission Delegated Regulation (EU) 2017/2100 of 4	* Commission Delegated Regulation (EU) 2017/2100 of 4	this is the footnote to (c) line 186	deleted

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.;	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.;	was deleted, same as the main text in line 186	
	Article 1,	first paragraph, point (19)			
G	190	(19) In Article 38(1), point (c) is replaced by the following:	(19) In Article 38(1), point (c) is replaced by the following:	(19) In Article 38(1), point (c) is replaced by the following:	(19) In Article 38(1), point (c) is replaced by the following: Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (19), amending	g provision, first paragraph		
G	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;;	(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;; Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (20)			
G	192	(20) Article 40 is amended as	(20) Article 40 is amended as	(20) Article 40 is amended as	(20) Article 40 is amended as

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		follows:	follows:	follows:	follows:
					Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (20)(a)			
G	193	(a) in paragraph 1, the first subparagraph is amended as follows:	(a) in paragraph 1, the first subparagraph is amended as follows:	(a) in paragraph 1, the first subparagraph is amended as follows:	(a) in paragraph 1, the first subparagraph is amended as follows: Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (20)(a)(i)			
G	194	(i) point (e) is replaced by the following:	(i) point (e) is replaced by the following:	(i) point (e) is replaced by the following:	(i) point (e) is replaced by the following: Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (20)(a)(i), ame	nding provision, first paragraph		
G	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	(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	(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	(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

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

140

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Regulation (EC) No 1907/2006;	Regulation (EC) No 1907/2006;	Regulation (EC) No 1907/2006;	Regulation (EC) No 1907/2006;
		,	,	,	Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (20)(a)(ii)	T		
G	196	(ii) points (g) and (h) are added:	(ii) points (g) and (h) are added:	(ii) points (g) and (h) are added:	(ii) points (g) and (h) are added: Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (20)(a)(ii), ame	nding provision, first paragraph		
G	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;	(g) where applicable, the reason for divergence from the most severe classification per hazard class included in the inventory referred to in Article 42; Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (20)(a)(ii), ame	nding provision, second paragraph		
G	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 <u>and without</u> <u>needing to acquire new data or</u> <u>new studies being necessary</u> , the reason for introducing a more severe classification per hazard	(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, the reason for introducing a more severe classification per hazard class compared to those included in the inventory referred to in Article 42.;

14625/5/23 REV 5 AT/CDP/RPG/nm 141 EN

COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		,	class compared to those included in the inventory referred to in Article 42.2;	2	Text Origin: Commission Proposal
	Article 1	, first paragraph, point (20)(a)(iia)			
G	198a			(iii) subparagraph 2 is replaced by the following:	(iii) subparagraph 2 is replaced by the following: Text Origin: Council Mandate
	Article 1,	, first paragraph, point (20)(a)(iia), am	ending provision, first paragraph		
G	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 notifier.	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 notifier. Text Origin: Council Mandate
	Article 1,	, first paragraph, point (20)(b)			
G	199	(b) paragraph 2 is replaced by the following:	(b) paragraph 2 is replaced by the following:	(b) paragraph 2 is replaced by the following:	(b) paragraph 2 is replaced by the following:

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

142

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (20)(b), amend	ding provision, numbered paragraph (2	2)	
G	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).;	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).; Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (20)(ba)	T.		
G	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		deleted Text Origin: EP Mandate

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

143

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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)			
G	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:	(21) in Article 42(1), the third subparagraph is replaced by the following:	(21) Article 42 is amended as follows: (a) in paragraph 1 in Article 42(1), the third subparagraph is replaced by the following: Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (21a)			
	201a				deleted
		, first paragraph, point (21a), amendii	ng provision, first paragraph		
G	202				G

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		The following information shall be made publicly available free of charge online:	The following information shall be made publicly available free of charge online <i>in a user-friendly format</i> :	The following information shall be made publicly available free of charge online:	The following information shall be made publicly available free of charge online: Text Origin: Commission Proposal
	Article 1,	first paragraph, point (21a), amendir	ng provision, first paragraph, point (a)		
G	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;	(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; Text Origin: Council Mandate
	Article 1,	first paragraph, point (21a), amendir	ng provision, first paragraph, point (b)		
G	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;	(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; Text Origin: Commission Proposal

145 14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 1,	first paragraph, point (21a), amendin	g provision, first paragraph, point (c)		
G	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.	(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. Text Origin: Commission Proposal
	Article 1.	first paragraph, point (21a), amendin	ng provision, first paragraph, point (ca)	, first subparagraph	
G	205a			(d) the date of the latest update of the classification and labelling.	(d) the date of the latest update of the classification and labelling. Text Origin: Council Mandate
	Article 1,	first paragraph, point (21a), amendin	ng provision, first paragraph, point (ca)	, second subparagraph	
G	205b			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.';	Information referred to in Article 40(1)(a) shall be made publicly available 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. The Agency shall provide information on legitimate grounds on which confidentiality claims may be made.

14625/5/23 REV 5 AT/CDP/RPG/nm 146 COMPET 1 EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					The Agency shall take measures to identify undue confidentiality claims, including IT screenings and spot checks. Text Origin: Council Mandate
	Article 1	, first paragraph, point (21a), amendir	l ng provision, second paragraph		
G	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.;	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	deleted Text Origin: Commission Proposal
	Article 1,	first paragraph, point (21b)			
G	206a		(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."		(21a) (b) the following paragraph 3a is added: "3a. Where the Agency considers that an entry is incomplete, incorrect or obsolete it shall request the notifier to notify the correct entry." Text Origin: EP Mandate
	Article 1,	, first paragraph, point (21c)			

14625/5/23 REV 5 AT/CDP/RPG/nm 147 COMPET 1

EN

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
c 206b	(21b) The following Article -43 is inserted: Article -43 Right to request action from competent authorities and the Commission 1. Any natural or legal person, individually or in association, shall be entitled to submit substantiated evidence to competent authorities as referred to in Article 43 or the Commission, such as peerreviewed 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 mixture or labelling process. 2. The competent authorities or the Commission shall diligently and impartially assess the information submitted in accordance with paragraph 1, adding the evidence submitted to all other available evidence using a weight of evidence approach.		(21c) In Article 46 the following paragraph 1a is added: "1a. For the purpose of paragraph 1, the authorities responsible for enforcement referred to in Article 43 shall follow up on complaints or reports related to non-compliance with this Regulation, and verify that the corrective action referred to in Article 3(16) of Regulation 2019/1020 has been taken;"

148 14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1



Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	3. Where the evidence		
	submitted shows non-compliance		
	with one or several of the		
	requirements on the classification,		
	labelling and packaging of		
	substances and mixtures,		
	enforcement measures shall be		
	initiated in accordance with		
	Article 47.		
	4. Where the assessment has		
	shown that the substance meets		
	the criteria for classification in		
	any of the hazard classes referred		
	to in Article 36(1), the competent authority or the Commission shall		
	initiate a process of harmonised		
	classification and labelling.		
	Where the assessment has shown		
	a wide dispersive use of and/or		
	consumer exposure to the		
	substance or mixture concerned,		
	the competent authority or the		
	Commission shall initiate a risk		
	management process under		
	Article 59, Article 69, or Article		
	68(2) of Regulation (EU) No		
	1907/2006. Where the assessment		
	has shown a lack of information		
	on the risk to health or the		
	environment posed by a hazardous		
	substance or mixture, the		
	competent authority or the		
	Commission shall require		
	companies or any other relevant		

149 14625/5/23 REV 5 AT/CDP/RPG/nm EN COMPET 1

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 1, first paragraph, point (21d)	actor to provide more information, with a view to taking risk management measures under Title VI, VII or VIII of Regulation (EU) 1907/2006, where necessary. 5. Where the evidence submitted should have been included in the registration dossier submitted under Regulation (EU) No 1907/2006 but was omitted by the registrant, the enforcement measure shall be initiated under Article 126 of Regulation (EU) No 1907/2006 against registrants the registration of whom is non-compliant. 6. The competent authority or the Commission, shall, within 6 months, inform the natural or legal persons referred to in paragraph 1, of its opinion on the evidence and concerns submitted under paragraph 1, and of any steps it plans to take to address those concerns, providing the reasons for both the opinion reached and the steps proposed. 7. Competent authorities and the Commission shall publish an annual report on the requests received and how they have been dealt with.		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
6 206c	Commission Proposal	(21c) The following Article -43a is added: Article -43a Access to justice 1. Any natural or legal person which has submitted a substantiated concern in accordance with Article -43a shall have access to an administrative or judicial procedure to review the procedural and substantive legality of the decisions, acts or omissions of the relevant competent authority under this Regulation. 2. Member States shall ensure access to administrative or judicial procedures to review their decisions, acts and omissions, in accordance with national law or practice. Decisions, acts and omission 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		EP drops AM

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

151

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			information is made available to the public on access to administrative and judicial review procedures.		
	Article 1,	, first paragraph, point (22)			
G	207	(22) Article 45 is amended as follows:	(22) Article 45 is amended as follows:	(22) Article 45 is amended as follows:	(22) Article 45 is amended as follows: Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (22)(a)			
G	208	(a) paragraph 1 is replaced by the following:	(a) paragraph 1 is replaced by the following:	(a) paragraph 1 is replaced by the following:	(a) paragraph 1 is replaced by the following: Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (22)(a), amend	ing provision, numbered paragraph (1		
G	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.;	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.;

COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Commission Proposal
	Article 1,	first paragraph, point (22)(b)			
G	210	(b) the following paragraphs 1a, 1b and 1c are inserted:	(b) the following paragraphs 1a, 1b and 1c are inserted:	(b) the following paragraphs 1a, 1b and 1c are inserted:	(b) the following paragraphs 1a, 1b and 1c are inserted: Text Origin: Commission Proposal
	Article 1,	first paragraph, point (22)(b), amend	ing provision, first paragraph		
G	211	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.';	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.'; Text Origin: Commission Proposal
	Article 1,	first paragraph, point (22)(b), amend	ing provision, second paragraph		
G	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,	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,	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,	1b. Importers and downstream users placing on the market mixtures that are classified as hazardous on the basis of their health <i>effects</i> or physical effects,

COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		shall submit to the body or bodies appointed in accordance with paragraph 1 the harmonised information referred to in Part B of Annex VIII.	shall submit to the body or bodies appointed in accordance with paragraph 1 the harmonised information referred to in Part B of Annex VIII.	shall submit to the body or bodies appointed in accordance with paragraph 1 the harmonised information referred to in Part B of Annex VIII.	shall submit to the body or bodies appointed in accordance with paragraph 1 the <i>harmonised</i> information referred to in Part B of Annex VIII. Text Origin: Council Mandate
	Article 1,	, first paragraph, point (22)(b), amend	ling provision, third paragraph		
G	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 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.;	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 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.;	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 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.';	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 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. 2;
	Article 1,	, first paragraph, point (22)(c)			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
214	(c) in paragraph 2, point (b) is replaced by the following:	(c) in paragraph 2, point (b) is replaced by the following:	(c) in paragraph 2, point (b) is replaced by the following:	(c) in paragraph 2, point (b) is replaced by the following: Text Origin: Commission Proposal
Article 1	, first paragraph, point (22)(c), amend	ing provision, first paragraph		
c 215	(b) where requested by a Member State, the Commission or the Agency, to undertake a statistical analysis to identify where improved risk management measures may be needed.;	(b) where requested by a Member State, the Commission or the Agency, to undertake a statistical analysis to identify where improved risk management measures may be needed.;	(b) where requested by athe Member State, the Commission or the Agency, to undertake a statistical analysis to identify where improved risk management measures may be needed.';	(b) where requested by athe Member State, the Commission or the Agency, to undertake a statistical analysis to identify where improved risk management measures may be needed.2; Text Origin: Council Mandate
Article 1	., first paragraph, point (22)(d)			
216	(d) paragraph 3 is replaced by the following:	(d) paragraph 3 is replaced by the following:	(d) paragraph 3 is replaced by the following:	(d) paragraph 3 is replaced by the following: Text Origin: Commission Proposal
Article 1	., first paragraph, point (22)(d), amend	ling provision, numbered paragraph (3	3)	
217	3. The appointed bodies shall have	3. The appointed bodies shall have	3. The appointed bodies shall have	3. The appointed bodies shall have

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.;	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.;	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.';	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 <i>in accordance with paragraph 1</i> . 2;
	Article 1,	, first paragraph, point (23)			
G	218	(23) Article 48 is replaced by the following:	(23) Article 48 is replaced by the following:	(23) Article 48 is replaced by the following:	(23) Article 48 is replaced by the following: Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (23), amending	g provision, first paragraph		
G	219	'Article 48	Article 48	Article 48	CArticle 48 Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (23), amending	g provision, second paragraph		
G	220	Advertisement	Advertisement	Advertisement	Advertisement Text Origin: Commission

COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Proposal
	Article 1,	first paragraph, point (23), amending	g provision, numbered paragraph (1)		
O	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 hazardstatements and supplemental EUH statements set out in Annex II.	1. Any advertisement for a substance classified as hazardous shall indicate the relevant hazard pictogrampictograms, the signal word, hazard statements and supplemental EUH statements set out in Annex II. 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, the hazard class and the hazard statements. Text Origin: Council Mandate
	Article 1,	first paragraph, point (23), amending	g provision, numbered paragraph (2)		
G	222	2. Any advertisement for a mixture classified as hazardous or covered by Article 25(6) shall indicate the hazard pictogram, the signal word, the hazard class and the hazard statements.	2. Any advertisement for a mixture classified as hazardous or covered by Article 25(6) shall indicate the hazard pictogram, the signal word, the hazard class and the hazard statements. Any advertisement for sale of mixtures to the general public shall, in addition, indicate "always read and follow the information on the	2. Any advertisement for a mixture classified as hazardous or covered by Article 25(6) shall indicate the hazard pictogrampictograms, the signal word, the hazard class and the hazardstatements and supplemental EUH statements set out in Annex II.	2Any advertisement for a mixture classified as hazardous or covered by Article 25(6) shall indicate the hazard pictogrampictograms, the_signal word, hazard statements and supplemental EUH statements set out in Annex II. Any advertisement for sale of mixtures to the general public shall, in

