Council of the European Union
General Secretariat

Interinstitutional files:
2022/0432 (COD)

Brussels, 08 June 2023

WK 7539/2023 INIT

LIMITE

ENT
MI
IND
ENV
SAN
CHIMIE
CONSOM
CODEC

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

NOTE

From: To:	General Secretariat of the Council Working Party on Technical Harmonisation (Dangerous Substances - Chemicals)
N° prev. doc.: N° Cion doc.:	CM 2899/23; ST 9689/23, and ST 9690/23 ST 16258 2022 ADD 1 - 8
Subject:	Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Revision) - Comments by BE, BG, DK, EL, FI, IT, LV, NL, SI, DE, LT, PL, FR, PT, IE, AT on the Revised Presidency Compromise Proposal

Delegations will find in the Annex a consolidated table with the comments by Member States on the full text of the Presidency's compromise proposal on the CLP revision, as set out in document ST 9689/23.

Revised Presidency Compromise Proposal – ST 9689/23	**Drafting Suggestions BE, BG, DK, EL, FI, IT, LV, NL, SI, DE, LT, PL, FR, PT, IE, AT**	**Comments BE, BG, DK, EL, FI, IT, LV, NL, SI, DE, LT, PL, FR, PT, IE, AT**
Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures		
Cluster A – Labelling and Sales		
Subgroup A1: Labelling obligations/exemptions		FI: FI: we support the comments repeatedly made by LV regarding the sale of fuel to jerry-cans, and hope that this long-standing EU-wide issue could be addressed as a part of this revision.
Articles in A1		
(8) in Article 23, the following point (g) is added:		
‘(g) ammunition as defined in Article		LT:

1(1), point (3), of Directive (EU) 2021/555 of the European Parliament and of the Council[1] unless it **is an article according to** ~~falls within~~ the definition ~~of an article~~ in Article 2, point (9), **that falls within the scope of Article 4(8)** of this Regulation.		We welcome this change. FR: 1. The French authorities wish to ensure that the new wording allows for derogation from the labelling obligations for all explosives, including those mentioned in article 4(8). 2. Could the Presidency clarify its interpretation of article 4(8) obligations read in combination with recital 7 and article 23(g)?
(9) Article 25 is amended as follows:		
(x) paragraph 3 is replaced by the following:		
3. 'The supplier may include supplemental information in the section for supplemental information on the label other than that referred to in paragraphs 1, 2 and 6 to 9, provided that that information does not make it more difficult to identify the label elements referred to in Article 17(1) (a) to (g) and that it provides further details and does not contradict or cast		

[1] Directive (EU) 2021/555 of the European Parliament and of the Council of 24 March 2021 on control of the acquisition and possession of weapons (OJ L 115, 6.4.2021, p. 1).'

doubt on the validity of the information specified by those elements.’;		
(a) in paragraph 6, the first subparagraph is replaced by the following:		
~~(10)~~		
‘6. The special ~~specific~~ labelling rules set out in Part 2 of Annex II shall apply to mixtures containing substances referred to in part 2 of that Annex.’;		
(~~a~~b) the following paragraph 9 is added:		
‘9. Label elements resulting from requirements set out in other Union acts shall be placed in the section for supplemental information on the label.’;		
(11) Article 29 is amended as follows:		
(a) paragraph 1 is replaced by the following:		
‘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 section~~s~~ 1.5.1.~~1. and 1.5.1.2.~~ of Annex I.’;		
(b) paragraph 3 is replaced by the following:		
‘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.’;		**LV**: In the current compromise text, an exemption from the labelling provisions is introduced for fuel that is being filled directly into a vehicle at filling station. Although, the exemption is not applicable when the same fuel at the same filling stations is being filled into jerrycans. As a result, in the latter case a copy of the fuel label shall be provided to a consumer by the filling station. We would like to emphasize that such provision is not enforceable either from the practical point of view, nor from the rational sense perspective, especially when the fuel is being filled at the self-service filling stations by the consumers. At self-service filling stations normally, there are no employees who could hand over a label copy to the consumer. We truly do not understand why we need to foresee provisions that most likely will not be fulfilled in practice and will not be enforceable and enforced.

		We strongly consider that even though currently there are no labelling exemptions for fuel at all, we shall try to resolve this fuel labelling issue completely covering both cases, i.e. when fuel is being filled directly into vehicle and when it is being filled into a jerrycan. In this respect, we offer two alternative solutions: 1) in Part 5 of Annex II we extend the labelling exemption also covering the fuel, which is being filled into jerrycans; or 2) for such fuel filling we introduce requirements *mutatis mutandis* from Section 3.4. of Part 3 of Annex II, in particular Points (a) and (b).
(c) the following paragraph~~s~~ 4b ~~and 4c are~~ is inserted:		
'4b. By derogation from Article 17(1), the labelling requirement set out in that Article shall not apply to packaging of ammunition that is intended for use~~d~~ by defence forces, ~~in combat zones or shipped to such zones~~ where labelling in accordance with that requirement would constitute an unacceptable security risk for the cargo, the soldiers ~~and~~ or the staff, and sufficient camouflaging cannot be ensured.	DK: By derogation from Article 17(1), the labelling requirement set out in that Article shall not apply to packaging of ammunition that is intended for use~~d~~ by defence forces, ~~in combat zones or shipped to such zones~~ where labelling in accordance with that requirement would	DK: Denmark proposes the deletion of the word "unacceptable" as regards the security risk for easier enforcement purposes. The word "unacceptable" introduces discretion for the enforcement authorities, and the

	constitute a~~n unacceptable~~ security risk for the cargo, the soldiers ~~and~~ or the staff, and sufficient camouflaging cannot be ensured.	technical capabilities of the enforcement authorities is not within the area of expertise as to assess, what makes a security risk "unacceptable". FI: FI: we have a scrutiny reservation due to ongoing discussions with the Ministry of Defence. **LV**: Considering that Paragraph 8 of Article 4 applies for explosive articles, we would like to seek some clarity, what is understood by ammunition under Paragraph 4b of Article 29. Does the ammunition include substances and mixtures only, or does it include explosive articles as well? In our opinion this should be clearly emphasized at least in the corresponding Recital 7. IE: We question if is it necessary to say …*for the cargo, the soldiers or the staff*"? It may be just sufficient to say *an unacceptable* ***safety or*** *security risk.* If this is to remain, then we suggest changing '*soldiers*' to *defence forces'*

~~4c.~~ ~~Where paragraph 4b applies~~ In this case, manufacturers, importers or downstream users shall provide to the defence force the safety data sheet or, if no safety data sheet is required, a ~~leaflet containing~~ copy of the label elements ~~information referred to~~ in accordance with Article 17~~(1)~~.'; 	IE: Editorial suggestion: defence force**s**	
(12) Article 30 is replaced by the following:		
'Article 30		
Updating information on labels		
1. In case of a change regarding the classification ~~and~~ **or** labelling of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in accordance with Article 25, the supplier **of that substance or that mixture** shall ensure that the label is updated **without undue delay and no later than** ~~within~~ 6 months after the results of the new evaluation referred to in Article 15(4) were obtained by, or communicated to, that supplier.	BE: 1. In case of a change regarding the classification ~~and~~ **or** labelling of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in accordance with Article 25, the supplier **of that substance or that mixture** shall ensure that the label is updated **without undue delay and no later than** ~~within~~ 6 months after the results of the new evaluation referred to in Article 15(4) were obtained by, or communicated to, that supplier ***[, and in any case no later than 18 months after the change***	BE: BE proposes to complement the individual timelines by a cumulative timeline fixed for the entire supply chain, particularly for additional or more severe classifications or labeling, in order to avoid long delays in case there are many actors in the supply chain. A cumulative timeline of 18 months could be added in article 30(1). This would also facilitate market surveillance as it would be challenging for market surveillance authorities to check when, and if, each supplier obtained the information on the new classification. FI:

	regarding the classification or labelling].	
	FI:	FI: This paragraph is only about updating the label according to the changes in classification towards more severe or if new supplemental information is required. If the label must be changed due to other reasons, such as change in contact details of the supplier, then paragraph 2 is applied. Please look also at the ECHA labelling and packaging guidance, section 2.4.
	FI: Please change "or" back to "and" > ..classification **and** labelling…	
	IT:	Please reconsider the time-limits, as their applicability seems to be too ambitious.
	In case of a change regarding the classification or labelling of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in accordance with Article 25, the supplier of that substance or that mixture shall ensure that the label is updated ~~**without undue delay and no later than**~~ **within** 6 months after the results of the new evaluation referred to in Article 15(4) were obtained by**,** or communicated to**,** that supplier.	IT:
	SI:	We think it is not applicable the expression "without undue delay". It is more realistic a specific period and the difference between different actor.
	1. In case of a change regarding the classification ~~and~~ **or** labelling of a substance or a mixture, which results in the addition of a new hazard class or in a more severe	Concerning a possible cumulative period, we think that it would be easier to define if only 2 actors were involved (manufacturer/importer of a substance and 1 formulator of mixtures, and the cumulative period would be 12months), but if the formulators were two (please, think to a mixture in the mixture) that

	classification, or which requires new supplemental information on the label in accordance with Article 25, the supplier **of that substance or that mixture** shall ensure that the label is updated **~~without undue delay and no later than~~** within 6 months after the results of the new evaluation referred to in Article 15(4) were obtained by, or communicated to, that supplier. DE: 1. In case of a change regarding the classification ~~and~~ **or** labelling of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in accordance with Article 25, the supplier **of that substance or that mixture** shall ensure that the label is updated **without undue delay and no later than** ~~within 6~~**12** months after the results of the new evaluation referred to in Article 15(4) were obtained by, or communicated to, that supplier. IE: Editorial suggestion: that substance or ~~that~~	cumulative period would be 18 months and so on. If we maintained the current proposal with a specific time for each actors involved, it would be clearer to individuate who blocks the communication and, in the meantime, who receives a communication can not ignore it. SI: We are of the opinion that provision **without undue delay** would be difficult to control in practice. Therefore we propose to delete it and keep within. DE: The proposed 6 month are too short for all internal processes linked to a relabeling in a company. We suggest at least 12 months. PL: We propose to extend the period from 6 months to 18 months. From a practical point of view, the period of 6 months is not feasible. PT:

	mixture	PT has a scrutiny reservation on the deadlines. IE: We have reservations about the re-introduction of the phrase 'without undue delay'. From an enforcement point of view, this has always been a difficult term to contend with, as there is no clear definition. We do note that the insertion of the 6-month deadline which will assist in the enforcement of this provision. However, it will not be possible to enforce the provision until the 6 months have been reached, regardless of whether 'without undue delay' is included or not.
2. Where a change regarding the classification ~~and~~ **or** labelling of a substance or a mixture is required other than that referred to in paragraph 1, the supplier **of that substance or that mixture** shall ensure that the label is updated **without undue delay and no later than** ~~within~~ 18 months after the results of the new evaluation referred to in Article 15(4) were obtained **by, or communicated to, that supplier**.	FI: FI: If no reconsideration regarding longer transitional periods is foreseen, please delete "without undue delay and no later than" and retain "within" 18 months… IT:	BE: A cumulative timeline doesn't seem necessary when the changes relate to less (severe) classifications or labelling, as a delay won't have a negative impact on the safe use of the product.

	2. Where a change regarding the classification or labelling of a substance or a mixture is required other than that referred to in paragraph 1, the supplier of that substance or that mixture shall ensure that the label is updated **~~without undue delay and no later than~~ within** ~~-~~18 months after the results of the new evaluation referred to in Article 15(4) were obtained by, or communicated to, that supplier. SI: 2. Where a change regarding the classification ~~and~~ **or** labelling of a substance or a mixture is required other than that referred to in paragraph 1, the supplier **of that substance or that mixture** shall ensure that the label is updated **~~without undue delay and no later than~~** within ~~-~~18 months after the results of the new evaluation referred to in Article 15(4) were obtained **by, or communicated to, that supplier**. IE: Editorial suggestion: that substance or ~~that~~	FI: FI: Please reconsider the time-limits, as their applicability seems to be too ambitious. IT: Previous comment SI: We are of the opinion that provision **without undue delay** would be difficult to control in practice. Therefore we propose to delete it and keep within. PT: Although PT has a scrutiny reservation on the deadlines of paragraph 1, we welcome the changes introduced in the Presidency Proposal. IE: Our comment with respect to undue delay also

	mixture	applies here.
	SI:	
2a. Suppliers shall cooperate in accordance with Article 4(9) to complete the changes to the labelling **and** without undue delay **inform concerned actors in the supply chain about their obligations to update labels**.	DK: 2a. Suppliers shall cooperate in accordance with Article 4(9) to complete the changes to the labelling **and** without undue delay **inform concerned actors in the supply chain,** *with whom the supplier has a contractual or similar relationship,* **about their obligations to update labels** *within four weeks after results of the new evaluation referred to in Article 15(4) were obtained by, or communicated to, that supplier.* IT: Suppliers shall cooperate in accordance with Article 4(9) to complete the changes to the labelling ~~**and**~~ without undue delay ~~**inform concerned actors in the supply chain about their obligations to update labels.**~~ PT:	DK: Denmark proposes that the requirement to communicate classification changes to connected suppliers should be subject to a four-week deadline. This is for two reasons. Firstly, a four-week deadline would ensure that the cumulative timeline between manufacturer and consumer would be kept to a minimum, while still ensuring that each supplier in the supply chain has 6 or 18 months respectively to update labels for paragraph 1 and 2 respectively. Secondly, a four-week deadline would remove doubt as to the interpretation of "without undue delay", as compliance with the requirement can be established through documenting that information has been sent to the relevant suppliers.

	Suppliers shall cooperate in accordance with Article 4(9) to complete the changes to the labelling **and** without undue delay **inform concerned actors in the supply chain about the new classification and their obligations to update labels**. IE: Editorial suggestion: *inform concerned actors in the supply chain ~~about~~ of their **subsequent** obligations to update labels.*	Furthermore, while we appreciate the simplicity of the term "concerned actors" as opposed to "connected suppliers", as we put forward in our proposal, it would be helpful for enforcement purposes, if this term is either defined in a subparagraph to paragraph 2a or included within the recital text. Denmark emphasises the importance of proximity built through contractual or similar relationships, when allocating responsibility for communication of classification changes. The term "concerned actors" could be interpreted broadly and lead to confusion as to allocation of responsibility for communicating classification changes within the supply chain. IT: We would like to keep the previous version in order to avoid a removal of responsibility to the actors down in the supply chain, that would be a possible consequence where underlined that an actor up the chain has to inform (and remind) to the dowstream actor about its obligations to update labels. PT:

		PT welcomes the changes introduced in the Presidency Proposal. However, in our view there is still room for improvement. We propose to add the need to inform about the new classification as well (see proposal for amendment). IE: As already indicated, we have concerns about the use of the term 'without undue delay' as it leaves enforcement of this provision very open-ended. We suggest that consideration be given to introducing a deadline by which suppliers must inform concerned actors about the obligations to update labels.
3. Paragraphs 1 and 2 shall not apply where a change regarding the classification and labelling of a substance or a mixture was triggered by a harmonised classification and labelling of a substance set out in a delegated act adopted pursuant to Article 37(5) or by a provision set out in a delegated act adopted pursuant to Article 53(1). In such cases, the supplier shall ensure that the label is updated by the date set out in the respective delegated act.		

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'.		
(13ac) ~~in~~ Article 31 is amended as follows:		
(a) paragraph 1 is replaced by the following:		
'1. Labels shall be firmly affixed to one or more surfaces of the packaging immediately containing the substance or mixture and shall be readable horizontally when the package is set down normally. The label may be presented in the form of a fold-out-label.'		
[(b) see (13b) in subgroup A2 below]		
(c) paragraph ~~(3),~~ is replaced by the following ~~sentence is added~~:		
'3. The label elements referred to in Article 17(1) shall be clearly and indelibly marked. They shall stand out clearly from the background and they shall be of such size and spacing as to be easily read. They shall be formatted in accordance with section	EL: We prefer option b) of the question of annotation document ST 9690/23: ***"Introduce requirements for the form and***	BE: BE supports the introduction of requirements for the form and design of fold-out labels in the

1.2.1. of Annex I.'; ***[Please also insert here any comments on the steering question from the PCY about requirements on form and design for fold-out labels as set out in separate annotation document ST 9690/23]***	***design of fold-out labels by inserting the proposed new section 1.2.1.6. in Annex I.*** IT: *Section 1.2.1.6* *vi. "where applicable, the unique formula identifier* ***unless already applied on the packaging****"* DE: *1.2.1.6. The front page of the fold-out label shall*	Regulation, by inserting the proposed new section 1.2.1.6. in Annex I. We support the Presidency's proposed wording for this new section, including signal words in all languages of the label that are used in the inside pages and UFI code. For the UFI code, an exemption to include it on the front page could be foreseen when it is printed or affixed on the inner packaging next to the other label elements as foreseen in Part A, 5.3., of Annex VIII. DK: Denmark strongly supports the inclusion of provisions relating to the design for fold-out labels and the wording of the proposal as set out in the Presidency's steering question on this matter. EL: Justification: We prefer the inclusion in the legal text because the guidance is not obligatory. FI:

	include at least the following elements: *i. name, address and phone number of supplier(s);* *ii. ii. nominal quantity of the substance or mixture in the package made available to the general public, unless this quantity is specified elsewhere on the package;* *iii. iii. the product identifiers in all languages of the label in accordance with Article 18(2) for substances and Article18(3)(a) for mixtures;* *iv. iv. where applicable, hazard pictograms;* *v. v. where applicable, signal words in all languages of the label that are used in the inside pages;* *vi. vi. where applicable, the unique formula identifier;* *vii. vii. a reference to the full safety information inside the fold-out label in all languages of the label or a symbol to inform a user that the label can be opened and to illustrate that additional information is available on inside pages;* *viii. an abbreviation of the language (country code or language code) for all the languages that are used in the inside pages.* AT: ix. where applicable, hazard statements in all	FI: Regarding fold-out label, we support option b) and are of the opinion that the same provisions should apply to both front and the back page. IT: Concerning the proposal of Section 1.2.1.6, we have no objection to insert an indication of what to report on the first page of the folding labels, if limited precisely to what is already in

	languages of the label that are used in the inside pages;	the Guideline. On the other hand, we do not agree on integrating with the UFI because regulation 2020/1677, the latest modification of Annex VIII of the CLP, has introduced the possibility of indicating the UFI directly on the packaging and not on the label. So, we believe that it shouldn't be inserted as a mandatory requirement for the first page of fold-out label. **LV** answer to ***PRES Question 1***: For the sake of legal clarity, we would prefer to introduce the requirements in the new Section 1.2.1.6. of Annex I, rather than in a guidance document. SI: Regarding Annex I , 1.2.1.6 we support option **b** e.g. introducing the requirements for the form in design of fold-out labels. DE: We clearly prefer option b). The guidelines include examples of how to design easy-to-

		read fold-out labels. However, experience clearly shows that these guidelines are rarely applied. It is imperative that the most important labelling elements are always shown on the outer label. We therefore support the proposal to make include the elements already listed in the guidelines in Annex I of the CLP Regulation. However, we suggest an amendment to the specifics of the provisions. The listing includes a certain inconsistency in its dealing with multiple languages. Some elements of the label are inherently language neutral. These are the pictograms (iv) and the UFI (vi) and in a narrow interpretations of the meaning also the supplier information (i) and nominal quantity (ii) (though auxiliary information to this may be language dependent). The language dependent elements signal word (v), reference to full information (vii) and language code (viii) therefore all need to be translated in all languages of the label. However, the product identifier (iii) is also language dependent but is treated in the listing as language independent. Especially in the case of trade names (which may differ between marketed territories) and different alphabets (Latin, Greek, Bulgarian), translation is without doubt necessary. We therefore propose to amend the provision to reflect this. LT:

		We prefer the requirements for the form and design of fold-out labels by inserting the proposed new section 1.2.1.6. in Annex I. PL: Poland prefers option B with insertion new obligations to the new section of Annex I. Generally guidance's are non-legally binding documents. Any tips given only in the guidance can be treated as a suggestion, not as an obligation. FR: FR supports the proposal to add a section to Annex I to specify the requirements for the layout of folding labels (information to be indicated on the first page). These information could also be required on the part of the label directly affixed to the packaging. This allows to provide information to the user if the label is removed or damaged. PT: PT does not oppose to either of the options

		proposed by the PRES in document ST 9690/23. IE: We are of the opinion that it is best if the requirements for the fold out labels are placed in the legal text rather than guidance. This would help enforcement in particular. With respect to the UFI, we note the intervention of CION at the meeting on May 31st indicating that a provision in Annex VIII allows for the UFI to be placed on the packaging next to the label information. UFIs tend to be updated more frequently than classifications and so there is the option to place the UFI on the package beside the labelling information. We suggest that this is addressed in this section for fold out labels to continue to allow for this, with a reference made to Annex VIII part A 5.3: which states that *Instead of including the UFI in the supplemental information on the label, the submitter may opt to print or affix it on the inner packaging located with the other label elements* AT: AT supports option b) of the annotations to the

		revised Presidency Compromise Proposal. In terms of the objectives of the CLP-Regulation, additional legal provisions regarding the form and design of the labelling of fold-out-labels are essential. In addition to the option b) AT would propose to list the hazard statements in several languages on the front page.
(14) in Article 32, paragraph 6 is deleted;		
Changes to Annex I in A1		SI: General comment regarding font size: we are still of the opinion that this provision shall be explained in the guidelines. Otherwise, it would be possible to have enforcement problems of this provision in practice.
(2) Section 1.2.1.4. is replaced by the following:		
'1.2.1.4. The dimensions of the label and of each pictogram, and the font size of letters shall be as follows:	SI: 1.2.1.4. The dimensions of the label and of each pictogram, ~~and the font size of letters~~	BE: BE supports the Presidency's proposal.

	shall be as follows:	SI: We are still of the opinion that is more appropriate place for the provision regarding the font size of letters in the guidelines. Therefore we propose to delate "and the font size of letters"
Table 1.3		SI: We are still of the opinion that is more appropriate place of the provision regarding the font size of letters in the guidelines. Therefore in the table 1.3 the column with the font size shall be deleted!
Minimum dimensions of labels, pictograms and font size	EL: In categories: capacity of the package: • not exceeding 3 litres, • greater than 3 litres but not exceeding 50 litres" the minimum font size should be 2 mm, at least for the signal word and the hazard statements.	EL: We consider that the font size of 1.4 mm is already too small to be easily legible. The most important elements of the label, concerning the protection of human health and the environment should be easily legible, otherwise the purpose of the label is undermined.

	SI: **Minimum dimensions of labels, pictograms ~~and font size~~**	SI: See comment above. We propose to delate "and font size". IE: We note the changes and can agree with them.
[please refer to the table in ST 9689/23]	DK: [Insert as subparagraph under Table 1.3] *Suppliers may use a smaller font size than the font sizes set out in Table 1.3 provided that all the following conditions are satisfied:* *a) The font size used must not have an x-height that is under 80 percent of the x-height that applies for the applicable package capacity.* *b) All labelling information required according to Article 17(1) is provided on the physical label.*	DK: Denmark refers to our statement on this issue uploaded to the delegates portal. A solution to the problem of readability must be proportionate to the costs involved. Denmark believes that the supplemental use of digital labelling – subject to certain conditions – can achieve this goal. NL: Regarding the new labelling requirements, we still believe we should hold on to the current 1,2mm X-height as recommended in the Guidance. We do not think it's necessary to

	c) *The supplier creates a digital label for the product, which replicates the content of the physical label in full and fulfills the technical requirements set out in Article 34b.* d) *The supplier can demonstrate that the compulsory information required according to this regulation cannot fit upon a label with the applicable dimensions for the capacity of the package in question when using the x-height required for that package capacity.*	increase the minimum font size, since legibility is based on more factors than just the minimum size. Secondly, as we have also previously mentioned, we think the costs for industry regarding the minimum sizes for larger containers do not outweigh the benefits of being able to read containers from a further distance – containers will still be legible from an appropriate distance if the smaller font sizes are used. In our opinion, there is no need to increase the minimum font size on the basis of the container size. Regarding the question by the Presidency, we prefer option b: to include the requirements of the form and design of fold-out labels in Annex I rather than in the guidance as this is consistent with the original requirements. PT: PT welcomes the Presidency Proposal regarding the introduction of x-height in mm in the last column heading of Table 1.3.
(3) the following Section 1.2.1.5. is added:		

'1.2.1.5. The text on the label shall have the following characteristics:		
(a) <u>printed in black on a white</u> ~~the~~ background ~~of the label shall be white~~;	IT: a) printed in black on a white background, **<u>allowing the use of recycled paper;</u>**	IT: We are especially worried about the "white" background because of the increasing use of recycled paper both for packaging and the label. At the same time avoiding treatment of the recycled paper in order to obtain a "total" white (please, *see the attached file* as an example of what the industries already do in order to use recycled paper as packaging where printing on it and bleaching the relevant part of the hazard label but without obtain a "total" white).) We would like to ask for a flexible approach on the "white", trying to have an acceptable "dirty white", when it is a consequence of a recycle process. Even if examples could be put in the guidance we wish to explain the flexible approach also in the article.

