CLP proposal – table for MS comments following Presidency clustering

Important: In order to guarantee that your comments appear accurately, please:
*- **do not modify the table format** by adding/removing/adjusting/merging/splitting cells and rows. Any such modification would probably block the running of the consolidation macro.*
*- **do not use active track-changes**. Any track changes in your completed table should have been accepted and therefore appear as normal text (by contrast, strike-through, bold, underline and italics are acceptable because the consolidation macro can handle them).*
*- **do not use a coloured font or "text highlight colour"**. It is important that the consolidated table can be printed in black-and-white and still make sense. We cannot process any formats that would prevent this.*
*- **do not insert mathematical formulae or tables** as the macro cannot process these.*
*- **place ALL comments within your completed questionnaire**.*
This would hinder the consolidation of your comments.

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
General comments on the proposal as a whole		
Cluster A – Labelling and sales		
Subgroup A1. Labelling obligations/exemptions		
Articles in A1		
(8) in Article 23, the following point (g) is added:		
'(g) ammunition as defined in Article 1(1), point (3), of Directive (EU) 2021/555 of the European Parliament and of the Council* unless it falls within the definition of an article in Article 2, point (9), of this Regulation.		
** Directive (EU) 2021/555 of the European Parliament and of the Council of 24 March 2021 on control of the acquisition and*		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
possession of weapons (OJ L 115, 6.4.2021, p. 1).';		
(9) Article 25 is amended as follows:		
(a) in paragraph 6, the first subparagraph is replaced by the following:		
'6. The specific labelling rules set out in Part 2 of Annex II shall apply to mixtures containing substances referred to in 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:		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
'1. Where the packaging of a substance or a mixture is either in such a shape or form or is so small that it is impossible to meet the requirements laid down in Article 31 for a label or a fold-out label in the languages of the Member State in which the substance or mixture is placed on the market, the label elements set out in Article 17(1), shall be provided in accordance with sections 1.5.1.1. and 1.5.1.2. of Annex I.';	1. Where the packaging of a substance or a mixture is either in such a shape or form or is so small that it is impossible to meet the requirements laid down in Article 31 for a label or a fold-out label ~~in the languages of the Member State in which the substance or mixture is placed on the market~~, the label elements set out in Article 17(1), shall be provided in accordance with sections 1.5.1.1. and 1.5.1.2. of Annex I.';	In order to avoid incoherence with other parts of the regulation referring to the language (s). In fact, the art 17(2) states what language(s) can be used, to avoid confusion we suggest deleting the reference in art. 29.1. In addition, we suggest verifying the other parts of the regulation.
(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.';		
(c) the following paragraphs 4b and 4c are inserted:		
'4b. By derogation from Article 17(1), the labelling requirement set out in that Article shall not apply to packaging of ammunition	'4b. By derogation from Article 17(1), the labelling requirement set out in that Article shall not apply to packaging of ammunition	

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
that is used by defence forces in combat zones or shipped to such zones where labelling in accordance with that requirement would constitute an unacceptable security risk for the cargo, the soldiers and the staff, and sufficient camouflaging cannot be ensured.	as defined in Article 1(1), point (3), of Directive (EU) 2021/555 of the European Parliament and of the Council that is used by defence forces in combat zones or shipped to such zones where labelling in accordance with that requirement would constitute an unacceptable security risk for the cargo, the soldiers and the staff, and sufficient camouflaging cannot be ensured.	
4c. Where paragraph 4b applies, manufactures, importers or downstream users shall provide to the defence force the safety data sheet or a leaflet containing the information referred to in Article 17(1).’;		
(12) Article 30 is replaced by the following:		
‘Article 30		
Updating information on labels		
1. In case of a change regarding the classification ~~and labelling~~ of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in	1. In case of a change regarding the classification ~~and labelling~~ of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in	The starting point of the timeline to update the label is the evaluation under art. 15(4) that refers to the classification only, so the word “labelling” and the beginning of the sentence are not consistent and redundant.