14625/5/23 REV 5 AT/CDP/RPG/nm 157 EN COMPET 1

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		product label.		addition, indicate "always read and follow the information on the product label. the hazard class and the hazard statements. Text Origin: Council Mandate
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;		2a. Any advertisement for a substance or a mixture classified as hazardous shall not contain statements that shall not appear on the label or packaging of that substance or mixture in accordance with Article 25(4).
Article 1	, first paragraph, point (23), amending	g provision, numbered paragraph (2b)		
222b			3. By way of derogation from paragraph 1 and 2, the hazard pictograms and signal word may	3. By way of derogation from paragraph 1 and 2, the hazard pictograms and signal word may

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

158

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				be omitted where the advertisement is non-visual.';	be omitted where the advertisement is non-visual.';
					Text Origin: Council Mandate
	Article 1,	first paragraph, point (24)			
G	223	(24) the following Article 48a is added:	(24) the following Article 48a is added:	(24) the following Article 48a is added:	(24) the following Article 48a is added: Text Origin: Commission Proposal
	Article 1,	first paragraph, point (24), amending	provision, first paragraph		
G	224	Article 48a	Article 48a	Article 48a	Article 48a Text Origin: Commission Proposal
	Article 1,	first paragraph, point (24), amending	provision, second paragraph		
G	225	Distance sales offers	Distance sales offers	Distance sales offers	Distance sales offers Text Origin: Commission Proposal
	Article 1,	first paragraph, point (24), amending	provision, third paragraph		
G	226				C

	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 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.';	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 17.2; Text Origin: Council Mandate
Article 1	, first paragraph, point (25)			
s 227	(25) Article 50 is amended as follows:	(25) Article 50 is amended as follows:	(25) Article 50 is amended as follows:	(25) Article 50 is amended as follows: Text Origin: Commission Proposal
Article 1	, first paragraph, point (25)(-a)			
s 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;"		(-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;" Text Origin: EP Mandate
Article 1	, first paragraph, point (25)(a)			

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G	228	(a) in paragraph 2, point (b) is replaced by the following:	(a) in paragraph 2, point (b) is replaced by the following:	(a) in paragraph 2, point (b) is replaced by the following:	(a) in paragraph 2, point (b) is replaced by the following: Text Origin: Commission Proposal
	Article 1,	first paragraph, point (25)(a), amend	ing provision, first paragraph		
G	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 <i>up to date</i> 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 44.2;	(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 <i>up to date</i> 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 44.2; Text Origin: EP Mandate
	Article 1,	first paragraph, point (25)(b)	I	I	
G	230	(b) the following paragraph 3 is added:	(b) the following paragraph 3 is added:	(b) the following paragraph 3 is added:	(b) the following paragraph 3 is added: Text Origin: Commission Proposal
	Article 1,	first paragraph, point (25)(ba)			
G	230a				G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		deleted		
Article 1	1, first paragraph, point (25)(b), amend	ding provision, numbered paragraph (3	3)	
G 231	3. Where the Agency acts as an appointed body in accordance with Article 45(1a), it shall put in place the tools necessary to provide access to the information to the relevant appointed body or bodies of the appointing Member State to fulfil their tasks with regard to emergency health response and preventative measures.	3. Where the Agency acts as an appointed body in accordance with Article 45(1a), it shall put in place the tools necessary to provide access to the information to the relevant appointed body or bodies of the appointing Member State to fulfil their tasks with regard to emergency health response and preventative measures.	3. Where the Agency acts as an appointed body in accordance with Article 45(1a), it shall put in place the tools necessary to provide access to the information to the relevant appointed body or bodies of the appointing Member State to fulfil their tasks with regard to emergency health response and preventative measures.	3. Where the Agency acts as an appointed body in accordance with Article 45(1a), it shall put in place the tools necessary to provide access to the information to the relevant appointed body or bodies of the appointing Member State to fulfil their tasks with regard to emergency health response and preventative measures.
Article 2	1, first paragraph, point (25)(ba)			
G 231a		(ba) the following paragraphs are added: "3a. The Agency shall be provided with adequate resources to support its work. 3b. In order to provide adequate expertise, support, and thorough scientific evaluations, appropriate and stable funding for		(ba) the following paragraphs are added: "3a. The Agency shall be provided with adequate resources to support its work." Text Origin: EP Mandate

162 14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			the Agency shall be ensured."		
	Article 1	, first paragraph, point (25)(bb)			
G	231b			(25a) In Article 52, paragraph 2 is replaced by the following:	(bb) In Article 52, paragraph 2 is replaced by the following: Text Origin: Council Mandate
	Article 1	, first paragraph, point (25)(bb), amen	ding provision, first paragraph		
G	231c			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 provisional measure for a time period defined in the decision or to require the Member State to revoke the provisional measure.	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 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 (26)			
G	232	(26) Article 53 is amended as follows:	(26) Article 53 is amended as follows:	(26) Article 53 is amended as follows:	(26) Article 53 is amended as follows:

COMPET 1

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Text Origin: Commission Proposal
Article	1, first paragraph, point (26)(-a)			
6 232a		(-a) In Article 53, paragraph 1 is replaced by the following: "1. The Commission may adjust and adapt Articles 6(5), 11(3), 12, 14, 18(3)(b), 23, 25 to 29 and 35(2) second and third subparagraph and Annexes I to VII to technical and scientific progress, including 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		EP drops AM

14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1

EN

164

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 54(4)."		
	Article 1,	, first paragraph, point (26)(a)			
G	233	(a) the following paragraphs 1a to 1b are inserted:	(a) the following paragraphs 1a to 1b are inserted:	(a) the following paragraphs 1a to 1b are inserted:	(a) the following paragraphs 1a to 1b are inserted: Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (26)(a), amend	ing provision, first paragraph		
G	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	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 adaptinclude 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 Unionthat 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	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 adaptinclude 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 Unionthat 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

COMPET 1

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		which is critical to protect the societal needs and a high level of protection of human health and the environment shall be easily accessible on the label;	the societal needs and a high level of protection of human health and the environment;	into account the level of digital readiness among all population groups in the Union, account the societal needs and a high level of protection of human health and the environment; Text Origin: Council Mandate
Artic	e 1, first paragraph, point (26)(a), amend	ling provision, second paragraph		
g 235	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 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 ArticleArticles 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:	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 ArticleArticles 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: Text Origin: Council Mandate
Artic	e 1, first paragraph, point (26)(a), ameno	ling provision, second paragraph, poin	t (a)	

COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G	236	(a) ensure coherence with other relevant Union acts;	(a) ensure coherence with other relevant Union acts;	(a) ensure coherence with other relevant Union acts;	(a) ensure coherence with other relevant Union acts; Text Origin: Commission Proposal
	Article 1,	first paragraph, point (26)(a), amend	ing provision, second paragraph, poin	t (b)	
G	237	(b) encourage innovation;	(b) encourage innovation;	(b) encourage innovation;	(b) encourage innovation; Text Origin: Commission Proposal
	Article 1,	first paragraph, point (26)(a), amend	ing provision, second paragraph, poin	t (c)	
G	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;	(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; Text Origin: Commission Proposal
	Article 1,	first paragraph, point (26)(a), amend	ing provision, second paragraph, poin	t (d)	
G	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 <u>as</u> well as the readiness of the	(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

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

167

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			necessary wireless and other technological infrastructure allowing unrestricted access to the information on chemicals;		necessary wireless and other technological infrastructure allowing unrestricted access to the information on chemicals; Text Origin: EP Mandate
	Article 1,	first paragraph, point (26)(a), amend	ing provision, second paragraph, poin	t (e)	
G	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.	(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. Text Origin: Commission Proposal
	Article 1.	first paragraph, point (26)(b)			
G	241	(b) paragraph 2 is replaced by the following:	(b) paragraph 2 is replaced by the following:	(b) paragraph 2 is replaced by the following:deleted	(b) paragraph 2 is replaced by the following: Text Origin: Commission Proposal
	Article 1,	first paragraph, point (26)(b), amend	ing provision, numbered paragraph (2)	
G	242	2. The Commission or the Member States acting in the interest of the Union shall, in the manner appropriate to their role in	2. The Commission or the Member States acting in the interest of the Union shall, in the manner appropriate to their role in	deleted	2. The Commission, acting on behalf of the Union and the Member States, or the Member States acting in the interest of the

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		the relevant UN fora, promote the harmonisation of the criteria for classification and labelling of endocrine disruptors for human health, endocrine disruptors for the environment, persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances as well as alternative test methods at the level of the UN.;	the relevant UN fora, promote the harmonisation of the criteria for classification and labelling of endocrine disruptors for human health, endocrine disruptors for the environment, persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances as well the development of criteria for immunotoxic and neurotoxic substances as well as alternative test methods, including new approach methods and in particular non-animal methods at the level of the UN to address existing and emerging hazard classes.';		Union shall, in the manner appropriate to their role in the relevant UN fora, cooperate with a view to promote the harmonisation of the criteria for classification and labelling of endocrine disruptors for human health, endocrine disruptors for the environment, persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances as well as the adaptation of criteria for alternative approaches, in particular non-animal test methods, and the assessment at the level of the UNneed for new criteria for immunotoxic and neurotoxic substances.';
	Article 1,	first paragraph, point (26)(c)			
G	243	(c) the following paragraph 3 is added:	(c) the following paragraph 3 is added:	deleted	(c) the following paragraph 3 is added: Text Origin: Commission Proposal

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 1,	first paragraph, point (26)(ca)			
G	243a		deleted		6
	Article 1,	first paragraph, point (26)(c), amend	ing provision, numbered paragraph (3)	
G	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 more than twelve months after non-animal data are included in harmonised criteria for classification and labelling at the level of the UN.	deleted	3. The Commission shall regularly evaluate the development of alternative test methodsapproaches referred to in Article 13(1) of Regulation (EC) No 1907/2006 for classification of substances and mixtures, in particular non-animal test methods, 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 to adapt the criteria, preferably nor more than eighteen months after non-animal data are included in harmonised criteria for classification and labelling at the level of the UN.

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

170

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: EP Mandate
	Article 1,	, first paragraph, point (26)(c), amend	ing provision, numbered paragraph (3	a)	
G	244a		(ca) In Article 53, paragraph 3a is added as following: "3a. The Commission shall assess the introduction of hazard criteria for immunotoxicity and neurotoxicity by 31 December 2025 and, where appropriate, adopt delegated acts in accordance with Article 53a. The Commission shall foster the rapid introduction of those hazard classes at the UNGHS."		deleted Ep drops AM Text Origin: EP Mandate
	Article 1,	first paragraph, point (27)			
G	245	(27) Article 53a is amended as follows:	(27) Article 53a is amended as follows:	(27) Article 53a is amended as follows:	(27) Article 53a is amended as follows: Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (27)(a)			
G	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:	(a) in paragraph 2, the first sentence is replaced by the following:	(a) in paragraph 2, the first sentence is replaced by the following:

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Commission Proposal
	Article 1,	first paragraph, point (27)(a), amend	ing provision, first paragraph		
O	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 Regulation];	The power to adopt delegated acts referred to in Articles 37(5), 37(7), 37(8), 45(4) 53(1), 53(1a), 53(1b), 53(3) and 53(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 force of this Regulation] date of entry into force of this Regulation];	The power to adopt delegated acts referred to in Articles 37(5), 37(7), 37(8), 45(4) 53(1), 53(1a) and 53(1b) shall be conferred on the Commission for a period of five years from [OP please insert the date = the date of entry into force of this Regulation];	The power to adopt delegated acts referred to in Articles 37(5), 37(7), 37(8), 45(4) 53(1), 53(1a) and 53(1b) shall be conferred on the Commission for a period of five years from [OP please insert the date = the date of entry into force of this Regulation]; Text Origin: Commission Proposal
	Article 1,	first paragraph, point (27)(b)			
G	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:	(b) in paragraph 3, the first sentence is replaced by the following:	(b) in paragraph 3, the first sentence is replaced by the following: Text Origin: Commission Proposal
	Article 1,	first paragraph, point (27)(b), amend	ling provision, first paragraph		
G	249	۵		4	·

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.2;	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), may be revoked at any time by the European Parliament or by the Council.; Text Origin: Commission Proposal
	Article 1	, first paragraph, point (27)(c)			
G	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:	(c) in paragraph 6, the first sentence is replaced by the following:	(c) in paragraph 6, the first sentence is replaced by the following: Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (27)(c), amend	ing provision, first paragraph		
G	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	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	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	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

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

173

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		that period, the European Parliament and the Council have both informed the Commission that they will not object.;	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. 2;	that period, the European Parliament and the Council have both informed the Commission that they will not object.;	that period, the European Parliament and the Council have both informed the Commission that they will not object.;
					Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (28)			
G	252	(28) Article 53c is replaced by the following:	(28) Article 53c is replaced by the following:	(28) Article 53c is replaced by the following:	(28) Article 53c is replaced by the following: Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (28), amending	g provision, first paragraph		
G	253	Article 53c	Article 53c	Article 53c	Article 53c Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (28), amending	provision, second paragraph		
G	254	Separate delegated acts for different delegated powers	Separate delegated acts for different delegated powers	Separate delegated acts for different delegated powers	Separate delegated acts for different delegated powers Text Origin: Commission Proposal

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 1,	first paragraph, point (28), amending	provision, third paragraph		
G	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.;	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.; Text Origin: Commission Proposal
	Article 1,	first paragraph, point (29)			
G	256	(29) Article 54 is replaced by the following:	(29) Article 54 is replaced by the following:	(29) Article 54 is replaced by the following:	(29) Article 54 is replaced by the following: Text Origin: Commission Proposal
	Article 1,	first paragraph, point (29), amending	provision, numbered paragraph (1)		
G	257	1. The Commission shall be assisted by the Committee established by Article 133 of Regulation (EC) No 1907/2006.	1. The Commission shall be assisted by the Committee established by Article 133 of Regulation (EC) No 1907/2006.	1. The Commission shall be assisted by the Committee established by Article 133 of Regulation (EC) No 1907/2006.	1. The Commission shall be assisted by the Committee established by Article 133 of Regulation (EC) No 1907/2006.