(b) the distance between two lines shall be **appropriate for the selected** ~~equal or above 120 % of the~~ font size **to be easily legible**;	PT: (b) the distance between two lines shall be **appropriate for the selected** ~~equal or above 120 % of the~~ font size **to be easily legible** **(minimum of 120 % of the font size);** IE: Editorial suggestion: **such that** ~~appropriate for~~ the ~~selected~~ font size ~~to be~~ **is** easily legible	DE: We do not oppose flexibility in principle, but ask the Commission to explain its reasons for the amendment in more detail. Without specific information, it is difficult to understand the need for the amendment. PT: Regarding point (b), we prefer to quantify the distance as foreseen in the previous wording, as it is more easily verifiable. See proposal for amendment.
(c) a single font shall be used that is easily legible and without serifs;		
(d) the letter spacing shall be appropriate for the selected font to be ~~comfortably~~ easily legible.		
For the labelling of inner packaging where the contents do not exceed 10 ml, the font size	DK:	DK:

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.'	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~~~~,~~. ***The most critical hazard statements shall be placed on the label of the inner packaging, and the ~~where it is deemed important to place the most critical hazard statement and where the~~*** outer packaging must meet~~s~~ the requirements ***~~of~~ set out in*** Article 17.'	Denmark is uncertain as to how the phrase "where it is deemed important" should be interpreted and therefore suggests a rewording to provide greater clarity.
	[Information about what the ***most critical hazard is should be added]*** SI:	Information about what hazard statements or in which situation a hazard statement could be regarded as the most critical hazard statement should be added. Could you please clarify what the relation is between this paragraph, and the changed wording of paragraph 1.5.2.4.1, where packaging with less than 10ml is also regulated?
	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.' IE:	E.g. does "the most critical hazard statement" in this paragraph correspond to the hazard classes and categories listed in1.5.2.4.1? SI: We are still of the opinion that is more appropriate place for this provision in the guidelines. Therefore, we propose to delate

	Editorial suggestion: For ~~the labelling of~~ inner packaging where the contents do not exceed 10 ml, **on which** ~~where~~ it is deemed important to **indicate** ~~place~~ the critical hazard statement and where the outer packaging meets the requirements of Article 17, the font size may be smaller than indicated in Table 1.3, as long as it remains legible	"smaller than indicated in Table 1.3, as long as it remains". PT: PT has reservation on the expression "as long as it remains legible", notably after the deletion of the segment "for a person with average eyesight".
(4) the following Section 1.3.7. is added:		
'1.3.7. ***Ammunition***		
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 ammunition that qualifies as a substance or mixture **and that is shot through ~~a firearm~~ a weapon system**, 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: Modification to take into account the fact that the shooting of ammunition is not only through a firearm. IE: We are not sure that the term '*qualifies*' is the most appropriate term here. It may be better to say *in the case of ammunition that **is** a substance or mixture.*

(5) the heading of Section 1.5.1. is replaced by the following:		
'1.5.1. Exemptions from Article 31 in accordance with Article 29(1)';		
(6) Section 1.5.1.1. is replaced by the following:		
'1.5.1.1. Where Article 29(1) applies, the label elements referred to in Article 17 may be provided on a tie-on tag or on an outer packaging.';		
(7) Section 1.5.1.2. is replaced by the following:		
'1.5.1.2. Where section 1.5.1.1. applies, the label on any inner packaging shall contain at least hazard pictograms, the signal word, the product identifier referred to in Article 18(2) for substances or the trade name or ~~the~~ designation ~~of the mixture~~ referred to in Article 18(3), point (a) for mixtures, and the name and telephone number of the suppliers of the substance or mixture.';	IE: Editorial suggestion: and the name and telephone number of the supplier**(s)**	IE:
(8) the heading of Section 1.5.2. is replaced by the following:	FR: Proposal to replace the section 1.5.2.3 by the	FR: Please take into account that the Regulatory

	following paragraph : 'Section 1.5.2.2 shall not apply to substances or mixtures within the scope of **Regulation (EC) No 1107/2009 or Regulation (EU) No 528/2012.'**	references need to be updated on section 1.5.2.3 (consistency with the provision on section 1.5.2.5).
'1.5.2. Exemptions from Article 17 in accordance with Article 29(2)';	FR: Please consider to add in section 1.5.2 the following provisions : '**The reduced labelling allowed for small packaging under Article 29(2) can only be applied if it is not possible to provide the full label information in one of the ways specified under Art 29(1) and Annex I, 1.5.1. If a hazardous substance or mixture is to be placed on the market in a small container without outer packaging or tie-on tag, then the container must bear the full label information, as specified in Article 17.**'	FR: This provisions are in line with the Q&A from ECHA n°1856 (dated 27/10/2021) which is applied by enforcement bodies.
(9) Section 1.5.2.4.1. is replaced by the following:		
'1.5.2.4.1. The label elements required by Article 17 may be omitted from the inner packaging where the contents of the inner packaging do not exceed 10 ml and ~~either~~ any of the following applies:		DK: Denmark notes that it is possible to exempt labelling if the substances or mixtures are to be classified as hazardous to the environment as is the case now with the current CLP regulation.

		Changing 1.5.2.4.1 to the current wording in the compromise text would weaken environmental protection. We suggest that both human health and the environment must be taken into account. This is especially important for substances with a high M-factor, or for mixtures containing such substances, as even small amounts of such substances or mixtures could pose a risk for the environment.
(a) the substance or mixture is placed on the market for supply to a distributor or downstream user for scientific research and development or quality control analysis and the inner packaging is contained within outer packaging that meets the requirements set out in Article 17;		
(b) the substance or mixture does not require labelling in accordance with Part 1~~,~~ <u>or</u> 2 ~~or 4~~ of Annex II and is not classified in any of the following hazard classes and categories:		DK: Please see our comments regarding the addition of a further two points to this list, which relate to environmental hazard classes and categories, The addition of these categories is important so as to ensure the new exemptions available for labelling of packages under 10 ml do not weaken environmental protection.

(i) Acute toxicity, **any** categor~~yies 1 to 4~~;		
(ii) Specific target organ toxicity – Single exposure, categories 1 and 2;		
(iii) Specific target organ toxicity – repeated exposure, **any** categor~~yies 1 and 2~~;		
(iv) Skin corrosion/irritation, category 1 (sub-categories 1A, 1B and 1C);		
(iv1) Serious Eye Damage, category 1;	FR: **(v)** Serious Eye Damage, category 1;	FR: Numbering adjustment (Serious eye damage hazard category is not included in the Skin Corrosion/Irritation hazard class)
(iv2) Skin Sensitisation, **any** category ~~1 (sub-categories 1A and 1B)~~;	SI: ~~iv2) Skin Sensitisation, **any** category 1 (sub-categories 1A and 1B);~~ FR:	SI: Regarding our opinion this provision shall exclude essential oils. Therefore we propose to delete it. LT:

	(vi) Skin sensitisation, any category;	FR: Numbering adjustment (Skin sensitizers are not included in the Skin Corrosion/Irritation hazard class)
(v) Respiratory sensitisation, **any** category ~~1 (sub-categories 1A and 1B)~~;	FR: **(vii)** Respiratory sensitisation, any category;	FR: Numbering adjustment
(vi) Aspiration hazard;	FR: **(viii)** Aspiration hazard;	FR: Numbering adjustment
(vii) Germ cell mutagenicity, any category;	FR: **(ix)** Germ cell mutagenicity, any category;	FR: Numbering adjustment
(viii) Carcinogenity, any category;	FR: **(x)** Carcinogenity, any category;	FR: Numbering adjustment

(ix) Reproductive toxicity, any category;	FR: **(xi)** Reproductive toxicity, any category;	FR: Numbering adjustment
(x) ~~Flammable solids, categories 1 and 2.;~~		
(xi) Endocrine disrupt**ion**~~ors~~ for human health, any category;	FR: **(xii)** Endocrine disruption for human health, any category;	FR: Numbering adjustment
	DK: xii) substances classified with Aquatic Acute 1 or Aquatic Chronic, with an M-factor equal to or above 100. (xiii) Mixtures containing one or more substance(s) classified with either Aquatic Acute 1 or Aquatic Chronic 1, and the values calculated using either point 4.1.3.5.5.3.1 or point 4.1.3.5.5.4.1 in CLP annex I part 4 (sum of classified substances) in annex X, is equal to or above 2500.	DK: As previously stated, Denmark regards the addition of the categories set out in the column to the left – points xii) and xiii) as important environmental warnings. The addition of these categories to point b) is important so as to ensure the new exemptions available for labelling of packages under 10 ml do not weaken environmental protection. Substances (b, xii) classified with either Aquatic Acute 1 or Aquatic Chronic 1, with an M-factor equal to or above 100. Mixtures (b, xiii) containing one or more substance(s)

		classified with either Aquatic Acute 1 or Aquatic Chronic 1, and the values calculated using either point 4.1.3.5.5.3.1 or point 4.1.3.5.5.4.1 in CLP annex I part 4 (sum of classified substances) in annex X, is equal to or above 2500
(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.'; FR: (c) the substance or mixture requires labelling in accordance with Part 1 or 2 of Annex II but is not classified in any of the hazard classes and categories referred to in point (b) and has an inner packaging that is contained within outer packaging that meets the requirements set out in Article 17. **In this case the label shall include : "Packaging must be kept for future reference".**'		FR: When the user throws away the packaging, he has no longer access to security information. The label must indicate that the packaging must be kept.
Changes to Annex II in A1		
(2) Part 5 is replaced by the following:		
'PART 5: HAZARDOUS SUBSTANCES AND MIXTURES TO WHICH ARTICLE 29(3) APPLIES		
Ready mixed cement and concrete in the wet state shall be accompanied by a copy of the label elements in accordance with Article 17.		

For a substance or a mixture supplied at a filling station and directly pumped into a receptacle that forms an integral part of a vehicle and from where the substance or mixture is normally not intended to be removed, the label elements referred to in Article 17 shall be provided on a visible place on the respective pump.’;	DK: ~~For a substance or a mixture supplied at a filling station and directly pumped into a receptacle that forms an integral part of a vehicle and from where the substance or mixture is normally not intended to be removed, the label elements referred to in Article 17 shall be provided on a visible place on the respective pump.~~ ***For pumps used to sell petrol or diesel at service stations, as defined in Directive 94/63/EC, the label elements referred to in Article 17 shall be provided on a visible place on the respective pump.”*** FR: For a substance or a mixture supplied at a filling station and directly pumped into a receptacle that forms an integral part of a vehicle and from where the substance or mixture is normally not intended to be removed, the label elements referred to in Article 17 shall be provided on a visible place, **from the normal user position,** on the respective pump**.**’;	DK: Denmark suggests a slight rewording of this provision so as to make it clear, that pumping fuel into a jerry at a filling station via a petrol pump is covered by this provision. That is to say, that petrol pumped into jerry cans falls under the bulk sales provision in Article 29(3), as this petrol is supplied via a petrol pump with the primary purpose of refuelling cars. Instead of placing a new definition of filling stations into the Regulation, some of the confusion on this matter can be avoided through reference to an existing definition in EU legislation. PL: Poland is of the opinion that this provision should be clarified and clearly indicated which elements of the label from Art. 17 should be placed on the pumps. In our opinion, the labeling can be omitted from: (a) the name, address and telephone number of the supplier or suppliers; (b) the nominal quantity of the substance or mixture in packages made available to the

		general public, unless this quantity is specified elsewhere on the package; (c) UFI. FR: The user should not have to go around the pump to read the information.
Recitals relating to A1		
(7) While **the majority of** ammunition is usually considered **as** an article, ~~Ammunition it might qualifying as~~ **in some cases, it may be** a substance or a mixture ~~and, in such cases,~~. **Where ammunition is determined to be a substance or a mixture,** it is to bear a label affixed to the surface of the packaging immediately containing the substance or the mixture (inner packaging)~~, which is typically the ammunitions' cartridge~~. Affixing a label to that~~e cartridge~~ inner packaging might however cause safety problems for the user, as the label could interfere with the correct functioning of the ammunition and could damage the firearm. Such ammunition should therefore be allowed to bear a label affixed to the next packaging layer instead of the inner packaging. In addition, labelled ammunition~~, which~~ **that** is **intended for** ~~exclusively~~ use~~d~~ by national defence forces ~~in combat zones~~, could, in	DK: (7) While **the majority of** ammunition is usually considered **as** an article, ~~Ammunition it might qualifying as~~ **in some cases, it may be** a substance or a mixture ~~and, in such cases,~~. **Where ammunition is determined to be a substance or a mixture,** it is to bear a label affixed to the surface of the packaging immediately containing the substance or the mixture (inner packaging)~~, which is typically the ammunitions' cartridge~~. Affixing a label to that~~e cartridge~~ inner packaging might however cause safety problems for the user, as the label could interfere with the correct functioning of the ammunition and could damage the firearm. Such ammunition should therefore be allowed to bear a label affixed to the next packaging	DK: Denmark proposes, as also stated in art. 29(4b), that the word "unacceptable" is removed as regarding the context of security risk, as it is deemed unnecessary to preform the evaluation, whether or not the security risk for the armed forces is "unacceptable". LT: We welcome this change. FR:

specific cases, constitute an unacceptable safety or security risk for the cargo, soldiers ~~and~~ **or** staff, if sufficient camouflaging cannot be ensured. For such cases, it is necessary to provide for an exemption from the labelling requirements and allow for alternative ways of communicating the hazard information.	layer instead of the inner packaging. In addition, labelled ammunition~~, which~~ **that** is **intended for** ~~exclusively~~ use~~d~~ by national defence forces ~~in combat zones~~, could, in specific cases, constitute a**n ~~unacceptable~~** safety or security risk for the cargo, soldiers ~~and~~ **or** staff, if sufficient camouflaging cannot be ensured. For such cases, it is necessary to provide for an exemption from the labelling requirements and allow for alternative ways of communicating the hazard information. FR: (7) While **the majority of** ammunition is usually considered **as** an article, ~~Ammunition it might qualify~~ing ~~as~~ **in some cases, it may be** a substance or a mixture ~~and, in such cases,~~**. Where ammunition is determined to be a substance or a mixture,** it is to bear a label affixed to the surface of the packaging immediately containing the substance or the mixture (inner packaging)~~, which is typically the ammunitions' cartridge~~. Affixing a label to that~~e cartridge~~ inner packaging might however cause safety problems for the user, as the label could interfere with the correct functioning of the ammunition and could damage the ~~**firearm**~~ **weapon system**. 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~~,~~	It is proposed to replace "firearm" by "weapon system" to take into account cases when the ammunition is not shot through a firearm. IE: We thank PRES for taking our wording suggestions on board here. Please see our previous comment on the security risk issues on article 29

	~~which~~ **that** is **intended for** ~~exclusively~~ used~~d~~ by national defence forces ~~in combat zones~~, could, in specific cases, constitute an unacceptable safety or security risk for the cargo, soldiers ~~and~~ **or** staff, if sufficient camouflaging cannot be ensured. For such cases, it is necessary to provide for an exemption from the labelling requirements and allow for alternative ways of communicating the hazard information.	
(8) In order to enhance clarity, all supplemental labelling requirements should be placed together in one Article.		
(9) Part 2 of Annex II to Regulation (EC) No 1272/2008 sets out rules for additional hazard statements to be included on the label of certain mixtures listed in Part 2 of that Annex. Given that those statements provide important additional information in specific cases, they should be applied to all mixtures referred to in Part 2 of Annex II, regardless of whether they are classified and whether they contain any classified substance.		
(10) To increase enforceability of the obligation placed on suppliers to update their labels after a change in the classification and labelling of their substance or mixture, a deadline should be laid down as regards that obligation. A similar obligation placed on		

registrants is set out in Commission Implementing Regulation (EU) 2020/1435[2]. Where the new hazard class is additional to an existing hazard class or represents a more severe hazard class or category, or where new supplemental labelling elements are required under Article 25, the deadline to update the labelling information in the case of adaptation of the classification in accordance with the result of a new evaluation should be set at 6 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. In case where a classification is updated to a less severe hazard class or category without triggering classification in an additional hazard class or new supplemental labelling requirements, the deadline for updating the labels should remain at 18 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. It should also be clarified that, in cases of harmonised classification and labelling, the deadlines to update the labelling information should be set at the date of application of the provisions setting out the new or amended classification and labelling of the substance concerned,		

[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.)

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).		
(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~~ possibility to use ~~of~~ fold-out labels on a regular basis.~~,~~ It is therefore appropriate to allow labels to be presented in a form of fold-out labels, applying the general rules on application and formatting to ensure ~~while~~ readability~~ of 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		IE: By saying *it is appropriate to provide for the labelling elements of other chemicals*, this

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.		suggests that other chemicals would be covered beyond ready mixed cement and concrete in a wet state and fuels supplied at filling stations. However, the legal text only covers ready mixed cement and concrete in a wet state and fuels and appears exhaustive in that regard, so this wording may need to be reconsidered. Additionally, it may be better to refer to *substances or mixtures supplied at filling stations* and not just fuels to allow for mixtures such as AdBlue to also be covered.
Subgroup A2: Digital labelling		
Articles in A2		
(2c) in Article 2, the following points *[7a, ~~and~~ 38]* and 39 are added:		
[…]		
‘(39) ‘data carrier’ means a linear bar code symbol, a two-dimensional symbol or other automatic identification data capture medium that can be read by a device’;	FR: ‘(39) ‘data carrier’ means a linear bar code symbol, a two-dimensional symbol or other automatic identification data capture medium that can be read by a device **that are widely used’**;	FR: The information on the digital label must be easily accessible before the purchase.

(13b) ~~in~~ Article 31 is amended as follows:		
[(a) see (13ac) in subgroup A1 above]		
(b) the following paragraph 1a is inserted:		
'1a. Where a digital label pursuant to Article 34a(1) is used, a data carrier to that digital label shall be firmly affixed or printed on the physical label or on the packaging next to the label in such a way that it can be processed automatically by digital devices **that are** widely used ~~by consumers~~.		IT: Agree, in the guidance could be described some examples of digital devices "widely" used.
Where label elements pursuant to Article 34a(2) are provided on a digital label only, the data carrier shall be accompanied by the statement "More **hazard** information available online" or by a similar indication.'	DK: Where label elements pursuant to Article 34a(2) are provided on a digital label only, the data carrier shall be accompanied by the statement "More **hazard** information available online" ~~***or by a similar indication***~~.' IT: Where label elements pursuant to Article 34a(2) are provided on a digital label only, the data carrier shall be accompanied by the statement **"**More ~~**hazard**~~ information on **safe**	DK: Denmark suggests for the purposes of clarity and simplicity, that "or by a similar indication" is removed. This would also ease enforcement of this provision. IT: We prefer other expression instead the word "hazard" to recall the CLP information on safe use.

	use available online" or by a similar indication.' FR: Where label elements pursuant to Article 34a(2) are provided on a digital label only, the data carrier shall be accompanied by the statement "More ~~**hazard**~~ information available online" or by a similar indication.	FR: Please consider to delete the term 'hazard' of the statement. The digital label could give other information such as warnings against bad practices (for example: packaging with child-resistant fastening shall be securely *reclosed).* PT: PT welcomes the amendment made with the introduction of the word "hazard" (in the phrase "More hazard information available online"); we consider relevant that the consumer clearly perceives that what he/she is going to read on the digital label is associated with information about hazards. IE: While we appreciate that CLP refers to hazard, it may be more appropriate to use the word 'safety' here, especially when it comes to consumers as they may understand that term better. Additionally, the information may go beyond just information on hazards.
[(c) see (13ac) in subgroup A1 above]		

(15) in Title III, the following Chapter 3 is added:		
‘*CHAPTER 3*		
Labelling ~~F~~f**ormats ~~of the labelling~~**		
Article 34a		
Physical and digital labelling		
1. The label elements for substances and mixtures referred to in Article 17 shall be provided~~:(a)~~ on a label in a physical form (‘physical label’).~~; or (b) both on a~~ In addition to the physical label, ~~and on a~~ the label elements referred to in Article 17 may be provided in a digital form (‘digital label’).		BE: Given that there is still a lack of conclusive data or feedback to further specify the conditions and requirements for digital labels, BE is in favour of the principle of laying down the same requirements in terms of information content and format for both physical and digital labels. BE therefore strongly supports this amendment, which provides clarity and legal certainty.
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.		FI: FI: Are there any grey areas where instructions for use could only be supplied digitally? The

		challenge lies there where there are no sector specific product regulation, e.g. paints. DE: "In general, we acknowledge the advantage of digital labelling, although we regard the proposal as very far-reaching. From our point of view, the exception would allow that in the future, i.e. in the event of a corresponding amendment to Annex I 1.6 by means of a delegated act, there could be a digital only labelling for mandatory elements. This is not acceptable. In order to protect consumers, all ingredients to be labelled as well as hazard statements and warnings must be listed on the physical label and may not be shifted, even partially, to digital-only labelling. It is therefore mandatory to clearly define those label requirements that are excluded from Annex I 1.6."
Where **those** label elements are provided on a digital label only, suppliers shall, upon oral or written request or when the digital label is temporarily unavailable at the time of purchase of the substance or mixture, provide those label elements by alternative means. Suppliers shall provide those elements independently of a purchase and free of charge.		DK: Denmark thanks the Presidency and the Commission for their explanation on the

		interpretation of this provision at the CLP working party meeting of 31st May. Denmark agrees that this is an area where the best approach may be to follow the application of this provision in practice before determining whether more specific rules are necessary. In the short term, guidance on interpretation of this provision is therefore the best way forward. IT: agree DE: In line with our reservations above, we also question this addition. Given the large number of products in the retail sector, this obligation is impracticable, very burdensome and does not enable consumers to make informed purchasing decisions. In particular, consumers who do not have access to a smartphone are at a considerable disadvantage and prevented from making an informed purchase decision based on health protection. They will always have to request written labelling information. This will overburden older consumers in particular.

