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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Delegations
N° prev. doc.:	CM 1886/23 - related document WK 1216/2023 - related document
N° Cion doc.:	ST 16528/23 + ADD 1 - 9 - COM (2022) 748 Final
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 Regulation) - Comments by Member States on Clusters A and B

Delegations will find in the Annex the table with comments by Member States on the Clusters A and B of the Proposal for revision of the CLP Regulation. The table is for reference in view of the Meeting of the Working party on Technical Harmonisation (Dangerous Substances - Chemicals) on 13 March 2023.

CLP proposal – table for MS comments following Presidency clustering

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- do not use active track-changes. Any track changes in your completed table should have been accepted and therefore appear as normal text (by contrast, strike-through, bold, underline and italics are acceptable because the consolidation macro can handle them).

- do not use a coloured font or "text highlight colour". It is important that the consolidated table can be printed in black-and-white and still make sense. We cannot process any formats that would prevent this.

- do not insert mathematical formulae or tables as the macro cannot process these.

- place ALL comments within your completed questionnaire.

This would hinder the consolidation of your comments.

Commission Proposal: Clustering proposed by the Presidency WK 1216/2023	Drafting Suggestions BE, GR, HU, IE, NL, PL, PT, SI, SK, LV, FR, CZ, AT, DE, IT, ES, MT, BG, DK	Questions, comments, and justifications of drafting suggestions BE, GR, HU, IE, NL, PL, PT, SI, SK, LV, FR, CZ, AT, DE, IT, ES, MT, BG, DK
	IT:	
General comments on the Proposal	PL: Poland appreciates the efforts and work of the Commission on the draft regulation. We welcome introduction of the new solutions, especially in the field of new digital labeling technologies but still we think that the provisions need further development in order to make the digital labelling be more applicable and widely useful. FR: Proposed drafting for Article 31(1): Labels <u>or a fold-out labels</u> shall be firmly affixed to one or more surfaces of the	NL: NL: we would like to suggest to include a requirement in current article 17 regarding the Unique Formula Identifier (UFI) for mixtures, currently required under Annex VIII to be affixed to the label. SK: SK CLP CA welcomes the CLP proposal. It is a comprehensive package with the priority of better identification and classification of hazardous chemicals, improving communication on chemical hazards and addressing legal gaps and high levels of non-compliance. We support the proposed

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	packaging immediately containing the substance or mixture and shall be readable horizontally when the package is set down normally	revision of the CLP Regulation in terms of ordinary legislative procedure. SK CLP CA is of the opinion that the EU initiatives related to the introduction of new hazard classes/criteria in the CLP Regulation should fully reflect and follow the outcome of the discussion at the UN level to ensure compliance with the UN GHS principles and secure a global process of harmonization of chemicals. SK CLP CA is of the opinion that extension of the date of application from 18 to 24 months from the date of entry into force give the industry sufficient time to implement the various changes. In addition, it could be appropriate to comply the terminology of CLP with Regulation (EU) 2019/1020 in terms “placing on the market” and “supplier”. As part of an extensive revision of the CLP Regulation, we consider it appropriate to update references to other specific legislations, means repealed directives that

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		are replaced by European Regulations. For example to state in the whole wording of the revision of CLP Regulation references to PPPR, BPR, Medical Devices Regulation, Cosmetics Regulation, etc. Please consider to update it in all parts of CLP Regulation because of consistency, not only in e.g. Article 36(2) as mentioned in the Commission's presentation for Working Party on Technical Harmonisation (Dangerous Substances - Chemicals) WK 731/2023 INIT „Replaces the references to the repealed directives by references to the Biocidal products Regulation and the Plant Protection products Regulation“. This would contribute to the clarity of the regulation up to date. FR: If the fold-out label is to become widespread, it should be included in Article 31 on general labelling rules. It would not be logical for this possibility to be derived solely from an amendment to the provisions on exemption conditions DK:

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		We are still analysing the revised proposal and have a parliamentary and general scrutiny reservation. We look forward to constructive negotiations. You will find our provisional remarks on the following pages. We are at your disposal if the Presidency or the Commission should have comments and or questions.
	PL: Provisions of (Art. 1, point 11) concerning obligations on fold-out labelling in MS languages are not clear enough and may need further development. FR: Section 1.5.2.3 FR: Changes to Annex II in A1 3. PART 3: SPECIAL RULES ON PACKAGING	PL: Will fold-out labels according to the new provisions be applicable to many product markets, meaning different EU countries? FR: Regulatory references need to be updated FR: 3.1.1.1 & 3.2.1.1 Please consider to add 'Endocrine disruption for human health' DK:

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		A revision of the regulation on labelling requirements for plant protection products (Regulation (EU) No 547/2011) is currently being discussed in parallel with the revision of the CLP regulation. Is the COM aware of other parallel processes regarding for example labelling of other chemical products? Could the Presidency elaborate on how the updated rules for labelling of plant protection products plays into the process with the revision of the CLP-regulation?
<u>Cluster A – Labelling and sales</u>		DK: Fold out-labels on plant protection and biocidal products was brought up as potentially problematic by Denmark on the latest working group meeting on February 22nd 2023. The problems arise from the national approvals that can vary from member state to member state. In effect, this can cause confusion as to what use is approved in the member states, if a user reads the label in a different language than the national languages of their country and could subsequently lead to incorrect and illegal use. Denmark therefore suggests an

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		exemption from using fold-out labels for plant protection and biocidal products governed by Regulation (EC) No 1107/2009 and Regulation (EU) No 528/2012, respectively.
	DK: The Commission is empowered to adopt delegated acts in accordance with Article 53a amending Article 6(5), Article 11(3), Articles 12 and 14, point (b) of Article 18(3), Article 23, Articles 25 to 29, the second and third subparagraphs of Article 35(2) and Annexes I to VIII, including adopting delegated acts on the inclusion of new hazard classes, in order to adapt them to technical and scientific progress, taking due account of the further development of the GHS, in particular any UN amendments relating to the use of information on similar mixtures, and considering the developments in internationally recognised chemical	DK: Denmark welcomes the suggested changes to article 53, though there is still a need for clarification on the different paragraphs. In addition, the wording of article 53.1 is still ambiguous and it would be preferable that the paragraph clearly states that the Commission can adopt new hazard classes via delegated acts without the possibility to delete them via delegated acts.

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	programmes and of the data from accident databases. Where imperative grounds of urgency so require, the procedure provided for in Article 53b shall apply to delegated acts adopted pursuant to this paragraph.	
Subgroup A1. Labelling obligations/exemptions		
Articles in A1		
	DE: (8) in Article 23, the following point (g) is added:	DE: The addition of Article 23 point g has to be rescinded. According to Article 1(4) MS may already allow exemptions in the interest of defence. Also, pursuant to German law, the new definition of Article 23 point g would not even apply to the Bundeswehr, as the definition refers to Directive (EU) 2021/555, which is transposed into national law as the Weapons Act, from which the Bundeswehr is, in turn, exempted.

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		Also, according to ECHA, ammunition cartridges are considered as “articles” and therefore not labelled. We are not aware of any problems that would require such an additional exemption. The proposal is therefore not necessary.
(8) in Article 23, the following point (g) is added:	GR: We agree	
	DE: ‘(g) ammunition as defined in Article 1(1), point (3), of Directive (EU) 2021/555 of the European Parliament and of the Council* unless it falls within the definition of an article in Article 2, point (9), of this Regulation. BG: ‘(g) ammunition as defined in Article 1(1), point (3), of Directive (EU) 2021/555 of the European Parliament and of the Council* unless it falls within the definition of an article in Article 2, point (9), of this Regulation.	MT: MT would like to place a scrutiny reservation on Art 23 point (g). BG: To make it clear that only articles are excluded from the derogation. This will avoid overlap between the two definitions in respect of some ammunition. We support the inclusion of clarification on the scope in a guidance - especially which ammunition are not considered articles.

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‘(g) ammunition as defined in Article 1(1), point (3), of Directive (EU) 2021/555 of the European Parliament and of the Council* unless it falls within the definition of an article in Article 2, point (9), of this Regulation.	FR: ‘(g) equipment and 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 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.	HU: In our understanding, the “unless it falls [...]” term means that articles are not covered by CLP regulation, therefore, it should be clarified in the text. However, we would like to also mention that Article 4 (8) states that “articles referred to in section 2.1 of Annex I shall be classified, labelled and packaged...” and we consider that ammunitions (in case they are articles) fall under this provision. PT: We agree with this exemption and consider that it will provide a more harmonized approach at EU level. FR: The scope of the derogation including only ammunition is too narrow: it lacks the explosives in class ML.4 of the EU Common Military List. A reference to items as listed in classes ML.3 and ML.4 of this list is necessary for the defence sector.

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		Also, the last sentence “<i>unless it falls within the definition of an article in Article 2 point (9) of this Regulation</i>” do not seem relevant since the ammunition qualified as articles must then respond to Article 4, point 8 : “<u>articles</u> referred to in section 2.1 of Annex I <u>shall be classified, labelled and packaged in accordance with the rules for substances and mixtures</u> before being placed on the market”. As well as this, because the notion of article is not defined in the common military list of the European Union and the directive (EU) 2021/555, there is no reason to exclude articles. CZ: CZ apply the scrutiny reservation (we are waiting for a response from the mining authority).
<i>* Directive (EU) 2021/555 of the European Parliament and of the Council of 24 March 2021 on control of the acquisition and</i>		

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<i>possession of weapons (OJ L 115, 6.4.2021, p. 1).²;</i>		
(9) Article 25 is amended as follows:	GR: We agree ES: Paragraph 2 should be amended as follows (not in the COM proposal): 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 Regulation (CE) 1107/2009 . The statement shall be worded in accordance with Part 4 of Annex II and Part 3 of Annex III to this Regulation.	ES: Directive 91/414/ECC was repealed by Regulation (CE) 1107/2009
(a) in paragraph 6, the first subparagraph is replaced by the following:		
	DE: '6. The specific labelling rules set out in Part 2 of Annex II shall apply to mixtures	DE: Extending the regulation to mixtures containing both hazardous and non-

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	containing <u>hazardous substances, or that lead to the formation or release of a hazardous substance during their use</u>, referred to in that Annex.’; ES: ‘6. The specific labelling rules set out in Part 2 of Annex II shall apply to mixtures, classified or not as hazardous, containing substances referred to in Part 2 of that Annex.’; BG: The specific labelling rules set out in Part 2 of Annex II shall apply to mixtures containing substances referred to in that Part of Annex II.’	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. ES: To add clarity and in line with recital 9: <i>Part 2 of Annex II to Regulation (EC) No 1272/2008 sets out rules for additional hazard statements to be included on the label of certain mixtures listed in Part 2 of that Annex. Given that those statements provide important additional information in specific cases, they should be applied to all mixtures referred to in Part 2 of Annex II, regardless of whether they are classified and whether they contain any classified substance.</i> In addition, if part 2 of Annex II is not specified, it could refer to any mixtures containing substances referred in any part of Annex II. BG:

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		For clarity.
‘6. The specific labelling rules set out in Part 2 of Annex II shall apply to mixtures containing substances referred to in that Annex.’;	IE: The labelling rules set out in Part 2 of Annex II shall apply to specific <u>certain</u> mixtures	IE: If ‘specific’ is retained here, then we suggest that the text in Annex II is changed from ‘special’ to ‘specific’
(a) the following paragraph 9 is added:	FR: Change (a) by (b)	FR (a) was already used in the previous paragraph DK:
	MT: ‘9. Label elements resulting from requirements set out in other Union acts shall be placed in the section for supplemental information on the label.’;	MT: MT suggests that this addition is removed. This could create a contradiction with other Union laws with regards to labelling, such as the placement of certain mandatory information on the main label.
‘9. Label elements resulting from requirements set out in other Union acts shall be placed in the section for supplemental information on the label.’;		NL: NL: the proposed section 1.6 in Annex I allows supplemental information to be provided on a digital label only. In combination with this provision – article 25

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		paragraph 9 – the proposal seems to allow label elements required in other Union acts to be moved to the digital label. We understand that physical labelling would still be required under other Union acts, however, we wonder whether this provision might be confusing and we would like to suggest to include a sentence to make the above clear. SI: Which Union acts had the Commission in mind in this Article? Could the examples of such supplemental labelling be provided?
(11) Article 29 is amended as follows:	IE: Suggestion for Article 29(2) to reflect our comment across: “If the contents of the package do not exceed 125 ml, then the labelling information may be reduced, for certain hazard classes and categories, in accordance with Section 1.5.2 of Annex I” DK:	IE: We suggest that consideration is given to separating the provisions of Article 29(1) and 29(2) so as to not have these 2 provisions inextricably linked. Presently, the reduced labelling for small packaging, as foreseen by Article 29(2), cannot be applied on the immediate packaging without firstly having exhausted the possibilities outlined in

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	Label elements resulting from requirements set out in other Union acts shall be placed in the section for supplemental information on the label. <i>However, mandatory labelling elements resulting from other Union legislation may not only be included on the digital label, but must also be placed on the physical label or according to the rules laid out in the other Union legislation;</i>	Article 29(1) (as also explained in ECHA FAQ 1856). We are of the opinion that consideration should be given to changing this, especially as we consider it was allowed for under the DPD. The change would allow the content of packaging < 125ml, within the scope of 1.5.2.1, to be reduced without first having to consider Article 29(1). This would enable suppliers of products <125ml to use both solutions if they wish, whilst not being forced to use outer packaging /tie on label, if there is no need to do so. This would also reduce packaging waste. DK: The proposal states that labelling from other Union acts should be placed in the section for supplemental information on the label. Does this mean that for example information on small parts in toys that can cause suffocation is only given on the digital label? And how will this affect pesticidal and biocidal products?

