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MEETING DOCUMENT

From:	Presidency
To:	Working Party on Technical Harmonisation (Dangerous Substances - Chemicals)
N° prev. doc.:	ST 7616 2023
N° Cion doc.:	ST 16258 2022 ADD 1 - 8
Subject:	Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Revision) - Comments by AT, BE, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK on the Presidency compromise proposal on Subgroups A1 and A2

Presidency Compromise Proposal on Subgroups A1 and A2 (ST 7616/23)	Drafting Suggestions AT, BE, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK	Comments AT, BE, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK
		PL: Poland appreciates the opportunity to present comments on the updated and previously discussed provisions of CLP Regulation. We welcome introduction of the solutions for fold out labels usage. The compromise text in the area of Subgroup A1 and A2 of the Cluster document is progressing in the right direction for what we thank the Presidency and the Commission.
Cluster A – Labelling and Sales		
Subgroup A1: Labelling obligations/exemptions		
<u>Articles in A1</u>		
(8) in Article 23, the following point (g) is added:		
‘(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 in Article 2, point (9), of this Regulation.	FR: ‘(g) <u>equipment and</u> ammunition <u>as listed as ML3 and ML4 equipment in the common military list of the European Union (notice 2020/C 85/01 adopted by</u>	FR: We wish to recall here the importance of our request to extend the exemption for ammunition considered as articles under Article 23(g) (in the light of Recital 7) to ML3 and ML4 military equipment as provided for in the Common Military

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).’

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	<u>the Council on 17 February 2020)</u> or 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. LT: ‘(g) ammunition as defined in Article 1(1), point (3), of Directive (EU) 2021/555 of the European Parliament and of the Council² unless it falls within the definition of an article in Article 2, point (9), of this Regulation.	List. Furthermore, it seems important, for the clarification of the exemption of ammunition considered as articles, to underline its articulation with Article 4(8). While the wording of recital 7 allows some ammunition classified as articles to be considered exempted from the labelling requirement, the proposed revision of the regulation does not propose an amendment of Article 4(8), which states: "For the purposes of this Regulation, the articles referred to in Annex I, section 2.1, shall be classified, labelled and packaged in accordance with the rules applicable to substances and mixtures before they are placed on the market. We therefore see a contradiction between Articles 4(8) and 23(g). This contradiction should be managed. Could you clarify that the combination of recital 7 and article 23(g) allows exempting some ammunition including articles, those related to section 2.1? LT: We are positive regarding this derogation and the compromise text. But we still have some doubts regarding the definition of ammunition.

² 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).’

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		As we understand, CLP labelling requirements apply to all natures of ammunition placed on the market, including articles. Why regarding the definition of ammunition in Art. 23(g) the exemption of labelling is foreseen just for ammunition that is defined as substances and mixtures, but not as articles. In the recital 7 it is explained that the exemption would be mainly used for articles, that under CLP are qualified as substances or mixtures and should be labelled accordingly. But they are still articles under definition in CLP Art. 2(9). To avoid misinterpretation, we suggest deleting the second part of point g “unless it falls within the definition of an article in Article 2, point (9), of this Regulation “.
(9) Article 25 is amended as follows:	ES: Paragraph 2 is replaced by the following: 2. A statement shall be included in the section for supplemental information on the label where a substance or mixture classified as hazardous falls within the scope of Directive 91/414/EEC <u>Regulation (CE) 1107/2009</u>.	ES: Directive 91/414/ECC was repealed by Regulation (CE) 1107/2009. IT: we agree

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	The statement shall be worded in accordance with Part 4 of Annex II and Part 3 of Annex III to this Regulation.	
<u>(x) paragraph 3 is replaced by the following:</u>	EL: We agree	IT: we agree
<u>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.’;</u>		DK: Denmark interprets the revised provision, when read in conjunction with section 1.6 in Annex II, as to mean, that mandatory declarations arising from obligations under other Union legislation shall not be presented on the digital label alone. Denmark asks the Commission to confirm that this interpretation of the provision is correct IT: we agree NL: We thank the Presidency for taking our comments into account regarding the ambiguity concerning the requirements for label elements from other Union legislation. We do not see however how the ambiguity has been resolved by including the new provision under article 25 paragraph 3.

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		We would like to suggest amending proposed section 1.6 in Annex I, as to make clear that when other Union acts require certain label elements to be on the physical label, these label elements should not be moved to the digital label pursuant to article 25 paragraph 9 and section 1.6 Annex I. Please see the draft suggestion for section 1.6 of Annex I: ‘1.6. Label elements that may be provided on a digital label only (a) Supplemental information referred to in Article 25(3), <u>provided that other Union legislation does not require the label elements to be placed on the physical label</u>’; PT: PT welcomes the clarification proposal. IT: we agree
(a) in paragraph 6, the first subparagraph is replaced by the following:		
(10)		
‘6. The special specific labelling rules set out in Part 2 of Annex II shall apply to mixtures containing substances referred to in part 2 of that	DE: ‘6. The special labelling rules set out in Part	DE: As explained in the Working Party Meeting, extending the

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Annex.';	2 of Annex II shall apply to mixtures containing hazardous substances, <u>or that lead to the formation or release of a hazardous substance during their use</u> , referred to in part 2 of that Annex.';	regulation to mixtures containing both hazardous and non-hazardous substances appears to be too extensive. An extension to mixtures that do not contain any hazardous substances, but which can give rise to them during use, seems more appropriate. This would also close the current regulatory gap regarding EUH212. IT: we agree PT: PT welcomes the editorial proposals.
(ab) the following paragraph 9 is added:	EL: We agree	
'9. Label elements resulting from requirements set out in other Union acts shall be placed in the section for supplemental information on the label.';		
(11) Article 29 is amended as follows:		
(a) paragraph 1 is replaced by the following:		IT: we agree

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‘1. Where the packaging of a substance or a mixture is either in such a shape or form or is so small that it is impossible to meet the requirements laid down in Article 31 for a label or a fold-out label in the languages of the Member State in which the substance or mixture is placed on the market, the label elements set out in Article 17(1), shall be provided in accordance with sections 1.5.1.4. and 1.5.1.2. of Annex I.’;	EL: We insist to propose the addition of the bold text as follows: 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, <i>on the packaging immediately containing the substance or the mixture</i>, in the languages of the Member State in which the substance or mixture is placed on the market, the label elements set out in <i>Article 17(1)</i>, shall be provided in accordance with sections 1.5.1.4. and 1.5.1.2. of Annex I. ES: ‘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	DK: See comments to Article 31(1) with regard to digital labels. EL: <u>Justification:</u> For clarity reasons. It is not easy to have to go to Article 31 to understand which package (i.e. inner, outer) Article 29(1) refers to. IT: we agree ES: A typo: the word “section” is in singular and not in plural FI: FI: It should be clarified what elements must be on the first page of a fold-out label. We are of the opinion that all elements listed in article 17 should be on the first page.

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	market, the label elements set out in Article 17(1), shall be provided in accordance with sections 1.5.1.1. and 1.5.1.2. of Annex I.’;	IT: we agree PT: PT welcomes the Presidency Proposal based on the concept that the fold-out labels is a form of label. PT also welcomes the editorial proposal.
	EL: We insist propose the addition of the bold text: “If the full label information cannot be provided <i>on inner packaging</i> in the way specified in paragraph 1 <i>and outer packaging (or tie-on tag)</i>, the label information may be reduced in accordance with section 1.5.2 of Annex I. FR: (b) paragraph 2 is replaced by the following: 2. If the full label information cannot be provided in the way specified in paragraph 1 the label information may be reduced in accordance with section 1.2.2 of Annex I. The reduced labelling allowed for small packaging under Article 29(2) and	EL: <u>Justification:</u> It is very important to clarify which package Article 29(2) refers to. The addition our proposal is in accordance with the conclusion of the relevant Practical Issue F-35.4 (Forum (ECHA)): <i>“So Article 29(1) must apply, before application of Art 29(2) is considered. Once conditions for application of Art 29(2) are met, this exemption can apply to both inner and outer packaging /tie on tag already affected by an exemption under Article 29(1)”.</i> FR: Please consider here the Q&A from ECHA n°1856 (dated 27/10/2021), applied by enforcement bodies.