		The newly added requirement to provide the information by alternative means is not effective in practice. Considering the vast amount of different products being offered at regular chemist warehouses, it seems burdensome for the shops to have alternative means of information at hand for every product. As a result, the simplification for the producer leads to a complication of the purchase process and the retailers.
3. Where the information is provided through a digital label, the requirements for digital labels set out in Article 34b shall apply.	IE: Editorial comment: ~~the~~	
Article 34b		
Requirements for digital labels~~ling~~		
1. The supplier who pursuant to Article 31(1a) places a data carrier linking to a digital label ~~for substances and mixtures~~ shall ensure that the digital label satisfies~~y~~ the following general rules and technical requirements:		PT: We welcomes the proposal to specifically state that the supplier who places a data carrier linking to a digital label on a product is responsible for the digital label and the connection to the product.
(a) all label elements referred to in Article 17(1) shall be provided **together** in		PT:

one place and separated from other information;		PT welcomes the inclusion of the word "together" in the sentence which is considered essential for the proper reading of hazard information as a whole.
(b) the information on the digital label shall be searchable;		
(c) the information on the digital label shall be accessible to all users in the Union and shall remain accessible for a period of **at least** 10 years or **for a longer period where required by other Union legislation**~~where the information is provided in accordance with other Union legislation, for the period of time required by that legislation~~;	PL: (c) the information on the digital label shall be accessible to all users in the countries where the substance or the mixture is placed on the market or made available on the market and shall remain accessible for a period of at least 10 years or for a longer period where required by other Union legislation.	PL: The physical label or the digital label must be prepared in the official language or languages of the Member States where the substance or mixture is placed or made available on the market as required by law. The digital information is available in the Member State where the substance or mixture is placed or made available on the market.
(d) the digital label shall be accessible free of charge, without the need to register, download or install applications, or to provide a password;		
(e) the information on the digital label shall be presented in a way that also addresses the needs of vulnerable groups and support, as relevant, the necessary adaptations to facilitate access to the information by those groups;	PT: (e) the information on the digital label shall be presented in a way that also addresses the needs of ~~vulnerable groups~~ "**people with**	PT: In regard to the reference to "vulnerable groups", we would suggest the use of a more specific/targeted expression such as "people

	visual disabilities" and support, as relevant, the necessary adaptations to facilitate access to the information by those groups;	with disabilities", although this is also a very large concept. In our view, the main disabilities to be considered, in this regard, would be visual impairment, colorblindness, etc. When speaking about websites, the information is normally referenced as accessible, and this concept is widely used.
(f) the information on the digital label shall be accessible with no more than two clicks;		
(g) the digital label shall be accessible through digital technologies widely used and compatible with all major operating systems and browsers;		
(h) when the information on the digital label is ~~available~~ **accessible** in more than one language, the choice of language shall not be conditioned ~~on~~ **by** the geographical location **when accessed**;		
~~(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;~~		

(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.~~		
2. ~~Suppliers shall provide, on oral or written demand or when the digital label is temporarily unavailable at the time of purchase of the substance or mixture, the label elements provided on a digital label only in accordance with Article 34a(2) by alternative means. Suppliers shall provide those elements independently of a purchase and free of charge.~~		
3. It is prohibited to track, analyse or use any usage information for purposes going beyond what is absolutely necessary for provision of digital labelling.’;		
(26a) Article 53 is amended as follows:	BE: (26a) **<u>in</u>** Article 53**<u>, paragraph 1, first subparagraph</u>** is ~~**amended**~~ **replaced** as follows:	BE: This delegation of powers to the Commission relates to essential elements of this legislation, i.e. the information to be provided to ensure user safety or environmental protection. We therefore believe that this delegation does not

	‘1. 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**, except for section 1.6. of Annex I,** 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 programmes and of the data from accident databases.**’**	comply with the conditions set out in Article 290 TFEU. In addition to its unfounded legal basis, the delegation does not seem to us to be sufficiently precise, as required by the case law of the CJEU and the relevant inter-institutional agreements. In the event that work needs to be done on a more precise delegation, we have noted the great difficulty of identifying, at this stage and at this level of the negotiations, more specific criteria to be taken into account when drawing up the delegated act. We therefore propose to transform this empowerment into a revision clause (see below) and to specify that the empowerment to the Commission currently in force does not cover the section 1.6. of Annex I (listing the information that may only be made available by digital means).
(a) the following paragraphs 1a to 1b are inserted:	BE: ~~**(a) the following paragraphs 1a to 1b are inserted:**~~	

‘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~~ and to the level of digital readiness among all population groups in the Union. When adopting those delegated acts, the Commission shall take into account the societal needs and ensure that label elements are only included in section 1.6. of Annex I provided that they are not instrumental for the ~~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 and to the level of digital readiness among all population groups in the Union. When adopting those delegated acts, the Commission shall take into account the societal needs and ensure that label elements are only included in section 1.6. of Annex I provided that they are not instrumental for the a high level of protection of human health and the environment;~~** DE: **The Commission is empowered to adopt delegated acts in accordance with Article 53a to amend section 1.6. of Annex I in order to adapt the label elements referred to in Article 34a(2) to technical progress or and to the level of digital readiness among all population groups in the Union. When adopting those delegated acts, the Commission shall take into account the societal needs and ensure that label elements**	DK: Denmark shares the concerns voiced by other Member States that the use of digital labelling reflects a political choice and balance, where expansion of the scope of digital labelling, particularly with regard to determination of the elements, which do not need to be placed upon the physical product, could be contrary to the political choice taken on digital labelling. Denmark looks forward to examining the Presidency’s proposals for this provision, particularly in light of the Commission Legal Services at the CLP working party meeting of 31st May. We are still examining the wording of the proposal put forward by Belgium in their non-paper of 2 June on the deletion of paragraphs 1a and 1b, the amendment to paragraph 1 and the inclusion of a new provision with a review clause. We can though in principle support the Belgian approach. FI:

	are only included in section 1.6. of Annex I provided that they are not instrumental for the a high level of protection of human health and the environment. Any labelling of ingredient, hazard statements and warnings shall not be included in section 1.6 of Annex I AT: ~~The Commission is empowered to adopt delegated acts in accordance with Article 53a to amend section 1.6. of Annex I in order to adapt the label elements referred to in Article 34a(2) to technical progress or and to the level of digital readiness among all population groups in the Union. When adopting those delegated acts, the Commission shall take into account the societal needs and ensure that label elements are only included in section 1.6. of Annex I provided that they are not instrumental for the a high level of protection of human health and the environment;~~	IT: We thank about the clarification offered by legal service of the Consilium, we understood the precautionary approach described by the Commission on balance the technical progress and the digital readiness in order to modify the section 1.6, and in meantime following the discussion at GHS level. We are open both solution: maintain the test or delete it because the delegate power is already enclosed under the current art 53a. DE: The specific criteria, which COM has to take into account when adopting the delegated acts, seem all together very indistinct. Especially "digital readiness" is a requirement, which is not possible to be determined in clear way. The ambiguity of the requirements also leads to legal uncertainties as regards the legitimacy of the delegated act itself. AT: We support the proposal to empower the European Commission to adapt the regulation to international developments (GHS) by means

		of a delegated act. This empowerment is already included in Art. 53 para 1. In this discussion it will be crucial which labelling elements must be attached to the packaging in order to protect the health of consumer, workers and the environment.
1b. In order to adjust to technological changes and ~~(~~future~~)~~ developments in the field of digitalisation, the Commission is empowered to adopt delegated acts in accordance with Article 53a to supplement this Regulation by laying down further details on the requirements for the digital labelling referred to in Articles 34a and 34b. Those requirements shall cover, in particular, the IT solutions which may be used, and the alternative means for providing the information. When adopting such ~~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 Articles 34a and 34b. Those requirements shall cover, in particular, the IT solutions which may be used, and the alternative means for providing the information. When adopting such those delegated acts, the Commission shall:~~** AT: ~~1b. In order to adjust to technological changes and (future)~~	DK: As with paragraph 1a, Denmark awaits the Presidency's proposed rewording with interest.

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

	AT: ~~(b) encourage innovation;~~	
(c) ensure technological neutrality by applying no constraints or prescriptions on choices of technology or equipment, within the bounds of compatibility and interference avoidance;	BE: **~~(c) ensure technological neutrality by applying no constraints or prescriptions on choices of technology or equipment, within the bounds of compatibility and interference avoidance;~~** AT: ~~(c) ensure technological neutrality by applying no constraints or prescriptions on choices of technology or equipment, within the bounds of compatibility and interference avoidance;~~	
(d) take into account the level of digital readiness among all population groups in the Union;	BE: **~~(d) take into account the level of digital readiness among all population groups in the Union;~~** AT:	

	~~(d) take into account the level of digital readiness among all population groups in the Union;~~	
(e) ensure that digitalisation does not compromise the protection of human health and the environment.’;	BE: ~~**(e) ensure that digitalisation does not compromise the protection of human health and the environment.’;**~~ **Article (NEW) xx** **Review** **No lather than … [three years after the date of entry into force of this Regulation], the Commission shall present an impact assessment accompanied, if appropriate, by a legislative proposal to extend the list of label elements, in section 1.6. of Annex I, allowed to be provided only in a digital format and to specify the technical requirements in Article 34b for the digital labelling, taking account of initiatives and innovation taken on the basis of the provisions of this Regulation.**	BE: We understand that digital development is still on an upward curve, as is the collection of information and feedback on these digital resources. A review clause would give us a more substantial impact assessment on this aspect in particular. We have tried to list some of the aspects that we consider essential to take into account. We propose a revision based on 4 axes: (1) the development of criteria for identifying information that is instrumental for the safety of the user or the protection of the environment; (2) the possible extension of the information listed in section 1.6. of Annex I; (3) the specification of the requirements for digital labelling referred to in Article 34b; (4) consideration of the environmental impact of both types of label.

	This assessment should consider the feasibility of defining substantiated criteria for identifying information that is instrumental for the safety of the user or the protection of the environment in order to ensure that that digitalisation does not compromise the protection of human health and the environment. **The review shall include an asssessment of the level of digital readiness among all population groups in the Union, including easy access to digital resources enabling to ensure a high level of protection for health and the environment. This review should also serve to determine whether digital tools effectively contribute to public awareness and a better understanding of labels.** **This review shall also address the technical progress in order to assess the need to set additional technical requirements, such as access, format and update conditions and the order in which the information is displayed. The Commission shall assess compatibility and coherence of those supplemental requirements with other Union legislation.**	

	The assessment shall include a quantification and comparison of physical and digital labels in terms of their environmental impact. AT: ~~(e) ensure that digitalisation does not compromise the protection of human health and the environment.';~~	
Changes to Annex I in A2		
(10) the following Section 1.6. is added:		
'1.6. **Label elements that may be provided on a digital label only**		
(a) Supplemental information referred to in Article 25(3)';		
Recitals relating to A2		
(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	PT: (12) Regulation (EC) No 1272/2008 needs to be adjusted to technological and societal	PT: PT welcomes the revised text in the Presidency Proposal and only has an editorial proposal.

hazard communication, especially for vulnerable population groups, such as people with visual impairments, and for people who do not speak the national language of a Member State. Therefore, it is necessary to provide for voluntary digital labelling and to lay down technical requirements **that the supplier who places a data carrier linking to** ~~for~~ such **a** label~~ling~~ **must satisfy**. **These technical requirements on the digital label should however not affect the responsibilities of all suppliers to ensure that labelling requirements are fulfilled when placing a substance or mixture on the market.** In order to provide for legal certainty, it is appropriate to specify ~~the~~ **which** label elements **required under this Regulation** 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**, while not affecting the labelling requirements or possibilities for digital labelling laid down in other Union legislation**.	changes in the field of digitalisation and be prepared for future developments. Digital labelling could improve the efficiency of hazard communication, especially for ~~vulnerable population groups, such as~~ people with visual ~~**impairments**~~ **disabilities,** and for people who do not speak the national language of a Member State. (…) In order to provide for legal certainty, it is appropriate to specify ~~the~~ **which** label elements **required under this Regulation** ~~**that**~~ are allowed to be provided in a digital format only. (…) IE: Editorial comment which label elements required under this Regulation ~~that~~ are allowed to be provided	Regarding the reference to "vulnerable groups", we would suggest the use of a more specific/targeted expression such as "people with disabilities", although this is also a very large concept. In our view, the main disabilities to be considered in this regard, would be visual impairment, colorblindness, etc. This text is adjusted with the Article 34b, (e). When speaking about websites, the information is normally referenced as accessible, and this concept is widely used.
(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	BE: (13) ~~**In order to adapt t**~~The label elements allowed to be provided only in a digital format **and the technical requirements for the**	BE: Adaptation of the recitals with the suggested review clause

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.	**digital labelling should be reviewed, in accordance with this Regulation, to assess whether** ~~**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 **should be extended and whether the technical requirements for the digital labelling should be further specified. This review should be conducted on the basis on an in-depth analysis, in close cooperation with the Member States, and in consultation with relevant stakeholders.**	
(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.	BE: ~~**(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.**~~	BE: Adaptation of the recitals with the suggested review clause

Subgroup A3. Refill sales		
Articles in A3		
(2c) in Article 2, the following points *[7a and 38]* to 41 are added:		
[…]		
40. 'refill' means an operation by which a consumer or a professional user fills its own **package** ~~container, which fulfils the packaging function,~~ with a hazardous substance or mixture offered by a supplier **in the course of an industrial or professional activity** ~~in the context of a commercial transaction~~.	DK: 40. 'refill' means an operation by which a consumer or a professional user fills ~~***its own***~~ ***a*** **package** ~~container, which fulfils the packaging function,~~ with a hazardous substance or mixture offered by a supplier **in the course of an industrial or professional activity** ~~in the context of a commercial transaction~~. EL: We propose the following change:	DK: Please see our comments to point j1). Furthermore, we refer to our comments under Annex II, Part 5 on the definition of service stations. EL: Justification: For safety reasons. As we have

	‘refill’ means an operation by which a ***consumer’s or a professional user’s*** ~~fills its~~ own package, ***or a package provided by the supplier is filled*** with a hazardous substance or mixture offered by a supplier in the course of an industrial or professional activity. FR: 40. ‘refill’ means an operation by which a consumer or a professional user fills ~~**its own**~~ **an appropriate and secure**~~-~~ package with a hazardous substance or mixture offered by a supplier in the course of an industrial or professional activity. PT: 40. ‘refill’ means an operation by which a consumer or a professional user fills ~~**a its own**~~ **package** ~~container, which fulfils the packaging function,~~ ~~**with a hazardous substance or mixture**~~ offered by a supplier **in the course of an industrial or professional activity** ~~in the context of a commercial transaction~~.	already supported, the filling must be done either automatically by a machine or by the supplier in a refill station. The passive voice (***is filled)*** is in alignment to the relevant definition of the legislative proposal for detergents. In addition, a possibility to exchange a consumer’s or a professional’s own package with a suitable clean package provided by the supplier should not be excluded. In this case a recycling of the packages is achieved. FI: FI: scrutiny reservation: we are waiting for the new wording replacing term “own”. IT: agree FR: The container cannot be chosen by the consumer itself. A consumer may use an inappropriate container. For example a container that is normally used for food products such as bottles of sodas or fruit juice or jars of jam. A CLP compliant container must be made available by the supplier, **at**

		least for the first purchase. Consumers cannot determine on their own which container will be suitable for the product purchased. This container provided by the supplier shall also bear CLP compliant labelling. PT: PT welcomes the inclusion of definitions of "refill" and "refill station", and also of the word "package" instead of "container, which fulfils the packaging function", as it is clearer and more specific. We consider, however, that the reference to "its own package" is not appropriate as the refill activity could involve the customer container or a container provided by the shop. We therefore propose to delete the word "own". Additionally, we consider that the reference to "with **a hazardous** substance or mixture" should be removed. Please note that the packaging definition (article 2 (36)) does not include this reference. IE: We had commented previously that saying *'fills its own container'* suggests that the only option is for a consumer/professional user to

		take their own container to the refill station which will not always be the case. We had suggested to change the text to *...consumer or a professional user fills **a** package* . At the WG meeting on May 31st, CION explained that the intention behind this wording is that the package should be for the consumers own use rather than their own package per se that the consumer brings to the refill station; it is still for the consumers own use even if they did not own it themselves. We now understand the intention behind the wording and while it could be interpreted in the way that CION intends, we nonetheless feel that at a minimum the intention will need to be explained in guidance. To avoid any ambiguity in interpretation, we would suggest amending the wording to something along the lines of: '*refill' means an operation by which a consumer or a professional user themselves fills packaging with a hazardous substance or mixture offered by a supplier in the course of an industrial or professional activity* . And we actually think that 'themselves' could even be superfluous here.

41. ‘refill station’ means a place where a supplier offers to consumers or professional users hazardous substances or mixtures that can be **acquired**~~purchased~~ through refill**, either manually or through automatic or semi-automatic equipment**.’;	DE: 41. ‘refill station’ means a ~~place~~ **setup** ~~where~~ **through which** a supplier offers to consumers or professional users hazardous substances or mixtures that can be **acquired**~~purchased~~ through refill**, either manually or through automatic or semi-automatic equipment**.’; PT: 41. ‘refill station’ means a place where a supplier offers to consumers or professional users ~~**hazardous**~~ substances or mixtures that can be **acquired**~~purchased~~ through refill**, either manually or through automatic or semi-automatic equipment**.’	DE: We acknowledge that the definition of a refill station has been becoming clearer and is more in line of the definition of “refill” in the draft detergent regulation. However, the phrasing “refill station means a place […]”, especially with the amendment of “[…] manually or through […] equipment.” still suggests that the refill station is a geographical place, like a gas station, or the store as such. In combination with the newly proposed provisions for labelling of the refill station, this is considered to be confusing. At least in the case where (semi-)automatic equipment is used, labelling of such equipment would be desired. The definition however states, that the “equipment” is not equal to, but only part of the “refill station”. The proposed amendment would allow to consider different situations in a store or place of purchase as a “refill station”, including not only the equipment in the narrow sense, but also adjoined parts like storage bins for packaging or adjacent walls to display labelling information. PT:

		PT welcomes the revised text in the Presidency Proposal and only has a proposal for amendment. IE: We previously commented in writing on this definition and we are still of the opinion that it may need to be changed. We suggest: *'refill station' means a place where hazardous substances or mixtures are provided to consumers or professional users by a supplier through refill, either manually or through automatic or semi-automatic equipment*
(16) in Article 35, the following paragraph 2a is added:	DE: (15a) Article 35 paragraph 2 subparagraph 4 is replaced by the following: „Where a liquid consumer detergent, as defined in Article 2(1) of Regulation (EC) No 648/2004 of the European Parliament and of the Council1, is contained in a soluble packaging for single use, the additional requirements of section 3.3 of Annex II shall apply.“	DE: Compared to liquid consumer laundry detergents packaged in water-soluble films, liquid detergents for automatic dishwashers for private households packaged in water-soluble films have been available on the market only for a short time. The latter are currently not covered by the requirements of the CLP Regulation, as it only addresses liquid consumer laundry detergents. This type of products for consumer automatic dishwasher

	(16) in Article 35, the following paragraph 2a is added:	detergents is still relatively new on the market. However, it is to be expected that its market share will increase. Therefore, a similar number of poisoning cases can be expected as when liquid detergents packaged in water-soluble films were introduced. For precautionary reasons, and in particular to protect children, poisoning incidents that may be caused by this particular type of product need to be prevented. The extension of the scope of Article 35 paragraph 2 subparagraph 4 to „detergents“ serves the purpose of covering future product developments as well.
	EL: We propose the addition in art. 35(2) subparagraph 4, of the text in bold: *Where a liquid consumer laundry and **dishwasher** detergent, as defined in Article 2(1a) of Regulation (EC) No 648/2004 of the European Parliament and of the Council, is contained in a soluble packaging for single use, the additional requirements of section 3.3 of Annex II shall apply*.	EL: Justification: Because there is not only liquid consumer laundry detergent in a soluble packaging for single use. In recent years innovative products have been introduced in the market such as liquid ***dishwasher*** *detergents for a single use which have gained a significant market share.*
‘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.		

This paragraph shall not apply to hazardous substances or mixtures supplied to the general public without packaging in accordance with Article 29(3).'; Changes to Annex II in A3 (1) in Part 3, the following Section 3.4. is added: '3.4. Supply via ~~R~~refill stations When h~~H~~azardous substances or mixtures are supplied ~~referred to~~ in accordance with Article 35(2a), the supplier shall ensure that ~~meet~~ the following conditions are met: (a) the refill station shall carry ~~a the~~ label~~s~~~~ling~~ corresponding to the label~~s~~ for each~~and packaging requirements applicable at the date of placing on the market of the~~ hazardous substance or mixture supplied at the ~~are fulfilled for every refill~~ station;	DE: (0) in Part 3, Section 3.3. is amended: The term "laundry detergents" is replaced by the term "detergents" in each case. (1) in Part 3, the following Section 3.4. is added: PT: (a) the refill station shall carry **and provide a** ~~a the~~ label~~s~~~~ling~~ corresponding to the label~~s~~ for each~~and packaging requirements applicable at the date of placing on the market of the~~ hazardous substance or mixture supplied at the ~~are fulfilled for every refill~~ station;	PT: We support the comments of other MS regarding the need to provide the label to be fixed in the container when necessary for substances or mixture supplied via refill stations. See proposal for amendment.

(b) ~~a~~the ~~label or~~ labels on the refill station shall be~~is~~ firmly affixed **horizontally** on a visible place ~~of the refill station~~ and fulfil the requirements in Article 31 **paragraphs 2 to 4 mutatis mutandis** ~~with a font size that is easily legible and without serifs~~;	FI: FI: Please remove the Latin expression "*mutatis mutandis*" and use English	FI: FI: The legal text should be easily read by all actors without expertise in legal terminology in Latin. PT: PT welcomes the amendment to include "paragraphs 2 to 4" in the text. However, we consider that it should also be included a reference to the minimum font size required for the refill station. Additionally we consider that this font size may be different than the font size established in Section 1.2.1.4 in Annex I which is dependent on the capacity of the package and not related to refill station. Section 1.2.1.4 should be adapted to include these requirements.
~~(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;~~	EL: We do not agree with the deletion	DK: Denmark does not support the deletion of this provision and refers to our general remarks as set out under point f1). EL:

		Justification: the deletion reduces the level of protection of human health and the environment
~~(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;~~	EL: We do not agree with the deletion	DK: Denmark does not support the deletion of this provision and refers to our general remarks as set out under point f1). EL: Justification: the deletion reduces the level of protection of human health and the environment
~~(e) overfilling packaging is technically prevented;~~	EL: We do not agree with the deletion	DK: Denmark does not support the deletion of this provision and refers to our general remarks as set out under point f1).
~~(f) filling a substance or mixture into unsuitable packaging is technically prevented;~~	EL: We do not agree with the deletion	DK: Denmark does not support the deletion of this

		provision and refers to our general remarks as set out under point f1). EL: Justification: the deletion reduces the level of protection of human health and the environment
(f1) risk mitigation measures are applied to ensure that exposure of humans, especially of children, **and the environment** is avoided **as far as possible**~~or, if not possible, minimized~~;	EL: We propose the deletion of the phrase: "as far as possible"	DK: Denmark is disappointed to see that points c)-f), i) and j) have not been reintroduced in the compromise text. Denmark argued for a greater specificity in the safety criteria relating to refill stations. The formulation put forward in point f1) leaves too much room to interpretation, which makes enforcement of these important safety criteria significantly harder for enforcement agencies. While there may well have been room for even greater specificity for these provisions, the nature of the restrictions were clearly sensible and manageable restrictions for suppliers. Furthermore concrete rules are not only easier for enforcement agencies; they also provide certainty for suppliers.

		Denmark is thus unclear as to the rationale for compressing the safety criteria relating to the handling of hazardous substances by non-professional users into a more loosely defined provision in the form of point f1). As such, we oppose the decision not to reintroduce points c), d), e), and f) in the compromise text and ask the Presidency to put forward the reasoning for this change. Similarly we remain opposed to the decision to not reinstate points i) and j). EL: <u>Justification:</u> For safety reasons, especially for the protection of children. PL: Poland would like to raise some concerns regarding term “risk mitigation measures”. Such general term is open to the interpretation and may cause serious enforcement difficulties among member states. Some explanations has been added to the recital, however in the future such explanation will not be visible in the consolidated text. Therefore, this provision needs to be developed

		in more precise manner.
(g) at the moment of refill, the supplier is ~~reachable~~available on site for **maintenance and** immediate **assistance**~~routine and~~**, including** emergency assistance;		IT: Hanno aggiunto manutenzione. ☺ Come da noi suggeito. *We deem important to clarify at the least in the guidance:* *- what the real supplier is: it could be appropriate to refer the "Final distributor" that is responsible for refill station and be able to do maintenance;* *- who emergency assistance involves, in particular this task should be referred to the person that has the same task under OSH legislation.* IR: Sulla manutenzione forse esula dal campo di applicazione del CLP e forse non è chiaro ma se si mantiene va chiarito PT: PT welcomes the amendments made in Presidency proposal.

		IE: Is a requirement for maintenance outside the scope of CLP? It suggest maintenance of the machine itself i.e. if it stops working; a link to CLP is not clear. If it stays in the legal text, then guidance on its scope will be required.
(h) ~~refill stations are not operated outdoors and outside business hours where immediate assistance cannot be provided;~~	AT: (h) refill stations are not operated outdoors	AT: We are in favour of keeping the original proposal that refilling stations should not be operated outdoors.
~~(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: Denmark does not support the deletion of this provision and refers to our general remarks as set out under point f1). EL: <u>Justification:</u> the deletion reduces the level of protection of human health and the environment
(j) ~~staff of the supplier are~~		DK:

~~appropriately trained to minimise safety risks to consumers, professional users and themselves, and follow the necessary hygiene and cleaning protocols;~~		Denmark does not support the deletion of this provision and refers to our general remarks as set out under point f1). EL: Justification: the deletion reduces the level of protection of human health and the environment
(j1) **for every refilled package,** the requirements on hazard communication in the form of labelling set out in Title III **of this Regulation** are fulfilled ~~for every refilled package~~;	DK: (j1) **for every refilled package,** the requirements on hazard communication in the form of labelling set out in Title III **of this Regulation** are fulfilled ~~for every refilled package~~***, including the provision of a label to the refill station user at the time of a refilling, which the supplier shall ensure is applied to the refilled package***;	DK: We were pleased to hear from both the Commission and the Presidency at the working party meeting of 31 May that the intention behind the provision is to ensure that refill station users receive a label that meets the criteria set out in Article 17(1) – and that the Commission believes that this condition is fulfilled. However, our concern relates to the reference to "own package" in the definition of refill in Article 2(40), which would suggest that the supplier itself does have control of the container used for refill. We have suggested a slight reformulation of Article 2(40), which may go some way to creating greater clarity. However, we have put forward an additional change to j1) to remove doubt as to the

		labelling obligations of suppliers. The same comment applies to point j2). LT: We welcome this change. FR: How can the label be compliant if the user comes with his **own** package? Instructions must be given at least for the first purchase. (see FR comment regarding the definition of "refill") PT: PT supports the amendments made in subparagraphs (j1) e (j2).
(j2) **for every refilled package** the requirements on packaging set out in Title IV **of this Regulation** are fulfilled ~~for every refilled package~~;	DK: (j2) **for every refilled package** the requirements on packaging set out in Title IV **of this Regulation** are fulfilled ~~for every refilled package~~***, including the provision of a label to the refill station user at the time of a refilling, which the supplier shall ensure is***	DK: Please see our comments to point j1) IT:

	applied to the refilled package; IT: (j2) for every refilled package the requirements on packaging set out in Title IV of this Regulation are fulfilled. **Each actors in the supply chain should cooperate for assuring that information about minimal requirement is available and visible at the refill station for a adequate packaging;** FR: Please consider to add the new following paragraph : **'(j3) at least for the first refill, the refill station shall make available package and label compliant with this Regulation for each proposed hazardous substance and mixture.'**	In order to reuse packaging, it is appropriate to give information to the consumer and professional user to avoid inappropriate packaging, unless it is exchanged during the refill operation. In the guidance could be added an example of a minimal decalogue on an appropriate package, for instance the following: - Reclosable - Undamaged or unbroken - Inside clean without residue - avoid shape or design likely to attract for children or to mislead consumers - Avoid similar presentation or a design used for foodstuff or animal feeding stuff or medicinal or cosmetic products - Remove the old label - If in the package is preprinted the UFI, please cover it or delete it FR: How can the package be compliant if the user comes with his **own** package? Instructions must be given at least for the first purchase.