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		Denmark finds that it is important to underline that the label elements from other EU regulations should always be presented on the physical label without exception if it is required from other EU-legislations.
(a) paragraph 1 is replaced by the following:		
	DE: If fold-out labels are to be made an unconditional option to provide the mandatory labelling then the proposed wording of Article 29(1) should be kept but a further amendment of Article 31(1) should be considered. Article 31(1): 1. Labels <u>or fold-out labels</u> 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. IT:	AT: Hazard information should be presented properly and clearly. This proposal is intended to permit fold-out labels in general. Therefore, further legal regulations with regard to form and design should be established in order to avoid different interpretations in the respective member states which could lead to distortion of competition and different levels of protection of human health and the environment. On the other hand we should pay attention to ensure that practical and flexible solutions for fold-out labels are possible. DE:

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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 1.5.1.1. 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 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. 1.5.1 of Annex I.’	If fold-out labels are to be made an unconditional option to provide the mandatory labelling, then they should be introduced as a general option in Article 31. IT: In order to avoid incoherence with other parts of the regulation referring to the language (s). In fact, the art 17(2) states what language(s) can be used, to avoid confusion we suggest deleting the reference in art. 29.1. In addition, we suggest verifying the other parts of the regulation. ES: For clarity and a better understanding, reference to Annex I (section 1.5.1) shall be maintain as it already stands in CLP. BG: Scrutiny reservation concerning fold-out labels

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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 1.5.1.1. and 1.5.1.2. of Annex I.’;	GR: We propose the addition of the text in bold 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, on the packaging immediately containing the substance or the mixture, 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 1.5.1.1. and 1.5.1.2. of Annex I.	GR: <u>Justification:</u> <i>By adding the text in bold, it becomes easier for the reader to understand to which packaging (i.e. inner, outer) Article 29(1) refers.</i> PT: In principle, we can accept this approach, however a more detailed analysis of Sections 1.5.1.1. and 1.5.1.2 of Annex I is being done. AT: Regarding Art. 29 para 2 CLP-Reg. we would like to note, that the Austrian Authority takes para 1 and 2 to mean that para 2 is practically not relevant. It is usually always possible to label products by means of a tie-on tag, outer packaging or (currently) fold-out label.
	GR: We propose the addition of the text in bold in Article 29(2):	GR: <u>Justification:</u> It is very important to clarify which package Article 29(2) refers to. The addition we propose is in accordance with

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	“If the full label information cannot be provided <i>on inner</i> packaging <i>or on an outer packaging, or tie-on tag</i> , in the way specified in paragraph 1, the label information may be reduced in accordance with section 1.5.2 of Annex I.	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/fold-out label/tie on tag already affected by an exemption under Article 29(1)”.</i>
(b) paragraph 3 is replaced by the following:		DK: We have concerns regarding using fold-out labels as a rule. With a broader use of foldout labels it must be insured that the consumers can find the relevant information easily. What will the rules be for fold-out labels with regards to the order of the required information on the labels? Will the guidance be updated to accommodate the fold-out labels? Denmark strongly recommends that clear rules are made for the number of languages

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		present on a label and also rules for prioritizing these. From a consumer protection standpoint, a long and multi lingual fold-out label could cause confusion. As it is part of the intention with this revision to strengthen hazard communication, updated rules for foldout-labels are a necessity.
	ES: Proposal to add a new paragraph 3b: Where a hazardous substance or mixture is supplied to consumers and professionals via refill stations according to article 35 (2a) , it should be accompanied by a copy of the label elements in accordance with Article 17.	ES: Label information should also be supplied to the users, and not only placed on the refill station. BG: Is it intended to include substances other than fuels in Part 5?
‘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.’;	GR: We agree	SI: Proposed text in Part 5 of Annex II shall be corrected in order to be clearer as in the practice CAs get a lot of questions on the

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		implementation of such labelling. Therefore see also our comments Annex II. LV: At this stage we have some general doubts regarding amendments made to Point 3 of Article 29 and Part 5 of Annex II. According to these amendments, a requirement to hand over a copy of the label will not be in place when mixtures (particularly fuel, AdBlue etc.) are filled specifically and directly into vehicle tanks. In this regard, the label will need to be placed on the appropriate pump. In practice, however, there are situations where these mixtures are filled at service stations not in the vehicles, but in jerry cans. Therefore, it is unclear how the supplier of the mixture will be able to implement in practice the requirement to provide a copy of the label. In this regard we would like to suggest expanding the scope of obligation also to cover mixtures that are being filled in jerry cans at service stations.
	DE:	DE:

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	(c) the following paragraphs 4b and 4c are inserted:	The insertion of paragraphs 4b and 4c has to be rescinded. It is not possible to distinguish between ammunition used in combat zones and other ammunition. Also, according to ECHA, ammunition cartridges are considered as “articles” and therefore not labelled according to CLP. Ammunition for armed forces is not procured for ”combat zones” only, but for inland training, extraterritorial operations etc. Different labelling for different uses of the same ammunition is not purposeful. Also, labelling of ammunition for defence forces (for NATO Members) is comprehensively regulated in Standardisation Agreements (STANAG). There is an adequate hazard communication already in place. Any separate regulation (for ammunition for combat zones) increases the risk of interfering with the interoperability of NATO partners, due to some being part of the EU and some not. Furthermore, Article 1(4) provides already today an exemption for MS.

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(c) the following paragraphs 4b and 4c are inserted:	GR: We agree	
	DE: ‘4b. By derogation from Article 17(1), the labelling requirement set out in that Article shall not apply to packaging of ammunition that is used by defence forces in combat zones or shipped to such zones where labelling in accordance with that requirement would constitute an unacceptable security risk for the cargo, the soldiers and the staff, and sufficient camouflaging cannot be ensured. IT: ‘4b. By derogation from Article 17(1), the labelling requirement set out in that Article shall not apply to packaging of ammunition as defined in Article 1(1), point (3), of <u>Directive (EU) 2021/555 of the European Parliament and of the Council</u> that is used by defence forces in combat zones or shipped to such zones where labelling in accordance with that requirement would constitute an	

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	unacceptable security risk for the cargo, the soldiers and the staff, and sufficient camouflaging cannot be ensured.	
‘4b. By derogation from Article 17(1), the labelling requirement set out in that Article shall not apply to packaging of ammunition that is used by defence forces in combat zones or shipped to such zones where labelling in accordance with that requirement would constitute an unacceptable security risk for the cargo, the soldiers and the staff, and sufficient camouflaging cannot be ensured.	FR: ‘4b. By derogation from Article 17(1), the labelling requirement set out in that Article shall not apply to packaging of equipment and ammunition listed in Article 23, g), <u>with the purpose of</u> being used by defence forces in combat zone or shipped to such zones where labelling in accordance with that requirement would constitute an unacceptable security risk for the cargo, the soldiers and the staff, and sufficient camouflaging cannot be ensured.	LV: The derogation introduced in Point 4b is rather confusing. An exemption from the labelling requirements is applicable specifically to ammunition, that is intended to be used in combat zones or shipped to such zones, and the derogation is not in place for storage of such ammunition in warehouses. The ammunition in general is not being produced depending on the purposes, for which it is intended to be used or shipped. Ammunition stored in a warehouse can also be sent to the combat zone, depending on the demand and necessity. Therefore, extension of such derogation, covering also storage, would be logical and more acceptable. FR: Ammunition and military equipment must first be stored in the supply chain and

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		military depots on French territory as far as French defence is concerned, before being sent to combat zones. It would be a problem to have a label on EU territory, to be removed for shipping to combat zones /field operations, notably for practical reasons. Equipements ML3 et ML4 and ammunition are generally purchased in batches (several hundred or even several thousand). The armed forces draw from these lots for exercises or combat. All explosives and ammunition of the same batch must be treated in the same way. <u>Camouflaging is not only a question of colour.</u> The composition of the paint is as great as colour in ensuring the absence of reflection and therefore detection. <u>A label would interfere with this stealth capacity.</u>
	DE: 4c. Where paragraph 4b applies, manufactures, importers or downstream	

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	users shall provide to the defence force the safety data sheet or a leaflet containing the information referred to in Article 17(1).’;	
4c. Where paragraph 4b applies, manufactures, importers or downstream users shall provide to the defence force the safety data sheet or a leaflet containing the information referred to in Article 17(1).’;	HU: 4c. Where paragraph 4b applies, manufactures, importers or downstream users shall provide to the defence force the safety data sheet in accordance with REACH Regulation or a leaflet containing the information referred to in Article 17(1).’; FR: 4c. Where paragraph 4b applies, <u>manufacturers</u>, importers or downstream users shall provide to the defence force the safety data sheet or a leaflet containing the information referred to in Article 17(1). DK: It is proposed to use the following text to include ammunition that are to be used (intended) and not currently used. (current use):	HU: In our view a leaflet cannot be considered as equivalent to the safety data sheet with regard to the information requirements. IE: With respect to the option to use a ‘leaflet’, as this is not an option availed of under the legislation this far, guidance may be required as to how this will work in practice. DK: As the suggested changes regarding ammunition are still being assessed by the Ministry of Justice in Denmark, these changes are addressed in a preliminary fashion. Could the term ‘defence forces’ be more closely defined? Is this the national defence forces as suggested in recital 7?

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	"By derogation from Article 17(1), the labelling requirement set out in that Article shall not apply to packaging of ammunition that is <u>to be</u> used by defense forces in combat zones or shipped to such zones where labeling in accordance with that requirement would constitute an unacceptable security risk for the cargo, the soldiers and the staff, and sufficient camouflage cannot be ensured." And: "the cargo, the soldiers <u>or</u> the staff"	Could the term 'combat zone' be more closely defined? Does this also cover military areas? And how is the border of a combat zone defined? Could the term 'unacceptable' be more closely defined in relation to 'security risk'? Could there be a conflict of interest for the armed forces to inform surveillance authorities about the products they are using in the combat zones? Could this exemption be redundant in nature as there are no active combats on EU soil?
(12) Article 30 is replaced by the following:	GR: We agree	DK:
'Article 30		
Updating information on labels		DK:

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		In relating to subsection 1 and 2 below. We welcome the introduction of a cut-off date and note that the implementation of the requirement was previously stated with: "without undue delay". In this article, the responsibility is imposed on the suppliers. It would be beneficial to have a clear definition of which financial actor is responsible. This in order to ensure uniform enforcement across Member States. Denmark suggests that the responsibility could be placed at the first level of supplier within the EU. This could be defined in the guidance document. As audit focuses, among other things on easier regulatory compliance for SMEs in particular, this particular relationship of responsibility should be clarified. This makes enforcement more uniform across the member states, and at the same time SMEs are ensured easier compliance with the rules, as these are most often

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		included as either importers or downstream users.
	IT: 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 <u>9</u> months after the results of the new evaluation referred to in Article 15(4) were obtained. ES: 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 18 months after the results of the new	IT: The starting point of the timeline to update the label is the evaluation under art. 15(4) that refers to the classification only, so the word “labelling” and the beginning of the sentence are not consistent and redundant. Much time for the supplier chain appears to be more realistic, since the introduction of a fixed 6-months time limit for label changes for both substance and mixture is far too short for downstream users such as our industry sectors. Some classification changes require upfront adaptations in transport, storage and usage of the product by at least two or even more actors in the supply chain. ES: The new CLP Regulation proposal requires labels to be updated within 6 months in case a new hazard class or a more severe

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	evaluation referred to in Article 15(4) were obtained. BG: 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 adapting the classification of the substance or the mixture results of the new evaluation as referred to in Article 15(4) were obtained.	classification needs to be assigned to a substance or a mixture, or when new supplemental information on the label is required. This timeline is too short and inconsistent with current practices which have proven adequate to allow re-design, re-printing of labels and re-labelling of packages. Especially for downstream users the fixed 6-month time limit for label changes is far too short. The actors in the supply chain need more flexibility. Depending on the case, a changed C&L is more than just an update of the label. It might cause further duties regarding usage, storage, and transport of the product, which need to be implemented as well. Therefore, the relabelling of a product is usually a coordinated action between supplier and customer to ensure the implementation of required measures before the new label for the product is provided. Consistent with current rules, we recommend that 18 months should be the timeline for all label updates - that is the

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		normal timeline for ATP's when CLH becomes mandatory for specific substances. 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 legislation. This could be resolved by aligning with the definition found within the BPR etc, which refers to 'first making available'. BG:

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		In order the reference to Article 15(4) to be more precise. Scrutiny reservation concerning the period – we have to provide enough time to stakeholders, taking into account the long chemicals supply chain.
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.	PL: We suggest prolongation of term – entry into force of this provision at least from 6 to 18 months. Preferable term: 24 months. SI: 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 12 months after the results of the new	IE: At the meeting on 22/2, CION clarified that there is a 6-month period to update the label for a substance and then if a mixture contains that substance, then there is a further 6-month period from then to update the label for the mixture. In our opinion, the text is not clear in this regard and may be open to interpretation as it refers to both substance and mixture in the one paragraph. We therefore suggest giving consideration to separating out the requirements for substances and mixtures. Is article 15(4) the correct article to refer to here? We agree that the results of the evaluation carried out under article 15 is a good starting point for setting a deadline to

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	evaluation referred to in Article 15(4) were obtained.	update the labels but are not sure that 15(4) is the most appropriate article to refer to. Perhaps just referral to article 15 would be optimal? PL: In comparison to current obligations, the suggested new label update deadline of 6 months seems to be too short to meet the needs of the vast and complex value chains system in the UE economy (chemical industry has the key impact on other segments of the economy). The proposed deadline of 6 months in order to update the labels in case of a reclassification (additional hazard, more stringent classification) is not achievable and not acceptable. Therefore, the deadline for all label updates should be at least 18 months, which is also in line with the CLH schedules for the ATP where 18 months is given as the default term. Attention should be focused on fact that the supplies of unit packaging, which is ordered

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		by producers of chemical goods. Very often, supplies of unit packaging, such as PE BIG-Bag's, etc., are planned and purchased well in advance due to shortages of raw materials on the market. In a situation where the manufacturer of a chemical substance or mixture is forced to update the classification and labeling, he poses only 6 months to use the packaging with the "old classification", which in turn may lead to unused packaging and the need to dispose of it (which is contrary to the assumptions of the OŚ - minimizing generated waste). Packaging with the old classification cannot be used for other purposes, e. g. packaging for construction waste, because it will contain information on hazards inadequate to the packaging waste. We also suggest that the European Commission should consider carrying out a survey among fertilizer producers regarding the amount of used unit packaging after the entry into force of the new fertilizer regulation - as an example of waste of raw materials resulting from the legislation not being adjusted to the current situation on the market.

