Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	**Drafting suggestions** **AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT**	**Comments** **AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT**
Cluster A – Labelling and sales		
Subgroup A3. Refill sales		**DK:** The definition of filling stations lies outside the scope of Cluster A3. However, the issue has relevance for the scope of the definition of refill stations. Denmark reiterates the need for clarity on this matter, including whether refilling jerry cans with fuel at a filling station would fall within the scope of Article 2(41), or whether this would be considered to be an example of bulk sales. Denmark suggests that the definition of filling stations is tightened so as to clearly state, that jerry cans used at filling stations fall within the bulk sales are subject to the same rules as for refuelling cars directly at petrol stations.
Articles in A3		
(2c) in Article 2, the following points *[7a ~~and~~ 38]* **to 41** are added:		

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[…]		
	1. **EL:** We propose the following changes :	
40. ‘refill’ means an operation by which a consumer or a professional user fills its own container, which fulfils the packaging function, with a hazardous substance or mixture offered by a supplier in the context of a commercial transaction.	**DE:** ~~40. ‘refill’ means an operation by which a consumer or a professional user fills its own container, which fulfils the packaging function, with a hazardous substance or mixture offered by a supplier in the context of a commercial transaction.~~ **40. refill’ means the operation by which a substance or mixture is filled in-store from a large container or station in the end-users’ own package either manually or through automatic or semi-automatic equipment;** **EL:**40. ‘refill’ means an operation by which a consumer or a professional user fills its own container, which fulfils ~~the packaging function~~ **the requirements on packaging set out in Title IV**, with a hazardous substance or mixture offered by a supplier in the context of a commercial transaction. **LT:‘**refill’ means an operation by which a consumer or a professional user fills **a**~~its own~~	**DE:** Under consideration of the recently adopted draft for a revised detergents regulation, we suggest to keep the definition of “refill” consistent between both regulations, as currently most mixtures sold in refill will be also detergents. However, the draft of the detergents regulation does not contain a definition of the term “refill station”, albeit making use of the term in the text. Furthermore, the proposed definition for “refill” is ambiguous in a way that leaves it open to interpretation what may be meant by “own container”. Does it mean that the container must be in possession of the consumer or professional user before the filling commences? How are situations interpreted, where the container is (initially) made available by the place of purchase? Or does it mean that only self-service should be considered “refill” in the meaning of the CLP Regulation? The proposed definition in the detergent regulation is in several ways more precise in this regard and we propose to utilise it in CLP as well. **EL:**

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	container, which fulfils the packaging function, with a hazardous substance or mixture offered by a supplier in the context of a commercial transaction. **PT:** 40. 'refill' means an operation by which a consumer or a professional user fills ~~**its own**~~ **a** container, which fulfils the packaging function, **or have the container filled** with ~~a~~ ~~**hazardous**~~ substance or mixture offered by a supplier in the context of a commercial transaction. **SI:** **40. 'refill' means an operation by which a consumer or a professional user fills its own container, ~~which fulfils the packaging function,~~ with a hazardous substance or mixture offered by a supplier in the context of a commercial transaction.** **IT:** 40. 'refill' means an operation by which a consumer or a professional user fills its own container, which fulfils the packaging	Justification: " The term *"the packaging function"* is very vague, whereas the packaging requirements are clearly defined in Title IV **FI:** **FI:** pls, check that the use of terms "container" and "package" are logical and consistent throughout the text. **FI:** In practice the consumer could also be filling the contained provided by the supplier. Should this possibility also be taken into account in this definition of refill? **FI:** Why is the definition only limited to commercial transactions? How about free offers which is also covered by the definition on placing on the market? **FI:** Pls, check that this definition is in line with the definitions for "use", "downstream user" and "supplier". **FI:** Term "hazardous substance or mixture" is not in line with the CLP legal text, see e.g. Art- 17 "substance or mixture classified as hazardous..". **IE:**IE editorial comment: consumer or professional user fills ~~its~~ **their** own container. By saying 'fills their own container' suggests that the

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	function, with a hazardous substance or mixture **or with mixture with supplemental information on the label** offered by a supplier in the context of a commercial transaction.	only option is for consumer/professional user to take their own container to the refill station which will not always be the case. Suggest to change the text to *…consumer or a professional user fills **a** container which fulfils the packaging function…* **LT:**We welcome the definitions of 'refill' and 'refill station'. The definition of 'refill' could be clarified because a consumer or a professional user not always fills its own container. The container can be provided by a supplier of hazardous substance or mixture. **PT:**PT welcomes the inclusion of definitions of "refill" and "refill station". Considering the reference to "own container" is there not the possibility to have an employer of the shop that performs the refill with the customer container or a container provided by the shop? In this case, the definition of refill should be adapted. Additionally the reference to "with **a hazardous** substance or mixture" should be removed, similarly to the packaging definition (article 2 (36)), as a reference to a hazardous substances or mixtures would be included in the established obligation. **SI:** In order to increase clarity and comprehensibility of the definition we propose to delete "**which fulfils the packaging function, "**. **IT:**

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		We appreciate the effort to align the definition to other legislations e.g reg. packaging. We retain important to avoid inconsistencies, during the parallel evolution of both legislations CLP and "packaging". We deem important to clarify in the guidance: - what "its own container" means taking into account that in the 1^selling the consumer or professional user receives a container that can be used again. In particular, the packaging has to be adeguate. -It could be also clarified the meaning of packaging function - clarify what the real supplier is: it could be appropriate to refer the "Final distributor" that is responsible for refill station. - clarify that in the context of commercial transaction there are also those product offered free of charge in the respect of the definition which in the article 2(18) of CLP. We underline that some kind of products not classified hazardous but with labelling obligation (e.g. mixture not classified dangerous but with a substance sensibiliser with duty of EUH208, or that mixture with a duty set up in the Annex II "*contains*…") risk to be excluded by the new rules of the refill.

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41. 'refill station' means a place where a supplier offers to consumers or professional users hazardous substances or mixtures that can be purchased through refill.';	**DE:** ~~41. 'refill station' means a place where a supplier offers to consumers or professional users hazardous substances or mixtures that can be purchased through refill.';~~ **EL:** 41. 'refill station' means a place where a supplier offers to consumers or professional users hazardous substances or mixtures that can be purchased through refill **according to Annex II, paragraph 3.4.'**; **PT:** 41. 'refill station' means a place where a supplier offers to consumers or professional users ~~**hazardous**~~ substances or mixtures that can be purchased through refill.'; **IT:** 41. 'refill station' means a place where	**DE:** We propose to delete the definition of refill station. First, as mentioned above, the draft of the detergent regulation does not have a definition of refill station, albeit using the term in the text. Second: the proposed new definition for refill explicitly encompasses manual and semi-automatic processes, which may be ill-described by the term "station". Further, the definition does not add anything to the definition of "refill" but the phrase "a place". From our point of view this phrasing does not improve the understanding of the meaning of refill station as the term "place" is very broad and a station (i.e. an apparatus) is not commonly referred to as a place. This might be true for places like gas stations, though the initial meaning of refill station in the first Commission draft was clearly meant to be an apparatus. We think that with the addition of "manually or through automatic or semi-automatic equipment;" in the definition of "refill", a definition for refill station is superfluous, if slight amendments to Annex II to are made. **EL:**

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	a supplier offers to consumers or professional users hazardous substances or mixtures **or with mixture with supplemental information on the label** that can be purchased through refill.**';**	Justification: For clarity reasons. **FI:** **FI:** See comments above relate to terms and offering free of charge. **FI:** We are concerned about the fact that if the consumer can use their own containers, how can the supplier be responsible for compliance in case there is no "check" at the point of sale that the label is affixed to the container and that the container is suitable? **IE:** IE editorial comment: we suggest a re-work of the definition as follows: '*refill station' means a place where a supplier offers hazardous substances or mixtures to consumers or professional users for purchase through refill* IE editorial comment: if the structure of the definition stays as is and the above suggestion is not taken up, then we suggest the following edit: ~~that can be~~ **for** purchase~~d~~ through refill **PT:** See comment on "refill" definition. **IT:**

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		We appreciate the effort to align the definition to other legislations e.g reg. packaging. We retain important to avoid inconsistencies, during the parallel evolution of both legislations CLP and "packaging". We deem important to clarify in the guidance what the real supplier is: it could be appropriate to refer the "Final distributor" that is responsible for refill station We underline that some kind of products not classified hazardous but with labelling obligation (e.g. mixture not classified dangerous but with a substance sensibiliser with duty of EUH208, or that mixture with a duty set up in the Annex II "*contains*…") risk to be excluded by the new rules of the refill.
(16) in Article 35, the following paragraph 2a is added:	**EL:**	
'2a. Hazardous substances or mixtures may be supplied to consumers and professional users via refill stations only if~~,~~ ~~in addition to the requirements set out in Titles III and IV,~~ the conditions laid down in section 3.4 of Annex II are fulfilled.	**DE:** 2a. Hazardous substances or mixtures may be supplied to consumers and professional users via refill ~~stations~~ only if the conditions laid down in section 3.4 of Annex II are fulfilled. **EL:**	**DE:** Consequential change **FI:** **FI:** See comments above relate to terms. **FI:** The obligation to attach a label on the refill station should be in the core text and more specific rules can be

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	We agree	in the annex.
This paragraph shall not apply to hazardous substances or mixtures supplied to the general public without packaging in accordance with Article 29(3).';		**IT:** agree
Changes to Annex II in A3		
(1) in Part 3, the following Section 3.4. is added:		
'3.4. **Supply via ~~R~~refill stations**	**DE:** 3.4. Supply via refill ~~stations~~	**DE:** Consequential change **DK:** The many deletions suggested in the compromise text do not provide clearer definitions and we find the wording of the original proposal is to be preferred. In litra f1 it states that risk mitigation measures should be applied, however, these do not have any criteria for when this is done correctly and leaves much room for interpretation.

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		Denmark would like at greater degree of granularity. As such, Denmark would like not o-nly to see that the deleted points are reintroduced, but that the level of detail is increased so as to create clearer and more workable rules. These points are expanded upon under points c)-f), h) and i). **HU:Do we understand correctly, that refill stations are re-fillers i.e. downstream users with all the relevant DU obligations? If so, some explanation on that would be needed.**
When h~~H~~azardous substances or mixtures **are supplied** ~~referred to~~ in **accordance with** Article 35(2a), **the supplier** shall **ensure that** ~~meet~~ the following conditions **are met**:	**IT:** When hazardous substances or mixtures **or mixture with supplemental information on the label** are supplied in accordance with Article 35(2a), the supplier shall ensure that the following conditions are met:	**CZ:** We agree. **DK:** Denmark supports that substances and mixtures with the specified hazard classes may not be sold via refill. —Substances and mixtures meeting the criteria for aquatic toxicity category 1 and 2 should be added to the list. There can be a risk that the refill station is located near a drain, this could especially be the case in smaller shops.

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		If aquatic toxicity is not added, we suggest that a subparagraph is added stating that the refill station must be placed at least x meters from a drain and not outside. **HU:**The legal text should emphasise that the supplier's obligation is to ensure that: - a proper container to be provided to the consumer purchasing the product for the first time, if necessary, - the label is provided and affixed on the container during the purchase. **IE:** We welcome the streamlining of this section and the deletion of the sub sections proposed to be deleted. We are of the opinion that the further details on requirements for the refill stations should be included in guidance, as opposed to the legal text. **IT:** Clarify in the guidance what the real supplier is: it could be appropriate to refer the "Final distributor" that is responsible for refill station.
(a) **the refill station shall carry a** ~~the~~ labell~~ing~~ **corresponding to the label for each**~~and packaging requirements applicable at the date of placing on the market of the~~ hazardous substance or mixture **supplied at**	**DE:** (a) the **larger container or** refill station shall carry a label corresponding to the label for each hazardous substance or mixture supplied at the station;	**CZ:** We agree. **DE:** Consequential change

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the ~~are fulfilled for every refill~~ station;	**EL:** We propose the addition of the text in bold: a) the refill station shall carry a label/**labels** corresponding to the label for each hazardous substance or mixture supplied at the station, **in addition to the label that each refill packaging shall bear, according to article 17(1)**;	**EL:** Justification: a) (label/**labels):** in order to include the case where more than one product is sold in the refill station . b) the provisions relating to the refill station are new and if there is no explicit mention of the existing obligation that each refill packaging shall bear a label (in accordance with Article 17(1)), there is a risk of misunderstanding c) it is important to be clear that there are two obligations. **FI:** **FI:** Could this perhaps be clarified by referring to substance and mixtures to be refilled in one packaging/container? Or does this mean that the consumer or professional user could make their own mixtures? **HU:**Consider merging with point (b), since both points are about labels. **PT:** We support the comments of other MS regarding the

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		need to provide the label to be fixed in the container when necessary for substances or mixture supplied via refill stations. A new provision should be included in Section 3.4 in Annex II.
(b) ~~a~~**the** label **or labels on the refill station shall be**~~is~~ firmly affixed on a visible place ~~of the refill station~~ and **fulfil the requirements in Article 31** ~~with a font size that is easily legible and without serifs~~;	**DE:** (b) the label or labels on the **larger container or** refill station shall be firmly affixed on a visible place and fulfil the requirements in Article 31; **DK:** (b) ~~a~~**the** label **or labels on the refill station shall be**~~is~~ firmly affixed on a visible place ~~of the refill station~~ and **fulfil the requirements in Article 31** ~~with a font size that is easily legible and without serifs~~; **All information provided on the label shall also be provided to the consumer on a physical label at the time of refill, which the consumer is advised to attach to the refill container.** **EL:** We propose the following changes: the label or labels on the refill station shall be firmly affixed on a visible place and fulfil	**CZ:** We agree. **DE:** Consequential change **DK:** Does the reference to Article 31 mean that a consumer will receive a label when refilling their own container at the refill station or should the container already have the label attached when refilling? Denmark proposes, as set out in our drafting suggestion that refill station users are provided with a label, which sets out the label information specified in Article 17(1), after using a refill station. This will ensure that refill station users take important product information home with them. It is important that consumers receive the correct information about the product so that they can take appropriate action in case of emergency. **EL:**

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	the requirements ~~in Article 31~~ **of article 17 and 18.** **PT:** (b) ~~a~~ the label or labels on the refill station shall be ~~is~~ firmly affixed on a visible place ~~of the refill station~~ and fulfil the requirements in Article 31**(2), (3) and (4); the minimum font size shall be X** ~~with a font size that is easily legible and without serifs~~;	Justification: Article 31 refers to the packaging immediately containing the substance and not to the refill station. Otherwise, a reference to the "refill station" should be added in article 31(1). **FI:** **FI:** We suggest to considered adding that the requirements of Art. 31 should be applied "as adapted" since there is e.g a requirement that the label shall be readable horizontally when the package is set down normally. **HU:**Consider merging with point (a), since both points are about labels. **IE:** IE editorial comment: ~~a~~ the label**(s)** ~~or labels~~ **PT:** PT considers that the new text needs revision, Article 31 (1) establishes "labels shall be firmly affixed to one or more surfaces of the packaging immediately containing the substance or mixture and shall be readable horizontally when the package is set down normally" and this is not applicable to refill stations. Additionally we consider that a font size requirement should be established for the refill stations. Our understanding of Section 1.2.1.4 in Annex I is that the font size is dependent on the capacity of the package and not related to refill station.