		(see FR comment regarding the definition of "refill") PT: See the comment on subparagraph (j1).
(k) hazardous ~~no~~ substances or mixtures ~~may~~ **shall** not be provided at ~~through~~ a refill station if ~~meets~~ the criteria for classification in any of the following hazard classes **or differentiations** are met: ***[Please also see separate annotation document ST 9690/23 for steering question from the PCY about striking the right balance in (k)]***	EL: We prefer to include ***skin sensitisation, serious eye damage and specific target organ toxicity in the list in (k).***	DK: With regard to the Presidency's steering question on this matter, Denmark supports the inclusion in the compromise text of all the listed categories under point k). EL: Justification: For safety reasons **LV** answer to the ***PRES Question 2***: In order to protect the non-professional consumers from undesired health risks that can be potentially caused by chemicals, we can support listing of skin sensitization and specific target organ toxicity hazards under Annex II Part 3 Section 3.4. Point (k), specifying appropriate hazard classes (Skin Sensitization Category 1, Specific target organ toxicity Category 1 and 2).

		NL: We posed a few questions in the working party meeting of 31-5 because we started wondering if CLP is the suitable legislation to regulate the substances allowed to be supplied by refill stations; we wonder whether this should be regulated under other regulations where risk or socio-economic analyses would be performed, e.g. REACH. We have agreed to consult the Council Legal Service on these questions. Regarding the list under (k). We have previously stated that we would like to see skin sensitisation omitted from list k, and we stand by this opinion. We believe that refill stations have the potential to reduce packaging waste and find it important that a right balance should be made between facilitating more sustainable sales forms and the protection of the consumer. Considering the fact that refill stations will often be used for cleaning products that contain biocides that will meet the criteria under skin sensitisation, we believe we should look at the risks involved by allowing skin sensitisation to be supplied by refill stations – and we think this small risk can be accepted in light of the purpose of supplying chemicals through refill stations. Also taking into account the following:

		- The consumer will be informed of the hazards by the label on the refill station and on the container. - Some consumers will already be aware of their sensitivity to certain substances, and skin sensitisation is normally an effect that disappears when there's no more exposure. We believe it would be a considerable limitation for refill stations if skin sensitisation is excluded. Regarding STOT SE 3, we do not think this hazard class should be omitted from the list because of the risk of inhalation exposure which cannot be as easily prevented at a refill station. DE: We favour the inclusion of skin sensitisation and STOT SE 1 and 2 in the list of exclusion criteria. However in comparison to other lists (e.g. the newly introduced list in Annex I 1.5.2.4.1.), the inclusion of STOT SE 3 seems disproportionate. Especially considering that at least STOT SE 3 H332 is comparable to Skin Irrit. 2 or Eye Irrit. 2, which are deliberately not included in the list.

		Substances and mixtures classified as skin sensitizing should generally be supplied to consumers as little as possible, and accidental dermal exposure during filling must also be expected in the context of refill sales. The inclusion of STOT SE categories 1 and 2 makes sense, since serious health hazards are involved. This is also reflected in other legislation (e.g. Biocidal products classified as STOT SE 1 cannot be authorised for use by consumers.) PL: Poland identified the issue with fuels sold in jerrycans at filling stations which do not fall within the provisions of Article 29(3). It seems that according to the current proposal, it will be necessary to create two separates stations for the sale of the same fuel intended for receptacle that forms an integral part of a vehicle and for sale in jerrycans for e.g. vehicles that are not authorized to go on the road or other technical equipment. Moreover, the list of substances or mixtures with hazard classes which shall not be provided at a refill station may exclude the possibility to refill jerrycans with fuels. Therefore we suggest to add additional

		exemptions for fuels sold in jerrycans or take a reasonable approach to the hazard classes of substance or mixtures that cannot be provided at refill station. FR: FR is not opposed to the addition of skin sensitisation, specific target organ toxicity, explosive and oxidizing. The retailing of bleach products is not possible in France. As biocidal products, they are not allowed for refill. PT: PT considers that the refilling of products classified as skin sensitisation (any category) could be allowed, in line with industry's concern about the high number of free-to-use consumer products with this classification, taking in consideration that in our view the refilling activity by itself does not constitute a higher risk than the risk of domestic use. Thus, we can, in principle, support the removal of this classification from the list (k). It should be noted in this regard that Skin corrosion/irritation, category 2, was also not included in the list (k).

		We do not support the removal of the classification *Specific target organ toxicity – Single exposure*, since it is a classification by single exposure, whose severity deserves particular attention in terms of conditions of use and exposure. Although we understand the concern expressed by Austria regarding substances classified as STOT SE Cat. 3 H335 (May cause respiratory irritation), we believe that this danger cannot be overlooked. We therefore propose to keep this entry in list (k) as planned: "(ii) Specific target organ toxicity – Single exposure, any category".
(i) Acute toxicity, **any** categor~~y~~**ies** ~~1 – 4~~;		
[(ii) Specific target organ toxicity – Single exposure, **any** categor~~y~~**ies** ~~1, 2 and 3~~;**]**	IT: (ii) Specific target organ toxicity – Single exposure, ~~**any**~~ categor**ies** 1, 2 SI: ~~[(ii) Specific target organ toxicity – Single exposure, **any** categor~~**y**~~ies 1, 2 and 3;]~~ DE:	BE: BE supports this hazard class in point k. Even if some products could be excluded from refill sales on this basis, this would there encourage their substitution by less hazardous products. IT:

	[(ii) Specific target organ toxicity – Single exposure, ~~any~~ categor~~y~~ies 1~~,~~ and 2 ~~and 3~~;] AT: (ii) Specific target organ toxicity – Single exposure, categories 1, 2 and category 3, if classified with H336 (narcotic effect)	We agree to allow the refill for STOT 3 only SI: We support the deletion of this hazard, as we share the concerns for refill sales of detergents. DE: See comment above. We agree with the inclusion of STOT SE Categories 1 and 2. PT: As already mentioned before, PT can´t support the removal of this entry. AT: The proposal to prohibit certain substances in refill stations also includes substances labelled STOT SE 3, H335, which are contained in detergents. In order to allow the refilling of such detergents, it would have to be considered to exclude H 335 from the prohibition. The effects of substances/mixtures classified as H335 (respiratory tract irritation) are comparable to substances/mixtures classified as irritant for eyes and skin, which are allowed

		for refill sale.
(iii) Specific target organ toxicity – repeated exposure, **any** category~~ies 1 and 2~~;		
(iv) Skin corrosion/irritation, category 1 (sub-categories 1A, 1B and 1C);	FI: FI: Please remove the word "irritation"	FI: FI: The aim is to only exclude chemicals that are corrosive, not those that can cause skin irritation. Also, in the section with the Serious eye damage, eye irritation is left out.
(iv-bis) Serious eye damage, category 1;		
(v) Respiratory sensitisation, **any** category ~~1 (sub-categories 1A and 1B)~~;		
[(v-bis) Skin sensitisation, **any** category ~~1 (sub-categories 1A, 1B)~~;]	FI: FI: Please leave out Skin sensitation hazard class IT: ***delete***	BE: BE supports this hazard class in point k. Even if some products could be excluded from refill sales on this basis, this would there encourage their substitution by less hazardous products.

	SI: ~~[(v bis) Skin sensitisation, **any** category 1 (sub-categories 1A, 1B);]~~	DK: Denmark supports the inclusion of this category and asks that the square brackets are removed. FI: FI: The same safety measures must be taken whether the chemical is supplied at a refill station or received as packed by the supplier, therefore we think that the hazard class Skin sensitisation can be removed from the list. IT: We have doubts about to prohibit the refill of skin sensitisation classified product, because being a property that has effects on already predisposed subjects, we believe that the ban on the sale of these products by a refill station would be excessive compared to the real benefit, especially when exposure to the product is limited as in this case SI: We support the deletion of this hazard, as we share the concerns for refill sales of detergents

		DE: We agree. See comment above LT: We have flexible position regarding skin sensitisation. A lot of consumers are using products classified as skin sensitisers, the hazard will be communicated in the refill station, so the risk should be minimised. Seeking to reduce the amount of packaging waste it should be allowed to purchase these products through a refill station. PL: By way of compromise Poland suggest to delete this hazard class. Such a pragmatic approach will allow the sale of detergents and reduce the amount of packaging. Leaving such a provision would make it possible to limit the sale of allergenic detergents, while cosmetics that would have the same effect would be sold in refill stations. PT: As already mentioned before, PT can support

		the removal of this classification from the list (k).
(vi) Aspiration hazard;		
(vii) Germ cell mutagenicity, any category;		
(viii) Carcinogenicity, any category;		
(ix) Reproductive toxicity, any category;		
(x) Flammable gases, **any** category~~ies 1A, 1B and 2~~;		
(xi) Flammable liquids, categories 1 and 2;		
(xii) Flammable solids, **any** category~~ies 1 and 2~~.**;**		
(xiii) [insert: Endocrine disruption~~or~~ for human health, **any** category~~ies 1 and 2~~]~~.~~**'**;		DK: Denmark supports the inclusion of this category and asks that the square brackets are removed.

(xiv) [insert: Endocrine disrupt**ion**~~or~~ for the environment, **any** category ~~1 and 2~~];		DK: Denmark supports the inclusion of this category and asks that the square brackets are removed.
(xv) [insert: Persistent, **B**~~b~~ioaccumulative and **T**~~t~~oxic ~~(PBT)~~];		DK: Denmark supports the inclusion of this category and asks that the square brackets are removed.
(xvi) [insert: Very **P**~~p~~ersistent and **V**~~v~~ery **B**~~b~~ioaccumulative ~~(vPvB)~~];		DK: Denmark supports the inclusion of this category and asks that the square brackets are removed.
(xvii) [insert: Persistent, **M**~~m~~obile and **T**~~t~~oxic ~~(PMT)~~];		DK: Denmark supports the inclusion of this category and asks that the square brackets are removed.
(xviii) [insert Very **P**~~p~~ersistent and **V**~~v~~ery **M**~~m~~obile ~~(vPvM)~~].		DK: Denmark supports the inclusion of this category and asks that the square brackets are

		removed. IE: On the inclusion/non-inclusion of certain hazard classes, we commented in writing following the last meeting that consideration should be given to allowing the inclusion of hazard classes that are already 'out there' in commonly used consumer products. We are not sure as to what is the difference between buying a product on the shelf in a supermarket and buying it through a refill station and using it as a consumer/professional user, with respect to risk (provided that the provisions with respect to packaging and labelling are complied with for the re-filled product as per this section). Regarding skin sensitization, we would be open to its non-inclusion. Consumers are likely using products classified as skin sensitisers purchased by other means than through a refill station and should be aware of how to handle and use these products safely. We are conscious of getting the balance right here between being protective on the one hand versus ensuring that the aims of this section can be fulfilled and that we do not exclude products for which it is the intention to provide them via refill sales and it is safe to do so, on the other hand. We also need to bear in mind the aims of the circular economy and the

		benefits that providing products via refill stations can bring in that regard.
By way of derogation from point (a~~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.’;	FR: By way of derogation from point (a), a single **easily legible** 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, **including additional EUH statements**, provided that the label clearly indicates the name of each substance or mixture that it applies to. **This display must avoid the risk of confusion between the various substances or mixtures proposed**.	FR: 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 (EUH 208) in the compositions of the products will be different.
Recitals relating to A3:		
(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	IE: Editorial suggestion: in order to ensure safety and the protection of human health **and the environment.** We feel this addition is needed considering that PBTs are included in list.	BE: BE supports the inclusion of the prevention of contamination in the risk mitigation measures, as it is one of the most important risks linked to refill sales. Next to the microbiological issue, it covers the risk of contamination by residues in reused packagings. FR:

substances of mixtures meeting the criteria for classification in those hazard classes and categories, in order to ensure safety and the protection of human health. Risk mitigation measures should be in place to ensure that refill can be performed safely, for example by preventing overfilling**, contamination** and operation by children as well as avoiding reaction between substances and mixtures provided through the station, or with residues in refilled packages.		If the specific measures are no longer mentioned in the section 3.4 of Annex II, there should be guidelines to support small operators in the implementation of this new risk mitigation measures provision. It should be noted that the CLP Regulation does not impose an expiry date, a batch number or a microbiological quality requirement for products. Storage or durability periods may, however, be imposed by sectoral regulations such as the biocides regulation or the building products regulation. Currently, no expiry date is imposed on detergents.
Subgroup A4. Online sales	FR: Please consider to add the following article 48b: **"Statements such as 'non-toxic', 'non-harmful', 'non-polluting', 'ecological' or any other statements indicating that the substance or mixture is not hazardous or any other statements that are inconsistent with the classification of that substance or mixture shall not appear on advertisements or offers of any substance or mixture."**	FR: This double prohibition exists in the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012): the statements prohibited on the label are also prohibited in advertisements. It should be the same for the CLP regulation.
Articles in A4		
(3) in Article 4, ~~paragraph 10 is replaced by~~ the following paragraph 11 is added:	IT:	IT:

	in Article 4, paragraph 10 is replaced by the following: "10. A substance or a mixture shall not be placed on the market unless a supplier has ensured in the course of an industrial or professional activity that the substance or the mixture fulfils the requirements set out in this Regulation."	we return back on the initial proposal of the commission because what indicated in paragraph 4(11) continue to rise doubts on its applicability .
'10. ~~A substance or a mixture shall not be placed on the market unless~~ .		
11. A natural or legal person established outside the Community can place substances and mixtures on the market only if it ensures that a supplier in the Community ~~has ensured~~ in the course of an industrial or professional activity ~~that the substance or the mixture~~ fulfils the requirements set out in this Regulation with regard to the substances and mixtures in question.';	DK: 11. A natural or legal person established outside the Community can place substances and mixtures on the market only if it ensures that a supplier in the Community ~~has ensured~~ in the course of an industrial or professional activity ~~that the substance or the mixture~~ fulfils the requirements set out in this Regulation with regard to the substances and mixtures in question. ***Details of the supplier that has ensured compliance with this Regulation must be presented upon the label as well as the product passport, in the event that other Union legislation requires the use of a***	DK: Denmark is encouraged to see that the Presidency's proposal for Article 4(11) has been retained. Establishing a legal duty for economic actors based outside of the Union is a vital step towards ensuring a level playing field for CLP-compliant suppliers within the Union as well as protecting consumers and environment against the risks of hazardous chemical products. The issue of enforcement still remains. Denmark would ask the Presidency to once again consider the use of product passports as a means of documenting CLP-compliance, as we propose in our suggestion for alteration of the compromise text. Our compromise proposal

	product passport for the substance or mixture in question. Substances or mixtures that do not meet these requirements may be confiscated by customs authorities.; IT: (3) in Article 4, the following paragraph 11 is added: ~~A natural or legal person established outside the Community can place substances and mixtures on the market only if it ensures that a supplier in the Community in the course of an industrial or professional activity fulfils the requirements set out in this Regulation with regard to the substances and mixtures in question~~.' **A natural or legal person established outside the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on supplier under this Regulation, differently any other supplier established in the Community, including a market place, fulfils the requirements set out in this Regulation.**	also takes accounts of the suggestion put forward by Austria with regard to providing details of the supplier in the Union that is to be held responsible for compliance with the CLP regulation. A positive documentary requirement, which identifies both the supplier within the EU and sets out documentary evidence confirming compliance with the CLP, would aid enforcement of this provision. FI: FI: in our opinion the term "supplier" should not be used here in order to avoid confusion, and the coherence with other relevant legislation should be ensured. Also, as expressed by other MSs, we also question the enforceability, and hence the relevance of this provision. IT: As general comment we agree with the intention of this paragraph , anyway we try to rewording. **LV**: As stated in the corresponding Recital 1 of the compromise text the aim is to avoid situations where a consumer becomes *de jure*

		and *de facto* an importer when buying substances and mixtures from third countries via distance sales. We still do not understand how this obligation will be implemented and enforced from a practical perspective. We are highly concerned that the result of such obligation will place fair-minded importers, who will have established their representatives in the EU, in an unequal position comparing to dishonest ones. This might push the fair-minded importers towards entering a shadow economy and this obligation might turn out in a result opposite to the pursued objective. LT: The wording of Article 4(11) still may lead to difficulties in ensuring the enforcement, as responsibility is imposed on the third-country supplier and not on the EU supplier. PT: PT has some doubts about the feasibility and enforcement of this rule. IE: We appreciate the explanation provided by PRES as to why no changes have been made to this article at the WG meeting on May 31st.

		However, we still have concerns on this article, especially on its enforceability. We commented in writing following the last meeting that by stating that *A natural or legal person established outside the Community can place substances and mixtures on the market only if it ensures that*…. appears to place a legal obligation on the non-EU supplier. The interpretation would be that if the person outside the EU does not ensure that an EU supplier fulfils the obligations of the Regulation then there is a breach of the Regulation. But, that breach would lie with the person who had to ensure something needed to be done/in place –i.e. the non EU-person. If this is the case, then this obligation cannot be enforced under CLP, as the duty holder is outside the EU. In our opinion, the legal text must give legal responsibility to an EU legal entity so that enforcement action can be taken on an EU entity. It is not clear as to with which actor the legal obligation rests. A link between the non-EU company and the EU supplier responsible for ensuring compliance of the product placed in the EU market is missing. Using the term '**a** supplier' could be interpreted as meaning any supplier in

		the EU, as opposed to one directly linked to the non-EU company supplying that substance or mixture. We suggest 2 options for text for consideration, with option 1 being our preferred option: Option 1: *A supplier established in the Community, in the course of an industrial or professional activity, must fulfil the requirements set out in this Regulation with regard to hazardous substances or mixtures which originate from outside the EU and placed on the market via on-line sales* Option 2: *Hazardous substances and mixtures which originate from outside the EU shall not be placed on the market via on-line sales unless a supplier in the Community, in the course of an industrial or professional activity, fulfils the requirements set out in this Regulation with regard to the hazardous substances or mixtures in question.*
(23) Article 48 is replaced by the following:		
‘*Article 48*		
Advertisement	FR:	

	Please consider to add a definition of advertisement in article 2: **"advertisement is understood as being at the pre-stage of offers, notably as information designed to promote messages of a natural or legal person, whether or not against remuneration"**	
1. Any advertisement for a substance classified as hazardous shall indicate the relevant hazard pictograms, ~~the~~ signal word, ~~the hazard class and the~~ hazard statements and supplemental EUH statements set out in Annex II.	FR: Any advertisement for a substance classified as hazardous shall indicate the ~~**relevant**~~ hazard pictograms, signal word, hazard statements and supplemental EUH statements set out in Annex II. PT: 1. Any advertisement for a substance classified as hazardous shall indicate the relevant hazard pictograms, the signal word, ~~the hazard class and~~ the hazard statements and supplemental ~~**EUH**~~ **hazard** statements set out in Annex II.	IT: If we focus on an advertisement for only one product we agree, anyway we request examples in guidance when the advertisement is for more products FR: The term "relevant" introduces an ambiguity and may be interpreted differently by operators. In our view, all the pictograms provided for in clause 17 should be mentioned. Clause 26 already provides for priority rules. PT: PT proposes an editorial amendment in order to adjust to the terminology used thought the CLP Regulation, namely in article 38, 40 and annex II Part I title: "supplemental EUH

		statements" to "supplemental hazard statements".
2. Any advertisement for a mixture classified as hazardous or covered by Article 25(6) shall indicate the relevant hazard pictograms, ~~the~~ signal word, ~~the hazard class and the~~ hazard statements and supplemental EUH statements set out in Annex II.	FR: Any advertisement for a mixture classified as hazardous or covered by Article 25(6) shall indicate the ~~**relevant**~~ hazard pictograms, signal word, hazard statements and supplemental EUH statements set out in Annex II. PT: 2. Any advertisement for a mixture classified as hazardous or covered by Article 25(6) shall indicate the relevant hazard pictogram**s**, the signal word, ~~the hazard class and~~ the hazard statements and supplemental ~~**EUH**~~ **hazard** statements set out in Annex II. AT: Any advertisement for a mixture classified as hazardous or covered by Article 25(6) shall indicate the relevant hazard pictograms and the signal word~~, the hazard class and the hazard statements~~ **and supplemental EUH**	FR: The term "relevant" introduces an ambiguity and may be interpreted differently by operators. In our view, all the pictograms provided for in clause 17 should be mentioned. Clause 26 already provides for priority rules. PT: PT proposes an editorial amendment in order to adjust to the terminology used thought the CLP Regulation, namely in article 38, 40 and annex II Part I title: "supplemental EUH statements" to "supplemental hazard statements". AT: We welcome the deletion of the hazard classes and still consider the hazard statements for mixtures to be inappropriate and disproportionate in relation to online purchases.

	~~**statements set out in Annex II**~~.	
3. By way of derogation from paragraph 1 and 2, the hazard pictograms and signal word may be omitted where the advertisement is non-visual.**';**		
(24) the following Article 48a is added:		
'*Article 48a*		
Distance sales offers	FR: Please consider to add a definition of offer in article 2: **"offer is understood as invitation by a natural or legal person to conclude a purchase contract"**	
Suppliers placing substances or mixtures on the market through distance sales shall~~, within the offer,~~ clearly and visibly indicate **in the offer** the label elements referred to in Article 17.';	DK: ***Suppliers and legal or physical persons established outside the Community*** placing substances or mixtures on the market through distance sales shall~~, within the offer,~~ clearly and visibly indicate **in the offer** the label elements referred to in Article 17. ***OR***	DK: Despite the assurances given at the working party meeting of 31st May, Denmark restates once again our concerns on the wording of Article 48a, where the requirements on distance sales offers apply only to suppliers. Yet again, we see it as a positive sign, that the concerns we have raised relate to issues where we believe our intentions are aligned – that the rules on online sales offers apply to all. And

	Offers for substances or mixtures that are placed ~~Suppliers placing substances or mixtures~~ on the market through distance sales shall~~, within the offer,~~ clearly and visibly indicate **in the offer** the label elements referred to in Article 17.'; ***2. Online platforms subject to Regulation (EU) 2022/2065 that facilitate the distance sales of substances or mixtures subject to this regulation, but neither satisfy the definition of a supplier nor of placing on the market, must ensure their platforms are designed in a way to ensure sellers comply with the labelling requirements set out in this Regulation.*** **LV**: We propose to supplement Article 48a with additional paragraph 2 as follows: *2. The sales offer shall be written in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.* *Suppliers may use more languages in their sales offers than those required by the Member States, provided that the same details appear in all languages used.* DE: Suppliers **offering** substances or mixtures **for sale** on the market through distance sales shall, clearly and visibly indicate in the offer the label elements referred to in Article 17.';	although we were encouraged to hear, that the Commission believes that this problem is solved with the current wording of the compromise text, we put forward our concerns once again in order to make sure this issue is settled. As recognized in Article 4(11), third country sellers also target consumers within the EU, yet they do not fall within the definition of a supplier. As these legal or physical persons established outside of the Union are then not required to comply with the requirement in Article 48a, these sellers are as such not in breach of the provision. It then remains uncertain as to what requirement this in turn imposes upon the supplier named in Article 4(11). In a similar vein, a third country seller may leave the process of operating an online sales channel in the hands of an online platform, where the online platform does not easily fit within the definition of a supplier under the CLP. As such, Denmark suggests that Article 48a is reformulated with the intention of clarifying that the duty set out in Article 48a applies regardless of the place of establishment of the economic actor. This could for instance be achieved through one of the following two means.

		The first method could be through the expansion of the legal subject in article 48a from "suppliers" to "suppliers and natural or legal persons outside the Community". The second method could be to reformulate Article 48a along the lines of Article 48, which instead of being targeted against a particular economic actor is applicable for all advertisements regardless of the identity or place of establishment of the advertiser. The advantage of this second method would be, that the "distance sales offer" itself is regulated, potentially better enabling the use of webpage blocking in the enforcement of this provision. Furthermore, the requirements relating to distance sales ought also apply to online marketplaces, which may or may not fall under the definition of a supplier or with regard to placing on the market – the two key conditions set out under Article 48(1). As such, Denmark suggests the inclusion of a second subparagraph relating to the responsibilities of online platforms. This second paragraph would strengthen and clarify the requirements in Recital 30 relating to online platforms under the Digital Services Act to ensure that platforms are designed in a manner so as to ensure compliance with Union product legislation.