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

175

EN

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	That committee shall be a committee within the meaning of Regulation (EU) No 182/2011*.';	That committee shall be a committee within the meaning of Regulation (EU) No 182/2011*.';	That committee shall be a committee within the meaning of Regulation (EU) No 182/2011*.';	That committee shall be a committee within the meaning of Regulation (EU) No 182/2011*.';
				Text Origin: Commission Proposal
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.	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. Text Origin: Commission Proposal
Article 1	ı , first paragraph, point (29), amending	provision, third paragraph		
259	* Regulation (EU) 182/2011;	* Regulation (EU) 182/2011;	* Regulation (EU) 182/2011;	* Regulation (EU) 182/2011; Text Origin: Commission Proposal
Article 1	, first paragraph, point (29a)			
259a		(29a) the following article is inserted: "Article 54a Review Clause No sooner than [insert date six years after the date of entry into	(29a) the following Article 54a is added: 'Article 54a Review By [insert date four years after the date of entry into force of this	(29a) the following Article 54a is added: 'Article 54a Reporting and review 1. By [insert date five years after

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

176

EN

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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).";	Regulation], the Commission shall present a report to the European Parliament and the Council on the applicable articles regarding classification of substances containing more than one constituent. The report may be accompanied by an appropriate legislative proposal.'	the date of entry into force of this Regulation], the Commission shall present a scientific report to the European Parliament and the Council regarding the examination of the information on substances containing more than one constituent extracted from plants. The report may be accompanied, if appropriate, by a legislative proposal.' 2. By [office of publications please insert date = 5 years from the date of entry into force of this Regulation], the Commission shall present an evaluation report to the European Parliament and the Council and the European Economic and Social Committee, assessing the need to extend requirements in sections 3.1 and 3.2 of Annex II on child-resistant fastenings and tactile warnings to other hazard classes. If justified by the results of the report, the Commission shall act in accordance with Article 53 (1). Text Origin: Council Mandate
Article 1,	first paragraph, point (29b)			
259b				
3,7,0				

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

177

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					deleted
	Article 1,	first paragraph, point (30)			
G	260	(30) in Article 61, the following paragraph 7 is added:	(3029b) in Article 61, the following paragraph 7 is added:	(30) in Article 61, the following paragraph 7 is added:	(30) in Article 61, the following paragraph 7 isand 8 are added: Text Origin: Commission Proposal
	Article 1	, first paragraph, point (30a)			
O	260a		a) In Article 61, the following paragraph is added: "7a. Mixtures which have been classified, labelled and packaged in accordance with Article 1(1), Article 4(10), Article 5, Article 6(3) and (4), Article 9(3) and (4), Article 25(6) and (9), Articles 29, 30 and 35, Article 40(1) and (2), Article 42(1), third subparagraph, Article 48, section 1.2.1. of Annex I, section 1.5.1.2 of Annex I, section 1.5.2.4.1 of Annex I, Parts 3 and 5 of Annex II, Part A, the first subparagraph of section 2.4, of Annex VIII, Part B, section 1, of Annex VIII, Part B, the third paragraph of section 3.1, of Annex VIII, Part B, section 3.6,		deleted EP drops AM

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

178

EN

	Commission Proposal	EP Mandate	Council Ma	ndate	Draft Agreement
		of Annex VIII, Part B, the first row of Table 3 of Section 3.7, of Annex VIII, Part B, the first paragraph of Section 4.1, of Annex VIII, Part C, sections 1.2 and 1.4, of Annex VIII, and Part D, sections 1, 2 and 3, of Annex VIII as applicable on [OP: please insert the date = the day before the entry into force of this Regulation] and which were placed on the market before [OP: please insert the date = the first day of the month following 24 months after the date of entry into force of this Regulation are not required to be classified, labelled and packaged in accordance with this Regulation as amended by Regulation/ of the European Parliament and of the Council* [OP: please complete the reference in the footnote – it should be the reference to this Regulation] until [OP: please insert the date = the first day of the month following 48 months after the date of entry into force of this Regulation]."			
Article 1	, first paragraph, point (30), amending	g provision, numbered paragraph (7), f	first subparagraph		
y 261	·	c	c		· ·

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

Commission Proposal

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

EP Mandate

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), 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 IOP: 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

Council Mandate

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)25 (3). 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, and section 1.5.1.2 of Annex I, section 1.5.2.4.1 of Annex I 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 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, 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 .../...

Draft Agreement

AT/CDP/RPG/nm 14625/5/23 REV 5 180 EN

COMPET 1

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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].	packaged in accordance with this Regulation as amended by Regulation/of the European Parliament and of the Council* [OP: please complete the reference in the_footnote – it should be the reference to this Regulation]_until [OP: please insert the date = the first day of the month following 42 months after the date of entry into force of this Regulation].	packaged in accordance with this Regulation as amended by Regulation/ of the European Parliament and of the Council* [OP: please complete the reference in the footnote—it should be the reference to this Regulation]—until— [OP: please insert the date = the first day of the month following 42 months after the date of entry into force of this Regulation]. [OP: please insert the date = the day before the entry into force of this Regulation] and which were placed on the market before [OP: please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation] are not required to be classified, labelled and packaged in accordance with this Regulation as amended by Regulation/ of the European Parliament and of the Council [OP: please complete the reference in the footnote—it should be the reference to this Regulation] until [OP: please insert the date = the first day of the month following 42 months after the date of entry into force of this Regulation].	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 paragraph of Section 4.1, of Annex VIII, Part C, sections 1.2 and 1.4, of Annex VIIIday of the month following 42 months after the date of entry into force of this Regulation]. 8. Substances and mixtures which have been classified, labelled and packaged in accordance with Article 18(3), Article 31(3) and section 1.2.1. and Part D, sections 1, 2 and 3, of Annex VIII—I, 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 1824 months after the date of entry into force of this Regulation as a mended by Regulation/of the European Parliament and of the Council* [OP: please complete the

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

181

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					should be the reference to this Regulation]—until [OP: please insert the date = the first day of the month following 4248 months after the date of entry into force of this Regulation]. Text Origin: Council Mandate
	Article 1,	, first paragraph, point (30), amending	provision, numbered paragraph (7),	second subparagraph	
G	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).;	* 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).; Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (31)			
G	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;	(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; Text Origin: Commission Proposal
	Article 1,	, first paragraph, point (32)	I		
G	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;	(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;

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

182

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Commission Proposal
	Article 1,	first paragraph, point (33)			
G	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.	(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. Text Origin: Commission Proposal
	Article 2				
G	266	Article 2	Article 2	Article 2	Article 2 Text Origin: Commission Proposal
	Article 2((1)			
G	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.	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. Text Origin: Commission Proposal
	Article 2((1a), first subparagraph			

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G	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]: (1a), first subparagraph, point (-a)	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]:	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]: EP drops AM Text Origin: Commission Proposal
G	268a	(1a), in st subparagraph, point (-a)	2a. The following provisions shall apply to mixtures from [OP: please insert the date = the first day of the month following 24 months after the date of entry into force of this Regulation]: (a) Article 1, points (1), (4), (5), (6), (7), (10), (11), (12), (15), (16), (20), (21), (23) and (24); (b) points (2), (3), (7), (9) and (10) of Annex I; (c) Annex II; (d) points (1)(c), (2), (3) and (4) of Annex III.		deleted EP drops AM
	Article 2	(1a), first subparagraph, point (a)			
G	269	(a) Article 1, points (1), (4), (5), (6), (7), (10), (11), (12), (15), (16),	(a) Article 1, points (1), (4), (5), (6), (7), (10), (11), (12), (15), (16),	(a) Article 1, points (1), (4), (5), (6), (7), (10), (11), (12), (15), (16),	(a) Article 1, points (1)(3)(b), (4), (5), (6), (7), (10)(9)(x), (11), (12),

184 14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		(20), (21), (23) and (24);	(20), (21), (23) and (24);	(20), (21), (23), and (24);	(13)(a), (13)(b), (15), (16), (20), (21), (23) and (24);
					Text Origin: Commission Proposal
	Article 2((1a), first subparagraph, point (b)			
G	270	(b) points (2), (3), (7), (9) and (10) of Annex I;	(b) points (2), (3), (7), (9) and (10) of Annex I;	(b) points (2), (3), (7), (9) and (10) of Annex I;	(b) points (2), (3)(3)(a), (7), (9) and (10) of Annex I; Text Origin: Commission Proposal
	Article 2((1a), first subparagraph, point (c)			
G	271	(c) Annex II;	(c) Annex II;	(c) Annex II;	(c) Annex II; Text Origin: Commission Proposal
	Article 2((1a), first subparagraph, point (d)			
G	272	(d) points (1)(c), (2), (3) and (4) of Annex III.	(d) points (1)(c), (2), (3) and (4) of Annex III.	(d) points (1)(c), (2), (3) and (4) of Annex III.	deleted Text Origin: Commission Proposal
	Article 2((1a), second subparagraph			
	272a				

14625/5/23 REV 5

AT/CDP/RPG/nm

COMPET 1

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Article 2a. The following provisions shall apply from [OP: please insert the date = the first day of the month following 24 months after the date of entry into force of this Regulation]: (a) Article 1, points (1), (7c) [point corresponding to the change in Article 18(3)(b)], (13)(c), (22)(b) and (22)(d); (b) points (2) and (3) of Annex I; (c) Annex III This line should be added in the final consolidated version as Article 2a.
Article 2	(3)			
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, 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,	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,	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, 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,	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)10, Article 25(3), Articles 29, Article 30, Article 31(1), Article 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 subparagraph of section 2.4, of Annex

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

186

EN

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the third paragraph of section 3.1, of Annex VIII, Part B, section 3.6, of Annex VIII, Part B, the first row of Table 3 of Section 3.7, of Annex VIII, Part B, the first paragraph of Section 4.1, of Annex VIII, Part C, sections 1.2 and 1.4, of Annex VIII, and Part D, sections 1, 2 and 3, of Annex VIII to Regulation (EC) No 1272/2008 as applicable on [OP: please insert the date = the day before the date of entry into force of this Regulation], substances and mixtures may until [OP: please insert the date = the last day of the month following 17 months after the date of entry into force of this Regulation] be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by the following provisions of this Regulation:	the third paragraph of section 3.1, of Annex VIII, Part B, section 3.6, of Annex VIII, Part B, the first row of Table 3 of Section 3.7, of Annex VIII, Part B, the first paragraph of Section 4.1, of Annex VIII, Part C, sections 1.2 and 1.4, of Annex VIII, and Part D, sections 1, 2 and 3, of Annex VIII to Regulation (EC) No 1272/2008 as applicable on [OP: please insert the date = the day before the date of entry into force of this Regulation], substances may until [OP: please insert the date = 18months after the date of entry into force of this Regulation] and mixtures may until [OP: please insert the date = the last day of the month following 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:	the third paragraph of section 3.1, of Annex VIII, Part B, section 3.6, of Annex VIII, Part B, the first row of Table 3 of Section 3.7, of Annex VIII, Part B, the first paragraph of Section 4.1, of Annex VIII, Part C, sections 1.2 and 1.4, of Annex VIII, and Part D, sections 1, 2 and 3, of Annex VIII to Regulation (EC) No 1272/2008 as applicable on [OP: please insert the date = the day before the date of entry into force of this Regulation], substances and mixtures may until [OP: please insert the date = the last day of the month following 17 months after the date of entry into force of this Regulation] be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by the following provisions of this Regulation:	VIII, Part B, the third paragraph of section 3.1, of Annex VIII, Part B, the first paragraph of section 3.6, of Annex VIII, Part B, the first row of Table 3 of Section 3.7, of Annex VIII, Part B, the first paragraph of Section 4.1, of Annex VIII, Part C, sections 1.2 and 1.4, of Annex VIII, and Part D, sections 1.2 and 3, of Annex VIII to Regulation (EC) No 1272/2008 as applicable on [OP: please insert the date = the day before the date of entry into force of this Regulation], substances and mixtures may until [OP: please insert the date = the last day of the month following 17 months after the date of entry into force of this Regulation] be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by the following provisions of this Regulation: EP drops AM Text Origin: Commission Proposal
Article 2	(3), point (a)			
G 274	(a) Article 1, points (1), (4), (5),	(a) Article 1, points (1), (4), (5),	(a) Article 1, points (1), (4), (5),	(a) Article 1, points (1), (4), (5),