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	Annex I, 1.5.2., can only be applied if it is not possible to provide the full label information in one of the ways specified under Art 29(1) and Annex I, 1.5.1. If a hazardous substance or mixture is to be placed on the market in a small container without outer packaging or tie-on tag, then the container must bear the full label information, as specified in Article 17.	
(b) paragraph 3 is replaced by the following:	EL: We agree	
‘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.’;	IE: Suggest to change “in that Part” to “in that Part of Annex II”	
(c) the following paragraphs 4b and 4e are <u>is</u> inserted:	EL: We agree	

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‘4b. By derogation from Article 17(1), the labelling requirement set out in that Article shall not apply to packaging of ammunition that is <u>intended for</u> 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 <u>or</u> the staff, and sufficient camouflaging cannot be ensured.		IT: we agree
4e. Where paragraph 4b applies <u>In this case</u>, manufactures, importers or downstream users shall provide to the defence force the safety data sheet <u>or, if no safety data sheet is required,</u> a leaflet containing <u>copy of the label elements</u> information referred to in <u>accordance with</u> Article 17(1).’;	FR: 4e. Where paragraph 4b applies In this case, manufacturesmanufacturers, importers or downstream users shall provide to the defence force the safety data sheet or, if no safety data sheet is required, a leaflet containing copy of the label elements information referred to in accordance with Article 17(1).’;	FR: Please use the term ‘manufacturers’ and not ‘manufactures’. IT: we agree PT: PT welcomes the changes introduced regarding ammunitions, namely in regard to the clarification of the scope and the proposed changes so that the safety data sheet is always provided when required according to the legislation, and only when safety data sheet is not mandatory a copy of the label may be used.

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(12) Article 30 is replaced by the following:		
'Article 30		
Updating information on labels		
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 <u>by or communicated to that supplier.</u>	DE: 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 618 months after the results of the new evaluation referred to in Article 15(4) were obtained by or communicated to that supplier. EL: We agree ES: 1. In case of a change regarding the	BE: Instead of 6 month for each actor in the supply chain to update the label as from when this actor obtains the information on stricter classification and labelling, we would prefer a cumulative timeline fixed for the entire supply chain. If there are many different suppliers along the supply chain, the update can be considerably delayed, or even never happen if there is a loss of information in the supply chain. In addition, it would be challenging for market surveillance authorities to check when - and if - each supplier obtained the information on the new classification. On the other hand, the addition of a paragraph on cooperation between suppliers seems not sufficient to ensure that any distributor will have the information in a timely manner. If individual timelines would be decided, they should only be applicable to manufacturers, importers and downstream users, but not to distributors.

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	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 without undue delay within 6 months after the results of the new evaluation referred to in Article 15(4) were obtained <u>by or communicated to that supplier.</u> IE: Editorial suggestions the supplier of the substance or the mixture 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 by, or communicated to, that supplier. PL: Due to the addition of a new hazard classes or in case of a more severe classification we kindly ask for considering the possibility to extend the 6 months transition period to at least 12	DE: A cumulative deadline is difficult to implement. Preference should be given to a clearly defined individual period of 18 months. The current provision provides the necessary flexibility in this regard. In addition, a transitional period of 18 months applies to a new or amended entry in the harmonised classification and labelling. This would provide a more appropriate timeframe. ES: We would prefer to indicate the absence of unnecessary delay together with the established legal deadline and not in a new paragraph. Otherwise, it could lead to confusion. In addition, the lack of coherence between the CLP legislation and other regulatory frameworks (e.g. those covering biocides, cosmetics and detergents) with respect to the definition of ‘placing on the market’ continues to be a major issue when it comes to the relabelling of products already in the supply chain as differences arise in the interpretation of whether and how these updating requirements apply to them, especially in enforcement and inspections. The revision of the CLP regulation offers an opportunity to correct this lack of consistency of CLP with other chemicals

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	months period.	legislation. This could be resolved by aligning with the definition found within the BPR etc, which refers to ‘first making available’. FI: FI: We prefer “without undue delay” FR: If this addition is beneficial for formulators, it could be difficult to enforce when the supply chain has many operators: the delays in updating classifications and labelling could be disproportionate. These delays will affect the updating information relating to poison centers. IT: Thanks for the clarification offered during the meeting on the meaning that 6months +6months depending on the activities of the supplier. Anyway we prefer more time: 9 months instead of 6 months to updating of the labelling information SK::

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		We are of the opinion that, in the case of more severe classification, the period for updating the label should not exceed a cumulative 6 months for substances and longer period e.g. 12 months for mixtures. IE: We agree with, and welcome, the setting of a deadline by which labels must be updated when a new evaluation results in a new hazard class or a more severe classification or which requires new supplemental information. However, we feel that the 6 month deadline may be problematic in some cases. We suggest that consideration is given to extending this deadline somewhat, perhaps to 9 months. We note the addition of <i>or communicated to the supplier</i> in Article 30(1). While we understand the reason for this addition, we note that it may lead to enforcement issues, as it may be difficult to ascertain when the information was communicated to the supplier. LT: Having in mind the current wording obliging suppliers to update the label ‘without undue delay’, and the complexity of supply chaine, we think that proposed 6 moths timeline is sufficient.

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		We believe that cumulative timelines would be not suitable for requirement to update label. PL: It is critical to grant sufficient time for all actors in the supply chain to update their labels and to sustainably exhaust their stocks. From the label artwork update perspective, the reason for a label update has absolutely no influence on the efforts to be carried out. Downstream users are in the middle of the supply chain and they depend on their suppliers for classification information. The proposed six-month transition period may be very difficult to meet for manufacturers. Such an obligation will cause scrapping, product-reworking/relabelling and unnecessary transport of many chemical goods. Consequently too short term of reclassification may cause environmental pollution. The risk seems to be high, so proposed obligation seems to be in contrary with the objectives of the Green Deal Strategy. SI: We are of the opinion that every actor in the supply chain should have 6 months time (after receiving the information) to update the label.

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		PT: PT considers that an individual timeline would be more appropriate as the supply chain may have variable complexities. We also consider that this timeline should be linked to the results of the new evaluation are obtained or received. We consider however that a deadline could also be defined for the communication of the information to the following actor in the supply chain (preferably before the update of the label in order to expedite the process). PT is still assessing if the 6 months period (if individually for each supply chain actor) is adequate.
2. Where a change regarding the classification and labelling of a substance or a mixture is required other than that referred to in paragraph 1, the supplier shall ensure that the label is updated within 18 months after the results of the new evaluation referred to in Article 15(4) were obtained.	EL: We agree ES: 2. Where a change regarding the classification and labelling of a substance or a mixture is required other than that referred to in paragraph 1, the supplier shall ensure that the label is updated without undue delay within 18 months after the results of the new evaluation referred to in Article	ES: For consistency with paragraph 1, we believe that in paragraph 2, the same change should also be introduced. Therefore, the text “by or communicated to that supplier” should be added at the end of this second paragraph. The same comment regarding the absence of unnecessary delay as for paragraph 1 applies. IE:

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	15(4) were obtained by or communicated to that supplier. PL: “...the supplier shall ensure that the label is updated within 24 months after the results of the new evaluation referred to in Article 15(4) were obtained.”	Currently, in CLP article 30(2), there is a requirement to update labels with other information within 18 months (changes to information on labels could be for other reasons not related to classification e.g. change in address, telephone number, product identifier, etc). It is not clear if this requirement is now still in article 30(2). Recital 10 refers to <i>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</i>, so it would appear that article 30(2) only refers to changes related to classification. PL: We state that currently proposed transitional period obligation for the revised provisions of the Regulation may be very difficult to meet for the industry. We would like to repeat that any changes implemented to the safety data sheets (labelling and classification) are linked with the registration dossier, which must also be updated - this process is significantly longer and more complex than just updating the labels and safety data sheets. Additionally new hazard classes listed in the draft regulation, in particular the classification of a substance as the endocrine disruptor (ED) in the SK:man body and the environment, may in some cases cause additional tests to

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		be performed in order to adapt the documentation to the new guidelines. We draw special attention to the fact that the registration dossier should be updated first in order to maintain consistency with the safety data sheets and labels. Due to the fact that above mentioned process is difficult, expensive and lengthy, we propose to extend this period to at least 24 months. SI: We are of the opinion that every actor in the supply chain should have 6 months time (after receiving the information) to update the label.
<u>2a. Suppliers shall cooperate in accordance with Article 4(9) to complete the changes to the labelling without undue delay.</u>	DK: Suppliers shall cooperate in accordance with Article 4(9) to complete the changes to the labelling without undue delay. Where a change regarding the classification and labelling of a substance or a mixture is required according to either paragraph 1 or 2 of this Article, the supplier in question must inform all connected suppliers of the need to update the label	DK: Denmark welcomes the reintroduction of the requirement for suppliers to cooperate to ensure that changes to labelling occur without undue delay. The legal effect of this requirement with regard to Article 30(1)&(2) is unclear. Denmark suggests sharpening this requirement to ensure that information on the need to update product labels occurs expediently, which of course is to the benefit of consumers. Denmark suggests that suppliers must communicate the need to update labels to other suppliers, with whom the supplier in question has a trading

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	within four weeks after the results of the new evaluation referred to in Article 15(4) were obtained by or communicated to that supplier. For the purpose of this paragraph, connected suppliers are defined as other suppliers for the product, with whom the supplier in question has either supplied the product to or received the product from. ES: Delete.	relationship, within four weeks of receiving the results of a new evaluation according to Article 15(4). The effect of the Danish proposal would be that the timeframe for changing labels will be shortened, while at the same time ensuring that suppliers still maintain 6 and 18 month windows for adopting labelling changes according to Articles 30(1) and 30(2) respectively EL: <u>Comment:</u> In our view it is not necessary to add this subparagraph, because paragraph 4(9) already refers to the cooperation between suppliers in order to meet the requirements for classification, labelling and packaging. ES: Regarding the new paragraph 2a added, we do not consider it necessary if the above changes proposed in paragraphs 1 and 2 are accepted. Additionally, we do not see the need to refer here to the general obligations of providers in Article 4.9. FR: We are in favour of adding subparagraph 2a to article 30 to avoid undue delays in taking into account a more stringent voluntary classification. However, cooperation between operators will depend on the balance of commercial relations

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		between operators in the same supply chain. PT: In our view the Presidency Proposal in order to ensure cooperation could be reinforced, the indication of “cooperation” is not enforceable.
3. Paragraphs 1 and 2 shall not apply where a change regarding the classification and labelling of a substance or a mixture was triggered by a harmonised classification and labelling of a substance set out in a delegated act adopted pursuant to Article 37(5) or by a provision set out in a delegated act adopted pursuant to Article 53(1). In such cases, the supplier shall ensure that the label is updated by the date set out in the respective delegated act.	EL: We agree	
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’;		

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(13ac) in Article 31 <u>is amended</u> <u>as follows:</u>		
<u>(a) paragraph 1 is replaced by the following:</u>		
<u>‘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.’</u>	AT: The fold-out label on the immediately visible side shall contain at least hazard pictograms, the product identifier referred to in Article 18 and name, telephone number of the supplier and the hazard statements of the substance or mixture in the languages which are specified in the fold-out-label. DK: <u>‘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.</u> <u>Where a fold-out label is used, the following elements must be printed on the front side of the label:</u> - <u>the relevant hazard pictograms,</u>	AT: In terms of the objectives of the CLP-Regulation, additional legal provisions regarding the form and design of the labelling of fold-out-labels are essential. A fold-out-label should contain an overview of the most important labelling elements according to Annex I 1.5.1.2. and the hazard statements in several languages on the immediately visible side. The full information could be presented in the fold-out label in an unspecified order. BE: Specific provisions on the way labelling information should be presented in fold-out labels should be foreseen, particularly on the information that should be directly legible without opening it. DK: Denmark is generally positive regarding the broader use of fold-out labels. However, we have some concerns regarding the ease of use for the consumers especially concerning the

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	- <u>trade name,</u> - <u>supplier identity,</u> - <u>UFI code,</u> - <u>signal word in all languages of the label,</u> - <u>language codes indicating languages covered by the label, and</u> <u>symbol informing the user that the label can be opened and indicating that the additional information is available on inside pages.'</u> EL: We agree	number of languages presented on these labels. As the Commission recognises in the impact assessment, long multi-lingual labels can result in an information overload for consumers and workers: “Readability has continuously been point for discussion, as highlighted by the chemicals Fitness Check which found evidence to indicate that labels can become overloaded with information. That makes it difficult for consumers and workers to focus on essential hazard and use information, reducing the effectiveness of hazard communication, particularly on products supplied in small packaging and when multilingual labels are required.” It is important that the most important information is clearly made available to users in the official language of the relevant member state. As such, Denmark suggests that the provision is adopted so as to ensure, that relevant information, including both the hazard pictogram and the signal word in all languages used in the label are presented on the front side of the fold-out label. EL: <u>Comment:</u> The addition of the last sentence is deemed necessary in relation to the changes made in paragraph 1.5.1 of annex I, in order to avoid confusion.

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		ES: We consider that this wording makes it clear that the use of fold-out label is an option that can be used by default, tSK:s making its use more flexible. IE: If the intention is to always mean ‘labels including fold-out labels’ when ‘labels’ is indicated in the legal text, is there a need to have a definition of label to ensure clarity is provided that label also means fold-out label? PT: PT welcomes the Presidency Proposal based on the concept that the fold-out labels is a form of label.
		AT: In discussions with national authorities and stakeholders, it has been proposed to indicate SVHC in mixtures. It was suggested to list the SVHC in the digital label or - if the relevant classification is not already evident from other labeling

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		elements - to make the SVHC recognisable not in name but via the CAS Number on the physical label. The term "SVHC" should be placed in brackets after the name or CAS number.
<i>[(b) see (13b) in subgroup A2 below]</i>		
(c) paragraph (3), is replaced by the following sentence is added:		
'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.';	FI: FI: ... The label elements referred to in Article 17(1) shall be clearly and indelibly marked <i>on the label or on the first page of the fold out label.</i>	DE: The conversion of the currently used labels is not easy to accomplish. It requires sufficient time for the necessary changes. FI: FI: We would like to add that in case of a fold-out label the provisions in article 17(2) should also apply and must be on the first page of the label.
(14) in Article 32, paragraph 6 is deleted;	EL: We agree	
<u>Changes to Annex I in A1</u>		

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		SI: General comment regarding font size of letters and distance between two lines: we are of the opinion that both provisions shall be explained in the guidelines. Otherwise, it would be possible to have enforcement problems of these provisions in practice.
(2) Section 1.2.1.4. is replaced by the following:		
<i>[To be discussed in light of separate document]</i>		LT: We appreciate the detailed information in separate document (WK 4187/2023 INIT) regarding the legibility of labels and other labelling requirements. We support proposed requirement and belief that the varying font heights for the different packaging sizes are important because we agree with the Commission's arguments that the labels on larger packaging are typically read from a larger distance.
'1.2.1.4. The dimensions of the label and of each pictogram, and the font size of letters shall be as follows:	SI: 1.2.1.4. The dimensions of the label and of each pictogram, and the font size of letters shall be as follows:	SI: We are of the opinion that is more appropriate place for the provision regarding the font size of letters in the guidelines. Therefore we propose to delete following text "and the font size of letters"