		LV: We are quite cautious about the enforceability of requirements for distance selling offers as set in Article 48a. Although there is a reference to Article 17, it still cannot be certainly concluded from this reference in which language or languages of the Member State the labeling elements should be indicated in the distance sales offers. For the sake of clarity and appropriate enforcement, we propose to supplement Article 48a by indicating the language or languages in which distance sales offers should be presented. DE: The amendment should clarify that Article 48a specifically refers to the offer stage and does not require the proof of a product being actually shipped to the customer. The term "making available" as a subcategory of "placing on the market" depends in case of distant sales sometimes on the actual shipment of the goods (see blue guide p. 22). To avoid any possible margins for misinterpretation, the offering should be the key element. FR: FR supports the addition of the obligation of legibility of offers on the internet. Some vendors put pictures of the CLP labelling but

		these are not readable when zoomed.
	DE: **For the purpose of this regulation, Article 22 of Regulation [GPSR] shall also be applicable to the infringement of any requirement of this regulation.**	DE: In Article 22 of the "Regulation on General Product Safety", special obligations for online marketplaces for dangerous products have been provided for. It would be necessary that corresponding obligations for online marketplaces apply in all cases of infringement of the CLP Regulation, even if the infringement is initially of a formal nature and does not directly lead to a "dangerous product". In order to close this regulatory gap in the CLP Regulation, corresponding obligations for online marketplaces to eliminate also formal infringements should be included in the CLP Regulation.
<u>Recitals relating to A4</u>		
(1) In order to keep pace with globalisation, technological development and new means of sale, such as online sales, it is necessary to adapt Regulation (EC) No 1272/2008 of the European Parliament and of the Council. While under that Regulation it is assumed that all responsible actors in the supply chain are established in the Union, practical experience has shown that economic operators established outside the Union sell chemicals online directly to the general public in the Union.	DK: (1) In order to keep pace with globalisation, technological development and new means of sale, such as online sales, it is necessary to adapt Regulation (EC) No 1272/2008 of the European Parliament and of the Council. While under that Regulation it is assumed that all responsible actors in the supply chain are established in the Union, practical experience	DK: Denmark recognises the need to examine enforcement issues related to the new provisions on online sales. However, these enforcement issues must not act as a barrier for adopting rules in this area. We believe that there are solutions in this area, where perhaps horizontal rules in other EU legislation can play a role. Therefore, Denmark proposes that

Hence, enforcement authorities are unable to enforce Regulation (EC) No 1272/2008 against economic operators not established in the Union. It is therefore appropriate to require that there is a supplier established in the Union, which ensures that the substance or the mixture in question meets the requirements set out in that Regulation when it is being placed on the market, including via distance sales, such as via online market places. This provision, together with requirements in [Proposal for a Regulation of the European Parliament and of the Council on General Product Safety], Regulation (EU) 2022/2065 of the European Parliament and of the Council on a Single Market For Digital Services and Regulation (EU) 2019/1020 of the European Parliament and of the Council on Market Surveillance and Compliance of Products, would improve compliance with and enforcement of the Regulation (EC) No 1272~~7~~/2008 and thereby ensure a high level of protection of human health and the environment. In order to ~~prevent~~ **avoid** situations where consumer becomes *de jure* and *de facto* an importer when buying the substance or the mixture via distance sales from the economic operators established outside the Union, it is necessary to specify that the supplier which ensures that the substance or the mixture in question meets the requirements set out in that Regulation acts in course of an industrial or professional activity.	has shown that economic operators established outside the Union sell chemicals online directly to the general public in the Union. Hence, enforcement authorities are unable to enforce Regulation (EC) No 1272/2008 against economic operators not established in the Union. It is therefore appropriate to require that there is a supplier established in the Union, which ensures that the substance or the mixture in question meets the requirements set out in that Regulation when it is being placed on the market, including via distance sales, such as via online market places. This provision, together with requirements in [Proposal for a Regulation of the European Parliament and of the Council on General Product Safety], Regulation (EU) 2022/2065 of the European Parliament and of the Council on a Single Market For Digital Services and Regulation (EU) 2019/1020 of the European Parliament and of the Council on Market Surveillance and Compliance of Products, would improve compliance with and enforcement of the Regulation (EC) No 1272~~7~~/2008 and thereby ensure a high level of protection of human health and the environment. In order to ~~prevent~~ **avoid** situations where consumer becomes *de jure* and *de facto* an importer when buying the substance or the mixture via distance sales from the economic operators established outside the Union, it is necessary to specify that the supplier which ensures that the substance or the mixture in question meets the	Member States should share their experiences on these issues – potentially via CARACAL – with a view to producing a report on best practice and Member States' experiences with enforcement. The report could also prove to be a catalyst for future minor adjustments to the Regulation.

	requirements set out in that Regulation acts in course of an industrial or professional activity. ***Given the complexity of the subject matter in question, the Commission will ask Member States to share their experiences with regard to the enforcement of the new provisions on online sales. The Commission will collate these experiences in a report, which will be presented to Member States no later than three years after the coming into effect of this regulation, with a view to sharing best practice on this matter and potential barriers to enforcement.*** IE: Editorial comment; ~~Hence~~, ~~e~~**E**nforcement authorities	
(29) Regulation (EC) No 1272/2008 regulates advertisement of hazardous substances and mixtures in a general manner and provides that an advertisement for a substance classified as hazardous is to mention the hazard classes or hazard categories concerned, and an advertisement for a mixture classified as hazardous or a mixture containing a classified substance is to mention the types of hazards indicated on the label where such advertisement allows concluding a contract for purchase without first having sight of the label. This obligation should be changed to ensure	PT: (29) Regulation (EC) No 1272/2008 regulates advertisement of hazardous substances and mixtures in a general manner and provides that an advertisement for a substance classified as hazardous is to mention the hazard classes or hazard categories concerned, and an advertisement for a mixture classified as hazardous or a mixture containing a classified substance is to mention the types of hazards indicated on the label where such	PT: PT proposes an editorial amendment in order to adjust to the terminology used thought the CLP Regulation: "supplemental EUH statements" to "supplemental hazard statements".

that the advertisement of hazardous substances and mixtures contains all the information which is most important in terms of safety and protection of ~~the~~ human health and the environment. Therefore, the advertisement should contain the hazard pictogram, the signal word~~, the hazard class and~~ the hazard statements **and supplemental EUH statements, with derogations for non-visual advertisement**. The hazard category should not be provided, as it is reflected by the hazard statement.	advertisement allows concluding a contract for purchase without first having sight of the label. This obligation should be changed to ensure that the advertisement of hazardous substances and mixtures contains all the information which is most important in terms of safety and protection of ~~the~~ human health and the environment. Therefore, the advertisement should contain the hazard pictogram, the signal word~~, the hazard class and~~ the hazard statements **and supplemental ~~EUH~~ hazard statements, with derogations for non-visual advertisement**. The hazard category should not be provided, as it is reflected by the hazard statement.	
(30) Regulation (EC) No 1272/2008 does not explicitly refer to offers, let alone to distance sales offers. Consequently, it does not address specific problems arising from distance sales, such as online sales. Whereas advertisements is understood as being at the pre-stage of offers, notably as information designed to promote messages of a natural or legal person, whether or not against remuneration, offers are understood as invitations by a natural or legal person to conclude a purchase contract. This differentiation should justify the requirement of providing more hazard information in offers than in advertisements. In order to keep pace with technological development and new means of sale, it is necessary to require the		

labelling elements to be indicated in case of distance sales, including via online market places, in order for the compliance by design obligations laid down for providers of online marketplaces in Article 31 of Regulation (EU) 2022/2065 of the European Parliament and of the Council[3] ~~should~~ to apply ~~for the purpose of~~ in relation to such labelling information ~~required by Article 17 of Regulation (EC) No 1272/2008~~. The enforcement of those obligations is subject to the rules laid down in Chapter IV of Regulation (EU) 2022/2065.		
Cluster B – Classification		
Subgroup B1. Rules on Classification		
Articles in B1		
(2b) in Article 2, the following points *[~~7a and~~]* 38 *[to 41]* are added:		
[…]		
38. ‘acute toxicity estimates’ means numeric values which are used to classify~~criteria according to which~~ substances		

[3] Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act) (OJ L 277, 27.10.2022, p. 1).

and mixtures ~~are classified~~ in one of four acute toxicity hazard categories based on the oral, dermal or inhalation exposure route.’;		
(5) in Article 6, paragraphs 3 and 4 are replaced by the following:		
‘3. For the evaluation of mixtures pursuant to C~~c~~hapter 2 of this Title in relation to the ‘germ cell mutagenicity’, ‘carcinogenicity’, ‘reproductive toxicity’, ‘endocrine disruption~~g property~~ for human health’ and ‘endocrine disruption~~g property~~ for the environment’ hazard classes referred to in sections 3.5.3.1, 3.6.3.1, 3.7.3.1, 3.11.3.1 and 4.2.3.1 of Annex I, the manufacturer, importer or downstream user shall only use the relevant available information referred to in paragraph 1 for the substances in the mixture and not for the mixture itself.		FI: :
~~However, w~~**W**here the available test data on the mixture itself demonstrates germ cell mutagenic, carcinogenic or toxic to reproduction properties, or endocrine disruption~~g properties~~ for human health or the environment which have not been identified from the relevant available information on the individual substance referred to in the first subparagraph, that data shall also be taken into account for the purposes of the evaluation of the mixture referred to in the first subparagraph.		

4. For the evaluation of mixtures pursuant to Chapter 2 of this Title in relation to the 'biodegradation, persistency, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment', 'persistent, bioaccumulative and toxic[2]~~,~~ or ~~'~~very persistent and very bioaccumulative properties', 'persistent, mobile and toxic[2] ~~and~~or ~~'~~very persistent and very mobile properties' hazard classes referred to in sections 4.1.2.8, 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall only use the relevant available information referred to in paragraph 1 for the substances in the mixture and not for the mixture itself**.**'; FI: FI: please replace term biodegradation with term rapid degradation PT: 4. For the evaluation of mixtures pursuant to Chapter 2 of this Title in relation to the '**~~biodegradation~~ rapid degradability**, persistency, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment', 'persistent, bioaccumulative and toxic[2]~~,~~ or ~~'~~very persistent and very bioaccumulative properties', 'persistent, mobile and toxic[2] ~~and~~ or ~~'~~very persistent and very mobile properties' hazard classes referred to in sections 4.1.2.8, 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall only use the relevant available information referred to in paragraph 1 for the substances in the mixture and not for the mixture itself**.**'; FI: FI: as commented already earlier, we propose the change to "rapid degradability" because we assume that this refers to the rapid degradability criterion for the aquatic chronic toxicity classification, which takes into account both biotic and abiotic degradation. Please note, that "rapid degradability" is not the same as "ready biodegradability". The latter term refers to a specific type of tests (the ready biodegradability tests) and the results/conclusion from those tests. The fulfilment of "rapidly degradable" can be demonstrated by a ready biodegradability test but also by other types of data. PT: PT proposes to change "biodegradation" to "rapid degradability" to align with the title in 4.1.2.9 of Annex I.
(6) in Article 9, paragraphs 3 and 4 are replaced by the following:		

‘3. Where the criteria referred to in paragraph 1 cannot be applied directly to available identified information, manufacturers, importers and downstream users shall carry out an evaluation by applying a weight of evidence determination using expert judgement in accordance with section 1.1.1 of Annex I to this Regulation, weighing all available information having a bearing on the determination of the hazards of the substance or the mixture, and in accordance with section 1.2 of Annex XI to Regulation (EC) No 1907/2006.	DE: 3. Where the criteria referred to in paragraph 1 cannot be applied directly to **all** available identified information**, or where hazards are defined by multiple criteria**, manufacturers, importers and downstream users shall carry out an evaluation by applying a weight of evidence determination using expert judgement in accordance with section 1.1.1 of Annex I to this Regulation, weighing all available information **across all individual and relevant criteria** having a bearing on the determination of the hazards of the substance or the mixture, and in accordance with section 1.2 of Annex XI to Regulation (EC) No 1907/2006.	DE: We support the proposed amendment of the EP. “Where more comprehensive and more refined data are available for the assessment of substances, these data should be used in the hazard classification process to avoid false negative as well as false positive results. Otherwise, safe substances could be considered hazardous and banned from the use in Europe under chemicals legislation relying on the CLP Regulation, putting competitiveness of European producers at risk while leading to more imports of finished products from other geographic areas.”
4. When evaluating hazard information for mixtures, manufacturers, importers and downstream users shall, where test data for the mixture itself are inadequate or unavailable, apply the bridging principles referred to in section 1.1.3. of Annex I and in each section of Parts 3 and 4 of that Annex for the purposes of the evaluation.		
If more than one similar tested mixture is available ~~W~~when applying the bridging principles, manufacturers, importers and downstream users may ~~integrate~~ apply a weight of evidence determination using expert	NL: If more than one similar tested mixture is available ~~W~~when applying the bridging	NL: We would like to reiterate the importance of

judgement in accordance with section 1.1.1. of Annex I to this Regulation, weighing all available information having a bearing on the determination of the hazards of the mixture, and in accordance with section 1.2. of Annex XI to Regulation (EC) No 1907/2006 to select the most suitable similar tested mixture**s according to Article 6(5)** for decision on classification. ~~The rules on bridging principles in section 1.1.3 of Annex I shall in this case remain applicable even in a weight of evidence determination~~.	principles, manufacturers, importers and downstream users ~~**may**~~ **shall** ~~integrate~~ apply a weight of evidence determination using expert judgement in accordance with section 1.1.1. of Annex I to this Regulation, weighing all available information having a bearing on the determination of the hazards of the mixture, and in accordance with section 1.2. of Annex XI to Regulation (EC) No 1907/2006 to select the most suitable similar tested mixture**s according to Article 6(5)** for decision on classification. ~~The rules on bridging principles in section 1.1.3 of Annex I shall in this case remain applicable even in a weight of evidence determination~~.	changing MAY to SHALL in the first sentence of paragraph 4, to clarify that it is mandatory to apply the weight of evidence determination when if more than one similar tested mixture is available (to select the most suitable similar tested mixture or mixtures). The wording is such that it only requires the weight of evidence approach if data is available on more than one similar tested mixture. So no "far fetched" impact is expected.
When evaluating the hazard information for mixtures, manufacturers, importers and downstream users shall, where that information does not permit the application of the bridging principles in accordance with the first and second subparagraphs, evaluate the information by applying the other method or methods set out in Parts 3 and 4 of Annex I.';	NL: When evaluating the hazard information for mixtures, manufacturers, importers and downstream users shall, where that information does not permit the application of the bridging principles in accordance with the first and second subparagraphs, evaluate the information by applying the other method or methods set out in Parts 3 and 4 of Annex I.';	
(7) Article 10 is replaced by the following:		
'*Article 10*		

Concentration limits, M-factors and acute toxicity estimates for classification of substances and mixtures		
1. Specific concentration limits and generic concentration limits are limits assigned to a substance indicating a threshold at or above which the presence of that substance in another substance or in a mixture as an identified impurity, additive or individual constituent leads to the classification of the substance or mixture as hazardous.		
Specific concentration limits shall be set by the manufacturer, importer or downstream user where adequate and reliable scientific information shows that the hazard of a substance is evident when ~~the~~ **such a** substance is present at a level below the concentrations set for any hazard class in Part 2 of Annex I or below the generic concentration limits set for any hazard class in Parts 3, 4 and 5 of Annex I.	DE: Specific concentration limits shall be set by the manufacturer, importer or downstream user where adequate and reliable scientific information shows that the hazard of a substance is evident when ~~the~~ **such a** substance is present at a level below the concentrations set for any hazard class in Part 2 of Annex I or below the generic concentration limits set for any hazard class in Parts 3~~, 4~~ and 5, as well as hazard classes 4.2 in Part 2, of Annex I.	DE: We propose to clarify, that for the new Hazard classes for PBT/vPvB and PMT/vPvM no specific concentrations limits can be set, as agreed during the discussions at CARACAL between Participants and COM.
Manufacturers, importer or downstream users may set a specific concentration limit of a substance ~~I~~in exceptional circumstances ~~specific concentration limits may be set by the manufacturer, importer or downstream user~~ where ~~that manufacturer, importer or~~	DE: **Manufacturers, importer or downstream users may set a specific concentration limit of a substance** ~~I~~in exceptional circumstances	DE: We propose to clarify, that for the new Hazard classes for PBT/vPvB and PMT/vPvM no

~~downstream user has~~ adequate, reliable and conclusive scientific information **shows** that ~~a~~ **the** hazard of a substance classified as hazardous is not evident at a level above the concentrations set for the relevant hazard class in Part 2 of Annex I or above the generic concentration limits set for the relevant hazard class in Parts 3, 4 and 5 of that Annex.	~~specific concentration limits may be set by the manufacturer, importer or downstream user~~ where ~~that manufacturer, importer or downstream user has~~ adequate, reliable and conclusive scientific information **shows** that ~~a~~ **the** hazard of a substance classified as hazardous is not evident at a level above the concentrations set for the relevant hazard class in Part 2 of Annex I or above the generic concentration limits set for the relevant hazard class in Parts 3~~, 4~~ and 5, as well as hazard class 4.2 in Part 2, of Annex I.	specific concentrations limits can be set, as agreed during the discussions at CARACAL between Participants and COM.
2. **Manufacturers, importers and downstream users shall establish** M-factors for substances classified as hazardous to the aquatic environment, acute category 1 or chronic category 1~~, shall be established by manufacturers, importers and downstream users~~.		
3. Acute toxicity estimates for substances classified as acutely toxic for human health shall be established by manufacturers, importers and downstream users.		
4. By way of derogation from paragraph 1, **second and third subparagraph,** specific concentration limits shall not be set for harmonised hazard classes or differentiations		PT: PT welcomes the clarification.

for substances included in Part 3 of Annex VI ~~for which a specific concentration limit is given in that Part~~.		
5. By way of derogation from paragraph 2, M-factors shall not be established for harmonised hazard classes or differentiations for substances included in Part 3 of Annex VI for which an M-factor is given in that Part.		
However, where an M-factor is not given in Part 3 of Annex VI for substances classified as hazardous to the aquatic environment, acute category 1 or chronic category 1, an M-factor based on available data for the substance shall be set by the manufacturer, importer or downstream user. When a mixture including the substance is classified by the manufacturer, importer or downstream user using the summation method, this M-factor shall be used.		IT: It appear more consistent in paragraph 5
6. By way of derogation from paragraph 3, acute toxicity estimates shall not be established for harmonised hazard classes or differentiations for substances included in Part 3 of Annex VI for which an acute toxicity estimate is given in that Part.		
7. When setting the specific concentration limit, M-factor or acute toxicity estimate,		

manufacturers, importers and downstream users shall take into account any specific concentration limits, M-factors or acute toxicity estimate for that substance which have been included in the classification and labelling inventory.		
~~However, where an M-factor is not given in Part 3 of Annex VI for substances classified as hazardous to the aquatic environment, acute category 1 or chronic category 1, an M-factor based on available data for the substance shall be set by the manufacturer, importer or downstream user. When a mixture including the substance is classified by the manufacturer, importer or downstream user using the summation method, this M-factor shall be used.~~		
8. Specific concentration limits set in accordance with paragraph 1**, second and third subparagraph,** shall take precedence over the concentration limits set out in the relevant sections of Part 2 of Annex I or the generic concentration limits for classification set out in the relevant sections of Parts 3, 4 and 5 of that Annex.		
9. The Agency shall provide further guidance for the application of paragraphs 1, 2 and 3.		

10. Where a mixture contains a substance which is classified as hazardous solely due to the presence of an identified impurity, additive or individual constituent, the concentration limits referred to in paragraph 1**, second and third subparagraph,** shall apply to the concentration of that identified impurity, additive or individual constituent in the mixture.		
11. Where a mixture contains another mixture, the concentration limits referred to in paragraph 1**, second and third subparagraph,** shall apply to the concentration of the identified impurity, additive or individual constituent referred to in paragraph 10 in the resulting final mixture.’;		
(19) In Article 38(1), point (c) is replaced by the following:		
‘(c) the specific concentration limits, M-factors or acute toxicity estimates, where applicable;’;		
Changes to Annex I in B1		
(1) Section 1.1.1.3. is replaced by the following:		
‘1.1.1.3. A weight of evidence determination means that all available		

information bearing on the determination of hazard is considered together, such as the results of suitable in vitro tests, relevant animal data, human experience such as occupational data and data from accident databases, epidemiological and clinical studies and well-documented case reports and observations. For substances, information from the application of the category approach (grouping, read-across) and (Q)SAR results are also considered. The quality and consistency of the data shall be given appropriate weight. Information on substances related to the substance being classified shall be considered, as appropriate. Information on substances or mixtures related to the mixture being classified shall be considered in accordance with Article 9(4). Information on the site of action and the mechanism or mode of action study results shall also be considered. Both positive and negative results shall be assembled together in a single weight of evidence determination.’;		
<u>Recitals relating to B1</u>		
(4) In order to improve legal certainty and implementation with regard to the evaluation of hazard information for mixtures where no or inadequate test data are available for the mixture itself, the interaction between the application of the bridging principles and a weight of evidence determination using expert judgement should be clarified. Such	DE: (4) In order to improve legal certainty and implementation with regard to the evaluation of hazard information for mixtures where no or inadequate test data are available for the mixture itself, the interaction between	DE: We support the proposed amendment of the EP. “Where more comprehensive and more refined data is available for the assessment of

clarification should ensure that the weight of evidence determination complements but does not substitute the application of the bridging principles. It should also be clarified that if bridging principles cannot be applied to evaluate a mixture, manufacturers, importers and downstream users should use the calculation method or other methods described in Parts 3 and 4 of Annex I to Regulation (EC) No 1272/2008. It should also be clarified which criteria, when not met, determine when a weight of evidence determination using expert judgment is to be carried out.	the application of the bridging principles and a weight of evidence determination using expert judgement should be clarified. Such clarification should ensure that the weight of evidence determination complements but does not substitute the application of the bridging principles. It should also be clarified that if bridging principles cannot be applied to evaluate a mixture, manufacturers, importers and downstream users should use the calculation method or other methods described in Parts 3 and 4 of Annex I to Regulation (EC) No 1272/2008. It should also be clarified which criteria, when not met, determine when a weight of evidence determination using expert judgment is to be carried out. **Recognizing that the application of criteria for information on the different hazard classes is not always straightforward and simple, and bearing in mind that a specific hazard class may be defined by multiple criteria, manufacturers, importers and downstream users should apply, as above, weight of evidence determinations involving expert judgement to arrive at adequate results. The weight of evidence should give due consideration to all available information, irrespectively of possibilities for direct comparison with the criteria; it does not mean averaging results, nor it is a worst-case approach. For hazard classes defined by multiple criteria, a single weight**	substances, these data should be also used in the hazard classification process to avoid false negative as well as false positive results. Otherwise, safe substances could be considered hazardous and its use banned in Europe under chemicals legislation relying on the CLP Regulation, putting competitiveness of European producers at risk while leading to more imports of finished products from other geographies, jeopardizing European strategic autonomy.”

	of evidence determination should take into account the individual assessments with regard to each of the criteria as well as any interdependencies between the properties defined by these criteria.	
(5) To avoid over-classification of mixtures which contain substances classified as hazardous solely due to the presence of an impurity, an additive or an individual constituent, and of mixtures which contain other mixtures with such substances, the classification should only be mandatory if such impurity, additive or individual constituent is contained in the mixture or in the final mixture at or above a certain concentration limit as referred to in Annex I to Regulation (EC) No 1272/2008.		
(6) Acute toxicity estimates are mainly used to determine the classification for human health acute toxicity of mixtures containing substances classified for acute toxicity. Substances can be classified in one of four acute toxicity hazard categories based on the oral, dermal or inhalation exposure route according to certain numeric criteria. Acute toxicity values are expressed as (approximate) LD50 (oral, dermal) or LC50 (inhalation) values or as acute toxicity estimates. It is appropriate to specify the meaning of, and further specify, acute toxicity estimates to increase their clarity and consistency. As acute		

toxicity estimates are part of the harmonised classification and labelling elements of substances classified for acute toxicity they should be included in the proposal, opinion and decision for harmonised classification of a substance for acute toxicity. In the same way as M-factors and concentration limits, acute toxicity estimates should, together with a justification, be notified to the Agency in view of their inclusion in the classification and labelling inventory.		
New subgroup B1.a Classification of forms		FR: FR supports the proposals made by the Presidency to clarify the labelling and the classification of specific forms of substance. However, FR regrets that the provisions are limited to clarifying current practices, which does not resolve the difficulties encountered in recent cases such as titanium dioxide in interpreting the concept of intrinsic property. This concept could be defined in the CLP text, as it is already used in the GHS ("the degree of the capacity of a product to harm depends on its intrinsic properties, i.e. its capacity to interfere with normal biological processes and its capacity, for example, to burn, explode and corrode") and mentioned in the CLP ECHA guidance document (2017) in a paragraph relating to physical hazards which introduces the notion of intrinsic property: "hazard

		classification is based on intrinsic properties of the substance or mixture which are determined not only by its physical state but also its form".
Articles in B1a		
(xx) In Article 4, the third paragraph is replaced by the following:	DE: **(xx) in Article 2, the following points [~~7a and 38~~ *to 42]* are added:** **42. 'form of a substance' means the three-dimensional shape of a substance, in particular sphere, tube, platelet, fibre.** **In Article 4, the third paragraph is replaced by the following:**	IT: Concerning the modification on article 4.3 and article 13 we agree, if it is maintained with this formulation. DE: The term "form of a substance", which has not been defined so far, has to be introduced in order to take into account the shape of a substance. This is necessary as the term "form" is already used throughout the regulation with a different meaning. With the introduction of the term the general legislative practice of defining terms already at the beginning of a set of rules is followed and, on the other hand, the introduction of the term is justified due to its importance within the concerned articles. Additionally, the legal certainty will be increased.

