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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Delegations
N° prev. doc.:	CM 2193/23 - related document WK 1216/2023 - related document
N° Cion doc.:	ST 16528/23 + ADD 1 - 8 - COM (2022) 748 Final
Subject:	Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) - Comments by Member States on Sub-Group A4, Cluster B, and Sub-Clusters C1 and C3

Delegations will find in the Annex the table with comments by Member States on Sub-Group A4, Cluster B, and Sub-Clusters C1 and C3 of the Proposal for revision of the CLP Regulation.

The table covers the text discussed at the Working Party meeting on Technical Harmonisation (Dangerous Substances - Chemicals) 13 March 2023 (CM 1886/23), and it is for reference in view of the Working Party meeting on 5 April 2023.

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.*
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*- **place ALL comments within your completed questionnaire**.*
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Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting Suggestions** AT, BE, BG, CZ, DE, DK, EL, ES, FR, HU, IE, IT, LT, LV, NL, PT, SI, SK, FI	**Questions, comments and justifications** AT, BE, BG, CZ, DE, DK, EL, ES, FR, HU, IE, IT, LT, LV, NL, PT, SI, SK, FI
Subgroup A4. Online sales		FR: The French authorities welcome the proposal from Belgium to discuss the classification of specific forms of a substance in the CLP regulation. They thank the Commission to have received positively this proposal during the last meeting at the Council. The French authorities support the principle and would be happy to discuss further some concrete proposals e.g. in an ad-hoc technical group together with the Commission and the support of ECHA. SI: Regarding our opinion in practice will be a problem with using of some media (like audio media, face book etc.. which do not allow to provide all needed labelling elements). Therefore we propose to

		empower the Commission to adopt delegated act in order to further specifying the conditions, details and examples on **Online sales, Advertisement** as well as technical requirements for the **Digital labelling**. See also SI comments by Digital labelling!
		FR: Include a definition of **offers** and **advertisements**, for a better application of articles 48 and 48a. The wording of recital 30 could be reused without prejudice to existing harmonised provisions on advertising and distance selling: -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. To facilitate the application of Articles 9.3 and 9.4, a definition of '**expert judgement**' could be included in Article 2 either in terms of scientific qualification (such as the responsible person in the cosmetics regulation) or in terms of responsibility and/or independence from the supplier.

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. This would hinder the consolidation of your comments.

Articles in A4		
(3) in Article 4, paragraph 10 is replaced by the following:	DE: (3) in Article 4, paragraph 10 is replaced by the following <u>and paragraphs 11 and 12 are added</u>:	EL:
'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.';	BE: '10. A substance or a mixture shall not be placed on the market unless a supplier **<u>established within the European Union</u>** 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.'; DE: '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. <u>11. For the purposes of Article 4(10) in cases of a direct import by a consumer from</u>	AT: Austria welcomes the fact that online sales is more firmly anchored in the CLP Regulation. The Market Surveillance Regulation 2019/1020 requires in Articles 4 and 5 that an economic operator established in the Union has to assume appropriately specified obligations, if necessary appointing a representative according to Article 5. Such an analogous provision in the CLP-V is supported as it would make enforcement more effective. If mixtures or substances do not comply with the CLP Regulation, online marketplaces should also be held directly responsible for the relevant provision. Ensuring an equivalent level of protection on both sales channels (physical points of sale and online sales platforms) should be a

	an economic operator that is not established in the Union, the supplier referred to in paragraph 10 shall be mandated by said economic operator to ensure that the substance or the mixture fulfils the requirements set out in this Regulation for importers. The mandated supplier shall provide a copy of the mandate to the enforcement authorities upon request, in a Union language determined by the enforcement authority. The name, address and telephone number of the mandated supplier shall be indicated on the label. Mandated suppliers shall have the appropriate means to be able to fulfil their tasks. 12. Custom authorities shall not release hazardous substances and mixtures imported by consumers unless a supplier according to Article 4 (10) is indicated on the label'; DK: 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	priority. To achieve this goal, it is necessary that purchasers find the same information about hazard characteristics on online sales platforms as they do in physical points of sale. For this purpose, it is necessary that the full information on hazard characteristics is mandatory on the presentation page of the sales platform (online). BE: **Supplier** is defined in article 2 (26) as : 'any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture'. This definition does not state that the supplier has to be established within the EU. The requirement for the supplier to be established in the European Union, as mentioned in Recital (1), could be introduced in article 4 (10). By analogy, see notably cosmetics regulation n° 1223/2009: article 4 (1): 'Only cosmetic products for which a legal or natural person is designated within the Community as 'responsible person' shall be placed on the market.'

	the mixture fulfils the requirements set out in this Regulation. **Online platforms, as defined in Regulation (EU) 2022/2065, that facilitate distances contracts for a substance or a mixture between a trader based outside of the Community, and a party based inside the Community other than a supplier, are to be considered importers for the purposes of paragraphs 1 and 4. Where an online platform has appointed a legal representative, as provided for in Regulation (EU) 2022/2065, the legal representative is to be held responsible for compliance with these requirements.** IE: IE: We suggest to revert to the wording in the current text and replace 'the substance or the mixture fulfils the requirements' with 'the substance or the mixture complies with' LT: '10. A substance or a mixture shall not be placed on the market unless a supplier **established within the Community** has ensured in the course of an industrial or professional activity that the substance or	BE considers that clarifications are needed in the text on the following issues : - **The responsibilities for the classification of substances and mixtures :** In most chapters regarding classification, it is referred to manufacturers, importers and/or downstream users. Article 4(9) states that 'Suppliers in a supply chain shall cooperate to meet the requirements for classification, labelling and packaging in this Regulation.' The role and responsibilities of the supplier when he is not manufacturer, importer nor downstream user should be further clarified. - **The responsibilities for the submission of information for poison centres :** Some suppliers are not covered by the requirements to submit information for poison centres. The current provisions on these requirements refer to downstream users and importers, and in some specific cases to distributors. - **The responsibilities if there is no supplier within the EU when a consumer buys on line a product from a third coutry :** Who is liable for products sold on line to consumers by operators in third countries if

	the mixture fulfils the requirements set out in this Regulation.'; SI: 11. Suppliers placing substances or mixtures on the market through distance sales shall be established in the Union. ';	there is no supplier mandated within the EU ? How can inspection services act against non-compliant products offered on line to consumers by operators in third countries when there is no supplier mandated within the EU ? DE: In principle, it makes sense that when chemicals are imported from outside the EU, a professional entity is responsible for ensuring compliance with the legal requirements. However, if this responsible entity is not a professional importer, but a private person, i.e. consumer, enforcement measures would need to be addressed to the private person. In such cases, the only option for introducing effective enforcement actions or sanctions would be to mandate customs to withhold privately imported shipments. In this respect, a provision would have to be designed which authorises customs authorities to intervene. Customs could be mandated to withhold shipments from release for free circulation that are imported by consumers unless a supplier described in Article 4 (10) is indicated on the label. Customs could deduce from the address of the shipment that the goods are imported by a private individual and they could deduce from the

		labelling that it is or might be a hazardous substance/mixture. In order to improve enforcement of the Regulation it also needs to be ensured that the supplier indicated in Article 4(10) is identifiable and specifically mandated to be responsible for the substance or mixture as provided to the consumer. This needs to be ensured by mandating a specific supplier for this task. Such a provision could, for example, be taken over from Article 5 of the Market Surveillance Regulation. Further, it might be sensible to clarify what requirements a supplier under Article 4(10), and more specifically such a mandated supplier, has under this regulation. The provided drafting suggestion are by no means meant as a final proposal but may be used as a starting point for a more thorough discussion on the matter. DK: Denmark welcomes the intention behind the statement set out in recital 30, which recognises the regulatory gap with regard to online platforms. However, the measures proposed in the amended Article 4(10) do not address the real issue behind the rationale for recital 30 – namely where

		online platforms facilitate distance contracts between consumers and traders based outside of the Community. In these situations, the trader is not a supplier as defined in Article 2(26), as the trader is not based inside the Community. At the same time, if the contract is completed through direct delivery of the product from the third country trader to the consumer, the online marketplace will be regarded as neither an importer nor a distributor as defined in Article 2(17) and (20) respectively. Given that there will be no "supplier" in these situations, responsibility for compliance with the requirements set out in Title II-IV will fall upon the final consumer, who will be regarded as the *de facto* and *de jure* importer, as the Commission recognises in recital 30 of the proposed CLP revision. Denmark proposes that Article 4(10) is amended so as to close this presumably unintended gap in the regulation. Denmark proposes that where an online platform facilitates distance contracts between third country traders and parties within the Community other than suppliers, that the online platform is to be regarded as an importer for the purposes of paragraphs 1 and 4. For all other purposes, online

		platforms will only fall under the remit of the CLP in the event that they satisfy the supplier definition set out in Article 2(26). Denmark does not believe that the solution is to create a situation where responsibility disappears. Responsibility in these situations ought to lie with online platforms, that actively, knowingly and motivated by profit facilitate the introduction into the community of products that do not meet the requirements set out in the CLP-Regulation. Placing online platforms on a par with importers strengthens consumer protection, and Community traders will compete on a level playing field with non-Community traders. Amending the CLP to reflect the commercial reality of online sales, as put forward in the Danish proposal, will greatly reduce the likelihood of consumers becoming *de jure* importers, hence fulfilling the ambitions set out in recital 30, yet at the same time not creating a vacuum of responsibility. As such, Denmark suggests the omission of the qualifying requirement – "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". There will be situations where

		it may still be necessary to hold consumers liable for compliance with the CLP – for instance, when consumers physically import hazardous products in to the Community, which must then be confiscated. Furthermore, from an enforcement perspective, it will be difficult to verify whether a business in industrial or professional activity has ensured that the substance complies with the requirement. With respect to the horizontal nature of the Digital Services Act, Denmark proposes that where an online platform has identified a legal representative under the Digital Services Act, the legal representative is responsible for compliance with the requirements in Article 4. This will enable market surveillance authorities to enforce compliance with the CLP through sanctions against legal or natural persons based within the Community. Through utilising the mechanisms already established under the Digital Services Act, the revised CLP will demonstrate a uniform approach to the allocation of responsibility with regard to product liability. The CLP regulation establishes *lex specialis* with regard to product safety, where the vital safety interests at stake necessitate specific rules for the classification, labelling and

		packaging of substances and mixtures. These interests necessitate stringent rules, clear allocation of responsibility, and the absence of regulatory gaps. The Danish proposal strikes the necessary balance between respecting the horizontal nature of the Digital Services Act and the need to ensure consumer safety. EL: Comment: Although article 4(10) is a general provision which is not only refers on-line sales , we welcome that the addition: "…*a supplier has ensured in the course of an industrial or professional activity*" . According to article 2 of CLP regulation (paragraph 26) the *"Supplier" means any manufacturer, importer, downstream user or distributor*, which, according to paragraphs 15, 17 19 and 20 , *"is a natural or legal person* ***established within the Community***…Therefore, it is not necessary to add the phrase ***"****Supplier* ***established in the EU"*** as many M-S have proposed, although it will be useful for clarity reasons. HU: We agree with the comments of the other delegations that further clarification is

		needed in the text about this obligation, otherwise practical and enforceability problems would arise and, moreover, the original intention of the legislator would not be fulfilled, either. IE: IE: In the case of a consumer purchasing a substance or mixture on-line from a non-EU operator, in practice, how will the EU supplier be set up and put in place? Is it the responsibility of the non-EU operator to ensure that an EU supplier is in place (similar to the Only Representative arrangement under REACH)? In our opinion, the changes to article 4(10) are not sufficiently clear in this regard and should be amended to reflect what is required when a consumer is supplied directly by a non-EU supplier. Such clarification would be of particular benefit to the enforcement of this provision. (reference here to recital 1) LT: To ensure the enforcement of compliance with online sales requirements, the text should be clarified that suppliers have to be established within the EU. LV:

		According to Article 4(10) amendments an EU established supplier will be responsible for ensuring that CLP requirements are met with regard to substances and mixtures that are being placed on the marked through online sales. However, we are concerned that these amendments in practice will not solve the problem with supervision of such obligation, because enforcement authorities will not be able to check every single shipment from outside the EU, especially those, which are being shipped directly to the end-consumers on AliExpress, Amazon or other online trading platforms. There are millions of such shipments. Furthermore, we would like to also note, that a transition period might be needed for adjustment to this new obligation. PT: Despite the amendment to Article 4(10), requiring the existence of a supplier established in the Union to ensure that the substance or mixture complies with the requirements laid down in the CLP Regulation when it is placed on the market, including through distance sales, this wording does not seem to resolve all possible situations. It can solve, through the concept of "single representative" used in REACH, cases where the substance or mixture is in the context of a professional

		or industrial activity. However, we have doubts as to whether they will be involved outside the scope of a professional or industrial activity, in which it will not be avoided for the consumer to become an importer when buying the substance or mixture through distance sales to economic operators established outside the EU. SI: We are of the opinion that the provision on obligation of the supplier to be established in EU shall be provide also in Article 4 not only in recital 1. Therefore, we prose to add following para 11 of Article 4.: "11. Suppliers placing substances or mixtures on the market through distance sales shall be established in the Union." FI: This should perhaps be clarified in order to make it very clear that the supplier has to be established within the Union. It is not clear that the supplier must be appointed. In addition, guidance is needed.
(23) Article 48 is replaced by the following:		FR: This article does not prevent a company located outside the European Union from

		selling directly online to a European consumer or indirectly on a market place. It just avoids consumers being legally responsible.
'*Article 48*	EL: We agree	
Advertisement		SI: Due to the fact that for audio (e.g. radio) as well as for visual media such advertising is not possible, we propose to improve proposed Article 48.
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.	DE: 1. Any advertisement for a substance classified as hazardous shall indicate the relevant hazard pictogram(s), the signal word~~, the hazard class~~ and the hazard statement(s). DK: Any advertisement for a substance classified as hazardous shall indicate ~~the relevant hazard pictogram, the signal word,~~ the hazard class ~~and~~**,** the hazard statements and **any relevant supplemental**	AT: The proposed advertising provisions, e.g. the mandatory indication of the hazard class and hazard statements for mixtures for any advertisement are not appropriate and disproportionate in relation to distance sales offers. DE: Providing the hazard class without a category would be confusing to the consumer, especially in the case of CMR Cat. 2 substances/mixtures. The Commission states that the category

	label elements set in Annex II (EUH-phrases). Any advertisement**, with the exception of non-visual advertisements, for a substance classified as hazardous shall also indicate the relevant hazard pictogram and the signal word.** NL: 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. IT 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>	information is already conveyed by the hazard statement. While this is technically not correct for all hazard classes/categories, the information on the hazard class can equally be derived from the hazard statement. DK: Denmark suggests an amendment to Article 48 (1) and (2), which refer to 'any advertisement'. The Commission's proposal is only suitable for visual advertisements. It would be difficult to include all the elements stated in the revised Article 48 in an oral advertisement – for instance radio and podcast advertisements. In the case of digital or televisual advertisements, requirements as to the duration of visual notices on labelling requirements need to be set out in the regulation. Similarly, there are no requirements regarding size, accessibility, font, background colour, or duration as to how long the information must be provided. Please also see the Danish comments to point 1.2.1.4 in Annex I. Furthermore, Denmark seeks confirmation that advertisements on online platforms, regardless of whether the online platform is

		based in the EU or outside of the EU, will continue to be covered by Article 48, and that following the passing of the Digital Services Act, legal representatives for online platforms will be accountable for compliance with the CLP? LT: We support the distinction of the requirements between advertisement and distance sales offers. We strongly support the requirement to indicate hazard pictograms and signal words and hazard statements instead of hazard categories – this hazard information is more useful for consumers than hazard categories. We understand that is not possible to indicate hazard pictograms in the verbal advertisement, therefore the derogation for hazard pictograms could be done in this advertisement form. For visual advertisement hazard pictograms are important because they are the primary triggers to get consumer attention to hazard information about chemical products. NL: NL: we would like to propose to omit the hazard class from being mentioned in the

		advertisement. Normally, the hazard class is reflected in the hazard statement. We therefore wonder whether it has added value to require the mentioning of the hazard class on top of that. Additionally, it could be confusing since in some occasions, the hazard class consists of two differentiated categories that do not always apply to the substance or mixture, e.g. the hazard class "Respiratory or Skin Sensitisation". Most substances or mixtures will only be classified for skin sensitisation and not respiratory sensitisation as well. PT: We agree with the comments to include some detail on advertisement definition and also the distinction between oral and written advertisement. SK: We do not consider it appropriate to require the introduction of pictograms if this is not required in the contract. We propose to consider whether the H statement is sufficient. IT 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.	DE: 2. Any advertisement for a mixture classified as hazardous or covered by Article 25(6) shall indicate the hazard pictogram(s), the signal word, ~~the hazard class and~~ the hazard statement(s) and the labelling elements referred to in Annex II Part 2, as applicable. DK: Any advertisement for a mixture classified as hazardous or covered by Article 25(6) shall indicate ~~the relevant hazard pictogram, the signal word,~~ the hazard class ~~and,~~ the hazard statements and **any**	DE: Providing the hazard class without a category would be confusing to the consumer, especially in the case of CMR Cat. 2 substances/mixtures. The Commission states that the category information is already conveyed by the hazard statement. While this is technically not correct for all hazard classes/categories, the information on the hazard class can equally be derived from the hazard statement. Mixtures that are only labelled pursuant to Article 25(6) do not have to be labelled with pictograms, hazard statements and a

	relevant supplemental label elements set in Annex II (EUH-phrases). Any advertisement**, with the exception of non-visual advertisements, for a mixture classified as hazardous or covered by Article 25(6) shall also indicate the hazard pictogram and the signal word.** NL: 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. IT 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. <u>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.</u>	signal word, but only require labelling pursuant to Annex II Part 2. Therefore, for such mixtures the provision would not lead to any requirements. DK: See comments to Article 48(1) NL: NL: please see the comment on article 48(1): we do not think the hazard class should be required in the advertisement. Normally, the hazard class is reflected in the hazard statement, so we wonder whether it has added value to require the mentioning of the hazard class on top of that. Additionally, it could be confusing since in some occasions, the hazard class consists of two differentiated categories that do not always apply to the substance or mixture, e.g. the hazard class "Respiratory or Skin Sensitisation". Most substances or mixtures will only be classified for skin sensitisation and not respiratory sensitisation as well. SK: We do not consider it appropriate to require the introduction of pictograms if this is not required in the contract.

		We propose to consider whether the H statement is sufficient. IT See previous comment
(24) the following Article 48a is added:		FI: Generally, the consistency with GPSR should be respected, and where a conscious divergence is made, this should be clearly indicated/explained e.g. in the recitals.
'*Article 48a*	EL: We agree	
Distance sales offers	DK: **Distance ~~sales~~ contracts offers**	IE: IE: We suggest that a definition for 'distance sales', or at least a reference to a definition in legislation such as the Digital Services Act or the Market Surveillance Regulation, is provided.
Suppliers placing substances or mixtures on the market through distance sales shall clearly indicate the label elements referred to in Article 17.';	DE: Suppliers placing substances or mixtures on the market through distance sales shall ~~clearly~~ indicate the label elements referred to in Article 17 in the direct context of the offer.';	AT: Austria welcomes the fact that online sales is more firmly anchored in the CLP Regulation. The Market Surveillance Regulation 2019/1020 requires in Articles 4 and 5 that an economic operator established

	DK: **1.** Suppliers placing **a** substance~~s~~ or **a** mixture~~s~~ on the market through distance ~~sales~~ **contracts** shall clearly indicate the label elements referred to in Article 17. **2. Online platforms, as defined in Regulation (EU) 2022/2065, that facilitate distances contract offers for a substance or a mixture between a trader based outside of the Community, and a party based inside the Community other than a supplier, are to be considered suppliers for the purposes of paragraph 1. Where an online platform has appointed a legal representative, as provided for in Regulation (EU) 2022/2065, the legal representative is to be held responsible for compliance with this requirement.** LV: Suppliers placing substances or mixtures on the market through distance sales shall clearly indicate the label elements referred to in Article 17(1) in the official language(s) of the Member State(s) where the substance or mixture is placed on the market through distance sales, unless the Member State(s) concerned provide(s) otherwise.	in the Union has to assume appropriately specified obligations, if necessary appointing a representative according to Article 5. Such an analogous provision in the CLP-V is supported as it would make enforcement more effective. If mixtures or substances do not comply with the CLP Regulation, online marketplaces should also be held directly responsible for the relevant provision. Ensuring an equivalent level of protection on both sales channels (physical points of sale and online sales platforms) should be a priority. To achieve this goal, it is necessary that purchasers find the same information about hazard characteristics on online sales platforms as they do in physical points of sale. For this purpose, it is necessary that the full information on hazard characteristics is mandatory on the presentation page of the sales platform (online). DE: The term "clearly indicated" should be further elaborated here. If necessary, a reference to specific regulations could be included in the appendix. The size of the information in relation to the text should be clarified, the question of how exactly and at which point in time the offer the labelling elements must be placed (e.g. not in

	IT 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'	footnotes) etc. This is the only way to ensure (effective) enforcement. DK: Denmark welcomes the Commission's recognition of the need to address the issue of distance contracts in the CLP. However, adequately reflecting the true nature of the online market requires that online platforms are fully included within the remit of this provision. Online marketplaces will not necessarily meet the definition of a supplier as we have detailed in our comments to Article 4(10). Denmark proposes the inclusion of a second paragraph, which clarifies that online platforms are considered suppliers for the purpose of Article 48a(1), when an online platform facilitates distance contracts offers between a trader based outside of the Community and a party within the Community, which does not satisfy the definition of a supplier as per Article 2(26). Online platforms perform a role similar to importers and distributors in these situations, which the scope of the provision ought to reflect. Not only would this reflect the commercial reality of the online market, it would help

		ensure, that traditional webshops within the EU are not placed at a competitive disadvantage in comparison to online suppliers based outside of the EU. For the reasons set out in our comments to Article 4(10), where an online platform has identified a legal representative under the Digital Services Act, the legal representative ought to be held responsible for compliance with the requirements in Article 48a. This will enable market surveillance authorities to enforce compliance with the CLP through sanctions against legal or natural persons based within the Community. From an enforcement perspective, Denmark broadly welcomes the proposal for an Article 48a, and find that it makes sense to introduce an article on distance sales. However, to ensure interpretative consistency with other EU legislation, Denmark suggests that Article 48a refers to distance contract offers rather than distance sale offers. Where distance contract offers take place through digital or televisual advertisements, requirements as to the duration of notices on labelling requirements need to be set out

		in the regulation. The term 'clearly indicate' also needs to be defined in order to create legal certainty for both market surveillance authorities and the economic actors that fall under the remit of the CLP. For instance, is it permissible to use drop-down menus, much further down the page in small print, or simply link to the digital marking on another website entirely? Denmark suggests that the Commission issues an interpretative guidance note with regard to the issues noted above. IE: IE: We suggest that this article states where the suppliers should indicate the label elements, i.e. in the offers. LV: The proposal to separate advertisements and distance sales offers is fully welcome. Although, it is unclear in which language(s) label elements in distance sales offer should be provided. Information on a substance or a mixture classified as dangerous must be in a language understandable to the consumer. However, with the current wording it is not clear whether the Article 48a stipulates that the information should be provided in the official language of the Member State whose consumers can purchase the product

		on a website maintained by the operator in another Member State. SK: According to the current wording of distance sales offers, we have doubts about their practical application and also difficulties in the field of enforcement. IT we clearly prefer referring to all general rules of article 17
	DE: *New Article 48b* **Online Marketplaces** 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 the upcoming "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.
Recitals relating to A4		FR: This provision could be further developed to clarify the term 'clearly' and indicate

		where the label elements shall be indicated.
	FR: Please consider adding an 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 provision is applicable for online label through article 25 but should also be implemented for advertisements and distance sales offers. Only mandatory information is regulated whereas a double prohibition is clearly provided for in articles 69 and 72 of Regulation 518/2012 on biocidal products. It should be the case for CLP too.
(1) In order to keep pace with globalisation, technological development and new means of sale, such as online sales, it is necessary to adapt Regulation (EC) No 1272/2008 of the European Parliament and of the Council. While under that Regulation it is assumed that all responsible actors in the supply chain are established in the Union, practical experience has shown that economic operators established outside the Union sell chemicals online directly to the general public in the Union. Hence, enforcement authorities are unable to enforce Regulation (EC) No 1272/2008 against economic operators not established in the Union. It is therefore appropriate to require that there is	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 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	BE: This recital indicates that, under the current Regulation No 1272/2008, it is only assumed that all responsible actors in the supply chain are established in the Union. A clear provision should be added to ensure that substances and mixtures shall not be placed on the market unless a supplier established within the Union is liable for their compliance. DK: Denmark proposes an amendment to recital 1 and refers to the Danish proposal for Article 4(10). As noted above with regard to Article 4(10), Denmark has sympathy for