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		The X in the drafting suggestions should be updated when the font size associated with the dimensions of the label in Section 1.2.1.4 in Annex I are concluded.
~~(c) substances and mixtures are only refilled in suitable and clean packaging without any visible residues, which are cleaned before reuse in case of suspected microbiological or other invisible contamination;~~	**DK:** (c) substances and mixtures are only refilled in suitable and clean packaging without any visible residues, which are cleaned before reuse in case of suspected microbiological or other invisible contamination; **EL:** We propose the replacement of this paragraph with of the following text: ***c) "substances and mixtures are only refilled in suitable packaging which is automatically cleaned and dried by the refilling or cleaning machine to avoid any visible residues"***.	**CZ:** We agree, it is not enforceable and controllable. **DK:** Denmark believes that the proposal for point c) ought to be reinstated instead of being rolled into point f1). While certain elements of the provision remain open to interpretation – "suitable", "clean" "visible residues" – the scope of the requirement is clearer through a dedicated and more detailed provision on cleanliness of refill packaging. However, Denmark's support for retaining point c) is contingent upon the publication of guidance on interpretation of the provision. In particular, guidance ought to clarify the minimum requirements for compliance with the provision. Would it for instance be acceptable for a supplier to place a sign by the refill station advising users on packaging requirements? Requirements for packaging should fulfil the provisions already set out in Article 35 of the CLP-regulation: Prevent accidents by normal use and handling, not be able to leak during the lifetime of the product and therefore resist normal handling, wear and tear, the lid

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		tightly fitting after opening, non-reacting with the content within and so forth. As the provision states that "which are cleaned before reuse in case of suspected microbiological or other invisible contamination", and this responsibility is placed on the supplier, we propose that the guidance should further provide that cleaning procedures and stations should be available at the supplier and only handled by professionals or by automation, so to not de facto endangering the consumer. **EL:** Justification: Automatic cleaning of packaging will ensure that no harmful compounds are formed by chemical reactions and that no pathogenic micro-organisms develop. Given the importance of proper cleaning to the protection of consumer health, it is not sufficient to simply add a relative general reference to recital 15.
	EL: We propose the addition of another point with the following wording: ***c1)Any supplier in the refill station has the role of downstream user with all obligations***	**EL:** Justification: According to article 4, article 45 etc. there are different obligations among the different suppliers in the supply chain. There is a need to define the role of the refill station supplier in order to be possible to impose

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	that this implies in the framework of the CLP regulation	sanctions in the case of non compliance. Furthermore, this is very important for the enforcement of article 45.
~~(d) the buttons to operate the refill station are out of reach of children and the refill station is not designed in a way to attract the curiosity of children;~~	**DE:** **(d) the outlet and the controls to operate or dispense from the larger container or the refill station are out of reach of children and the larger container or refill station is not designed in a way to attract the curiosity of children;** **DK:** (d) the buttons to operate the refill station are out of reach of children and the refill station is not designed in a way to attract the curiosity of children; **EL:** we don't agree with the deletion of this paragraph.	**DE:** We think it would be adequate to keep this provisions as it is only in a general manner covered by the new paragraph f1). Furthermore, f1) may also be difficult to enforce **DK:** As with point c) Denmark believes that this provision should be reinstated contingent upon the publication of guidance upon interpretation of the provision. The guidance should address the interpretation of issues such as "out of reach of children" by outlining indicative intervals for e.g. the height of the operating panel or the placement of the refill station (i.e. in an adjacent room or similarly) with clear indications that children are not allowed in unless under adult supervision/accompanied by adults. The guidance should also address the "not designed in a way to attract the curiosity of children". We propose the guidance take into account how to handle images and videos at the station, except when the images or videos solely and clearly indicates how to use the refill station correctly to minimize accidents. The guidance should also take into account how use of visually or audibly enticing installations, and e.g. blinking lights should should be handled in case of an emergency/accident.

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		Guidance should also be given regarding advertisement marketed (among others) children at or near the refill station – respecting freedom of expression but heightening the safety and protection of children.
~~(e) overfilling packaging is technically prevented;~~	**DK:** (e) overfilling packaging is technically prevented; **In order to technically prevent overfilling, suppliers may require the use of designated containers such as minimum size.** **EL:** we don't support the deletion of this paragraph.	**DK:** Again, as with both points c) and d), Denmark believes that this point should be reinstated contingent upon the production of clear guidance on examples of the technical measures that would fulfil this requirement. Guidance issues to be included include - measures to prevent the operation of the refill station, even when users do not follow usage instructions, through technical prevention of overfilling. - technical prevention of filling unless packaging is present (no pouring if no package). Furthermore, suppliers should be allowed to require the use of specific packaging at the refill station in order to technically prevent overfilling.
~~(f) filling a substance or mixture into unsuitable packaging is technically prevented;~~	**DK:** (f) filling a substance or mixture into unsuitable packaging is technically prevented; **In order to technically prevent**	**DK:** Again, as with points c), d) and e), Denmark believes that this point ought to be reinstated contingent upon the production of clear guidance on technical measures that

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	the use of unsuitable packaging, suppliers may require the use of designated containers such as minimum size.	would fulfil this requirement. As with point e), Denmark suggests, that it should be made clear, that suppliers may require the use of specific packaging in order to fulfil the requirements set out in this provision. Denmark believes that if it is *not* allowed for the supplier to require only specific packaging to be used at the refill station, it should be included in this litra f (and possibly also litra e) to manually prevent overfilling and using unsuitable packaging by having an employee checking the packaging to these requirements and possibly filling the packaging.
(f1) risk mitigation measures are applied to ensure that exposure of humans, especially of children, is avoided or, if not possible, minimized;	**DK:** **~~(f1) risk mitigation measures are applied to ensure that exposure of humans, especially of children, is avoided or, if not possible, minimized;~~** **EL:** We propose the deletion of the text below in bold:"risk mitigation measures are applied to ensure that exposure of humans, especially of children, is avoided **~~or, if not possible,~~**	**CZ:** We agree. **DK:**For the reasons listed above, Denmark believes that this provision should be deleted in favour of reinstating points c), d), e), and f). **EL:** Justification: We think it is not enough to minimize the exposure to children, as they are a vulnerable population group and

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	~~**minimized**~~"	their protection must be ensured **IE:** IE editorial suggestion: is avoided **as far as reasonably practicable** ~~or, if not possible, minimized;~~ **IT:** agree
(g) at the moment of refill, the supplier is ~~reachable~~**available on site** for immediate **routine and emergency** assistance;	**EL:** We propose the replacement of the text: ~~"at the moment of refill, the supplier is reachable **available on site** for immediate **routine and emergency** assistance;"~~ with the following text in bold: **"The refill operation shall be performed by the stuff of the supplier."** **HU:**(g) at the moment of refill, ~~the supplier is reachable~~**available on site for immediate routine and emergency assistance** ~~at the moment of refill~~**, immediate routine and emergency assistance is available for consumers and professional users**; **IT:** (g) at the moment of refill, the supplier is ~~reachable~~ available on site for immediate routine **maintenance** and emergency assistance;	**CZ:** How will the operation be ensured, for example, at a gas station during the night hours? **DK:** Denmark find the provided changes to this provision to be adequate and welcome this change. **EL:** Justification: In order to protect human health and to avoid any incident. **FI:** **FI:** Is this within the scope of CLP? And what is meant by emergency assistance in this context? **HU:**Editorial change. This list is introduced with the wording "[…] the supplier shall ensure […]", therefore, there is no need to repeat it here.

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		IE: IE editorial comment: suggest to delete 'and routine' as it is not clear as to what is meant by 'routine assistance'. It could be interpreted as routine assistance with for example operating the refill station, which is outside the scope of CLP. Guidance will be required as to the extent of emergency assistance that the supplier would be expected to provide e.g. trained in first aid. In our opinion, the key thing here is that the relevant information is available to the supplier on site when emergency assistance is required. **IT:** We deem important to clarify at the least in the guidance: - what the real supplier is: it could be appropriate to refer the "Final distributor" that is responsible for refill station and be able to do maintenance; - who emergency assistance involves, in particular this task should be referred to the person that has the same task under OSH legislation.
~~(h) refill stations are not operated outdoors and outside business hours where immediate assistance cannot be provided;~~	**AT:** (h) refill stations are not operated outdoors **EL:**	**AT:** We are in favour of keeping the original proposal that refilling stations should not be operated outdoors.

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	we don't support the deletion	**DK:** Denmark finds that the revision of litra g secures the purpose of this litra h, and the deletion of this provision is therefore welcomed. **EL:** Justification:.In order to ensure the protection of human health and the sound management of an incident.
~~(i) the substances or mixtures provided through a refill station do not react with each other in a way that could endanger clients or staff;~~	**EL:** we don't support the deletion	**DK:** Denmark finds that this provision should be kept and not deleted, but that it needs further clarification, which preferably should be introduced in some form of guidance, or a revision of the text as given in the drafting suggestions could be introduced. Guidance should address: • Reaction of the substances or mixtures with the packaging, the refill station and the immediate surroundings. • The substances or mixtures endangering the clients or staff in themselves. • The substances or mixtures endangering the clients or staff by the way of providing them. The substances or mixtures forming reaction products by themselves, with the packaging, the refill station or the

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		immediate environment (surroundings), that are endangering the clients or staff.
~~(j) staff of the supplier are appropriately trained to minimise safety risks to consumers, professional users and themselves, and follow the necessary hygiene and cleaning protocols;~~	**EL:** we don't support the deletion	**DK:** Denmark find that the purpose of this provision is not ensured in the proposed revision and wonders, why it have been removed, as the purpose is considered necessary. **EL:** Justification: For safety reasons
(j1) the requirements on hazard communication in the form of labelling set out in Title III are fulfilled for every refilled package;	**EL:** We agree **SI:** Option 1: **(j1) ~~the requirements on hazard communication in the form of labelling set out in Title III are fulfilled for every refilled package.~~** The supplier is obliged to provide the user with an appropriate label**;** Option 2: **(j1) ~~the requirements on hazard~~**	**IE:** IE comment: It is clear from j1 that the supplier must ensure that the requirements for labelling are fulfilled for every refilled package (in other words, a properly labelled container leaves the premises). Guidance will be required as to how this requirement can be met by suppliers e.g. the provision of labels at the refill station, or at the point of sale or the provision of pre-labelled containers for those customers who do not take their own containers to the refill station. **SI:** In our opinion, this provision does not clearly state how or when the label shall be placed on the refilled package. Therefore we propose to delate it and replace it by the following one:

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	~~**communication in the form of labelling set out in Title III are fulfilled for every refilled package.**~~ The supplier is obliged to provide the user with an appropriate label to be placed on the packaging **;** **IT:** **(j1)** the requirements on hazard communication in the form of labelling set out in Title III are fulfilled for every refilled package. **Each actors in the supply chain should cooperate to insure this provision**;	Option 1: *"The supplier is obliged to provide the user with an appropriate label."* Option 2: *"The supplier is obliged to provide the user with an appropriate label to be placed on the packaging."* **IT:** We deem it is important to distinguish the different responsibility between the "final distributor" and the first supplier up in the supply chain.
(j2) the requirements on packaging set out in Title IV are fulfilled for every refilled package;	**EL:** We agree **IT:** (j2) the requirements on packaging set out in Title IV are fulfilled for every refilled package. **Each actors in the supply chain should cooperate to insure this provision**;	**IE:** IE comment: the obligation on the supplier in this regard is clear from j2. However, again, guidance will be required as to how this can be fulfilled, especially with respect to containers that are brought to the refill station by the consumer/professional user and how compliant those containers are. **IT:** The requirements set out in title IV appear difficult to apply by the "final distributor" because the consumer or the professional user could use its own packaging that

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		could not respect all requirements indicated in the article 35. Anyway, the "final distributor" should be responsible to verify that the packaging appears at least adequate to the scope. Therefore, the first supplier, up in the supply chain, should inform the "final distributor" on the minimal conditions that a packaging, brought by consumer o professional users, should have to be adequated.
(k) **hazardous** ~~no~~ substance**s** or mixture**s may not be** provided **at** ~~through~~ a refill station **if** ~~meets~~ the criteria for classification in any of the following hazard classes **are met**:	**DE:** (k) hazardous substances or mixtures may not be provided at ~~a~~ refill ~~station~~ if the criteria for classification in any of the following hazard classes are met: **EL:** We propose the following changes: k) hazardous substances or mixtures **shall not be** provided at through a refill station if meets the criteria for classification in any of the following hazard classes are met:	**DE:** Consequential change **DK:** Denmark is pleased to see that the categories for serious eye damage and skin sensitisation have been included. As other environmental hazard classes have been included here, we believe that the criteria for aquatic toxicity, category 1 and 2, should be listed here. An inclusion of aquatic toxicity, category 1 and 2 would provide for a higher level of environmental protection following the revision of the regulation. Denmark suggests that for the purposes of consistency – se for instance points vii, viii and ix – and clarity,

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		categories 1A, 1B and 2 are replaced with "any category". Through specifying the category numbers, the wording suggests that there are categories that are not subject to the general restriction set out in point k, which is not the case. **EL:** Justification : If it is optional it will not be implemented in practice and enforcement will be impossible **IE:** IE comment: we understand that at the next Tech Harm WG meeting, a discussion on what hazard classes should be included here or not will be had and we welcome that discussion. As a general observation, perhaps consideration should be given to allowing the inclusion of hazard classes that are already 'out there' in commonly used consumer products. We are not sure as to what is the difference between buying a product on the shelf in a supermarket and buying it through a refill station and using it as a consumer/professional user, with respect to risk (provided that the provisions with respect to packaging and labelling are complied with for the re-filled product as per this section). Notwithstanding our comment above and the one below under v bis, we suggest that consideration be given to

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		including the Aquatic Acute and/or Aquatic Chronic 1 hazard classes, if the list of hazard classes remain as is.
(i) Acute toxicity, categories 1 – 4;		
	EL: The following hazard classes must be added: ➢ explosives, and ➢ oxidizing (liquid solid)	**EL:** Justification: We believe that the proposed risk classes are important If refilling is prohibited by Explosives legislation it is not necessary to add the specific hazard class
(ii) Specific target organ toxicity – Single exposure, categories 1, 2 and 3;	**AT:** (ii) Specific target organ toxicity – Single exposure, categories 1, 2 and category 3, if classified with H336 (narcotic effect)	**AT:** The proposal to prohibit certain substances in refill stations also includes substances labelled STOT SE 3, H335, which are contained in detergents. In order to allow the refilling of such detergents, it would have to be considered to exclude H 335 from the prohibition. The effects of substances/mixtures classified as H335 (respiratory tract irritation) are comparable to substances/mixtures classified as irritant for eyes and skin, which are allowed for refill sale.