3. If a substance is subject to harmonised classification and labelling in accordance with Title V, through an entry in part 3 of Annex VI, that substance shall be classified in accordance with that entry, and a classification of that substance in accordance with Title II shall not be performed for the hazard classes, differentiations and forms or physical states covered by that entry.		DK: Denmark supports the intention behind the addition in cluster B1a. IT:
The harmonised classification of that substance shall apply to all its forms and physical states unless the entry in Part 3 of Annex VI specifies that a harmonised classification applies to a specific form and physical state of that substance.	BE: **The harmonised classification of that substance shall apply to all its forms and physical states unless the entry in Part 3 of Annex VI specifies that a harmonised classification applies to a specific form and physical state of that substance *[, or where a specific form or physical state deserves a more severe classification]*.**	BE: BE proposes to add *[, or where a specific form or physical state deserves a more severe classification]* to article 4(3), second §, in order to ensure that manufacturers, importers and downstream users shall still proceed to self-classifications when specific forms or physical states deserve a more severe classification than foreseen in Part 3 of Annex VI. This would notably be necessary for nanoforms when the harmonised classification of the substance has been based on data coming from its non-nano form.

		In addition, BE still considers that the clarification of the concept of 'intrinsic property' is needed in order to ensure legal certainty for the future application of the CLP Regulation, independently of the ongoing Court Case on titanium dioxide which refers to the current provisions. The Commission already detailed how this concept should be defined in order to align with current practice: 'intrinsic property' should be understood as referring to the intrinsic hazard emanating from both a substance and a certain form or physical state of a substance, including particle toxicity. We see different options to insert the definition of intrinsic property: 1a. A general definition in article 2 1b. A definition in Annex I for the hazard classes concerned 2. A recital explaining why articles 4, 13 [, 37(1) and 37(2)] are adapted in order to point out forms or physical states: proposal: "**In order to ensure that a certain form or physical state of a substance having an impact on its intrinsic hazardous properties is taken into account for its classification, the form and the physical state of a substance should be referred to in the**

		articles setting general principles for classification." We also support the Presidency's proposal to insert a clarification in Article 37(1) and 37(2) stating that both self-classification and harmonised classification are based on the same set of criteria and general principles for classification. IE: Does the word different need to added here? ….that a **different** harmonised classification applies….
However, where the substance also falls within one or more hazard classes or differentiations or it is in a form or physical state not covered by an entry in Part 3 of Annex VI, classification under Title II shall be carried out for those hazard classes or, differentiations and forms or physical states.		
(xx) Article 13 is replaced by the following:		
Article 13		

Decision to classify substances and mixtures		
If the evaluation undertaken pursuant to Article 9 and Article 12 shows that the hazards associated with the substance or mixture meet the criteria for classification in one or more hazard classes or differentiations in Parts 2 to 5 of Annex I, manufacturers, importers and downstream users shall classify the substance or mixture or, if scientifically justified, specific forms or physical states thereof, in relation to the relevant hazard class or classes or differentiations by assigning the following:		DK: Denmark suggest that a subparagraph is added in order to specify that no classification is needed in regards to eg. Skin Irritation H315, Eye irritation H319 or STOT SE 3; H335.if the effect is only seen because of "mechanical" action. Since it is not relevant to classify based on all forms or physical states, we find that it could be beneficial to a further text in order to illustrate what is meant by "specific forms or physical states", for example poorly soluble low toxicity (PSLT) particles could be listed. IT:
(a) one or more hazard categories for each relevant hazard class or differentiation;		
(b) subject to Article 21, one or more hazard statements corresponding to each		FI:

hazard category assigned in accordance with (a).		FI: this codification should also be reflected in the recitals.
	BE: Recital relating to B1a: ***In order to ensure that a certain form or physical state of a substance having an impact on its intrinsic hazardous properties is taken into account for its classification, the form and the physical state of a substance should be referred to in the articles setting general principles for classification.***	BE: See comment on article B1a hereabove.
Subgroup B2. MOCS		PT: PT has a scrutiny reservation on Subgroup B2 (MOCS).
Articles in B2		
[Please see also separate annotation document ST 9690/23 for steering question from the PCY on MOCS]	EL: We support the combination of option B and C	DK: The Presidency asks in the annotations if the delegations can support their suggested package regarding MOCS. Denmark can support the wording on MOCS but have outstanding issues with how and to what extent

		the revised rules for evaluating substances with more than one constituent might affect the current process within RAC and the CA's. The Commission mentioned at the WP THC on May 31st that the current wording of the compromise text will codify current practice. However, we have been alerted to the fact that ECHA is of the opinion that biocide active substances will now be considered to be subject to classification according to the calculation rules on the basis of its constituents and hence, the evaluation practice will change. Would it be possible to further illuminate why ECHA would have this opinion, when the opinion of the Commission seems to be that there is no change in how active substances are assessed? We attach the presentation from ECHA in which the opinion is presented. **LV** answer to ***PRES Question 3***: We can support PRES proposed way forward. We believe that inclusion of explanation to the Recital 2 (Option B) and clarification and settlement of conditions for the laying down of specific provisions in Annex I (Option C) will address the issue with MOCSs. In addition, we support the idea of extending the transition period as well. NL:

		We support the new Presidency Compromise Proposal text on MOCS. We find it important that derogation is made possible for situations where there is adequate and reliable scientific argumentation. We do not support the insertion of a general derogation, e.g. for essential oils and/or UVCBs because we do not believe there is, currently, any scientific reason to treat essential oils and/or UVCBs differently from other substances containing more than one constituent. We believe derogations should be based on a case-by-case scientific assessment. We prefer not to have an increased transition period requiring adherence to the new paragraph in article 5. We are not sure what the added value would be to include an increased delay for this amendment specifically. If justified however, we would not object a longer transition period either. LT: We support the changes of the provision combining options B and C. We can be flexible regarding a transitional period to delay the date of application for the provisions in Article 5(3).

		PL: We want to emphasize that the discussion on the derogation for MOC should be on scientific base only, not on politics. The purpose of introducing Art. 5 (3) is to clarify the existing provisions of art. 11 of the CLP Regulation. In our opinion, all work should aim at clarifying these obligations, not complicating them. The current proposal introduces the possibility to amend Annex I by adding specific provisions through the delegated act procedure. It has been stressed in many discussions and fora that the delegated acts procedure is intended for non-essential elements of a legislative act, so we have concerns if that procedure is appropriate in that case. In the spirit of compromise we can support the proposal of combine options B (adding an explanation to Recital 2) and C (Article 5(3) explaining the process and specifying the conditions for establishing specific provisions in Annex I), however specific provisions must be included in the text of the proposal. The text should indicate that : • each case of derogation will be assessed cas-by-case, • socio-economic impacts will not be

		taken into account, • exemptions will not be limited to the specific applications. We would like to point out that the process of establishing specific requirements (derogations) should be based on full transparent procedures. It should be also clarified who can apply for such exemptions. PT: PT has a scrutiny reservation on Subgroup B2 (MOCS). AT: we would like to wait for the upcoming meeting on MOCS-CLP regulation, 14/6/2023 and the discussions befor commenting further
(2a) in Article 2, the following points ~~7a~~ *[and 38* ***to 41****]* are added:		
‘7a. ~~‘multi-constituent substance’ means a substance that contains more than one constituent.~~		
(4) in Article 5, the following paragraph 3 is added:		

'3. A ~~multi-constituent~~ substance containing ~~at least~~more than one constituent, in the form of an individual constituent, an identified impurity or an additive for which relevant information referred to in paragraph 1 is available, shall be examined in accordance with the criteria set out in this paragraph, using the available information on those constituents as well as on the substance**. When the criteria set out in this paragraph are not suitable for certain substances containing more than one constituent, the Commission shall, in light of all relevant information on the concerned substances, use the procedure referred to in Article 53 to amend Annex I to lay down specific provisions**~~, [unless Annex I lays down a specific provision]~~.	BE: '3. A ~~multi-constituent~~ substance containing ~~at least~~more than one constituent, in the form of an individual constituent, an identified impurity or an additive for which relevant information referred to in paragraph 1 is available, shall be examined in accordance with the criteria set out in this paragraph, using the available information on those constituents as well as on the substance**. When *[an opinion of the Committee for Risk Assessment concludes that]* the criteria set out in this paragraph are not suitable for certain substances containing more than one constituent, the Commission shall, in light of *[this opinion]*** ~~all relevant information on the concerned substances~~**, use the procedure referred to in Article 53 to amend Annex I to lay down specific provisions**~~, [unless Annex I lays down a specific provision]~~. IT: '3. A substance containing more than one constituent, in the form of an individual constituent, an identified impurity or an additive for which relevant information referred to in paragraph 1 is available, shall be	BE: BE supports the clarification of the process for exemptions to the provisions of article 5(3). In order to ensure that exemptions are based on scientific criteria determined by the Risk Assessment Committee, we propose an adaptation of the wording of article 5(3) and of the corresponding recital. BG: We would like to thank the Presidency for all efforts to improve the text, however for us the derogation under Annex I is still remain uncertain and problematik due to the following elements: – who makes the assessment regarding whether the criteria are suitable for specific substances?; – if this is the industry, it is not legally clear what evidence is required, how and to whom this information is provided - there is no procedure for this, timeframe and scope are unclear (one or grope of substances, one or more classes); – the decision on whether to propose a derogation depends entirely on the Commission's discretion, it is not clear

	examined in accordance with the criteria set out in this paragraph, using the available information on those constituents as well as on the substance. When the criteria set out in this paragraph are not suitable for certain substances containing more than one constituent, the Commission shall, in light of all relevant information on the concerned substances, **such as the availability of data on substance itself already realised and evaluated**, use the procedure referred to in Article 53 to amend Annex I to lay down specific provisions, ~~,~~	when RAC provides an opinion and whether the Commission will consider it; it is imperative to delay the date of application of paragraph 3 - the transitional period of **4-5 years** have to be envisaged in order enough time to be provided for the preparation and submission of dossier, its assessment by RAC, the elaboration, consultation and adaptation of the delegated act by the EC. FI: FI has no position yet. IT: The proposal of the Presidency with the possibility of derogations appears acceptable **if combined with the proposal to postpone** the entering in force of article 5(3), because this would allow accurate evaluations on the possible derogations. From the point of view of the enter in force (article 2) we prefere 42 months. Anyway we continue to underline that if a reliable study on a substance itself is already produced also for other regulations and evaluated (registration reach or PPP, biocide) it should be used. So it would be essential to consider including in Annex I and in the

		recitals a general principle to safeguard tests and data already realised and evaluated. PT: PT has a specific scrutiny reservation on this.
For the evaluation of ~~multi-constituent~~ substances containing more than one constituent pursuant to Chapter 2 of this Title in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine disruption~~g property~~ for human health' and 'endocrine disruption~~g property~~ for the environment' hazard classes referred to in sections 3.5.3.1, 3.6.3.1, 3.7.3.1, 3.11.3.1. and 4.2.3.1. of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual constituents in the substance.	IT: For the evaluation of substances containing more than one constituent pursuant to Chapter 2 of this Title in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine disruption for human health' and 'endocrine disruption for the environment' hazard classes referred to in sections 3.5.3.1, 3.6.3.1, 3.7.3.1, 3.11.3.1. and 4.2.3.1. of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the **known** individual constituents in the substance.	IT: It is not always possible to know every single constituent of the chemical composition of substances (e.g. UVCB). We should avoid additional testing to identify unknown constituents
Relevant available information on the ~~multi-constituent~~ substance itself shall be taken into account where one of the following conditions are met:		
(a) the information demonstrates germ cell mutagenic, carcinogenic, or toxic to		

reproduction properties, or endocrine disruption~~g properties~~ for human health or the environment;		
(b) the information supports the conclusions based on the relevant available information on the constituents in the substance.		
Relevant available information on the ~~multi-constituent~~ substance itself showing absence of ~~certain~~ the properties referred to in (a) or less severe properties shall not override the relevant available information on the constituents in the substance.		
For the evaluation of ~~multi-constituent~~ substances containing more than one constituent pursuant to Chapter 2 of this Title in relation to the 'biodegradation, persistence, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment', 'persistent, bioaccumulative and toxic'~~,~~ or '~~-~~very persistent and very bioaccumulative', 'persistent, mobile and toxic'~~,~~ ~~and~~ or '~~-~~very persistent and very mobile' hazard classes referred to in sections 4.1.2.8, 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual constituents in the substance.	IT: For the evaluation of substances containing more than one constituent pursuant to Chapter 2 of this Title in relation to the 'biodegradation, persistence, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment', 'persistent, bioaccumulative and toxic or very persistent and very bioaccumulative', 'persistent, mobile and toxic -or very persistent and very mobile' hazard classes referred to in sections 4.1.2.8, 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall use the relevant available information	IT: It is not always possible to know every single constituent of the chemical composition of substances (e.g. UVCB). We should avoid additional testing to identify unknown constituents

	referred to in paragraph 1 for each of the **known** individual constituents in the substance.	
Relevant available information on the ~~multi-constituent~~ substance itself shall be taken into account where one of the following conditions are met:		
(a) the information demonstrates ~~biodegradation,~~ persistence, mobility, ~~and~~ bioaccumulation properties **or** ~~and~~ lack of **(rapid)** biodegradation.	FI: FI: please replace term biodegradation with term rapid degradation	FI: FI: as commented already earlier, we propose the change to “rapid degradability” because we assume that this refers to the rapid degradability criterion for the aquatic chronic toxicity classification, which takes into account both biotic and abiotic degradation. Please note, that “rapid degradability” is not the same as “ready biodegradability”. The latter term refers to a specific type of tests (the ready biodegradability tests) and the results/conclusion from those tests. The fulfilment of “rapidly degradable” can be demonstrated by a ready biodegradability test but also by other types of data.
(b) the information supports the conclusions based on the relevant available information on the constituents in the		

substance.		
Relevant available information on the ~~multi-constituent~~ substance itself showing absence of ~~certain~~ the properties referred to in (a) or less severe properties shall not override the relevant available information on the constituents in the substance.**';**		
	BG: **(4a) in Article 5, the following paragraph 4 is added:** **"Paragraph 3 shall not apply to UVCB substances of biological origin."** SI: 4. Paragraph 3 shall not apply to UVCB substances of biological origin.	BG: We consider that the criteria set out in this paragraph are **not suitable** for that specific group of substances (see our doc. **WK 7254/2023**). Currently, there is sufficient scientifically substantiated data that justify and necessitate the exclusion of UVCB substances of biological origin. SI: We share the concerns of some Member states regarding the possible new classification procedure of essential oils, as we are particularly bothered by the fact that proposed derogation for mentioned substances under Annex I is not certain and clear enough. Therefore we support BG proposal (from BG Non-paper) to introduce clear derogation already into Article 5 by adding following paragraph 4: *"Paragraph 3 shall not apply to*

		UVCB substances of biological origin."
Recitals relating to B2*:*		
(2) From a toxicological point of view, substances ~~with~~ **containing** more than one constituent ~~('multi-constituent substances')~~ are no different from mixtures composed of two or more substances. In accordance with Article 13 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[4], aimed to limit animal testing, data on **substances containing more than one constituent** ~~multi-constituent substances~~ is to be generated under the same conditions as data on any other substance, while data on individual constituents of a substance is normally not to be generated, except where individual constituents are also substances registered on their own. Where data on individual constituents is available, **substances containing more than one constituent**~~multi-constituent substances~~ should be evaluated and classified following the same classification rules as mixtures, unless **a delegated act amending** Annex I to Regulation (EC) No		

[4] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

1272/2008 **and containing** ~~provides for a~~ specific provision**s** for those ~~multi-constituent~~ substances **is adopted**.		
Specific provisions could be provided into Annex I on the basis of adequate and reliable scientific argumentation. Such derogations would be needed for cases where using data on constituents and calculation rules would result in a less appropriate classification of the complex substances than by using data on the substance itself. This could be the case for example when a complex substance contains only structurally similar constituents or when there is proof of antagonistic effects among constituents. When necessary, an opinion of the Risk Assessment Committee should provide an assessment of the scientific argumentation.	BE: **Specific provisions could be provided into Annex I on the basis of adequate and reliable scientific argumentation. Such derogations would be needed for cases where using data on constituents and calculation rules would result in a less appropriate classification of the complex substances than by using data on the substance itself. This could be the case for example when a complex substance contains** ~~only structurally similar constituents or when there is proof of antagonistic effects among constituents. When necessary, an opinion of the Risk Assessment Committee should provide an assessment of the scientific argumentation~~ ***[constituents interacting with each other. Such interactions could have an impact on the hazard of the whole substance, notably when antagonistic effects occur. The scientific criteria for the derogations should be based on the opinion of the Risk Assessment Committee.]*****.** IT:	BE: See comments on article 5(3). IT: In general, we underline the importance to use recent studies already done under the European legislation (REACH, PPP, biocide) and already evaluated under the relevant processes, in order to classify these substances in an adequate and reliable manner (also to “declassify” the substance itself). DE: Please provide a more detailed explanation of how a derogation mechanism with specific provision will look like. IE: The term *complex substance* is not in the text so far. Propose changing to *substance with*

	Specific provisions could be provided into Annex I on the basis of adequate and reliable scientific argumentation. Such derogations would be needed for cases where using data on constituents and calculation rules would result in a less appropriate classification of the complex substances than by using data on the substance itself. This could be the case for example when a complex substance contains only structurally similar constituents or when there is proof of antagonistic effects among constituents or **when data on substance itself are already evaluated under other legislative procedure (e.g. Compliance check and CORAP of the regulation (CE) n.1907/2006, Autorisathion process of the regulation (UE) 528/2012, Authorisation process of the (UE) 1107/2009).** When necessary, an opinion of the Risk Assessment Committee should provide an assessment of the scientific argumentation. IE: Editorial comment: could be provided int~~o~~ Annex I	*more than one constituent* for consistency
(3) It is normally not possible to sufficiently assess the endocrine disrupting properties for human health and the		

environment and the persistent, bioaccumulative and mobile properties of a mixture or of a **substance containing more than one constituent** ~~multi-constituent substance~~ on the basis of data on that mixture or substance. The data for the individual substances of the mixture or for the individual constituents of **substances containing more than one constituent**~~the multi-constituent substance~~ should therefore normally be used as the basis for hazard identification of those **substances containing more than one constituent** ~~multi-constituent substances~~ or mixtures. However, in certain cases, data on those **substances containing more than one constituent**~~multi-constituent substances~~ themselves may also be relevant. This is the case in particular where that data demonstrates endocrine disrupting properties for human health and the environment, as well as persistent, bioaccumulative and mobile properties, or where it supports data on the individual constituents. Therefore, it is appropriate that data on **substances containing more than one constituent**~~multi-constituent substances~~ are used in those cases.		
Cluster C – Regulatory procedures		
Subgroup C1. New Hazard Classes		
Articles in C1		NL:

		Regarding the discussion held on the working party of 2-5 and the open-ended deadline as proposed in the Steering Note ST 9690/23, please find our comments below. In principle, we are in favour of expanding article 37(8) to include substances currently under assessment under the PPPR and BPR. We will be able to support this expansion of article 37(8) if the final opinion is available at the time of adoption. If the final opinion is not available however, we would not support uptake of the particular mixture in CLP. We understand that this potentially introduces a problem that when the cut-off date has passed and the final opinion is published after this date, a transfer would not take place to Annex VI automatically. We would however not support an open-ended deadline as it allows new classifications being proposed outside of the CLP process. It may be better to align the cut-off dates with the dates of the transition periods requiring the new hazard classes to be proposed though CLP or a combined CLP/BPR/PPPR process as laid down in the delegated act with the new hazard classes.

(xx) in Article 18(3), point (b) is replaced by the following:		
'(b) the identity of all substances in the mixture that contribute to the classification of the mixture as regards acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitisation, specific target organ toxicity (STOT), aspiration hazard, or endocrine disruption for human health.'		
(17) in Article 36, paragraph 1 is amended as follows:		
(a) point (a) is replaced by the following:		
'(a) respiratory sensitisation, category 1, 1A or 1B (Annex I, section 3.4.)';		
(b) the following points (e) to (j) are added:		
'(e) endocrine disruption for human health, category 1 or 2 (Annex I, section 3.11.);		
(f) endocrine disruption for the environment, category 1 or 2 (Annex I, section 4.2.);		

(g) persistent, bioaccumulative and toxic ~~(PBT)~~ (Annex I, section 4.3.~~-~~);		
(h) very persistent, very bioaccumulative ~~(vPvB)~~ (Annex I, section 4.3.~~-~~);		
(i) persistent, mobile and toxic ~~(PMT)~~ (Annex I, section 4.4.~~-~~);		
(j) very persistent, very mobile ~~(vPvM)~~ (Annex I, section 4.4)~~.~~’;		
(c) paragraph 2 is replaced by the following:		
‘2. Substances that are active substances falling within the scope of Regulation (EC) No 1107/2009 or Regulation (EU) 528/2012 shall be subject to harmonised classification and labelling. For such substances, the procedures set out in Article 37(1), (4), (5) and (6) shall apply.’;		
(18f) Article 37 is amended as follows:		
[…]		
(f) the following paragraphs ~~7 and 8~~ are inserted:		

‘7. By 1 January 2026, ~~T~~the Commission shall adopt delegated acts in accordance with Article 53a to amend Table 3 of Part 3 of Annex VI to this Regulation by inclusion of substances as endocrine disruption~~or category 1~~ for human health **category 1**~~properties~~, endocrine disruption~~or category 1~~ for **the** environment ~~category~~ **category 1**~~properties~~, as persistent, bioaccumulative and toxic or as very persistent and very bioaccumulative together with relevant classification and labelling elements where, on ~~…~~ [~~OP: please insert the date = the *date of entry into force of Commission Delegated Regulation (EU) …i.e. delegated act on the new hazard classes - reference to be added once adopted*~~ 1 January 2025~~]~~, those substances have been included in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006.		BE: BE supports a more open cut-off date in order to allow for the semi-automatic harmonised classification of substances for which the inclusion in the candidate list won’t be finalised on 1st January 2025. DK: Denmark supports the intention of article 37(7) to transfer substances identified with the new hazard classes under REACH to annex VI in CLP. However, we still find that the same should be the case for substances that are problematic in the environment, such as persistent, mobile and toxic and very persistant and very mobile substances. The addition of such substances would take all the new hazard classes into account. With the transfer of substances from other regulations into CLP, we believe that it is not necessary to reevaluate them. The suggested rule of transferring substances only applies to substances included in the

		candidate list before the entry into force of the new hazard classes. What about the period between the entry into force of the hazard classes and the adoption of the revision — which may take several years? IT: We agree with the timing proposed even if we suggest to check that the criteria on the "new hazard classes" continue to be really all satisfied, before to include the substances in Annex VI Part 3. FR: FR strongly supports this transitional period. PT: Although we consider that the deadline of 1 January 2026 may be sufficient to transpose the substances identified by previous processes under the different regulations (example candidate list) by January 2025, we have doubts whether by January 2025 all SVHC processes initiated without prior CLH will be completed.