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
accordance with Article 25, the supplier shall ensure that the label is updated within 6 months after the results of the new evaluation referred to in Article 15(4) were obtained.	accordance with Article 25, the supplier shall ensure that the label is updated within ~~6~~ 9 months after the results of the new evaluation referred to in Article 15(4) were obtained.	Much time for the supplier chain appears to be more realistic, since the introduction of a fixed 6-months time limit for label changes for both substance and mixture is far too short for downstream users such as our industry sectors. Some classification changes require upfront adaptations in transport, storage and usage of the product by at least two or even more actors in the supply chain.
2. Where a change regarding the classification and labelling of a substance or a mixture is required other than that referred to in paragraph 1, the supplier shall ensure that the label is updated within 18 months after the results of the new evaluation referred to in Article 15(4) were obtained.	2. Where a change regarding the classification ~~and labelling~~ of a substance or a mixture is required other than that referred to in paragraph 1, the supplier shall ensure that the label is updated within 18 months after the results of the new evaluation referred to in Article 15(4) were obtained.	The starting point of the timeline to update the label is the evaluation under art. 15(4) that refers to the classification only, so the word "labelling" and the beginning of the sentence are not consistent and redundant.
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	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	Coherently with previous comments.

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
53(1). In such cases, the supplier shall ensure that the label is updated by the date set out in the respective delegated act.	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’;		
(13) in Article 31(3), the following sentence is added:	in Article 31(3), the following sentence is ~~added~~ replaced:	It should be verified in all proposal test accordingly.
‘3. The label elements referred to in Article 17(1) shall be clearly and indelibly marked. They shall stand out clearly from the background and they shall be of such size and spacing as to be easily read. They shall be formatted in accordance with section 1.2.1 of Annex I.’;		
(14) in Article 32, paragraph 6 is deleted;		
Changes to Annex I in A1		
(2) Section 1.2.1.4. is replaced by the following:		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
'1.2.1.4. The dimensions of the label and of each pictogram, and the font size of letters shall be as follows:		The implementation of the proposal could require more time than that proposed in the transition period.
Table 1.3		
Minimum dimensions of labels, pictograms and font size		
[please refer to the table 1.3 in Section 1.2.1.4 in Annex I]		The information required on the label by other legislations (e.g. detergents, biocide, PPP) is more and more so the minimum font size could not realistically allow all mandatory information in the label. The proposal font size does not appear feasible. Italian association categories can provide numerous examples that show how the proposal would result in much larger labels, sometimes larger than the packaging surface to which they need to be attached. Consequently, this would jeopardise the efforts that some sectors are doing in order to reduce the amount of packaging used (anticipating voluntarily the PPWR regulation). Other implication of the proposal could result in a considerable increase of use of

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
		fold-out labels, especially where multiple languages are involved, leading to more material used and an increasing waste of labels at the end-of-life. In addition, we suggest to follow the discussion on the minimum font size under other legislation e.g food legislation. We are not against the proposal and we deemed more appropriate to continue the technical discussion.
(3) the following Section 1.2.1.5. is added:		The implementation of the proposal could require more time than that proposed in the transition period.
'1.2.1.5. The text on the label shall have the following characteristics:		
(a) the background of the label shall be white;	Delete	This requirement is not necessary and will lead to the change of layout for several labels (i.e. Preprinted labels on paperboard boxes, lithographed labels). We believe it could be sufficient to grant the legibility between the background and the text (it appears sufficient to refer to

