Council of the European Union
General Secretariat

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NOTE

From: To:	Presidency Working Party on Technical Harmonisation (Dangerous Substances - Chemicals)
N° prev. doc.: N° Cion doc.:	WK 1216/2023 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, DE, DK, EL, ES, FI, FR, , IE, IT, LT, NL, PL, PT, SI, SK on the Commission proposal subgroups C2+C4_Cluster D

CLP proposal – table for MS comments following Presidency clustering

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

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Cluster C – Regulatory procedures		
Subgroup C1. New hazard classes	AT, BE, BG, DK, EL, ES, FI, FR, SK, IE, IT, LT, NL, PL, SI, PT **Comments already provided in table 1.2**	AT, BE, BG, DK, EL, ES, FI, FR, SK, IE, IT, LT, NL, PL, SI, PT **n/a**
Subgroup C2. Classification and Labelling inventory		
Articles in C2		
(20) Article 40 is amended as follows:	EL: We agree	DK; Denmark supports the initiatives presented in this cluster. NL:

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		General comment regarding the C&L inventory: We would like to suggest to include a requirement for industry to notify the end of putting a substance on the market.
(a) paragraph 1, the first subparagraph is amended as follows:	FR: (a) **in** paragraph 1, the first subparagraph is amended as follows:	NL: Current sub-paragraph 1 includes a derogation for the information under points a to f that has already been submitted to ECHA as part of a REACH registration. We would like to suggest to also include paragraphs g and h to this derogation, since the information to which these points refer is also included in the REACH registration dossier. Current paragraph 3 of article 40: the second sentence of current paragraph 3 of article 40 no longer applies and we would like to propose for this paragraph to be deleted (please see underlined text): "3. Substances placed on the market on or after 1 December 2010 shall be notified in

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		accordance with paragraph 1 within one month after their placing on the market. <u>However, substances placed on the market before 1 December 2010 may be notified in accordance with paragraph 1 before that date.</u>" PT:
(i) point (e) is replaced by the following:		
'(e) specific concentration limits, M-factors or acute toxicity estimates, where applicable, in accordance with Article 10, together with a justification referred to in the relevant parts of sections 1, 2 and 3 of Annex I to Regulation (EC) No 1907/2006;'		
(ii) points (g) and (h) are added:		
'(g) where applicable, the reason for divergence from the most severe classification per hazard class included in the inventory referred to in Article 42;	IT: '(g) ~~where applicable,~~ the reason for divergence from the most severe classification per hazard class included in	DE: Please check whether such an obligation is already established in Article 16(1) ES:

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	the inventory referred to ~~in Article 42~~ **information submitted as part of registration;** SI: ‘(g) where applicable, ~~the~~ a brief ~~reason~~ explanation for divergence from the most severe classification per hazard class included in the inventory referred to in Article 42;	The CLP Revision proposal requires the notifiers to justify (where applicable) the reasons for divergence from the most severe classification. The divergence needs to be addressed per hazard class included in the inventory and/or for introducing a more severe classification per hazard class compared to those included in the inventory. As the C&L Inventory does not contain any supporting data/study, it is important to bear in mind that the notifier may normally justify only its own classification based on supporting data available to him/her, but he/she is generally not able to assess why another notifier concludes a different classification due to lack of access to data from the other notifier(s), unless they have both registered under REACH for the same volume band. Therefore, a justification of divergence from another notification is not always possible without having access to the supporting data of that notification. FR:

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		Among notifications of the same substance, how to identify "reference" notifications and those considered "divergent"? IT: Concerning the high burden to give reasons from point of view of the companies it could be reasonably to ask the reason limiting to those registered. In this case the reason could be evalutated also by ECHA. Collect the reasons also for not registered substance without an evaluation of them self could be an effort without a real benefit. We ask that Echa will support with appropriate tools the industries's efforts. NL: Points g and h: we support adding a provision as such, however, we wonder what this entails in practice and how extensive the justification for divergence should be. We would suggest to have guidance developed. SI:

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		A number of severe classifications for a substance are simply wrong and should not be a reference point. On the other hand we understand the reasoning behind this obligation. Therefore we suggest to delate " the reason " and add "a brief" in order to clarify that only a very brief explanation is expected, e.g. no tests etc.
(h) where applicable, the reason for introducing a more severe classification per hazard class compared to those included in the inventory referred to in Article 42.'; (i)	IT: (h) ~~where applicable~~, the reason for introducing a more severe classification per hazard class compared to those included in the inventory referred to ~~in Article 42.~~ **information submitted as part of registration**'; SI: (h) where applicable, ~~the~~ a brief ~~reason~~ explanation for introducing a more severe classification per hazard class compared to those included in the inventory referred to in Article 42.';	DE: Please check whether such an obligation is already established in Article 16(1) ES: (same comments as for new point (g)) IT: See previous comment NL: Points g and h: we support adding a provision as such, however, we wonder what this entails in practice and how extensive the justification for divergence