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		PT: We welcome the definition of a specific time frame for paragraph 1 and we are open to further discuss what would be a feasible and appropriate time frame. In this regard, a similar approach could be considered for article 15. SI: We are aware that longer transition period means less protection for users of hazardous chemicals. But it is necessary to have in mind the problems with implementations of the measures in practice due to the complexity of supply chains. Therefore we think that more time (at least 12 months) for updating is needed. See also comments by recital 10. SK: We are of the opinion for possible extension of time for updating information on labels.
	IT:	IT:

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	2. Where a change regarding the classification and labelling of a substance or a mixture is required other than that referred to in paragraph 1, the supplier shall ensure that the label is updated within 18 months after the results of the new evaluation referred to in Article 15(4) were obtained. 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 within 18 months after the results of the new evaluation referred to in Article 15(4) were obtained. BG: 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 adapting the classification of the	The starting point of the timeline to update the label is the evaluation under art. 15(4) that refers to the classification only, so the word “labelling” and the beginning of the sentence are not consistent and redundant. ES: Coherence with amendment suggested for article 30.1. Establishing a unique updating period for all types of changes regarding the classification and labelling, makes paragraph 2 unnecessary. No need to distinguish between different types of changes. MT: MT seeks clarification on whether this refers to unharmonized substances or mixtures only. BG: See comments on para 1

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	substance or the mixture results of the new evaluation as referred to in Article 15(4) were obtained.	
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.	PL: The supplier shall ensure that the label is updated within 36 months after the results of the new evaluation referred to in Article 15(4) were obtained. DK: The following wording is proposed: “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 <u>without undue delay and</u> within 6 months after the results of the new evaluation referred to in Article 15(4) were obtained.”	PL: The proposed transitional period for the revised provisions of the Regulation is 18 months, which will be a true challenge for the industry so to meet new obligations in this respect. It should be remembered that changes to the safety data sheets (labelling and classification) are a derivative of 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. Additional classes of hazards listed in the draft regulation, in particular the classification of substances as endocrine disruptors (ED) in the human body and the environment, may in some situations force additional tests to be performed in order to adapt the documentation to the new guidelines. Toxicological and ecotoxicological studies are a very long-term process within the work of SIEFs or consortia because they are

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		associated with considerable costs and limited possibilities to perform tests on vertebrates. It cannot be ruled out that the results of tests for new hazard classes will result in a situation in which the DNEL and PNEC values will decrease, which in turn will lead to the need to carry out a new chemical assessment for the identified uses and obtain negative RCR values (which are currently assessed as positive). However, it will change the toxicological and ecotoxicological modeling in the safety assessment for the identified uses. Therefore, we pay special attention to the fact that the registration dossier should be updated first in order to maintain consistency between the registration dossier and the safety data sheet, which is a difficult, cost-intensive and lengthy process. Therefore, we propose to extend this period to 36 months. SK: We are of the opinion for possible extension of time for updating information on labels.

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		DK: Changed from “without undue delay” to “within 6 months”. It would be beneficial to have a firm definition of when the 6-month period starts. Is it when the evaluation is approved? Is it when ECHA accepts the new classification? Is it when the classification is registered in C&L Inventory? Article 15.4 only mentions manufacturers, importers and down stream users. What are the rules for other actors who update classifications? Please also see the remarks for article 30.
	IT: 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	IT: Coherently with previous comments. ES: Coherence with amendments suggested for article 30.1 and article 30.2 No longer reference to paragraph 2 is needed if it is deleted.

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	such cases, the supplier shall ensure that the label is updated by the date set out in the respective delegated act. ES: 3.2 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.	Current paragraph 3 becomes paragraph 2 (if paragraph 2 is deleted).
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	DK: The following wording is proposed: “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 <u>without undue delay and</u> within 18 months after the results	SI: DK: It would be beneficial to have a firm definition of when the 18-month period starts. Is it when the evaluation is approved? Is it when ECHA accepts the new

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label is updated by the date set out in the respective delegated act.	of the new evaluation referred to in Article 15(4) were obtained.”	classification? Is it when the classification is registered in C&L Inventory? Article 15.4 only mentions manufacturers, importers and down stream users. What are the rules for other actors who updates classifications? Please also see the remarks for article 30.
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’;		
	IT: in Article 31(3), the following sentence is added <u>replaced</u> : ES: (13) in Article 31(3), the following sentence is added paragraph 3 is replaced by the following :	IT: It should be verified in all proposal test accordingly. ES: Point 3 in article 31 is not added, but modified.
(13) in Article 31(3), the following sentence is added:		DK: The proposal says that the labeling must be updated for products covered by Regulation

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		(EC) No 1107/2009 or Regulation (EU) No 528/2012. What about products that are covered by other EU-legislations as well as the CLP-regulation? Furthermore, it is unclear what scope this provision has in relation to Art. 25, subsection 9, and thus whether biocidal and pesticidal products must be physically labelled in full (i.e. physical and digital label are identical) regardless of article 25, subsection 9. Denmark suggests that it is clearly stated if certain labelling provisions stemming from different EU-legislations have priority over others.
	DE: ‘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, <u>colour</u> and spacing as to be easily read. They shall be formatted in accordance with section 1.2.1 of Annex I.’;	AT: Hazard information should be presented properly and clearly. This proposal is intended to permit fold-out labels in general. Therefore, further legal regulations with regard to form and design should be established in order to avoid different interpretations in the respective

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	ES: ‘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.’;	member states which could lead to distortion of competition and different levels of protection of human health and the environment. On the other hand we should pay attention to ensure that practical and flexible solutions for fold-out labels are possible. The following could be discussed: A fold-out label could provide an overview of the most relevant labelling elements according to Annex I 1.5.1.2. and the hazard statements in several languages on the readable visible side of the fold-out label. The full information could be provided in the fold-out label. In addition, for very small container (less than 20ml) consideration should be given to inserting an additional line in Table 1.3. of Annex I setting 6pt as the minimum font size for the fold-out label and an exemption for Annex I 1.2.1.5.b (distance between two lines) DE: To further improve readability of labels the text colour should be also prescribed. The

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		formatting rules for text size and spacing are a refinement of the more general requirement that label elements shall “stand out clearly from the background and [...] shall be of such size and spacing as to be easily read” and address the latter part of the requirement. Specifying the background colour of the label alone is not suitable to ensure that the text stands out clearly from the background. Only by also prescribing the text colour this can be finally ensured. This would also reflect the original SE proposal. ES: While the new provisions allowing the use of fold-out labels are welcomed, the new rules for formatting labels are too stringent and too specific, particularly those prescribing a minimum font size and spacing requirements. It is a fact that labels are increasingly difficult to read as a result of additional information requirements (often due to substance reclassifications). However,

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		setting minimum font sizes and rules relating to line spacing and background is not the answer to this challenge. A slight increase in font size would increase legibility, but the proposed increase is unnecessary and impractical: it would make current label sizes unusable for most products and would reduce the number of languages that can be placed on one label and thus, considerably limit flexibility. In addition, companies would need new or updated software's to manage those requirements. In our view, specific formatting rules should be kept in the guidance document, as is currently the case. It is more practical to specify formatting rules in the CLP implementation guides, where examples can be included and the wide variety of scenarios that may exist can be more flexibly addressed. It is important for suppliers to retain the flexibility regarding font size etc., 'as long

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		as the obligatory information on the label can be easily read' (current CLP guidelines). The font type used plays as much a part, if not more, than minimum font size (examples where implementing the proposed changes in Annex I will result in much larger labels, some larger than the packaging surface to which they need to be attached could be provided). The specification in the proposal for the background colour of the label limited to white ONLY is an unjustified restriction on label design for many containers where the label is directly lithographed and where the background colour may vary for reasons of branding, marketing, etc. These changes will also result in a considerable increase in the use of fold-out labels, especially where multiple languages are involved, leading to more resource use and increased waste from labels at end -of- life.

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		We propose to reject the amendments proposed to sections 1.2.1.4 and 1.2.1.5, and thus not setting new minimum requirements for labels
‘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.’;	GR: We agree FR: ‘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.’;	PT: In principle, we can accept this approach, however a more detailed analysis of Section 1.2.1 of Annex I is being done. SK: - FR: Either the entire article 31(3) is replaced nor a sentence is added. Considering the wording used in modification (13), the proposal was only to add a sentence at the end of the paragraph. AT: In discussions with national authorities and stakeholders, it has been proposed to indicate SVHC in mixtures. If this proposal is also supported by other Member States

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		and the European Commission it would have to be discussed how this can be implemented in a suitable way. In our discussion, for example, it was suggested to list the SVHC in the digital label or to make them recognisable not in name but via the CAS Number on the physical label.
(14) in Article 32, paragraph 6 is deleted;	GR: We agree DK: We propose the following wording: "The label elements referred to in Article 17(1) shall be clearly and indelibly marked. They shall be formatted in accordance with section 1.2.1 of Annex I."	DK: The passage; "stand out clearly from the background", is regarded as relatively unclear. It is not a given when something appears "clear". We propose (see also the addition of point 1.2.1.5 in Annex I) that in relation to a requirement for a white background, black writing is required, with respect to point 1.2.1.2 regarding hazard pictograms. Finally, it is our overall assessment that this provision can be reformulated to the following: "The label elements referred to in Article 17(1) shall be clearly and indelibly marked."

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		<i>They shall be formatted in accordance with section 1.2.1 of Annex I.”.</i> Thus, the 2nd point is removed in the text, as it is considered redundant if there is compliance with 1.2.1 in Annex I, and the other remark is considered as well. It would make the regulation easier to understand and follow if the requirements for the text do not appear both in this provision and in an annex.
Changes to Annex I in A1		DK: No remarks, but the remarks to article 25(9) should be noted.
(2) Section 1.2.1.4. is replaced by the following:		SI: General comments: We believe that prescribing the minimum font size and distance between two lines is not an appropriate way to improve label readability. In the past, before the CLP Regulation come into force, some EU members (e.g. SI, AT...) already had such provisions in their national laws, but they did

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		not contribute to improve the readability of labels. In addition, there will also be a problem with the control of such provisions (e.g. text fonts and distance between two lines). Last but not least based on our experiences, global suppliers would definitely omit smaller languages due to space constraints.
	ES: ‘1.2.1.4. The dimensions of the label and of each pictogram, and the font size of letters shall be as follows:	IT: The implementation of the proposal could require more time than that proposed in the transition period. ES: See justification for amendment proposed to article 31.3
‘1.2.1.4. The dimensions of the label and of each pictogram, and the font size of letters shall be as follows:	GR: We agree PL: Poland kindly asks for taking into account to specify minimum font size in millimeters,	PL: The proposed minimum font size - 8 pt, is too large for the practical implementation of information obligations. SI:

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	not in pt (point size for different fonts may result in different capitalization of their letters). SI: 1.2.1.4. The dimensions of the label and of each pictogram, and the font size of letters shall be as follows:	See the general comments above. We propose to delete following text: <i>and the font size of letters</i>
Table 1.3		PT: Minimum font size 8 pt for packaging not exceeding 3 litre may not be readable depending on the font type.
	ES: Minimum dimensions of labels, pictograms and font size	ES: See justification for amendment proposed to article 31.3
Minimum dimensions of labels, pictograms and font size	SI: Minimum dimensions of labels, pictograms and font size DK:	HU: We suggest using mm as the unit of measurement for setting the font size, because even if the size in pt would be the same, actual sizes would vary depending on

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	Minimum font size for containers with a capacity between 50-500 liters: 12pt. Minimum font size for containers with a capacity above 500 liters: 12pt.	the different font types used. See examples below: Arial 12 Consolas 12 Tahoma 12 Comic Sans 12 IE: We appreciate that it is stipulated that the font should be without serifs. While this may be sufficient, we also suggest that further consideration is given to specifying a font type should be considered PL: By specifying the minimum font size, the space on the product label for other information will be additionally limited, which will be a significant logistical and financial challenge for entrepreneurs. SI: See the general comments above. We propose to delete following text:

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		<i>and font size</i> DK: Denmark suggests that the minimum font size for packages with a capacity of 50-500 litres and packages with a capacity above 500 litres is set at 12 pt. With 12 pt, Denmark have been informed that the industry should not need to change label printers and thus, this would eliminate costs for the industry as a whole. The updated CLP-guidance should include guidance on how to enforce the rules on minimum font size.
		IT: The information required on the label by other legislations (e.g. detergents, biocide, PPP) is more and more so the minimum font size could not realistically allow all mandatory information in the label. The proposal font size does not appear feasible. Italian association categories can

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		provide numerous examples that show how the proposal would result in much larger labels, sometimes larger than the packaging surface to which they need to be attached. Consequently, this would jeopardise the efforts that some sectors are doing in order to reduce the amount of packaging used (anticipating voluntarily the PPWR regulation). Other implication of the proposal could result in a considerable increase of use of fold-out labels, especially where multiple languages are involved, leading to more material used and an increasing waste of labels at the end-of-life. In addition, we suggest to follow the discussion on the minimum font size under other legislation e.g food legislation. We are not against the proposal and we deemed more appropriate to continue the technical discussion. MT:

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		MT would like to place a scrutiny reservation on table 1.3. Furthermore, MT would like to seek clarification on the font style, as different font styles occupy different area for the same given font size.
[please refer to the table 1.3 in Section 1.2.1.4 in Annex I]	GR: We agree SI: In the table 1.3 the column with the font size shall be deleted!	NL: NL: Table 1.3 in section 1.2.1.4 in Annex I sets out minimum font and label sizes depending on the capacity of the package. We wonder whether it is necessary to require larger font and label sizes when the packaging is larger and whether this would result in greater readability. The larger font and label sizes would result in higher costs for industry and we wonder whether this is outweighed by the benefits of having larger labels and larger texts. SI: See the general comments above.
		IT:

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		The implementation of the proposal could require more time than that proposed in the transition period.
(3) the following Section 1.2.1.5. is added:		
	ES: 1.2.1.5. The text on the label shall have the following characteristics:	ES: See justification for amendment proposed to article 31.3 MT: Whilst MT understands the reasoning behind these characteristics (to improve readability), MT is of the opinion that the characteristics which are being proposed could pose restrictions on the manufacturer and would therefore like to ask whether these are necessary.
‘1.2.1.5. The text on the label shall have the following characteristics:	GR: We agree	SI: LV: Amendments made in Point 1.2.1.5 of Part 1 of Annex I do rise some concerns. The

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		amendments stipulate that if the volume of the packaging does not exceed 10 ml, the font size of the inner packaging label may be less than the one indicated in Table 1.3 with a specific provision that the label is legible for a person with an average eyesight. And it is rather unclear how the CLP controlling authorities will be able to verify in practice this requirement. Is the Commission intending to draw up some sort of guidelines in respect to clarify the term “a person with an average eyesight”?
	NL: <u>[add in] (a) the font colour of the text shall be black;</u> DE: (a) <u>the text on the label shall be black,</u> the background of the label shall be white; IT: Delete ES:	NL: NL: since the background of the label is white, we would like to suggest to include a requirement for the font colour to be black, which will stand out clearly from the white background. DE: To further improve readability of labels the text colour should be also prescribed. The formatting rules for text size and spacing are a refinement of the more general requirement that label elements shall “stand

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	(a) the background of the label shall be white;	out clearly from the background and [...] shall be of such size and spacing as to be easily read” and address the latter part of the requirement. Specifying the background colour of the label alone is not suitable to ensure that the text stands out clearly from the background. Only by also prescribing the text colour this can be finally ensured. This would also reflect the original SE proposal. IT: This requirement is not necessary and will lead to the change of layout for several labels (i.e. Preprinted labels on paperboard boxes, lithographed labels). We believe it could be sufficient to grant the legibility between the background and the text (it appears sufficient to refer to article 31.3 and it could be useful to add examples in the guidance for the sake of the legibility, in particular taking into account colour visual deficiencies). ES:

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		See justification for amendment proposed to article 31.3
(a) the background of the label shall be white;	NL: (a)(b) the background of the label shall be white; DK:	HU: We suggest making it clear, that the text refers only to the CLP part of the label. PL: The introduction of a white background for the text of the warning label will have enormous consequences for entrepreneurs. The practical implementation of this obligation will mean that the replacement of all chemical mixture labels present on the market. SK: It is necessary to consider the white background of the label, as the amendment of regulation (EU) no. 547/2011 on the labeling of plant protection products, where the color of the label is assumed according to the risk of the product. DK:

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		Please note the remarks to art. 31(3) with relations to this point.
	IT: Delete ES: (b) — the distance between two lines shall be equal or above 120 % of the font size;	AT: The following could be discussed: In addition, for very small container (less than 20ml) consideration should be given to inserting an additional line in Table 1.3. of Annex I setting 6pt as the minimum font size for the fold-out label and an exemption for Annex I 1.2.1.5.b (distance between two lines) IT: This requirement is too strict, without any recognizable benefit for hazard communication. In the guidance could be add some examples to guarantee the legibility. ES: See justification for amendment proposed to article 31.3

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(b) the distance between two lines shall be equal or above 120 % of the font size;	NL: (b)(c) 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; DK: We propose the following wording: “the background of the label shall be white <u>and the text black</u>”	SI: See the general comments above. We propose to delete point b). DK: We note that it is required that the background is white. However, white is technically a broad term (how white), we therefore propose that a color code is inserted instead. To this we add that in addition to the proposed text, one could add "... <i>and the text black</i>", again with a color code. In addition to this point, please note the remarks to art. 31(3).
	ES: (c) a single font shall be used that is easily legible and without serifs;	ES: See justification for amendment proposed to article 31.3
(c) a single font shall be used that is easily legible and without serifs;	NL: (c)(d) a single font shall be used that is easily legible and without serifs; DK:	IE: We suggest that the font color should be black so that the label elements are in a black font on a white background.

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	In relation to the remarks, we propose the following wording: ”... shall be equal <u>to</u> or above...”.	DK: This seems to be a rather large distance between the lines, which will also result in less space on the label for the required information? On what basis is 120 % chosen? It is proposed to introduce a concrete size-measurement, which could be 120 % or above distance between lines with respect to the size in mm of the largest letter used. Moreover, the following phrasing should be used:”... shall be equal <u>to</u> or above 120 % ...”
	ES: (d) the letter spacing shall be appropriate for the selected font to be comfortably legible.	ES: See justification for amendment proposed to article 31.3
(d) the letter spacing shall be appropriate for the selected font to be comfortably legible.	NL: (d) (e) the letter spacing shall be appropriate for the selected font to be comfortably legible.	IE: We are of the opinion that ‘comfortably legible’ is subjective. If this remains, then guidance will be required.

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	DE: 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.’ BG: 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.	DE: Missing space MT: MT would like to point out that the phrase ‘person with average eyesight’ is very subjective and may result in an unharmonized approach in its application. BG: average eyesight is unclear – the labelling shall remain legible for all persons.
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	BE: 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	BE: Typo GR:

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statement and where the outer packaging meets the requirements of Article 17.’	with average eyesight, where <u>it is</u> deemed important to place the most critical hazard statement and where the outer packaging meets the requirements of Article 17.’ NL: 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 <u>it is</u> deemed important to place the most critical hazard statement and where the outer packaging meets the requirements of Article 17.’ 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.’	<u>Comment:</u> The phrase as long as it remains legible for a person with average eyesight" is too indefinite. As there is no a minimum limit for the font size it cannot be enforceable. In addition to that, the 8pt is already too small. HU: We consider that the provision of ‘average eyesight’ can be problematic in terms of enforceability. Also certain vulnerable groups (e.g. elderly) normally do not have average eyesight. IE: We are of the opinion that ‘remains legible for a person with average eyesight’ is subjective. We suggest consideration instead be given to a minimum font size for such small packages PT:

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		Minimum font size of 8 pt for packaging not exceeding 3 litre may not be readable depending on the font type. SI: See the general comments above. We propose to delate following text: <i>smaller than indicated in Table 1.3, as long as it remains</i> SK: It could be appropriate to define the term “average eyesight”. CZ: The Czech Republic indicates a certain reserve towards some changes in the labelling of chemical substances and mixtures. The proposed text introduces a relatively complicated expression of a person with average eyesight, further introduces requirements for minimum font size in units outside the metric system. In general, the Czech Republic welcomes the changes to Annex I, however, these changes should lead to the elimination of existing

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		interpretive ambiguities, and not to the creation of new interpretative ambiguities. DK: This provision contains ambiguity. When is the distance "appropriate", and how is it assessed whether something is "comfortably legible"? A definition or at least some guidance should be introduced if this rule is to be enforced.
	DE: (4) — the following Section 1.3.7. is added:	DE: As Article 29(4b) and (4c) are rejected, there is no need for the corresponding addition of Annex I Section 1.3.7.
(4) the following Section 1.3.7. is added:	GR: We agree	DK: “Average EyeSight” - How is this defined? Is it up to the suppliers to do this? At the meeting on 22nd of February the COM defined this as people who can see without spectacles (dioprine 0?). Denmark suggest

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		that the term is defined more closely and this could be included in the new CLP-guidance.
	DE: ‘1.3.7. Ammunition	MT: MT would like to place a scrutiny reservation on section 1.3.7.
‘1.3.7. Ammunition		
	DE: In the case of ammunition that qualifies as a substance or mixture and that is shot through a firearm, the labelling elements may be provided on the intermediate packaging instead of on the inner packaging, or, if there is no intermediate packaging, on the outer packaging.’;	
In the case of ammunition that qualifies as a substance or mixture and that is shot through a firearm, the labelling elements may be provided on the intermediate packaging instead of on the inner packaging, or, if there is no intermediate packaging, on the outer packaging.’;	FR: In the case of equipement and ammunition listed in article 23 (g) 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 suggest 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 FR:

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		The "shot through a firearm" proposal is not appropriate for the military use, as it does not cover much of the ammunition and equipment used in the combat zone. In fact, shot through a gun is not the only explosive that is unsafe to label. <u>Bombs, grenades and airborne munitions are examples of directly released pyrotechnic devices.</u> Adding a tag to basket-guided munitions can create a <u>risk of interference between the munition and the munition's guidance system.</u> In addition, the surface treatment of some military equipment is incompatible with the placement of labels or graphics. At last, the rockets are used in baskets that are not firearms, and their propulsion is obtained by an integrated propellant engine:

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(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.’;	GR: We agree	
(7) Section 1.5.1.2. is replaced by the following:		

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	DE: ‘1.5.1.2. Where section 1.5.1.1. applies, the label on any inner packaging shall contain at least <u>the</u> hazard pictograms, the signal word, <u>the product identifier</u> referred to in Article 18(2) or the trade name or the designation of the mixture referred to in Article 18(3), point (a), <u>respectively</u> and the name and telephone number of the suppliers of the substance or mixture.’; ES: 1.5.1.2. Where section 1.5.1.1. applies, the label on any inner packaging shall contain at least hazard pictograms, the signal word, the trade name or the designation of the mixture the product identifier referred to in Article 18(3), point (a), and the name and telephone number of the suppliers of the substance or mixture.	DE: Referring to Article 18(3) a) leaves the provision without a requirement to state the name of a substance as Art. 18(3) a) only refers to mixtures. Referring to Art. 18(2) for the product identifier for substances would be appropriate. Also, the derogation for very small packaging under 1.5.2.4.2. still requires the full product identifier, therefore refereeing to the product identifier in general (as in the original text) would also be an option. ES: As it stands in the proposal, in case of a substance there is no obligation to include the product identifier. We think this is an important element of the label which must be mandatory. Thus including a reference to the product identifier (as it is already in CLP) will cover both substances and mixtures.
‘1.5.1.2. Where section 1.5.1.1. applies, the label on any inner packaging shall contain at least hazard pictograms, the signal word, the	GR: We propose the addition of the text in bold:	GR:

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trade name or the designation of the mixture referred to in Article 18(3), point (a), and the name and telephone number of the suppliers of the substance or mixture.’;	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), <i>the UFI if it exists</i> and the name and telephone number of the suppliers of the substance or mixture”. NL: ‘1.5.1.2. Where section 1.5.1.1. applies, the label on any inner packaging shall contain at least hazard pictograms, the signal word, the trade name or the designation of the mixture referred to in Article 18(3), point (a), <u>and</u> the name and telephone number of the suppliers of the substance or mixture <u>and a link to the digital label</u>.’; <u>‘Where it concerns a mixture, the label on any inner packaging shall also contain the Unique Formula Identifier.’</u> SI:	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. IE: The label should also contain the UFI to ensure that poisons centres can retrieve information on the mixture in an emergency. NL: NL: we would like to suggest to require a link to the digital label on the inner packaging. Secondly, we would like to suggest to include the UFI as a label requirement to the inner packaging of mixtures. SI: We propose to delete the “signal word” on inner packaging since this could pose a problem in practice. Namely the “signal

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	1.5.1.2. Where section 1.5.1.1. applies, the label on any inner packaging shall contain at least hazard pictograms, the signal word, the trade name or the designation of the mixture referred to in Article 18(3), point (a), and the name and telephone number of the suppliers of the substance or mixture. In the case of small inner packaging equal or less than 125 ml signal word shall be omitted. ' FR: 1.5.1.2. Where section 1.5.1.1. applies, the label on any inner packaging shall contain at least hazard pictograms, the signal word, the trade name or the designation of the mixture referred to in Article 18(3), point (a), and the name and telephone number of the suppliers of the substance or mixture. <u>The reduced labelling allowed for small packaging under Article 29(2) and Annex I, section 1.5.2, can only be applied if it is not possible to provide the full label</u>	word” shall be indicated in all languages (where the chemical shall be placed on the market), but there is no room for it on a small inner packaging. Therefore we propose to add following text: <i>In the case of small inner packaging equal or less than 125 ml signal word shall be omitted.</i> FR: Consider here the Q&A from ECHA n°1856 (dated 27/10/2021), applied by enforcement bodies.

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	<u>information in one of the ways specified under Art 29(1) and Annex I, section 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.</u>	
(8) the heading of Section 1.5.2 is replaced by the following:		
		AT: Regarding Art. 29 para 2 CLP-Reg. we would like to note, that the Austrian Authority takes para 1 and 2 to mean that para 2 is practically not relevant. It is usually always possible to label products by means of a tie-on tag, outer packaging or (currently) fold-out label.
'1.5.2. Exemptions from Article 17 in accordance with Article 29(2)';	GR: We agree	

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(9) Section 1.5.2.4.1 is replaced by the following:	DK:	
‘1.5.2.4.1 The label elements required by Article 17 may be omitted from the inner packaging where the contents of the inner packaging do not exceed 10 ml and either of the following applies:	GR: We agree IE: either any of the following applies	DK: The addition of text that makes it clear that certain classifications are not allowed so as not to exempt from labelling. However, it is noted that it is possible to exempt labelling if the substances/mixtures are to be classified as hazardous to the environment. We suggest that both human health and the environment must be taken into account i.e. this should also include eye damage and skin sensitization.
(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;		PT: Point (a) appears to be more complex and difficult to read than the previous wording. We propose to keep the previous wording with bullets.

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	DE: the substance or mixture does not require labelling in accordance with Part 1 <u>or 2 or 4</u> of Annex II and is not classified in any of the following hazard classes and categories:	DE: Part 4 of Annex II contains special labelling provision for Biocidal and Plant Protection Products. Annex I Section 1.5.2.5. already states that the 10 ml derogation does not apply to substances or mixtures under 1107/2009 or 528/2012
(b) the substance or mixture does not require labelling in accordance with Part 1, 2 or 4 of Annex II and is not classified in any of the following hazard classes and categories:	BE: (b) the substance or mixture does not require labelling in accordance with Part 1, 2 or 4 of Annex II, the inner packaging is contained within outer packaging that meets the requirements set out in Article 17 and the substance or mixture is not classified in any of the following hazard classes and categories: NL: [insert] (xii) <u>Serious eye damage, category 1;</u> (xiii) <u>Skin sensitisation, category 1, 1A and 1B;</u>	BE: In the Commission proposal, (b) would apply even if there is no outer packaging that meets the requirements of Article 17. As foreseen by 1.5.2.4.2., the only information available would be the identifier and, where appropriate, hazard pictograms, for substances or mixtures classified in other classes/categories than those mentioned under (b), when they are in packaging of less than 10 ml. NL: NL: we would like to suggest to include all hazard classes that result in irreversible damage for human health. That would be the

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		following hazard classes in addition to the ones stated under b: - Serious eye damage category 1 - Skin sensitisation – category 1, 1A and 1B Effects of substances falling under these categories can occur even in small amounts. This is also in analogy with current 1.5.2.1.1 and 1.5.2.1.2 in Annex I, where serious eye damage cat 1 and skin sensitisation cat 1, 1A and 1B are excluded as well. PT: As other Member-States, we consider that this list must be revised in order to include other hazards that can have serious consequences for human health if not used properly, such as skin sensitisation, serious damage to eyes/eye irritation and flammable liquids. FR:

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		Please consider to add skin sensitisation, category 1 (sub-categories 1A and 1B), PBT/vPvB and PMT/vPvM hazard classes.
(i) Acute toxicity, categories 1 to 4;		
(ii) Specific target organ toxicity – Single exposure, categories 1 and 2;		DK: Should be "any category" as used in points vii, viii, ix and xi, as we believe this encompasses all categories.
(iii) Specific target organ toxicity – repeated exposure, categories 1 and 2;		
(iv) Skin corrosion/irritation, category 1 (sub-categories 1A, 1B and 1C);	BE: (iv) Skin corrosion/irritation, category 1 and (sub-categories 1A, 1B and 1C);	BE: Improvement of the wording, as it refers to different classifications. HU: Please explain why eye damage is not listed. DK:

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		Should be "any category" as used in points vii, viii, ix and xi, as we believe this encompasses all categories.
	BE: (...) Serious eye damage/eye irritation, categories 1 and 2 DE: Add new item: Skin sensitisation category 1 (sub-categories 1A and 1B)	BE: The hazard class serious eye damage/eye irritation should be added. Information on these hazards on the inner packaging is essential to protect the health of users. DE: Adding Skin sensitisation would add consistency, as under c) a mixture that contains low amounts of a skin sensitizer and requires additional labelling could benefit from the derogation but would require a fully labelled outer packing, while a mixture with a high amount of skin sensitizers could be placed on the market without any labelling (except pictograms).
(v) Respiratory sensitisation, category 1 (sub-categories 1A and 1B);	BE: (...) Respiratory sensitisation, category 1 and (sub-categories 1A and 1B); DK:	BE: Improvement of the wording, as it refers to different classifications. HU:

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	Skin corrosion/irritation, category 1 (sub-categories 1A, 1B and 1C);	Please explain why skin sensitisation is not listed. DK: .
	BE: (...) Skin sensitisation, category 1 and sub-categories 1A and 1B;	BE: The hazard class skin sensitisation should be added. Information on this hazard on the inner packaging is essential to protect the health of users.
(vi) Aspiration hazard;		DK: Should be "any category" as used in points vii, viii, ix and xi, as we believe this encompasses all categories.
(vii) Germ cell mutagenicity, any category;		
	DE: Carcinogenicity, any category	DE: Typo (term Carcinogenicity is principally used in REACH as well as in CLP)
(viii) Carcinogenity, any category;		

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(ix) Reproductive toxicity, any category;		
		DE: Why is (only) the hazard class flammable solids mentioned among the physical hazards? It is not clear why the derogation should not be applicable to flammable solids, but does apply to other more severe physical hazard classes.
(x) Flammable solids, categories 1 and 2.;		HU: Please explain why only this physical hazard is mentioned here. Moreover, we suggest to add flammable liquids too, as the package may contain a liquid.
(xi) Endocrine disruptors for human health, any category;		SK: We noted that hazard serious eye irritation/serious eye damage is not included in the list of hazards. DK:

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		Should be "any category" as used in points vii, viii, ix and xi, as we believe this encompasses all categories.
	DE: (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.';	DE: Part 4 of Annex II contains special labelling provision for Biocidal and Plant Protection Products. Annex I Section 1.5.2.5. already states that the 10 ml derogation does not apply to substances or mixtures that fall under Regulations 1107/2009 or 528/2012.
(c) the substance or mixture requires labelling in accordance with Part 1, 2 or 4 of Annex II but is not classified in any of the hazard classes and categories referred to in point (b) and has an inner packaging that is contained within outer packaging that meets the requirements set out in Article 17.';		
		AT: Regarding tactile hazard warning a distinct wording of the CLP Regulation should be

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		considered for packaging – in particular for inner packaging.
Changes to Annex II in A1		
(2) Part 5 is replaced by the following:	GR: We agree	
'PART 5: HAZARDOUS SUBSTANCES AND MIXTURES TO WHICH ARTICLE 29(3) APPLIES	GR: We agree	
Ready mixed cement and concrete in the wet state shall be accompanied by a copy of the label elements in accordance with Article 17.	GR: We agree SI: 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 suggest it is clarified as to how the label elements should be provided. This could be addressed in guidance if not in the legal text. SI: We propose that the provision concerning informing of the customers (users) in this case should be more precise. In practice based on our experiences, the suppliers of motioned chemicals could have problems with the understanding of such provisions. Various

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		variants of informing the users could appear on the market. We propose that in this case a copy of the label should be issued and provided. Therefore we propose to delete: <i>elements</i>.
	ES: 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 17.1 (c), (d), (e), (f), (g), (h) shall be provided on the respective pump on a visible and legible place.	ES: We see no need to include in the label of pump the name, address and telephone number of the supplier(s) (article 17(1)a) and the nominal quantity of the substance or mixture in the package made available to the general public, unless this quantity is specified elsewhere on the package (article 17(1)b). On the other side, elements on the label shall be visible to the users. Proposal as it stands enables placing the label elements, anywhere even if they are not visible. MT: MT would like to place a scrutiny reservation. However, MT would also like to make the following remarks;

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		• Is this easily implementable? • Does this only involve affixing a label on the pump? Does the label have to be changed each time a different batch of fuel is used?
For a substance or a mixture supplied at a filling station and directly pumped into a receptacle that forms an integral part of a vehicle and from where the substance or mixture is normally not intended to be removed, the label elements referred to in Article 17 shall be provided on the respective pump.';	GR: We agree	
Recitals relating to A1		
	DE: 7) ——— Ammunition qualifying as a substance or a mixture is to bear a label affixed to the surface of the packaging immediately containing the substance or the mixture (inner packaging), which is typically the ammunitions' cartridge. Affixing a label to the cartridge might however cause safety problems for the user, as the label could	DE: Recital 7 has to be removed in accordance with the proposed change of the corresponding Article 23. MT: MT would like to place a scrutiny reservation on recital 7.

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	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.	
(7) Ammunition qualifying as a substance or a mixture is to bear a label affixed to the surface of the packaging immediately containing the substance or the mixture (inner packaging), which is typically the ammunitions' cartridge. Affixing a label to the cartridge might however cause safety problems for the user, as the label could interfere with the correct functioning of the ammunition and could damage the firearm. Such ammunition should therefore be	GR: We agree FR: (7) Ammunition qualifying as a substance or a mixture is to bear a label affixed to the surface of the packaging immediately containing the substance or the mixture (inner packaging), which is typically the	FR: It is more appropriate to speak about the ammunition body, the ammunition cartridge being classified as an article. The reference to "ammunition used exclusively in combat zones" seems excessive; indeed, some ammunition is also used by forces during training; the term "exclusively" should indeed be deleted.

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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.	ammunitions' body cartridge. Affixing a label to the body cartridge might however cause safety problems for the user, as the label could interfere with the correct functioning of the ammunition and could damage the ammunition launcher. 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	French armies use about 3000 different configurations of explosives. Among these explosives, some are too small to accommodate the danger elements required by the CLP, while others have a complex shape in both 2D and 3D. Explosives, including ammunition in the strict sense of the term, used by the French armed forces are purchased, stored and maintained in operational condition by the joint ammunition support service. The storage time of an explosive is greater than the time of use, the Government's policy being to have a stockpile that ensures national defense in the event of a major event. Also, the classification is not done at the level of the explosive, but at the level of the package (explosive(s) in the packaging). An explosive can only be transported or stored in packaging approved for the transport of dangerous goods. Illustration of stored explosives:

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(8) In order to enhance clarity, all supplemental labelling requirements should be placed together in one Article.	GR: We agree	
	DE: (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	DE: Recital 9 has to be adapted in accordance with the proposed change of the corresponding Article 25.

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	they are classified and whether they contain any classified substance. <u>containing hazardous substances, or that lead to the formation or release of a hazardous substance during their use.</u>	
(9) Part 2 of Annex II to Regulation (EC) No 1272/2008 sets out rules for additional hazard statements to be included on the label of certain mixtures listed in Part 2 of that Annex. Given that those statements provide important additional information in specific cases, they should be applied to all mixtures referred to in Part 2 of Annex II, regardless of whether they are classified and whether they contain any classified substance.	GR: We agree	
	ES: (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)	ES: See justification for amendment proposed to article 30.1.

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	2020/1435¹. Where the new hazard class is additional to an existing hazard class or represents a more severe hazard class or category, or where new supplemental labelling elements are required under Article 25, the deadline to update the labelling information in the case of adaptation of the classification in accordance with the result of a new evaluation should be set at 6 18 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	

¹ Commission Implementing Regulation (EU) 2020/1435 of 9 October 2020 on the duties placed on registrants to update their registrations under Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 331, 12.10.2020, p.24.)

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	update the labelling information should be set at the date of application of the provisions setting out the new or amended classification and labelling of the substance concerned, which is usually 18 months from the date of entry into force of those provisions. The same applies in case of changes triggered by other delegated acts adopted in light of the adaptation to technical and scientific progress, for instance as a result of the implementation of new or amended provisions of the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).	
(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) 2020/1435². Where the new hazard class is	GR: We agree SI: (10) To increase enforceability of the obligation placed on suppliers to update their labels after a change in the	SI: More time (at least 12 months) for updating is needed. See also comments by Article 30. 1.

² 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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additional to an existing hazard class or represents a more severe hazard class or category, or where new supplemental labelling elements are required under Article 25, the deadline to update the labelling information in the case of adaptation of the classification in accordance with the result of a new evaluation should be set at 6 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. In case where a classification is updated to a less severe hazard class or category without triggering classification in an additional hazard class or new supplemental labelling requirements, the deadline for updating the labels should remain at 18 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. It should also be clarified that, in cases of harmonised classification and labelling, the deadlines to update the labelling information should be	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) 2020/1435³. Where the new hazard class is additional to an existing hazard class or represents a more severe hazard class or category, or where new supplemental labelling elements are required under Article 25, the deadline to update the labelling information in the case of adaptation of the classification in accordance with the result of a new evaluation should be set at 12 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	

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.)

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set at the date of application of the provisions setting out the new or amended classification and labelling of the substance concerned, which is usually 18 months from the date of entry into force of those provisions. The same applies in case of changes triggered by other delegated acts adopted in light of the adaptation to technical and scientific progress, for instance as a result of the implementation of new or amended provisions of the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).	day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. It should also be clarified that, in cases of harmonised classification and labelling, the deadlines to update the labelling information should be set at the date of application of the provisions setting out the new or amended classification and labelling of the substance concerned, which is usually 18 months from the date of entry into force of those provisions. The same applies in case of changes triggered by other delegated acts adopted in light of the adaptation to technical and scientific progress, for instance as a result of the implementation of new or amended provisions of the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).	
	ES: (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	ES: See justification for amendment proposed to article 31.3

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	not provide for a minimum font size of labels that would ensure readability. As a result of advancements in labelling technologies, more flexibility should be given to suppliers by providing for a broader use of fold-out labels, while readability of labels should be ensured by laying down minimum font size and formatting requirements.	
(11) Regulation (EC) No 1272/2008 only allows for the use of fold-out labels if the general rules for the application of labels cannot be met due to the shape or form of the packaging or its small size, whilst it does not provide for a minimum font size of labels that would ensure readability. As a result of advancements in labelling technologies, more flexibility should be given to suppliers by providing for a broader use of fold-out labels, while readability of labels should be ensured by laying down minimum font size and formatting requirements.	GR: We agree SI: (11) Regulation (EC) No 1272/2008 only allows for the use of fold-out labels if the general rules for the application of labels cannot be met due to the shape or form of the packaging or its small size, whilst it does not provide for a minimum font size of labels that would ensure readability. As a result of advancements in labelling technologies, more flexibility should be given to suppliers by providing for a broader use of fold-out labels, while readability of	SI: See the general comments above (Section 1.2.1.4. is replaced by the following:) We propose to delate following text: <i>while readability of labels should be ensured by laying down minimum font size and formatting requirements</i>

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	labels should be ensured by laying down minimum font size and formatting requirements.	
(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.	GR: We agree	
Subgroup A2. Digital labelling		
Articles in A2		
(15) in Title III, the following Chapter 3 is added:		
'CHAPTER 3		

CLP proposal – table for MS comments following Presidency clustering

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Formats of the labelling	IE: Suggest to change title to Labelling Format	
<i>Article 34a</i>		
		AT: We support the proposal of keeping the physical labelling of hazardous substances and mixtures. We support the proposal to empower the European Commission to adapt the regulation to European developments by means of a delegated act, but this should also include international standards. 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.
Physical and digital labelling		
1. The label elements referred to in Article 17 shall be provided:	GR: We agree	IE:

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	IE: Suggest to indicate substances and mixtures in <u>34a first</u> and not then indicate it in 34b	IE would also suggest only option b should apply in paragraph 1. The digital label will help to ensure that users with impaired vision are not discriminated against.
(a) on a label in a physical form ('physical label'); or		
		MT: MT seeks clarification on where to put the supplemental information if digital labelling is not used.
(b) both on a physical label and on a label in a digital form ('digital label').		PT: As other Member-States we have doubts concerning this wording in conjunction with Point 2. Therefore, the wording should be revised to make it clear that the physical label is mandatory, and the digital label is voluntary.
	DE: 2. By way of derogation from paragraph 1, the suppliers may provide the label elements	DE: The exception would allow that in the future, i.e. in the event of a corresponding

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	set out in section 1.6. of Annex I on a digital label only.	amendment to Annex I 1.6 by means of a delegated act, labelling could also be carried out exclusively in digital form for mandatory elements. Therefore, this derogation should be deleted: A purely digital labelling is only acceptable if it is voluntarily providing additional information.
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.	GR: We agree	PT: This article should be revised in line with Commission's explanation to the proposal, <i>i.e.</i> only label elements that are not instrumental in protection of health and safety, of the environment, and that are not obligatory under GHS may be replaced by a digital label. DK:
Article 34b	DK: 2. By way of derogation from paragraph 1, the suppliers may provide non-mandatory	DK: Denmark finds that it is important to underline that the mandatory label elements from other EU regulations should always be

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	the label elements set out in section 1.6. of Annex I on a digital label only.	presented on the physical label unless other rules exist in the other EU regulation. Label elements from other EU-legislations cannot only be present in a digital format. Paragraph 2: It is assumed that section 1.6 has been made in order to be able to update the Annex if it becomes possible to move elements other than those provided for in Article 25(3) (section 1.6 of Annex I refers only to Article 25(3)).
Requirements for digital labelling		
1. The digital label for substances and mixtures shall satisfy the following general rules and technical requirements:	IE: See comment above on 34(a) NL: <u>[insert] (j) the link to the digital label is clearly marked as a link containing chemical hazard information.</u>	NL: NL: we would like to suggest to add a provision to mark the link to the digital label as chemical hazard information, so it is clear to the user what the link refers to. PT: Although we are still assessing this, we consider that the items of n. ° 1 should be revised and eventually reorganized.

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		The different use of the expressions «<i>digital label</i>» and «<i>the information on the digital label</i>» may create some interpretative doubts. For instance, only the digital label shall be accessible free of charge or should the information on it as well be accessible free of charge? Eventually a clear distinction between what is applicable only to the digital label and what is applicable to the information on it should be considered through the reorganization of the items.
(a) all label elements referred to in Article 17(1) shall be provided in one place and separated from other information;	IE: Shall be provided in one place one location	
		ES: Clarification for the concept “searchable” needed: Does it refer to the internet or to inside the label's website or inside the physical packaging?

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(b) the information on the digital label shall be searchable;		DK: Denmark asks that the updated CLP-guidance contain rules for digital labelling if there are deviations between the digital and physical labelling.
		ES: Clarification for the concept “all users” needed. Possible existence of firewalls, https accreditations, etc. may be something the provider of the digital label has no possibility to prevent.
(c) the information on the digital label shall be accessible to all users in the Union,		
(d) the digital label shall be accessible free of charge, without the need to register, download or install applications, or to provide a password;		DK: How can this be ensured as there are citizens who do not have access to the internet or digital tools? Should there be shops to make the information available?