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(iii) Specific target organ toxicity – repeated exposure, categories 1 and 2;		
(iv) Skin corrosion/irritation, category 1 (sub-categories 1A, 1B and 1C);		
(iv-bis) Serious eye damage category 1;	**HU:**(iv-bis) Serious eye damage**/eye irritation,** category 1;	**BE:** We support the inclusion of this hazard class. **HU:**For consistency, we propose to include the precise hazard class.
(v) Respiratory sensitisation, category 1 (sub-categories 1A and 1B);		
(v-bis) Skin sensitisation category 1 (sub-categories 1A, 1B);		**BE:** We support the inclusion of this hazard class. **IE:** IE comment: At the meeting on May 2nd, some delegations proposed to not include skin sensitisation category 1 in this list of hazard classes. We would be open to this non-inclusion. Consumers are likely using products classified as skin sensitisers purchased by other means than through a refill station and should be aware of how to handle and use these products safely. The same comment likely applies to skin irritation (point iv

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		above). We are conscious of getting the balance right here between being protective on the one hand versus ensuring that the aims of this section can be fulfilled and that we do not exclude products for which it is the intention to provide them via refill sales and it is safe to do so, on the other hand. We also need to bear in mind the aims of the circular economy and the benefits that providing products via refill stations can bring in that regard. **NL:** Regarding the addition of skin sensitisation, we would strongly suggest to have this hazard class omitted from the exclusion list. Even though skin sensitisation has irreversible effects, we believe it should not be included in the list. We would like to ask to consider the following: - Refill stations will often be used for cleaning products that contain biocides that will meet the criteria under skin sensitisation. - Considering the fact that the consumer will be informed of these hazards by the label on the refill station and they will be informed of this according to point (j1) and (j2), we believe exposure could be avoided and we think we

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		could accept the small risk involved here. - It is important to realise some consumers will already be aware of their sensitivity to certain substances, and skin sensitisation is normally an effect that disappears when there's no more exposure. We think we could accept the small risk involved in light of the circular economy and to reduce waste.
(vi) Aspiration hazard;		
(vii) Germ cell mutagenicity, any category;	**HU:**(vii) Germ cell mutagenicity, ~~any category~~ **categories 1A, 1B and 2**;	**HU:**For consistency, we propose to include the hazard categories, similarly to the other hazard classes on the list.
(viii) Carcinogenicity, any category;	**HU:**(viii) Carcinogenicity, ~~any category~~ **categories 1A, 1B and 2**;	**HU:**For consistency, we propose to include the hazard categories, similarly to the other hazard classes on the list.
(ix) Reproductive toxicity, any category;	**HU:**(ix) Reproductive toxicity, ~~any category~~ **categories 1A, 1B and 2**;	**HU:**For consistency, we propose to include the hazard categories, similarly to the other hazard classes on the list.

Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	**Drafting suggestions** **AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT**	**Comments** **AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT**
(x) Flammable gases, categories 1**A, 1B** and 2;	**DK:** Flammable gases, any category	
(xi) Flammable liquids, categories 1 and 2;		
(xii) Flammable solids, categories 1 and 2~~.~~**;**	**DK:** Flammable solids, any category	**DK:** Should be ”any category” as used in points vii, viii and ix, as we believe this encompasses all categories.
(xiii) [insert: Endocrine disruptor for human health, categories 1 and 2].~~²~~;	**DK:** Endocrine disruptor for human health, any category	**DK:** Should be ”any category” as used in points vii, viii and ix, as we believe this encompasses all categories.
(xiv) [insert: Endocrine disruptor for the environment, category 1 and 2];	**DK:** Endocrine disruptor for the environment, any category	**DK:** Should be ”any category” as used in points vii, viii and ix, as we believe this encompasses all categories.
(xv) [insert: Persistent, bioaccumulative		

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and toxic (PBT)];		
(xvi) [insert: Very persistent and very bioaccumulative (vPvB)];		
(xvii) [insert: Persistent, mobile and toxic (PMT)];		
(xviii) [insert Very persistent and very mobile (vPvM)].		
By way of derogation from point (**a**~~b~~), a single label on the refill station may be used for several substances or mixtures for which the label elements referred to in Article 17(1) are identical, provided that the label clearly indicates the name of each substance or mixture that it applies to.’;	**BE:** By way of derogation from point (**a**~~b~~), a single label on the refill station may be used for several substances or mixtures for which the label elements referred to in Article 17(1) are identical, provided that the label clearly indicates the name of each substance or mixture that it applies to ***and which of them is effectively present in the refill station at the time of the offer*** ;	**BE:** The substance or mixture effectively present in the refill station at the time of the offer should be clearly identified if several substances/mixtures are mentioned on the refill station label. **CZ:** We agree.
Recitals relating to A3:		

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(15) Regulation (EC) No 1272/2008 currently does not lay down any specific rules for labelling and packaging of substances or mixtures supplied to the general public and professional users via refill stations. Considering the increasing trend of selling products, including certain chemicals such as detergents, without packaging to reduce waste and to facilitate more sustainable sales forms, it is appropriate to set out specific rules and conditions for such type of sales, and establish a list of hazard classes and categories prohibiting such refill station sales for substances of mixtures meeting the criteria for classification in those hazard classes and categories, in order to ensure safety and the protection of human health. **Risk mitigation measures should be in place to ensure that refill can be performed safely, for example by preventing overfilling and operation by children as well as avoiding reaction between substances and mixtures provided through the station, or with residues in refilled packages.**	**BE:** (15) Regulation (EC) No 1272/2008 currently does not lay down any specific rules for labelling and packaging of substances or mixtures supplied to the general public and professional users via refill stations. Considering the increasing trend of selling products, including certain chemicals such as detergents, without packaging to reduce waste and to facilitate more sustainable sales forms, it is appropriate to set out specific rules and conditions for such type of sales, and establish a list of hazard classes and categories prohibiting such refill station sales for substances of mixtures meeting the criteria for classification in those hazard classes and categories, in order to ensure safety and the protection of human health. **Risk mitigation measures should be in place to ensure that refill can be performed safely, for example by preventing *contamination, exceeding shelf live*, overfilling and operation by children as well as avoiding reaction between substances and mixtures provided through the station, or with residues in refilled packages.**	**BE:** Considering that contamination, particularly microbiological contamination, is one of the main risks posed by refill sales, it should be explicitly mentioned in the examples of risks that should be prevented. For substances and mixtures at risk of degradation, information on shelf live should be kept along the distribution chain to ensure their safe use. It is notably of importance for substances/mixtures for which it is not covered by sectorial legislations. **CZ:** It is not clear how it will be possible to technically ensure it. **EL:** Justification: An obligation stated in a recital is not binding. **IT:** As consequence of the deletion in the Annex II, Section 3.4 letter c) we suggest to delete the reference to the residues.

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	EL: We agree with the addition of the text in bold but we don't agree with the deletion of the relevant provisions (see our comments above) in section 3.4 of Annex II. **IT:** (15) Regulation (EC) No 1272/2008 currently does not lay down any specific rules for labelling and packaging of substances or mixtures supplied to the general public and professional users via refill stations. Considering the increasing trend of selling products, including certain chemicals such as detergents, without packaging to reduce waste and to facilitate more sustainable sales forms, it is appropriate to set out specific rules and conditions for such type of sales, and establish a list of hazard classes and categories prohibiting such refill station sales for substances of mixtures meeting the criteria for classification in those hazard classes and categories, in order to ensure safety and the protection of human health. Risk mitigation measures should be in place to ensure that refill can be performed safely,	

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	for example by preventing overfilling and operation by children as well as avoiding reaction between substances and mixtures provided through the station, ~~**or with residues in refilled packages**~~.	
Subgroup A4. Online sales		
Articles in A4		
(3) in Article 4, ~~paragraph 10 is replaced by~~ the following **paragraph 11 is added**:	**DE:** (3) in Article 4, the following paragraph**s** 11 **and 12 are** added **EL:** The text of the paragraph 10 is replaced. So, the replaced text shall be numbered as 10 instead of 11	
~~'10. A substance or a mixture shall not be placed on the market unless :~~		**DK:** Denmark welcomes the decision to retain Article 4(10)

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		in its current form. It remains the Danish position, that while enforcement of the CLP regulation should primarily be targeted at suppliers acting in a professional or industrial context, where this is not possible, it may be necessary to enforce CLP-compliance through confiscation of dangerous products imported by private consumers.
11. A natural or legal person established outside the Community can place substances and mixtures on the market only if it ensures that a supplier **in the Community** ~~has ensured~~ in the course of an industrial or professional activity ~~that the substance or the mixture~~ fulfils the requirements set out in this Regulation **with regard to the substances and mixtures in question**.'; 	**AT:** **11. A natural or legal person established outside the Community ~~can~~ shall place substances and mixtures on the market only if it ensures that a supplier established within the Community** ~~has ensured~~ **and indicated on the label** in the course of an industrial or professional activity ~~that the substance or the mixture~~ fulfils the requirements set out in this Regulation **with regard to the substances and mixtures in question**.'; **DE:** 11. A natural or legal person established outside the Community can place substances and mixtures on the market only if it ensures that a supplier in the Community has ensured in the course of an industrial or professional activity that the substance or the mixture	**AT:** Given that the supplier according to Article 4(11) will be indicated on the label enforcement authorities can directly address this supplier **DE:** The amendment results in a clarification that leads to an improvement compared to the previous text (see e.g. insertion of the requirement "in the Community"), but does not resolve our concerns with enforceability, as it still does not authorise the responsible actor (customs authorities) to act. Therefore, a new paragraph 12 should be added. **DK:** Denmark warmly welcomes the addition of paragraph 11, whereby natural or legal persons established outside the Union may only place substances and mixtures on the market, if a supplier in the Community has ensured

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	fulfils the requirements set out in this Regulation with regard to the substances and mixtures in question. **12. Custom authorities shall not release dangerous substances and mixtures imported by consumers unless a supplier according to Article 4 (11) is indicated on the label'**; **DK:** 11. A natural or legal person established outside the Community can place substances and mixtures on the market only if it ensures that a supplier in the Community ~~has ensured~~ in the course of an industrial or professional activity ~~that the substance or the mixture~~ fulfils the requirements set out in this Regulation with regard to the substances and mixtures in question.'; **Where a natural or legal person established outside the Community places substances or mixtures on the Community Market, a product passport that complies with the conditions set out in [Insert Article number] of the [Ecodesign Regulation] must be created for the substances or mixture before the product enters the Community market. The**	compliance with the CLP regulation. It has long been the Danish position that non-EU economic actors ought not to be subject to less stringent requirements than EU suppliers when selling products on the EU market. EU suppliers should be able to compete on a level playing field. Most importantly, consumer safety and environmental protection is strengthened through widening the scope of the CLP-regulation to non-EU economic actors. The effectiveness of this provision will be determined by the ability of member states to ensure compliance. Denmark is aware of the development of various proposals for product passports in Union legislation, thereby enabling customs authorities to enforce product compliance at the border. Denmark suggests that a provision is included within the CLP regulation requiring economic actors – both suppliers and economic actors established outside of the Union – to document compliance with the CLP Regulation in the product passport, by clearly stating the responsible supplier in the Community. Failure to comply with this should result in the substance or mixture not being able to pass customs by confiscation for the purpose of seizure or return of the

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	product passport must document the substance or mixture's compliance with this regulation and include details by which the supplier in the Community can be identified so that customs authorities and market surveillance authorities can verify compliance with this regulation. Customs authorities may deny entry to non-compliant products upon entry into the Community market. **EL:** We propose the following text instead of the paragraph 10: 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 the mixture fulfils the requirements set out in this Regulation.'; **PT:** **11. A natural or legal person established outside the Community can place substances and mixtures on the Community market only if it ensures that** a supplier **in the Community** ~~has ensured~~ in the course of an industrial or professional	substance/mixture with full compensation of the consumer including applicable taxes and delivery charges. The provision as it is proposed is not easily enforceable if non-compliance occurs. Therefore, the introduction of the product passport with the above requirements and sanctions would highly strengthen this very relevant provision. **EL:** Justification: "*A natural or legal person established outside the Community"* has no obligation under CLP. Therefore, it makes no sense to mention this person in paragraph 4.10 **FI:** **FI:** Is this Article meant to cover also non-hazardous substance and mixtures? **FI:** Would it be clearer from the enforcement perspective, if the non-EU actor would have to appoint an actor in the union to fulfil the duties of importer in case of direct supplies to consumers? **FI:** It seems that we are back in the situation where the consumer would de facto and de jure become an importer in case the non-EU actor ignores its duties.