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		(6), (7), (10), (11), (12), (16), (20), (21) and (23);	(6), (7), (10), (11), (12), (16), (20), (21) and (23);	(6), (7), (10), (11), (12), (16), (20), (21) and (23);	(6), (7), (10)(9)(x), (11), (12), (13)(a), (13)(b), (16), (20), (21)(a) and (23); Text Origin: Commission Proposal
	Article 2((3), point (b)			
G	275	(b) points (2), (3), (7) and (9) of Annex I;	(b) points (2), (3), (7) and (9) of Annex I;	(b) points (2), (3), (7) and (9) of Annex I;	(b) points (2), (3)(3)(a), (7) and (9) of Annex I; Text Origin: Commission Proposal
	Article 2((3), point (c)			
G	276	(c) Annex II;	(c) Annex II;	(c) Annex II;	(c) Annex II; Text Origin: Commission Proposal
	Article 2((3), point (d)			
G	277	(d) points (1)(c), (2), (3) and (4) of Annex III.	(d) points (1)(c), (2), (3) and (4) of Annex III.	(d) points (1)(c), (2), (3) and (4) of Annex III.	deleted Text Origin: Commission Proposal
	Article 2,	fourth paragraph -a			

14625/5/23 REV 5 188 AT/CDP/RPG/nm COMPET 1

EN

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
277a				4. By way of derogation from Article 1(1), 18(3)(b), Article 31(3), Article 45(1) and (3), section 1.2.1 of Annex I, part A, section 2.1, of Annex VIII, part A, the first sub-paragraph of section 2.4 of Annex VIII, Part B, section 1 of Annex VIII, Part B, section 1 of Annex VIII, Part B, the third paragraph of section 3.1 of Annex VIII, Part B, section 3.6 of Annex VIII, Part B, the first row of Table 3 of Section 3.7 of Annex VIII, Part B, the first paragraph of Section 4.1 of Annex VIII, Part C, sections 1.2 and 1.4 of Annex VIII, and Part D, sections 1, 2 and 3 of Annex VIII to Regulation (EC) No 1272/2008 as applicable on [OP: please insert the date = the day before the date of entry into force of this Regulation], substances and mixtures may until [OP: please insert the date = the last day of the month following 23 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:

14625/5/23 REV 5 AT/CDP/RPG/nm EN COMPET 1



		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					(a) Article 1, points (1), (7c) [point corresponding to the change in Article 18(3)(b)], (13)(c), (22)(b) and (22)(d); (b) points (2) and (3) of Annex I; (c) Annex III.
	Article 2,	, fourth paragraph	T		
G	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.	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. Text Origin: Commission Proposal
	Formula				
G	279	Done at Brussels,	Done at Brussels,	Done at Brussels,	Done at Brussels, Text Origin: Commission Proposal
	Formula				
G	280	For the European Parliament	For the European Parliament	For the European Parliament	For the European Parliament Text Origin: Commission Proposal
	Formula				

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G	281	The President	The President	The President	The President Text Origin: Commission Proposal
	Formula				
G	282	For the Council	For the Council	For the Council	For the Council Text Origin: Commission Proposal
	Formula				
G	283	The President	The President	The President	The President Text Origin: Commission Proposal
	Annex I				
G	284	Annex I	Annex I	Annex I	Annex I Text Origin: Commission Proposal
	Annex I,	first paragraph			
G	285	Part 1 of Annex I to Regulation (EC) No 1272/2008 is amended as	Part 1 of Annex I to Regulation (EC) No 1272/2008 is amended as	Part 1 of Annex I to Regulation (EC) No 1272/2008 is amended as	Part 1 of Annex I to Regulation (EC) No 1272/2008 is amended as

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		follows:	follows:	follows:	follows:
					Text Origin: Commission Proposal
	Annex I,	second paragraph			
G	286	(1) Section 1.1.1.3. is replaced by the following:	(1) Section 1.1.1.3. is replaced by the following:	(1) Section 1.1.1.3. is replaced by the following:	(1) Section 1.1.1.3. is replaced by the following: Text Origin: Commission Proposal
	Annex I,	second paragraph, amending provisio	n, first paragraph		
G	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	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	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	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

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

192

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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 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 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 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 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 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 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 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.; Text Origin: Commission Proposal
	Annex I,	third paragraph			
G	288	(2) Section 1.2.1.4. is replaced by the following:	(2) Section 1.2.1.4. is replaced by the following:	(2) Section 1.2.1.4. is replaced by the following:	(2) Section 1.2.1.4. is replaced by the following: Text Origin: Commission Proposal
	Annex I,	third paragraph, amending provision,	first paragraph		
G	289	, 1.2.1.4.			G

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Annex I,	third paragraph, amending provision,	first paragraph, first subparagraph		
G	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:	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: Text Origin: Commission Proposal
	Annex I,	third paragraph, amending provision,	first paragraph, second subparagraph	1	
G	291	Table 1.3	Table 1.3	Table 1.3	Table 1.3 Text Origin: Commission Proposal
	Annex I,	third paragraph, amending provision,	first paragraph, third subparagraph		
G	292	Minimum dimensions of labels, pictograms and font size	Minimum dimensions of labels, pictograms and font size	Minimum dimensions of labels, pictograms and font size	Minimum dimensions of labels, pictograms and font size Text Origin: Commission Proposal
	Annex I,	third paragraph, amending provision,	first paragraph, Table 1, Column 1, Ro	ow 1	
G	293	Capacity of the package			

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Commission Proposal
	Annex I,	third paragraph, amending provision,	first paragraph, Table 1, Column 1, Ro	ow 2	
G	294	Not exceeding 3 litres:	Not exceeding 3 litres:	Not exceeding 3 litres:	Not exceeding 3 litres: Text Origin: Commission Proposal
	Annex I,	third paragraph, amending provision,	first paragraph, Table 1, Column 1, Ro	ow 3	
G	295	Greater than 3 litres but not exceeding 50 litres:	Greater than 3 litres but not exceeding 50 litres:	Greater than 3 litres but not exceeding 50 litres:	Greater than 3 litres but not exceeding 50 litres: Text Origin: Commission Proposal
	Annex I,	third paragraph, amending provision,	first paragraph, Table 1, Column 1, Ro	ow 4	
G	296	Greater than 50 litres but not exceeding 500 litres:	Greater than 50 litres but not exceeding 500 litres:	Greater than 50 litres but not exceeding 500 litres:	Greater than 50 litres but not exceeding 500 litres: Text Origin: Commission Proposal
	Annex I,	third paragraph, amending provision,	first paragraph, Table 1, Column 1, Ro	ow 5	
G	297	Greater than 500 litres:	Greater than 500 litres:	Greater than 500 litres:	Greater than 500 litres: Text Origin: Commission Proposal

195 14625/5/23 REV 5 AT/CDP/RPG/nm EN COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Annex I,	third paragraph, amending provision,	first paragraph, Table 1, Column 2, Ro	ow 1	
G	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	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 Text Origin: Commission Proposal
	Annex I,	third paragraph, amending provision,	first paragraph, Table 1, Column 2, Ro	ow 2	
G	299	If possible, at least 52x74	If possible, at least 52x74	If possible, at least 52x74	If possible, at least 52x74 Text Origin: Commission Proposal
	Annex I,	third paragraph, amending provision,	first paragraph, Table 1, Column 2, Ro	ow 3	
G	300	At least 74x105	At least 74x105	At least 74x105	At least 74x105 Text Origin: Commission Proposal
	Annex I,	third paragraph, amending provision,	first paragraph, Table 1, Column 2, Ro	ow 4	
â	301	At least 105x148	At least 105x148	At least 105x148	At least 105x148 Text Origin: Commission Proposal

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

196

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Annex I,	third paragraph, amending provision,	first paragraph, Table 1, Column 2, Ro	pw 5	
G	302	At least 148x210	At least 148x210	At least 148x210	At least 148x210 Text Origin: Commission Proposal
	Annex I,	third paragraph, amending provision,	first paragraph, Table 1, Column 3, Ro	ow 1	
G	303	Dimensions of each pictogram (in millimetres)	Dimensions of each pictogram (in millimetres)	Dimensions of each pictogram (in millimetres)	Dimensions of each pictogram (in millimetres) Text Origin: Commission Proposal
	Annex I,	third paragraph, amending provision,	first paragraph, Table 1, Column 3, Ro	ow 2	
G	304	Not smaller than 10x10 If possible, at least 16x16	Not smaller than 10x10 If possible, at least 16x16	Not smaller than 10x10 If possible, at least 16x16	Not smaller than 10x10 If possible, at least 16x16 Text Origin: Commission Proposal
	Annex I,	third paragraph, amending provision,	first paragraph, Table 1, Column 3, Ro	pw 3	
G	305	At least 23x23	At least 23x23	At least 23x23	At least 23x23 Text Origin: Commission Proposal
	Annex I,	third paragraph, amending provision,	first paragraph, Table 1, Column 3, Ro	ow 4	

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G	306	At least 32x32	At least 32x32	At least 32x32	At least 32x32 Text Origin: Commission Proposal
	Annex I,	third paragraph, amending provision,	first paragraph, Table 1, Column 3, Ro	pw 5	
G	307	At least 46x46	At least 46x46	At least 46x46	At least 46x46 Text Origin: Commission Proposal
	Annex I,	third paragraph, amending provision,	first paragraph, Table 1, Column 4, Ro	pw 1	
G	308	Minimum font-size	Minimum font-size	Minimum font-size (x-height in millimeters)	Minimum font-size (x-height in millimeters) Text Origin: Council Mandate
	Annex I,	third paragraph, amending provision,	first paragraph, Table 1, Column 4, Ro	ow 2	
G	309	8pt	8pt 1,4 (x-height in millimeters)	8pt1,4	8pt[Line 1: Capacity of the package: Not exceeding 0,5 litres; Dimensions of the label: If possible, at least 52x74; Dimensions of each pictogram: Not smaller than 10x10 If possible, at least 16x16; Minimum Font Size:] 1,2 [Line 2: Capacity of the package: Greater than 0,5 litres but not

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

198

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					exceeding 3 litres; Dimensions of the label: If possible, at least 52x74; Dimensions of each pictogram: Not smaller than 10x10 If possible, at least 16x16; Minimum Font Size: 11,4 This cell is to be split into two in the final version, given the agreement foresees 2 different rows as specified in the text of the 4th column (text for the 2 different rows in between brackets).
	Annex I,	third paragraph, amending provision,	first paragraph, Table 1, Column 4, Ro	ow 3	
G	310	12pt	12pt1,8 (x-height in millimeters)	12pt 1,8	12pt1.8 Text Origin: Council Mandate
	Annex I,	third paragraph, amending provision,	first paragraph, Table 1, Column 4, Ro	ow 4	
G	311	16pt	16pt2,4 (x-height in millimeters)	16pt 2,0	16pt 2,0 Text Origin: Council Mandate
	Annex I,	third paragraph, amending provision,	first paragraph, Table 1, Column 4, Ro	ow 5	
G	312	20pt';	20pt';3,0 (x-height in millimeters)	20pt 2,0 ';	20pt 2,0';

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Council Mandate
	Annex I,	fourth paragraph			
G	313	(3) the following Section 1.2.1.5. is added:	(3) the following Section 1.2.1.5. is added:	(3) the following Section 1.2.1.5. is added:	(3) the following Section 1.2.1.5. is added: Text Origin: Commission Proposal
	Annex I,	fourth paragraph a			
G	313a				G
	Annex I,	fourth paragraph, amending provision	n, first paragraph, first subparagraph		
G	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:	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: Text Origin: Commission Proposal
	Annex I,	fourth paragraph, amending provision	n, first paragraph, first subparagraph,	point (a)	
G	315	(a) the background of the label shall be white;	(a) the background of the label shall be white;	(a) the background of the label shall beprinted in black on a white background;	(a) the background of the label shall be printed in black on a white background;

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Council Mandate
	Annex I,	fourth paragraph, amending provision	n, first paragraph, first subparagraph,	point (b)	
G	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;	(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;	(b) the distance between two lines shall be equal or above 120 % of the font size; Text Origin: Commission Proposal
	Annex I,	fourth paragraph, amending provision	n, first paragraph, first subparagraph,	point (c)	
G	317	(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;	(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; Text Origin: Commission Proposal
	Annex I,	fourth paragraph, amending provision	n, first paragraph, first subparagraph,	point (d)	
G	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 legible.	(d) the letter spacing shall be appropriate for the selected font to be-comfortably easily legible.	(d) the letter spacing shall be appropriate for the selected font to be <i>comfortably easily</i> legible. Text Origin: Council Mandate
	Annex I,	fourth paragraph, amending provision	n, first paragraph, second subparagrap	ph	
G	319	For the labelling of inner packaging where the contents do	For the labelling of inner packaging where the contents do	For the labelling of inner packaging where the contents do	For the labelling of inner packaging where the contents do

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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 itisit 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.'	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 eyesighteasily legible, where itisit 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 17.2
Annex I,	fourth paragraph a			
319a		In Annex I, part I, the following section is added: Section 1.2.1.5.a For multilingual labels, the languages shall be ordered in a logical way, e.g. alphabetically.	(3a) the following Section 1.2.1.6. is added:	(3a) the following Section 1.2.1.6. is added: Text Origin: Council Mandate
Annex I,	point 1.			
319b				1. 1.2.1.6 Fold-out labels
Annex I,	point 1., amending provision, first par	agraph		
319c			c	6