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Minimum dimensions of labels, pictograms and font size	SI: Minimum dimensions of labels, pictograms and font size	SI: See comment above. We propose to delete following text: “and font size”.
[please refer to the table 1.3 in Section 1.2.1.4 in Annex I]	DK: Column “Minimum font size” 16 pt 12pt . Where a font size of at least 12pt, but below 16pt is used, all information on the physical label must also be provided on a digital label, which fulfils the technical requirements set out in Article 34b. The data carrier used to access the digital label must comply with the same minimum dimensions as those that apply for pictograms. 20pt 12 pt . Where a font size of at least 12pt, but below 20pt is used, all information on the physical label must also be provided on a digital label, which fulfils the technical requirements set out in Article 34b. The data carrier used to access the digital label	DK: Denmark recognises the need to set out criteria relating to the formatting of labels. This is particularly a problem with regard to smaller consumer oriented products, where Denmark does not object to the Commission’s proposals for font sizes of 8pt and 12pt for respectively packages not exceeding 3 litres and packages greater than 3 litres but not exceeding 50 litres. Denmark acknowledges the Commission’s well-reasoned typographical arguments for containers of these sizes as put forward in its non-paper on the matter. However, Denmark believes that the Commission’s proposals for font sizes of 16pt and 20pt for respectively packages greater than 50 litres but not exceeding 500 litres and packages greater than 500 litres are unnecessary. Products of this size are generally only relevant for industrial users, where it is fair to assume, that users will or ought to be aware of product

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	must comply with the same minimum dimensions as those that apply for pictograms. PT: Minimum font size <u>(x-height in mm)</u>	risks, not least because of repeat use of these products. Furthermore, it is unclear why users would not simply move closer to the container to read the label. While smaller containers are containers that user <i>pick up</i>, larger containers are containers that users <i>walk up</i> to. Furthermore, label text works in tandem with the pictograms that accompany the text. Pictograms draw attention to the need for users to acquaint themselves with critical safety information. Accordingly, Denmark believes that a font size of 12 is also sufficient with regard to readability for these package categories. Feedback from Danish industry is clear – larger font sizes will for many suppliers necessitate the use of larger labels, which in turn will require investing in new printers that are capable of printing these larger labels. Requiring a font size of over 12pt will entail significant costs for many businesses. Initial estimates from industry put these costs at 15-30 million euros in Denmark alone. A minimum font size of 12pt reduces these costs significantly for the vast majority of labels of these sizes, as premature investment in new printers will be unnecessary. To reduce the cost for industry Denmark proposes a minimum font size of 12pt for use on labels on all containers over 3 litres. However, for containers between 50 litres – 500 litres and containers over 500 litres, where a supplier uses a font size of under 16pt and 20pt respectively, the supplier <u>must</u> also provide access to a digital label, where the contents of the label in its entirety is replicated in digital form. Furthermore, the data carrier used must comply with the same minimum

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		dimensions as for a pictogram in the same package capacity category. Denmark remains of the belief, that labels will still be easily readable at a font size of at least 12pt. However, the Danish proposal ensures a suitable alternative method to read the label. Not only will this result in significant cost reductions for industry, the proposal for supplementary digital labelling will also have the advantage of potentially enabling easy access to product information in a multitude of languages to the benefit of multinational workforces, which in turn supports the intentions set out in proposed recital 12. At the same time, as the Commission notes in its non-paper, the digital label will be scalable, allowing users to adjust the font size according to their own needs. Denmark does not believe that this change will require alterations to the remainder of the proposed regulation – neither the annexes nor the articles. In the event that this is the case, Denmark stands ready to assist in any further reformulation. NL: Regarding the minimum x-height, we do believe a minimum x-height is preferred over a requirement in points. However, we do wonder what the reasons are behind picking a minimum x-height of 1,4 mm over, for example, 1,2mm, which is the minimum size required for food labels – as is referred to in the non-paper from the Commission. Are there actual findings in

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		the Fitness check that conclude that the x-height of 1,2mm as prescribed in the Guidance, is too small? For larger containers, we are still not convinced that the costs for industry of requiring larger font and label sizes is outweighed by the benefits. Has it been assessed that this would indeed, solve a problem that is currently existing? SI: We are of the opinion that is more appropriate place of the provision regarding the font size of letters in the guidelines. Therefore in the table 1.3 the column with the font size shall be deleted! PT: PT shares the concern express by other Member-States regarding labels legibility and considers that minimum font size 8 pt for packaging not exceeding 3 liter could not be readable depending on the font type. We also consider that the use of x-height as defined in Regulation (EU) N° 1169/2011 is a good option instead of font size. PT proposes that in Table 1.3 the last column heading includes

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		x-height (as defined Regulation (EU) N° 1169/2011). The values in that column should be converted from pt to x-height in mm. PT is still assessing the suggestions made by other MS concerning packages for industrial use.
(3) the following Section 1.2.1.5. is added:		
‘1.2.1.5. The text on the label shall have the following characteristics:		DE: The conversion of the currently used labels is not easy to accomplish. It requires sufficient time for the necessary changes. PL: We think that the font size shall be specified in millimeters, not in pt (point size for different fonts may result in different capitalization of their letters). In addition we recommend such a solution because it seems to be more effective for evaluation processes by the Inspection Authorities.
(a) printed in black on a white the background of the label shall be white;		LT:

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		We strongly support Compromise text. PT: PT welcomes, in this regard, the Presidency Proposal regarding printing in black on a white background.
(b) the distance between two lines shall be equal or above 120 % of the font size;	SI: (b) the distance between two lines shall be equal or above 120 % of the font size;	SI: We are of the opinion that is more appropriate place for this provision in the guidelines. Therefore, we propose to delete point b).
(c) a single font shall be used that is easily legible and without serifs;	ES: d) a single font shall be used that is easily legible and without serifs and with a minimum x-height of 0.9mm;	ES: We would like to insist that establishing the font size in the legislative text (in Annex I section 1.2.1.4) introduces unnecessary complexity for labelling, and may make it unfeasible to include the necessary information on labels, even on the largest pack sizes, as the proposed size is unnecessarily large and takes up too much space. Furthermore, readability is more influenced by the type of font than by its size. Our proposal would be firstly to remove from the legislative text any requirement on font size and, in any case, in line with the requirements in Regulation 1169/2011 which it has been

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		proposed to take as a reference for formatting requirements, to include only a minimum height requirement instead of a font size. To illustrate how font type is more important than font size, see this text in which the Muli font for the same font size is significantly larger than Calibri: Muli tamaño 11 Calibri tamaño 11
(d) the letter spacing shall be appropriate for the selected font to be comfortably easily legible.		
For the labelling of inner packaging where the contents do not exceed 10 ml, the font size may be smaller than indicated in Table 1.3, as long as it remains legible for a person with average eyesight, where it is deemed important to place the most critical hazard statement and where the outer packaging meets the requirements of Article 17.’	DK: For the labelling of inner packaging where the contents do not exceed 10 ml, the font size may be smaller than indicated in Table 1.3, as long as it remains legible for a person with average eyesight, where it is deemed important in order to place the most critical hazard statement and where the outer packaging meets the requirements of Article 17.’	DK: The wording: “deemed important”, leaves too much room for interpretation and we suggest that it is deleted. . . FR: We found inconsistencies between this proposal and the non-paper from the Commission: 1) <i>Section 1.2.1.5 : [...] For the labelling of inner packaging where the contents do not exceed 10 ml, the</i>