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		should be. We would suggest to have guidance developed. SI: Similar as by point g) above. PT:
(b) paragraph 2 is replaced by the following:	FR: 'The information referred to in (a) to **(h)** shall not be notified, if it has been submitted to the Agency as part of a registration pursuant to Regulation (EC) No 1907/2006, or if it has already been notified by that notifier.'	FR: Please consider modifying the provision to include informations (g) and (h).
'2. The information listed in paragraph 1 shall be notified to the Agency by the notifier(s) concerned at the latest 6 months after a decision to change the classification and labelling of the substance has been taken pursuant to the review referred to in Article 15(1).';	ES: '2. The information listed in paragraph 1 shall be **updated and** notified to the Agency by the notifier(s) concerned at the latest 6 months after a decision to change the classification and labelling of the substance has been taken pursuant to the review referred to in Article 15(1).';	ES: A change in the classification and labelling of a substance in accordance to article 15 can trigger a new notification or an update in an already existing entry. Thus we rather maintain the term "update" as in the current text. FI:

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	FI: FI:... after the notifier(s) has/have decided to change the classification…	FI: the originally proposed wording might be a bit misleading as no formal decision is required according to Art. 15. SK: SK CA CLP appreciates the aim of Commission to solve the deviations between active and obsolete classifications in the CL Inventory. However, it is not clearly understandable how will be ensured the deletion of obsolete entries. We welcome the proposal of Commission to update notifications 6 months after the decision to change the classification. But it is not entirely clear when the 6-month notification period begins. LT: Now it is not required to notify acute toxicity estimates regarding Article 40(1), therefore it should be clear if notifications must be updated within 6 months after regulation enters into force just to add acute toxicity estimates.

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		The mandate to remove the obsolete notifications from Inventory should be given to ECHA in legal text.
(21) in Article 42(1), the third subparagraph is replaced by the following:		
'3. The following information shall be made publicly available free of charge online:	BG: '~~3.~~ The following information shall be made publicly available free of charge online: ES: '~~3.~~ The following information shall be made publicly available free of charge online: FI: FI: Delete no 3 NL: '~~3.~~ The following information shall be made publicly available free of charge online:	BG: Technical correction ES: The number "3" should be removed since it is not a paragraph but the third subparagraph of Article 42.1. FI: FI: In article 42(1) there is no subnumbering of paragraphs NL: The sub-paragraphs in Article 42(1) are not numbered, hence the suggestion to omit the number 3.
	FR:	

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	'~~3.~~ The following information shall be made publicly available free of charge online:	
(a) information referred to in Article 40(1), point (a), except where a notifier duly justifies why such publication is potentially harmful for its commercial interests or the commercial interests of any other concerned party;	DE: (a) information referred to in Article 40(1), point (a), except where a notifier duly justifies why such publication is potentially harmful for its **research and development activities,** commercial interests **or the research and development activities** or commercial interests of any other concerned party; ES: (a) information referred to in Article 40(1), point (a), except where a notifier duly justifies why such publication is potentially harmful for its commercial interests or the commercial interests of any other concerned party **and it is accepted by the Agency**;	DE: R & D activities should be excluded in order not to jeopardise innovation. It shall also be ensured that this information cannot be used by third parties for commercial purposes, for example. Where this is not possible, the publication of the information referred to in Article 40(1)(a) should be excluded. EL: Comment: In our view "Commercial interests" may be undermined when the information referred to in Article 118 of the REACH Regulation is disclosed. However, according to the same article *"where urgent action is essential to protect human health, safety or the environment, such as emergency situations, the Agency may disclose the*

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		information referred to in this paragraph". ES: It could be useful to clarify which commercial interests justifies the exception for the publication the information in Article 40(1) point (a). Furthermore, REACH regulation stipulates that ECHA should accept the justification not to publish this information. This should also be included in the CLP.
	FR: (a) information referred to in Article 40(1), point (a), except where a notifier duly justifies why such publication is potentially harmful for its commercial interests, ***defence and national security*** or the commercial interests of any other concerned party;	FR: Defence safety need to be added to the reasons for not making public online the identity of a company that places an "Article 39" substance on the market and must notify ECHA under Article 40. This, in order to prevent the public communication of the Ministry of the Armed Forces as a user of a substance. This would in fact be contrary to the interests of national defence and could be used by a hostile force.

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		IT:
(b) in the case of group notifications, the identity of the importer or manufacturer submitting the information on behalf of the other members of the group;	SI: ~~(b) in the case of group notifications, the identity of the importer or manufacturer submitting the information on behalf of the other members of the group;~~	SI: There is no added value to publish the names of notifier. On the opposite, we expect a significant additional administrative burden for ECHA when processing confidentiality claims. Since the inventory has no tonnage-cut-off-value for the notification, also lots of notifiers are active in R&D. Therefore we propose to delate the whole Article 4 (1b). In addition, as an alternative, we propose to introduce a mechanism to remove entries, which were inactive over a longer time period (see proposal below).
(c) information in the inventory which corresponds to the information referred to in Article 119(1) of Regulation (EC) No 1907/2006.	DE: (c) information in the inventory which corresponds to the information referred to in Article 119(1) of Regulation (EC) No 1907/2006,	DE: To facilitate the notifiers obligation to come to an agreed entry and to increase the usefulness of the inventory for the public and the value chains, the reasons for