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
		article 31.3 and it could be useful to add examples in the guidance for the sake of the legibility, in particular taking into account colour visual deficiencies).
(b) the distance between two lines shall be equal or above 120 % of the font size;	Delete	This requirement is too strict, without any recognizable benefit for hazard communication. In the guidance could be add some examples to guarantee the legibility.
(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 legible.		
For the labelling of inner packaging where the contents do not exceed 10 ml, the font size may be smaller than indicated in Table 1.3, as long as it remains legible for a person with average eyesight, where itis deemed important to place the most critical hazard statement and where the outer packaging meets the requirements of Article 17.'		
(4) the following Section 1.3.7. is added:		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
'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.';		Concerning the word "ammunition", it should clarified e.g. by a note the reference to the Directive 2021/555
(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:		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
'1.5.1.2. Where section 1.5.1.1. applies, the label on any inner packaging shall contain at least hazard pictograms, the signal word, the trade name or the designation of the mixture referred to in Article 18(3), point (a), and the name and telephone number of the suppliers of the substance or mixture.';	1.5.1.2. Where section 1.5.1.1. applies, the label on any inner packaging shall contain at least hazard pictograms, the signal word, the product identifier referred to in Article18(2) or ~~the trade name or the designation of the mixture referred to~~ in Article 18(3), point (a), and the name and telephone number of the suppliers of the substance or mixture	In the proposal appears missing the situation where the packaging contains a substance such as.
(8) the heading of Section 1.5.2 is replaced by the following:		
'1.5.2. ***Exemptions from Article 17 in accordance with Article 29(2)';***		
(9) Section 1.5.2.4.1 is replaced by the following:		
'1.5.2.4.1 The label elements required by Article 17 may be omitted from the inner packaging where the contents of the inner packaging do not exceed 10 ml and either of the following applies:		
(a) the substance or mixture is placed on the market for supply to a distributor or downstream user for		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
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, 2 or 4 of Annex II and is not classified in any of the following hazard classes and categories:		
(i) Acute toxicity, categories 1 to 4;		
(ii) Specific target organ toxicity – Single exposure, categories 1 and 2;		
(iii) Specific target organ toxicity – repeated exposure, categories 1 and 2;		
(iv) Skin corrosion/irritation, category 1 (sub-categories 1A, 1B and 1C);		
(v) Respiratory sensitisation, category 1 (sub-categories 1A and 1B);		
(vi) Aspiration hazard;		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
(vii) Germ cell mutagenicity, any category;		
(viii) Carcinogenity, any category;		
(ix) Reproductive toxicity, any category;		
(x) Flammable solids, categories 1 and 2.;		
(xi) Endocrine disruptors for human health, any category;		
(c) the substance or mixture requires labelling in accordance with Part 1, 2 or 4 of Annex II but is not classified in any of the hazard classes and categories referred to in point (b) and has an inner packaging that is contained within outer packaging that meets the requirements set out in Article 17.’;		
Changes to Annex II in A1		
(2) Part 5 is replaced by the following:		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
'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 the respective pump.';		
Recitals relating to A1		
(7) Ammunition qualifying as a substance or a mixture is to bear a label affixed to the surface of the packaging immediately containing the substance or the mixture (inner packaging), which is typically the ammunitions' cartridge. Affixing a label to the cartridge might however cause safety problems for the user, as the label could interfere with the correct functioning of the ammunition and could		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
damage the firearm. Such ammunition should therefore be allowed to bear a label affixed to the next packaging layer instead of the inner packaging. In addition, labelled ammunition, which is exclusively used by national defence forces in combat zones, could, in specific cases, constitute an unacceptable safety or security risk for the cargo, soldiers and staff, if sufficient camouflaging cannot be ensured. For such cases, it is necessary to provide for an exemption from the labelling requirements and allow for alternative ways of communicating the hazard information.		
(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.		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
(10) To increase enforceability of the obligation placed on suppliers to update their labels after a change in the classification and labelling of their substance or mixture, a deadline should be laid down as regards that obligation. A similar obligation placed on registrants is set out in Commission Implementing Regulation (EU) 2020/1435[1]. Where the new hazard class is additional to an existing hazard class or represents a more severe hazard class or category, or where new supplemental labelling elements are required 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	(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~~ 9 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	Coherently with the previous comment on (12) art 30.1

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

[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.)

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
requirements, the deadline for updating the labels should remain at 18 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. It should also be clarified that, in cases of harmonised classification and labelling, the deadlines to update the labelling information should be set at the date of application of the provisions setting out the new or amended classification and labelling of the substance concerned, which is usually 18 months from the date of entry into force of those provisions. The same applies in case of changes triggered by other delegated acts adopted in light of the 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).	requirements, the deadline for updating the labels should remain at 18 months from the day on which the results of a new evaluation on the classification of that substance or that mixture were obtained. It should also be clarified that, in cases of harmonised classification and labelling, the deadlines to update the labelling information should be set at the date of application of the provisions setting out the new or amended classification and labelling of the substance concerned, which is usually 18 months from the date of entry into force of those provisions. The same applies in case of changes triggered by other delegated acts adopted in light of the 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		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
ensure readability. As a result of advancements in labelling technologies, more flexibility should be given to suppliers by providing for a broader use of fold-out labels, while readability of labels should be ensured by laying down minimum font size and formatting requirements.		
(16) Regulation (EC) No 1272/2008 does not lay down rules on the labelling of chemicals supplied to the general public without packaging except for ready mixed cement and concrete in a wet state. In order to enhance legal clarity and ensure a better protection of citizens, it is appropriate to provide for the labelling elements of other chemicals, such as fuels supplied at filling stations and intended to be pumped into receptacles from where they are normally not intended to be removed.		
Subgroup A2. Digital labelling		
Articles in A2		
(15) in Title III, the following Chapter 3 is added:		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
‘*CHAPTER 3*		
Formats of the labelling		
Article 34a		
Physical and digital labelling		
1. The label elements referred to in Article 17 shall be provided:		
(a) on a label in a physical form (‘physical label’); or		
(b) both on a physical label and on a label in a digital form (‘digital label’).		
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.		
Article 34b		
Requirements for digital labelling		

CLP proposal – table for MS comments following Presidency clustering

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Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
1. The digital label for substances and mixtures shall satisfy the following general rules and technical requirements:		
(a) all label elements referred to in Article 17(1) shall be provided in one place and separated from other information;		
(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,		
(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;		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
(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 digital label is available in more than one language, the choice of language shall not be conditioned on the geographical location;		
(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.		Keeping the digital label 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 could be an IT system problem.