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	ES: None	ES: A clarification or a definition of “vulnerable group” should be given
(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;		IE: We consider that vulnerable groups may need to be defined. At a minimum, this needs to be addressed in guidance. As a general comment, further consideration needs to be given to vulnerable people and the UFI code. For example, a blind person is unable to read the UFI as it is currently displayed on labels. This may lead to difficulties if a blind person needs to contact a Poisons Centre in the event of an accidental poisoning. FR: A definition of “vulnerable groups” should be included. The definition proposed in Regulation 528/2012 on biocidal products, in its Article 3, could be used. DK:

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		It should be noted that with this requirement, it will not be possible for some users to use, for example, a QR-code or the like, as this requires an application for reading that must be installed. The same applies to scanning tools for link addresses etc. This has specific relevance when considered in conjunction with <i>litra i</i> just below within this, which indirectly presumes the use of this type of applications.
		ES: More clarification needed. This requirement should not be a problem as long as current and future policies on data protection, cookies, etc. are taken into account and not considered in those “two clicks” maximum.
(f) the information on the digital label shall be accessible with no more than two clicks;		LV: The requirement to maintain a digital label for 10 years after a liquidation of a company rises some concerns. Such a requirement cannot be fulfilled in terms of both legal and practical aspects, because after a liquidation

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		company's obligations normally are not being taken over and at this stage it is rather unclear how this obligation might be controlled and against which person the proceedings should be initiated in case of a failure to comply with this requirement. Furthermore, we consider that the development and maintenance of separate databases for digital labels will entail disproportionate costs for economic operators, in particular SMEs, which could be prevented, for example, by the development of a single harmonized database maintained by ECHA. DK: It must be specified what vulnerable groups must be taken into account and how these considerations must be made specifically. Is it a special requirement for the text size, reading aloud, several languages, or what is the intention? It will not be possible to enforce this provision in its current form, without specification of which considerations must be implemented in the digital label.

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(g) the digital label shall be accessible through digital technologies widely used and compatible with all major operating systems and browsers;		DK: It must be made clear from where the two clicks are required. If it is from scanning the physical product, does it also include the clicks it takes to open the reader or, for example, scanning the QR-code. If it is in relation to online trading, then it must be specified whether the advertising situation (art. 48) or the online purchase situation pursuant to art. 48a is regarded, and how. Finally, it should be considered, whether taps on a keyboard or a "press on a phone" is considered clicks.
		ES: More clarification needed. Maybe it would be more practical to set the requirement conditioned to the language of the software the customer is using if available and by default the language of the country where the product is marketed.

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		Example: I am in Germany, but I am just travelling, and I don't speak German. With the digital access I can understand everything if my phone is in Spanish and there is a Spanish version of the digital label. Like when you enter ECHA and it comes out in your language by default. DK:
(h) when the digital label is available in more than one language, the choice of language shall not be conditioned on the geographical location;		
	DE: (i) the link to the digital label shall be printed or placed physically, visibly and legibly on the <u>packaging or the physical label</u> and in such a way that it can be processed automatically by digital devices widely used by consumers;	DE: The term “product” is not used in the CLP-Regulation. ES: Suggestion to be more generic for this requirement. Technologies are advancing very fast. For example, NFC solution automatically would open the digital label in a mobile phone without any click, just

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		having the mobile phone close to the product.
(i) the link to the digital label shall be printed or placed physically, visibly and legibly on the product in such a way that it can be processed automatically by digital devices widely used by consumers;		IE: We seek clarification as to whether the link to the digital label also refers to for example a QR code that would allow the information to be scanned from the label. We suggest that the link is clearly marked as ‘chemical hazard information’, or similar wording, so as to ensure that the user knows what the link refers to DK: Does the proposed text give the option that the digital label does not necessarily have to be available in the national language corresponding to the geographical location, or does it mean that several languages must be accessible regardless of the geographical location? If so, in which languages should it be available? And should one actively choose language before being provided with the digital label?

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		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.
(j) the digital label shall remain available for a period of 10 years, including after an insolvency, a liquidation or a cessation of activity in the Union of the supplier that created it, or for such longer period required under other Union legislation covering the information that it contains.	SI: the digital label shall remain available for a period of 10 5 years, including after an insolvency, a liquidation or a cessation of activity in the Union of the supplier that created it, or for such longer period required under other Union legislation covering the information that it contains.	IE: To avoid difficulties with having to maintain the actual digital label for 10 years which may be problematic and costly for industry, consideration could be given to changing this to a requirement to maintain the information required to complete the digital label, rather than maintaining the digital label itself PT:

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		How can this disposition be applicable in cases of insolvency? SI: We believe that 10 years is a long period. , Therefore we propose to delete 10 and put 5 years in the text, as shorter period would be more appropriate for CLP practice. DK: A question arises as to how "processed automatically" is defined, cf. comments to <i>litra d</i>. In relation to ensuring accessibility, we propose that rules or at least guidance material be made for requirements to the URL, such as length, number of special characters, etc.
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	IE: Suppliers shall provide, on oral or written demand upon request DK:	GR: <u>Comment:</u> “alternative means” shall be defined DK:

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only in accordance with Article 34a(2) by alternative means. Suppliers shall provide those elements independently of a purchase and free of charge.	Suggestion: the digital label shall remain available for a period of 10 years, including after an insolvency, a liquidation or a cessation of activity in the Union of the supplier that created it, or for such longer period required under other Union legislation covering the information that it contains.	Denmark suggests a new wording of this article that does not mention insolvency, liquidation or cessation of business, as we believe this is already described in article 49(2). The proposed text implies the requirement that there is a need for recording when products are discontinued, in the event that a company later ceases to exist. In which format will data be required to be stored? Also, with the current wording of article 49, subsection 2 there is still a lack of provision in cases where a business simply stops operating in the EU and no new owner takes over the responsibilities.
		ES: Maybe this provision is not needed. The current law on data protection would cover this.
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’;	GR: We agree	DK: How is it supposed to happen, a store is a supplier, so they should be able to print the

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		information to customers? Or 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.
(26a) Article 53 is amended as follows:		SK: We understand the Commission inclines to be flexible in the new trends of digital labelling. However, as part of this revision the powers of the Commission are expanded. We are of the opinion that this issue should

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		be solved through an ordinary legislative procedure. DK: Enforcement of this provision is in general far from the regular areas of enforcement for the Market Surveillance Authorities (MSA), and will require vast additions of new competences and resources for the MSAs.
	DE: (a) the following paragraphs 1a to 1b are inserted:	DE: Consequential change due to the deletion of paragraph 1a
(a) the following paragraphs 1a to 1b are inserted:	BE: (a) the following paragraphs 1a to 1b are inserted:	
	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 to in Article 34a(2) to technical progress or to the level of digital readiness among all population groups in the Union. When	AT: We support the proposal to empower the European Commission to adapt the regulation to European developments by means of a delegated act, but this should also include international standards. In this discussion it will be crucial which labelling elements must be attached to the

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	adopting those delegated acts, the Commission shall take into account the societal needs and a high level of protection of human health and the environment;	packaging in order to protect the health of consumer, workers and the environment. DE: As Article 34a(2) is rejected, there is no need for the corresponding empowerment to change Annex I Section 1.6.
‘1a. The Commission is empowered to adopt delegated acts in accordance with Article 53a to amend section 1.6. of Annex I in order to adapt the label elements referred to in Article 34a(2) to technical progress or to the level of digital readiness among all population groups in the Union. When adopting those delegated acts, the Commission shall take into account the societal needs and a high level of protection of human health and the environment;	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 human health and the environment; GR: We agree	BE: Belgium does not support the empowerment of the Commission to adopt delegated acts to amend section 1.6. of Annex I specifying the label elements which may be provided on digital label only. We consider that such amendments may not be considered as adaptations to technical or scientific progress but concern essential elements of the Regulation. Hazard communication is one of the main objectives of the CLP Regulation, for the purpose of protecting health and the environment. Recital 49 of CLP states that, “in general, substances and mixtures, especially those supplied to the general public, should be supplied in packaging together with the

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		necessary labelling information”. Physical labelling ensures direct availability of essential information, even if this information could be further clarified. The current proposal aims notably at improving hazard communication. The impact assessment report notes that the use of digital labels could have a negative impact on the well-being of groups of population without access to these digital tools and that, according to consulted stakeholders, this is an important drawback to be taken into account. In the current proposal, section 1.6. of Annex I covers non-mandatory supplemental information which would not compromise hazard communication. The enlargement of this section to any mandatory labelling element foreseen by the CLP Regulation would require an in-depth analysis of the social, health and environmental impacts. Political choices will be required when envisaging the possibility to replace critical physical information by digital information only. PT:

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		We can accept the adoption of a delegation act to amend this section if article 34b is changed in line with Commission's explanation to the proposal, <i>i.e.</i> only label elements that are not instrumental in protection of health and safety, of the environment, and that are not obligatory under GHS may be replaced by a digital label.
	DE: 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 Article 34b. Those requirements shall cover, in particular, the IT solutions which may be used, and the alternative means for providing the information. When adopting those delegated acts, the Commission shall:	DE: Consequential change due to the deletion of paragraph 1a MT: MT has concerns with the introduction of the new hazard classes into the CLP regulation by a delegated act. In MT's view, the introduction of the new hazard classes is considered as an essential element to the CLP regulation.

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1b. In order to adjust to technological changes and (future) developments in the field of digitalisation, the Commission is empowered to adopt delegated acts in accordance with Article 53a to supplement this Regulation by laying down further details on the requirements for the digital labelling referred to in Article 34b. Those requirements shall cover, in particular, the IT solutions which may be used, and the alternative means for providing the information. When adopting those delegated acts, the Commission shall:	BE: 1b. In order to adjust to technological changes and (future) developments in the field of digitalisation, the Commission is empowered to adopt delegated acts in accordance with Article 53a to supplement this Regulation by laying down further details on the requirements for the digital labelling referred to in Article 34b. Those requirements shall cover, in particular, the IT solutions which may be used, and the alternative means for providing the information. When adopting those delegated acts, the Commission shall: GR: We agree	
(a) ensure coherence with other relevant Union acts;		
(b) encourage innovation;		

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(c) ensure technological neutrality by applying no constraints or prescriptions on choices of technology or equipment, within the bounds of compatibility and interference avoidance;		
		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.
(d) take into account the level of digital readiness among all population groups in the Union;		
(e) ensure that digitalisation does not compromise the protection of human health and the environment.		
Changes to Annex I in A2		

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	DE: (10) ——— the following Section 1.6. is added:	DE: As Article 34a(2) is rejected, there is no need for a new Section 1.6. in Annex I
(10) the following Section 1.6. is added:	GR: We agree	
	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
‘1.6. Label elements that may be provided on a digital label only		
	DE: (a) ——— Supplemental information referred to in Article 25(3)’;	DE: As Article 34a(2) is rejected, there is no need for a new Section 1.6. in Annex I ES: Suggestion to increase the scope of information allowed only on the digital label allowing more information to be provided in digital-only format, beyond its use for non-mandatory supplementary labelling elements. Suggestion to combine this

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		measure with possible additional labelling simplification measures. Digitisation of product information, currently contained on physical labels, is essential to ensure that labels remain legible, especially as label information requirements have increased significantly in recent years and continue to do so as more product information is generated and labelling requirements derived from other sector specific legislation beyond CLP also need to be considered. The industry is strongly committed to ensuring the safe use of products placed on the market by providing all the information necessary to do so, and for this information to be truly useful and to remain legible, the space usually available on packaging is often already insufficient. The digitisation options offered by the CLP revision are not sufficient to solve the problem of the possible and usual insufficient space on the physical label.
(a) Supplemental information referred to in Article 25(3)';		

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Recitals relating to A2	DK:	DK: Denmark finds that it is important to underline that the mandatory label elements from other EU regulations should always be presented on the physical label unless the other EU legislation clearly provides other rules about labelling. Mandatory label elements from other EU-legislations cannot only be present in a digital format unless it is clearly stated in the other legislations. Should a sentence be added that if other legislation requires the text to be on the label, is not enough that this a digital label? Similar comments have also been inserted in Articles 25 and 34a
	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	DE: Recital 12 has to be adapted in accordance with the proposed change of the corresponding Article 34(a).

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	efficiency of hazard communication, especially for vulnerable population groups and people who do not speak the national language of a Member State. Therefore, it is necessary to provide for voluntary digital labelling and to lay down technical requirements for such labelling. In order to provide for legal certainty, it is appropriate to specify the label elements that are allowed to be provided in a digital format only. That possibility should only exist for information which is not instrumental for the safety of the user or the protection of the environment.	
(12) Regulation (EC) No 1272/2008 needs to be adjusted to technological and societal changes in the field of digitalisation and be prepared for future developments. Digital labelling could improve the efficiency of hazard communication, especially for vulnerable population groups and people who do not speak the national language of a Member State. Therefore, it is necessary to provide for voluntary digital labelling and to lay down technical requirements for such labelling. In order to	BE: (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 some vulnerable population groups and people who do not speak the national language of a Member State. Therefore, it is necessary to provide for	BE: The positive impact of digital labelling is mainly pointed out for visually impaired consumers in the impact assessment. Digital labelling could have a neutral or negative impact for consumers suffering from other types of impairments or vulnerabilities.

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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.	voluntary digital labelling and to lay down technical requirements for such labelling. In order to provide for legal certainty, it is appropriate to specify the label elements that are allowed to be provided in a digital format only. That possibility should only exist for information which is not instrumental for the safety of the user or the protection of the environment. GR: We agree	
	DE: (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	DE: Recital 13 has to be removed in accordance with the proposed change of the corresponding Article 53.