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	<u>(d) information referred to in Article 40(1), points (g) and (h).</u>	divergence should also be published in the inventory.
	AT: (d) the date of the notification.	AT: Including the date of the notification could help to keep the database up to date.
	BG: The Agency shall grant access to the information **that concerns a substance in the inventory** and is not referred to in the first subparagraph to other parties subject to Article 118 of Regulation (EC) No 1907/2006.’;	BG: Our understanding is that here we refer to the information that is not included in the inventory; otherwise it is not clear what this provision requires. The first subparagraph is the inventory! FI: FI: Please rephrase this sentence since it is difficult to understand. To which regulation does “*referred to in the first subparagraph”* refer to?
The Agency shall grant access to the information in the inventory that concerns a substance and is not referred to in the first subparagraph to other parties subject to Article 118 of Regulation (EC) No 1907/2006.’;		FR: The terms ‘first subparagraph’ are confusing, it is not clear which paragraph is targeted. Please consider clarifying the provision.
	AT:	AT:

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	The Agency shall remove inactive entries from the inventory. An entry is considered to be inactive, when the notifier has not update the entry within 2 years and after this period has not reacted on a request of the Agency to confirm the correctness of the entry. SI: (new) The Agency shall remove inactive entries from the inventory. An entry is considered to be inactive, when the notifier has not update the entry within 2 years and after this period has not reacted on a request of the Agency to confirm the correctness of the entry.	Giving ECHA the mandate to remove old entries – e.g. from companies, which do not exist anymore – the quality of the inventory could be improved. This would make the CLI a more valuable database for chemical properties. SI: Giving ECHA the mandate to remove old entries e.g. from companies, which do not exist anymore shall regarding our opinion improve the quality of the inventory. In addition this shall also make the C&L Inventory more valuable database for chemical properties. Therefore we propose to introduce a mechanism to remove entries, which were inactive over a longer time period (see new subparagraph of Article 42 (3).
Recitals relating to C2	EL: We agree	ES: (same comments as for new point (g)) As the C&L Inventory does not contain any supporting data/study, it is important to bear in mind that the notifier may normally justify only its own classification based on

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		supporting data available to him/her, but he/she is generally not able to assess why another notifier concludes a different classification due to lack of access to data from the other notifier(s), unless they have both registered under REACH for the same volume band. Therefore, a justification of divergence from another notification is not always possible without having access to the supporting data of that notification
(24) Manufacturers and importers often notify different information for the same substance to be included in the Agency's inventory for classification and labelling. In some cases, such divergences result from different impurities, physical states or other differentiations and may be justified. In other cases, the divergences are due to differences in data used for classification, or to disagreement between notifiers or registrants in the case of joint submission of data in accordance with Regulation (EC) No 1907/2006, or to obsolete classification entries. As a result, the classification and labelling inventory contains divergent classifications, which	IT: (24) Manufacturers and importers often notify different information for the same substance to be included in the Agency's inventory for classification and labelling. In some cases, such divergences result from different impurities, physical states or other differentiations and may be justified. In other cases, the divergences are due to differences in data used for classification, or to disagreement between notifiers or registrants in the case of joint submission of data in accordance with Regulation (EC) No 1907/2006, or to obsolete classification entries. As a result,	IT: The proposal is aligned to the comments on article 40(1) g) h)DE: Consequential amendment ES: It is unclear which the notifier bears the responsibility of engaging with other notifiers(s) in case of divergence. The concept of lead registrant applies only to REACH not CLP. The legal text should clarify that aligning on diverging classifications should only be required when practically achievable, without having to

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makes the inventory less effective as a hazard collection and communication tool and leads to incorrect classifications, ultimately hindering the ability of Regulation (EC) No 1272/2008 to protect human health and the environment. Therefore, the notifiers should be required to provide reasons for divergence from the most severe classification or for introducing a more severe classification per hazard class for the same substance to the Agency. To address divergences between more recent and obsolete classifications, notifiers should be required to update their notifications within 6 months after a decision to change the classification and labelling of a substance has been taken pursuant to a review in Article 15(1) of that Regulation.	the classification and labelling inventory contains divergent classifications, which makes the inventory less effective as a hazard collection and communication tool and leads to incorrect classifications, ultimately hindering the ability of Regulation (EC) No 1272/2008 to protect human health and the environment. Therefore **for the substance registered**, the notifiers should be required to provide reasons for divergence from the most severe classification or for introducing a more severe classification per hazard class for the same substance to the Agency. To address divergences between more recent and obsolete classifications, notifiers should be required to update their notifications within 6 months after a decision to change the classification and labelling of a substance has been taken pursuant to a review in Article 15(1) of that Regulation.DE: (25) In order to enhance transparency of notifications as well as to facilitate the notifiers' duty to come to an agreed notification entry for the same	purchase new data/studies. Further guidance on when that requirement is applicable and how that requirement should be fulfilled would need to be developed by ECHA.