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				1.2.1.6 The front page of the fold-out label shall include at least the following elements:	1.2.1.6 The front page of the fold- out label shall include at least the following elements: this should be 1.2.1.6.1. in the consolidated text, system doesn't allow it here Text Origin: Council Mandate
	Annex I,	point 1., amending provision, first par	agraph, point (a)		
G	319d			(i) name, address and phone number of supplier(s);	(i) name, address and phone number of supplier(s); Text Origin: Council Mandate
	Annex I,	point 1., amending provision, first par	agraph, point (b)		
G	319e			(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;	(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; Text Origin: Council Mandate
	Annex I,	point 1., amending provision, first par	agraph, point (c)		
G	319f			(iii) the product identifiers in	(iii) the product identifiers in

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

203

EN

		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;	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; Text Origin: Council Mandate
	Annex I,	point 1., amending provision, first par	agraph, point (d)		
G	319g			(iv) where applicable, hazard pictograms;	(iv) where applicable, hazard pictograms; Text Origin: Council Mandate
	Annex I,	point 1., amending provision, first par	agraph, point (e)		
G	319h			(v) where applicable, signal words in all languages of the label that are used in the inside pages;	(v) where applicable, signal words in all languages of the label that are used in the inside pages; Text Origin: Council Mandate
	Annex I,	point 1., amending provision, first par	agraph, point (f)		
G	319i			(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;	(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;

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

204

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Council Mandate
	Annex I,	point 1., amending provision, first par	agraph, point (g)		
G	319j			(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;	(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; Text Origin: Council Mandate
	Annex I,	point 1., amending provision, first par	agraph, point (h)		
G	319k			(viii) an abbreviation of the language (country code or language code) for all the languages that are used in the inside pages.	(viii) an abbreviation of the language (country code or language code) for all the languages that are used in the inside pages. Text Origin: Council Mandate
	Annex I,	point 1., amending provision, first par	agraph, point (i)		
	3191				(i) 1.2.1.6.2 The inner pages of the fold-out label shall contain all the label elements provided for in

14625/5/23 REV 5 AT/CDP/RPG/nm 205
COMPET 1 EN

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				Article 17(1), except for the hazard pictogram and the supplier identification, in each of the languages mentioned on the front page and grouped by language, using the language abbreviation (country code or language code).
Annex I,	point 1., amending provision, first par	agraph, point (j)		
319m				(j) 1.2.1.6.3 The back page of the fold-out label shall contain all the label elements provided on the front page, except for the abbreviations of the languages that are used in the inside pages.
Annex I,	fifth paragraph			
320	(4) the following Section 1.3.7. is added: Text Origin: Commission Proposal			
Annex I,	fifth paragraph, amending provision,	first paragraph, first subparagraph		
321	1.3.7. Ammunition	1.3.7. Ammunition	1.3.7. Ammunition	1.3.7. Ammunition

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

206

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Commission Proposal
	Annex I,	fifth paragraph, amending provision,	first paragraph, second subparagraph		
O	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 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 asis 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 asis 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.2; Text Origin: Council Mandate
	Annex I,	sixth paragraph			
G	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:	(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: Text Origin: Commission Proposal
	Annex I,	sixth paragraph, amending provision,	first paragraph		
G	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)	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)

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	,	,	,	Text Origin: Commission Proposal
Annex	I, seventh paragraph	-		
325	(6) Section 1.5.1.1. is replaced by the following:	(6) Section 1.5.1.1. is replaced by the following:	(6) Section 1.5.1.1. is replaced by the following:	(6) Section 1.5.1.1. is replaced by the following: Text Origin: Commission Proposal
Annex	I, seventh paragraph, amending provisi	on, 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.;	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.; Text Origin: Commission Proposal
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:	(7) Section 1.5.1.2. is replaced by the following:	(7) Section 1.5.1.2. is replaced by the following: Text Origin: Commission

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Proposal
	Annex I,	eighth paragraph, amending provision	n, first paragraph		
O	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 telephone number of the suppliers of the substance or mixture.;	1.5.1.2. Where section 1.5.1.1. applies, the label on any inner packaging shall contain at least 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 telephone number of the suppliers of the substance or mixture.;	1.5.1.2. Where section 1.5.1.1. applies, the label on any inner packaging shall contain at least hazard pictograms, the signal word, the trade name or the designation of the mixture product identifier referred to in Article 18(2) for substances or the trade name or designation referred to in Article 18(3), point (a) for mixtures, and the name and telephone number of the suppliers of the substance or mixture.';	1.5.1.2. Where section 1.5.1.1. applies, the label on any inner packaging shall contain at least hazard pictograms, the signal word, the trade name or the designation of the mixture product identifier referred to in Article 18(2) for substances or the trade name or designation referred to in Article 18(3), point (a) for mixtures, and the name and telephone number of the suppliers of the substance or mixture. 2;
	Annex I,	ninth paragraph			
G	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:	(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: Text Origin: Commission Proposal
	Annex I,	ninth paragraph, amending provision	, first paragraph		
G	330				C

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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)';	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)'; Text Origin: Commission Proposal
	Annex I,	tenth paragraph			
G	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:	(9) Section 1.5.2.4.1 is replaced by the following:	(9) Section 1.5.2.4.1 is replaced by the following: Text Origin: Commission Proposal
	Annex I,	tenth paragraph, amending provision	, first paragraph		
G	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 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:	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: Text Origin: Council Mandate
	Annex I,	tenth paragraph, amending provision	, first paragraph, point (a)		
G	333	(a) the substance or mixture is	(a) the substance or mixture is	(a) the substance or mixture is	(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;	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;	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;	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; Text Origin: Commission Proposal
/	Annex I,	tenth paragraph, amending provision	, first paragraph, point (b)		
G	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 any of the following hazard classes and categories:	(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 any of the following hazard classes and categories:	(b) the substance or mixture does not require labelling in accordance with Part 1, 2 or 4 or 2 of Annex II and is not classified in any of the following hazard classes and categories:	(b) the substance or mixture does not require labelling in accordance with Part 1, 2 or 4 or 2 of Annex II and is not classified in any of the following hazard classes and categories: Text Origin: Council Mandate
1	Annex I,	tenth paragraph, amending provision	, first paragraph, point (b)(i)		
G	335	(i) Acute toxicity, categories 1 to 4;	(i) Acute toxicity, categories 1 to 4; first paragraph, point (b)(ii), first sub	(i) Acute toxicity, eategories 1 to 4any category;	(i) Acute toxicity, categories 1 to 4any category; Text Origin: Council Mandate

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G	336	(ii) Specific target organ toxicity – Single exposure, categories 1 and	(ii) Specific target organ toxicity – Single exposure, categories 1 and	(ii) Specific target organ toxicity – Single exposure, categories 1 and 2;	(ii) Specific target organ toxicity – Single exposure, categories 1 and 2: Text Origin: Council Mandate
	Annex I,	tenth paragraph, amending provision	, first paragraph, point (b)(ii), second	subparagraph	
G	337	2;	2;	——————————————————————————————————————	2;deleted Text Origin: Council Mandate
	Annex I,	tenth paragraph, amending provision	, first paragraph, point (b)(iii), first sub	paragraph	
G	338	(iii) Specific target organ toxicity – repeated exposure, categories 1	(iii) Specific target organ toxicity – repeated exposure, categories 1	(iii) Specific target organ toxicity – repeated exposure, eategories +any category;	(iii) Specific target organ toxicity – repeated exposure, categories Lany category; Text Origin: Council Mandate
	Annex I,	tenth paragraph, amending provision	, first paragraph, point (b)(iii), second	subparagraph	
G	339	and 2;	and 2;	and 2;deleted	and 2;deleted Text Origin: Council Mandate
	Annex I,	tenth paragraph, amending provision	, first paragraph, point (b)(iv)		
G	340	(iv) Skin corrosion/irritation, category 1 (sub-categories 1A, 1B	(iv) Skin corrosion/irritation, category 1 (sub-categories 1A, 1B	(iv) Skin corrosion/irritationcorrosion,	(iv) Skin corrosion/irritationcorrosion,

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		and 1C);	and 1C);	category 1-(sub-categories 1A, 1B and 1C), any sub-category;	category 1 (sub-categories 1A, 1B) and 1C), any sub-category;
					Text Origin: Council Mandate
	Annex I,	tenth paragraph, amending provision	, first paragraph, point (b)(iva)		
G	340a		(iva) Serious eye damage category 1/eye irritation, category 2;	(iv1) Serious Eye Damage, category 1;	(iva) Serious Eye Damage, category 1; Text Origin: Council Mandate
	Annex I,	tenth paragraph, amending provision	, first paragraph, point (b)(ivb)		
G	340b			(iv2) Skin Sensitisation, any category	deleted Text Origin: Council Mandate
	Annex I,	tenth paragraph, amending provision	, first paragraph, point (b)(v)		
G	341	(v) Respiratory sensitisation, category 1 (sub-categories 1A and 1B);	(v) Respiratory sensitisation, category 1 (sub-categories 1A and 1B);	(v) Respiratory sensitisation, eategory 1 (sub-categories 1A and 1B) any category;	(v) Respiratory sensitisation, category 1 (sub-categories 1A and 1B)any category; Text Origin: Council Mandate
	Annex I,	tenth paragraph, amending provision	, first paragraph, point (b)(va)		
G	341a		(va) Skin sensitisation, category 1 (sub-categories 1A and 1B);		deleted

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				EP dropped its AM
Annex I,	tenth paragraph, amending provision,	first paragraph, point (b)(vi)		
342	(vi) Aspiration hazard;	(vi) Aspiration hazard;	(vi) Aspiration hazard;	(vi) Aspiration hazard; Text Origin: Commission Proposal
Annex I,	tenth paragraph, amending provision	, first paragraph, point (b)(vii)		
343	(vii) Germ cell mutagenicity, any category; Text Origin: Commission Proposal			
Annex I,	tenth paragraph, amending provision	, first paragraph, point (b)(viii)		
344	(viii) Carcinogenity, any category;	(viii) Carcinogenity, any category;	(viii) Carcinogenity, any category;	(viii) Carcinogenity, any category; Text Origin: Commission Proposal
Annex I,	tenth paragraph, amending provision	, first paragraph, point (b)(ix)		
345	(ix) Reproductive toxicity, any category;	(ix) Reproductive toxicity, any category;	(ix) Reproductive toxicity, any category;	(ix) Reproductive toxicity, any category; Text Origin: Commission

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

214

EN

	nnex I,	tenth paragraph, amending provision,	first paragraph point (h)(v)		Proposal
		tenth paragraph, amending provision,	first paragraph point (h)(v)		
6 34	346		, iirst paragrapii, poilit (b)(x)		
		(x) Flammable solids, categories 1 and 2.;	(x) Flammable solids, categories 1 and 2.;	deleted	deleted
Ann	nnex I,	tenth paragraph, amending provision,	first paragraph, point (b)(xi)		
G 34	347	(xi) Endocrine disruptors for human health, any category;	(xi) Endocrine disruptors for human health, any category;	(xi) Endocrine disruptors disruption for human health, any category;	(xi) Endocrine disruptorsdisruption health, any category; Text Origin: Council Mandate
Ann	nnex 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 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 Anne but is not classified in any of the hazard classes and categories referred to in point (b) and has a inner packaging that is containe within outer packaging that meet the requirements set out in Artic 17.';	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

215 14625/5/23 REV 5 AT/CDP/RPG/nm EN COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Annex I,	eleventh paragraph			
G	349	(10) the following Section 1.6. is added:	(10) the following Section 1.6. is added:	(10) the following Section 1.6. is added:	(10) the following Section 1.6. is added: Text Origin: Commission Proposal
	Annex I,	eleventh paragraph, amending provis	ion, numbered paragraph (1.6)		
G	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	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 Text Origin: Commission Proposal
	Annex I,	eleventh paragraph, amending provis	ion, numbered paragraph (1.6), point	(a)	
G	351	(a) Supplemental information referred to in Article 25(3);	(a) Supplemental information referred to in Article 25(3);	(a) Supplemental information referred to in Article 25(3);	(a) Supplemental information referred to in Article 25(3); Text Origin: Commission Proposal
	Annex II				
G	352	Annex II	Annex II	Annex II	Annex II Text Origin: Commission Proposal

COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Annex II,	first paragraph			
G	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:	Annex II to Regulation (EC) No 1272/2008 is amended as follows:	Annex II to Regulation (EC) No 1272/2008 is amended as follows: Text Origin: Commission Proposal
	Annex II,	first paragraph a			
G	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".		EP drops AM
	Annex II,	second paragraph			
G	353b		(-1b) in Part 3 of Annex II,		

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			section 3.2.1. is replaced by the following: "3.2.1. Packaging to be fitted with a tactile warning Where substances or mixtures are supplied to the general public and classified for acute toxicity, skin corrosion/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, 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".		EP drops AM
	Annex II,	second paragraph			
G	354	(1) in Part 3, the following Section 3.4. is added:	(1) in Part 3, the following Section 3.4. is added:	(1) in Part 3, the following Section 3.4. is added:	(1) in Part 3, the following Section 3.4. is added: Text Origin: Commission Proposal