		In view of the above, we consider that the deadline of January 2025 should be extended, at least until June 2025, to consider the ongoing dossiers. AT: It has been brought to our attention that substances identified as EDs via a request to MSC for an opinion in accordance with article 77(3) c of REACH are not considered in Art 37 (7) as well as PMT are not considered in Art 37 (7). Does substances identified as EDs via a request to MSC for an opinion in accordance with article 77(3) c of REACH and PMT find consideration under Art 37 (7) CLP? To use resources in an efficient way, the date until transfer of substances already identified as ED/PBT/vPvB and included into the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006 to Table 3 of Part 3 of Annex VI of CLP Regulation needs to be at least the 31. 1. 2025: This date ensures that substances identified at the MSC in December 2024 are still transferred into the CLP regulation by amending Table 3 of Part 3 of Annex VI in accordance with Article 53a of the CLP regulation. Although the OSOA principle is acknowledged, in this period until REACH is amended an efficient transition

		needs to be warranted.
The inclusion of the substances, referred to in the first subparagraph, in Table 3 of Part 3 of Annex VI to this Regulation shall be carried out on the basis of the respective criteria for which those substances have been included in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006.~~2~~		
8. By 1 January 2026, ~~T~~the Commission shall adopt delegated acts in accordance with Article 53a to amend Table 3 of Part 3 of Annex VI by inclusion of substances together with relevant classification and labelling elements where, on ~~… [OP: please insert the date = *the date of entry into force of Commission Delegated Regulation (EU) …i.e. the delegated act on the new hazard classes - reference to be added once adopted*~~ 1 January 2025~~]~~ those substances have not been approved, under Regulation (EC) No 1107/2009 or Regulation (EU) No 528/2012 or have been approved ~~with derogation~~ in accordance with the relevant provisions of those Regulations, due to either of the following characteristics:	EL: In principle we might support the DG SANTE proposal. We are waiting for the new compromise text on the issue, in order to finalize our opinion FR: 8. By 1 January 2026, the Commission shall adopt delegated acts in accordance with Article 53a to amend Table 3 of Part 3 of Annex VI by inclusion of substances together with relevant classification and labelling elements where, on 1 January 2025 **a decision on the approval or the renewal of approval of** those substances **has been adopted** ~~have not been approved~~, under Regulation (EC) No 1107/2009 or Regulation (EU) No 528/2012**, and those substances**	BE: BE supports a more open cut-off date in order to allow for the semi-automatic harmonised classification of substances for which the dossiers won't be finalised on 1st January 2025. DK: Denmark supports that article 37(8) should be formulated in a way that encompasses and respects the processes related to the approval of active substance under Regulation (EC) 1107/2009 and Regulation (EC) No 528/2012. DG SANTE expressed at the WP THC on May 31st that it would not be possible to meet the suggested deadline for BPR. Denmark would like to stress that the best forward is to ensure that the substances are processed without unnecessary delays. With the current time lines suggested many substances under BPR would be on the market for an additional 18 months when

	were identified as having ~~or have been approved in accordance with the relevant provisions of those Regulations, due to~~ either of the following characteristics:	being evaluated as ED or PBT. This is hardly appropriate or the intention with the revision. IT: We agree with the timing proposed even if we suggest to check that the criteria for the "new hazard classes" continue to be really all satisfied, before to include the substances in Annex VI Part 3. LT: We think that all on-going assessments should be transferred to Annex VI of the CLP Regulation when finalised, therefore we prefer the open-ended deadline, proposed by Presidency. FR: Regarding the first change proposed : The terms "have not been approved" are not correct, as it does not catch all the cases. Substances having those properties have been approved under BPR (they are not always banned). Some substances may also benefit from some derogation. A more general reference to the fact that "a decision on the approval or renewal of approval has been adopted", is therefore appropriate. Regarding the second change proposed : The

		decision to approve or not approve a substance is not necessarily "due to the identification as ED or PBT/vPvB". It would be better to simply refer to the fact that the active substances were identified as meeting the criteria under the Biocidal Products Regulation (BPR) and Plant Protection Products Regulation (PPPR).
(a) endocrine disruptor in accordance with Section 3.6.5 or Section 3.8.2 of Annex II to Regulation (EC) No 1107/2009;		
(b) persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with Section 3.7.2. or 3.7.3. of Annex II to Regulation (EC) No 1107/2009;		
(c) endocrine disruptor for human health or for the environment in accordance with Article 1 of Commission Delegated Regulation (EU) 2017/2100[5];		
(d) persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with		

[5] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301 of 17.11.2017 p.1.';

Article 5(1), point (e), of Regulation (EU) No 528/2012.		
The inclusion of the substances, referred to in the first subparagraph, in Table 3 of Part 3 of Annex VI shall be carried out on the basis of the respective criteria that they meet in accordance with the acts referred to in that subparagraph, points (a) to (d).~~,~~	FR: The inclusion of the substances, referred to in the first subparagraph, in Table 3 of Part 3 of Annex VI shall be carried out on the basis of the respective criteria that they meet in accordance with the acts referred to in that subparagraph, points (a) to (d). **The Commission shall also adopt delegated acts for substances for which applications for approval or renewal of approval in accordance with the relevant provisions of Regulation (EC) No 1107/2009 were submitted before or on 1 January 2025. It shall adopt these delegated acts after it has adopted the respective decision on their approval or renewal of approval.** **The Commission shall also adopt such delegated acts for substances for which by the date of 1 January 2025:** **a) the evaluating competent authority has submitted its draft assessment report on the approval or renewal of approval to the Agency in accordance with the relevant provisions of Regulation (EU) No 528/2012,**	FR: FR supports an extension of the transitional period to some active substances for which an assessment is currently on-going under the Plant Protection Product Regulation (PPPR) and/or Biocidal Products Regulation (BPR). Please consider to add the provisions in bold. The first paragraph aims to cover substances under the PPPR, with the objective to cover all-ongoing applications for approval or renewal of approval submitted before a certain date. The delegated acts setting the harmonised classification would be adopted after the decision on the approval/ non-approval is adopted by Commission under the PPPR. The second paragraph aims to cover substances under the BPR for the following cases : a) This provision covers the reports under peer review, for which the report was submitted to ECHA by Member States under BPR since 1st Sept 2013. It can cover applications for approval, or renewal of approval.

	or **b) the application was submitted for the purpose of Directive 98/8/EC and the Member State's evaluation in accordance with that Directive has been completed by 1 September 2013, but no decision on the approval was adopted before that date, or** **c) the Agency has submitted to the Commission an opinion pursuant to Article 75(1)(g) of Regulation (EU) No 528/2012 following a request to establish whether the respective criteria referred to in point (c) and (d) of the first subparagraph are met.** **The Commission shall adopt these delegated acts after it has adopted the respective decision on their approval or renewal of approval, or after the Agency has submitted to the Commission an opinion pursuant to point (c).**	b) This provision covers the reports under peer review which are "backlog reports" submitted by Member States to the Commission prior 1st September2013, but still under peer review at ECHA level today. The wording is inspired by the wording used in Article 90 of the BPR. This provision covers opinions provided by ECHA in the context of early reviews performed under Article 15 of the BPR, like iodine and PVP iodine which are identified as ED category 1 in an ECHA opinion adopted in 2022.
		AT: The clean-up of the minimum classification (* entries of Annex VI) should be considered in the revision. When revising entries, it should be mandatory that all minimum classifications (* entries) are taken into account and cleaned up. On the one hand, a clear improvement of the

		visibility of a minimum classification and the existing obligation to search in the various databases should be created, on the other hand, the minimum classification should also be cleaned up.
Recitals relating to C1		
(17a) As the new hazard classes and criteria introduced by Commission Delegated Regulation[6] allow for the harmonised classification and labelling of substances of the highest concern with regard to health and environment, they should normally be subject to harmonised classification and labelling and added to the list of hazard classes which includes respiratory sensitisation, germ cell mutagenicity, carcinogenicity and reproductive toxicity. Sub-categorisation of the hazard class for respiratory sensitisation in sub-category 1A or 1B should be performed where sufficient information to classify in those hazard sub-categories is available, in order to avoid over- or under-classification.	IE: Editorial comment: regard to **human** health and environment	
[In view of the rapid development of scientific knowledge and the long-standing expertise of the European Chemicals Agency (the 'Agency') and the European Food Safety		

[6] [Commission Delegated Regulation amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures, OJ XX of XX p XX.]

Authority (the 'Authority') on the one hand, and the limited resources of Member States' competent authorities to develop harmonised classification proposals on the other, the Commission should have the right to request the Agency and the Authority to develop a harmonised classification and labelling proposal.]		
(20) The criteria for inclusion of substances in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006 are equivalent to those of certain hazard classes and categories included in Annex I to Regulation (EC) No 1272/2008. In view of the high level of evidence required for inclusion in the candidate list, the substances currently on that list should be included in Table 3 in Part 3 of Annex VI to Regulation (EC) No 1272/2008.		IE: Suggest to indicate in the recital that these substances will be included in Annex VI as Category 1 EDs.
(21) As the criteria for substances to qualify as endocrine disruptor for human health or the environment included in sections 3.6.5. and 3.8.2. of Annex II to Regulation (EC) No 1107/2009 and in Commission Delegated Regulation (EU) 2017/2100, and those to qualify as endocrine disruptor for human health or the environment included in Annex I to Regulation (EC) No 1272/2008, are equivalent, substances which qualify as meeting the criteria for endocrine disruptor properties in accordance with Commission Regulation		

(EU) 2018/605 and Commission Delegated Regulation (EU) 2017/2100 should be included as endocrine disrupt**ion**~~ors~~ ~~category 1~~ for human health **category 1** or endocrine disrupt**ion**~~ors~~ ~~category 1~~ for the environment **category 1** in Table 3 in Part 3 of Annex VI to Regulation (EC) No 1272/2008.		
(22) As Article 5(1), point (e), of Regulation (EU) No 528/2012[7] refers to the PBT and vPvB criteria included in Annex XIII to Regulation (EC) No 1907/2006 to identify the PBT and vPvB properties of active substances and as those criteria are equivalent to those included in Annex I to Regulation (EC) No 1272/2008, the active substances meeting the criteria to qualify as PBT and vPvB under Regulation (EU) No 528/2012 and under Annex XIII to Regulation (EC) No 1907/2006 should be included in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008. As PBT and vPvB properties included in sections 3.7.2. and 3.7.3. of Annex II to Regulation (EC) No		

[7] Regulation (EC) No 528/2012 of 22 May 2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products
(OJ L 167 of 27.6.2012 p.1).

1107/2009 of the European Parliament and of the Council[8] are equivalent to those included in Annex I to Regulation (EC) No 1272/2008, the active substances meeting the criteria to qualify as PBT and vPvB according to those criteria in sections 3.7.2. and 3.7.3. of Annex II to Regulation (EC) No 1107/2009 should be included in Table 3 in Part 3 of Annex VI to Regulation (EC) No 1272/2008.		
(23) As the substances referred to in recitals **21**~~30~~ and **22**~~31~~ have already been assessed by the European Food Safety Authority or the Agency as well as the Commission which has decided upon by them, they should be included in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 by a delegated act, without prior consultation of the Agency as provided for in Article 37(4) of Regulation (EC) No 1272/2008.	FR: (23) As the substances referred to in recitals 21 and 22 have already been assessed by the European Food Safety Authority or the Agency as well as the Commission which has decided upon by them, they should be included in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 by a delegated act, without prior consultation of the Agency as provided for in Article 37(4) of Regulation (EC) No 1272/2008. **To avoid duplication of work by authorities under Regulation (EC) No 1272/2008 and Regulation (EC) 1107/2009, delegated acts should also be adopted for substances for which applications for approval or renewal of approval have been**	FR: Please consider to add this elements to reflect the modifications proposed in article 37(8).

8 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

	submitted in accordance with the relevant provisions of Regulation (EC) No 1107/2009 before or on 1 January 2025. To avoid duplication of work by authorities under Regulation (EC) No 1272/2008 and Regulation (EU) 528/2012, this should also apply to substances for which, by 1 January 2025, the evaluating competent authority has submitted its draft assessment report on the approval or renewal of approval to the Agency in accordance with the relevant provisions of Regulation (EU) No 528/2012, or substances for which the application was submitted for the purpose of Directive 98/8/EC and the Member State's evaluation in accordance with that Directive has been completed by 1 September 2013 but no decision on the approval was adopted before that date, or substances for which the Agency has submitted to the Commission an opinion pursuant to Article 75(1)(g) of Regulation (EU) No 528/2012 concluding that they meet those criteria.	
Subgroup C2. Classification and Labelling inventory		
<u>Articles in C2</u>		
(20) Article 40 is amended as follows:		
(a) paragraph 1, the first subparagraph	FR:	

is amended as follows:	(a) **in** paragraph 1, the first subparagraph is amended as follows:	
(i) point (e) is replaced by the following:		
‘(e) specific concentration limits, M-factors or acute toxicity estimates, where applicable, in accordance with Article 10, together with a justification referred to in the relevant parts of sections 1, 2 and 3 of Annex I to Regulation (EC) No 1907/2006;’;		
(ii) points (g) and (h) are added:		
‘(g) where applicable, the reason for divergence from the most severe classification per hazard class included in the inventory referred to in Article 42;		DE: Comment: With the intended amendments justifications for a less severe classification have to be made. Lots of unnecessary communication along the supply chains will be triggered and further information requirements for the inventory will lead to more bureaucracy without beneficial effects. The proposed justification of deviation from the most severe classification in the inventory is not workable, as with each change of the most severe classification all justifications provided so far will become meaningless. Instead of increasing the administrative burden, the objectives of promoting transparency and knowledge on the

		hazards of substances can be achieved better by focusing the CLI on the harmonised C&L (Annex VI) and the joint C&L from REACH registrations. This information is of higher value than the notifications kept in the inventory database, which may already differ for the same substances and do not claim to be up-to-date. There is a high number of erroneous or obsolete classifications of substances, as well as diverging classifications for the same substance in the European Chemical Agency's classification and labelling inventory ('inventory), with almost 60% of companies having multiple notified classifications for a single substance, as stated in the explanatory memorandum of the current proposal. Additional (and extended) notification duties in Articles 40(1), 40(2) and 42(1) will bring no added value. The substance-wise check of each individual hazard class of each notification for divergence is time-consuming and will bring questionable results, which will be outdated anyway with the next submission of another notifier.
(g) where applicable, the reason for introducing a more severe classification per hazard class compared to those included in the inventory referred to in Article 42.';	IT: **(h)** where applicable, the reason for introducing a more severe classification per hazard class compared to those included in the inventory referred to in Article 42.';	IT: Editorial change DE:

		See comment above
(iii) subparagraph 2 is replaced by the following:		
The information referred to in (a) to (h) shall not be notified, if it has been submitted to the Agency as part of a registration pursuant to Regulation (EC) No 1907/2006, or if it has already been notified by that notifier.		
(b) paragraph 2 is replaced by the following:		
'2. The information listed in paragraph 1 shall be notified to the Agency by the notifier(s) concerned at the latest 6 months after a decision to change the classification and labelling of the substance has been taken pursuant to the review referred to in Article 15(1).';		
(21) in Article 42(1), the third subparagraph is replaced by the following:		
'~~3.~~ The following information shall be made publicly available free of charge online:		
(a) information referred to in Article 40(1), point (a)~~, except where a notifier duly justifies why such publication is~~		

~~potentially harmful for its commercial interests or the commercial interests of any other concerned party~~;		
(b) in the case of group notifications, the identity of the importer or manufacturer submitting the information on behalf of the other members of the group;		
(c) information in the inventory which corresponds to the information referred to in Article 119(1) of Regulation (EC) No 1907/2006~~.~~**;**		
(d) the date of the latest update of the classification and labelling.		LT: Support.
~~The Agency shall grant access to the information in the inventory that concerns a substance and is not referred to in the first subparagraph to other parties subject to Article 118 of Regulation (EC) No 1907/2006.~~		
Information referred to in Article 40(1)(a) shall not be made publicly available where a notifier duly justifies why publication of such information is potentially harmful for its commercial interests or the commercial interests of any other concerned party.’;		DK: Denmark repeats the question we put forward at the last working party meeting, as we believe our question may have been misinterpreted as a reference to point d) rather than the exemption set out in the subparagraph directly under point d. We ask the Presidency to confirm, that the changes put

		forward do not represent a change to the publication exemptions for suppliers as the CLP applies today. If one of the purposes of the revision is to achieve a higher level of transparency in the classification processes, a move of this nature would be a contradictory measure. Denmark is concerned that with the current wording of the compromise text, ECHA may receive many more requests for exemptions, that would be time consuming to evaluate and perhaps groundless.
	AT: The Agency shall remove inactive entries from the inventory. An entry is considered to be inactive, when the notifier has not update the entry within 2 years and after this period has not reacted on a request of the Agency to confirm the correctness of the entry.	AT: Giving ECHA the mandate to remove old entries – e.g. from companies, which do not exist anymore – the quality of the inventory could be improved. This would make the CLI a more valuable database for chemical properties.
<u>Recitals relating to C2</u>		
(24) Manufacturers and importers often notify different information for the same substance to be included in the Agency's inventory for classification and labelling. In some cases, such divergences result from different impurities, physical states or other differentiations and may be justified. In other		

cases, the divergences are due to differences in data used for classification, or to disagreement between notifiers or registrants in the case of joint submission of data in accordance with Regulation (EC) No 1907/2006, or to obsolete classification entries. As a result, the classification and labelling inventory contains divergent classifications, which makes the inventory less effective as a hazard collection and communication tool and leads to incorrect classifications, ultimately hindering the ability of Regulation (EC) No 1272/2008 to protect human health and the environment. Therefore, the notifiers should be required to provide reasons for divergence from the most severe classification or for introducing a more severe classification per hazard class for the same substance to the Agency. To address divergences between more recent and obsolete classifications, notifiers should be required to update their notifications within 6 months after a decision to change the classification and labelling of a substance has been taken pursuant to a review in Article 15(1) of that Regulation.		
(25) In order to enhance transparency of notifications as well as to facilitate the notifiers' duty to come to an agreed notification entry for the same substance, certain information notified to the Agency's classification and labelling inventory should be made publicly available, free of charge.		

Without prejudice to the protection of commercial interests, that information should include the identity of the notifiers as, knowing whom to contact, would facilitate the objective of coming to an agreed entry to be included in that classification and labelling inventory. In the case of notifications by a group of manufacturers or importers, it should suffice to make publicly available the identity of the notifier submitting the information on behalf of the other members of the group.		
Subgroup C3. Procedure for Harmonised Classification		
Articles in C3		
(18a-e) Article 37 is amended as follows:		
(a) paragraph 1 is replaced by the following:		
'1. A competent authority may submit to the Agency a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof.		
The Commission may ~~ask~~ **request** the Agency or the European Food Safety Authority	PT:	PT:

established in accordance with Article 1(2) of Regulation (EC) No 178/2002[9] to prepare a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof. The Commission may subsequently submit the proposal to the Agency.	The Commission may ~~ask~~ **request** the Agency or the European Food Safety Authority established in accordance with Article 1(2) of Regulation (EC) No 178/2002 to prepare a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof. **The Agency or European Food Safety Authority may prepare a proposal.** **When a proposal is prepared by the European Food Safety Authority, this Authority** ~~**The Commission**~~ may ~~**subsequently**~~ submit the proposal to the Agency, **and informs the Commission**.	Regarding the procedure for harmonized classification proposal requested to ECHA by Commission, PT proposes a similar process than the one established for the REACH SVHC identification and restriction processes, where the Commission requests ECHA to prepare a proposal and ECHA becomes the dossier submitter. In our view, an additional step requiring the COM to send the dossier prepared by ECHA or EFSA to ECHA should be avoid. We would also consider that ECHA and EFSA would be more prepared to adjust the proposal, if required upon receipt by the Agency.
The proposals referred to in the first and the second subparagraphs shall follow the format set out in Part 2 of Annex VI and contain the relevant information provided for in Part 1 of Annex VI.		
(b) in paragraph 2, the first subparagraph is replaced by the following:		

[9] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p.1)';

'2. Manufacturers, importers or downstream users of substances may submit to the Agency a proposal for harmonised classification and labelling of those substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, provided that there is no entry in Part 3 of Annex VI for such substances in relation to the hazard class or differentiation covered by that proposal.';		
(c) the following paragraph 2a is inserted:		
'2a. Before submitting a proposal to the Agency, a competent authority, manufacturer, importer or downstream user shall notify the Agency of its intention to submit a proposal for harmonised classification and labelling**.** ~~, and, in the case of t~~**T**he Commission **shall also notify to the Agency of its**~~, the~~ request to the Agency or the European Food Safety Authority to prepare such proposal.		
Within one week from receipt of the notification, the Agency shall publish the name and, where relevant, the EC and CAS numbers of the substance(s), the status of the proposal, the proposed classification and the name of the submitter. The Agency shall update the information on the status of the proposal after completion of each stage of the process	PT: Within one week from receipt of the notification, the Agency shall publish **the information therein, including** the name and, where relevant, the EC and CAS numbers of the substance(s), the status of the proposal, the	PT: We propose the following text to make it clear that the obligation to provide this information lays with the competent authority, manufacturer, importer or downstream user, or

referred to in Article 37(4) and (5).	proposed classification, **the expected date of submission** and the name of the submitter. The Agency shall update the information on the status of the proposal after completion of each stage of the process referred to in Article 37(4) and (5).	with the COM and not with ECHA. ECHA has the obligation to publish the information provided in the Registry of intentions.
Where a competent authority receives a proposal in accordance with paragraph 6, it shall notify the Agency and provide any relevant information on its reason for accepting or refusing the proposal. The Agency shall share that information with the other competent authorities.’;		
(d) paragraph 3 is replaced by the following:		
‘3. Where the proposal of the manufacturer, importer or downstream user concerns the harmonised classification and labelling of substances in accordance with Article 36(3), it shall be accompanied by the fee determined by the Commission in accordance with the **examination** procedure referred to in Article 54(2).’;		
(e) paragraphs 5 and 6 are replaced by the following:		
‘5. The Commission shall adopt without undue delay, delegated acts in	DK:	DK:

accordance with Article 53a, where it finds that the harmonisation of the classification and labelling of the substance concerned is appropriate, to amend Annex VI by inclusion of substances together with the relevant classification and labelling elements and, where appropriate, the specific concentration limits, M-factors or acute toxicity estimates in Table 3 of Part 3 of Annex VI.	'5. The Commission shall adopt without undue delay, delegated acts in accordance with Article 53a, where it finds that the harmonisation of the classification and labelling of the substance concerned is appropriate, to amend Annex VI by inclusion of substances together with the relevant classification and labelling elements and, where appropriate, the specific concentration limits, M-factors or acute toxicity estimates in Table 3 of Part 3 of Annex VI. ***The Commission may not use the same process to remove existing hazard classes.***	While Denmark is in support of the proposal that the Commission may adopt new hazard classes via delegated acts, Article 37(5) should be amended to make clear that this does not empower the Commission to remove hazard classes via delegated acts.
Where, in the case of harmonisation of classification and labelling of substances, imperative grounds of urgency so require, the procedure provided for in Article 53b shall apply to delegated acts adopted pursuant to this paragraph.		
6. Manufacturers, importers and downstream users who have new information which may lead to a change of the harmonised classification and labelling elements of substances in Part 3 of Annex VI shall submit a proposal in accordance with paragraph 2, second subparagraph, to the competent authority in one of the Member States in which the substances are placed on the market.';		AT: We see the need for companies for a direct request to revise existing CLH entries themselves, whereby these should be embedded in the following legal parameters: - Revisions should be made after a fixed time interval from the existing CLH entry. - New information must be obligatory and must be checked by ECHA whether it is data

		that could lead to a change of the entry (Accordance Check). - These revisions of CLH entries may only represent a certain percentage (e.g. 5%) of the RAC workload. - When revising entries, it is mandatory that all minimum classifications (* entries) are taken into account and cleaned up. This would reduce the burden on national authorites. ECHA's work should be remunerated accordingly.
[...]		
Recitals relating to C3		
(17b) *[As the new hazard classes and criteria introduced by Commission Delegated Regulation[10] allow for the harmonised classification and labelling of substances of the highest concern with regard to health and environment, they should normally be subject to harmonised classification and labelling and added to the list of hazard classes which includes respiratory sensitisation, germ cell mutagenicity, carcinogenicity and reproductive toxicity. Sub-categorisation of the hazard class for respiratory sensitisation in sub-category 1A*		

[10] [Commission Delegated Regulation amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures, OJ XX of XX p XX.]

or 1B should be performed where sufficient information to classify in those hazard sub-categories is available, in order to avoid over- or under-classification.] In view of the rapid development of scientific knowledge and the long-standing expertise of the European Chemicals Agency (the 'Agency') and the European Food Safety Authority (the 'Authority') on the one hand, and the limited resources of Member States' competent authorities to develop harmonised classification proposals on the other, the Commission should have the right to request the Agency and the Authority to develop a harmonised classification and labelling proposal.		
(18) Harmonised classification and labelling proposals need not necessarily be limited to individual substances and could cover a group of similar substances, where such similarity allows for similar classification of all substances in the group. The purpose of such grouping is to alleviate the burden on manufacturers, importers or downstream users, the Agency and the Commission in the procedure for harmonisation of classification and labelling of substances. It also avoids testing of substances when similar substances can be classified as a group.	IT: (18) Harmonised classification and labelling proposals need not necessarily be limited to individual substances and could cover a group of similar substances, where such similarity allows for similar classification of all substances in the group. The purpose of such grouping**, with appropriate justification**, is to alleviate the burden on manufacturers, importers or downstream users, the Agency and the Commission in the procedure for harmonisation of classification and labelling of substances. It also avoids testing of substances	IT: The companies have expressed their concerns on the grouping also for the CLH process, this would request a transparent justification on how structural similarity and dissimilarity prediction has been done on transparent scientific criteria. In addition, we would like to propose a time period for the public consultation more extent than the current when a CLH proposal regards grouping.

	when similar substances can be classified as a group.	
(19) To increase transparency and predictability of the proposals submitted to the Agency, the Member States' competent authorities, manufacturers, importers or downstream users should be required to notify the Agency of their intention to submit a proposal for harmonised classification and labelling, while the Commission should be required to notify the Agency of its request to the Agency or to the Authority to prepare such proposal. Furthermore, the Agency should be required to publish information on such intention or request and update the information regarding the submitted proposal at each stage of the procedure for the harmonised classification and labelling of substances. For the same reason, a competent authority that receives a proposal for revision of a harmonised classification and labelling submitted by a manufacturer, importer or downstream user should be required to communicate its decision to accept or refuse the proposal for revision to the Agency, which should share that information with the other competent authorities~~. receives a proposal for revision of a harmonised classification and labelling submitted by a manufacturer, importer or downstream user should be required to communicate its decision to accept or refuse the proposal for revision to the~~		

~~Agency, which should share that information with the other competent authorities~~.		
Subgroup C4. Other regulatory procedures and entry-into-force		
Articles in C4		
(xx) In Article 24(2), the second subparagraph is replaced by the following:		
'The level of the fees shall be determined by the Commission in accordance with the examination procedure referred to in Article 54(2) of this Regulation.'		
(xx) In Article 52, paragraph 2 is replaced by the following:		
'2. Within 60 days of receipt of the information from the Member State, the Commission shall in accordance with the examination procedure referred to in Article 54(2) either authorise the provisional measure for a time period defined in the decision or require the Member State to revoke the provisional measure.'		
(26b-c) Article 53 is amended as follows:		
(b) paragraph 2 is replaced by the following:		