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	substance, certain information notified to the Agency's classification and labelling inventory should be made publicly available, free of charge. Without prejudice to the protection of commercial interests, that information should include **the reasons for divergence and** identity of the notifiers as, knowing whom to contact, would facilitate the objective of coming to an agreed entry to be included in that classification and labelling inventory. In the case of notifications by a group of manufacturers or importers, it should suffice to make publicly available the identity of the notifier submitting the information on behalf of the other members of the group. EL: We agree	

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(25) In order to enhance transparency of notifications as well as to facilitate the notifiers' duty to come to an agreed notification entry for the same substance, certain information notified to the Agency's classification and labelling inventory should be made publicly available, free of charge. Without prejudice to the protection of commercial interests, that information should include the identity of the notifiers as, knowing whom to contact, would facilitate the objective of coming to an agreed entry to be included in that classification and labelling inventory. In the case of notifications by a group of manufacturers or importers, it should suffice to make publicly available the identity of the notifier submitting the information on behalf of the other members of the group.	AT, BE: BG, DK, EL, ES, FI, SK, IE, LT, NL, PL, PT, FR, IT,SI **Comments already provided in table 1.2** FR: (25) In order to enhance transparency of notifications as well as to facilitate the notifiers' duty to come to an agreed notification entry for the same substance, certain information notified to the Agency's classification and labelling inventory should be made publicly available, free of charge. Without prejudice to the protection of commercial interests, ***defense interests***, that information should include the identity of the notifiers as, knowing whom to contact, would facilitate the objective of coming to an agreed entry to be included in that classification and labelling inventory. In the case of notifications by a group of manufacturers or importers, it should suffice to make publicly available the identity of the notifier submitting the information on behalf of the other members of the group.	BE:BG:DK;EL:ES:FI:SK:IE:LT:NL:PL:PT: **n/a** FR: To be consistent with the FR proposed amendment of 42(1)

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		FR, IT, SI **n/a**
Subgroup C3. Procedure for harmonised classification		AT: **n/a**
Subgroup C4. Other regulatory procedures and entry-into-force		
Articles in C4	DK; The Commission is empowered to adopt delegated acts in accordance with Article 53a amending Article 6(5), Article 11(3), Articles 12 and 14, point (b) of Article 18(3), Article 23, Articles 25 to 29, the second and third subparagraphs of Article 35(2) and Annexes I to VIII, **including adopting delegated acts on the inclusion of new hazard classes**, in order to adapt them to technical and scientific progress, taking due account of the further development of the GHS, in particular any UN amendments relating to the use of information on similar	DK; Denmark welcomes the suggested changes to article 53, though there is still a need for clarification on the different paragraphs. In addition, the wording of article 53.1 is still ambiguous and it would be preferable that the paragraph clearly states that the Commission can adopt new hazard classes via delegated acts without the possibility to delete them via delegated acts.

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	mixtures, and considering the developments in internationally recognised chemical programmes and of the data from accident databases. Where imperative grounds of urgency so require, the procedure provided for in Article 53b shall apply to delegated acts adopted pursuant to this paragraph EL: We agree	
(26b-c) Article 53 is amended as follows:		
(b) paragraph 2 is replaced by the following:	FI: FI: … promote ~~the~~ harmonisation of ~~the~~ criteria for classification and labelling of endocrine disruptors for human health, endocrine disruptors for the environment	DK; Denmark finds that the text in the article would have a more logical flow if article 53(2) and 53(3) are switched. This way the obligation to evaluate new test methods is brought to the forefront as is done in recital 33 and the promotion of harmonised criteria in UN GHS based on conventional and alternative test methods is put into context.

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		FI: FI: Regarding the expression "the criteria", does this refer to the EU -criteria in the delegated act? If so, we suggest to delete "the" as shown.
'2. The Commission or the Member States acting in the interest of the Union shall, in the manner appropriate to their role in the relevant UN fora, promote the harmonisation of the criteria for classification and labelling of endocrine disruptors for human health, endocrine disruptors for the environment, persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances as well as alternative test methods at the level of the UN.';	AT: '2. The Commission or the Member States shall, in the manner appropriate to their role in the relevant UN fora, promote the harmonisation of the criteria for classification and labelling of endocrine disruptors for human health, endocrine disruptors for the environment, persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances as well as alternative test methods at the level of the UN.';	AT: We are in favor of not amending this paragraph.
(c) the following paragraph 3 is added:	DE: 3. **<u>Every three years</u>** the Commission shall ~~regularly~~ evaluate the development of	DE: It may prove synergistic to align the reporting duties of the Commission with

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Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, , IE, IT, LT, NL, PL, PT, SI, SK**	**Questions, comments and justifications of drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK**
	alternative test methods referred to in Article 13(1) of Regulation (EC) No 1907/2006 for classification of substances and mixtures. ES: 3. The Commission shall ~~regularly~~ evaluate the development of alternative test methods referred to in Article 13(1) of Regulation (EC) No 1907/2006 for classification of substances and mixtures**, every *[…]* years**.	those of ECHA pursuant to Article 117(3) of the REACH Regulation. DK; With regard to article 53(3) – how will the Commission evaluate the development of alternative test methods when the CLP regulation is not data generating in itself? ES: What does “regularly” mean? We suggest to specify how often this development of alternative test method is going to be evaluated
		FR: Please consider to define how the results of this evaluation must be presented by the Commission (through a report for example) and the periodicity of the evaluation (or its update).
3. The Commission shall regularly evaluate the development of alternative test methods referred to in Article 13(1) of Regulation (EC) No 1907/2006 for classification of substances and mixtures.		