A	Annex II,	second paragraph, amending provision	on, numbered paragraph (3,4), first su	hnaragraph	
			, - 8 - (-),	oparagraph	
G	355	3.4. Refill stations	3.4. Refill stations	3.4. '3.4. Supply via refill stations	3.4. <u>'3.4. Supply via refill stations</u> Text Origin: Council Mandate
А	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	l subparagraph	
G	356	Hazardous substances or mixtures referred to in Article 35(2a), shall meet the following conditions:	Hazardous substances or mixtures referred to in Article 35(2a), shall meet the following conditions:	When hazardous substances or mixtures referred to inare supplied in accordance with Article 35(2a), the supplier shall meet ensure that the following conditions are met:	When hazardous substances or mixtures referred to inare supplied in accordance with Article 35(2a), the supplier shall meet ensure that the following conditions are met: Text Origin: Council Mandate
Α	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	l subparagraph, point (a)	
G	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 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;	(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; Text Origin: Council Mandate

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G	358	(b) a label is firmly affixed on a visible place of the refill station and with a font size that is easily legible and without serifs;	(b) a label is firmly affixed on a visible place of the refill station and with a font size that is easily legible and without serifs; fulfils the requirements of Article 31	(b) a label is the labels on the refill station shall be firmly 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;	(b) a label is the labels on the refill station shall be firmly 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; Text Origin: Council Mandate
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	d subparagraph, point (ba)	
G	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;		EP drops its AM Text Origin: EP Mandate
	Annex II,	second paragraph, amending provisi	on, numbered paragraph (3.4), second	subparagraph, point (c)	
G	359	(c) substances and mixtures are only refilled in suitable and clean packaging without any visible residues, which are cleaned before	(c) substances and mixtures are only refilled in suitable and clean packaging without any visible residues, which are cleaned before	deleted	deleted

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		reuse in case of suspected microbiological or other invisible contamination;	reuse in case of suspected microbiological or other invisible contamination;		
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	subparagraph, point (d)	
G	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;	(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	deleted moved to row 362b
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	subparagraph, point (e)	
G	361	(e) overfilling packaging is technically prevented;	(e) overfilling packaging is technically prevented;	deleted	deleted
	Annex II,	second paragraph, amending provisi	on, numbered paragraph (3.4), second	subparagraph, point (f)	
G	362	(f) filling a substance or mixture into unsuitable packaging is technically prevented;	(f) filling a substance or mixture into unsuitable packaging is technically prevented;	deleted	deleted
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	subparagraph, point (fa)	
G	362a			(f1) risk mitigation measures are applied to ensure that exposure of humans, especially of children, and the environment is avoided as far as possible;	(fa) risk mitigation measures are applied to minimize the exposure of humans, especially of children, and of the environment;

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					this should be the firts of the examples that follow b)
					Text Origin: Council Mandate
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	subparagraph a	
	362b				measures are taken to prevent uncontrolled use of the refill station by children; check numbering in consolidated version
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	subparagraph a, point (g)	
G	363	(g) at the moment of refill, the supplier is reachable for immediate assistance;	(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;	(g) at the moment of refill, the supplier is <u>available on site for maintenance and reachable for immediate assistance, including emergency</u> assistance; Text Origin: Council Mandate
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	d subparagraph a, point (h)	
G	364	(h) refill stations are not operated outdoors and outside business hours where immediate assistance cannot be provided;	(h) refill stations are not operated outdoors and outside business hours where immediate assistance cannot be provided;	deleted	(h) refill stations are not can be operated outdoors and outside business hours where only if immediate assistance cannot be

14625/5/23 REV 5 AT/CDP/RPG/nm 222 COMPET 1 EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					provided;
	Annex II,	second paragraph, amending provision	 on, numbered paragraph (3.4), second	l subparagraph a, point (i)	
G	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;	(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	(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;
	Annex II,	second paragraph, amending provisi	on, numbered paragraph (3.4), second	l subparagraph a, point (j)	
G	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;	(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	(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;
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	l subparagraph a, point (ja)	
G	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;	(il) for every refilled package, the requirements on hazard communication in the form of labelling set out in Title III of this Regulation are fulfilled; Text Origin: Council Mandate
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	subparagraph a, point (jb)	
G	366b				G

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
				(j2) for every refilled package the requirements on packaging set out in Title IV of this Regulation are fulfilled;	(j2) for every refilled package the requirements on packaging set out in Title IV of this Regulation are fulfilled; Text Origin: Council Mandate
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	subparagraph a, point (k)	
G	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 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:	(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: Text Origin: Council Mandate
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	subparagraph a, point (k)(i)	
G	368	(i) Acute toxicity, categories 1 – 4;	(i) Acute toxicity, categories 1 – 4;	(i) Acute toxicity, categories 1—4any category;	(i) Acute toxicity, categories 1 4any category; Text Origin: Council Mandate
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	subparagraph a, point (k)(ii)	
G	369	(ii) Specific target organ toxicity – Single exposure, categories 1, 2	(ii) Specific target organ toxicity – Single exposure, categories 1, 2	(ii) Specific target organ toxicity – Single exposure, categories 1, 2	(ii) Specific target organ toxicity – Single exposure, categories 1, 2

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		and 3;	and 3;	and 3any category;	and 3any category;
					Text Origin: Council Mandate
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	subparagraph a, point (k)(iii)	
G	370	(iii) Specific target organ toxicity – repeated exposure, categories 1 and 2;	(iii) Specific target organ toxicity – repeated exposure, categories 1 and 2;	(iii) Specific target organ toxicity – repeated exposure, eategories 1 and 2any category;	(iii) Specific target organ toxicity - repeated exposure, eategories 1 and 2any category; Text Origin: Council Mandate
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	subparagraph a, point (k)(iv)	
G	371	(iv) Skin corrosion/irritation, category 1 (sub-categories 1A, 1B and 1C);	(iv) Skin corrosion/irritation, category 1 (sub-categories 1A, 1B and 1C);	(iv) Skin corrosion/irritationcorrosion, category 1-(sub-categories 1A, 1B and 1C), any sub-category;	(iv) Skin corrosion/irritationcorrosion, category 1 (sub-categories 1A, 1B) and 1C), any sub-category; Text Origin: Council Mandate
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	subparagraph a, point (k)(iva)	
G	371a		(iva) Serious eye damage category 1/eye irritation, category 2;	(iva) Serious eye damage, category 1;	(iva) Serious eye damage category 1; Text Origin: EP Mandate
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	subparagraph a, point (k)(v)	
G	372	(v) Respiratory sensitisation,	(v) Respiratory sensitisation,	(v) Respiratory sensitisation,	(v) Respiratory sensitisation,

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		category 1 (sub-categories 1A and 1B);	category 1 (sub-categories 1A and 1B);	category 1 (sub-categories 1A and 1B)any category;	category 1 (sub-categories 1A and 1B)any category;
					Text Origin: Council Mandate
	Annex II,	second paragraph, amending provisi	on, numbered paragraph (3.4), second	subparagraph a, point (k)(va)	
G	372a		(va) Skin sensitisation, category 1 (sub-categories 1A and 1B);	(va) Skin sensitisation, any category;	(va) Skin sensitisation, any category; Text Origin: Council Mandate
	Annex II,	second paragraph, amending provisi	on, numbered paragraph (3.4), second	subparagraph a, point (k)(vi)	
G	373	(vi) Aspiration hazard;	(vi) Aspiration hazard;	(vi) Aspiration hazard;	(vi) Aspiration hazard; Text Origin: Commission Proposal
	Annex II,	second paragraph, amending provisi	on, numbered paragraph (3.4), second	subparagraph a, point (k)(vii)	
G	374	(vii) Germ cell mutagenicity, any category;	(vii) Germ cell mutagenicity, any category;	(vii) Germ cell mutagenicity, any category;	(vii) Germ cell mutagenicity, any category; Text Origin: Commission Proposal
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	subparagraph a, point (k)(viii)	
G	375	(viii) Carcinogenicity, any category;	(viii) Carcinogenicity, any category;	(viii) Carcinogenicity, any category;	(viii) Carcinogenicity, any category;

14625/5/23 REV 5 AT/CDP/RPG/nm 226 EN

COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Commission Proposal
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	subparagraph a, point (k)(ix)	
G	376	(ix) Reproductive toxicity, any category;	(ix) Reproductive toxicity, any category;	(ix) Reproductive toxicity, any category;	(ix) Reproductive toxicity, any category; Text Origin: Commission Proposal
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	subparagraph a, point (k)(x)	
G	377	(x) Flammable gases, categories 1 and 2;	(x) Flammable gases, categories 1 and 2;	(x) Flammable gases, eategories 1 and 2any category;	(x) Flammable gases, eategories 1 and 2any category; Text Origin: Council Mandate
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	subparagraph a, point (k)(xi)	
G	378	(xi) Flammable liquids, categories 1 and 2;	(xi) Flammable liquids, categories 1 and 2;	(xi) Flammable liquids, categories 1 and 2;	(xi) Flammable liquids, categories 1 and 2; Text Origin: Commission Proposal
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	l subparagraph a, point (k)(xii)	
G	379	(xii) Flammable solids, categories 1 and 2.	(xii) Flammable solids, categories 1 and 2.	(xii) Flammable solids, categories 1 and 2 any category;	(xii) Flammable solids, categories 1 and 2.any category;

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Council Mandate
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	subparagraph a, point (k)(xiii)	
G	380	(xiii) [insert: Endocrine disruptor for human health, categories 1 and 2].';	(xiii) [insert: Endocrine disruptor for human health, categories 1 and 2].';	(xiii) [insert: Endocrine disruptordisruption for human health, eategories 1 and 2] any category2;	(xiii) <code>[insert:Endocrine disruptor disruption]</code> for human health, <code>categories 1 and 2]any category</code> ; Text Origin: Council Mandate
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	subparagraph a, point (k)(xiv)	
G	381	(xiv) [insert: Endocrine disruptor for the environment, category 1 and 2];	(xiv) [insert: Endocrine disruptor for the environment, category 1 and 2];	(xiv) [insert: Endocrine disruptordisruption for the environment, any category—1 and 2];	(xiv) finsert: Endocrine disruptordisruption for the environment, any category 1 and 2]; Text Origin: Council Mandate
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	subparagraph a, point (k)(xv)	
G	382	(xv) [insert: Persistent, bioaccumulative and toxic (PBT)];	(xv) [insert: Persistent, bioaccumulative and toxic (PBT)];	(xv) [insert: Persistent, Bioaccumulative and Toxic (PBT)] ;	(xv) <i>finsert:</i> Persistent, Bioaccumulative and Toxic <i>(PBT)]</i> ; Text Origin: Council Mandate
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	subparagraph a, point (k)(xvi)	
G	383				

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		(xvi) [insert: Very persistent and very bioaccumulative (vPvB)];	(xvi) [insert: Very persistent and very bioaccumulative (vPvB)];	(xvi) [insert: Very Persistent and Very Bioaccumulative (vPvB)] ;	(xvi) <i>finsert:</i> Very Persistent and Very Bioaccumulative (vPvB);
					Text Origin: Council Mandate
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	subparagraph a, point (k)(xvii)	
G	384	(xvii) [insert: Persistent, mobile and toxic (PMT)];	(xvii) [insert: Persistent, mobile and toxic (PMT)];	(xvii) [insert: Persistent, Mobile and Toxic (PMT)];	(xvii) <pre>finsert: Persistent, Mobile and Toxic (PMT); Text Origin: Council Mandate</pre>
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), second	subparagraph a, point (k)(xviii)	
G	385	(xviii) [insert Very persistent and very mobile (vPvM)].	(xviii) [insert Very persistent and very mobile (vPvM)].	(xviii) [insert- Very Persistent and Very Mobile (vPvM)] .	(xviii) <i>[insert</i> Very Persistent and Very Mobile <i>(vPvM)]</i> . Text Origin: Council Mandate
	Annex II,	second paragraph, amending provision	on, numbered paragraph (3.4), third s	ubparagraph	
G	386	By way of derogation from point (b), a single label on 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.;	By way of derogation from point (b), a single label on 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.;	By way of derogation from point (b)(a), a single label on 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.';	By way of derogation from point (b)(a), a single label on 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. 2;

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Annex II,	third paragraph	,	,	Text Origin: Council Mandate
G	387	(2) Part 5 is replaced by the following:	(2) Part 5 is replaced by the following:	(2) Part 5 is replaced by the following:	(2) Part 5 is replaced by the following: Text Origin: Commission Proposal
	Annex II,	third paragraph, amending provision	, first paragraph		
G	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	PART 5: HAZARDOUS SUBSTANCES AND MIXTURES TO WHICH ARTICLE 29(3) APPLIES	PART 5: HAZARDOUS SUBSTANCES AND MIXTURES TO WHICH ARTICLE 29(3) APPLIES Text Origin: Commission Proposal
	Annex II,	third paragraph, amending provision	, second paragraph		
G	389	Ready mixed cement and concrete in the wet state shall be accompanied by a copy of the label elements in accordance with Article 17.	Ready mixed cement and concrete in the wet state shall be accompanied by a copy of the label elements in accordance with Article 17.	Ready mixed cement and concrete in the wet state shall be accompanied by a copy of the label elements in accordance with Article 17.	Ready mixed cement and concrete in the wet state shall be accompanied by a copy of the label elements in accordance with Article 17. Text Origin: Commission

230 14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Proposal
	Annex II,	third paragraph, amending provision	, third paragraph		
O	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 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.';	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.'; Text Origin: Council Mandate
	Annex III				
G	391	Annex III	Annex III	Annex III	Annex III Text Origin: Commission Proposal

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex III. fi	rst paragraph -a			
391a	rst paragraph -a	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 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:		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 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:

232 14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1



Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	— Proposal The proposal shall		— Proposal The proposal shall
	include the identity of the		include the identity of the
	substance or substances		substance or substances
	concerned and the harmonised		concerned and the harmonised
	classification and labelling		classification and labelling
	proposed;		proposed;
	— Justification for the proposed		— Justification for the proposed
	harmonised classification and		harmonised classification and
	<u>labelling.</u>		<u>labelling.</u>
	A comparison of the available		A comparison of the available
	information with the criteria		information with the criteria
	contained in Parts 2 to 5, taking		contained in Parts 2 to 5, taking
	into account the general		into account the general
	principles in Part 1, of Annex I to		principles in Part 1, of Annex I to
	this Regulation shall be completed		this Regulation shall be completed
	and documented in the format set		and documented in the format set
	out in Part B of the Chemical		out in Part B of the Chemical
	Safety Report in Annex I to		Safety Report in Annex I to
	<u>Regulation (EC) No 1907/2006.</u>		<u>Regulation (EC) No 1907/2006.</u>
	— Justification for the proposed		— Justification for the proposed
	grouping of substances to		grouping of substances to
	harmonized classification and		harmonized classification and
	labelling.		labelling.
	Where a harmonised		Where a harmonised
	classification and labelling		classification and labelling
	proposal is made for a group of		proposal is made for a group of
	substances, the dossier shall		substances, the dossier shall
	include a scientific justification.		include a scientific justification.
	— Justification for other effects at Community level.		— Justification for other effects at Community level.
			For effects other than
	For effects other than carcinogenity, mutagenicity,		carcinogenity, mutagenicity,
	reprotoxicity, endocrine		reprotoxicity, endocrine
	disruption for human health and		disruption for human health and
	usi upuon joi numun neuun unu		usraphon for numan neath and

233 14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1



	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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."		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." Text Origin: EP Mandate
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 VIII to Regulation (EC) No 1272/2008 is amended as follows:	Annex VIII to Regulation (EC) No 1272/2008 is amended as follows: Text Origin: Commission Proposal
Annex	III, second paragraph			
393	(1) Part A is amended as follows:	(1) Part A is amended as follows:	(1) Part A is amended as follows:	(1) Part A is amended as follows: Text Origin: Commission Proposal

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

234

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Annex III	, second paragraph, point (a)			
G	394	(a) Section 1 is replaced by the following:	(a) Section 1 is replaced by the following:	(a) Section 1 is replaced by the following:	(a) Section 1 is replaced by the following: Text Origin: Commission Proposal
	Annex III	, second paragraph, point (a), amend	ing provision, numbered paragraph (1)	
G	395	1. Application	1. Application	1. Application	1. Application Text Origin: Commission Proposal
	Annex III	, second paragraph, point (a), amend	ing provision, numbered paragraph (1), point (1.1)	
G	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 Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2021.	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 Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2021.	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 meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2021.	1.1 Importers, downstream users and distributors referred to in Article 45(<u>1b</u>) and (1c) placing on the market mixtures for consumer use, within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2021. Text Origin: Council Mandate
	Annex III	, second paragraph, point (a), amend	ng provision, numbered paragraph (1), point (1.2)	
G	397	1.2. Importers, downstream users	1.2. Importers, downstream users	1.2. Importers, downstream users	1.2. Importers, downstream users

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.	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.	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.	and distributors referred to in Article 45(<u>1b</u>) <u>and (</u> 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. Text Origin: Council Mandate
	Annex III	, second paragraph, point (a), amendi	ng provision, numbered paragraph (1), point (1.3)	
G	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(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.	1.3. Importers, downstream users and distributors referred to in Article 45(<i>Ib</i>) 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. Text Origin: Council Mandate
	Annex III	, second paragraph, point (a), amendi	ng provision, numbered paragraph (1), point (1.4)	
G	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)	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)	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	1.4. Importers, downstream users and distributors referred to in Article 45(<u>1b</u>) and (1c) having submitted information relating to hazardous mixtures to a body appointed in accordance with

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.	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.	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.	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. Text Origin: Council Mandate
	Annex III	, second paragraph, point (a), amend	ing provision, numbered paragraph (1), point (1.5)	
G	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 mixture, as changed, on the market.;	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 mixture, as changed, on the market.;	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 placing that mixture, as ehanged, on the market.';	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 placing that mixture, as changed, on the market. 2;
	Annex III	, second paragraph, point (b)			
G	401	(b) Section 2.1 is replaced by the following:	(b) Section 2.1 is replaced by the following:	(b) Section 2.1 is replaced by the following:	(b) Section 2.1 is replaced by the following: Text Origin: Commission

COMPET 1

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Proposal
III, second paragraph, point (b), amend	ing provision, numbered paragraph (2	.1)	
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.;	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.; Text Origin: Commission Proposal
III, second paragraph, point (c)			
(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:	(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: Text Origin: Commission Proposal
11	subparagraph, the following point (6) is added:	subparagraph, the following point (6) is added: subparagraph, the following point (6) is added:	subparagraph, the following point subparagraph, the following point subparagraph, the following point

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G	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.;	(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.; Text Origin: Commission Proposal
	Annex III	, third paragraph			
G	405	(2) Part B is amended as follows:	(2) Part B is amended as follows:	(2) Part B is amended as follows:	(2) Part B is amended as follows: Text Origin: Commission Proposal
	Annex III	, third paragraph, point (a)			
G	406	(a) the following Section 1.1a. is inserted:	(a) the following Section 1.1a. is inserted:	(a) the following Section 1.1a. is inserted:	(a) the following Section 1.1a. is inserted: Text Origin: Commission Proposal
	Annex III	, third paragraph, point (a), amending	provision, first paragraph		

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G	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	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 Text Origin: Commission Proposal
	Annex III	, third paragraph, point (a), amending	g provision, second paragraph		
G	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.	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. Text Origin: Commission Proposal
	Annex III	, third paragraph, point (a), amending	provision, third paragraph		
G	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.;	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.; Text Origin: Commission Proposal
	Annex III	, third paragraph, point (b)			

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G	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:	(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: Text Origin: Commission Proposal
	Annex III	, third paragraph, point (b), amending	provision, first paragraph		
O	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 shall be notified even if the component is potentially not, or not permanently, present in cases	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 shall be notified even if the component is potentially not, or not permanently, present in cases	Components which are not present in a mixture shall not be notified. However, if thethose 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 shall be notified even if the component is potentially not, or not permanently, present in cases	Components which are not present in a mixture shall not be notified. However, if thethose 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 shall be notified even if the component is potentially not, or not permanently, present in cases

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		where the indicated concentration range in Part D includes 0 %.;	where the indicated concentration range in Part D includes 0 %.;	where the indicated concentration range in Part D includes 0 %.';	where the indicated concentration range in Part D includes 0 %.2;
					Text Origin: Council Mandate
	Annex III	, third paragraph, point (c)			
G	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:	(c) the title of Section 3.6. is replaced by the following:	(c) the title of Section 3.6. is replaced by the following: Text Origin: Commission Proposal
	Annex III	, third paragraph, point (c), amending	provision, numbered paragraph (3.6)		
G	413	3.6. Mixtures with a composition conforming with a standard formula;	3.6. Mixtures with a composition conforming with a standard formula;	3.6. Mixtures with a composition conforming with a standard formula;	3.6. Mixtures with a composition conforming with a standard formula; Text Origin: Commission Proposal
	Annex III	, third paragraph, point (d)	_	_	
G	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:	(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: Text Origin: Commission

COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Proposal
	Annex III	, third paragraph, point (d), amending	provision, first paragraph		
G	415	"			G
	Annex III	, third paragraph, point (d), amending	provision, Table 2, Column 1, Row 1		
G	416	'Fuel name	" 'Fuel name	"Fuel name	'Fuel name Text Origin: Commission Proposal
	Annex III	, third paragraph, point (d), amending	provision, Table 2, Column 2, Row 1		
G	417	Product description';	Product description';	Product description';	Product description'; Text Origin: Commission Proposal
_]	Annex III	, third paragraph, point (d), amending	provision, second paragraph		
G	418	п			G
	Annex III	, third paragraph, point (e)			
G	419				G

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(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; :	(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; :
				Text Origin: Commission Proposal
Anne	III, third paragraph, point (e), amending	g provision, first paragraph		
⁶ 420	- 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;	- 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; Text Origin: Commission Proposal
Anne	III, fourth paragraph			
421	(3) Part C is amended as follows:	(3) Part C is amended as follows:	(3) Part C is amended as follows:	(3) Part C is amended as follows: Text Origin: Commission Proposal
Anne	III, fourth paragraph, point (a)			
422	(a) Section 1.2. is replaced by the following:	(a) Section 1.2. is replaced by the following:	(a) Section 1.2. is replaced by the following:	(a) Section 1.2. is replaced by the following:

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (a), amendii	ng provision, numbered paragraph (1.2	2)	
G	423	1.2. Identification of the mixture, submitter and contact point	1.2. Identification of the mixture, submitter and contact point	1.2. Identification of the mixture, submitter and contact point	1.2. Identification of the mixture, submitter and contact point Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (a), amendii	ng provision, second paragraph		
G	424	Product identifier	Product identifier	Product identifier	Product identifier Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (a), amendii	ng provision, second paragraph, first ir	ndent	
G	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.	- 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. Text Origin: Commission Proposal

14625/5/23 REV 5 AT/CDP/RPG/nm 245
COMPET 1 EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Annex III	, fourth paragraph, point (a), amendi	ng provision, second paragraph, secor	nd indent	
G	426	- Unique Formula Identifier(s) (UFI)	- Unique Formula Identifier(s) (UFI)	- Unique Formula Identifier(s) (UFI)	- Unique Formula Identifier(s) (UFI) Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (a), amendi	ng provision, second paragraph, third	indent	
G	427	- Other identifiers (authorisation number, company product codes)	- Other identifiers (authorisation number, company product codes)	- Other identifiers (authorisation number, company product codes)	- Other identifiers (authorisation number, company product codes) Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (a), amendi	ng provision, second paragraph, fourt	n indent	
G	428	- In case of group submission, all product identifiers shall be listed.	- In case of group submission, all product identifiers shall be listed.	- In case of group submission, all product identifiers shall be listed.	- In case of group submission, all product identifiers shall be listed. Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (a), amendi	ng provision, third paragraph		
G	429	Name and product description of standard formula or name of fuel	Name and product description of standard formula or name of fuel	Name and product description of standard formula or name of fuel	Name and product description of standard formula or name of fuel Text Origin: Commission

14625/5/23 REV 5 AT/CDP/RPG/nm 246
COMPET 1 EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Proposal
	A 10 10 11 111	fourth roughly point (a) are and in	a province third paragraph first ind		
	Annex III	, fourth paragraph, point (a), amendir	ng provision, third paragraph, first ind	ent	
G	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)	- 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) Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (a), amendir	ng provision, third paragraph, second	indent	
G	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)	- Fuel name as specified in Table 3 of Part B (where applicable)	- Fuel name as specified in Table 3 of Part B (where applicable) Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (a), amendir	ng provision, fourth paragraph		
G	432	Contact details of the submitter and contact point	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 pointContact 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 Text Origin: Council Mandate
	Annex III	, fourth paragraph, point (a), amendir	ng provision, fourth paragraph, first in	dent	
G	433				G

14625/5/23 REV 5 AT/CDP/RPG/nm 247 COMPET 1

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		- Name	- Name	- Name	- Name
					Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (a), amendi	ng provision, fourth paragraph, second	d indent	
G	434	- Full address	- Full address	- Full address	- Full address Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (a), amendi	ng provision, fourth paragraph, third in	ndent	
G	435	- Telephone number	- Telephone number	- Telephone number	- Telephone number Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (a), amendi	ng provision, fourth paragraph, fourth	indent	
G	436	- E-mail address	- E-mail address	- E-mail address	- E-mail address Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (a), amendii	ng provision, fifth paragraph		
G	437	Contact details for rapid access to additional product information (24 hours/7 days). Only for limited	Contact details for rapid access to additional product information (24 hours/7 days). Only for limited	Contact details for rapid access to additional product information (24 hours/7 days). Only for limited	Contact details for rapid access to additional product information (24 hours/7 days). Only for limited

14625/5/23 REV 5 AT/CDP/RPG/nm 248 EN

COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		submission.	submission.	submission.	submission.
					Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (a), amendir	ng provision, fifth paragraph, first inde	ent	
G	438	- Name	- Name	- Name	- Name Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (a), amendir	ng provision, fifth paragraph, second in	ndent	
G	439	- Telephone number (accessible 24 hours per day, 7 days per week)	- Telephone number (accessible 24 hours per day, 7 days per week)	- Telephone number (accessible 24 hours per day, 7 days per week)	- Telephone number (accessible 24 hours per day, 7 days per week) Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (a), amendir	ng provision, fifth paragraph, third ind	ent	
G	440	- E-mail address;	- E-mail address;	- E-mail address;	- E-mail address; , Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (b)			
	ATTICX III	, roaren paragrapii, point (b)			
G	441	(b) Section 1.4. is replaced by the			

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		following:	following:	following:	following:
					Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (b), amendi	ng provision, numbered paragraph (1.	4), first subparagraph	
G	442	1.4. Information on the mixture components and interchangeable	1.4. Information on the mixture components and interchangeable	1.4. Information on the mixture components and interchangeable	1.4. Information on the mixture components and interchangeable Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (b), amendii	ng provision, numbered paragraph (1.	4), second subparagraph	
G	443	component groups	component groups	component groups	component groups Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (b), amendi	ng provision, second paragraph		
G	444	Identification of the mixture components	Identification of the mixture components	Identification of the mixture components	Identification of the mixture components Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (b), amendi	ng provision, second paragraph, first i	ndent	
G	445				6