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	activity ~~that the substance or the mixture~~ fulfils the requirements set out in this Regulation **with regard to the substances and mixtures in question**.'; **PUBLIC**	**IE:** IE comment: By stating that *A natural or legal person established outside the Community can place substances and mixtures on the market only if it ensures that….* appears to place a legal obligation on the non-EU supplier. If this is the case, then this obligation can't be enforced under CLP as the duty holder is outside the EU and it should be re-considered. In our opinion, the legal text must give legal responsibility to an EU legal entity (similar to the authorised representative under Art. 5 of the Market Surveillance Regulations). A link between the non EU company and the EU supplier responsible for ensuring compliance of the product placed in the EU market is also missing. Using the term '**a** supplier' could be interpreted as meaning **any** supplier in the EU, as opposed to one directly linked to that non EU company supplying that substance or mixture. Overall, we have concerns about the enforceability of this article and it may not help to solve the issues currently experienced with respect to on-line sales. It is not clear as to with which actor the legal obligation rests. We are of the opinion that there must be a link between the non-EU company and the EU supplier who

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		is responsible for ensuring compliance of the products. At the meeting on May 2nd, CION clarified, in response to interventions on this, that it is not the intention that the non-EU company would appoint a representative but rather that a supplier in the EU would take responsibility for the compliance of the products. It is difficult to envisage as to how this will actually happen and it may be too open ended to work in practice. CION also noted that the intention would be that an EU supplier would be named on the customs declaration and if there is no EU supplier, then the product would not be in compliance with CLP. Again, whether this would work in practice is questionable. Will customs Authorities need to check each declaration for an EU supplier? What is then the link to the CLP enforcement authorities for the purpose of enforcement of the provisions of CLP for the product? And on whom can any enforcement action be taken? We suggest to amend the wording of article 11 along the lines of *hazardous substances and mixtures which originate from outside the EU shall not be placed on the market via on-line sales unless the non-EU manufacturer's designated supplier in the Community, in the course of an industrial or professional activity, fulfils the requirements set out in this Regulation with regard to the hazardous substances or mixtures in question.* **LT:**Thank you for addition of "in the Community", but

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		this wording of Article 4(11) still may lead to difficulties in ensuring implementation and enforcement, as responsibility is imposed on the third-country supplier and not on the EU supplier. **PT:** PT welcomes the new proposal to introduce an explicit obligation for the actor outside of the Union to appoint a responsible representative.
(23) Article 48 is replaced by the following:		
'*Article 48*		**HU:**As the hazard information has to be understandable for the consumer, we are wondering what the language of the required information for the advertisement/distance sales offer would be, if the product can be purchased from any Member State.
Advertisement		
1. Any advertisement for a substance classified as hazardous shall indicate the relevant hazard pictograms, the signal	**EL:** We agree **PT:**	**DK:** Denmark welcomes this change to the provision. We find that further changes are necessary to address for

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word, ~~the hazard class and~~ the hazard statements **and supplemental EUH statements set out in Annex II**.	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 statements and supplemental ~~**EUH**~~ **hazard** statements set out in Annex II. **IT:** Any advertisement for a substance classified as hazardous, **which allows to conclude a contract for purchase,** shall indicate the relevant hazard pictograms, the signal word, the hazard statements and supplemental EUH statements set out in Annex II. **Any other advertisement for a substance classified as hazardous shall advice at least to pay attention to the label with hazard information.**	how *long* the indication should be provided in e.g. video and TV advertisements. Maybe this could be provided in a guidance document. In addition, guidance on whether the indication may be provided on a rolling banner or should be stationarity placed in the advertisement. It is further necessary to address in what manner the indication should be provided: Size of the font, text and background colour and so forth. **IE:** IE editorial comment: ~~the~~ signal word, ~~the hazard class and the~~ hazard statements… **PT:** PT proposes an editorial amendment in order to adjust to the terminology used thought the CLP Regulation, namely in article 38, 40 and annex II Part I title: "supplemental EUH statements" to "supplemental hazard statements". **IT:** Agree with the changes proposed. In addition, the proposal offers a way to educate the general public to read the label.

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2. Any advertisement for a mixture classified as hazardous or covered by Article 25(6) shall indicate the **relevant** hazard pictogram**s**, the signal word, ~~the hazard class and~~ the hazard statements **and supplemental EUH statements set out in Annex II**.	**AT:** 2. Any advertisement for a mixture classified as hazardous or covered by Article 25(6) shall indicate the **relevant** hazard pictogram**s** **and** the signal word~~, the hazard class and the hazard statements **and supplemental EUH statements set out in Annex II**~~. **EL:** We agree **PT:** 2. Any advertisement for a mixture classified as hazardous or covered by Article 25(6) shall indicate the relevant hazard pictogram**s**, the signal word, ~~the hazard class and~~ the hazard statements and supplemental ~~**EUH**~~ **hazard** statements set out in Annex II. **IT:** Any advertisement for a mixture classified as hazardous or covered by Article 25(6), which allows to conclude a contract for purchase, shall indicate the relevant hazard pictograms, the signal word, the hazard statements and	**AT:** We welcome the deletion of the hazard classes and still consider the hazard statements for mixtures to be inappropriate and disproportionate in relation to online purchases. **DK:** Denmark welcomes this change to the provision. We find that further changes are necessary to address for how *which amount of time* the indication should be provided in e.g. video and TV advertisements. Maybe this could be provided in a guidance document. In addition, guidance on whether the indication may be provided on a rolling banner or should be stationary placed in the advertisement. It is further necessary to address in what manner the indication should be provided: Size of the font, text and background colour and so forth. **PT:** PT proposes an editorial amendment in order to adjust to the terminology used thought the CLP Regulation, namely in article 38, 40 and annex II Part I title: "supplemental EUH statements" to "supplemental hazard statements". **IT:** Agree with the changes proposed. In addition, the proposal offers a way to educate the

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	supplemental EUH statements set out in Annex II. 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.	general public to read the label.
3. By way of derogation from paragraph 1 and 2, the hazard pictograms and signal word may be omitted where the advertisement is non-visual.';	**DK:** 3. By way of derogation from paragraph 1 and 2, the hazard pictograms and signal word may be omitted ~~where the~~ **for audio-only** advertisement**s, such as radio or podcast advertisements and similar** ~~is non-visual.~~'; **EL:** We propose the addition of the text: «… provided that this information is communicated in an alternative way» **LT:**By way of derogation from paragraph 1 and 2, the hazard pictograms ~~and signal word~~ may be omitted where the advertisement is non-visual.'	**DK:** Denmark welcomes this change to the provision. We find that changes are necessary to address for how *long* the indication of hazard statements and supplemental EUH statements may in audible advertisements. It could be read aloud so fast that the indication in practise is not audible. In addition, guidance should address, if there should be a short pause in between each hazard statement as to not providing confusion or misleading all together. Similarly, advertisements can be made by other means, e.g. tangible (for blind people), and guidance should be provided for this too. We have therefore suggested a minor alteration to the proposed revision.

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		LT: We believe that signal word could be communicated even if the advertisement is not visual. **IT:** Agree
(24) the following Article 48a is added:		
'*Article 48a*		
Distance sales offers		
Suppliers placing substances or mixtures on the market through distance sales shall**,** **within the offer,** clearly **and visibly** indicate the label elements referred to in Article 17.';	**EL:** We agree	**DK:** Denmark reiterates the pressing need to expand the scope of article 48a to include economic actors that do not fall under the definition of a supplier. Denmark regards this issue to be a cornerstone for ensuring the success of the new measures on online

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		sales, as put forward in the compromise text. The intention with regard to online platforms is clear, as the changes to recital 30 not only reflect, but amplify, economic actors from third countries do not appear to be covered by this provision. While this issue primarily relates to online platforms, but inspired by the proposals put forward for article 4(11), Denmark suggests that the provision is amended to include both suppliers and natural or legal persons established outside the Community, that place substances or mixtures on the market. If the Presidency and the Commission believes that our interpretation of Article 48(a) is incorrect, Denmark would appreciate that this issue is dealt with in the steering notes for the next meeting of the CLP working group so the issue can be addressed in plenum. **FI:** **FI:** It can be difficult to enforce this obligation in case the online market place is located outside the Union and the sales offer is target to different Member States, while the person responsible for fulfilling this obligations is established only in one Member State. **IE:** IE comment: is the 'supplier' here the supplier that is referred to in article 11?

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		IT: Agree
Recitals relating to A4	**EL:** *We agree*	
(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 a supplier established in the Union, which	**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 operators not established in the Union. It is therefore appropriate to require that there is a supplier established in the Union, which ensures that	**DK:** Given the changes made to Article 4(10) and (11), Denmark would suggest a rewording of the recital to reflect that consumers can still be regarded as de jure and de facto importers with regard to import of non-CLP compliant products from sellers based in third countries. Denmark suggests that "prevent" is replaced with "reduce the likelihood of" **FI:** **FI:** pls, use either the term "in the Community" as in articles above or the term "in the Union" as in these recitals, not both. **FI:** pls, consider also referring to the Market Surveillance Regulation which defines online offers targeted to EU as placing on the market as well as the e-commerce directive 2000/31/EC, which sets rules for the advertisement of consumer goods.

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ensures that the substance or the mixture in question meets the requirements set out in that Regulation when it is being placed on the market, including via distance sales**, such as via online market places**. This provision**, together with requirements in [Proposal for a Regulation of the European Parliament and of the Council on General Product Safety], Regulation (EU) 2022/2065 of the European Parliament and of the Council on a Single Market For Digital Services and Regulation (EU) 2019/1020 of the European Parliament and of the Council on Market Surveillance and Compliance of Products,** would improve compliance with and enforcement of the Regulation (EC) No 1272~~7~~/2008 and thereby ensure a high level of protection of human health and the environment. In order to prevent 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	the substance or the mixture in question meets the requirements set out in that Regulation when it is being placed on the market, including via distance sales, such as via online market places. This provision, together with requirements in [Proposal for a Regulation of the European Parliament and of the Council on General Product Safety], Regulation (EU) 2022/2065 of the European Parliament and of the Council on a Single Market For Digital Services and Regulation (EU) 2019/1020 of the European Parliament and of the Council on Market Surveillance and Compliance of Products, would improve compliance with and enforcement of the Regulation (EC) No 1272~~7~~/2008 and thereby ensure a high level of protection of human health and the environment. In order to ~~prevent~~ **reduce the likelihood of** 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.	**IT:** Agree

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professional activity.		
(29) Regulation (EC) No 1272/2008 regulates advertisement of hazardous substances and mixtures in a general manner and provides that an advertisement for a substance classified as hazardous is to mention the hazard classes or hazard categories concerned, and an advertisement for a mixture classified as hazardous or a mixture containing a classified substance is to mention the types of hazards indicated on the label where such advertisement allows concluding a contract for purchase without first having sight of the label. This obligation should be changed to ensure that the advertisement of hazardous substances and mixtures contains all the information which is most important in terms of safety and protection of **the human health and** 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.	**HU:**[…] Therefore, the advertisement should contain the relevant hazard pictograms, the signal word, ~~the hazard class~~, the hazard statements **and supplemental EUH statements**~~. The hazard category should not be provided, as it is reflected by the hazard statement.~~	**DK:** Denmark welcomes the clarifications set out in Article 48 including the introduction of a derogation for non-visual advertisements as set out in paragraph 3. Issues still remain with regard to readability of the warnings displayed in adverts. For video advertisements, a rule establishing how long these warnings must be displayed on screen would also assist with enforcement. **HU:**Editorial change in order to be consistent with Article 48. **IE:** IE editorial comment: of ~~the~~ human health and the environment **IT:** Agree

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(30) Regulation (EC) No 1272/2008 does not explicitly refer to offers, let alone to distance sales offers. Consequently, it does not address specific problems arising from distance sales, such as online sales. Whereas advertisements is understood as being at the pre-stage of offers, notably as information designed to promote messages of a natural or legal person, whether or not against remuneration, offers are understood as invitations by a natural or legal person to conclude a purchase contract. This differentiation should justify the requirement of providing more hazard information in offers than in advertisements. In order to keep pace with technological development and new means of sale, **it is necessary to require the labelling elements to be indicated in case of distance sales, including via online market places, in order for** the compliance by design obligations laid down for providers of online marketplaces in Article 31 of Regulation (EU) 2022/2065		**FI:** **FI:** this sentence needs to be rewritten to be more readable: "In order to keep pace with technological development and new means of sale, **it is necessary to require the labelling elements to be indicated in case of distance sales, including via online market places, in order for** the compliance by design obligations laid down for providers of online marketplaces in Article 31 of Regulation (EU) 2022/2065 of the European Parliament and of the Council[2] ~~should~~ **to** apply ~~for the purpose of~~ **in relation to such** labelling information ~~required by Article 17 of Regulation (EC) No 1272/2008~~." **IT:** Agree

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of the European Parliament and of the Council[1] ~~should~~ **to** apply ~~for the purpose of~~ **in relation to such** labelling information ~~required by Article 17 of Regulation (EC) No 1272/2008~~. The enforcement of those obligations is subject to the rules laid down in Chapter IV of Regulation (EU) 2022/2065.		
Cluster B – Classification		
Subgroup B1. Rules on Classification		**DK:** Denmark would like to thank the Commission for the non-paper on CLP-principles as it clarifies the rules on using bridging principles and weight of evidence with expert judgement. Denmark is very positive about the

[2] 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).

[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).

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		non-paper being incorporated into the guidance for CLP. Denmark would note that the decision diagram on the last page of the non-paper has a flaw: The box with "Is there sufficient data to apply BPs?", it is only possible to answer "no/impossible". We find that a green arrow (yes/possible) is needed and assume that it should point to the box with "classify using bridging principles". Furthermore, the arrows pointing to the box "mixture classified" makes no sense, as the indicate "yes/possible". The box should be deleted and instead a headline for the diagram should be e.g. "decision diagram for mixture classification". This will further justify the coloring scheme of the diagram, which is at the moment non-explanatory for those, who do not already know. Also we find that "Is there sufficient data to apply BPs?" should be changed to: Can bridging according to Annex I section 1.1.3 to CLP be applied? Denmark suggests that the starting point in diagram is indicated.