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 acts in course of an industrial or professional activity.	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 1272~~7~~/2008 and thereby ensure a high level of protection of human health and the environment. In order to ~~prevent~~ **reduce the likelihood of** situations where **a** consumer becomes *de jure* and *de facto* an importer when buying the substance or the mixture via distance ~~sales~~ **contracts** from the economic operators established outside the Union, it is necessary to specify that **online platforms are to be regarded as suppliers in these instances.** ~~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.~~ EL: We agree FI: No 12727/2008 > No 1272/2008	the Commission's desire to limit situations where the consumer *de jure* and *de facto* becomes an importer when buying substances or mixtures via distance contracts. However, the solution is not to reduce the total level of accountability in the regulation, but to ensure that accountability is allocated fairly, including with regard to online platforms. Without an adequate solution to the problem of online platforms, it remains necessary to be able to enforce compliance with the CLP upon consumers for the sake of broader consumer protection by disincentivising the importation of illegal chemical products through the confiscation of non-compliant products. Removing this enforcement power will otherwise result in the opening of a new route for the importation of non-CLP compliant chemicals into the Community. LV: There is a typo error in the regulation number in the 5th sentence. The correct regulation number should be '1272/2008'. SI: In order to be more exact on obligation on EU establishment of supplier, we propose to add Article 4.11.

		See also comment above.
(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.	EL: We agree SK: … 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 environment….	DK: Denmark fully supports the intention behind this recital. Labels provide consumers with important information on the safety of the products they purchase. And where products are purchased online it is important that this information is communicated by other means. It is as such important, that the regulation does not create a digital divide between online platforms and traditional webshops, regardless of whether the online platform falls within the current scope of suppliers – for instance where online platforms facilitate distance sales from traders based outside of the Community. SK: We propose to consider insert safety and protection of the human health not only safety and protection of the environment… We do not consider it appropriate to require the introduction of pictograms if this is not required in the contract. We propose to consider whether the H statement is sufficient.

(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, 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[1] should apply for the purpose of labelling information required by Article 17 of Regulation (EC) No 1272/2008. The enforcement of those obligations is subject to the rules laid down in Chapter IV of Regulation (EU) 2022/2065.		CZ: CZ believes that the obligation of online marketplaces to design and organise their online interfaces in a way that enables suppliers to comply with their obligations regarding product safety information under applicable Union law laid down by the Regulation (EU) 2022/2065 on a Single Market For Digital Services (DSA) is a sufficient provision. CZ would not support any proposal that would be incoherent with the DSA. DK: While Denmark welcomes the clarification, that labelling requirements apply to online platforms, it remains the case that Denmark regards this as a first step, but not a full solution to the problems posed by online platforms. The regulation needs to be clearer with regard to the specific obligations of online platforms, given that the definition of suppliers does not fully apply to online platforms. Denmark suggests that the consequences of inclusion of online platforms within the scope of the Digital Services Act ought to

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

		be set out in a Commission guidance note. Furthermore, Denmark draws attention to the inclusion of online platforms in the Danish proposals for amendments to Articles 4(10) and 48a.
Cluster B – Classification		
Subgroup B1. Rules on Classification		
Articles in B1		
(2b) in Article 2, the following points [7a and] 38 are added:	EL: We propose two more definitions to be added: 1. ***"Refill station"*** 2. ***"Ingredients"*** ***or*** ***"constituent"***: for "substances in multi-constituent substances" and ***"component"***: for "substances or mixtures in mixture"	EL: Justification: "*Refill station"*:It is a new term added in article 35.2a. It is very important to be defined the term *"Ingredients"* (if it refers to substances and "mixtures in mixture"), especially for the application of the Bridging principle: "Similar mixture" (Annex I, paragraph 1.1.3.5) . It is worth to mention that in paragraph 1.1.3 the term "ingredients" refers to substances. In addition in GHS the term "ingredients" refers to as 'substance in mixture' If COM believes that the term *"Ingredients"* shall not be used it must be deleted in many paragraphs of CLP (in

		paragraph 1.1.3, 1.1.3.5, 3.1.3.1, 3.1.3.3, 3.1.3.5.1, 3.1.3.6, 3.2.2.1 etc. and replaced by another term well defined in article 2 . Otherwise, there will be a confusion especially for the enforcement.
[…]		
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.';	EL: We agree NL: 38. 'acute toxicity estimates' means numeric **values based on** which substances and mixtures are classified in one of four acute toxicity hazard categories based on the oral, dermal or inhalation exposure route.';	NL: NL: in section 3.1.2.1 (Annex I), it says that acute toxicity values are expressed as (approximate) LD50 (oral, dermal) or LC50 (inhalation) values or as acute toxicity estimates (ATE). We'd like to suggest to change article 2 point 38 to say "values" instead of "criteria". PT: In principle, we can accept it.
(5) in Article 6, paragraphs 3 and 4 are replaced by the following:		PT: In principle, we can accept it.
	EL: Having in mind the amendments in article 6 para 3 we would like to mention the following: the wording of the relevant paragraphs referred to the bridging principles in Annex I, that is been repeated in the	EL: Justification: For the evaluation of mixtures classification in relation to the some hazard classes like CMR , ED the information for ***the substances in the mixture and not for the mixture itself shall only be used.***

	mentioned hazard classes ((CMR , ED) (3.5.3.3, 3.6.3.3, 3.7.3.3, 3.11.3.3. and 4.2.3.3 of Annex I, as well as in article 6 paragraph 5), has to be corrected as it follows: "Where the mixture itself has not been tested to determine its … hazard, but there are sufficient data on ***~~the individual ingredients and~~*** similar tested mixtures, to adequately characterize the hazards of the mixture, these data shall be used in accordance with the applicable bridging rules set out in section 1.1.3".	Furthermore, for the above mentioned classes, according to the CLP criteria (3.5.3.1, 3.5.3.1, 3.6.3.1, 3.7.3.1, 3.11.3.1. and 4.2.3.1. of Annex I,) if there are no data for the substances in the mixture, subsequently data for the whole mixture (i.e. 3.5.3.2), must be investigated. If there are no data also for the whole mixture then a bridging principle approach must be applied. ***If there are "sufficient data on the individual ingredients" then the classification of the mixture must be based on these data. There is no need to use a bridging principle.*** Therefore, the text "***the individual ingredients and"*** from paragraphs (3.5.3.3, 3.6.3.3, 3.7.3.3, 3.11.3.3. and 4.2.3.3 of Annex I must be deleted. The proposed rewording could also be used for the relevant paragraphs of the other classification classes (i.e. 3.1.3.5.1, 3.2.3.2.1, 3.3.3.2.1, 3.4.3.2.1, 3.8.3.3.1, 3.9.3.3.1, 3.10.3.2.1), where firstly the mixture itself has not been tested, then bridging principles, under concrete rules (par.1.1.3 of Annex I), for similar tested mixtures shall be investigated (tiered approach). FR:

		The definition of ATE needs a reformulation. ATE is a value (and not a numeric criteria) and is defined as the dose level which induces 50% mortality in an acute toxicity study (LD50 or LC50) or the estimated LD50 or LC50 using fixed dose procedure or the acute toxic class method. This value is used to classify a substance into one of several categories. For mixtures, the ATE value is used to estimate the potency of a mixture by calculation. The estimated potency is then used to classify the mixture into a hazard category.
'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 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 .	EL: SI: '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 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 all the relevant available information referred to in paragraph 1 for the substances in the mixture or ~~and not~~ for the mixture itself .	LT: Text should be aligned with the Commission Delegated Regulation. SI: We believe that all available information should be used for classification of mixture. Therefore we propose to stay in line with the general approach of UN-GHS (ST/SG/AC.10/30/Rev.9, Chapter 1.3.2.3.2) and correct proposed text.

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.	EL: We agree SI: ~~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.~~ FI: endocrine disrupting properties for human health > Endocrine disruption for human health endocrine disrupting properties for the environment > endocrine disruption for the environment	SI: We propose to delete proposed text as becomes irrelevant with the amendment of Article 6.3, first part. FI: Please revise the names of the hazard classes according to the Delegated Act
4. For the evaluation of mixtures pursuant to Chapter 2 in relation to the 'biodegradation, persistency, mobility and bioaccumulation' properties within the	EL: We agree SI:	SI: See comment above.

'hazardous to the aquatic environment', 'persistent, bioaccumulative and toxic', 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' and 'very persistent and very mobile' hazard classes referred to in sections 4.1.2.8, 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall only use the relevant available information referred to in paragraph 1 for the substances in the mixture and not for the mixture itself ';	3. For the evaluation of mixtures pursuant to Chapter 2 in relation to the 'biodegradation, persistency, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment', 'persistent, bioaccumulative and toxic', 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' and 'very persistent and very mobile' hazard classes referred to in sections 4.1.2.8, 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall ~~only~~ use all the relevant available information referred to in paragraph 1 for the substances in the mixture or ~~and not~~ for the mixture itself . FI: biodegradation > rapid degradability? persistent, bioaccumulative and toxic', 'very persistent and very bioaccumulative' >persistent, bioaccumulative and toxic or very persistent, very bioaccumulative properties FI: persistent, mobile and toxic' and 'very persistent and very mobile' > persistent,	FI: Proposal to change to "rapid degradability" because we assume that here this refers to the rapid degradability criterion for the aquatic chronic toxicity classification, which takes into account biotic and abiotic degradation. 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. Please revise the names of the hazard classes according to the Delegated Act

	mobile and toxic or very persistent, very mobile properties	
	EL: *We propose the addition of the text in the beginning of paragraph 5 of article 6: «**Without prejudice to paragraphs 3 and 4**….. where no or inadequate test data on the mixture itself of the kind referred to in paragraph 1……"*	EL: Justification: According to paragraph 3, 4 of article 6 for the evaluation of mixtures of some hazard classes shall only be used the relevant available information 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.	EL: We agree	
4. When evaluating hazard information for mixtures, manufacturers, importers and downstream users shall, where test data for	AT:	AT:

the mixture itself are inadequate or unavailable, apply the bridging principles referred to in section 1.1.3. of Annex I and in each section of Parts 3 and 4 of that Annex for the purposes of the evaluation.	4. When evaluating hazard information for mixtures, manufacturers, importers and downstream users shall, where test data for the mixture itself are inadequate or unavailable and only the information referred to in Article 6(5) is available, 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. DE: 4.When evaluating hazard information for mixtures, manufacturers, importers and downstream users shall, where test data for the mixture itself are inadequate or unavailable and the information referred to in Article 6(5) is available, 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. IT 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	The reference to Article 6(5) form the original text in the CLP Regulation should be maintained. This direct reference from Article 9(4) to the information referred to in Article 6(5) is extremely important in order to have a good enforceability of the basic requirement that bridging principles shall be applied only to the type of information referred to in Article 6(5). In practice, during evaluation duty holders tend to apply bridging principles to information other than referred to in Article 6(5) and this is why this important clarification should remain in Article 9(4) of the proposed text of the CLP Regulation. DE: Addition of the specific reference to which data must be available IT Considering the specific referent to the mixtures it is not appropriate indicate the manufactures (of substances). We suggest to the Commission that coherently the article 6.5 (and perhaps in other parts of the regulation) should be changed.