Presidency Compromise Proposal on Subgroups A1 and A2 (ST 7616/23)	Drafting Suggestions AT, BE, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK	Comments AT, BE, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK
	SI: For the labelling of inner packaging where the contents do not exceed 10 ml, the font size may be smaller than indicated in Table 1.3, as long as it remains legible for a person with average eyesight, where it is deemed important to place the most critical hazard statement and where the outer packaging meets the requirements of Article 17.’	<i>front size may be smaller than indicated in Table 1.3, as long as it remains legible, where it is deemed important to place the most critical hazard statement and where the outer packaging meets the requirements of Article 17 (p 6/7 ST/ 7616/23)</i> 2) Considerations for the legibility of labels for chemicals WK 4187/2023, p9: <i>Labels on small packaging For small packaging below 125 mL, the proposal does not prescribe a particular font height for the inner packaging, other than the need for the label to be legible.</i> SI: We are of the opinion that is more appropriate place for this provision in the guidelines. Therefore, we propose to delate “smaller than indicated in Table 1.3, as long as it remains”. PT: PT has reservation on the expression “as long as it remains legible”.
(4) the following Section 1.3.7. is added:		
‘1.3.7. <i>Ammunition</i>		

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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.’;		IE: We had previously suggested that consideration be given to including a reference here to the new exemption set out in Article 29(4b) regarding no requirement for a label for ammunition used by Defence Forces. This has not been taken up and we suggest that further consideration be given to it for completion and clarity.
(5) the heading of Section 1.5.1. is replaced by the following:		
‘1.5.1. Exemptions from Article 31 in accordance with Article 29(1)’;		
(6) Section 1.5.1.1. is replaced by the following:		
‘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.’;		
(7) Section 1.5.1.2. is replaced by the following:		
‘1.5.1.2. Where section 1.5.1.1.	AT:	AT:

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applies, the label on any inner packaging shall contain at least hazard pictograms, the signal word, <u>the product identifier referred to in Article 18(2) for substances or</u> the trade name or the designation of the mixture referred to in Article 18(3), point (a) <u>for mixtures</u>, 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, <u>the product identifier referred to in Article 18(2) for substances or</u> the trade name or the designation of the mixture referred to in Article 18(3), point (a) <u>for mixtures</u>, and the name and telephone number of the suppliers of the substance or mixture and for mixtures the UFI-code.’; EL: We insist for the following addition : “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), <u>the UFI if it exists</u> and the name and telephone number of the suppliers of the substance or mixture”.	Editorial comment: adding the UFI code EL: We agree with the new wording and we suggest an addition of the UFI if it exists, because a UFI is very important to be in the inner packaging in a case of an emergency health response. NL: We would like to propose to require the UFI as a label requirement to the inner packaging of mixtures when section 1.5.1.1 applies, to ensure that poison centres can retrieve information on the mixture in case of an emergency health response.
(8) the heading of Section 1.5.2₂ is replaced by the following:	EL:	FR:

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	We agree	Please take into account that the Regulatory references need to be updated on section 1.5.1.3
'1.5.2. Exemptions from Article 17 in accordance with Article 29(2)';		
(9) Section 1.5.2.4.1. is replaced by the following:		
'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:		DK: Denmark finds that the suggested changes to annex I part 1.5.2.4.1 still give rise to some confusion regarding the different hazard classes presented. For the sake of consistency, the wording should be 'any category', also for 'acute toxicity', 'specific target organ toxicity – repeated exposure' and 'respiratory sensitization', as one could mistakenly be misled to believe that some categories are not included.. Also, Denmark note that it is possible to exempt labelling if the substances or mixtures are to be classified as hazardous to the environment. We suggest that both SK:man health and the environment must be taken into account. This is especially important for substances with a high M-factor, or for mixtures containing such substances, as even small amounts of such substances or mixtures could pose a risk for the environment.

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		PT: PT welcomes the editorial proposals.
(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;		
(b) the substance or mixture does not require labelling in accordance with Part 1, or 2-4 of Annex II and is not classified in any of the following hazard classes and categories:		
(i) Acute toxicity, categories 1 to 4;	DK: (i) Acute toxicity, categories 1 to 4 <u>any category</u> ;	
(ii) Specific target organ toxicity –		

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Single exposure, categories 1 and 2;		
(iii) Specific target organ toxicity – repeated exposure, categories 1 and 2;	DK: Specific target organ toxicity – repeated exposure, categories 1 and 2 any category ;	
(iv) Skin corrosion/irritation, category 1 (sub-categories 1A, 1B and 1C);	DK: Skin corrosion/irritation, category 1 including sub-categories 1A, 1B and 1C; FR: (iv) Skin corrosion/irritation, category 1 (sub-categories 1A, 1B and 1C) including Serious Eye Damage, category 1 ;	
<u>(iv1) Serious Eye Damage, category 1;</u>	ES: <u>(iv1) Serious Eye Damage, category 1;</u> FR: Please read above	ES: Please, revise the numbering. This hazard class is not a subsection of the class that appears in position (iv) since they are independent hazard classes and, therefore, should be renumbered as (v). This would lead to the change in the numbering of the hazard classes listed below.

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		NL: We are happy to see that serious eye damage and skin sensitisation have been added in the Presidency's compromise proposal.
<u>(iv2) Skin Sensitisation, category 1 (sub-categories 1A and 1B);</u>	DK: Skin sensitisation, category 1 (sub-categories 1A and 1B) <u>any category;</u> Or Skin sensitisation, category 1 <u>including sub-categories 1A and 1B.</u> ES: <u>(ivi2) Skin Sensitisation, category 1 (sub-categories 1A and 1B);</u> FR: <u>(v) Skin Sensitisation, category 1 (sub-categories 1A and 1B);</u>	ES: Please, revise the numbering. This hazard class is not a subsection of the class that appears in position (iv) since they are independent hazard classes and, therefore, should be renumbered as (vi). This would lead to the change in the numbering of the hazard classes listed below. FR: Skin sensitizers are not included in the Skin Corrosion/Irritation hazard category. SI: Regarding our opinion this new provision shall exclude essential oils. Therefore we propose to delete it.

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	SI: (iv2) Skin Sensitisation, category 1 (sub-categories 1A and 1B);	
(v) Respiratory sensitisation, category 1 (sub-categories 1A and 1B);	DK: Respiratory sensitisation, category 1 (sub-categories 1A and 1B) <u>any category</u> ; Or Respiratory sensitisation, category 1 <u>including sub-categories 1A and 1B.</u>	ES: Please, revise the numbering.
(vi) Aspiration hazard;		ES: Please, revise the numbering.
(vii) Germ cell mutagenicity, any category;		ES: Please, revise the numbering.
(viii) Carcinogenity, any category;		ES:

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		Please, revise the numbering.
(ix) Reproductive toxicity, any category;		ES: Please, revise the numbering.
(x) — Flammable solids, categories 1 and 2;		
(xi) Endocrine disruptors for SK:man health, any category;		ES: Please, revise the numbering.
	DK: (xii) substances classified with Aquatic Acute 1 or Aquatic Chronic, with an M- factor equal to or above 100. (xii) Mixtures containing one or more substance(s) classified with either Aquatic Acute 1 or Aquatic Chronic 1, and the values calculated using either point 4.1.3.5.5.3.1 or point 4.1.3.5.5.4.1 in CLP annex I part 4 (sum of classified substances) in annex X, is equal to or above 2500.	DK: Substances (b, xii) classified with either Aquatic Acute 1 or Aquatic Chronic 1, with an M-factor equal to or above 100. Mixtures (b, xii) containing one or more substance(s) classified with either Aquatic Acute 1 or Aquatic Chronic 1, and the values calculated using either point 4.1.3.5.5.3.1 or point 4.1.3.5.5.4.1 in CLP annex I part 4 (sum of classified substances) in annex X, is equal to or above 2500.