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		SI: General comments: We propose that the content of Commission's WK 5146/2023 INIT on the bridging principles shall be included in the guidelines. We also support the proposal regarding the introduction of the forms/physical states into Articles 4 and 13. But we believe that there is still enough room for improvement. At the same time, we suggest that the details of this topic shall be explained in the guidelines.
Articles in B1		
(2b) in Article 2, the following points ~~*[7a and]*~~ 38 *[to 41]* are added:		
[…]		
38. 'acute toxicity estimates' means numeric **values which are used to classify**~~criteria according to which~~ substances and mixtures ~~are classified~~ in one of four acute toxicity hazard categories based on the oral, dermal or inhalation exposure route.';		**IT:** Agree

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(5) in Article 6, paragraphs 3 and 4 are replaced by the following:		
'3. For the evaluation of mixtures pursuant to chapter 2 **of this Title** in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine disrupti**o**~~ng property~~ for human health' and 'endocrine disrupti**o**~~ng 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.		**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	**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~~	**SI:** Regarding our opinion the proposed provisions are not in line with UN-GHS (chapter 1.3.2.3.2). Our proposal aims to fix this discrepancy. Therefore we propose to delate following part: " *which have not been identified from the relevant available information on the individual substance*

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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.	~~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.	*referred to in the first subparagraph"* **IT:** Agree
4. For the evaluation of mixtures pursuant to Chapter 2 **of this Title** in relation to the 'biodegradation, persistency, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment', 'persistent, bioaccumulative and toxic~~,~~ **or** ~~'~~very persistent and very bioaccumulative **properties**', 'persistent, mobile and toxic~~'~~ ~~and~~**or** ~~'~~very persistent and very mobile **properties**' hazard classes referred to in sections 4.1.2.8, 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall only use the relevant available information referred to in paragraph 1 for the substances in the mixture and not for the mixture itself**.**';	**PT:** 4. For the evaluation of mixtures pursuant to Chapter 2 of this Title in relation to the '~~**biodegradation**~~ **rapid degradability**, persistency, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment', 'persistent, bioaccumulative and toxic~~,~~ or ~~'~~very persistent and very bioaccumulative properties', 'persistent, mobile and toxic~~'~~ ~~and~~ or ~~'~~very persistent and very mobile properties' hazard classes referred to in sections 4.1.2.8, 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall only use the relevant available information referred to in paragraph 1 for the substances in the mixture and not for the mixture itself**.**'; **SI:**	**FI:** **FI:** As stated in our earlier comments, we consider that "biodegradation" should be replaced by "rapid degradability". As an editorial comment, we note that in some parts of the text, these property terms "biodegradation, persistency, mobility and bioaccumulation" are not in apostrophes. We understand the use of apostrophes when referring to the hazard class names such as "very persistent and very mobile properties" but we are not sure why they are in apostrophes also when only the individual properties are considered. Whichever of these approaches is chosen, please check consistency within the whole text. **PT:** We propose to change "biodegradation" to "rapid degradability" to align with the title in 4.1.2.9 of Annex

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	4. For the evaluation of mixtures pursuant to Chapter 2 **of this Title** in relation to the 'biodegradation, persistency, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment', 'persistent, bioaccumulative and toxic', **or** 'very persistent and very bioaccumulative **properties**', 'persistent, mobile and toxic' ~~and~~**or** 'very persistent and very mobile **properties**' hazard classes referred to in sections 4.1.2.8, 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall only use the relevant available information referred to in paragraph 1 for the substances in the mixture and not for the mixture itself**.** However, where test data on the mixture itself is available for 'biodegradation, persistency, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment', 'persistent, bioaccumulative and toxic', or 'very persistent and very bioaccumulative properties', 'persistent, mobile and toxic' or 'very persistent and very mobile properties', that data shall also be taken into account for the purposes of the evaluation of the mixture	I. **SI:** Regarding our opinion the proposed provisions are not in line with UN-GHS (chapter 1.3.2.3.2). Our proposal aims to fix this discrepancy. Therefore we propose to add following text: *"However, where test data on the mixture itself is available for 'biodegradation, persistency, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment', 'persistent, bioaccumulative and toxic', or 'very persistent and very bioaccumulative properties', 'persistent, mobile and toxic' or 'very persistent and very mobile properties', that data shall also be taken into account for the purposes of the evaluation of the mixture referred to in the first subparagraph"* **IT:** Agree

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	referred to in the first subparagraph’;	
(6) in Article 9, paragraphs 3 and 4 are replaced by the following:		
‘3. Where the criteria referred to in paragraph 1 cannot be applied directly to available identified information, manufacturers, importers and downstream users shall carry out an evaluation by applying a weight of evidence determination using expert judgement in accordance with section 1.1.1 of Annex I to this Regulation, weighing all available information having a bearing on the determination of the hazards of the substance or the mixture, and in accordance with section 1.2 of Annex XI to Regulation (EC) No 1907/2006.		
4. When evaluating hazard information for mixtures, manufacturers, importers and downstream users shall, where test data for the mixture itself are inadequate or unavailable, apply the bridging principles	**AT:** 4. When evaluating hazard information for mixtures, manufacturers, importers and downstream users shall, where test data for the mixture **to be classified** itself are	**AT:**We prefer the proposal as given in the non-paper (wk 5146/2023 INIT). .

Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	Drafting suggestions AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT	Comments AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT
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.	inadequate or unavailable, apply the bridging principles referred to in section 1.1.3. of Annex I and in each section of Parts 3 and 4 of that Annex for the purposes of the evaluation.	
If more than one similar tested mixture is available ~~W~~**w**hen applying the bridging principles, manufacturers, importers and downstream users may ~~integrate~~ **apply** a weight of evidence determination using expert judgement in accordance with section 1.1.1. of Annex I to this Regulation, weighing all available information having a bearing on the determination of the hazards of the mixture, and in accordance with section 1.2. of Annex XI to Regulation (EC) No 1907/2006 **to select the most suitable similar tested mixture for decision on classification**. The rules on bridging principles in section 1.1.3 of Annex I shall **in this case** remain applicable even in a weight of evidence determination.	**AT:** **If a choice of more than one similar tested mixture is available** ~~W~~**w**hen applying the bridging principles, manufacturers, importers and downstream users may ~~integrate~~ **apply** a weight of evidence determination using expert judgement in accordance with section 1.1.1. of Annex I to this Regulation, weighing all available information having a bearing on the determination of the hazards of the mixture, and in accordance with section 1.2. of Annex XI to Regulation (EC) No 1907/2006 **to select the most suitable similar tested mixture according to Article 6(5) for decision on classification**. The rules on bridging principles in section 1.1.3 of Annex I shall **in this case** remain applicable even in a weight of evidence determination. **DE:** If more than one similar tested mixture is	**AT:** The Bridging Principle "interpolation" (1.1.3.4 in Annex I) requires two similar tested mixtures to be applicable. This provision applies to situations where a choice has to be made from more than one similar tested mixture. A direct reference to Article 6(5) would strengthen the basic requirement that the bridging principles apply only to the type of information referred to in Article 6(5). **DE:** We appreciate the amendment proposed and the support the intention of the provision wholeheartedly. Though we suggest some editorial changes to improve clarity.

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	available when applying the bridging principles, manufacturers, importers and downstream users may **need to** apply ~~a weight of evidence determination using~~ **the weight of evidence approach by** expert judgement in accordance with section 1.1.1. of Annex I to this Regulation, weighing all available information having a bearing on the determination of the hazards of the mixture, and in accordance with section 1.2. of Annex XI to Regulation (EC) No 1907/2006 to select the most ~~suitable similar tested mixture for decision on classification~~ **appropriate similar tested mixture(s) according to Art. 6 (5) to decide on the classification.** ~~The rules on bridging principles in section 1.1.3 of Annex I shall in this case remain applicable even in a weight of evidence determination.~~ **EL:** We propose the addition of the following text in bold: …..to select the most suitable similar tested mixture for decision on classification ***which leads to the most protective scenario for human health and the environment.***	We especially think that the last sentence of the draft paragraph gives too much emphasis on the point that the bridging principle remain applicable in this particular case, raising the question in which cases they may not remain applicable (in our view there are no cases where they do not remain applicable. Besides maybe the exceptions for CMR mixtures) **EL:** Justification: The "bridging principles" are applied according to the concrete rules described in 1.1.3 of Annex I. The rules cannot be applied in a weight of evidence approach, because they are either met or not met. Only *"When applying the bridging principles, if more than one similar tested mixture is available, manufacturers, importers and downstream users may a weight of evidence determination using expert judgement, to select the most suitable similar tested mixture for decision on classification* ***which leads to the most protective scenario for human health and the environment".*** See also our document "*EL CA position on doc : Non-Paper: Considerations by the Commission on the improvement of CLP bridging principles".* **NL:** We would like to thank the Commission for their non-paper on the bridging principles. The non-paper sheds a

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	We do not agree with the last sentence and we propose its deletion: ….~~The rules on bridging principles in section 1.1.3 of Annex I shall~~ **in this case** ~~remain applicable even in a weight of evidence determination.~~ **NL:** **If more than one similar tested mixture is available** ~~W~~**w**hen applying the bridging principles, manufacturers, importers and downstream users ~~*may*~~ *shall* ~~integrate~~ **apply** a weight of evidence determination using expert judgement in accordance with section 1.1.1. of Annex I to this Regulation, weighing all available information having a bearing on the determination of the hazards of the mixture, and in accordance with section 1.2. of Annex XI to Regulation (EC) No 1907/2006 **to select the most suitable similar tested mixture***s* **for decision on classification**. The rules on bridging principles in section 1.1.3 of Annex I shall ~~***in this case***~~ remain applicable *even in a weight*	lot of light on the intention of the provisions, which we support. We also thank the Presidency for the compromise proposal on the articles, however, we do have a few suggestions to improve paragraph 4 in order to clarify the requirements regarding bridging principles. First of all, we would like to change "may" to "shall" to make it clear that it is mandatory to apply the weight of evidence determination when more than one similar tested mixture is available to select the most suitable similar tested mixture or mixtures. Please also see the strike-out of "may" and the addition of "shall" in italics in the drafting suggestion. Secondly, we would like to add that multiple mixtures should be selected when interpolation (Annex I section 1.1.3.4) is used. Please see the addition of the letter 's' in italics to the word mixture in the second half of the paragraph in the drafting suggestion. Finally, we think that the last sentence of the paragraph, "The rules on bridging principles in section 1.1.3 of Annex I shall in this case remain applicable even in a weight of evidence determination", is confusing. It might suggest that bridging principles are applicable within a Weight of Evidence. We would therefore propose to shorten the sentence to "The rules on

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	of evidence determination.	bridging principles in section 1.1.3 of Annex I shall remain applicable." Please also see the strike-out of "in this case" and "even in a weight of evidence determination" in italics in the drafting suggestion. **IT:** Agree
When evaluating the hazard information for mixtures, manufacturers, importers and downstream users shall, where that information does not permit the application of the bridging principles in accordance with the first and second subparagraphs, evaluate the information by applying the other method or methods set out in Parts 3 and 4 of Annex I.';		
(7) Article 10 is replaced by the following:		
'*Article 10*		

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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		

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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		

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differentiations for substances included in Part 3 of Annex VI ~~for which a specific concentration limit is given in that Part~~.		
5. By way of derogation from paragraph 2, M-factors shall not be established for harmonised hazard classes or differentiations for substances included in Part 3 of Annex VI for which an M-factor is given in that Part.		
6. By way of derogation from paragraph 3, acute toxicity estimates shall not be established for harmonised hazard classes or differentiations for substances included in Part 3 of Annex VI for which an acute toxicity estimate is given in that Part.		
7. When setting the specific concentration limit, M-factor or acute toxicity estimate, manufacturers, importers and downstream users shall take into account any specific concentration limits, M-factors or acute toxicity estimate for that substance which have been included in the		

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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.		
9. The Agency shall provide further guidance for the application of paragraphs 1, 2 and 3.		

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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.		
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.’;		
(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;’;		

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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	**NL:** [Addition of the following sentence :] "In a tiered approach the weight of evidence assessment may be limited to the data within that tier."	**NL:** We would like to, again, 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."

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mechanism or mode of action study results shall also be considered. Both positive and negative results shall be assembled together in a single weight of evidence determination.’;		
Recitals relating to B1		
(4) In order to improve legal certainty and implementation with regard to the evaluation of hazard information for 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.		

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It should also be clarified which criteria, when not met, determine when a weight of evidence determination using expert judgment is to be carried out.		
(5) To avoid over-classification of mixtures which contain substances classified as hazardous solely due to the presence of an impurity, an additive or an individual constituent, and of mixtures which contain other mixtures with such substances, the classification should only be mandatory if such impurity, additive or individual constituent is contained in the mixture or in the final mixture at or above a certain concentration limit as referred to in Annex I to Regulation (EC) No 1272/2008.		
(6) Acute toxicity estimates are mainly used to determine the classification for human health acute toxicity of mixtures containing substances classified for acute toxicity. Substances can be classified in one of four acute toxicity hazard categories based on the oral, dermal or inhalation exposure route according to certain numeric criteria. Acute toxicity values are expressed as (approximate) LD50 (oral, dermal) or		

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LC50 (inhalation) values or as acute toxicity estimates. It is appropriate to specify the meaning of, and further specify, acute toxicity estimates to increase their clarity and consistency. As acute toxicity estimates are part of the harmonised classification and labelling elements of substances classified for acute toxicity they should be included in the proposal, opinion and decision for harmonised classification of a substance for acute toxicity. In the same way as M-factors and concentration limits, acute toxicity estimates should, together with a justification, be notified to the Agency in view of their inclusion in the classification and labelling inventory.		
Please insert here comments on WK5466/23, in particular, regarding the draft amendments: *Article 4(3):* 3. If a substance is subject to harmonised classification and labelling in accordance with Title V, through an entry in part 3 of Annex VI, that substance shall be classified in accordance with that entry, and a classification of that substance in accordance with Title II shall not be performed for the hazard classes, differentiations and forms or	**BE:** *Article 4(3):* 3. If a substance is subject to harmonised classification and labelling in accordance with Title V, through an entry in part 3 of Annex VI, that substance shall be classified in accordance with that entry, and a classification of that substance in accordance with Title II shall not be performed for the hazard classes, differentiations and forms or	**BE:** Concerning the sentence proposed to be added in Article 4(3): "The harmonised classification of that substance shall apply to all its forms and physical states, unless the entry in Part 3 of Annex VI covers specific forms or physical states", it would mean that, for instance, even if the harmonised classification of a substance was based on data coming from its non-nano form, the nano form would be considered as covered by this classification except where specifically excluded. Such an approach would only be acceptable if, for all hazards, substances would always be classified and included in Part 3 of