	in each section of Parts 3 and 4 of that Annex for the purposes of the evaluation	
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.	AT: 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 referred to in Article 6(5) 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 when such ~~even in~~ a weight of evidence determination is integrated. DE: ~~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~~	AT: In order to remain consistent with the sentence in the end of this sub-paragraph, which was added in the proposed text as an important clarification ("The rules on bridging principles in section 1.1.3 of Annex I shall remain applicable …"), the weight of evidence integrated in the evaluation when applying bridging principles needs to remain limited to the evaluation of information referred to in Article 6(5) for the determination of the hazards of the mixture to be classified. DE: According to recital 4, the aim of the amendment seems to be to clarify the relationship between weight of evidence determination using expert judgement and the bridging principles. From our understanding, the notion to apply weight of evidence and expert judgment when applying the bridging principles is not in line with the data hierarchy principles of the GHS. When applying the bridging principles only very limited discretion is given. This discretion is in practice limited to the selection of the suitable reference

	~~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.~~ EL: We do not agree with the last sentence. We propose to delete it: ***~~The rules on bridging principles in section 1.1.3 of Annex I shall remain applicable even in a weight of evidence determination".~~*** IT 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.	mixture in the case that more than one possible reference mixture is available. Generally, such discretion on data preference is not specifically addressed in any parts of the Regulation when deciding on the classification. Therefore, mixing the two approaches (weight of evidence determination using expert judgement and the bridging principles) must be avoided. EL: <u>Justification:</u> The "bridging principles are applied according to the concrete rules described in1.1.3 of annex I). Therefore, we strongly disagree with the last phrase. In addition, the tiered approach must be applied according to the general rules of CLP for the classification of mixtures. Furthermore, it is not clarified what prevails, if the application of a bridging principle leads to a different classification than that resulted using a weight of evidence determination. The use of bridging principles, , simultaneously with the "weight of evidence approach using expert judgement", may lead to a confusion on the determination of the hazards of the mixture, unless if it is clarified that ***the most protective scenario for the human health and the environment*** should be considered for the evaluation of the classification of the mixture.

		NL: NL: the integration of a weight of evidence assessment when applying the bridging principles as included in article 9(4) seems unclear. Also, combining insufficient information on the mixture itself with information on tested similar mixtures would be inconsistent with GHS and would introduce inconsistencies between article 9 and the text in CLP, e.g. sections 3.2.3.2 and 3.3.3.2 in Annex I. The text in section 3.2.3.1 of GHS rev. 9 which describes the tiered approach for mixtures makes this even clearer. Bridging principles are already difficult to apply and to enforce, the combination with Weight of Evidence might make it even harder and the current provision might give room for different interpretations. Also it may result in erroneous classifications. We would like to ask the Commission to explain how such assessment can be applied and whether it is possible to clarify the provision to avoid confusion and different interpretations.

		In general we support the tiered approach for mixtures as described in GHS. If this should be changed, we would like to suggest to change this at GHS before changing this in CLP. Discussions on changing/clarifying the bridging principles in GHS is already ongoing in the GHS PCI informal working group. PT: In principle, we can accept it.
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.’;	DE: 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~~ subparagraph~~s~~, evaluate the information by applying the other method or methods set out in Parts 3 and 4 of Annex I.’; EL: We propose the following text to be added: ***This paragraph applies without prejudice to paragraphs 3 and 4 of article 6.*** IT When evaluating the hazard information for mixtures, ~~manufacturers,~~ importers and	DE: Consequential change EL: <u>Justification</u>: According to par. 3,4 of art.6 for the evaluation of mixtures of some hazard classes shall only be used the relevant available information for the substances in the mixture and not for the mixture itself **or using the bridging principle** .

	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:	EL: We agree	
‘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.		
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 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.	DE: 4. By way of derogation from paragraph 1, specific concentration limits shall not be set for harmonised hazard classes or differentiations for substances included in Part 3 of Annex VI ~~for which a specific concentration limit is given in that Part~~.	DE: Annex IV contains only information that has been positively identified. Any conclusions on legitimate non-classification are not reflected in this Annex. Likewise, in cases where the assessment for a potential SCL led to the conclusion that it is not scientifically valid to set an SCL results in the absence of this information in Annex VI. While there are entries in Annex VI for which no discussion on SCL setting has taken place, these entries cannot be easily distinguished from those that have been discussed and did not warrant setting an SCL. Allowing setting SCL for all substances in Annex VI that do not have an SCL would therefore also allow setting SCL for substances where RAC consciously decided to not set one. This seems not appropriate. NL: NL: we believe a provision is missing here to cover the situation where RAC concludes that the Generic Concentration Limit is applicable. This information is not included in Annex VI.

		We would therefore like to propose to include the GCL to the derogation under paragraph 4 and secondly, we would like to suggest to include the conclusions by RAC when the GCL is applicable, in Annex VI. This would be in analogy with the inclusion of the M=1 values. FI: A reference to the Notes in Annex VI could be added
		FR: By making the establishment of ATEs mandatory, under what conditions will mixture suppliers be allowed to use Table 3.1.2 of Annex I and the ATE conversion values in the calculation formula?
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.		
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.		
		FR: This first sentence does not seem necessary as implicit from paragraph 2 & 5. To be noted that a similar sentence has not been developed for SCL or ATE. Is it the correct place for the 2nd sentence? Is it needed in view of the definition of M-factor? If kept, shall not be placed under paragraph 7 but at the end of paragraph 5 or in a separate paragraph.
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 shall apply to the concentration of that identified impurity, additive or individual constituent in the mixture.	DE: 10. Where a mixture contains a substance which is classified as hazardous solely due to the presence of an identified ~~impurity, additive or~~ individual constituent, the concentration limits referred to in paragraph 1 shall apply to the concentration of that identified ~~impurity, additive or~~ individual constituent in the mixture.	DE: Consequential change (see proposed amendment to definitions in Article 2) NL: NL: we support the amended provisions for article 10. However, regarding paragraphs 10 and 11, we do wonder whether a provision should be added to clarify the rules when classifying mixtures according to notes J, K, L and M. PT:

		In principle, we agree with this. IT The proposal is certainly a positive aspect because it avoids overestimating the classification of the final mixture. Anyway it appears relevant to encourage the 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.';	DE: 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.';	DE: Consequential change (see proposed amendment to definitions in Article 2) IT 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 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.';	AT: '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 referred to in Article 6(5) 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.';	AT: In order to remain consistent with the sentence in the end of the second sub-paragraph of Article 9(4), which was added in the proposed text as an important clarification ("The rules on bridging principles in section 1.1.3 of Annex I shall remain applicable …"), the weight of evidence integrated in the evaluation when applying bridging principles needs to remain limited to the evaluation of information according to Article 6(5) for the determination of the hazards of the mixture to be classified (see Article 9(4)). For consistency between Article 9(4) and Section 1.1.1.3 of Annex I also Section 1.1.1.3 should refer to the information referred to in Article 6(5). DE: Consequential change (see proposed changes to Art. 9 (4)) Changes also relevant in Annex I 1.1.1.1. Where the criteria cannot be applied directly to available identified information, or where only the information referred to in Article 6(5) is available, the weight of

	DE: '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.'; EL:	evidence determination using expert judgment shall be applied in accordance with Article 9(3) or 9(4) respectively. NL: NL: we would like to suggest to make a distinction between a Weight of Evidence within a tier where only certain data is being used vs a total Weight of Evidence where all data is being used, as is the case in section 3.2.1.2 in Annex I. This would be in compliance with GHS revisions 8, 9 and 10. (See section 1.3.2.4.9 regarding total Weight of Evidence). An example of a text proposal would be: "In a tiered approach the weight of evidence assessment may be limited to the data within that tier."

	We agree	
Recitals relating to B1		
(4) In order to improve legal certainty and implementation with regard to the evaluation of hazard information for mixtures where no or inadequate test data are available for the mixture itself, the interaction between the application of the bridging principles and a weight of evidence determination using expert judgement should be clarified. Such clarification should ensure that the weight of evidence determination complements but does not substitute the application of the bridging principles. It should 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.	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 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~~ EL: We agree	DE: Consequential change (see proposed amendment to definitions in Article 2)

(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.	EL: We agree	
(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	EL: We agree	

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.		
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.	AT: 7a. 'more than one constituent substance' (MOCS) means a substance that contains more than one constituent. BG: ~~'7a. 'multi-constituent substance' means a substance that contains more than one constituent.~~ DE: '7a. '~~multi-constituent substance' means a substance that contains more than one constituent~~. 'constituent' means any	AT: We do not consider the definition of the term "multi constituent substances" to be appropriate, as the term "multi constituent substances" is already used for another definition in the current ECHA guidance on identification and naming of substances under REACH and CLP. The term used here refers to the comprehensive term for "multi constituent substances" and UVCB substances, which is usually described as "more than one constituent substances" (MOCS). Therefore, it is proposed to use the term "more than one constituent

	discrete chemical structure present in a substance or a mixture that can be characterised by its unique chemical identity. ES: ~~'7a. 'multi-constituent substance' means a substance that contains more than one constituent.~~ SI: ~~7a. 'multi-constituent substance' means a substance that contains more than one constituent~~	(MOCS)", which is already well established at expert level. In principle, we consider it more appropriate to introduce substance definitions first in the REACH Regulation (EC) No 1907/2006 and not in the CLP Regulation (EC) No 1272/2008. BE: The proposed definition could lead to legal difficulties. The term 'constituent' is not defined; if impurities are considered as constituents, all substances contain more than one constituent. Moreover, the proposed definition could create confusion with the definition of 'multi-constituent substance' set out in the "Guidance for identification and naming of substances under REACH and CLP" where concentration ranges for constituents are notably specified : "*Multi-constituent substance: As a general rule, a substance, defined by its composition, in which more than one main constituent is present in a concentration ≥10% (w/w) and <80% (w/w).*" BG: 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, where ECHA divides the substances into 3 different types: 1. Substances of well-defined chemical composition which are: - mono-constituent - one constituent is present at concentration of at least 80% (w/w) and contains up to 20% (w/w) of impurities and - multi-constituent (e.g. reaction masses) - several main constituents present at concentrations ≥ 10% and < 80% (w/w) 2. UVCB - substances of Unknown or Variable composition, Complex reaction products or Biological materials. We should only determine when available data on constituents (impurities, additives or constituents) prevail the available data on the whole substance. DE: The definition of "multi-constituent substance" aims at substances that consist of several constituents. However, the definition of the term "substance" already includes all constituents that result from the manufacturing process. In fact, any

		substance that is manufactured consists of several constituents. Thus, the newly added definition of "multi-constituent substance" is not expedient for the intended purpose, because it merely represents a linguistic modification of the already defined and established substance term and thus adds a second term for the same regulated object (substance). Also, the term “multi-constituent substance” is already used in chemicals legislation. The term “multi-constituent substance” has already been introduced and established in the ECHA guidelines for the identification and naming of substances under REACH and CLP. However, "multi-constituent substance" in the guidance means a substance that is defined by its quantitative composition and in which several main constituents are present in concentrations between ≥ 10% by mass (w/w) and < 80% by mass (w/w). The "multi-constituent substance" is therefore defined by the main constituents and does not include all constituents as in the proposed definition in Article 2. Thus, adding a well-established term with a different definition in CLP may lead to unnecessary confusion. Additionally, the term "multi-constituent substance" is only used in the proposed text in Articles 2 and 5. This would open up

		new scope for interpretation for the rest of the text of the regulation, in which the term "multi-constituent substance" is not systematically used. Instead of defining "multi-constituent substance", the term "constituent" should be introduced. The newly introduced classification logic is based on classifying a substance based on a hazardous constituent, independent of it being an impurity or other constituent. It seems appropriate to introduce a term that unambiguously distinguishes discrete chemical structures from de facto manufactured substances. Further elaboration of this definition could be done in the respective ECHA-Guidance. DK: We interpret that "multi-constituent substances" are subject to the same obligations as substances in themselves. However, interpretive doubts could arise from the current text under point 2 of the recitals, where it says that "multi-constituent substances" are no different from a mixture consisting of two or more substances from a toxicologist's point of view. Therefore, we have suggested a different wording of this recital cf. below. Furthermore, we suggest to have a definition of "constituent" and “UVCB” in article 2.