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
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:		
(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 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		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
societal needs and a high level of protection of human health and the environment;		
1b. In order to adjust to technological changes and (future) developments in the field of digitalisation, the Commission is empowered to adopt delegated acts in accordance with Article 53a to supplement this Regulation by laying down further details on the requirements for the digital labelling referred to in Article 34b. Those requirements shall cover, in particular, the IT solutions which may be used, and the alternative means for providing the information. When adopting those delegated acts, the Commission shall:		
(a) ensure coherence with other relevant Union acts;		
(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;		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
(d) take into account the level of digital readiness among all population groups in the Union;		
(e) ensure that digitalisation does not compromise the protection of human health and the environment.		
Changes to Annex I in A2		
(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 hazard communication, especially for vulnerable population groups and people who do not		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
speak the national language of a Member State. Therefore, it is necessary to provide for voluntary digital labelling and to lay down technical requirements for such labelling. In order to provide for legal certainty, it is appropriate to specify the label elements that are allowed to be provided in a digital format only. That possibility should only exist for information which is not instrumental for the safety of the user or the protection of the environment.		
(13) In order to adapt the label elements allowed to be provided only in a digital format to technical progress or to the level of digital readiness among all population groups in the Union, the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union to amend the list of label elements allowed to be provided only in a digital format, taking into account societal needs and a high level of protection of human health and the environment.		
(14) In order to adjust to technological changes and developments in the field of digitalisation, the Commission		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
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.		
Subgroup A3. Refill sales		
Articles in A3		
(16) in Article 35, the following paragraph 2a is added:		
'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.';		
Changes to Annex II in A3		
(1) in Part 3, the following Section 3.4. is added:		Annex II sets a number of requirements for the operation of these refilling stations and some open questions remain.