PUBLIC

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, , IE, IT, LT, NL, PL, PT, SI, SK**	**Questions, comments and justifications of drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK**
(27) Article 53a is amended as follows:		
(a) in paragraph 2, the first sentence is replaced by the following:	BE: 'The power to adopt delegated acts referred to in Articles 37(5), 37(7), 37(8), 45(4) **and** 53(1)**~~, 53(1a) and 53(1b)~~** shall be conferred on the Commission for a period of five years from [OP please insert the date = the *date of entry into force of this Regulation]* '; PT: 'The power to adopt delegated acts referred to in Articles 37(5), 37(7), 37(8), 45(4) 53(1), 53(1a) and 53(1b) shall be conferred on the Commission for a period of five years from [OP please insert the date = the *date of entry into force of this Regulation]*. **Concerning the five-year period from 26 July 2019, as amended by Regulation (EU) 2019/1243 of the European Parliament and of the Council, the Commission shall draw up a report in respect of the delegation of power not**	BE: (See comment on article 53(1a)) FI: FI: Does this mean that substances that have been identified as SVHC according to REACH can be included in Annex VI of CLP without the proper CLH-process also in the future? PT: The previous wording anticipated that this transference of power to the COM should be subject to a review in a period of 5 years after 26 July 2019. This text allows an additional period. Although we have no objections to this deadline, as a report was due 9 months before 26 July 2024, we wonder if the COM will still publish this report by this deadline,

PUBLIC

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, , IE, IT, LT, NL, PL, PT, SI, SK**	**Questions, comments and justifications of drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK**
	later than nine months before 26 July 2024.	notwithstanding the new deadline established. We propose an alternative text to be removed if is no longer necessary considering the publication date.
'The power to adopt delegated acts referred to in Articles 37(5), 37(7), 37(8), 45(4) 53(1), 53(1a) and 53(1b) shall be conferred on the Commission for a period of five years from [OP please insert the date = the *date of entry into force of this Regulation]* '; 		
(b) in paragraph 3, the first sentence is replaced by the following:	BE: 'The delegation of power referred to in Articles 37(5), 37(7) and 37(8), 45(4) **and** 53(1)**~~, 53(1a) and 53(1b),~~** may be revoked at any time by the European Parliament or by the Council.'; ES: 'The delegation of power referred to in Articles 37(5), 37(7) ~~and~~ 37(8), 45(4), 53(1), 53(1a) and 53(1b), may be revoked at any time by the European Parliament or by the Council.';	BE: (See comment on article 53(1a)) ES: It doesn´t make sense to have a different wording than in paragraph 2 of this article.

PUBLIC

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting suggestions** **AT, BE, BG, DE, DK, EL, ES, FI, FR, , IE, IT, LT, NL, PL, PT, SI, SK**	**Questions, comments and justifications of drafting suggestions** **AT, BE, BG, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK**
'The delegation of power referred to in Articles 37(5), 37(7) and 37(8), 45(4), 53(1), 53(1a) and 53(1b), may be revoked at any time by the European Parliament or by the Council.';		
(c) in paragraph 6, the first sentence is replaced by the following:	BE: 'A delegated act adopted pursuant to Articles 37(5), 37(7), 37(8), 45(4) **and** 53(1)~~**, 53(1a) and 53(1b),**~~ shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object.'; DE: 'A delegated act adopted pursuant to Articles 37(5), 37(7), 37(8), 45(4) 53(1)~~,~~ **and** 53(1a) ~~and 53(1b)~~, shall enter into force only if no objection has been	BE: (See comment on article 53(1a)) DE: Consequential change due to the proposed deletion of Article 53(1a). As a result, paragraph 1b becomes paragraph 1a. Therefore the citation of Article 53(1b) has to be deleted.

PUBLIC

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, , IE, IT, LT, NL, PL, PT, SI, SK**	**Questions, comments and justifications of drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK**
	expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object.’;	
‘A delegated act adopted pursuant to Articles 37(5), 37(7), 37(8), 45(4) 53(1), 53(1a) and 53(1b), shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object.’;		
(28) Article 53c is replaced by the following:		
‘*Article 53c*		

PUBLIC

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, , IE, IT, LT, NL, PL, PT, SI, SK**	**Questions, comments and justifications of drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK**
Separate delegated acts for different delegated powers		PT: In principle, we can accept the adoption of a separate delegated act in respect of each power delegated to it under the CLP Regulation adoption, with the exception of amendments to Annex VI, where Parts 1 and 2 of that Annex may be amended together with Part 3 of that Annex in one single act.
The Commission shall adopt a separate delegated act in respect of each power delegated to it pursuant to this Regulation, with the exception of amendments to Annex VI, where Parts 1 and 2 of that Annex may be amended together with Part 3 of that Annex in one single act.’;	EL: We agree	
(29) Article 54 is replaced by the following:		
‘1.The Commission shall be assisted by the Committee established by Article 133 of Regulation (EC) No 1907/2006. That committee shall be a committee within the	FR: ‘**Article 54** **Committee procedure**	BG: The procedure in Article 52(2) should be aligned accordingly.