		EL: *Comments : 1. There is a discrepancy between REACH guidances definition 'multi-constituent substance'* According to guidance "Identification and naming of substances under REACH and CLP", version 2, April 2017: *"If one constituent is present at a concentration of at least 80% (w/w) and the impurities make up no more than 20% (w/w), the substance will be considered as* ***mono-constituent****.* *If more than one main constituent is present in a concentration between 10% and 80% (w/w) the substance is considered as a* ***multi-constituent substance****.* 2. It is not clear if the new definition covers UVCB and mono-constituent subtances. In the above mentioned guidance the mono- and multi-constituent substances are well defined substances while "*UVCB are substances for which the number of constituents is high, or the composition is to a significant extent unknown, or the variability of composition is large or unpredictable. (In these cases a clear identification based on the chemical composition only is not possible and these will need to be considered as a substances of Unknown or Variable composition, Complex reaction products or Biological*

		materials (UVCB)). ES: 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, where ECHA divides the substances into 3 different types: 1. Substances of well-defined chemical composition which are: - mono-constituent - one constituent is present at concentration of at least 80% (w/w) and contains up to 20% (w/w) of impurities and - multi-constituent (e.g. reaction masses) - several main constituents present at concentrations ≥ 10% and < 80% (w/w) 2. UVCB - substances of Unknown or Variable composition, Complex reaction products or Biological materials. We should only determine when available data on constituents (impurities, additives or constituents) prevail the available data on the whole substance. LV:

		Multi-constituent substance (MOCS) definition introduced under Article 2(7a) is rather unclear. From the given definition it is not possible to identify what these substances are and how these substances differ from mixtures. The Commission previously has already explained that a detailed definition has already been provided in the CLP guidance document. Although, we would like to note that guidelines are not legally binding, and unclear MOCS definition might result in different interpretations between stakeholders and enforcement authorities. In this respect the legal framework should be clear and therefore, a more detailed MOCS definition would be very appreciated. NL: NL: in the ECHA guidance for identification and naming of substances under REACH and CLP, the definition of 'multi-constituent substance' is explained differently from the definition in proposed article 2, point 7a and article 5, paragraph 3. In the guidance, it defines the term 'multi-constituent substance' as *"a substance in which more than one main constituent is present in a concentration ≥10% (w/w) and*

		<80% (w/w)". This does not include any impurities or additives that are present in a concentration less than 10%, while it seems that article 5 does mean to include these impurities and additives. We would therefore propose to not use the term "multi-constituent substance" because we are afraid this would raise confusion. Perhaps a different term could be used or it could be avoided altogether by deleting article 2, point 7a and changing article 5, paragraph 3 to avoid the use of the term. Please see the drafting suggestions. PT: The multi-constituent definition should be harmonized with REACH multi-constituent definition or as alternative the MOCS – More Than One Constituent definition would be more adequate. The use of MOC would consider UVCB (substances of unknown or variable composition). SI: We are of the opinion that introduction of a new definition for a certain type of substances only in CLP is confusing and unnecessary. The coherence between REACH and CLP in this aspect are crucial.

		We also believe that the classification rules of certain substances shall be clarified without new definition. Therefore we propose to delete the new definition. SK: The introduction of the term MOCS is too general; we welcome more precise specification in CLP, which would be elaborated in more detail in the Guidance for identification and naming of substances under REACH and CLP. However, the Guidance should be based on definition in CLP. We are of the opinion that the definition of 'multi-constituent substance' in REACH and CLP should be the same.
(4) in Article 5, the following paragraph 3 is added:		
	FR: '7a. 'multi-constituent substance' means a substance containing at least one constituent in the form of an individual constituent, an identified impurity or an additive.	FR: The term 'constituent' is not defined. It will weaken the application of the text. In particular, it has a direct impact on the use of 'multi-constituent'. The definition of multi-constituent is different than the one used in the guidance for identification and naming of substances under REACH and CLP, which may create confusion and potential incompliances.

		Harmonisation between both regulations is needed.
'3. A multi-constituent substance containing at least one constituent, in the form of an individual constituent, an identified impurity or an additive for which relevant information referred to in paragraph 1 is available, shall be examined in accordance with the criteria set out in this paragraph, using the available information on those constituents as well as on the substance, unless Annex I lays down a specific provision.	BG: A ~~multi-constituent~~ substance containing ~~at least one~~ **constituents,** 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~~ **known** constituents as well as on the substance, unless Annex I lays down a specific provision. DE: '3. A ~~multi-constituent~~ substance containing at least one constituent, ~~in the form of an individual constituent, an identified impurity or an additive~~ for which relevant information referred to in paragraph 1 is available, shall be examined in accordance with the criteria set out in this paragraph, using the available information on those constituents as well as on the substance, unless Annex I lays down a specific provision. EL:	BE: There is no definition in CLP for 'constituent', nor for 'impurity' or 'additive'. The provision "*unless Annex I lays down a specific provision*" should be clarified. The procedure and the conditions to derogate should be set and mentioned in the present text. Derogations should only be foreseen for harmonized classifications and the burden of proof should not be shifted to member states. BG: To reflect the deletion of MCS definition The composition of mixtures is well known, whereas in the MCS case, it is not always possible to know every single constituent. We should avoid additional testing to identify unknown constituents. Clarification is needed on the text "unless Annex I lays down a specific provision" is unclear - it should be specified, at least in

	We propose the following corrections in bold and discrete delete: "A multi-constituent substance ~~containing~~ ***with at least one of its constituents***, 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 ***below*** in this paragraph, using the available information ***referred to in paragraph 1*** on those constituents as well as on the substance, unless Annex I lays down a specific provision". ES: A ~~multi-constituent~~ substance containing ~~at least one~~ **constituents,** 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~~ **known** constituents as well as on the substance, unless Annex I lays down a specific provision. NL: '3. A ~~**multi-constituent**~~ substance containing ~~**at least**~~ **more than** one	preamble 2, what kind of specific provisions the text refers to. DE: Consequential change (see proposed amendment to definitions in Article 2) EL: Justification: This paragraph is very confusing for clarity reason we propose a rewording of the text. ES: To reflect the deletion of MCS definition The composition of mixtures is well known, whereas in the MCS case, it is not always possible to know every single constituent. We should avoid additional testing to identify unknown constituents. Clarification is needed on the text "unless Annex I lays down a specific provision" is unclear - it should be specified, at least in preamble 2, what kind of specific provisions the text refers to. PT: We consider that this text can be simplified. SI:

	constituent, in the form of an individual constituent, an identified impurity or an additive for which relevant information referred to in paragraph 1 is available, shall be examined in accordance with the criteria set out in this paragraph, using the available information on those constituents as well as on the substance, unless Annex I lays down a specific provision. PT: 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 SI: 3. A ~~multi-constituent~~ substance containing at least one constituent above the applicable concentration limit, in the form of an individual constituent, an identified impurity or an additive for which relevant information referred to in paragraph 1 is available, shall be examined in accordance with the criteria set out in this paragraph, using the available information on those constituents as well as on the substance, unless Annex I lays down a specific provision.	See comments above . However we think that the relevant specific/generic concentration limits shall be take into consider in order to be clearer. Therefore we propose to delate "multi-constituent" and to add "above the applicable concentration limit" in proposed text.

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.	BG: 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. DE: 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.	DE: Consequential change (see proposed amendment to definitions in Article 2) DK: PT: For better reading we would suggest to include subparagraphs. This text could be included as subparagraph 3a. SI: See comments above. Furthermore, when reliable data on the substance (e.g. UVCB) is available (e.g. from a registration dossier), it should always be possible to use this data for classification. This follows also the general approach of UN-GHS, Chapter 1.3.2.3.2. Therefore we propose to delate "multi-constituent" and to add "or the substance itself." in proposed text. FI: Please revise the names of the hazard classes according to the Delegated Act.

	EL: We agree ES: 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. NL: For the evaluation of **~~multi-constituent~~** substances **containing more than one constituent** 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. SI: 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 or the substance itself. FI: endocrine disrupting properties for human health > Endocrine disruption for human health endocrine disrupting properties for the environment > endocrine disruption for the environment	
		FR: Clarification in the legal text is needed on the possibilities allowed for recourse to this

		rule in the case of a specific provision in Annex I. In any case the French authorities consider that any exemption must be based on a scientific justification. France is in favour to discuss further this article 5.3 in an ad hoc technical group together with the Commission and the support of ECHA. At this stage, France has a scrutiny reservation.
Relevant available information on the multi-constituent substance itself shall be taken into account where one of the following conditions are met:	BG: Relevant available information on the ~~multi-constituent~~ substance itself shall be taken into account where one of the following conditions are met: DE: Relevant available information on the ~~multi-constituent~~ substance itself shall be taken into account where one of the following conditions are met: EL: We agree ES: Relevant available information on the ~~multi-constituent~~ substance itself shall be taken into account where one of the following conditions are met: NL:	DE: Consequential change (see proposed amendment to definitions in Article 2) SI: See comments above.

	Relevant available information on the ~~**multi-constituent**~~ substance **containing more than one constituent** itself shall be taken into account where one of the following conditions are met: SI: 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 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.	SI: 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 properties or less severe properties shall not override the relevant	BG: Relevant available information on the ~~multi-constituent~~ substance itself showing	BG: Certain properties shall be replaced by CMR and ED properties, to be clear that

available information on the constituents in the substance.	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. DE: 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. EL: We agree ES: 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. NL:	rule is applicable only for CMR and ED endpoint. DE: Consequential change (see proposed amendment to definitions in Article 2) DK: ES: Certain properties shall be replaced by CMR and ED properties, to be clear that rule is applicable only for CMR and ED endpoint. SI: See comments above.