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
		Further clarifications, also with regard to the labelling of refillable containers and the retailer's responsibility, are required. The subjects involved are 3 actors (supplier, retailer, consumer) but their different responsibilities are not clearly defined. In particular, the requirements indicated in the letters c, g, j appear difficult to apply from both companies and enforcement point of view. It is advisable to have more clarifications and examples in a guidance
'3.4. **Refill stations**		
Hazardous substances or mixtures referred to in Article 35(2a), shall meet the following conditions:		
(a) the labelling and packaging requirements applicable at the date of placing on the market of the hazardous substance or mixture are fulfilled for every refill station;		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
(b) a label is firmly affixed on a visible place of the refill station and with a font size that is easily legible and without serifs;		
(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;		It is not clear how this aspect could be managed by the retailers. Taking into account that the major of packaging is not transparent, it appears difficult to see some residues. The consumer should be informed (e.g with an indication on a visible place of the refill station) about the cleaning of its packaging
(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;		
(e) overfilling packaging is technically prevented;		
(f) filling a substance or mixture into unsuitable packaging is technically prevented;		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
(g) at the moment of refill, the supplier is reachable for immediate assistance;		This requirement could be hard to manage. What kind of assistance is requested (e.g. only technical for the supply)? The way to contact the supplier should to be indicated on the refill station (e.g . assistance button/intercom for assistance/communication system). Perhaps a responsible person of the retailer should be trained to give the technical assistance to the consumer.
(h) refill stations are not operated outdoors and outside business hours where immediate assistance cannot be provided;		
(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;		
(j) staff of the supplier are appropriately trained to minimise safety risks to consumers, professional users and themselves, and follow the necessary hygiene and cleaning protocols;		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
(k) no substance or mixture provided through a refill station meets the criteria for classification in any of the following hazard classes:		
(i) Acute toxicity, categories 1 – 4;		
(ii) Specific target organ toxicity – Single exposure, categories 1, 2 and 3;		
(iii) Specific target organ toxicity – repeated exposure, categories 1 and 2;		
(iv) Skin corrosion/irritation, category 1 (sub-categories 1A, 1B and 1C);		
(v) Respiratory sensitisation, category 1 (sub-categories 1A and 1B);		
(vi) Aspiration hazard;		
(vii) Germ cell mutagenicity, any category;		
(viii) Carcinogenicity, any category;		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
(ix) Reproductive toxicity, any category;		
(x) Flammable gases, categories 1 and 2;		
(xi) Flammable liquids, categories 1 and 2;		
(xii) Flammable solids, categories 1 and 2.		
(xiii) [insert: Endocrine disruptor for human health, categories 1 and 2].';		
(xiv) [insert: Endocrine disruptor for the environment, category 1 and 2];		
(xv) [insert: Persistent, bioaccumulative and toxic (PBT)];		
(xvi) [insert: Very persistent and very bioaccumulative (vPvB)];		
(xvii) [insert: Persistent, mobile and toxic (PMT)];		
(xviii)[insert Very persistent and very mobile (vPvM)].		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
By way of derogation from point (b), a single label on the refill station may be used for several substances or mixtures for which the label elements referred to in Article 17(1) are identical, provided that the label clearly indicates the name of each substance or mixture that it applies to.’;		
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 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.		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
Subgroup A4. Online sales		
Articles in A4		
(3) 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.';	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. A natural or legal person established outside the Community who manufactures a substance or, formulates a mixture or produces an article referred to in section 2.1 annex I that is imported into 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.	It should be foreseen in the CLP an analogue figure of the only representative like in REACH that can assume some responsibilities under CLP This aspect should be seen as an opportunity for the outside the Community company. The Italian industrial sector supports this.
(23) Article 48 is replaced by the following:		
'*Article 48*		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
Advertisement		
1. Any advertisement for a substance classified as hazardous shall indicate the relevant hazard pictogram, the signal word, the hazard class and the hazard statements.	Any advertisement for a substance classified as hazardous <u>which allows to conclude a contract for purchase</u> shall indicate the relevant hazard pictogram, the signal word, the hazard class and the hazard statements. <u>Any other advertisement for a substance classified as hazardous shall advice at least to pay attention to the label with hazard information.</u>	The consequence of the adapted Article 48 is that hazard pictograms and hazard statements would have to be provided The proposal includes all kinds of advertisement (in magazines, on television, sell-catalogues, radio etc) but in the meantime make difference between them. In addition, the proposal offers a way to educate the general public to read the label. In order to clarify if a kind of advertisement is included in the first situation or in the second situation some examples/criteria could be explained in the guidance. Anyway examples/criteria in the guidance are strongly supported also if it will be maintained the COMM proposal.
2. Any advertisement for a mixture classified as hazardous or covered by Article 25(6) shall indicate the hazard pictogram, the signal word, the hazard class and the hazard statements.	Any advertisement for a mixture classified as hazardous or covered by Article 25(6) <u>which allows to conclude a contract for purchase</u> shall indicate the hazard pictogram, the signal word, the hazard class and the hazard statements.	See previous comment

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
	Any other advertisement for a mixture classified as hazardous or covered by Article 25(6) classified as hazardous shall advice at least to pay attention to the label with hazard information.	
(24) the following Article 48a is added:		
'*Article 48a*		
Distance sales offers		
Suppliers placing substances or mixtures on the market through distance sales shall clearly indicate the label elements referred to in Article 17';	Suppliers placing substances or mixtures on the market through distance sales shall clearly indicate the label elements referred to in Article 17.1 and in accordance with Article 17.2' ;	we clearly prefer referring to all general rules of article 17
Recitals relating to A4		
(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		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
that Regulation it is assumed that all responsible actors in the supply chain are established in the Union, practical experience has shown that economic operators established outside the Union sell chemicals online directly to the general public in the Union. Hence, enforcement authorities are unable to enforce Regulation (EC) No 1272/2008 against economic operators not established in the Union. It is therefore appropriate to require that there is a supplier established in the Union, which ensures that the substance or the mixture in question meets the requirements set out in that Regulation when it is being placed on the market, including via distance sales. This provision would improve compliance with and enforcement of the Regulation (EC) No 12727/2008 and thereby ensure a high level of protection of human health and the environment. In order to prevent situations where consumer becomes *de jure* and *de facto* an importer when buying the substance or the mixture via distance sales from the economic operators established outside the Union, it is necessary to specify that the supplier which ensures that the substance or the mixture in question meets the requirements set out in that Regulation		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
acts in course of an industrial or professional activity.		
(29) Regulation (EC) No 1272/2008 regulates advertisement of hazardous substances and mixtures in a general manner and provides that an advertisement for a substance classified as hazardous is to mention the hazard classes or hazard categories concerned, and an advertisement for a mixture classified as hazardous or a mixture containing a classified substance is to mention the types of hazards indicated on the label where such advertisement allows concluding a contract for purchase without first having sight of the label. This obligation should be changed to ensure that the advertisement of hazardous substances and mixtures contains all the information which is most important in terms of safety and protection of the environment. Therefore, the advertisement should contain the hazard pictogram, the signal word, the hazard class and the hazard statements. The hazard category should not be provided, as it is reflected by the hazard statement.		
(30) Regulation (EC) No 1272/2008 does not explicitly refer to		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
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, 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 apply for the purpose of labelling information required by Article 17 of Regulation (EC) No 1272/2008. The enforcement of those obligations is subject to the rules laid down in Chapter IV of Regulation (EU) 2022/2065.		