PUBLIC

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, , IE, IT, LT, NL, PL, PT, SI, SK**	**Questions, comments and justifications of drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK**
meaning of Regulation (EU) No 182/2011*.’;	1.The Commission shall be assisted by the Committee established by Article 133 of Regulation (EC) No 1907/2006. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011*.’;	
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.		
** Regulation (EU) 182/2011 …’;*	EL: We agree	
(30) in Article 61, the following paragraph 7 is added:		ES: The text proposed for this new paragraph 7 of Article 61 refers to substances and mixtures that have been classified, labelled and packaged in accordance with the provisions referred to in the following articles: Art. 1(1), Art. 4(10), Art. 5, Art. 6(3) and 6(4), Art. 9(3) and 9(4), Art. 25(6) and 25(9), Art. 29, Art. 30 and Art. 35. After these articles, which are specific to classification, labelling and packaging,

PUBLIC

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, , IE, IT, LT, NL, PL, PT, SI, SK**	**Questions, comments and justifications of drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK**
		others are cited that refer to other provisions of the CLP Regulation on notification to the Inventory, the Inventory itself, advertising and the information in Annex VIII, among others. Since Article 61 establishes the transitional provisions, it should be differentiated to which provisions it refers to and not encompass everything such as classification, labelling and packaging.
	SI: [OP: please insert the date = the first day of the month following ~~**42 months**~~ **60 months** after the date of entry into force of this Regulation].	IT: Considering the impact on the companies, also involved in the implementation of the Delegated Act n. 2023/707, we would like to ask to split for some articles (e.g. Article 5, Article 6(3) and (4), Article 25(6) and (9), Articles 29, 30 and 35 and the disposition for Annex I) differentiating the applicable date, between the substances and the mixtures in coherence with the Delegated Act. In addition, we would like to ask more time for the substances (24 months instead of 18months) and consequently for the mixtures 36 months (instead 18months).

PUBLIC

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, , IE, IT, LT, NL, PL, PT, SI, SK**	**Questions, comments and justifications of drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK**
		Following this parallelism with the approach of the Delegated Act, we would like to ask for substances already on the market 42months (as already proposed) and for mixtures already on the market 60 months. SI: We are of the opinion that in particular for mixtures, a longer transitional period is needed. Alternatively, two deadlines, one for substances (e.g. 48 months), and another longer-one for mixtures. (e.g. 60 months).
'7. Substances and mixtures which have been classified, labelled and packaged in accordance with Article 1(1), Article 4(10), Article 5, Article 6(3) and (4), Article 9(3) and (4), Article 25(6) and (9), Articles 29, 30 and 35, Article 40(1) and (2), Article 42(1), third sub-paragraph, Article 48, section 1.2.1. of Annex I, section 1.5.1.2 of Annex I, section 1.5.2.4.1 of Annex I, Parts 3 and 5 of Annex II, Part A, the first sub-paragraph of section 2.4, of Annex VIII, Part B, section 1, of Annex VIII, Part B, the third paragraph of section 3.1, of		

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Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, , IE, IT, LT, NL, PL, PT, SI, SK**	**Questions, comments and justifications of drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK**
Annex VIII , Part B, section 3.6, of Annex VIII, Part B, the first row of Table 3 of Section 3.7, of Annex VIII, Part B, the first paragraph of Section 4.1, of Annex VIII, Part C, sections 1.2 and 1.4, of Annex VIII, and Part D, sections 1, 2 and 3, of Annex VIII as applicable on … [OP: please insert the date = the day before the entry into force of this Regulation] and which were placed on the market before [OP: please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation] are not required to be classified, labelled and packaged in accordance with this Regulation as amended by Regulation …/… of the European Parliament and of the Council* [OP: please complete the reference in the footnote – it should be the reference to this Regulation] until … [OP: please insert the date = the first day of the month following 42 months after the date of entry into force of this Regulation].		
** Regulation (EU) .../... of the European Parliament and of the Council of ... on ... (OJ ...).';*		

PUBLIC

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting suggestions** **AT, BE, BG, DE, DK, EL, ES, FI, FR, , IE, IT, LT, NL, PL, PT, SI, SK**	**Questions, comments and justifications of drafting suggestions** **AT, BE, BG, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK**
Article 2 of the proposal amending the CLP Regulation		
1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	PL: **2. The following provisions shall apply from [OP: please insert the date = the first day of the month following 24 months after the date of entry into force of this Regulation]:**	PL: Authorities and Industry need realistic transition periods to implement any changes to CLP - both new obligations, changes to new hazard classes and classification criteria, and interim changes resulting from adaptation of the regulation to technical progress, e.g.: ATP to CLP. Even for "less complex" changes, the process of implementing label changes alone can take 6 to 12 months. Added to this are the processes of identifying/generating and evaluating new data, as well as the research and development work required to change product formulations. In addition, existing inventories of both finished products and and printed labels or printed packaging. Products have different rotation periods, which in the case of the less rotational ones, extends the time for making changes