	Relevant available information on the ~~**multi-constituent**~~ substance **<u>containing more than one constituent</u>** itself showing absence of certain properties or less severe properties shall not override the relevant available information on the constituents in the substance. SI: Relevant available information on the ~~multi-constituent~~ substance itself showing absence of certain properties or less severe properties shall not override the relevant	
For the evaluation of multi-constituent substances pursuant to Chapter 2 in relation to the 'biodegradation, persistence, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment' 'persistent, bioaccumulative and toxic', 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' and 'very persistent and very mobile' hazard classes referred to in sections 4.1.2.8 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual constituents in the substance.	BG: For the evaluation of ~~multi-constituent~~ substances pursuant to Chapter 2 in relation to the 'biodegradation, persistence, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment' 'persistent, bioaccumulative and toxic', 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' and 'very persistent and very mobile' hazard classes referred to in sections 4.1.2.8 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the	DE: Consequential change (see proposed amendment to definitions in Article 2) PT: For better reading we would suggest to include subparagraphs. This text could be included as subparagraph 3b. SI: See comments above. Furthermore, when reliable data on the substance (e.g. UVCB) is available (e.g. from a registration dossier), it should always be possible to use this data for classification.

	known individual constituents in the substance. DE: For the evaluation of ~~multi-constituent~~ substances pursuant to Chapter 2 in relation to the 'biodegradation, persistence, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment' 'persistent, bioaccumulative and toxic', 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' and 'very persistent and very mobile' hazard classes referred to in sections 4.1.2.8 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual constituents in the substance. EL: We agree ES: For the evaluation of ~~multi-constituent~~ substances pursuant to Chapter 2 in relation to the 'biodegradation, persistence, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment' 'persistent, bioaccumulative and toxic', 'very persistent and very	This follows also the general approach of UN-GHS, Chapter 1.3.2.3.2. Therefore we propose to delate "multi-constituent" and to add "or the substance itself." in proposed text. FI: We propose to change to "rapid degradability" because we assume that here "biodegradation" refers to the rapid degradability criterion for the aquatic chronic toxicity classification, which takes into account biotic and abiotic degradation. 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 Please revise the names of the hazard classes according to the Delegated Act

	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. NL: For the evaluation of ~~**multi-constituent**~~ substances **containing more than one constituent** pursuant to Chapter 2 in relation to the 'biodegradation, persistence, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment' 'persistent, bioaccumulative and toxic', 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' and 'very persistent and very mobile' hazard classes referred to in sections 4.1.2.8 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual constituents in the substance. SI:	

	For the evaluation of ~~multi-constituent~~ substances pursuant to Chapter 2 in relation to the 'biodegradation, persistence, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment' 'persistent, bioaccumulative and toxic', 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' and 'very persistent and very mobile' hazard classes referred to in sections 4.1.2.8 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual constituents in the substance or the substance itself. FI: biodegradation > "rapid degradability" persistent, bioaccumulative and toxic', 'very persistent and very bioaccumulative' >persistent, bioaccumulative and toxic or very persistent, very bioaccumulative properties persistent, mobile and toxic' and 'very persistent and very mobile' > persistent, mobile and toxic or very persistent, very mobile properties	
Relevant available information on the multi-constituent substance itself shall be	BE:	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 **two** following conditions are met: BG: Relevant available information on the ~~multi-constituent~~ substance itself shall be taken into account where one of the following conditions are met: DE: Relevant available information on the ~~multi-constituent~~ substance itself shall be taken into account where one of the following conditions are met: EL: We agree ES: Relevant available information on the ~~multi-constituent~~ substance itself shall be taken into account where one of the following conditions are met: SI: Relevant available information on the ~~multi-constituent~~ substance itself shall be taken into account where one of the following conditions are met:	Both conditions should be met. DE: Consequential change (see proposed amendment to definitions in Article 2) SI: See comments above.
	FR:	FR:

	For the evaluation of multi-constituent substances pursuant to Chapter 2 in relation to the 'biodegradation, persistence, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment' 'persistent, bioaccumulative and toxic', 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' and 'very persistent and very mobile' hazard classes referred to in sections **4.1.2.8, 4.1.2.9**, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual constituents in the substance.	A coma was missing.
(a) the information demonstrates biodegradation, persistence, mobility and bioaccumulation properties.	BE: (a) the information demonstrates ~~**biodegradation,**~~ persistence, mobility **or** ~~**and**~~ bioaccumulation properties.	BE: The demonstration of biodegradation seems not adequate in this context. The PBT guidance indicates that the assessment of the persistence of multi-constituent substances is not adequate if their composition does not consist of similar structures or is not well characterised; it may still contain a certain amount of constituents that are persistent although the amount of easily degradable constituents is high enough to lead to an overall degradation percentage sufficient to meet the criteria for ready biodegradation.

(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.	BG: 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. DE: 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. EL: We agree ES: Relevant available information on the ~~multi-constituent~~ substance itself showing absence of ~~certain~~ **biodegradation,**	BG: See comment on fourth subparagraph DE: Consequential change (see proposed amendment to definitions in Article 2) ES: See comment on fourth subparagraph SI: See comments above.

	persistence, mobility and bioaccumulation properties or less severe properties shall not override the relevant available information on the constituents in the substance. NL: Relevant available information on the ~~**multi-constituent**~~ substance **containing more than one constituent** itself showing absence of certain properties or less severe properties shall not override the relevant available information on the constituents in the substance. SI: 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**.**	
	BG: **(4a) in Article 5, the following paragraph 4 is added:** **"Paragraph 3 shall not apply to UVCB substances."** ES:	BG: It should be considered that UVCB substances cannot be identified well enough by their chemical composition because they contain a large number of constituents and the composition is often largely unknown, variable or difficult to predict. Other types of information are required to identify them, such as

	(4a) in Article 5, the following paragraph 4 is added: **"Paragraph 3 shall not apply to UVCB substances."**	origin/source and manufacturing process, and any significant change to the source or process may result in a different substance and thus the need for new tests. This group presents a real scientific and analytical challenge in respect to the analysis of the composition and structure of different constituents. We also would like to emphasize that UVCB include very different substances, such as polymers, petroleum products, essential oils and others with varying properties and hazard and risk profiles, which are very different from the core MCS group. In most cases UVCB encompass hundreds to thousands of different unknown constituents, which makes the analysis unpractical, unworkable and technically and economically unfeasible. Given the nature of these substances, in practice the proposed principle would be difficult to apply to them. **That's way we consider they should be excluded from the MCS concept.** ES: It should be considered that UVCB substances cannot be identified well enough by their chemical composition because they contain a large number of constituents and the composition is often largely unknown, variable or difficult to

		predict. Other types of information are required to identify them, such as origin/source and manufacturing process, and any significant change to the source or process may result in a different substance and thus the need for new tests. This group presents a real scientific and analytical challenge in respect to the analysis of the composition and structure of different constituents. We also would like to emphasize that UVCB include very different substances, such as polymers, petroleum products, essential oils and others with varying properties and hazard and risk profiles, which are very different from the core MCS group. In most cases UVCB encompass hundreds to thousands of different unknown constituents, which makes the analysis unpractical, unworkable and technically and economically unfeasible. Given the nature of these substances, in practice the proposed principle would be difficult to apply to them. **That's way we consider they should be excluded from the MCS concept.**
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	BG: (2) From a toxicological point of view, substances with more than one	BE: See comment on article 5(3). BG:

two or more substances. In accordance with Article 13 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[2], 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 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.	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[3], 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 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. DE: (2) From a toxicological point of view, substances with more than one constituent ~~('multi-constituent substances')~~	To reflect the deletion of MCS definition DE: Consequential change (see proposed amendment to definitions in Article 2) DK: No individual remarks, but please note the remarks to art. 2, point 7a. ES: To reflect the deletion of MCS definition SI: See comments above. FI: Could the relationship between UVCB-substances and multi-consituent substances be clarified here?

[2] 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).

[3] 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).

	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 composed of several constituents 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 with more than one constituent ~~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. (2a) Substances as defined in Article 2 7. are normally not manufactured as 100 % pure substances. Rather, they are composed of more than one constituent. If the composition of the substances is well defined, a formal distinction is made between main constituents and impurities. In the case of substances with complex	

	compositions, this distinction is not made. Such substances only consist of constituents. Annex VI is mostly a list of substances that are clearly defined by their molecular structure in the meaning of constituents (no indication of purity and impurities). In addition, it contains substances with complex compositions that cannot be clearly identified by their molecular structure, i.e. substances with a composition that is not precisely known or that varies in part or substances with a high number of constituents. As constituents may be relevant for the classification and labelling of substances it is appropriate to introduce a definition of that term. DK: 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**, however from a regulatory perspective and for the purposes of this Regulation, multi-constituent substances are to be regarded as substances**. In accordance with Article 13 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council , 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 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. EL: We agree ES: (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~~	

[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).

	~~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, ~~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. NL: (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[6], 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 to be generated, except where individual constituents are also substances registered	

[6] 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).

	on their own. Where data on individual constituents is available, ~~**multi-constituent**~~ substances **containing more than one constituent** 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 **containing more than one constituent**. SI: (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[7], 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 to be generated, except where individual constituents are also substances registered on their own. Where data on individual constituents is available, ~~multi-constituent~~	

[7] 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).

	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 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.	BG: (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 health and the environment, as well as persistent, bioaccumulative and mobile properties, or where it supports data on the individual constituents **or individual**	DE: Consequential change (see proposed amendment to definitions in Article 2) SI: See comments above. FI: Could the omission of "toxicity" be explained here?

	substances in the mixture. Therefore, it is appropriate that data on ~~multi-constituent~~ substances **or mixture** are used in those cases. DE: (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 <u>with more than one constituent</u> 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 <u>with more than one constituent</u> should therefore normally be used as the basis for hazard identification of ~~those~~ ~~multi-constituent~~ substances <u>with more than one constituent</u> or mixtures. However, in certain cases, data on ~~those~~ ~~multi-constituent~~ substances <u>with more than one constituent</u> 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 ~~multi-constituent~~	

	substances with more than one constituent are used in those cases. EL: We agree ES: (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 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. NL: (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 **containing more than one constituent** on the basis of data on that mixture or substance. The data for the individual substances of the mixture or for the individual constituents of the ~~**multi-constituent**~~ substance **containing more than one constituent** should therefore normally be used as the basis for hazard identification of those ~~**multi-constituent**~~ substances **containing more than one constituent** or mixtures. However, in certain cases, data on those ~~**multi-constituent**~~ substances **containing more than one constituent** themselves may also be relevant. This is the case in particular where that data demonstrates endocrine disrupting properties for human health and the environment, as well as persistent, bioaccumulative and mobile properties, or where it supports data on the individual constituents. Therefore, it is appropriate that data on ~~**multi-constituent**~~ substances	

	<u>containing more than one constituent</u> are used in those cases. SI: 3) It is normally not possible to sufficiently assess the endocrine disrupting properties for human health and the environment and the persistent, bioaccumulative and mobile properties of a mixture or of a ~~multi-constituent~~ substance on the basis of data on that mixture or substance. The data for the individual substances of the mixture or for the individual constituents of the multi-constituent substance should therefore normally be used as the basis for hazard identification of those ~~multi-constituent~~ substances or mixtures. However, ~~in certain cases,~~ data on those multi-constituent substances themselves may also be relevant. This is the case in particular where that data demonstrates endocrine disrupting properties for human health and the environment, as well as persistent, 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.~~	
<u>Cluster C – Regulatory procedures</u>		
	FR:	FR:

	~~It is normally not possible to sufficiently assess the endocrine disrupting properties for human health and the environment and the persistent, bioaccumulative and mobile properties of a mixture or of a multi-constituent substance on the basis of data on that mixture or substance.~~ The data for the individual substances of the mixture or for the individual constituents of the multi-constituent substance should ~~therefore normally~~ be used as the basis for hazard identification of those multi-constituent substances or mixtures. However, in certain cases, data on those multi-constituent substances themselves may also be relevant. This is the case in particular where that data demonstrates endocrine disrupting properties for human health and the environment, as well as persistent, 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.	There are 2 different situations: Mixture with generally no experimental data and therefore justifying the use of the rule, in contrast to multi-constituent substances / MOCS for which some data could exist or will be generated under REACH. The first sentence is misleading: we propose to delete it.
Subgroup C1. New hazard classes		
Articles in C1		
(17) in Article 36, paragraph 1 is amended as follows:	EL: We agree	PT:

		The amendments of Article 36 add the new hazard classes introduced via the delegated act (ED, PBT, vPvB, PMT, vPvM) to the list of hazards that are normally subject to harmonised classification and labelling (CLH). As these hazards are triggers for the identification of substances of very high concern, we consider that the same level of relevance shall apply for CLH purposes. We therefore support this amendment.
(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:		
	FR: '(a) respiratory sensitisation, category ~~1,~~ 1A or 1B (Annex I, section 3.4~~.~~)';	FR: Consistency with other hazard classes mentioned in this article (for example : (b) germ cell mutagenicity, category 1A, 1B or 2)
'(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.);		