[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).

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
Cluster B – Classification		
Subgroup B1. Rules on Classification		
Articles in B1		
(2b) in Article 2, the following points [7a and] 38 are added:		
[…]		
38. 'acute toxicity estimates' means numeric criteria according to which substances and mixtures are classified in one of four acute toxicity hazard categories based on the oral, dermal or inhalation exposure route.';		
(5) in Article 6, paragraphs 3 and 4 are replaced by the following:		
'3. For the evaluation of mixtures pursuant to chapter 2 in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine disrupting property for human health' and 'endocrine disrupting property for the environment' hazard classes referred to in		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
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 .		
However, where the available test data on the mixture itself demonstrates germ cell mutagenic, carcinogenic or toxic to reproduction properties, or endocrine disrupting properties for human health or the environment which have not been identified from the relevant available information on the individual substance referred to in the first subparagraph, that data shall also be taken into account for the purposes of the evaluation of the mixture referred to in the first subparagraph.		
4. For the evaluation of mixtures pursuant to Chapter 2 in relation to the 'biodegradation, persistency, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment', 'persistent, bioaccumulative and toxic', 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' and 'very persistent and very mobile' hazard classes referred to in sections 4.1.2.8, 4.1.2.9,		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
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 ’;		
(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.		
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	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	Considering the specific referent to the mixtures it is not appropriate indicate the manufactures (of substances). We suggest to the Commission that coherently the

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
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.	referred to in section 1.1.3. of Annex I and in each section of Parts 3 and 4 of that Annex for the purposes of the evaluation.	article 6.5 (and perhaps in other parts of the regulation) should be changed.
When applying the bridging principles, manufacturers, importers and downstream users may integrate a weight of evidence determination using expert judgement in accordance with section 1.1.1. of Annex I to this Regulation, weighing all available information having a bearing on the determination of the hazards of the mixture, and in accordance with section 1.2. of Annex XI to Regulation (EC) No 1907/2006. The rules on bridging principles in section 1.1.3 of Annex I shall remain applicable even in a weight of evidence determination.	When applying the bridging principles, ~~manufacturers~~, importers and downstream users may integrate a weight of evidence determination using expert judgement in accordance with section 1.1.1. of Annex I to this Regulation, weighing all available information having a bearing on the determination of the hazards of the mixture, and in accordance with section 1.2. of Annex XI to Regulation (EC) No 1907/2006. The rules on bridging principles in section 1.1.3 of Annex I shall remain applicable even in a weight of evidence determination.	
When evaluating the hazard information for mixtures, manufacturers, importers and downstream users shall, where that information does not permit the application of the bridging principles in accordance with the first and second subparagraphs, evaluate the information by applying the other method or methods set out in Parts 3 and 4 of Annex I.’;	When evaluating the hazard information for mixtures, ~~manufacturers,~~ importers and downstream users shall, where that information does not permit the application of the bridging principles in accordance with the first and second subparagraphs, evaluate the information by applying the other method or methods set out in Parts 3 and 4 of Annex I.’;	