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(c) the substance or mixture requires labelling in accordance with Part 1, or 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.';		
<u>Changes to Annex II in A1</u>		
(2) Part 5 is replaced by the following:		
'PART 5: HAZARDOUS SUBSTANCES AND MIXTURES TO WHICH ARTICLE 29(3) APPLIES		
Ready mixed cement and concrete in the wet state shall be accompanied by a copy of the label elements in accordance with Article 17.		IE: We had previously suggested that it is clarified as to how the label elements should be provided. We note that this has not been taken up in the compromise proposal so we maintain our point that it could be addressed in guidance if not in the legal text.

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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.’;	EL: We agree FR: 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 when the customer is using the pump on the respective pump.’;	FR: It seems difficult to force a filling station to issue a hazard label to be affixed to a jerry can when the pumps are fully automated. LT: We support labelling derogation for fuels and other chemicals directly pumped into vehicles, but receptacle, e.g., a jerrycan, shall be regularly labelled under CLP without any derogations.
<u>Recitals relating to A1</u>		
(7) <u>While ammunition is usually considered an article.</u> Ammunition <u>it might</u> qualifying as a substance or a mixture <u>and, in such cases,</u> 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 that <u>the cartridge inner</u>	EL: We propose the replacement of the text “<u>While ammunition is usually considered an article.</u> Ammunition <u>it might</u> qualifying as a substance or a mixture <u>and, in such cases,</u>” by the following rewording of the text in bold : <i>When ammunition is considered as an</i>	EL: <u>Justification:</u> Only explosive article are in the scope of CLP. Other articles are not classified labelled and packaged under CLP. ES: To be in line with the modification proposed in article 29,

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<u>packaging</u> might however cause safety problems for the user, as the label could interfere with the correct functioning of the ammunition and could damage the firearm. Such ammunition should therefore be allowed to bear a label affixed to the next packaging layer instead of the inner packaging. In addition, labelled ammunition, which is exclusively used by national defence forces in combat zones, could, in specific cases, constitute an unacceptable safety or security risk for the cargo, soldiers and staff, if sufficient camouflaging cannot be ensured. For such cases, it is necessary to provide for an exemption from the labelling requirements and allow for alternative ways of communicating the hazard information.	<i>explosive article or as a substance or a mixture classified according to CLP</i>, has to bear a label..... ES: (7) <u>While ammunition is usually considered an article</u>. Ammunition <u>it might</u> qualifying as a substance or a mixture <u>and, in such cases</u>, 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 that cartridge <u>inner packaging</u> might however cause safety problems for the user, as the label could interfere with the correct functioning of the ammunition and could damage the firearm. Such ammunition should therefore be allowed to bear a label affixed to the next packaging layer instead of the inner packaging. In addition, labelled ammunition, which is exclusively used by national defence forces in combat zones, could, in specific cases, constitute an unacceptable safety or security risk for the cargo, soldiers and <u>or the</u> staff, if sufficient camouflaging cannot be ensured. For such	paragraph 4b. FR: The intention of the first derogation is the problem of malfunctioning between weapon and ammunition due to the label, and the intention of the second derogation is related to safety (camouflage). The Commission's intention is important with regard to the place of the adverb "exclusively", which it links only to the verb "used by" and tSK:s to use, rather than to a geographical criterion of combat zone, it seems. It is therefore appropriate, for the sake of clarification, to precise this use as more important than the geographical character.

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	cases, it is necessary to provide for an exemption from the labelling requirements and allow for alternative ways of communicating the hazard information. FR: (7) While ammunition is usually considered an article, it might qualifying as a substance or a mixture and, in such cases, it is to bear a label affixed to the surface of the packaging immediately containing the substance or the mixture (inner packaging). Affixing a label to that inner packaging might however cause safety problems for the user, as the label could interfere with the correct functioning of the ammunition and could damage the firearm. Such ammunition should therefore be allowed to bear a label affixed to the next packaging layer instead of the inner packaging. In addition, labelled ammunition, which is exclusively used by national defence forces, <u>in particular</u> 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	

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	an exemption from the labelling requirements and allow for alternative ways of communicating the hazard information. IE: Editorial suggestion: While the majority of ammunition is usually considered as an article, in some instances, ammunition may be a substance or a mixture. In such cases, where ammunition is determined to be a substance or a mixture, it is to bear a label.....	
(8) In order to enhance clarity, all supplemental labelling requirements should be placed together in one Article.		
(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		

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are classified and whether they contain any classified substance.		
(10) To increase enforceability of the obligation placed on suppliers to update their labels after a change in the classification and labelling of their substance or mixture, a deadline should be laid down as regards that obligation. A similar obligation placed on registrants is set out in Commission Implementing Regulation (EU) 2020/1435 ³ . 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	PL: (10) To increase enforceability of the obligation placed on suppliers to update their labels after a change in the classification and labelling of their substance or mixture, a deadline should be laid down as regards that obligation. A similar obligation placed on registrants is set out in Commission Implementing Regulation (EU) 2020/1435⁴. 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	

³ Commission Implementing Regulation (EU) 2020/1435 of 9 October 2020 on the duties placed on registrants to update their registrations under Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 331, 12.10.2020, p.24.)

⁴ Commission Implementing Regulation (EU) 2020/1435 of 9 October 2020 on the duties placed on registrants to update their registrations under Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 331, 12.10.2020, p.24.)

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classification in accordance with the result of a new evaluation should be set at 6 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. In case where a classification is updated to a less severe hazard class or category without triggering classification in an additional hazard class or new supplemental labelling requirements, the deadline for updating the labels should remain at 18 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. It should also be clarified that, in cases of harmonised classification and labelling, the deadlines to update the labelling information should be set at the date of application of the provisions setting out the new or amended classification and labelling of the substance concerned, which is usually 18 months from the date of entry into force of those provisions. The same applies in case of changes triggered by other delegated acts adopted in light of the	information in the case of adaptation of the classification in accordance with the result of a new evaluation should be set at 12 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 24 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. It should also be clarified that, in cases of harmonised classification and labelling, the deadlines to update the labelling information should be set at the date of application of the provisions setting out the new or amended classification and labelling of the substance concerned, which is usually 24 months from the date of entry into force of those provisions. The same applies in case of changes triggered by other delegated acts adopted in light of the adaptation to technical and scientific	

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adaptation to technical and scientific progress, for instance as a result of the implementation of new or amended provisions of the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).	progress, for instance as a result of the implementation of new or amended provisions of the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).	
(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 <u>possibility to use of fold-out labels on a regular basis.</u> <u>It is therefore appropriate to allow labels to be presented in a form of fold-out labels, applying the general rules on application and formatting to ensure</u> while readability of labels should be ensured by laying down minimum font size and formatting requirements.	AT: In terms of the objectives of the CLP-Regulation a fold-out-label should contain an overview of the most important labelling elements according to Annex I 1.5.1.2. and the hazard statements in several languages on the immediately visible side. The full information should be presented in the fold-out label in an unspecified order. EL: We agree	PL: We strongly support this approach. PT: PT welcomes the Presidency Proposal based on the concept that the fold-out labels is a form of label.