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physical states covered by that entry. The harmonised classification of that substance shall apply to all its forms and physical states unless the entry in Part 3 of Annex VI covers specific forms or physical states. However, where the substance also falls within one or more hazard classes or differentiations or it is in a form or physical state not covered by an entry in Part 3 of Annex VI, classification under Title II shall be carried out for those hazard classes or, differentiations and forms or physical states. *Article 13:* If the evaluation undertaken pursuant to Article 9 and Article 12 shows that the hazards associated with the substance or mixture meet the criteria for classification in one or more hazard classes or differentiations in Parts 2 to 5 of Annex I, manufacturers, importers and downstream users shall classify the substance or mixture or, if scientifically justified, specific forms or physical states thereof, in relation to the relevant hazard class or classes or differentiations by assigning the following:	physical states covered by that entry. The harmonised classification of that substance shall apply to all its forms and physical states unless the entry in Part 3 of Annex VI covers specific forms or physical states***, or where a specific form or physical state deserves a more severe classification***. However, where the substance also falls within one or more hazard classes or differentiations or it is in a form or physical state not covered by an entry in Part 3 of Annex VI, classification under Title II shall be carried out for those hazard classes or, differentiations and forms or physical states. *Article 13:* If the evaluation undertaken pursuant to Article 9 and Article 12 shows that the hazards associated with the substance or mixture meet the criteria for classification in one or more hazard classes or differentiations in Parts 2 to 5 of Annex I, manufacturers, importers and downstream users shall classify the substance or mixture or, if scientifically justified, specific forms or physical states thereof, in relation to the relevant hazard class or classes or differentiations by assigning the following: ***Definition of "intrinsic property" in article 2 or in Annex I for the hazard classes***	Annex VI on the basis of data related to their most hazardous forms placed on the market, which is not the case in practice. It should also be kept in mind that classification mostly relies on available data and is thus dependent on data generated under other pieces of legislation such as REACH. The harmonised classification by default of all the forms and physical states of a substance would not reflect correctly their hazards and would reverse the burden of proof, particularly when there is a lack of data for some forms or states. On the other hand, this sentence ensures that all forms of a substance fall 'at least' under its harmonised classification, unless otherwise mentioned. If the sentence is kept, we propose to complete it this way: "The harmonised classification of that substance shall apply to all its forms and physical states, unless the entry in Part 3 of Annex VI covers specific forms or physical states**, or where a specific form or physical state deserves a more severe classification."** On the other hand, while the Presidency proposal contains interesting elements, we are of the opinion that it does not fully solve the issue of the classification of forms of substances, particularly for hazard classes referring to the intrinsic properties of a substance. There could still be different interpretations of the concept of "intrinsic properties" and of the possibility that a specific form could confer new intrinsic properties on a

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	concerned: An intrinsic property is a basic property of a substance as determined in standard tests or by other means designed to identify hazards, including a property emanating from a certain form or physical state of this substance. ***New Article 36 (4) : For all hazard classes, harmonised classifications should be based on the intrinsic hazard emanating from both a substance and a certain form or physical state of a substance, including particle toxicity.*** **EL:** We would like to inform you that we prefer option 1 to : "Proceed, based on the draft amendments to Article 4(3) and Article 13 presented by the Presidency" . Furthermore, we propose the following addition of the text in bold in article 4(3): *Article 4(3):* 3. If a substance is subject to harmonised classification and labelling in accordance with Title V, through an entry in part 3 of Annex VI, that substance shall be classified in accordance with that entry, and a classification of that substance in accordance with Title II shall not be performed for the hazard classes, differentiations and forms or	substance. Intrinsic properties are not mentioned for all hazard classes and we would like to point out particularly the following classes : • Germ cell mutagenicity: (Annex I, 3.5.2.3.2) : … The system is hazard based, classifying substances on the basis of their intrinsic ability to induce mutations in germ cells. The scheme is, therefore, not meant for the (quantitative) risk assessment of substances. • Carcinogenicity: (Annex I, 3.6.1.1): … Classification of a substance or mixture as posing a carcinogenic hazard is based on its intrinsic properties and does not provide information on the level of the human cancer risk which the use of the substance or mixture may represent; (Annex I, 3.6.2.2.1.): Classification as a carcinogen is made on the basis of evidence from reliable and acceptable studies and is intended to be used for substances which have an intrinsic property to cause cancer. • Reprotoxicant: (Annex I, 3.7.2.2.1): … Classification is made on the basis of the appropriate criteria, outlined above, and an assessment of the total weight of evidence (see 1.1.1). Classification as a reproductive toxicant is intended to be used for substances which have an intrinsic, specific property to produce an adverse effect on reproduction and substances shall not be so classified if such an effect is produced solely as a non-specific secondary consequence of other toxic effects.

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	physical states covered by that entry. The harmonised classification of that substance shall apply to all its forms and physical states unless the entry in Part 3 of Annex VI covers specific forms or physical states **or where a specific form or physical state deserves a more severe classification".** However, where the substance also falls within one or more hazard classes or differentiations or it is in a form or physical state not covered by an entry in Part 3 of Annex VI, classification under Title II shall be carried out for those hazard classes or, differentiations and forms or physical states. **LT:**"The harmonised classification of that substance shall apply to all its forms and physical states, unless the entry in Part 3 of Annex VI covers specific forms or physical states**, or where a specific form or physical state deserves a more severe classification**." **PT:** *Article 13:* If the evaluation undertaken pursuant to Article 9 and Article 12 shows that the hazards associated with the substance or mixture meet the criteria for classification in one or more hazard classes or	• Hazardous to the aquatic environment: (Annex I, 4.1.1.1.) : … (a) 'acute aquatic toxicity' means the intrinsic property of a substance to be injurious to an aquatic organism in a short-term aquatic exposure to that substance. … (g) 'chronic aquatic toxicity' means the intrinsic property of a substance to cause adverse effects to aquatic organisms during aquatic exposures which are determined in relation to the life-cycle of the organism. In the titanium dioxide Court case, the Commission argued that the concept of 'intrinsic property' should be understood as referring to the intrinsic hazard emanating from both a substance and a certain form or physical state of a substance, including particle toxicity. The ECHA Guidance on the Application of the CLP Criteria specifies the following in chapter 1.1.3. Hazard classification (p 46): "Classification according to CLP is based on intrinsic hazards, i.e. the basic properties of a substance or mixture as determined in standard tests or by other means designed to identify hazards. " A definition of "intrinsic property" based on these two statements would codify the current practice. In addition or as an alternative, a paragraph could be included in article 36 on harmonised classification to confirm that they should be based on the intrinsic hazard emanating from both a substance and a certain form or physical state of a substance, including particle toxicity. **DE:**

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	differentiations in Parts 2 to 5 of Annex I, manufacturers, importers and downstream users shall classify the substance or mixture or, if scientifically justified, specific forms or physical states thereof, in relation to the relevant hazard ~~**class or**~~ classes or differentiations by assigning the following:	In principle, we support the plan to anchor the established practice for the (harmonised) classification of substances in the CLP Regulation in a legally secure manner. In principle, the proposal of the Presidency can therefore be followed. However, in our view, the proposed draft text of Article 13 poses a considerable risk that, in the context of self-classification, exposure considerations based on highlighting the specific form could be used by suppliers for non-classification. In such cases, enforcement authorities would have to scientifically justify on a case-by-case basis that it is not a specific form relevant for classification after all. We therefore propose to supplement our proposed definition of "form of a substance" with an exemplary list of possible critical forms. In addition, we propose to include specific forms (e.g. WHO fibers) in an annex. The application of Article 13 could then be limited to the specific forms listed in this annex in order to prevent the misuse of a specific form for the purpose of non-classification. This would allow the scope to be limited to those forms that regularly result in a more stringent classification without lowering the level of protection. In addition, the respective mention of "physical state" should be deleted. The formulation "form and physical state" can be found in other parts of the CLP Regulation, but at this point (when considering forms) a reference to the physical state is not appropriate. **DK:**

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		We have read the suggestion with great interest and would like to thank the Presidency and Belgium for raising the issue and for issuing this document. Denmark is inclined to back solution number 1, as presented in the Presidency Flash, but are still working on the comments regarding this topic. Denmark suggests that a subparagraph is added in order to specify that no classification is needed with regards to eg. Skin Irritation H315, Eye irritation H319 or STOT SE 3; H335.if the effect is only seen because of "mechanical" action. Since it is not relevant to classify based on all forms or physical states, we find that it could be beneficial to a further text in order to illustrate what is meant by "specific forms or physical states", for example poorly soluble low toxicity (PSLT) particles could be listed. **EL:** Justification: We agree. We also believe that the text in red :The harmonised classification of that substance shall apply to all its forms and physical states unless the entry in Part 3 of Annex VI covers specific forms or physical states is ameliorated with the addition of the sentence in bold proposed by Belgium "**or where a specific form or physical state deserves a more severe classification"**

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		FI: FI supports the proposed clarifying amendments. However, we consider that the proposed sentence "The harmonised classification of that substance shall apply to all its forms and physical states unless the entry in Part 3 of Annex VI covers specific forms or physical states." needs to be clarified. The word "covers" makes the sentence difficult (note that, unless otherwise specified, the harmonised classification covers all forms and physical states). A possible solution could be "The harmonised classification of that substance shall apply to all its forms and physical states, unless the entry in Part 3 of Annex VI specifies that it applies only to specific forms or physical states." **LT:**Lithuania prefers to codify the current practice into the regulation and supports further work with Presidency proposal on the draft amendments to Article 4(3) and Article 13. We understand BE concerns and we could support an alternative solution proposed by BE to add a paragraph in Article 36 on harmonized classification, stating that for all hazard classes, harmonized classifications should be based on the intrinsic hazard emanating from both a substance and a certain form or physical state of a substance, including particle toxicity. In addition, we believe that **BE** proposal to add additional part to the sentence in Art 4(3) could be

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		beneficial in practice then the harmonized classification is not always related to the most hazardous form of substance placed on the market. **NL:** We would like to thank the Commission and the Presidency for the addition to these articles to include the current practice of classification of forms and physical states. We agree with the amendments to article 4(3) and article 13. We have previously suggested to add a definition for intrinsic properties in the body of the text (or either in the recitals and guidance). The form/physical state of a substance is partly determined by the properties of the substance. Each form of a substance has its own set of intrinsic properties. Certain properties (such as phase state) are general, other properties such as form, hardness, particle size are specific in character. The toxicology is often interrelated with these properties and the hazard classification for some substances are highly dependent on the intrinsic properties, e.g. the form. We were asked to draft up a definition of intrinsic properties. However, we believe it is important and necessary that this is looked into elaborately, and unfortunately, we were not able to do so in this short time period. We have, therefore, not been able to

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		commit to a definition. **PT:** We would prefer to proceed on the basis of the draft amendments to article 4(3) and article 13 presented in this proposal regarding the need to better clarify that differentiation is required when a particular form or physical state present a particular hazard; and that when is not the case the classification applies to all forms or physical states. We propose however an editorial amendment to article 13. **IT:** As regards Article 4(3), in principle we agree, however, we prefer to wait for the opinion of the Commission in order to examinate further the topic. As regards Article 13, we agree.
Subgroup B2. MOCS		
Articles in B2 (for Article 5(3), please see the Presidency's proposed alternatives in the separate annotation document – ST		**IE:** IE comment: Overall, we are in favour of option B in the

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8705/2023)		separate annotation document ST 8795/2023 **LT:**We prefer the option c) proposed by Presidency as the way forward: *clarify the process and set conditions for the laying down of specific provision in Annex I, through an explanatory paragraph mimicking the EP rapporteur's AM19: 'When the criteria set out in this paragraph is not suitable for a certain substance containing more than one constituent, the Commission shall, in light of all relevant information on the concerned substance, use the procedure referred to in Article 53 to amend Annex I to lay down specific provisions.'* **NL:** We support option B that adds an explanatory part in the recitals, giving examples of the criteria that could be applied in these specific provisions. We find it important that derogation is made possible for situations where there is adequate and reliable scientific argumentation. However, we do not support the insertion of a general derogation (e.g. for essential oils, as is suggested by a few Member States during the previous working group). Derogations should be based on a case-by-case scientific assessment. **PT:** Regarding the derogation 'unless Annex I lays down a specific provision' at the end of the first subparagraph of Article 5(3) and the SE Presidency proposal for the way

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		forward, we would prefer to clarify the process and set conditions for the laying down of specific provision in Annex I. PT would therefore prefer option c): "c) 'When the criteria set out in this paragraph is not suitable for a certain substance containing more than one constituent, the Commission shall, in light of all relevant information on the concerned substance, use the procedure referred to in Article 53 to amend Annex I to lay down specific provisions." **IT:** General comment: even if we agree with the new approach, we are concerned about the impossibility to use recent studies already done under the European legislation (REACH, PPP, biocide) and already evaluated under the relevant processes, also to "declassify" the substance itself.
(2a) in Article 2, the following points ~~7a~~ *~~[and 38~~ **to 41**]* are added:		
~~'7a. 'multi-constituent substance' means a substance that contains more than one constituent.~~	**DE:** **7a. 'constituent' means any unique chemical structure present in a substance or a mixture.**	**BE:** We support the deletion of this definition. **DE:** We appreciate and support the amendments made in the

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	EL: If the majority of M-S do not want the definition of "multi -constituent substance", we consider very usefull to have, at least, a clear definition of the terms, "components" "constituent" and "ingredients" in article 2, for the reasons explained in our previous comments. We propose the the use of the terms: ***"Ingredient" or "constituent"***: for substances in mixture" or "substances in multi-constituent substances" and ***"component"***: for "mixtures in mixture"	compromise. Nevertheless we think it would be beneficial to introduce a definition for the term constituent. **EL:** **LT:**We welcome the removal of MOCS definition. **PT:** PT agrees with the removal of the multi constituent substance. **IT:** Agree
(4) in Article 5, the following paragraph 3 is added:		**NL:** We support the Presidency Compromise Proposal regarding article 5.
'3. A ~~multi-constituent~~ substance containing ~~at least~~**more than** one constituent, in the form of an individual constituent, an identified impurity or an additive for which relevant information	**BE:** 3. A ~~multi-constituent~~ substance containing ~~at least~~**more than** one constituent, in the form of an individual constituent, an identified impurity or an additive for which relevant	**BE:** We support the application of the "mixture rule" for multi-constituent substances considering that carcinogenicity, mutagenicity, reproductive toxicity, endocrine disruption, bioaccumulation and mobile

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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].	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]~~***. **HU:**'3. A ~~multi-constituent~~ substance containing ~~at least~~**more than** one **individual** 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]. **SI:** '3. A ~~multi-constituent~~ substance containing ~~at least~~ **more than** 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	properties cannot be sufficiently assessed on the basis of data on such substances, due to the lack of sufficiently sensitive and validated test methods for multi-constituent substances. Moreover, as CLP is only based on existing data, the use of available data should be optimized, taking always into account data on constituents. Considering that negative test results obtained on complex substances should not override information on the hazard of their constituents, we do not support the possibility to apply exemptions to the "mixture rule". However, if such exemptions would be foreseen, the process should be clarified in the text and scientific criteria should be set by the Risk Assessment Committee. **CZ:** We agree. **DK:** Regarding article 5(3) and the suggested solutions presented in the flash – Denmark would be inclined to lean towards solution b as this has fewer consequences. However, we would like an elaboration of the different solutions as we think the differences between the solutions could be more clearly described. At the meeting in WP THC on the 2nd of May some

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	information on those constituents as well as on the substance as as such, ~~[~~unless Annex I lays down a specific provision~~]~~. **IT:** '3. A substance ~~containing at least one constituent, in the form of an individual constituent, an identified impurity or an additive~~ for which relevant information referred to in paragraph 1 is available **for an individual constituent (e.g. an identified impurity or an additive)** shall be examined in accordance with the criteria set out in this paragraph, using ~~the~~ **these** available information ~~on those constituents~~ as well as **the information** on the substance **itself**, unless Annex I lays down a specific provision.	member states indicated that they wanted UVCBs to be defined as something other than a substance with more than one constituent. Denmark believes that UVCBs ARE substances with more than one constituent and should follow the rules for said group of compounds. **HU:**If we understand correctly the core of the MOCS issue is the classification of MOCS based on the information available on individual constituents, therefore it is not clear to us why the new paragraph in Article 5 mentions impurities and additives as well. Also the corresponding recital explains the same concept. Therefore, we propose to delete impurity and additive in order to be consistent with the explanation in the corresponding recital. Alternatively consider to define the term of 'constituent'. As a general comment, and as another alternative option, we would also suggest to consider tackling these issues in the context of Article 10. **PT:** Regarding the derogation 'unless Annex I lays down a specific provision' at the end of the first subparagraph of Article 5(3) and the SE Presidency proposal for the way forward, we would prefer to clarify the process and set conditions for the laying down of specific provision in Annex I.