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
(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 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.		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions**	**Questions, comments and justifications of drafting suggestions**
In exceptional circumstances specific concentration limits may be set by the manufacturer, importer or downstream user where that manufacturer, importer or downstream user has adequate, reliable and conclusive scientific information that a hazard of a substance classified as hazardous is not evident at a level above the concentrations set for the relevant hazard class in Part 2 of Annex I or above the generic concentration limits set for the relevant hazard class in Parts 3, 4 and 5 of that Annex.		
2. M-factors for substances classified as hazardous to the aquatic environment, acute category 1 or chronic category 1, shall be established by manufacturers, importers and downstream users.		
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, specific concentration limits		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
shall not be set for harmonised hazard classes or differentiations for substances included in Part 3 of Annex VI for which a specific concentration limit is given in that Part.		
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.		
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.		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
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 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 proposal is certainly a positive aspect because it avoids overestimating the classification of the final mixture. Anyway it appears relevant to encourage the

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
the concentration limits referred to in paragraph 1 shall apply to the concentration of that identified impurity, additive or individual constituent in the mixture.		substance's supplier to provide a more appropriate range of the impurity in SDS.
11. Where a mixture contains another mixture, the concentration limits referred to in paragraph 1 shall apply to the concentration of the identified impurity, additive or individual constituent referred to in paragraph 10 in the resulting final mixture.';		See comment above
(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		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
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.’;		
Recitals relating to B1		
(4) In order to improve legal certainty and implementation with regard to the evaluation of hazard information for		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
mixtures where no or inadequate test data are available for the mixture itself, the interaction between the application of the bridging principles and a weight of evidence determination using expert judgement should be clarified. Such clarification should ensure that the weight of evidence determination complements but does not substitute the application of the bridging principles. It should 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.		
(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		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
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.		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
Subgroup B2. MOCS		
Articles in B2		
(2a) in Article 2, the following points 7a [and 38] are added:		
'7a. 'multi-constituent substance' means a substance that contains more than one constituent.	~~'7a. 'multi-constituent substance' means a substance that contains more than one constituent.~~	We consider this definition unnecessary without much benefit to the aim of clarifying classification rules for substances. Moreover, it differs from the definitions specified in the Guidance for identification and naming of substances under REACH and CLP,
(4) in Article 5, the following paragraph 3 is added:		
'3. A multi-constituent substance containing at least one constituent, in the form of an individual constituent, an identified impurity or an additive for which relevant information referred to in paragraph 1 is available, shall be examined in accordance with the criteria set out in this paragraph, using the available information on those constituents as well as	'3. A ~~multi-constituent~~ substance ~~containing at least one constituent, in the form of an individual constituent, an identified impurity or an additive~~ for which relevant information referred to in paragraph 1 is available **for an individual constituent (e.g. an identified impurity or an additive)** shall be examined in accordance with the criteria set	Consistently with the elimination of the multi-constituent definition, the writing proposal appears coherent with the current definition of substance. We ask to COMM clarification on the specific provision in the annex I

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
on the substance, unless Annex I lays down a specific provision.	out in this paragraph, using ~~the~~ **these** available information ~~on those constituents~~ as well as **the information** on the substance **itself**, unless Annex I lays down a specific provision.	
For the evaluation of multi-constituent substances pursuant to Chapter 2 in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine disrupting property for human health' and 'endocrine disrupting property for the environment' hazard classes referred to in sections 3.5.3.1, 3.6.3.1, 3.7.3.1, 3.11.3.1. and 4.2.3.1. of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual constituents in the substance.	For the evaluation of ~~multi-constituent~~ substances pursuant to Chapter 2 in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine disrupting property for human health' and 'endocrine disrupting property for the environment' hazard classes referred to in sections 3.5.3.1, 3.6.3.1, 3.7.3.1, 3.11.3.1. and 4.2.3.1. of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the **known** individual constituents in the substance.	Consistently with the elimination of the multi-constituent definition. 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:	Relevant available information on the ~~multi-constituent~~ substance itself shall be taken into account where one of the following conditions are met:	Consistently with the elimination of the multi-constituent definition.
(a) the information demonstrates germ cell mutagenic, carcinogenic, or toxic to reproduction properties, or endocrine		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
disrupting 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 properties or less severe properties shall not override the relevant available information on the constituents in the substance.	**Without prejudice to the relevant available information already evaluated under the relevant process of another european legislations (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),** relevant available information on the ~~multi-constituent~~ substance itself showing absence of ~~certain~~ **germ cell mutagenic, carcinogenic, or toxic to reproduction properties, or endocrine disrupting for human health or the environment properties** or less severe properties shall not override the relevant available information on the constituents in the substance.	Even if we agree with the new approach, we are concerned about the impossibility to use recent studies already done under the European legislation (REACH, PPP, biocide) and already evaluated under relevant processes, also to "declassify" the substance itself. Certain properties shall be replaced by CMR and ED properties, to be clear that rule is applicable only for CMR and ED endpoint.
For the evaluation of multi-constituent substances pursuant to Chapter 2 in relation	For the evaluation of ~~multi-constituent~~ substances pursuant to Chapter 2 in relation	Consistently with the elimination of the multi-constituent definition.