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		- Chemical/trade name of the components			
					Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (b), amendi	ng provision, second paragraph, secon	d indent	
G	446	- CAS number (where applicable)	- CAS number (where applicable)	- CAS number (where applicable)	- CAS number (where applicable) Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (b), amendi	ng provision, second paragraph, third	indent	
G	447	- EC number (where applicable)	- EC number (where applicable)	- EC number (where applicable)	- EC number (where applicable) Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (b), amendi	ng provision, second paragraph, fourth	n indent	
G	448	- UFI (where applicable)	- UFI (where applicable)	- UFI (where applicable)	- UFI (where applicable) Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (b), amendii	ng provision, second paragraph, fifth i	ndent	
G	449	- Standard formula name and product description (where	- Standard formula name and product description (where	- Standard formula name and product description (where	- Standard formula name and product description (where

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		applicable)	applicable)	applicable)	applicable)
					Text Origin: EP Mandate
	Annex III	, fourth paragraph, point (b), amendi	ng provision, second paragraph, sixth	indent	
G	450	- Fuel name (where applicable)';	- Fuel name (where applicable)';	- Fuel name (where applicable)';	deleted Text Origin: Commission Proposal
	Annex III,	, fourth paragraph, point (b), amendii	ng provision, third paragraph		
G	451	Name of interchangeable component groups (where applicable)	Name of interchangeable component groups (where applicable)	Name of interchangeable component groups (where applicable)	Name of interchangeable component groups (where applicable) Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (b), amendi	ng provision, fourth paragraph		
G	452	Concentration and concentration ranges of the mixture components	Concentration and concentration ranges of the mixture components	Concentration and concentration ranges of the mixture components	Concentration and concentration ranges of the mixture components Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (b), amendi	ng provision, fourth paragraph, first in	dent	
G	453				c

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		- Exact concentration or concentration range			
					Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (b), amendir	ng provision, fifth paragraph		
G	454	Classification of mixture components	Classification of mixture components	Classification of mixture components	Classification of mixture components Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (b), amendir	ng provision, fifth paragraph, first inde	ent	
G	455	- Hazard classification (where applicable)	- Hazard classification (where applicable)	- Hazard classification (where applicable)	- Hazard classification (where applicable) Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (b), amendir	ng provision, fifth paragraph, second i	ndent, first subparagraph	
G	456	- Additional identifiers (where applicable and relevant for health	- Additional identifiers (where applicable and relevant for health	- Additional identifiers (where applicable and relevant for health	- Additional identifiers (where applicable and relevant for health Text Origin: Commission Proposal
	Annex III	, fourth paragraph, point (b), amendir	ng provision, fifth paragraph, second i	ndent, second subparagraph	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
s 457	response)	response)	response)	response) Text Origin: Commission Proposal
Annex I	II, fourth paragraph, point (b), amendi	ng provision, sixth paragraph		
c 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);	List according to Part B, Section 3.1, fifth subparagraph (where applicable);	List according to Part B, Section 3.1, fifth subparagraph (where applicable); Text Origin: Commission Proposal
Anney I	 I, fifth paragraph			
6 459	(4) Part D is amended as follows:	(4) Part D is amended as follows:	(4) Part D is amended as follows:	(4) Part D is amended as follows: Text Origin: Commission Proposal
Annex I	II, fifth paragraph, point (a)			
G 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:	(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: Text Origin: Commission Proposal

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

254

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Annex III	, fifth paragraph, point (a), amending	provision, first paragraph		
G	461	п			G
	Annex III	, fifth paragraph, point (a), amending	provision, Table 3, Column 1, Row 1		
G	462	'Standard formula name	"Standard formula name	'Standard formula name	'Standard formula name Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (a), amending	provision, Table 3, Column 2, Row 1		
G	463	Cement Standard Formula 1'	Cement Standard Formula 1'	Cement Standard Formula 1'	Cement Standard Formula 1' Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (a), amending	provision, Table 4, Column 1, Row 1		
G	464	'Standard formula name	'Standard formula name	'Standard formula name	'Standard formula name Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (a), amending	provision, Table 4, Column 2, Row 1		
G	465				G

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Cement Standard Formula 2'	Cement Standard Formula 2'	Cement Standard Formula 2'	Cement Standard Formula 2'
					Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (a), amending	provision, Table 5, Column 1, Row 1		
G	466	'Standard formula name	'Standard formula name	'Standard formula name	'Standard formula name Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (a), amending	provision, Table 5, Column 2, Row 1		
G	467	Cement Standard Formula 3'	Cement Standard Formula 3'	Cement Standard Formula 3'	Cement Standard Formula 3' Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (a), amending	provision, Table 6, Column 1, Row 1		
G	468	'Standard formula name	'Standard formula name	'Standard formula name	'Standard formula name Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (a), amending	provision, Table 6, Column 2, Row 1		
G	469	Cement Standard Formula 4'	Cement Standard Formula 4'	Cement Standard Formula 4'	Cement Standard Formula 4' Text Origin: Commission Proposal

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

256

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Annex III	, fifth paragraph, point (a), amending	provision, Table 7, Column 1, Row 1		
G	470	'Standard formula name	'Standard formula name	'Standard formula name	'Standard formula name Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (a), amending	provision, Table 7, Column 2, Row 1		
G	471	Cement Standard Formula 5'	Cement Standard Formula 5'	Cement Standard Formula 5'	Cement Standard Formula 5' Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (a), amending	provision, Table 8, Column 1, Row 1		
G	472	'Standard formula name	'Standard formula name	'Standard formula name	'Standard formula name Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (a), amending	provision, Table 8, Column 2, Row 1		
G	473	Cement Standard Formula 6' , fifth paragraph, point (a), amending	Cement Standard Formula 6'	Cement Standard Formula 6'	Cement Standard Formula 6' Text Origin: Commission Proposal

14625/5/23 REV 5 257 AT/CDP/RPG/nm COMPET 1 EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G	474	'Standard formula name	'Standard formula name	'Standard formula name	'Standard formula name Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (a), amending	provision, Table 9, Column 2, Row 1		
G	475	Cement Standard Formula 7'	Cement Standard Formula 7'	Cement Standard Formula 7'	Cement Standard Formula 7' Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (a), amending	provision, Table 10, Column 1, Row 1		
G	476	'Standard formula name	'Standard formula name	'Standard formula name	'Standard formula name Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (a), amending	provision, Table 10, Column 2, Row 1		
G	477	Cement Standard Formula 8'	Cement Standard Formula 8'	Cement Standard Formula 8'	Cement Standard Formula 8' Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (a), amending	provision, Table 11, Column 1, Row 1		
G	478	'Standard formula name	'Standard formula name	'Standard formula name	'Standard formula name

14625/5/23 REV 5 AT/CDP/RPG/nm 258 COMPET 1

EN

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

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Cement Standard Formula 11'	Cement Standard Formula 11'	Cement Standard Formula 11'	Cement Standard Formula 11'
					Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (a), amending	provision, Table 14, Column 1, Row 1		
G	484	'Standard formula name	'Standard formula name	'Standard formula name	'Standard formula name Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (a), amending	provision, Table 14, Column 2, Row 1		
G	485	Cement Standard Formula 12';	Cement Standard Formula 12';	Cement Standard Formula 12';	Cement Standard Formula 12'; Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (a), amending	provision, Table 15, Column 1, Row 1		
G	486	'Standard formula name	'Standard formula name	'Standard formula name	'Standard formula name Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (a), amending	provision, Table 15, Column 2, Row 1		
G	487	Cement Standard Formula 13'	Cement Standard Formula 13'	Cement Standard Formula 13'	Cement Standard Formula 13' Text Origin: Commission Proposal

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

260

EN

		EP Mandate	Council Mandate	Draft Agreement
nex III	, fifth paragraph, point (a), amending	provision, Table 16, Column 1, Row 1		
188	'Standard formula name	'Standard formula name	'Standard formula name	'Standard formula name Text Origin: Commission Proposal
nex III	, fifth paragraph, point (a), amending	provision, Table 16, Column 2, Row 1		
189	Cement Standard Formula 14'	Cement Standard Formula 14'	Cement Standard Formula 14'	Cement Standard Formula 14' Text Origin: Commission Proposal
nex III	, fifth paragraph, point (a), amending	provision, Table 17, Column 1, Row 1		
190	'Standard formula name	'Standard formula name	'Standard formula name	'Standard formula name Text Origin: Commission Proposal
nex III	, fifth paragraph, point (a), amending	provision, Table 17, Column 2, Row 1		
191	Cement Standard Formula 15'	Cement Standard Formula 15'	Cement Standard Formula 15'	Cement Standard Formula 15' Text Origin: Commission Proposal
1º	nex III	nex III, fifth paragraph, point (a), amending Cement Standard Formula 15'	Pool Deex III, fifth paragraph, point (a), amending provision, Table 17, Column 2, Row 1 Cement Standard Formula 15' Cement Standard Formula 15'	Poex III, fifth paragraph, point (a), amending provision, Table 17, Column 2, Row 1 Cement Standard Formula 15' Cement Standard Formula 15' Cement Standard Formula 15'

14625/5/23 REV 5 AT/CDP/RPG/nm 261 COMPET 1

EN

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

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

262

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (a), amending	provision. Table 20. Column 2. Row 1		
G	497	Cement Standard Formula 18'	Cement Standard Formula 18'	Cement Standard Formula 18'	Cement Standard Formula 18' Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (a), amending	provision, Table 21, Column 1, Row 1		
G	498	'Standard formula name	'Standard formula name	'Standard formula name	'Standard formula name Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (a), amending	provision, Table 21, Column 2, Row 1		
G	499	Cement Standard Formula 19'	Cement Standard Formula 19'	Cement Standard Formula 19'	Cement Standard Formula 19' Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (a), amending	provision, Table 22, Column 1, Row 1		
G	500	'Standard formula name	'Standard formula name	'Standard formula name	'Standard formula name Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (a), amending	provision, Table 22, Column 2, Row 1		

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

263

EN

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
G	501	Cement Standard Formula 20';	Cement Standard Formula 20';	Cement Standard Formula 20';	Cement Standard Formula 20'; Text Origin: Commission Proposal
	Annex III	l, fifth paragraph, point (a), amending	provision, second paragraph		
G	502	"			G
	Annex III	, fifth paragraph, point (b)	,		
G	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 of the table with standard formula for gypsum is replaced by the following:	(b) In section 2, the two-first rowsrow of the table with standard formula for gypsum is replaced by the following two rows:	(b) In section 2, the two-first two-first of the table with standard formula for gypsum is replaced by the following two rows: Text Origin: Council Mandate
	Annex III	, fifth paragraph, point (b), amending	provision, first paragraph		
G	504	"			G
	Annex III	, fifth paragraph, point (b), amending	provision, Table 23, Column 1, Row 1		
G	505	'Standard formula name	'Standard formula name	" 'Standard formula name	'Standard formula name

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (b), amending	provision, Table 23, Column 1, Row 2		
G	506	Product description	Product description	Product description	Product description Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (b), amending	provision, Table 23, Column 2, Row 1		
G	507	— Gypsum binder Standard Formula	— Gypsum binder Standard Formula	— Gypsum binder Standard Formula	— Gypsum binder Standard Formula Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (b), amending	provision, Table 23, Column 2, Row 2		
G	508	Gypsum binder';	Gypsum binder';	Gypsum binder';	Gypsum binder'; Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (b), amending	provision, second paragraph		
G	509	11			G

14625/5/23 REV 5 AT/CDP/RPG/nm COMPET 1

EN

265

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement	
	Annex III	, fifth paragraph, point (c)				
G	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) In section 3, the two first rows of the tables with standard formulas for ready mixed concrete are replaced by the following:	(e)(a) (c) In section 3, the two first rowsrow of the tables with standard formulas for ready mixed concrete are replaced by the following:	(c) (c) In section 3, the two first to standard formulas for ready mixed concrete are replaced by the following: Text Origin: Council Mandate	
	Annex III	, fifth paragraph, point (c), amending	provision, first paragraph			
G	511	"			G	
	Annex III	, fifth paragraph, point (c), amending	provision, Table 24, Column 1, Row 1			
G	512	'Standard formula name	'Standard formula name	" 'Standard formula name	'Standard formula name Text Origin: Commission Proposal	
	Annex III, fifth paragraph, point (c), amending provision, Table 24, Column 1, Row 2					
G	513	Product description	Product description	Product description	Product description Text Origin: Commission Proposal	

COMPET 1

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Annex III	, fifth paragraph, point (c), amending	provision, Table 24, Column 2, Row 1		
G	514	— Ready mixed concrete Standard Formula 1	— Ready mixed concrete Standard Formula 1	— Ready mixed concrete Standard Formula 1	— Ready mixed concrete Standard Formula 1 Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (c), amending	provision, Table 24, Column 2, Row 2		
G	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°;	—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'; Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (c), amending	provision, Table 25, Column 1, Row 1		
G	516	'Standard formula name	'Standard formula name	'Standard formula name	'Standard formula name Text Origin: Commission Proposal
Annex III, fifth paragraph, point (c), amending provision, Table 25, Column 1, Row 2					
G	517	Product description	Product description	Product description	Product description

		Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
					Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (c), amending	provision, Table 25, Column 2, Row 1		
G	518	— Ready mixed concrete Standard Formula 2	— Ready mixed concrete Standard Formula 2	— Ready mixed concrete Standard Formula 2	— Ready mixed concrete Standard Formula 2 Text Origin: Commission Proposal
	Annex III	, fifth paragraph, point (c), amending	provision, Table 25, Column 2, Row 2		
G	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'.	—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		
G	520	"			G

14625/5/23 REV 5

COMPET 1

AT/CDP/RPG/nm

268

EN