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Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, , IE, IT, LT, NL, PL, PT, SI, SK**	**Questions, comments and justifications of drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK**
		considerably. Disposal of incompatible packaging materials, on the one hand, generates large costs for businesses, and on the other hand, has a negative impact on the environment.
2. The following provisions shall apply from [OP: please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation]:		
(a) Article 1, points (1), (4), (5), (6), (7), (10), (11), (12), (15), (16), (20), (21), (23) and (24);		
(b) points (2), (3), (7), (9) and (10) of Annex I;		
(c) Annex II;		
(d) points (1)(c), (2), (3) and (4) of Annex III.		
		IT:

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		Coherently with our comment on article 61, we would like to ask a spit between substances and mixtures, and align them respectively.
3. By way of derogation from Article 1(1), Article 4(10), Article 5, Article 6(3) and (4), Article 9(3) and (4), Article 25(6) and (9), Articles 29, 30 and 35, Article 40(1) and (2), Article 42(1), third sub-paragraph, Article 48, section 1.2.1. of Annex I, section 1.5.1.2 of Annex I, section 1.5.2.4.1 of Annex I, Parts 3 and 5 of Annex II, Part A, the first sub-paragraph of section 2.4, of Annex VIII, Part B, section 1, of Annex VIII, Part B, the third paragraph of section 3.1, of Annex VIII , Part B, section 3.6, of Annex VIII, Part B, the first row of Table 3 of Section 3.7, of Annex VIII, Part B, the first paragraph of Section 4.1, of Annex VIII, Part C, sections 1.2 and 1.4, of Annex VIII, and Part D, sections 1, 2 and 3, of Annex VIII to Regulation (EC) No 1272/2008 as applicable on [OP: please insert the date = the day before the date of entry into force of this Regulation], substances and mixtures may until … [OP: please insert		

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Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, , IE, IT, LT, NL, PL, PT, SI, SK**	**Questions, comments and justifications of drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK**
the date = the last day of the month following 17 months after the date of entry into force of this Regulation] be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by the following provisions of this Regulation:		
(a) Article 1, points (1), (4), (5), (6), (7), (10), (11), (12), (16), (20), (21) and (23);		
(b) points (2), (3), (7) and (9) of Annex I;		
(c) Annex II;		
(d) points (1)(c), (2), (3) and (4) of Annex III.		
Recitals relating to C4	EL: We agree	
(32) After consultation of the Commission expert group of Competent	EL:	FI:

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Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, , IE, IT, LT, NL, PL, PT, SI, SK**	**Questions, comments and justifications of drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK**
Authorities for REACH[1] and CLP[2], the Commission regularly adapts the Annexes to Regulation (EC) No 1272/2008 to technical and scientific progress. According to Article 53c of that Regulation, the Commission is to adopt a separate delegated act in respect of each power delegated to it. It has been difficult to apply that provision when amending different parts of Annex VI to Regulation (EC) No 1272/2008 that are subject to different empowerments. In particular in the case of simultaneous introduction of new notes into Part 1 of Annex VI to Regulation (EC) No 1272/2008 pertaining to new entries in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 and the introduction of new entries themselves in the same Annex, adoption of separated delegated acts has resulted in artificially separating intrinsically related provisions and thereby	We agree FI: FI: delete “without undue delay”	FI: What does “without undue delay” mean here? It has previously been suggested by the Commission that chapters 3.2. and 3.3. of the 8th GHS Edition could be implemented separately from other changes within that edition, although it was already known then that these chapters will be further updated in the 10th Edition of GHS. However, it was not supported by some MSs and the Commission withdrew the proposal. We think that the alternative methods and related classification criteria should only be implemented in CLP once the work has been completed in GHS. Also, for clarity it would be better to implement a complete new edition of GHS rather than individual items.

[1] 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).

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

PUBLIC

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, , IE, IT, LT, NL, PL, PT, SI, SK**	**Questions, comments and justifications of drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK**
affecting coherence by requiring simultaneous adoption of two different but related delegated acts. In such cases, it should be possible to adopt a single delegated act in respect of different delegated powers.		
(33) In accordance with Directive 2010/63/EU of the European Parliament and of the Council[3], it is necessary to replace, reduce or refine testing on animals. Implementation of Regulation (EC) No 1272/2008 should be based on the use of alternative test methods, suitable for the assessment of health and environmental classification of chemicals, wherever possible. In order to speed up the transition to non-animal methods, with the ultimate goal of fully replacing animal testing, as well as to improve the efficiency of chemical hazard assessments, innovation in the field of non-animal methods should be monitored and systematically evaluated, and the Commission and the Member	EL: We agree	

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

PUBLIC

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States acting in the interest of the Union should promote the inclusion of harmonised criteria based on available alternative methods in UN GHS and subsequently include those criteria in Regulation (EC) No 1272/2008 without undue delay.		
(37) To ensure that suppliers of substances and mixtures have time to adapt to rules on classification, labelling and packaging, the application of some provisions of this Regulation should be deferred. Substances and mixtures which are already placed on the market before the end of that deferral period, should be allowed to continue being placed on the market without being re-classified and re-labelled in accordance with this Regulation, to avoid additional burden on suppliers of substances and mixtures.	EL: We agree	
(38) In line with the transitional provisions of Regulation (EC) No 1272/2008 which allow the application of the new provisions at an earlier stage on a voluntary basis, suppliers should have the	EL: We agree	