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		PT would therefore prefer option c): "c) 'When the criteria set out in this paragraph is not suitable for a certain substance containing more than one constituent, the Commission shall, in light of all relevant information on the concerned substance, use the procedure referred to in Article 53 to amend Annex I to lay down specific provisions." **SI:** In order to stay in line with UN-GHS (chapter 1.3.2.3.2) our proposal aims to fix this discrepancy and to allow all available and scientifically justified data to be used for the classification. Therefore we propose to add following part: "above the applicable concentration limit " and "as such," as well as to delate brackets (e.g. option c) of the PCY's document). **IT:** Consistently with the elimination of the multi-constituent definition, the writing proposal appears coherent with the current definition of substance. In alignment with the current approach under the CLP and under the UN-GHS, all available and reliable information on constituents as well as whole substance data are used to assess the hazards. In addition, also in the Commission Delegated Regulation (EU) 2023/707,

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		recently published, introducing the new hazards in the CLP, does not refer to the use of only constituent level data for the classification for endocrine disrupting properties.
For the evaluation of ~~multi-constituent~~ substances **containing more than one constituent** pursuant to Chapter 2 **of this Title** in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine disruption~~g property~~ for human health' and 'endocrine disruption~~g property~~ for the environment' hazard classes referred to in sections 3.5.3.1, 3.6.3.1, 3.7.3.1, 3.11.3.1. and 4.2.3.1. of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual constituents in the substance.	**SI:** ~~For the evaluation of multi-constituent substances **containing more than one constituent** pursuant to Chapter 2 **of this Title** in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine disruption~~g property for human health' and 'endocrine disruption~~g property for the environment' hazard classes referred to in sections 3.5.3.1, 3.6.3.1, 3.7.3.1, 3.11.3.1. and 4.2.3.1. of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual constituents in the substance.~~ **IT:**	**SI:** In order to stay in line with UN-GHS (chapter 1.3.2.3.2) our proposal aims to fix this discrepancy and to allow all available and scientifically justified data to be used for the classification. Therefore we propose to delate the whole part. **IT:** It is not always possible to know every single constituent of the chemical composition of substances (e.g. UVCB). We should avoid additional testing to identify unknown constituents.

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	For the evaluation of substances pursuant to Chapter 2 in relation to the 'germ cell mutagenicity', 'carcinogenicity', 'reproductive toxicity', 'endocrine distruption for human health' and 'endocrine distruption 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.	
Relevant available information on the ~~multi-constituent~~ substance itself shall be taken into account where one of the following conditions are met:	**EL:** We do not support the deletion of the text in bold: Relevant available information on the ***multi-constituent*** substance itself, showing absence of certain the properties referred to in (a) or less severe properties shall not override the relevant available information on the constituents in the substance. **SI:** ~~Relevant available information on the multi-~~	**EL:** Justification: For clarity reasons

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	~~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 disrupti**o**n~~g properties~~ for human health or the environment;		
(b) the information supports the conclusions based on the relevant available information on the constituents in the substance.		
Relevant available information on the ~~multi-constituent~~ substance itself showing absence of ~~certain~~ **the** properties **referred to in (a)** or less severe properties shall not override the relevant available information on the constituents in the substance.	**EL:** We do not support the deletion of the text in bold: Relevant available information on the ***multi-constituent*** substance itself, showing absence of certain the properties referred to in (a) or less severe properties shall not override the relevant available information on the constituents in the substance.	**EL:** Justification: For clarity reasons **IT:** Even if we agree with the new approach, we are concerned about the impossibility to use recent studies already done under the European legislation (REACH, PPP, biocide) and already evaluated under relevant processes, also to "declassify" the substance itself.

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	IT: **Without prejudice to the relevant available information already evaluated under the relevant process of another European legislations (e.g. Compliance check and CORAP of the regulation (CE) n.1907/2006, Autorisathion process of the regulation (UE) 528/2012, Authorisation process of the (UE) 1107/2009),** relevant available information on the substance itself showing absence of the properties referred to in (a) or less severe properties shall not override the relevant available information on the constituents in the substance.	
For the evaluation of ~~multi-constituent~~ substances **containing more than one constituent** pursuant to Chapter 2 **of this Title** in relation to the 'biodegradation, persistence, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment', 'persistent, bioaccumulative and toxic', **or** 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' ~~and~~ **or** 'very persistent and very mobile' hazard classes	**PT:** For the evaluation of ~~multi-constituent~~ substances containing more than one constituent pursuant to Chapter 2 of this Title in relation to the '**~~biodegradation~~ rapid degradability**, persistence, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment', 'persistent, bioaccumulative and toxic', or 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' ~~and~~ or 'very	**FI:** **FI:**As stated in our earlier comments, we consider that "biodegradation" should be replaced by "rapid degradability". As an editorial comment, we note that in some parts of the text, the property terms "biodegradation, persistency, mobility and bioaccumulation" are not in apostrophes. We understand the use of apostrophes when referring to the hazard class names such as "very persistent and very mobile properties" but we are not sure why they are in

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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.	persistent and very mobile' hazard classes referred to in sections 4.1.2.8 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the individual constituents in the substance. **IT:** For the evaluation of substances 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', or 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' or 'very persistent and very mobile' hazard classes referred to in sections 4.1.2.8 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall use the relevant available information referred to in paragraph 1 for each of the **known** individual constituents in the substance.	apostrophes also when only the individual properties are considered. Whichever of these approaches is chosen, please check consistency within the whole text. **PT:** We propose to change "biodegradation" to "rapid degradability" to align with the title in 4.1.2.9 of Annex I. **IT:** It is not always possible to know every single constituent of the chemical composition of substances (e.g. UVCB). We should avoid additional testing to identify unknown constituents

Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	Drafting suggestions AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT	Comments AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT
Relevant available information on the ~~multi-constituent~~ substance itself shall be taken into account where one of the following conditions are met:		
(a) the information demonstrates ~~biodegradation,~~ persistence, mobility**,** ~~and~~ bioaccumulation properties **and lack of biodegradation**.	**PT:** (a) the information demonstrates ~~biodegradation,~~ persistence, mobility**,** ~~and~~ bioaccumulation properties and ~~lack of~~ **~~biodegradation~~ non rapid degradability.**	**DK:** At the WP THC meeting on May 2nd, a member state suggested to change 'lack of biodegradation' to 'lack of rapid degradability'. We think that the latter expression is already encompassed by the term 'persistent' and support the suggested wording proposed in the compromise proposal. **FI:** Referring to our earlier comments regarding the term "biodegradation", we consider that "lack of biodegradation" should be replaced by "lack of rapid degradability". As an editorial comment, please check consistency with other parts of the text where these property terms are in apostrophes, e.g. 'biodegradation, persistence, mobility and bioaccumulation' properties. We understand the use of apostrophes when referring to the hazard class names such as "very persistent and very mobile properties" but we are not sure why they are in apostrophes also when only the individual properties are considered. Whichever of these approaches is chosen, please check consistency within the whole text.

Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	Drafting suggestions AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT	Comments AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT
		If apostrophes are considered necessary also with individual properties, the current text could be "the information demonstrates 'persistence, mobility, and bioaccumulation' properties and lack of 'rapid degradability'". **PT:** PT welcomes the revised text and would only propose to change "biodegradation" to "rapid degradability" to align with the title in 4.1.2.9 of Annex I.
(b) the information supports the conclusions based on the relevant available information on the constituents in the substance.		
Relevant available information on the ~~multi-constituent~~ substance itself showing absence of ~~certain~~ **the** properties **referred to in (a)** or less severe properties shall not override the relevant available information on the constituents in the substance.**';**		
	BG: **(4a) in Article 5, the following paragraph 4 is added:** **"Paragraph 3 shall not apply to UVCB**	**BG:** In addition to the previously provided written comments, Bulgaria insists that the derogation regarding UVCB substances of biological origin should be established with **this amendment** to the Regulation, taking into

Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	Drafting suggestions AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT	Comments AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT
	substances of biological origin."	account the following: 1. We should consider existing scientific evidence that, in the case of UVCB substances of biological origin, such as all essential oils, the test results related to hazards often differ from those obtained when testing the individual substances it contains. An essential oil is not the sum of its chemical constituents and display properties that are a function of its overall composition vs. a single constituent. The constituents of essential oils have specific stereochemical properties that could change the toxicity, whereas many other MCS (e.g. petrochemicals) do not have these properties. Therefore, the component approach to these substances is scientifically questionable. Example 1 Basil essential oil *Estragole* - mutagenic constituent according to the mutagenicity/genotoxicity test. *Basil essential oil* (with ≥ 24% Estragole) - mutagenic effects of estragole not found with basil essential oil (REACH Registration Dossier) i.e. basil extract inhibits harmful effects of estragole. Example 2 Lavander Essential oil Analysis of *linalool* oxidized shows allergenic hazard - it is only the oxidised linalool that is allergenic. Analysis of Lavander Essential oil as a whole substance (with 30-35 % of linalool) shows very weak allergenic risk hazard, meaning that some antioxidant constituents

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		of EOs block the possible oxidation of linalool. Example 3 Rose Essential oil *Methyleugenol* - classified as Mutagen Category 2 (REACH Registration Dossier) *Rose essential oil* (with ≥ 2% Methyleugenol) - mutagenic effects not found with rose essential oil (CIR, Safety Assessment of Rosa damascena-derived Ingredients, 2022). If we apply the mixture rules, many substances would become classified as hazardous to human health and the environment **without enough scientific evidence,** although they are currently safely used in consumer products for many years. 2. Consumers and workers are not exposed to a single constituent but to the substance as whole. 3. The proposed exclusion under Annex 1 is uncertain, without a defined procedure and criteria for determining the exclusions. Furthermore, it is not clear how the substances will be classified during the period until the eventual granting of a derogation, which may take a significant amount of time.

Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	Drafting suggestions AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT	Comments AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT
Recitals relating to B2 (to be updated in line with discussion on articles):		**NL:** We support the Presidency Compromise Proposal on recitals relating to B2.
(2) From a toxicological point of view, substances with more than one constituent ('multi-constituent substances') are no different from mixtures composed of two or more substances. In accordance with Article 13 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[3], aimed to limit animal testing, data on multi-constituent substances is to be generated under the	**HU:**2) From a toxicological point of view, substances with more than one constituent ~~('multi-constituent substances')~~ are no different from mixtures composed of two or more substances. In accordance with Article 13 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[4], aimed to limit animal testing, data on **substances containing more than one constituent** ~~multi-constituent substances~~ is to	**HU:**Rephrase 'multi-constituent substance' to follow-up the deletion of the definition. **IT:** We suggest to delete the first part the recital 2 because we have doubt on the scientific bases and coherently with our rewriting proposal of the article 5.3(b). The other points are in coherence with the previous

[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).

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

Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	Drafting suggestions AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT	Comments AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT
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.	be generated under the same conditions as data on any other substance, while data on individual constituents of a substance is normally not to be generated, except where individual constituents are also substances registered on their own. Where data on individual constituents is available, **substances containing more than one constituent** ~~multi-constituent substances~~ should be evaluated and classified following the same classification rules as mixtures, unless Annex I to Regulation (EC) No 1272/2008 provides for a specific provision for those ~~multi-constituent~~ substances. **IT:** (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],	modifications.

[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).

Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	Drafting suggestions AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT	Comments AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT
	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.	
(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	**HU:**It is normally not possible to sufficiently assess the endocrine disrupting properties for human health and the environment and the persistent, bioaccumulative and mobile properties of a mixture or of a **substance containing more than one constituent** ~~multi-constituent substance~~ on the basis of data on that mixture or substance. The data for the individual substances of the mixture or for the individual constituents of the **substance containing more than one constituent** ~~multi-constituent substance~~	**IT:** The suggested points are coherent with the previous modifications

Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	Drafting suggestions AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT	Comments AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT
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.	should therefore normally be used as the basis for hazard identification of those **substances containing more than one constituent** ~~multi-constituent substances~~ or mixtures. However, in certain cases, data on those **substances containing more than one constituent** ~~multi-constituent substances~~ themselves may also be relevant. This is the case in particular where that data demonstrates endocrine disrupting properties for human health and the environment, as well as persistent, bioaccumulative and mobile properties, or where it supports data on the individual constituents. Therefore, it is appropriate that data on **substances containing more than one constituent** ~~multi-constituent substances~~ are used in those cases. **IT:** (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	

Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	Drafting suggestions AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT	Comments AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT
	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.	
Cluster C – Regulatory procedures		
Subgroup C1. New Hazard Classes		
Articles in C1		

Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	Drafting suggestions AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT	Comments AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT
(17) in Article 36, paragraph 1 is amended as follows:	**EL:** We agree	
(a) point (a) is replaced by the following:		
'(a) respiratory sensitisation, category 1, 1A or 1B (Annex I, section 3.4.);'		
(b) the following points (e) to (j) are added:		
'(e) endocrine disruption for human health, category 1 or 2 (Annex I, section 3.11.);		
(f) endocrine disruption for the environment, category 1 or 2 (Annex I, section 4.2.);		
(g) persistent, bioaccumulative and toxic (PBT) (Annex I, section 4.3.);		

Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	Drafting suggestions AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT	Comments AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT
(h) very persistent, very bioaccumulative (vPvB) (Annex I, section 4.3.);		
(i) persistent, mobile and toxic (PMT) (Annex I, section 4.4.);		
(j) very persistent, very mobile (vPvM) (Annex I, section 4.4).';		
(c) paragraph 2 is replaced by the following:		
'2. Substances that are active substances falling within the scope of Regulation (EC) No 1107/2009 or Regulation (EU) 528/2012 shall be subject to harmonised classification and labelling. For such substances, the procedures set out in Article 37(1), (4), (5) and (6) shall apply.';		
(18f) Article 37 is amended as follows:		

Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	Drafting suggestions AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT	Comments AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT
[…]		
(f) the following paragraphs ~~7 and 8~~ are inserted:		
'7. **By 1 January 2026,** ~~T~~**t**he 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 disrupt**ion**~~or~~ category 1 for human health ~~properties~~, endocrine disrupt**ion**~~or~~ 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*~~ **1 January 2025**~~]~~, those substances have been included in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006.	**DK:**	**BE:** We strongly support the postponement of the cut-off date referring to the inclusion in the candidate list for the semi-automatic harmonised classification procedure. **DK:** Denmark supports the intention behind Article 37(7) to transfer substances identified with the new hazard classes under REACH to Annex VI in CLP. However, Denmark reiterates our position, that substances that are problematic in the environment, such as persistent, mobile and toxic [PMT] and very persistent and very mobile substances [vPvM] should also be included within the scope of this provision. When comparing the classification criteria set for the new hazard classes, PMT and vPvM to the criteria set in REACH annex XIII for the identification of a substances as PBT and vPvB, it is evident that there is identical criteria in the two regulations - CLP and REACH for the properties P,T, vP and vB. When converting an article

Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	Drafting suggestions AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT	Comments AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT
		59 (SVHC) listing as "Equivalent level of concern having probable serious effects on the environment (Article 57f)", it would be possible to compare the information in the Annex XV in respect to mobility to the criteria set in CLP hazard classes for the PMT and vPvM. Based on that information a conversion from the SHVC listing to a CLP classification on CLP annex VI as either PMT or vPvM could be made. Denmark also seeks guidance on two points. Our interpretation of the proposed Article 37(7) is that with the transfer of substances from other regulations into CLP, it is not necessary to reevaluate these substances. We ask the Commission to confirm our interpretation. Furthermore, Denmark seeks the Commission's guidance as to the status for substances that are included in the REACH Candidate list after 1 January 2025. The proposal only applies to substances included on the candidate list as of 1 January 2025. This is before the various provisions of the newly adopted hazard classes under the CLP regulation take effect, as the new hazard classes will only be legally binding for products placed on the market after 1 May 2025 at the earliest. How does the Commission intend to ensure that the CLP regulation covers harmful substances, which are included on the Candidate list after 1 January 2025, but before the

Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	Drafting suggestions AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT	Comments AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT
		applicable hazard classes under the CLP regulation? **FI:** **FI:** As stated in our earlier comments, we do not support the automatic transfer of all proposed SVHC-listed substances to Annex VI of CLP as the processes are not equivalent. More detailed justification can be found in our earlier comments regarding recital 20 sent on 21.3.
The inclusion of the substances, referred to in the first subparagraph, in Table 3 of Part 3 of Annex VI to this Regulation shall be carried out on the basis of the respective criteria for which those substances have been included in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006.~~2~~		
8. **By 1 January 2026,** ~~T~~the Commission shall adopt delegated acts in accordance with Article 53a to amend Table 3 of Part 3 of Annex VI by inclusion of substances together with relevant classification and labelling elements where, on ~~… [OP: please insert the date = *the date of entry into force of Commission Delegated Regulation (EU) …i.e. the*~~		**DK:** Denmark supports that article 37(8) should be formulated in a way that encompasses and respects the processes related to the approval of active substance under Regulation (EC) 1107/2009 and Regulation (EC) No 528/2012. Denmark is of the understanding that a proposal for the wording of article 37(8) is underway from DG SANTE

Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	Drafting suggestions AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT	Comments AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT
~~*delegated act on the new hazard classes - reference to be added once adopted*~~ **1 January 2025**~~)~~ those substances have not been approved, under Regulation (EC) No 1107/2009 or Regulation (EU) No 528/2012 or have been approved ~~with derogation~~ in accordance with the relevant provisions of those Regulations, due to either of the following characteristics:		in collaboration with GROW and ENV and look forward to receiving this in due time. **FI:** **FI:** As stated in our earlier comments, we are still wondering whether it would 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;		
(b) persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with Section 3.7.2. or 3.7.3. of Annex II to Regulation (EC) No 1107/2009;		
(c) endocrine disruptor for human health or for the environment in accordance with		

Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	Drafting suggestions AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT	Comments AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT
Article 1 of Commission Delegated Regulation (EU) 2017/2100[6]; (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).~~²~~;		**AT:** The clean-up of the minimum classification (* entries of Annex VI) should be considered in the revision. When revising entries, it should be mandatory that all minimum classifications (* entries) are taken into account and cleaned up. On the one hand, a clear improvement of the visibility of a minimum classification and the existing obligation to

[6] 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.';

Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	Drafting suggestions AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT	Comments AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT
		search in the various databases should be created, on the other hand, the minimum classification should also be cleaned up.
Recitals relating to C1		
(17a) As the new hazard classes and criteria introduced by Commission Delegated Regulation[7] allow for the harmonised classification and labelling of substances of the highest concern with regard to health and environment, they should normally be subject to harmonised classification and labelling and added to the list of hazard classes which includes respiratory sensitisation, germ cell mutagenicity, carcinogenicity and reproductive toxicity. Sub-categorisation of the hazard class for respiratory sensitisation in sub-category 1A or 1B should be performed where sufficient information to classify in those hazard sub-categories is available, in order to avoid over- or under-classification.		

[7] [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.]

Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	Drafting suggestions AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT	Comments AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT
[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.		

Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	Drafting suggestions AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT	Comments AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT
(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.		

Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	Drafting suggestions AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT	Comments AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT
(22) As Article 5(1), point (e), of Regulation (EU) No 528/2012[8] refers to the PBT and vPvB criteria included in Annex XIII to Regulation (EC) No 1907/2006 to identify the PBT and vPvB properties of active substances and as those criteria are equivalent to those included in Annex I to Regulation (EC) No 1272/2008, the active substances meeting the criteria to qualify as PBT and vPvB under Regulation (EU) No 528/2012 and under Annex XIII to Regulation (EC) No 1907/2006 should be included in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008. As PBT and vPvB properties included in sections 3.7.2. and 3.7.3. of Annex II to Regulation (EC) No 1107/2009 of the European Parliament and of the Council[9] are equivalent to those included in Annex I to Regulation (EC) No		

[8] 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).

[9] 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).

Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	Drafting suggestions AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT	Comments AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT
1272/2008, the active substances meeting the criteria to qualify as PBT and vPvB according to those criteria in sections 3.7.2. and 3.7.3. of Annex II to Regulation (EC) No 1107/2009 should be included in Table 3 in Part 3 of Annex VI to Regulation (EC) No 1272/2008.		
(23) As the substances referred to in recitals 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.		
Subgroup C3. Procedure for Harmonised Classification		
Articles in C3		

Presidency Compromise Proposal on Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3 (ST 8697/23)	**Drafting suggestions** **AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT**	**Comments** **AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT**
(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 the term "Group of similar substances " as referred in recital 18.	**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 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:		
'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.	**HU:**'1. A competent authority may submit to the Agency a proposal for harmonised classification and labelling of ~~substances~~ **a substance or group of similar substances** and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof.	**HU:**Editorial change. Recital (18) states that "Harmonised classification and labelling proposals […] could cover a group of similar substances, where such similarity allows for similar classification of all substances in the group" while the condition of the grouping ('similarity') is missing from the proposed wording of Article 37 (1). Moreover, the proposed wording is also misleading, since it could be interpreted as if competent authorities

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		could only submit CLH proposals for groups and not for single substances.
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[10] to prepare a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof. The Commission may subsequently submit the proposal to the Agency.	**HU:**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[11] to prepare a proposal for harmonised classification and labelling of ~~substances~~ **a substance or group of similar substances** and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof. The Commission may subsequently submit the proposal to the Agency. **PT:** The Commission may ask the Agency or the European Food Safety Authority established	**HU:**Idem **PT:** Regarding the procedure for harmonized classification proposal requested to ECHA by Commission, PT proposes a similar process as the one established for the REACH SVHC identification and restriction processes, where the Commission requests ECHA to prepare a proposal and ECHA becomes the dossier submitter. In our view, a further step requiring the COM to send the dossier prepared by ECHA or EFSA to ECHA should be avoided. We also consider that ECHA and EFSA would be more prepared to adjust the proposal, if required upon receipt by the Agency.

[10] 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)';

[11] 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)';

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	in accordance with Article 1(2) of Regulation (EC) No 178/2002 to prepare a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof. **The Agency or European Food Safety Authority may prepare a proposal. When a proposal is prepared by the European Food Safety Authority, this Authority** ~~**The Commission subsequently**~~ may submit the proposal to the Agency, **and informs the Commission.**	
The proposals referred to in the first and the second subparagraphs shall follow the format set out in Part 2 of Annex VI and contain the relevant information provided for in Part 1 of Annex VI.		
(b) in paragraph 2, the first subparagraph is replaced by the following:		
'2. Manufacturers, importers or downstream users of substances may		

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submit to the Agency a proposal for harmonised classification and labelling of those substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, provided that there is no entry in Part 3 of Annex VI for such substances in relation to the hazard class or differentiation covered by that proposal.'; 		
(c) the following paragraph 2a is inserted:		
'2a. Before submitting a proposal to the Agency, a competent authority, manufacturer, importer or downstream user shall notify the Agency of its intention to submit a proposal for harmonised classification and labelling and, in the case of the Commission, the request to the Agency or the European Food Safety Authority to prepare such proposal.	**PT:** '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~~ The Commission~~,~~ **shall also notify to the Agency,** the request to the Agency or the European Food Safety Authority to prepare such proposal.	
Within one week from receipt of the notification, the Agency shall publish the	**PT:** Within one week from receipt of the	**PT:** Adapted in order to make clear that the obligation to

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name and, where relevant, the EC and CAS numbers of the substance(s), the status of the proposal**, the proposed classification** and the name of the submitter. The Agency shall update the information on the status of the proposal after completion of each stage of the process referred to in Article 37(4) and (5).	notification, the Agency shall publish **the information therein, including** the name and, where relevant, the EC and CAS numbers of the substance(s), the status of the proposal, the proposed classification, **the expected date of submission** and the name of the submitter. The Agency shall update the information on the status of the proposal after completion of each stage of the process referred to in Article 37(4) and (5).	provide this information lays with the competent authority, manufacturer, importer or downstream user, or with the COM and not with ECHA. ECHA has the obligation to publish the information provided in the Registry of intentions. **IT:** Agree
Where a competent authority receives a proposal in accordance with paragraph 6, it shall notify the Agency and provide any relevant information on its reason for accepting or refusing the proposal. The Agency shall share that information with the other competent authorities.’;		
(d) paragraph 3 is replaced by the following:		
‘3. Where the proposal of the manufacturer, importer or downstream user concerns the harmonised classification and labelling of substances in accordance with		

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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: 		
'5. The Commission shall adopt without undue delay, delegated acts in accordance with Article 53a**, where it finds that the harmonisation of the classification and labelling of the substance concerned is appropriate,** to amend Annex VI by inclusion of substances together with the relevant classification and labelling elements and, where appropriate, the specific concentration limits, M-factors or acute toxicity estimates in Table 3 of Part 3 of Annex VI. 		**IT:** Agree
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.		

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6. Manufacturers, importers and downstream users who have new information which may lead to a change of the harmonised classification and labelling elements of substances in Part 3 of Annex VI shall submit a proposal in accordance with paragraph 2, second subparagraph, to the competent authority in one of the Member States in which the substances are placed on the market.’;		**AT:** We see the need for companies for a direct request to revise existing CLH entries themselves, whereby these should be embedded in the following legal parameters: - Revisions should be made after a fixed time interval from the existing CLH entry. - New information must be obligatory and must be checked by ECHA whether it is data that could lead to a change of the entry (Accordance Check). - These revisions of CLH entries may only represent a certain percentage (e.g. 5%) of the RAC workload. - When revising entries, it is mandatory that all minimum classifications (* entries) are taken into account and cleaned up.
[…]		
Recitals relating to C3		
(17b) *[As the new hazard classes and*		

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criteria introduced by Commission Delegated Regulation[12] allow for the harmonised classification and labelling of substances of the highest concern with regard to health and environment, they should normally be subject to harmonised classification and labelling and added to the list of hazard classes which includes respiratory sensitisation, germ cell mutagenicity, carcinogenicity and reproductive toxicity. Sub-categorisation of the hazard class for respiratory sensitisation in sub-category 1A or 1B should be performed where sufficient information to classify in those hazard sub-categories is available, in order to avoid over- or under-classification.] 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		

12 [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.]

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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". **IT:** (18) Harmonised classification and labelling proposals need not necessarily be limited to individual substances and could cover a group of similar substances, where such similarity allows for similar classification of all substances in the group. The purpose of such grouping**, with appropriate justification**, is to alleviate the burden on manufacturers, importers or downstream users, the Agency and the Commission in the procedure for harmonisation of classification and labelling of substances. It also avoids testing of substances when similar substances can be classified as a group.	**EL:** Comment: The term "*similar classification*" must be defined or replaced by our proposal in the legal text. **IT:** The companies have expressed their concerns on the grouping also for the CLH process, this would request a transparent justification on how structural similarity and dissimilarity prediction has been done on transparent scientific criteria. In addition, we would like to propose a time period for the public consultation more extent than the current when a CLH proposal regards grouping.

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

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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.	~~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~~.	

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NOTE

From: To:	Presidency Working Party on Technical Harmonisation (Dangerous Substances - Chemicals)
N° prev. doc.: N° Cion doc.:	ST 8697/23 - related document ST 16258 2022 ADD 1 - 8
Subject:	Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Revision) - Comments by AT, BE, BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SI, IT on the Commission proposal Sub-Groups A3 and A4, Cluster B, and Sub-Groups C1 and C3