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
to the 'biodegradation, persistence, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment' 'persistent, bioaccumulative and toxic', 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' and 'very persistent and very mobile' hazard classes referred to in sections 4.1.2.8 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual constituents in the substance.	to the 'biodegradation, persistence, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment' 'persistent, bioaccumulative and toxic', 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' and 'very persistent and very mobile' hazard classes referred to in sections 4.1.2.8 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the **known** individual constituents in the substance.	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:	Relevant available information on the ~~multi-constituent~~ substance itself shall be taken into account where one of the following conditions are met:	Consistently with the elimination of the multi-constituent definition.
(a) the information demonstrates biodegradation, persistence, mobility and bioaccumulation properties.		
(b) the information supports the conclusions based on the relevant available information on the constituents in the substance.		

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
Relevant available information on the multi-constituent substance itself showing absence of certain properties or less severe properties shall not override the relevant available information on the constituents in the substance.	Relevant available information on the ~~multi-constituent~~ substance itself showing absence of ~~certain~~ **biodegradation, persistence, mobility and bioaccumulation** properties or less severe properties shall not override the relevant available information on the constituents in the substance.	Consistently with the elimination of the multi-constituent definition. Certain properties shall be replaced by biodegradation, persistence, mobility and bioaccumulation endpoint.
Recitals relating to B2		
(2) From a toxicological point of view, substances with 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 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	(2) ~~From a toxicological point of view, substances with 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[5], aimed to limit animal testing, data **is to be generated** on ~~multi-constituent~~ substances ~~is to be generated under the same conditions as data on any other substance~~, while data on individual constituents of a substance is normally not	we suggest to delete the first part the recital 2 because we have doubt on the scientific bases and coherently with our rewriting proposal of the article 5.3(b). The other points are in coherence with the previous modifications.

[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).

[5] 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).

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
to be generated, except where individual constituents are also substances registered on their own. Where data on individual constituents is available, multi-constituent substances should be evaluated and classified following the same classification rules as mixtures, unless Annex I to Regulation (EC) No 1272/2008 provides for a specific provision for those multi-constituent substances.	to be generated, except where individual constituents are also substances registered on their own. Where data on individual constituents is available, ~~multi-constituent~~ substances should be evaluated and classified following the same classification rules as mixtures, unless Annex I to Regulation (EC) No 1272/2008 provides for a specific provision for those ~~multi-constituent~~ substances.	
(3) It is normally not possible to sufficiently assess the endocrine disrupting properties for human health and the environment and the persistent, bioaccumulative and mobile properties of a mixture or of a multi-constituent substance on the basis of data on that mixture or substance. The data for the individual substances of the mixture or for the individual constituents of the multi-constituent substance should therefore normally be used as the basis for hazard identification of those multi-constituent substances or mixtures. However, in certain cases, data on those multi-constituent substances themselves may also be relevant. This is the case in particular where that data demonstrates endocrine disrupting properties for human health and	(3) It is normally not possible to sufficiently assess the endocrine disrupting properties for human health and the environment and the persistent, bioaccumulative and mobile properties of a mixture or of a ~~multi-constituent~~ substance on the basis of data on that mixture or substance. The data for the individual substances of the mixture or for the individual constituents of the ~~multi-constituent~~ substance should therefore normally be used as the basis for hazard identification of those ~~multi-constituent~~ substances or mixtures. However, in certain cases, data on those ~~multi-constituent~~ substances **or mixture** themselves may also be relevant. This is the case in particular where that data demonstrates endocrine disrupting properties for human	The suggested points are in coherence with the previous modifications

Commission proposal (following PCY proposed clustering, WK 1216/2023)	Drafting Suggestions	Questions, comments and justifications of drafting suggestions
the environment, as well as persistent, bioaccumulative and mobile properties, or where it supports data on the individual constituents. Therefore, it is appropriate that data on multi-constituent substances are used in those cases.	health and the environment, as well as persistent, bioaccumulative and mobile properties, or where it supports data on the individual constituents **or individual substances in the mixture**. Therefore, it is appropriate that data on ~~multi-constituent~~ substances **or mixture** are used in those cases.	