	FR: ‘(e) endocrine disruption for human health, category 1 or 2 (Annex I, section 3.11.);	FR: Deletion of the dot after the section number (consistency)
(g) persistent, bioaccumulative and toxic (PBT) (Annex I, section 4.3.);		
	FR: (f) endocrine disruption for the environment, category 1 or 2 (Annex I, section 4.2.);	FR: Deletion of the dot after the section number (consistency)
(h) very persistent, very bioaccumulative (vPvB) (Annex I, section 4.3.);		
	FR: (g) persistent, bioaccumulative and toxic (PBT) (Annex I, section 4.3.);	FR: Deletion of the dot after the section number (consistency)
(i) persistent, mobile and toxic (PMT) (Annex I, section 4.4.);		
	FR: (h) very persistent, very bioaccumulative (vPvB) (Annex I, section 4.3.);	FR: Deletion of the dot after the section number (consistency)
(j) very persistent, very mobile (vPvM) (Annex I, section 4.4).’;		
	FR: (i) persistent, mobile and toxic (PMT) (Annex I, section 4.4.);	FR: Deletion of the dot after the section number (consistency)
(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.';		NL: NL: we would like to point out that the regulation still refers to Directive 91/414/EEC and Directive 98/8/EC in other parts and would like to ask for these references to be updated.
(18f) Article 37 is amended as follows:		SK:
[…]		
(f) The following paragraphs 7 and 8 are inserted:		PT: SK: We are concerned about the extension of the Commission's power to issue Delegated Acts without a risk assessment by RAC. It could have a negative impact on the industry and also the quality of dossiers will be questionable.
'7. The Commission shall adopt delegated acts in accordance with Article 53a to amend Table 3 of Part 3 of Annex VI to	BE:	BE:

this Regulation by inclusion of substances as endocrine disruptor category 1 for human health properties, endocrine disruptor category 1 for environment 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*], those substances have been included in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006.	7. 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 disruptor category 1 for human health properties, endocrine disruptor category 1 for environment 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*]~~,** those substances have been included in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006. EL: We agree	BE supports the inclusion in Table 3 of Part 3 of Annex VI of these substances. Moreover, as substances could still be included in the candidate list of REACH for their endocrine disrupting properties or their PBT or vPvB properties after the proposed date, no cut-off date should be foreseen in this provision. DE: Due to the fact, that these inclusions of substances have not been considered by RAC, they need to be discussed thoroughly and, if necessary, scientifically, within CARACAL during the delegated act process. DK: Denmark supports the intention of article 37(7) to transfer substances identified as EDC, PBT and vPvB under REACH to annex VI in CLP. However, we find that the same should be the case for PMT and vPvM substances. Furthermore, we do believe that the text should be made clear as regards to whether it is necessary to carry out a new evaluation of the substances. We do not believe that it is necessary to make a new evaluation and this should be made clear from the text. Furthermore, this applies only 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? In addition, consideration should be given to whether substances included in the candidate list should be included at a later date. IE: IE: We seek clarification that this refers to substances that have been identified as SVHCs and included on the candidate list prior to the Entry into Force of the Delegated Act on the new hazard classes. While we see the reason for doing this, we note that procedurally, the agreement of the harmonised classification of these substances will not have followed the same process in ECHA through RAC as other substances. Some reflection on this may be required. PT: In principle, we can accept the adoption of a delegated act to amend Table 3 of Part 3 of Annex VI, when it is revised in line with COM explanation of the Proposal. Substances included on the candidate list (substances of very high concern) based on

		ED, PBT, vPvB criteria have undergone an evaluation/discussion in one of ECHA's Committees. In our view, these substances must be included in this Annex with the corresponding CLH. As the amendments of this annex, in light of the technical progress are already introduced by delegated act, the same procedure can be used in this case. We have therefore no objections. FI: Please see our comment on recital 20 relating to C1.
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.'		PT: In principle, we can accept the adoption of delegation act to amend Table 3 of Part 3 of Annex VI according to the previous comment. FI: This text needs to be reconsidered depending on which approach is chosen regarding the inclusion of candidate list substances (see also our comment on recital 20 relating to C1). The term "respective criteria" is unclear. ED's should be added to the following listing if they are meant to be Cat. 1:

		"SVHCs based on Art. 57 (d) shall be classified as persistent, bioaccumulative and toxic (PBT) SVHCs based on Art. 57 e shall be classified as very persistent, very bioaccumulative (vPvB) "
	FR: '7. The Commission shall adopt **within [OP: please insert the date = the first day of the month following 36 months after the entry into force of Commission Delegated Regulation (EU) …i.e. delegated act on the new hazard classes - reference to be added once adopted]** 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 disruptor category 1 for human health properties, endocrine disruptor category 1 for environment 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 first day of the month following 18 months after the entry into force of Commission Delegated Regulation (EU) …i.e. delegated act on the new hazard classes - reference to be added once adopted]**,	FR: The main issue here is that if the ongoing work on SVHC identification is not integrated (i.e. work conducted on SVHC identification started before the entry into force of the delegated act but not concluded at that date), Member states will have to conduct a CLH dossier in order to have the corresponding harmonised classification which is unnecessary workload. To avoid losing this work, we propose to change the date and consent a delay of 18 month after the entry into force of the delegated act introducing new hazard classes. This proposal should allow to cover most of the ongoing work. To be noted that this option is not ideal as it could prevent to take into account some SVHC identification that can be delayed for any reason and be adopted later. In addition, the French authorities consider that a deadline should be set for the Commission to analyse and make a

	those substances have been included in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006.	decision regarding all the SVHC concerned.
8. The Commission shall adopt delegated acts in accordance with Article 53a to amend Table 3 of Part 3 of Annex VI by inclusion of substances together with relevant classification and labelling elements where, on … [OP: please insert the date = *the date of entry into force of Commission Delegated Regulation (EU) …i.e. the delegated act on the new hazard classes - reference to be added once adopted*] those substances have not been approved, under Regulation (EC) No 1107/2009 or Regulation (EU) No 528/2012 or have been approved with derogation in accordance with the relevant provisions of those Regulations, due to either of the following characteristics:	DK: 8. The Commission shall adopt delegated acts in accordance with Article 53a to amend Table 3 of Part 3 of Annex VI by inclusion of substances together with relevant classification and labelling elements where, on … [OP: please insert the date = *the date of entry into force of Commission Delegated Regulation (EU) …i.e. the delegated act on the new hazard classes - reference to be added once adopted*] those substances have not been approved, under Regulation (EC) No 1107/2009 or Regulation (EU) No 528/2012 or have been approved ~~with derogation in accordance with the relevant provisions of those Regulations, due to~~ **in accordance with the relevant provisions of those Regulations, and it is concluded that the substance** has either of the following characteristics: EL: We agree	DE: Due to the fact, that these inclusions of substances have not been considered by RAC, they need to be discussed thoroughly and, if necessary, scientifically, within CARACAL during the delegated act process. DK: Denmark suggests to delete "with derogation" since an active substance can be approved as a biocidal active substance without the need for a derogation, if the substances is considered ED only with regards to the environment. Further the words are not of importance for the intention of the text. The point with the suggested change is, that the conclusion on approval/non-approval may not necessarily <u>be due</u> to the ED or PBT-properties, there might be other reasons (as well). And especially if it concerns ED with regards to the

		environment, that will not directly influence the decision. PT: In principle, we can accept the adoption of delegation act to amend Table 3 of Part 3 of Annex VI, when it is revised in line with COM explanation of the Proposal. Substances identified as ED, PBT, vPvB under Biocides and Plant Protection Products Regulations, have also undergone an evaluation. In our view, these substances must be included in this Annex with the corresponding CLH. As the amendments of this annex, in light of the technical progress are already introduced by delegated act, the same procedure can be used in this case. We have therefore no objections. FI: Would it be better to refer to the list of such substances, as in the current form the text refers also to substances for which an approval has never even been applied? Furthermore, the processes under the named Regulations are not identical to the CLH-process, and no categorization is carried out.
(a) endocrine disruptor in accordance with Section 3.6.5 or Section		

3.8.2 of Annex II to Regulation (EC) No 1107/2009;		
	FR: 8. The Commission shall adopt **within [OP: please insert the date = the first day of the month following 36 months after the entry into force of Commission Delegated Regulation (EU) …i.e. delegated act on the new hazard classes - reference to be added once adopted]** 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 first day of the month following 18 months after the entry into force of Commission Delegated Regulation (EU) …i.e. delegated act on the new hazard classes - reference to be added once adopted]** those substances have not been approved, under Regulation (EC) No 1107/2009 or Regulation (EU) No 528/2012 or have been approved with derogation in accordance with the relevant provisions of those Regulations, due to either of the following characteristics:	FR: Same justifications as the previous ones.
(b) persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with	PT: l	

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*;		
(d) persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with Article 5(1), point (e), of Regulation (EU) No 528/2012.		
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).’;		FI: Propose to clarify, in this subparagraph or in additional new subparagraph, the classification of each type of substances to be included, e.g. (see text proposal in our comment above on Art. 7 relating C1, for paragraph starting “The inclusion of the substances, referred to in the first subparagraph…”)
** 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.’;*		
		AT:

		The adjustment of the minimum classification (* entries of Annex VI Section 1.2.1) should be considered in the revision. When revising entries, it should be mandatory that all minimum classifications (* entries) are taken into account and revised. 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 corrected.
Recitals relating to C1		
(17a) As the new hazard classes and criteria introduced by Commission Delegated Regulation[8] 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	EL: We agree FI: Pls move this text to a separate recital: "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."	SI: We have some reservations regarding the inclusion of EFSA in the harmonization process. Furthermore we believe that ECHA, regardless of the amount of work in this area, must remain a key, main EU institution.

[8][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.]

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. [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.]		
(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.	BE: (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. EL:	BE: See comment on article 37 (7).

	We agree	
(21) As the criteria for substances to qualify as endocrine disruptor for human health or the environment included in sections 3.6.5. and 3.8.2. of Annex II to Regulation (EC) No 1107/2009 and in Commission Delegated Regulation (EU) 2017/2100, and those to qualify as endocrine disruptor for human health or the environment included in Annex I to Regulation (EC) No 1272/2008, are equivalent, substances which qualify as meeting the criteria for endocrine disruptor properties in accordance with Commission Regulation (EU) 2018/605 and Commission Delegated Regulation (EU) 2017/2100 should be included as endocrine disruptors category 1 for human health or endocrine disruptors category 1 for the environment in Table 3 in Part 3 of Annex VI to Regulation (EC) No 1272/2008.	EL: We agree	FI: The purpose of SVHC identification under REACH is different compared to that of harmonised classification under CLP. Also, the SVHC process is not identical to the CLH process. Not all SVHC proposals undergo MSC process (whether or not an SVHC case is referred to MSC for decision making depends on the comments submitted in the public consultation). This is a difference to CLH proposals, which all go through a RAC process. The level of scrutiny and transparency is not the same, and the public consultations that have been carried out have had a different focus. Also, the roles of the respective Committees are not comparable: while RAC members are independent experts, MSC members are not (REACH Art. 85). National priorities and political pressures can have an effect on the outcome of the SVHC-process. SVHC ED identifications are based on Art. 57 (f). No criteria for the identification of EDs have been available in the EU chemicals legislation prior to the introduction of ED-criteria in BPR and PPPR. Harmonized classification of adverse effects has not been required for ED identification under Art. 57 (f) and thus