'2. The Commission or the Member States acting in the interest of the Union shall, in the manner appropriate to their role in the relevant UN fora, promote ~~the~~ harmonisation of ~~the~~ criteria for classification and labelling of endocrine disrupt**ion**~~ors~~ for human health, endocrine disrupt**ion**~~ors~~ for the environment, persistent, bioaccumulative and toxic ~~(PBT)~~, very persistent and very bioaccumulative ~~(vPvB)~~, persistent, mobile and toxic ~~(PMT)~~ and very persistent and very mobile ~~(vPvM)~~ substances as well as alternative test methods at the level of the UN.';	AT: '2. The Commission or the Member States shall, in the manner appropriate to their role in the relevant UN fora, promote the harmonisation of the criteria for classification and labelling of endocrine disruptors for human health, endocrine disruptors for the environment, persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances as well as alternative test methods at the level of the UN.';	FI: FI: scrutiny reservation. We are awaiting how the comments made by Council Legal Service will be reflected in the next version. AT: We are in favor of not amending this paragraph.
(c) the following paragraph 3 is added:		
'3. The Commission shall regularly evaluate the development of alternative test methods referred to in Article 13(1) of Regulation (EC) No 1907/2006 for classification of substances and mixtures.'**;**		FI: FI: scrutiny reservation. We are awaiting how the comments made by Council Legal Service will be reflected in the next version.
(27) Article 53a is amended as follows:		
(a) in paragraph 2, the first sentence is replaced by the following:		

'The power to adopt delegated acts referred to in Articles 37(5), 37(7), 37(8), 45(4) 53(1), 53(1a) and 53(1b) shall be conferred on the Commission for a period of five years from [OP please insert the date = the *date of entry into force of this Regulation]*';	PT: 'The power to adopt delegated acts referred to in Articles 37(5), 37(7), 37(8), 45(4) 53(1), 53(1a) and 53(1b) shall be conferred on the Commission for a period of five years from [OP please insert the date = the *date of entry into force of this Regulation]*. **Concerning the five-year period from 26 July 2019, as amended by Regulation (EU) 2019/1243 of the European Parliament and of the Council, the Commission shall draw up a report in respect of the delegation of power not later than nine months before 26 July 2024.**	PT: The previous wording anticipated that this transference of power to the COM should be subject to a review in a period of 5 years after 26 July 2019. This text allows an additional period. Although we have no objections to this deadline, as a report was due 9 months before 26 July 2024, we wonder if the COM will still publish this report by this deadline, notwithstanding the new deadline established. We propose an alternative text to be removed if is no longer necessary considering the publication date.
(b) in paragraph 3, the first sentence is replaced by the following:		
'The delegation of power referred to in Articles 37(5), 37(7)**,** ~~and~~ 37(8), 45(4), 53(1), 53(1a) and 53(1b), may be revoked at any time by the European Parliament or by the Council.';		
(c) in paragraph 6, the first sentence is replaced by the following:		
'A delegated act adopted pursuant to Articles 37(5), 37(7), 37(8), 45(4)**,** 53(1), 53(1a) and 53(1b), shall enter into force only if no		

objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object.’;		
(28) Article 53c is replaced by the following:		
‘*Article 53c*		
Separate delegated acts for different delegated powers		
The Commission shall adopt a separate delegated act in respect of each power delegated to it pursuant to this Regulation, with the exception of amendments to Annex VI, where Parts 1 and 2 of that Annex may be amended together with Part 3 of that Annex in one single act.’;		PT: In principle, we can accept the adoption of a separate delegated act in respect of each power delegated to it under the CLP Regulation adoption, with the exception of amendments to Annex VI, where Parts 1 and 2 of that Annex may be amended together with Part 3 of that Annex in one single act.
(29) Article 54 is replaced by the following:		
‘1. The Commission shall be assisted by the Committee established by Article 133 of Regulation (EC) No 1907/2006. That	FR: ‘**Article 54**	

committee shall be a committee within the meaning of Regulation (EU) No 182/2011*.~~;~~	**Committee procedure** 1. The Commission shall be assisted by the Committee established by Article 133 of Regulation (EC) No 1907/2006. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011*.	
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.		
_____		
* *Regulation (EU) 182/2011 …*’;		
(30) in Article 61, the following paragraph 7 is added:		
‘7. Substances and mixtures which have been classified, labelled and packaged in accordance with ~~Article 1(1), Article 4(10),~~ Article 5, Article 6(3) and (4), Article 9(3) and (4), Article 25(6)~~ and (9)~~, Articles 29~~, 30 and 35, Article 40(1) and (2), Article 42(1), third sub-paragraph, Article 48~~, section 1.2.1. of Annex I, section 1.5.1.2 of Annex I, section 1.5.2.4.1 of Annex I~~, Parts 3 and 5 of Annex II, Part A, the first sub-paragraph of section 2.4, of Annex VIII, Part B, section 1, of Annex VIII, Part B, the third paragraph of section 3.1, of Annex VIII , Part B, section 3.6, of Annex VIII, Part B, the first row of Table 3 of Section~~	IT: 7. Substances ~~**and mixtures**~~ which have been classified, labelled and packaged in accordance with~~,~~ Article 5, Article 6(3) and (4), Article 9(3) and (4), Article 25(6)~~-~~, Articles 29~~,~~, section 1.2.1. of Annex I, section 1.5.1.2 of Annex I, section 1.5.2.4.1 of Annex I~~,~~ as applicable on … [OP: please insert the date = the day before the entry into force of this Regulation] and which were placed on the market before [OP: please insert the date = the first day of the month following ~~18~~ **24** months	IT: We express our concern that the proposals in both the OLP text and the Delegated Act have failed to take into account the need for sufficient time for mixture manufacturers to act with respect to relabelling due to substance reclassifications. We therefore call on the authorities to take into full consideration the need for adequate transition periods to be assigned within the legal texts, for downstream users to properly reclassify and relabel their mixtures. We

~~3.7, of Annex VIII, Part B, the first paragraph of Section 4.1, of Annex VIII, Part C, sections 1.2 and 1.4, of Annex VIII, and Part D, sections 1, 2 and 3, of Annex VIII~~ as applicable on … [OP: please insert the date = the day before the entry into force of this Regulation] and which were placed on the market before [OP: please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation] are not required to be classified, labelled and packaged in accordance with this Regulation as amended by Regulation …/… of the European Parliament and of the Council* [OP: please complete the reference in the footnote – it should be the reference to this Regulation] until … [OP: please insert the date = the first day of the month following 42 months after the date of entry into force of this Regulation].	after the date of entry into force of this Regulation] are not required to be classified, labelled and packaged in accordance with this Regulation as amended by Regulation …/… of the European Parliament and of the Council* [OP: please complete the reference in the footnote – it should be the reference to this Regulation] until … [OP: please insert the date = the first day of the month following 42 months after the date of entry into force of this Regulation].	recommend setting a minimum of 24 months for all transition periods that relate to mixtures. We would also strongly encourage the authorities to consider aligning the CLP, for this reason we suggest assigning the same timelines reported in the Delegated Act which differentiates between substances and mixtures. For this reason, we suggest to modify Art. 61 paragraph 7 (only for substances) and to add the new paragraph 7a for the mixtures
	IT: **7a. <u>Mixtures which have been classified, labelled and packaged in accordance with Article 5, Article 6(3) and (4), Article 9(3) and (4), Article 25(6), Articles 29, section 1.2.1. of Annex I, section 1.5.1.2 of Annex I, section 1.5.2.4.1 of Annex I as applicable on … [OP: please insert the date = the day before the entry into force of this Regulation] and which were placed on the market before [OP: please insert the date =</u>**	IT: See above for clarification

	the first day of the month following 36 months after the date of entry into force of this Regulation] are not required to be classified, labelled and packaged in accordance with this Regulation as amended by Regulation …/… of the European Parliament and of the Council* [OP: please complete the reference in the footnote – it should be the reference to this Regulation] until … [OP: please insert the date = the first day of the month following 60 months after the date of entry into force of this Regulation].	
_____		
* *Regulation (EU) .../... of the European Parliament and of the Council of ... on ... (OJ ...).*';		
Article 2 of the proposal amending the CLP Regulation		
Article 2		
1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.		
2. The following provisions shall apply from [OP: please insert the date = the first day of the month following 18 months after the		

date of entry into force of this Regulation]:		
(a) Article 1, points (1), (4), (5), (6), (7), (10), (11), (12), (15), (16), (20), (21), (23), and (24);		
(b) points (2), (3), (7), (9) and (10) of Annex I;		
(c) Annex II;		
(d) points (1)(c), (2), (3) and (4) of Annex III.		
3. By way of derogation from Article 1(1), Article 4(10), Article 5, Article 6(3) and (4), Article 9(3) and (4), Article 25(6) and (9), Articles 29, 30 and 35, Article 40(1) and (2), Article 42(1), third sub-paragraph, Article 48, section 1.2.1. of Annex I, section 1.5.1.2 of Annex I, section 1.5.2.4.1 of Annex I, Parts 3 and 5 of Annex II, Part A, the first sub-paragraph of section 2.4, of Annex VIII, Part B, section 1, of Annex VIII, Part B, the third paragraph of section 3.1, of Annex VIII , Part B, section 3.6, of Annex VIII, Part B, the first row of Table 3 of Section 3.7, of Annex VIII, Part B, the first paragraph of Section 4.1, of Annex VIII, Part C, sections 1.2 and 1.4, of Annex VIII, and Part D, sections 1, 2 and 3, of Annex VIII to Regulation (EC) No 1272/2008 as applicable on [OP: please insert the date =		

the day before the date of entry into force of this Regulation], substances and mixtures may until … [OP: please insert the date = the last day of the month following 17 months after the date of entry into force of this Regulation] be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by the following provisions of this Regulation:		
(a) Article 1, points (1), (4), (5), (6), (7), (10), (11), (12), (16), (20), (21) and (23);		
(b) points (2), (3), (7) and (9) of Annex I;		
(c) Annex II;		
(d) points (1)(c), (2), (3) and (4) of Annex III.		
Recitals relating to C4		
(32) After consultation of the Commission expert group of Competent Authorities for REACH[11] and CLP[12], the Commission		

[11] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

regularly adapts the Annexes to Regulation (EC) No 1272/2008 to technical and scientific progress. According to Article 53c of that Regulation, the Commission is to adopt a separate delegated act in respect of each power delegated to it. It has been difficult to apply that provision when amending different parts of Annex VI to Regulation (EC) No 1272/2008 that are subject to different empowerments. In particular in the case of simultaneous introduction of new notes into Part 1 of Annex VI to Regulation (EC) No 1272/2008 pertaining to new entries in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 and the introduction of new entries themselves in the same Annex, adoption of separated delegated acts has resulted in artificially separating intrinsically related provisions and thereby affecting coherence by requiring simultaneous adoption of two different but related delegated acts. In such cases, it should be possible to adopt a single delegated act in respect of different delegated powers.		
(33) In accordance with Directive 2010/63/EU of the European Parliament and of the Council[13], it is necessary to replace, reduce		

[12] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

[13] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

or refine testing on animals. Implementation of Regulation (EC) No 1272/2008 should be based on the use of alternative test methods, suitable for the assessment of health and environmental classification of chemicals, wherever possible. In order to speed up the transition to non-animal methods, with the ultimate goal of fully replacing animal testing, as well as to improve the efficiency of chemical hazard assessments, innovation in the field of non-animal methods should be monitored and systematically evaluated, and the Commission and the Member States acting in the interest of the Union should promote the inclusion of harmonised criteria based on available alternative methods in UN GHS and subsequently include those criteria in Regulation (EC) No 1272/2008 without undue delay.		
(37) To ensure that suppliers of substances and mixtures have time to adapt to rules on classification, labelling and packaging, the application of some provisions of this Regulation should be deferred. Substances and mixtures which are already placed on the market before the end of that deferral period, should be allowed to continue being placed on the market without being re-classified and re-labelled in accordance with this Regulation, to avoid additional burden on suppliers of substances and mixtures.		

(38) In line with the transitional provisions of Regulation (EC) No 1272/2008 which allow the application of the new provisions at an earlier stage on a voluntary basis, suppliers should have the possibility of applying the new classification, labelling and packaging provisions on a voluntary basis before the date of deferred application of this Regulation.		
(39) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States, because environmental pollution is transboundary and the citizens of the Union should benefit from an equal protection of their health and environment and because substances and mixtures should circulate freely on the Union market , but can rather, by reason of their scale, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.		
Cluster D – Poison centres		
Subgroup D1. Poison centres		
Articles in D1		

(1) in Article 1(1), the following point (f) is added:		
‘(f) providing an obligation for downstream users, importers and distributors referred to in Article 45(1**b**) **and 45(1c)** to submit information relevant for providing an adequate emergency health response to appointed bodies in accordance with Annex VIII.’;		
(22) Article 45 is amended as follows:		
(a) paragraph 1 is replaced by the following:		
‘1. Member States shall appoint a body or bodies responsible for receiving the relevant harmonised information relating to emergency health response and preventative measures, in accordance with Annex VIII.’;		
(b) the following paragraphs 1a, 1b and 1c are inserted:		
‘1a. Member States may appoint the Agency as the body responsible for receiving information relating to emergency health response and preventative measures referred to in paragraph 1.~~’~~;		
1b. Importers and downstream users		

placing on the market mixtures that are classified as hazardous on the basis of their health ~~effects~~ or physical effects, shall submit to the body or bodies appointed in accordance with paragraph 1 the ~~harmonised~~ information referred to in Part B of Annex VIII.		
1c. Distributors placing on the market mixtures that are classified as hazardous on the basis of their health ~~effects~~ or physical effects, shall submit to the ~~appointed~~ body or bodies **appointed in accordance with paragraph 1** the ~~harmonised~~ information referred to in Part B of Annex VIII where they further distribute those mixtures in other Member States, or where they rebrand or relabel the mixtures. This obligation does not apply if the distributors can demonstrate that the appointed body or bodies already received the same information from importers or downstream users.'; 		AT: It is unclear how a distributor in the role of a distributor can rebrand or relabel mixtures as this would classify him as a downstream user from an enforcement perspective.
(c) in paragraph 2, point (b) is replaced by the following:		
'(b) where requested by ~~a~~**the** Member State, the Commission or the Agency, to undertake a statistical analysis to identify where improved risk management measures may be needed.'; 	BE: '(b) where requested by ~~a~~**the** Member State~~, the Commission or the Agency,~~ to undertake a statistical analysis to identify where improved risk management measures	BE: BE does not support the possibility for the Commission and ECHA to get access on request to poison centres information.

	may be needed.’	This information is confidential and may be sensitive. Direct requests from the Commission or ECHA to poison centres are questionable and would increase the burden on them, reducing their ability to focus on urgent medical demands and prevention of incidents. In addition, some Member States chose to keep running their national notification system in parallel of the ECHA Portal and information received are thus fragmented. IE: We note this change and see the reasoning for it. However, it is not clear as to which MS is being referred to here and it may be necessary to stipulate that it is the MS where the mixture is placed on the market.
(d) paragraph 3 is replaced by the following:		
‘3. The appointed bodies shall have at their disposal all the information required from importers, downstream users and distributors referred to in paragraph 1c, to carry out the tasks for which they are responsible **in accordance with paragraph 1**.’;		
(25) Article 50 is amended as follows:		

(a) in paragraph 2, point (b) is replaced by the following:		
‘(b) provide competent authorities with technical and scientific guidance and tools on the operation and implementation of this Regulation and provide support to the helpdesks established by Member States under Article 44.’;		
(b) the following paragraph 3 is added:		
‘3. Where the Agency acts as an appointed body in accordance with Article 45(1a), it shall put in place the tools necessary to provide access to the information to the relevant appointed body or bodies of the appointing Member State to fulfil their tasks with regard to emergency health response and preventative measures.’**;**		
<u>Changes to Annex VIII in D1</u>		
(1) Part A is amended as follows:		
(a) Section 1 is replaced by the following:		
‘1. Application		

1.1 Importers, downstream users and distributors referred to in Article 45**(1b) and** (1c) placing on the market mixtures for consumer use, within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2021.		
1.2 Importers, downstream users and distributors referred to in Article 45**(1b) and** (1c) placing on the market mixtures for professional use, within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2021.		
1.3 Importers, downstream users and distributors referred to in Article 45**(1b) and** (1c) placing on the market mixtures for industrial use or mixtures with an end use not subject to notification within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2024.		
1.4 Importers, downstream users and distributors referred to in Article 45**(1b) and** (1c) having submitted information		

relating to hazardous mixtures to a body appointed in accordance with Article 45(1) before the dates of applicability mentioned in Sections 1.1, 1.2 and 1.3 and which are not in accordance with this Annex, shall for those mixtures not be required to comply with this Annex until 1 January 2025.		
1.5 By way of derogation from Section 1.4, if one of the changes described in Section 4.1 of Part B of this Annex occurs before 1 January 2025, importers, downstream users and distributors referred to in Article 45**(1b) and** (1c) shall comply with this Annex before placing that mixture~~, as changed,~~ on the market.’;		
(b) Section 2.1 is replaced by the following:		
‘2.1 This Annex sets out the requirements that importers, downstream users and distributors referred to in Article 45(1c) (‘submitters’) placing mixtures on the market shall fulfil in respect of the submission of information so that appointed bodies have at their disposal the information required to carry out the tasks for which they are responsible under Article 45.’;		

(c) in Section 2.4., first subparagraph, the following point (6) is added:		
'(6) 'composition conforming with a standard formula specified in Part D' means a composition which includes all the components listed in one of the standard formulas referred to in Part D of this Annex, where those components are present in the mixture in concentrations within the ranges specified in that standard formula.';		
(2) Part B is amended as follows:	FR: Please consider to include mixture components in nanoforms in section 3.3 of Part B such as followed : 'The following mixture components shall be indicated : (1) [no modification] (2) [no modification] **(3) mixture components in nanoforms**'	FR: FR considers that nanomaterials must be identified as such in the notification.
(a) the following Section 1.1a. is inserted:		
'1.1a. Name and product description of standard formula or name of fuel		

For mixtures with a composition conforming with a standard formula specified in Part D, the name and product description of the relevant standard formula as indicated in that Part shall be included in the submission.		
For fuels listed in Table 3, the name of the fuel shall be provided as indicated in that table.’;		
(b) in Section 3.1, the third paragraph is replaced by the following:		
‘Components which are not present in a mixture shall not be notified. However, if those components are notified as part of an interchangeable component group in accordance with Section 3.5. or their concentration has been submitted as a range of percentages in accordance with Sections 3.6. or 3.7, they may be notified if it is certain that they will be present in the mixture at some point in time. In addition, for mixtures with a composition conforming with a standard formula specified in Part D for which the composition is notified in accordance with Section 3.6, first indent, components listed in the relevant standard formula shall be notified even if the component is potentially not, or not permanently, present in cases where the indicated concentration range in Part D includes 0 %.’;		

(c) the title of Section 3.6. is replaced by the following:		
'3.6. Mixtures with a composition conforming with a standard formula';		
(d) in Section 3.7., the first row of Table 3 is replaced by the following:		
[please refer to table in ST 9689/23]		
(e) in Section 4.1, the first paragraph, the following indent is added~~,~~:		
'- when there are other changes to a mixture placed on the market which are relevant for the emergency health response referred to in Article 45';		
(3) Part C is amended as follows:		
(a) Section 1.2. is replaced by the following:		
'**1.2 Identification of the mixture, submitter and contact point**		
Product identifier		
– Complete trade name(s) of the product including, where relevant, brand name(s), name of the product		

and variant names as they appear on the label, without abbreviations or non-alphanumerical symbols and enabling specific identification of the product.		
– Unique Formula Identifier(s) (UFI)		
– Other identifiers (authorisation number, company product codes)		
– In case of group submission, all product identifiers shall be listed.		
Name and product description of standard formula or name of fuel		
– Standard formula name and product description as specified in Part D (where applicable)		
– Fuel name as specified in Table 3 of Part B (where applicable)		
*Contact details of the submitter**, as defined in section 2.1 of Part A of this Annex,** and contact point*		
– Name		

– Full address		
– Telephone number		
– E-mail address		
Contact details for rapid access to additional product information (24 hours/7 days). Only for limited submission.		
– Name		
– Telephone number (accessible 24 hours per day, 7 days per week)		
– E-mail address’;		
(b) Section 1.4. is replaced by the following:		
‘1.4. **Information on the mixture components and interchangeable component groups**		
Identification of the mixture components		
— Chemical/trade name of the components		
— CAS number (where applicable)		

— EC number (where applicable)		
— UFI (where applicable)		
— Standard formula name and product description (where applicable)		
——————Fuel name (where applicable)’~~;~~		
Name of interchangeable component groups (where applicable)		
Concentration and concentration ranges of the mixture components		
— Exact concentration or concentration range		
Classification of mixture components		
— Hazard classification (where applicable)		
— Additional identifiers (where applicable and relevant for health		
response)		
List according to Part B, Section 3.1, fifth subparagraph (where applicable)’;		
(4) Part D is amended as follows:		

(a) In section 1, the first row of the tables with standard formulas for cement are replaced by the following:		
[please refer to tables in ST 9689/23]		
(b) In section 2, the ~~two~~ first row~~s~~ of the table with standard formula for gypsum is replaced by the following **two rows**:		
[please refer to table in ST 9689/23]		
(c) In section 3, the ~~two~~ first row~~s~~ of the tables with standard formulas for ready mixed concrete are replaced by the following:		
[please refer to tables in ST 9689/23]		
Recitals relating to D1		
(26) Pursuant to Article 45(1) of Regulation (EC) No 1272/2008, appointed bodies in the Member States are to receive relevant information relating to emergency health response submitted by importers and downstream users placing on the market mixtures that are hazardous based on their health or physical effects. Distributors are not required to submit such information. In certain cases of distribution across borders from one Member State to another, or where distributors		

rebrand or relabel mixtures, the absence of such submission obligation causes information loss for the appointed bodies which may prevent them from providing adequate emergency health response. To address this situation, an obligation to submit information relating to emergency health response should also be introduced for distributors, where they further distribute hazardous mixtures in other Member States or where they rebrand or relabel hazardous mixtures.		
(27) Pursuant to Article 45(3) of Regulation (EC) No 1272/2008, appointed bodies are to have all the required information available to provide adequate emergency health response. The Agency already set up and maintains a Union level Poison Centres Notification portal, and established, developed and maintains a database containing information relating to emergency health response to assist some Member States in complying with that Regulation. Therefore, the Agency would be in a position to fulfil the task of receiving that information. To reduce administrative burden for Member States and take advantage of economies of scale, Regulation (EC) No 1272/2008 should provide for the option of appointing the Agency as a body responsible for receiving the relevant information, should a Member State wish to do so.		
(28) In addition to the Member States'		

appointed bodies, the Commission or the Agency should be able to use the information relating to emergency health responses for the purpose of carrying out statistical analysis. That would usefully complement information on the uses of substances submitted as part of registration under Regulation (EC) No 1907/2006, while enabling a better prioritisation of substances to be subject to harmonised classification and labelling under Regulation (EC) No 1272/2008 and feeding into the risk management processes under Regulation (EC) No 1907/2006, and potentially under other Union acts.		
(31) Apart from providing industry with technical and scientific tools on how to comply with Regulation (EC) No 1272/2008, the Agency should also provide competent authorities with such tools, for example databases, in order to foster implementation. Regulation (EC) No 12727/2008 should more in detail set out the Agency's remit in this regard. Furthermore, the Agency, acting as a body appointed by a Member State competent authority for receiving information for emergency health response, should provide the relevant national appointed body of that Member State access to that information.		
(34) Annex VIII to Regulation (EC) No 1272/2008 provides for harmonised		

information relating to emergency health response and preventative measures to be received by appointed bodies, and sets forth the general requirements, the information to be contained in a submission, the submission format and certain standard formulas. In order to provide legal certainty and clarity on the option for submission of information relating to standardised mixtures and fuels in the context of Annex VIII to Regulation (EC) No 1272/2008, that Regulation should define the term 'composition conforming with a standard formula', the obligation to provide the name and product description of the standard formula in the submission and of the fuel should be introduced, and the option to submit information on components even if they are not always present in certain cases should be provided for.		
(35) In order to provide further legal certainty and clarity of Annex VIII to Regulation (EC) No 1272/2008, that Regulation should further specify when submission updates are required, as well as ways of identifying the mixture, submitter and contact point by means of their product identifier.		
(36) Regulation (EC) No 1272/2008 should therefore be amended accordingly.		
	BE:	BE:

	END BG: **END** DK: **END** EL: **END** FI: **END** IT: **END** **END** NL:	**END** BG: **END** DK: **END** EL: **END** FI: **END** IT: **END** **END** NL:

	END SI: **END** DE: **END** LT: **END** PL: **END** FR: **END** PT: **END** IE:	**END** SI: **END** DE: **END** LT: **END** PL: **END** FR: **END** PT: **END** IE:

	END AT: **END**	**END** AT: **END**