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(16) Regulation (EC) No 1272/2008 does not lay down rules on the labelling of chemicals supplied to the general public without packaging except for ready mixed cement and concrete in a wet state. In order to enhance legal clarity and ensure a better protection of citizens, it is appropriate to provide for the labelling elements of other chemicals, such as fuels supplied at filling stations and intended to be pumped into receptacles from where they are normally not intended to be removed.		
Subgroup A2: Digital labelling		
<u>Articles in A2</u>		
(2c) <u>in Article 2, the following points</u> [7a, and 38] and 39 are added:	EL: We agree	
[...]		
<u>‘(39) ‘data carrier’ means a linear bar code symbol, a two-dimensional symbol or other automatic</u>	ES:	ES:

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<u>identification data capture medium that can be read by a device’;</u>	‘(39) ‘data carrier’ means a linear bar code symbol, a two-dimensional symbol or other automatic identification data capture medium that can be read by a device <u>or common app</u> FR: ‘(39) ‘data carrier’ means a linear bar code symbol, a two-dimensional symbol or other automatic identification data capture medium that can be read by a device <u>widely used by consumers’;</u>	We suggest broadening the definition to include reference to the use of apps. FR: The information on the digital label must be easily accessible before the purchase.
(13b) in Article 31 <u>is amended as follows:</u>		
<i>[(a) see (13ac) in subgroup A1 above]</i>		
<u>(b) the following paragraph 1a is inserted:</u>		
<u>‘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</u>	EL: We agree	ES: We suggest including a reference to professional/industrial users and a differentiation with regard to the device they can

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<u>next to the label in such a way that it can be processed automatically by digital devices widely used by consumers.</u>	ES: ‘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 widely used by the intended user of the product (industrial users, professional users or consumers).	use in addition to those used by consumers, which is the only type of user referred to in the text. It is usual that during digitalisation companies will invest in specific digital readers. On the other hand, consumers will use widely known mobile applications. PT:
<u>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 information available online" or by a similar indication.'</u>	DE: 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 information available online" or by a similar indication.' DK: Where label elements pursuant to Article	DE: Consequential change to proposed deletion of Art. 34a(2). DK: Denmark find that it is important to add this information to the

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	34a(2) are provided on a digital label only, the data carrier shall be accompanied by the statement EUH [insert correct numbers]: “More information available online” or by a similar indication.² EL: We agree IE: Editorial suggestion to change ‘More information’ to ‘More safety information’	label. However, to make it uniform and easier for the end-user, we suggest to make it a specific EUH-statement that must be used. This could be implemented by making a new EUH-statement in Annex II.
<i>[(c) see (13ac) in subgroup A1 above]</i>		
(15) in Title III, the following Chapter 3 is added:		
<i>‘CHAPTER 3</i>		
Labelling Formats of the labelling		

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<i>Article 34a</i>		
Physical and digital labelling		
1. The label elements for substances and mixtures referred to in Article 17 shall be provided: (a) on a label in a physical form ('physical label'), or (b) both on a <u>In addition to the physical label, and on a the label elements referred to in Article 17 may be provided</u> in a digital form ('digital label').	EL: We agree	PT: PT welcomes the changes introduced in article 34a (1 and 2) in order to better clarify that a physical label is always required.
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.	BE: 2. By way of derogation from paragraph 1, the suppliers may provide the following label elements set out in section 1.6. of Annex I on a digital label only: (a) Supplemental information referred to in Article 25(3). DE: 2. By way of derogation from paragraph 1, the suppliers may provide the label elements set out in section 1.6. of Annex I	BE: The provisions on label elements that may be provided only on a digital label should not be in an annex but in article 34a like similar provisions. DE: Paragraph 2 should be deleted as it is too far-reaching. The exception would allow that in the future, i.e. in the event of a corresponding amendment to Annex I 1.6 by means of a delegated act, there could be a digital only labelling for mandatory elements. A purely digital labelling is only acceptable if it is providing additional information, which is

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	on a digital label only.	already voluntary.
<u>Where 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.</u>	EL: We agree ES: 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.	DK: Denmark find that this provision requires further guidance. Should a store as a supplier be able to print the information to customers, how quickly should the information be provided, would it be possible to further narrow down who is responsible for supplying the information? In addition, it is practically difficult to make the information available in another way in the event of, for example, temporary unavailability. Is it expected that in the event of local network problems, a manufacturer can deliver the information to a specific dealer without any delay? This will be difficult to enforce, given that the market surveillance authority must be present at the situation, where there is temporary unavailability. ES: We propose this change in the text in order to avoid confusion and for the shake of clarity. In this way, it becomes more evident that it refers to the cases contemplated in the first subparagraph.

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3. <u>Where the information is provided through a digital label, the requirements for digital labels set out in Article 34b shall apply.</u>	EL: We agree	
<i>Article 34b</i>		
Requirements for digital labelling		DK: There is still ample room for interpretation with the current wording and Denmark would like to stress the fact that there is need for a very thorough guidance on this entire article (article 34b), including every provision.
1. The <u>supplier who pursuant to Article 31(1a) places a data carrier linking to a digital label for substances and mixtures shall ensure that the digital label</u> satisfies the following general rules and technical requirements:	EL: We agree	FR: The person responsible for the physical label must also be responsible for the digital label, which is optional to avoid to dilute responsibilities. He must take the necessary measures to avoid failures of the system or its provider. PT: PT also welcomes the proposal to specifically state that the supplier who places a data carrier linking to a digital label on a product is responsible for the digital label and the connection to the product.
(a) all label elements referred to in	IE:	

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Article 17(1) shall be provided in one place and separated from other information;	Editorial suggestion: change ‘shall be provided in one place’ to ‘shall be provided together in one place’	
(b) the information on the digital label shall be searchable;		
(c) the information on the digital label shall be accessible to all users in the Union <u>and shall remain accessible for a period of 10 years or where the information is provided in accordance with other Union legislation, for the period of time required by that legislation;</u>	ES: (c) the information on the digital label shall be accessible to all users in the Union and shall remain accessible for a period of 10 years 42 months or where the information is provided in accordance with other Union legislation, for the period of time required by that legislation; FR: (c) the information on the digital label shall be accessible to all users in the Union and shall remain accessible for a period of <u>at least 10 years or longer period required under other Union legislation covering the information that it contains;</u> or where the information is provided in accordance with other Union legislation;	ES: The 10-year accessibility requirement for digital labelling is unduly demanding and goes beyond the average lifetime of physical labels. A period of 42 months could be reasonable and coherent with the average time on the market of the products. In line with the time limit proposed in the revision in new Article 61.7 of 42 months for the application of the new provisions for products already on the market. FR: The 10-year time limit should not be reduced by another legislative provision providing for a shorter time limit. LT: We support the Presidency Compromise Proposal of 10 years

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	for the period of time required by that legislation;	or the period required by other Union legislation.
(d) the digital label shall be accessible free of charge, without the need to register, download or install applications, or to provide a password;		
(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;	PT: (e) the information on the digital label shall be presented in a way that also addresses the needs of vulnerable groups “people with visual disabilities” and support, as relevant, the necessary adaptations to facilitate access to the information by those groups;	IE: We previously indicated that vulnerable groups may need to be defined. While not taken up in the compromise proposal, we maintain our point that at a minimum, this needs to be addressed in guidance. We note the addition of the example of people with visual impairments as an example of a vulnerable group in recital 12 and this is welcomed. PT: In regard to the reference to “vulnerable groups”, we would suggest the use of a more specific/targeted expression such as “people with disabilities”, although this is also a very large concept. In our view, the main disabilities to be considered, in this regard, would be visual impairment, colorblindness, etc. When speaking about websites, the information is normally referenced as accessible, and this concept is widely used.

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(f) the information on the digital label shall be accessible with no more than two clicks;		PL: Accessing the information for differing language versions, esp. in MS with more than one official language may require more than two clicks and should be covered by guidance.
(g) the digital label shall be accessible through digital technologies widely used and compatible with all major operating systems and browsers;		
(h) when the <u>information on the</u> digital label is available in more than one language, the choice of language shall not be conditioned on the geographical location;		DK: Denmark finds that the necessary guidance for article 34b, including this provision, should provide clarity on what the choice of language then could legally be conditioned by. PL: We kindly ask for clarification.
(h) — the link to the digital label shall be printed or placed physically, visibly and legibly on the product in such a way that it can be processed automatically by digital devices widely used by consumers;		
(i) — the digital label shall remain available for a period of 10 years;		

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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.		
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.		
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.’;	ES: 23. It is prohibited to track, analyse or use any usage information for purposes going beyond what is absolutely necessary for provision of digital labelling.’;	DK: Denmark would like to point out that the provided compromise text has the provision, 34b(2), deleted, which is why we find, that the number on this provision should be 34b(2) and not 34b(3). ES: If paragraph 2 of Article 34b is deleted, the numbering of

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		paragraph 3 must be corrected, which becomes 2.
(26a) Article 53 is amended as follows:	EL: We agree	
(a) the following paragraphs 1a to 1b are inserted:	BE: (a) the following paragraphs 1a to 1b are inserted: DE: (a) the following paragraphs 1a to 1b are <u>is</u> inserted:	DE: Consequential change due to the deletion of paragraph 1a.
'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 <u>and</u> 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	AT: 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 and 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	AT: We support the proposal to empower the European Commission to adapt the regulation to international developments (GHS) by means of a delegated act. This empowerment is already included in Art. 53 para 1. In this discussion it will be crucial which labelling elements must be attached to the packaging in order to protect the health of consumer, workers and the environment.