		the compliance of the scientific assessment (e.g. in terms of level of detail and transparency of reporting) to the general principles of CLP regulation has not been required (Part 1 of Annex I and Part 2 of Annex VI of CLP). The SVHC identification has not provided for a categorisation of the ED substances, and it is thus possible that some substances that would only merit ED Cat 2 would be over-classified as ED Cat 1. A direct inclusion of these substances in Annex VI to Regulation (EC) No 1272/2008 could also create a precedence limiting RAC´s work in interpretation the new CLP criteria. For the reasons described above, we do not support a direct inclusion of SVHC ED substances in Table 3 in Part 3 of Annex VI to Regulation (EC) No 1272/2008. The above-mentioned differences in the SVHC and CLH processes are relevant also to PBT and vPvB cases (however, with the exception that whenever the T criterion comes from a human health classification, a harmonised classification is required for the adverse effect). However, the situation with PBTs and vPvBs is different compared to EDs as criteria and guidance for PBT/vPvB identification have been included under REACH, and as the new CLP criteria are

		largely similar to the current REACH criteria. Therefore, we consider that the PBT and vPvB substances on the candidate list should be included in Table 3 in Part 3 of Annex VI to Regulation (EC) No 1272/2008) provided that the guidance regarding PBT/vPvB classification will be equally conservative (or at least not less conservative) compared to the current guidance on PBT/vPvB identification under REACH. Further remarks regarding PBT guidance: It is important to recognise that the new CLP criteria do not specify all the conditions regarding the interpretation of the data, e.g., regarding PBT assessment. For example, the reference temperature of degradation half-lives for P/vP assessment is not specified in the CLP. Under REACH, the reference temperature is 12oC for fresh and estuarine water and sediment, and for soil, whereas the reference temperature for marine water and marine sediment is 9oC. Therefore, it is possible that the PBT/vPvB substances currently on the candidate list include substances which would not be PBT/vPvB if a higher reference temperature was used, or if the data is interpreted in a different way in some other

		aspects (for example, consideration of non-extractable residues in the assessment). The guidance for the new CLP hazard classes has not yet been developed and therefore it is not known what reference temperature(s) will be used for P/vP assessment under CLP. In our view, when including the REACH Art. 57 d and e substances as PBT/vPvB substances under CLP it should be ensured that the new CLP guidance will not deviate from the current REACH guidance to such extent that some of the candidate listed PBT/vPvB substances would not fulfil the PBT/vPvB under CLP. This includes, for example, that the reference temperatures to be used in the CLP guidance should not be higher than that used under REACH.
(22) As Article 5(1), point (e), of Regulation (EU) No 528/2012[9] 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	EL: We agree	FI: The criteria are the same, but the interpretation differs: a larger number of PPP-active substance might be recognized as PBT or vPvB if the evaluations were made according to REACH guidance (see also comment on recital 20). For instance, in the current assessment of PPP active substances, the reference temperature is generally 20oC and bound residues are not

[9] 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).

PBT and vPvB under Regulation (EU) No 528/2012 and under Annex XIII to Regulation (EC) No 1907/2006 should be included in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008. As PBT and vPvB properties included in sections 3.7.2. and 3.7.3. of Annex II to Regulation (EC) No 1107/2009 of the European Parliament and of the Council[10] 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.		considered when determining degradation half-lives for PPP substances.
(23) As the substances referred to in recitals 30 and 31 have already been assessed by the European Food Safety Authority or the Agency as well as the Commission which has decided upon by them, they should be included in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 by a delegated act, without prior consultation of the Agency as provided for in Article 37(4) of Regulation (EC) No 1272/2008.	BE: (23) As the substances referred to in recitals **~~30 and 31~~ 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	BE: The reference numbers of the recitals should be adjusted. FI: the Commission only makes a decision (with the REACH Committee) in those (rare) cases where the MSC has not been able to come up with one. The text in its current form might give the wrong impression of the processes.

[10] 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).

	the Agency as provided for in Article 37(4) of Regulation (EC) No 1272/2008. EL: We agree FI: recitals 30 and 31> 21 and 22	
Subgroup C3. Procedure for harmonised classification	FR: (23) As the substances referred to in recitals **20** and **21** 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: Editorial error
Articles in C3		
(18a-e) Article 37 is amended as follows:	EL: We propose to use the term ***"group of substances with identical classification"*** instead of "substances" or at least to use	EL: Comment: The term "substances" is undefined. We believe that for clarity reasons it is necessary to use the term "group of substances with identical

	the term "Group of similar substances " as referred in recital 18.	classification" instead of "substances" in the legal text. In addition, criteria in order to include substances in the same group must be defined. i.e. Substances with a similar molecular structure may have different behavior and impact to human health and the environment. Finally, "*a formal quality check mechanism, i.e. a conformity check, performed by ECHA*", proposed also by Industry (CEFIC) could be a good idea to avoid over or under estimate classification of a substance.
(a) paragraph 1 is replaced by the following:	EL: We agree	
'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.		DK:
The Commission may ask the Agency or the European Food Safety Authority established in accordance with Article 1(2) of Regulation (EC) No 178/2002* to prepare a proposal for harmonised classification and labelling of substances and, where appropriate, specific		AT: Austria acknowledges the need for the implementation of a CLH mandate of the European Commission - to ensure that the CLP Regulation is the central legal act for hazard classification and supports the

concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof. The Commission may subsequently submit the proposal to the Agency.		introduction of such a mandate of the European Commission to be able to initiate harmonised classifications. DE: In preliminary discussions, the planned empowerment of the Commission to initiate CLH dossiers was seen critical. In particular, the fact that the right to propose and initiate as well as the right to implement are both in the hands of one institution, i.e. the Commission. As part of the impact assessment, various options were considered as to how such a mandate for the Commission could be designed. In addition to the option of mandating ECHA to prepare the proposals for harmonised classifications and labelling, the options of being able to mandate service providers or Member States were also considered. The possibility of Member States being financially compensated by the Commission for the preparation of CLH dossiers was also a proposal put forward by the DECA during the preliminary discussions. The outcome of the impact assessment was that the cost of preparation by a Member State would be about one third lower than if they were prepared by ECHA, with some loss of synergies. It is unclear how, without further measures and without to the detriment of other RAC

		processes (restrictions, OELs, etc.), the number of CLH dossiers that can be processed per year will be increased simply by having additional dossiers per year prepared by ECHA or EFSA, assuming that the number of dossiers prepared by the Member States remains the same. Furthermore, the bottleneck in the process seems to be the capacity of the RAC, not the lack of regulatory bodies entitled to submit a proposal. Speeding-up the process could more easily be achieved by providing adequate resources to RAC. DK: Is it the expectation that EFSA and ECHA could process all likely suggested harmonized classifications? IE: IE: We note that the process proposed here is different to the REACH SVHC identification or the restriction processes where, when the Commission requests ECHA to prepare a proposal, ECHA then becomes the dossier submitter. Here for CLH proposals, it is intended that the Commission may submit the CLH proposal to ECHA. We would like to clarify why this is the case and whether it is the most efficient process?

		PT: We still have doubts on the relevance of EFSA to prepare harmonised classification and labelling proposals and wonder if it is pertinent/efficient to have two agencies doing the same task. Although EFSA deals with plant protection products the task to classify should be perform by just one Agency. A horizontal proposal for reallocation of EU technical and scientific work on chemicals to EU agencies is under assessment by COM. The legislative proposal aims at streamlining EU-level scientific and technical work on chemicals. This article does not seem in line with those objectives. SI: We have some reservations regarding the inclusion of EFSA. See our comment by recital 17a. FI: From the point of view of efficiency, the mandating of EFSA to prepare CLH-proposals is a positive initiative. We wonder however, if this could be problematic with respect to EFSA's role in the decision making process regarding PPPs. Could/should EFSA's role be limited

		only to preparing CLH proposals for PPP active substances?
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.		
** 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)';*		
(b) in paragraph 2, the first subparagraph is replaced by the following:	EL: We agree	
'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:	EL: We agree	
‘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 the Commission, the request to the Agency or the European Food Safety Authority to prepare such proposal.		BE: Practical modalities should be foreseen for the notification to ECHA of the intention to submit a proposal for harmonised classification and labelling. IE: IE: Is there a need to also include a time-frame in which the intention should be notified prior to submitting the proposal to the Agency? NL: NL: we wonder what is meant with ‘notification of a request’. We would think that the notification of a request by the Commission would include the same information as the notification of an intention by competent authorities, manufacturers, importers or downstream users. We would therefore propose to have paragraph 2a amended to make this clear. SI:

		We have some reservations regarding the inclusion of EFSA. See our comment by recital 17a. FI: Is it possible that this obligation is misused in order to prolong the CLH process?
Within one week from receipt of the notification, the Agency shall publish the name and, where relevant, the EC and CAS numbers of the substance(s), the status of the proposal and the name of the submitter. The Agency shall update the information on the status of the proposal after completion of each stage of the process referred to in Article 37(4) and (5).		
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.’;		BE: Practical modalities should be foreseen for the notification to ECHA of the received proposals and on the information to provide on the reason for accepting or refusing it. IE: IE: Is there a need for a deadline by which the Competent Authority must notify the Agency after they receive a proposal in accordance with Article 6?
	FR:	FR:

	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 type of classification being considered** 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).	This process of notification is mainly interesting if authorities have access to the type of classification being considered.
(d) paragraph 3 is replaced by the following:	EL: We agree	
'3. Where the proposal of the manufacturer, importer or downstream user concerns the harmonised classification and labelling of substances in accordance with Article 36(3), it shall be accompanied by the fee determined by the Commission in accordance with the procedure referred to in Article 54(2).';		
(e) paragraphs 5 and 6 are replaced by the following:	EL: We agree	
'5. The Commission shall adopt without undue delay, delegated acts in accordance with Article 53a to amend Annex VI by inclusion of substances together with the	DE: '5. The Commission shall adopt without undue delay, delegated acts in accordance	DE: The new version of Article 37(5) continues to provide that the opinions drawn up by

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.	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 RAC are to be implemented by the Commission without delay. However, the half sentence "(...) where it finds that the harmonisation of the classification and labelling of the substance concerned is appropriate (...)" has been deleted. It is unclear what the Commission intends to achieve with this deletion or what impact this would have on the substance discussions at CARACAL level. As there should be no change in this process and the responsibility of the Commission, these half sentence should be added again. DK: Denmark supports the initiatives presented in this article.
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	EL: We agree	AT:

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.’;		A revision of Art. 37 para. 6 CLP Regulation of already existing CLH entries by economic operators themselves, is supported, whereby these should be framed within the following legal parameters: - Revisions shall be made after a fixed time interval from the existing CLH entry. - New information must be obligatory and assessed by ECHA as to the data that could lead to a change in the entry (Accordance Check). - These revisions of CLH entries may only represent a certain percentage (e.g. 5%) of the RAC workload. - It is mandatory that all minimum classifications (* entries) are taken into account when revising entries. DK: Has the Commission considered to perhaps leave member states out the equation in this article and only notify ECHA? This is under the assumption that ECHA will then only have to deal with inquiries from economic actors.
		AT: The adjustment of the minimum classification (* entries of Annex VI Section 1.2.1) should be considered in the

		revision. When revising entries, it should be mandatory that all minimum classifications (* entries) are taken into account and revised. 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 corrected.
[…]		
Recitals relating to C3		
(17b) [As the new hazard classes and criteria introduced by Commission Delegated Regulation[11] 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	EL: We agree	

[11][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.]

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.	EL: We propose the term "***identical classification***" instead of "similar classification".	DK: It is not clear whether the Commission considers that there is a change from the current practice with the proposed wording. EL: <u>Comment:</u> The term "*similar classification*" must be defined or replaced by our proposal in the legal text. SK: We are concerned about the quality of CLH's proposals for group of similar substances. We are of the opinion that this

		provision will alleviate the burden neither on industry, nor authorities. We support an application of balanced approach considering also the quality of CLH proposals.
(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	EL: We agree	DK: There seems to be a copy/paste error, and the following have been added twice, and the duplication should be deleted: " 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."

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.		