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	needs and a high level of protection of human health and the environment.	
(13) In order to adapt the label elements allowed to be provided only in a digital format to technical progress or to the level of digital readiness among all population groups in the Union, the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union to amend the list of label elements allowed to be provided only in a digital format, taking into account societal needs and a high level of protection of human 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 human health and the environment. GR: We agree	DK: It should be defined in more detail what is meant by vulnerable groups. Since digital labelling is a tool for communication for people who do not speak the national language, this can only apply if additional languages are added digitally.
(14) In order to adjust to technological changes and developments in the field of digitalisation, the Commission should be empowered to adopt delegated	GR: We agree	SI: We propose that the Commission in this delegated act (on technical requirements for

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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.	SI: (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, online sales and advertisement.	the digital labelling) also specifies the conditions and details as well as examples on online sales and advertisement, as both issues are connected with the changing and developing of digitalisation. Therefore we propose to add following text: <i>online sales and advertisement.</i>
Subgroup A3. Refill sales		
Articles in A3		
(16) in Article 35, the following paragraph 2a is added:		IE: Article 35 is interpreted such that it does not cover non-hazardous mixtures which contain hazardous substances. However, Article 35 CLP is based on Article 9 of the Dangerous Preparations Directive (DPD), which did cover non-hazardous mixtures containing at

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		least one hazardous substance. It would therefore appear that the wording of Article 35 CLP changed the original intention of the DPD, i.e. to require packaging in accordance with Article 9 of the DPD for all preparations containing at least one dangerous substance. We therefore request that consideration be given to amending article 35(2) to ‘<i>packaging containing a hazardous substance or mixture, or a mixture containing at least one hazardous substance, supplied to the general public....</i>’.
	DE: ‘2a. Hazardous substances or mixtures may be supplied to consumers and professional users via refill stations only if, in addition to the requirements <u>for the labelling and packaging of the substance or mixture as it is supplied to the consumer or the professional</u> set out in Titles III and IV, the conditions laid down in section 3.4 of Annex II are fulfilled.’;	AT: Besides the labelling of refill stations and safe usage of the refill station, it must be ensured the the containers provided by the consumers are labelled (Art. 29 CLP Reg.) DE: The present draft text in Article 35(2a) and Annex II Section 3.4 only considers sales via automated filling stations and lays down detailed requirements for them. It is unclear

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		whether the proposed text aims to regulate refill sales as such or only to regulate the refill sale via this kind of filling station. It would be appropriate to cover the whole range of refill sales instead of only automated refill stations. We therefore propose to amend paragraph 2a to encompass all kinds of refill sales, while limiting refill sales to the specific conditions and kinds of refill sales laid down in the corresponding Annex II Section 3.4. The present draft text in Article 35(2a) and Annex II Section 3.4 only considers sales via automated filling stations and lays down detailed requirements for them. It is unclear whether the proposed text aims to regulate refill sales as such or only to regulate the refill sale via this kind of filling station. It would be appropriate to cover the whole range of refill sales instead of only automated refill stations. We therefore propose to amend paragraph 2a to encompass all kinds of refill sales, while limiting refill sales to the specific conditions and kinds of refill sales laid down in the corresponding Annex II Section 3.4.

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		The suggestion for the additional reference to ‘the mixture supplied to the customer or professional user’ means to clarify, that the labelling and packaging requirements of CLP actually refer to the product in the form in which it is sold to the customer. Under to the current wording, there is a slight legal uncertainty whether in refill sale, the bulk package or the individually filled package needs to be labelled. Our understanding is that both need to be labelled.
‘2a. Hazardous substances or mixtures may be supplied to consumers and professional users via refill stations only if, in addition to the requirements set out in Titles III and IV, the conditions laid down in section 3.4 of Annex II are fulfilled.’;		GR: <u>Comment:</u> To be added in article 2 definition of ‘refill station’ for clarity reasons. SK: We are of the opinion that hazardous substances or mixtures sold through refill station have to be labelled in any cases. That means a label is firmly affixed on filled packaging. When several hazardous chemicals are sold via refilled station, it is

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		necessary to label them to avoid confusion when using several products.
Changes to Annex II in A3		DK: We propose to insert a definition of “refill” stations, e.g. when is something a “refill” station and what is covered? Also not to confuse a refill station with substances and mixtures supplied to the general public without packaging (article 29,3)
(1) in Part 3, the following Section 3.4. is added:		
	ES: [definition for “refill station” is needed]	ES: Clarification of what is understood by <i>refill</i> <i>sales</i> is needed. Are those sales containers intended to "refill" or "recharge" the original containers or are those that can be filled at the place of sale? In any case, both types of products must comply, all through the entire supply chain (from the manufacturer to the company placing the product in the market – including

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		refill stations), not only Regulation 1272/2008 CLP but all the legislation to be applied (specific Spanish regulation – RD 770/1999 where transfer and dilution operations are regulated) so that all of them are responsible of the consumers safety. CLP itself already establishes the limitations of certain classification for household products (For example, for products classified as Corrosive for skin, Category 1A, it is compulsory to provide packaging to be fitted with child-resistant fastenings, based on Annex II of CLP Regulation, or the Regulation 1297/2014 which establishes measures related to liquid consumer laundry detergents in soluble packaging. It provides rules to avoid accidental exposure and poisoning of consumers, in particular young children, to hazardous chemicals supplied to the general public. The origin of this modification was to safeguard the consumer, including for packaged products such as detergent capsules). Thus, it is essential a clear definition of the responsibilities of the actors at every stage of the supply chain is needed.

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		We highlight that Compliance of the legislation from all the supply chain is crucial to avoid discrimination among all entities in the supply chain. MT: MT would like to place a scrutiny reservation on section 3.4
‘3.4. Refill stations		GR: <u>Comment:</u> We disagree with the conditions described in Annex II section 3.4 for Refill station . In our opinion_refilling could be allowed only via distribution machines, that : - recognize specific receptacles (i.e. with the suitable packaging material according to article 35) -provide automatically specific label on specific receptacle dedicated for a kind of a product (i.e. detergent) NL: NL: we wonder whether some of these provisions are clear enough on itself or

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		whether they require additional explanation. E.g. under (d), when would a station qualify as not being designed in a way to attract the curiosity of children? Or under (g), does that mean physically available for immediate assistance or would reachable by telephone suffice? Regarding (j) what are these hygiene and cleaning protocols?
	BG: Refill station that provide hazardous substances or mixtures referred to in Article 35(2a), shall meet the following conditions:	DE: As described in our proposals for amending Article 35(2a) we propose to limit refill sales to specific scenarios, which each have to be considered separately with respect to aspects of safety and practicability. Among the already described scenario of highly automated refill stations further scenarios for more simple refill stations and refill sales of fuel at gas stations in jerry cans, amongst other, should be considered. Scenarios to be considered: - Sale via automated filling stations - Sale via simple filling stations - Sale of fuel in jerry cans at gas stations. - ...

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		From our point of view, it would be appropriate that sales via simple filling stations, which are often used in smaller businesses, are also possible. In order to be able to guarantee this sale with a similar level of safety, minimum requirements must also be formulated for this, which should include minimum requirements for the filling stations as well as organisational measures. These may include, for example, dispensing by trained/expert staff. With regard to the dispensing of fuel in canisters at petrol stations, pumps at gas stations would normally not satisfy the requirements laid out by the draft text in regard to automated refill stations. For example they normally do not meet the requirements regarding the prevention for overfilling or that the use of unsuitable packaging is technically prevented. BG:

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		The requirements relate to the refill stations and their labelling
Hazardous substances or mixtures referred to in Article 35(2a), shall meet the following conditions:		
	DE: (a) the labelling and packaging requirements applicable at the date of placing on the market of the hazardous substance or mixture <u>in addition to the substance or mixture itself</u> are fulfilled for every refill station; ES: Propose to be deleted	DE: Clarification that the substance of mixture sold through refill sale need to be packaged and labelled in accordance with the regulation as well. ES: Is this point really needed? According to the proposed Article 35, paragraph 2a, hazardous substances may be supplied via refill stations if the requirements set out in Title III (Hazard communication in the form of labelling) and IV (Packaging) are fulfilled.
(a) the labelling and packaging requirements applicable at the date of placing on the market of the hazardous substance or mixture are fulfilled for every refill station;	GR: We propose the addition of the text in bold: (a) the labelling and packaging requirements applicable at the date of	BE: In the proposal, labelling requirements are only foreseen for the refill station. There is no provision ensuring the labelling of the refilled packaging,

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	placing on the market of the hazardous substance or mixture are fulfilled for every <i>package which is placed on the market at the refill station and</i> every refill station; IE: the labelling and packaging requirements applicable at the date of placing on the market of the hazardous substance or mixture are fulfilled for every refill station	particularly when the consumer brings his own packaging. GR: <u>Justification:</u> the term “refill station” is not included in essential provisions of the CLP regulation, i.e. articles 31(1) 17(1) and 17.1b and 4(10) and Annex I part 1 para 1.2.1.4 and table 1.3, art. 45 and annex VIII etc: 31(1) Labels shall be firmly affixed to the packaging. 17(1) <u>substances and mixtures</u> classified as hazardous are contained <u>in packaging shall bear a label</u> including the following elements 17(1)b. The quantity of the <u>substance is available on the package</u> Annex I part 1 para 1.2.1.4 and table 1.3: Dimensions of packaging. 4(10) : substances and mixtures shall fulfill the requirements of the regulation and not the refill station. HU:

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		Please clarify if this means that the package should be labelled at the time of the purchase. IE: We question the need to specify applicable at the date of placing on the market and suggest it could be deleted PT: Can you please clarify if this includes the need to label refilled package. We consider that the labelling of the refill package must be mandatory; we therefore propose to make this clear in the legal text. This is important also for purposes of communication to the information emergency health response in case of accident. SK: not clearly understandable this part LV:

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		When placing a mixture on the market, a refillable container shall be labelled for the first time. At this stage it is unclear how these labelling provisions will be addressed in practice, particularly by whom and how the initial label will be checked during a refill of this container. Especially, in cases when the label is being updated and the updated label will not match the initial one. DK: Denmark supports the introduction of requirements for “refill” sales. See note to Article 35(2a) for lack of definition of “refill” station. Would it be possible insert a requirement for the machine to provide a label that meets the requirements of CLP. This ensures that consumers can get the correct information on the packaging. The requirements in <i>litra c, e, f, g, h, and j</i>, are extremely difficult to enforce. It will be close to impossible to enforce whether the

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		packaging has any invisible contamination, and if the packaging is of the right quality. In addition, MSAs must check the technical safeguards against overfilling the packaging, that someone is available at the time of filling, that filling does not take place outside or otherwise outside opening hours (undefined term). Finally, that the staff employed are trained/educated to minimize risks for everyone and otherwise follow hygiene and cleaning protocols. These are all provisions far from the MSA's normal area of competence and require additional competences and resources to be able to enforce across member states. The provisions also requires odd work hours, and lastly some clear definitions of relevant training and who would be responsible for preparing and keeping protocols available for inspection.

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(b) a label is firmly affixed on a visible place of the refill station and with a font size that is easily legible and without serifs;	GR: We propose the addition of the text in bold: (b) a label is firmly affixed on a visible place of the refill station and with a font size that is easily legible and without serifs and the same label is provided automatically by the refill machine in order to be affixed to every package; SI: k) a copy of the label in accordance with Article 17 shall be provided.	GR: <u>Justification:</u> the same as above. To avoid human mistake and to ensure that the label is been updated and corresponded to the correct package. IE: We suggest a reference to Table 1.3 is provided here. We also suggest that there is an option to have a digital label/QR code at the refill station. ‘Easily legible’ is subjective, as noted previously. While we acknowledge that the general provisions for labelling also apply for refill stations, we nonetheless suggest that consideration is given to specifying minimal font sizes, etc with respect to the labels that will be affixed to the refill station to avoid any ambiguity. As it reads currently, it may

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		appear that the only requirement for the label affixed to the refill station is with respect to an easily legible font size without serifs (reference annex I section 1.2.1.5) SI: We believe that informing of users is key to reducing risk. It is therefore important that users have access to information about hazardous properties even after leaving the store. Therefore, we propose that in this case a copy of the label should be issued and provided as well. Furthermore an obligation to provide a copy of the label is need. Therefore we propose to add following additional point: <i>k) a copy of the label in accordance with Article 17 shall be provided.</i> .

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		DK: Are the transitional periods for labelling and packaging on refill stations the same as in article 30.1 and 30.2?
	BE: (...) the copy of the label is provided for any refill; ES: None BG: substances and mixtures are only refilled in clean packaging without any visible residues	BE: Alternative proposal if there is no provision ensuring that the label is affixed on the refilled packaging. ES: How and who is going to assure the compliance of packaging with these conditions? We think that it is especially difficult for the microbiological or other invisible contamination. MT: MT seeks clarification on what is meant by a 'suitable and clean packaging'. Furthermore, MT would like to ask whether the consumer can bring his/her own container and how the operator would know whether the container is clean. BG:

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		We consider that „suitable“ is covered by letter f) and the second part of the text should be omitted, since it is practically impossible to assess on-site the presence of microbiological and other invisible contamination.
(c) substances and mixtures are only refilled in suitable and clean packaging without any visible residues, which are cleaned before reuse in case of suspected microbiological or other invisible contamination;	GR: We propose the following rephrasing of the text: (c) substances and mixtures are only refilled in suitable and clean packaging which is automatically cleaned and dried by the refilling or cleaning machine to avoid without any visible residues, which are cleaned before reuse in case of suspected microbiological or other invisible contamination; SI: (c) substances and mixtures are only refilled in suitable and clean packaging without any visible residues, which are cleaned before reuse in case of suspected	GR: <u>Justification:</u> In order to avoid the formation of hazardous compounds from chemical reactions or the growth of pathogen microorganisms; IE: We appreciate that the rules that apply to traditional sales also apply to refill sales and that this is the underlying principle here. However, we are of the opinion that the obligations of the supplier in the scenario where the consumer brings their own container to the refill station are not explicitly laid out in the text and this could result in ambiguity and difficulties with enforcement. This particularly applies to the

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	microbiological or other invisible contamination; FR: (c) substances and mixtures are only refilled in suitable and clean packaging without any visible residues, which are cleaned before reuse in case of suspected microbiological or other invisible contamination, <u>in addition to the requirements set out in Titles III and IV</u> DK: (b) a label is firmly affixed on a visible place of the refill station and with a font size that is easily legible and without serifs in accordance with Annex I 1.2.1;	obligation on the supplier to ensure that the refilled package leaves the premises with a compliant label/hazard information, and in a clean and suitable container. Consideration could be given to explicitly stating the obligations of the supplier in that regard. We are of the opinion that some elements here, particularly points c, e and j may be a difficult requirement in practice and perhaps somewhat outside the scope of CLP. SI: We believe that in all cases packaging should be cleaned before reuse. Therefore we propose to delate following text: <i>in case of suspected microbiological or other invisible contamination;</i> CZ: To use the packaging in the "re-use" mode, it is necessary to point out that from the point of view of chemical safety, the proposed solution does not appear to be supervised and enforceable. It is not possible to check

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		whether the strict requirements for the packaging of chemical mixtures are met. The Czech Republic therefore proposes that the repeated use of the packaging should be allowed only for a certain firmly defined spectrum of chemical substances and mixtures, e.g. substances and mixtures which in the form supplied to the consumer are not classified as dangerous, or they only have a selected spectrum of danger. DK: There is a need for a definition of the “refill” station in order to place the label in the right place. — Should it not be placed on the container of the substance/mixture? Note in general that the requirements in relation to the readability of the text can be arranged by direct reference to 1.2.1 in Annex I. With this, it is ensured that the requirements are unambiguous and recognizable - and the requirements for, among other things, a white background, to be clearly legible, among others.