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societal needs and <u>ensure that label elements are only included in section 1.6. of Annex I provided that they are not instrumental for the</u> a high level of protection of SK:man health and the environment;	societal needs and ensure that label elements are only included in section 1.6. of Annex I provided that they are not instrumental for the a high level of protection of SK:man health and the environment; BE: ‘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 SK:man health and the environment; 1b. DE: 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	BE: BE considers that decisions on the information that could be provided by digital means only, relate to essential elements of the Regulation and require political choices. Such decisions should be adopted by the ordinary legislative procedure. DE: If Article 34a(2) and Annex I Section 1.6 is deleted, there is no need for the corresponding empowerment..

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	to in Article 34a(2) to technical progress and 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 ensure that label elements are only included in section 1.6. of Annex I provided that they are not instrumental for the protection of SK:man health and the environment;	
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 Articles <u>34a</u> 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 such those delegated acts, the Commission shall:	AT: 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 Articles <u>34a</u> 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 such those delegated acts, the Commission shall: DE:	DE: Consequential change due to the deletion of paragraph 1a and Article 34a(2).

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	1a. 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 Articles 34a <u>and</u> 34b. Those requirements shall cover, in particular, the IT solutions which may be used, and the alternative means for providing the information. When adopting such delegated acts, the Commission shall:	
(a) ensure coherence with other relevant Union acts;	AT: (a) ensure coherence with other relevant Union acts;	
(b) encourage innovation;	AT: (b) encourage innovation;	
(c) ensure technological neutrality by applying no constraints or prescriptions on choices of technology or equipment, within the bounds of compatibility and interference	AT: (c) ensure technological neutrality by applying no constraints or prescriptions on choices of technology or equipment, within	

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avoidance;	the bounds of compatibility and interference avoidance;	
(d) take into account the level of digital readiness among all population groups in the Union;	AT: (d) take into account the level of digital readiness among all population groups in the Union;	DE: The terms “digital readiness” and “population groups” may require further definition. Specifically, it should be ensured that the used terminology does not only cover the geographic and economic diversity of EU citizens, but also other factors, for example, such as demographic (age), physical (dis-)abilities and personal preferences.
(e) ensure that digitalisation does not compromise the protection of SK:man health and the environment. ² ;	AT: (e) ensure that digitalisation does not compromise the protection of SK:man health and the environment.²;	
<u>Changes to Annex I in A2</u>		
(10) the following Section 1.6. is added:	BE:	BE:

Presidency Compromise Proposal on Subgroups A1 and A2 (ST 7616/23)	Drafting Suggestions AT, BE, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK	Comments AT, BE, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK
	(10) the following Section 1.6. is added: DE: (10) the following Section 1.6. is added: EL: We agree	Transferred to article 34a. The provisions on label elements that may be provided only on a digital label should not be in an annex but in article 34a like similar provisions. DE: As Article 34a(2) is rejected, there is no need for a new Section 1.6. in Annex I.
‘1.6. Label elements that may be provided on a digital label only	BE: ‘1.6. Label elements that may be provided on a digital label only DE: 1.6. Label elements that may be provided on a digital label only	DE: As Article 34a(2) is rejected, there is no need for a new Section 1.6. in Annex I.
(a) Supplemental information referred to in Article 25(3)';	BE: (a) Supplemental information referred to in Article 25(3)'; DE:	DE: As Article 34a(2) is rejected, there is no need for a new Section 1.6. in Annex I. NL:

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	(a) Supplemental information referred to in Article 25(3)'; NL: (a) Supplemental information referred to in Article 25(3), <u>provided that other Union legislation does not require the label elements to be placed on the physical label</u>';	Please also see our previous comments regarding article 25(3). We would like to suggest amending proposed section 1.6 in Annex I, as to make clear that when other Union acts require certain label elements to be on the physical label, these label elements should not be moved to the digital label pursuant to article 25 paragraph 9 and section 1.6 Annex I.
<u>Recitals relating to A2</u>		
(12) Regulation (EC) No 1272/2008 needs to be adjusted to technological and societal changes in the field of digitalisation and be prepared for future developments. Digital labelling could improve the efficiency of hazard communication, especially for vulnerable population groups, <u>such as people with visual impairments,</u> and <u>for</u> people who do not speak the national language of a Member State. Therefore, it is necessary to provide for voluntary digital labelling and to lay down technical requirements for such labelling. In order to provide for	DE: (12) Regulation (EC) No 1272/2008 needs to be adjusted to technological and societal changes in the field of digitalisation and be prepared for future developments. Digital labelling could improve the efficiency of hazard communication, especially for vulnerable population groups, such as people with visual impairments, and for people who do not speak the national language of a Member State. Therefore, it is necessary to provide for voluntary digital labelling and to lay down technical	DE: Recital 12 has to be adapted in accordance with the proposed change of the corresponding Article 34(a). PT: In regard to the reference to “vulnerable groups”, we would suggest the use of a more specific/targeted expression such as “people with disabilities”, although this is also a very large concept. In our view, the main disabilities to be considered in this regard, would be visual impairment, colorblindness, etc. This text is adjusted with the Article 34b, (e).

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legal certainty, it is appropriate to specify the label elements that are allowed to be provided in a digital format only. That possibility should only exist for information which is not instrumental for the safety of the user or the protection of the environment.	requirements for such labelling. In order to provide for legal certainty, it is appropriate to specify the label elements that are allowed to be provided in a digital format only. That possibility should only exist for information which is not instrumental for the safety of the user or the protection of the environment. EL: We agree PT: (12) Regulation (EC) No 1272/2008 needs to be adjusted to technological and societal changes in the field of digitalisation and be prepared for future developments. Digital labelling could improve the efficiency of hazard communication, especially for vulnerable population groups, such as <u>people with visual impairments disabilities</u>, and <u>for</u> people who do not speak the national language of a Member State. Therefore, it is necessary to provide for voluntary digital labelling and to lay down technical requirements for such labelling. In order to provide for legal	When speaking about websites, the information is normally referenced as accessible and this concept is widely used.

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	certainty, it is appropriate to specify the label elements that are allowed to be provided in a digital format only. That possibility should only exist for information which is not instrumental for the safety of the user or the protection of the environment.	
(13) In order to adapt the label elements allowed to be provided only in a digital format to technical progress or to the level of digital readiness among all population groups in the Union, the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union to amend the list of label elements allowed to be provided only in a digital format, taking into account societal needs and a high level of protection of SK:man health and the environment.	BE: (13) In order to adapt the label elements allowed to be provided only in a digital format to technical progress or to the level of digital readiness among all population groups in the Union, the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union to amend the list of label elements allowed to be provided only in a digital format, taking into account societal needs and a high level of protection of SK:man health and the environment. DE: (13) In order to adapt the label elements	BE: See comment on article 53 (1a). DE: Recital 13 has to be removed in accordance with the proposed change of the corresponding Article 53.

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	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 SK: man health and the environment. EL: We agree	
(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.	EL: We agree	

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