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(d) the buttons to operate the refill station are out of reach of children and the refill station is not designed in a way to attract the curiosity of children;		DK: — What is suitable packaging? How will it be prevented that food packaging is not used for these purposes? If so, the packaging would not be able to be reused as food packaging again. — Who is responsible for ensuring that the packaging is suitable and clean? Please note the initial remarks to this point 3.4.
(e) overfilling packaging is technically prevented;		SK: What is meant by “technically prevented”? Should it be a specific barrier? If so, we are of the opinion that it is necessary to have a definition of “technical barrier”
		MT: MT would like to seek clarification on what is meant by ‘suitable packaging’.

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(f) filling a substance or mixture into unsuitable packaging is technically prevented;		DK: In practice, will this mean that hand pumps should not be used? These are currently used in “refill” shops. — Has the COM given any thought on how to comply with the requirement? Please note the initial remarks to this point 3.4.
	ES: (g) at the moment of refill, the staff of the supplier is reachable for immediate assistance; BG: at the moment of refill, the staff is available for immediate assistance	ES: In line with the wording of point (j) MT: MT would like to seek clarification on how the supplier would be reachable. BG: On site, the station staff can be contacted most quickly, especially since according to letter j) they are trained. It is not realistic for the supplier to be available at all times.
(g) at the moment of refill, the supplier is reachable for immediate assistance;	GR: We propose the rephrasing:	GR:

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	<i>The refilling must be done by the supplier</i> HU: at the moment of refill, the staff of the supplier is reachable for immediate assistance DK:	<u>Justification:</u> Our proposal aims to ensure protection of human health and to avoid characterizing a consumer as a “manufacturer” (i.e. according to the determination of Detergents Regulation and therefore responsible for placing that detergent on the market : “<i>Manufacturer’ means the natural or legal person responsible for placing a detergent or a surfactant for a detergent on the market; in particular, a producer, an importer, a packager working for his own account, or any person changing the characteristics of a detergent or of a surfactant for a detergent, or creating or changing the labelling thereof, shall be deemed to be a manufacturer....</i>” HU: We suggest referring to the staff of the supplier as in point (j). DK: The comments on paragraphs (c) and (e) are also relevant here.

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		Please note the initial remarks to this point 3.4.
(h) refill stations are not operated outdoors and outside business hours where immediate assistance cannot be provided;		DK: Please note the initial remarks to this point 3.4.
	ES: None	ES: It is possible that reactions between substances or mixtures provided through a refill station are unknown. Who will be the responsible to give this information?
(i) the substances or mixtures provided through a refill station do not react with each other in a way that could endanger clients or staff;		DK: Please note the initial remarks to this point 3.4. It would be beneficial with a clear definition of a refill station especially not to confuse refill stations with substances and mixtures sold without packaging.
		DE:

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		The term “appropriately trained” and “necessary hygiene and cleaning protocols” are not specific enough to allow proper implementation and enforcement. References to existing provisions or requirements should be added.
(j) staff of the supplier are appropriately trained to minimise safety risks to consumers, professional users and themselves, and follow the necessary hygiene and cleaning protocols;	BE: (j) staff of the supplier are appropriately trained to minimise safety risks to consumers, professional users and themselves, and follow the necessary hygiene, and cleaning and traceability protocols; SI: (j) staff of the supplier are appropriately trained to minimise safety risks to consumers, professional users and themselves, and follow the necessary hygiene and cleaning protocols;	BE: The loss of information should be avoided when refill stations are filled, e.g. on batch numbers or durability dates where appropriate. SI: We are of the opinion that this provision should be deleted as such type of trainings are matter of occupational health and safety legislation. Therefore we propose to delete point j). SK: Staff of the supplier are appropriately trained, but the training requirements for handling chemicals are not specified.
		AT:

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		The ban of certain substances or mixtures in refill stations also applies to substances labelled STOT SE 3, H335 which are also contained in laundry detergents. In order to enable the refill of such mixtures, it should be considered to remove H 335 from the proposed ban. BG: Scrutiny reservation on the listed hazard classes
(k) no substance or mixture provided through a refill station meets the criteria for classification in any of the following hazard classes:	GR: Explosives, oxidizing (liquid solid) skin sensitizers, serious eye damage must be added. NL: [insert] <u>xix Serious eye damage category 1;</u>	GR: <u>Justification:</u> Serious hazards classes, with obvious risks to human health and the environment, are missing NL: NL: we would like to suggest to include Serious eye damage category 1 because that would result in irreversible damage for human health that can occur in case of exposure of the substance in small amounts.

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		LV: Among the listed hazard classes, Eye Dam.1 is not listed. In the harmonized C&L inventory there are substances (for example, CAS No. 31506-43-1, 39148-24-8, 122035-71-6) possessing eye damage effects with no skin corrosion effects. In other words, for such substances eye damage effects cannot be covered by the skin corrosion effects. In order to protect an average consumer, it might be appropriate to complement the hazard listing by inclusion of Eye Dam.1. DK: Please note the initial remarks to this point 3.4
		IE: Include also substances/mixtures that can cause serious eye damage (Category 1)
(i) Acute toxicity, categories 1 – 4;		DK: Denmark supports that substances and mixtures with the specified hazard classes may not be sold via refill.

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		— Environmental hazard classes are also included, except for aquatic toxicity. Substances and mixtures meeting the criteria for aquatic toxicity category 1 and 2 should be added to the list, as well as substances meeting the criteria for skin sensitisation category 1A og 1B and serious eye damage. Denmark notes that if products labelled with H318 are exempt from refill stations, then many cleaning products cannot be sold via refill stations. It is noted, that in the following section, the”all categories” should also be used for points i, ii, iii, v, x, xii etc. Further, see the remarks to point 1.5.2.4 in annex I.
(ii) Specific target organ toxicity – Single exposure, categories 1, 2 and 3;		
(iii) Specific target organ toxicity – repeated exposure, categories 1 and 2;		
	DE:	DE:

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	Add new item: Serious eye damage category 1/eye irritation category 2	The severity of effects is comparable to that of skin corrosion and may lead to permanent impairment or loss of vision.
(iv) Skin corrosion/irritation, category 1 (sub-categories 1A, 1B and 1C);	BE: (iv) Skin corrosion/irritation, category 1 and (sub-categories 1A, 1B and 1C);	BE: Improvement of the wording, as it refers to different classifications. HU: Please explain why eye damage is not listed, because it is considered a relevant risk for consumers with regard to refill stations.
	BE: (...) Serious eye damage, category 1 DE: Add new item: Skin sensitiser category 1 (sub-categories 1A and 1B)	BE: The hazard class ‘serious eye damage’ should be added to the exclusion list, in order to prevent irreversible eye damage, notably in case of incident during the refill phase or product transfer from hands to eyes. DE: Skin sensitisation is a severe hazard especially in the context of mixtures marketed to consumers.

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(v) Respiratory sensitisation, category 1 (sub-categories 1A and 1B);	BE: (...) Respiratory sensitisation, category 1 and (sub-categories 1A and 1B); DK: (iv) Skin corrosion category 1 (sub- categories 1A, 1B and 1C);	BE: Improvement of the wording, as it refers to different classifications. HU: Please explain why skin sensitisation is not listed, because it is considered a relevant risk for consumers with regard to refill stations. DK: As skin irritation is category 2, we suggest that the expression is removed here.
(vi) Aspiration hazard;		DK: It should be ensured that detergents containing enzymes would be able to be sold via refill sales and still be compliant with the CLP-regulation. Enzymes classified as respiratory sensitisers in category 1 are today used in detergents. These are most often used in concentrations above 0,1 % and the detergents will need the EUH 208 statement. Will this mean that such detergent cannot be sold via refill stations? Or is the

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		criteria that the mixture meets the criteria for labelling and the concentration for a category 1 substance should be above 1 % before?
(vii) Germ cell mutagenicity, any category;		
(viii) Carcinogenicity, any category;		
(ix) Reproductive toxicity, any category;		
	DE: (x) Flammable gases, categories 1A, 1B and 2;	DE: Categories for Flam. Gas have changed with 12 th ATP Why are (only) the hazard classes flammable solids, liquids and gases mentioned among the physical hazards? It is not clear why other more severe physical hazard classes should be allowed for refill sale via refill stations.
(x) Flammable gases, categories 1 and 2;		
		DE:

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		Why are (only) the hazard classes flammable solids, liquids and gases mentioned among the physical hazards? It is not clear why other more severe physical hazard classes should be allowed for refill sale via refill stations.
(xi) Flammable liquids, categories 1 and 2;		
		DE: Why are (only) the hazard classes flammable solids, liquids and gases mentioned among the physical hazards? It is not clear why other more severe physical hazard classes should be allowed for refill sale via refill stations.
(xii) Flammable solids, categories 1 and 2.		
(xiii) [insert: Endocrine disruptor for human health, categories 1 and 2].’;		
(xiv) [insert: Endocrine disruptor for the environment, category 1 and 2];		

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(xv) [insert: Persistent, bioaccumulative and toxic (PBT)];		
(xvi) [insert: Very persistent and very bioaccumulative (vPvB)];		
(xvii) [insert: Persistent, mobile and toxic (PMT)];		
(xviii)[insert Very persistent and very mobile (vPvM)].		SK: In this part we are of the opinion, that the serious eye damage /(eye irritation) is missing as it is not mild hazard.
By way of derogation from point (b), a single label on the refill station may be used for several substances or mixtures for which the label elements referred to in Article 17(1) are identical, provided that the label clearly indicates the name of each substance or mixture that it applies to.’;	BE: By way of derogation from point (b), a single label on the refill station may be used for several substances or mixtures for which the label elements referred to in Article 17(1) are identical, provided that the label clearly indicates the name of each substance or mixture that it applies to and that the	BE: The substance or mixture in the refill station should be clearly identified if the label refers to several substances or mixtures. GR: <u>Comment</u>

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	substance or mixture contained in the refill station is clearly identified by this name.’;	A single label for more than one substance or mixtures is not allowed in CLP regulation even if the label elements referred to in Article 17(1) are identical. According to art. 17(1) “<i>a substance or mixture classified as hazardous and contained in packaging shall bear a label</i>”. IE: The label should also indicate the UFI for the mixture (if one is required), to ensure that poisons centres can retrieve information on the mixture in an emergency. FR: Clarifications needed, possible issue for enforcement: there will be a single label e.g. for different fragrances in a detergent or fabric softener. The classifications may be the same but the sensitisers in the compositions of the products will be different. Consumers need to be informed of the name of the sensitisers in the product.

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Recitals relating to A3		
	DE: (15) Regulation (EC) No 1272/2008 currently does not lay down any specific rules for <u>the supply of labelling and packaging</u> of substances or mixtures supplied to the general public and professional users via refill stations. Considering the increasing trend of selling products, including certain chemicals such as detergents, without packaging to reduce waste and to facilitate more sustainable sales forms, it is appropriate to set out specific rules and conditions for such type of sales, and <u>limiting refill sales to the specific conditions and kinds laid down in the corresponding Annex</u> establish a list of hazard classes and categories prohibiting such refill station sales for substances of mixtures meeting the criteria for classification in those hazard classes and categories, in order to ensure safety and the protection of human health. In addition, according to the general rules of this regulation, refill containers have to comply	DE: The recital seems to convey, that there are currently no rules for substances or mixtures supplied in refill sale. However, from our understanding, the main point is that there are currently no additional requirements for the refill process itself (i.e. design of the refill stations, organizational requirements with the shop). Therefore, it would be favourable to refer more generally to the supply of substances and mixtures through refill sale and further insert a clarification. Furthermore, the recital has to be adapted in accordance with the proposed change of the corresponding Article 35.

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	<u>with the packaging rules of Title III and need to be labelled according to Title IV of this regulation.</u>	
(15) Regulation (EC) No 1272/2008 currently does not lay down any specific rules for labelling and packaging of substances or mixtures supplied to the general public and professional users via refill stations. Considering the increasing trend of selling products, including certain chemicals such as detergents, without packaging to reduce waste and to facilitate more sustainable sales forms, it is appropriate to set out specific rules and conditions for such type of sales, and establish a list of hazard classes and categories prohibiting such refill station sales for substances of mixtures meeting the criteria for classification in those hazard classes and categories, in order to ensure safety and the protection of human health.	GR: We agree	
	AT: End DE:	AT: End DE:

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	End ES: End MT: End	End ES: End MT: End

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		BG: It is necessary to clarify the scope of the definition, which differs from that specified in the Guidance for identification and naming of substances under REACH and CLP. The manual divides the substances into 3 different types: 1. Substances of well-defined chemical composition which are: - mono-constituent - one constituent is present at concentration of at least 80% (w/w) and contains up to 20% (w/w) of impurities and

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		- multi-constituent (e.g. reaction masses) - several main constituents present at concentrations $\geq 10\%$ and $< 80\%$ (w/w) 2. UVCB - substances of Unknown or Variable composition, Complex reaction products or Biological materials. We are concerned that the scope of the proposed definition of MOCS is much wider – in practice, it is almost all substances. In this sense, we consider that the Impact Assessment should be supplemented regarding the proposed approach for the classification of MOCS as it is important to know the number of substances that will need clarification or reclassification and the potential impact on their downstream uses.
		BG: Clarification is needed whether in the absence of relevant available information for the individual constituent, an identified

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	BG: (4a) in Article 5, the following paragraph 4 is added: Paragraph 3 shall not apply to UVCB substances.	BG: It should be considered that UVCB substances cannot be identified well enough by their chemical composition because they contain a large number of constituents and the composition is often largely unknown, variable or difficult to predict. Other types of information are required to identify them, such as origin/source and manufacturing process, and any significant change to the source or process may result in a different substance and thus the need for new tests. This group presents a real scientific and analytical challenge in respect to the analysis of the composition and structure of different constituents. We also would like to emphasize that UVCB include very different substances, such as polymers, petroleum products, essential oils and others with

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		varying properties and hazard and risk profiles, which are very different from the core MOCS group. In most cases UVCB encompass hundreds to thousands of different unknown constituents, which makes the analysis unpractical, unworkable and technically and economically unfeasible. Given the nature of these substances, in practice the proposed principle would be difficult to apply to them. That's way we consider they should be excluded from the MOCS concept.
		BG: Clarification is needed – see comment on art. 5(3)
	BG: End	BG: End

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