PUBLIC

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, , IE, IT, LT, NL, PL, PT, SI, SK**	**Questions, comments and justifications of drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK**
possibility of applying the new classification, labelling and packaging provisions on a voluntary basis before the date of deferred application of this Regulation.		
(39) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States, because environmental pollution is transboundary and the citizens of the Union should benefit from an equal protection of their health and environment and because substances and mixtures should circulate freely on the Union market , but can rather, by reason of their scale, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,		

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Cluster D – Poison centres	FR: **Annex VIII. Part B** 3.2.3. Identification by generic component identifiers By way of derogation from Sections 3.2.1 and 3.2.2, the generic component identifiers “perfumes”, or “colouring agents” may be used for mixture components used exclusively to add perfume or colour, where the following conditions are met: — the mixture components are not classified for any health hazard, — the concentration of mixture components identified with a given generic component identifier does not exceed in total: (a) 1 % for the sum of perfumes; and (b) 10 % for the sum of colouring agents. 3.3. Mixture components subject to submission requirements The following mixture components shall be indicated:	FR: Even though this is not included in the Commission's proposals, the French authorities wish to raise two additional points: - In order to have a better knowledge on product, the poison center need to have more information on the mixture components.Some substances that are not classified can have an effect on human health (i.e allergenic properties). For these reasons, French authorities would like to discuss a lowering of the declaration thresholds to 1% for the sum of perfumes and 10% for the sum of colouring agents. - It would also be useful to include substances and mixtures containing nanomaterial forms in the declaration to the poison control centres. Nanomaterials have to be identified as such in the notification.

PUBLIC

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	(1) mixture components classified as hazardous on the basis of their health or physical effects which: — are present in concentrations equal to or greater than 0,1 %, — are identified, even if in concentrations lower than 0,1 %, unless the submitter can demonstrate that those components are irrelevant for the purposes of emergency health response and preventative measures; (2) mixture components not classified as hazardous on the basis of their health or physical effects which are identified and present in concentrations equal to or greater than 1 %. **(3) mixture components in nanoforms**	
Subgroup D1. Poison centres		
Articles in D1		
(1) in Article 1(1), the following point (f) is added:	DE: ‘(f) providing an obligation for downstream users, importers and distributors referred to in Article 45	DE: The reference to Article 45(1) does not relate to downstream users, importers or distributors in the proposed amended

PUBLIC

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	<u>paragraphs (1b) and (1c)</u> to submit information relevant for providing an adequate emergency health response to appointed bodies in accordance with Annex VIII.’;	version of this paragraph. Reference to downstream users, importers and distributors are made in the newly introduced paragraphs 1b and 1c, respectively. IE: We suggest that a reference to the PCN portal is provided here, perhaps in a footnote. This footnote could reference the uniform portal and how the notifications are directed to each Member State. In our experience, this is an issue of confusion amongst stakeholders. We appreciate it is referenced in recital 27 but feel the text could benefit from also having it here. It’s important to include distributors, so that they have a direct obligation to notify the hazardous chemical mixtures they place on the market. This ensure that poisons centres have the information they need to provide an adequate emergency health response for all hazardous chemical mixtures.
‘(f) providing an obligation for downstream users, importers and		PT:

PUBLIC

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, , IE, IT, LT, NL, PL, PT, SI, SK**	**Questions, comments and justifications of drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK**
distributors referred to in Article 45(1) to submit information relevant for providing an adequate emergency health response to appointed bodies in accordance with Annex VIII.’;		
(22) Article 45 is amended as follows:		
(a) paragraph 1 is replaced by the following:	PT: ‘1. Member States shall appoint a body or bodies responsible for receiving the relevant ~~**harmonised**~~ **information** relating to emergency health response and preventative measures, in accordance with Annex VIII.’;	PT: We support MT suggestion and propose a revision of the text.
‘1. Member States shall appoint a body or bodies responsible for receiving the relevant harmonised information relating to emergency health response and preventative measures, in accordance with Annex VIII.’;		

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Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, , IE, IT, LT, NL, PL, PT, SI, SK**	**Questions, comments and justifications of drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK**
(b) the following paragraphs 1a, 1b and 1c are inserted:		BG: It is necessary to clarify the role of ECHA and how it will support the national authorities if it is designated to receive this information. IE: We support the option for Member States to appoint the Agency as the body responsible for receiving information relating to emergency health response. We are of the opinion however that, at a minimum, clear guidance will be required as to the (limited) role for the Agency in this regard. It is our understanding that the Agency will not have obligations to carry out tasks as an Appointed Body as such and those obligations will remain with the Member States i.e. the Agency will only receive notifications under Article 45(1) but will not provide any other functions under article 45(2). Consideration may need to be given to having this clearly stated in the legal text.
‘1a. Member States may appoint the Agency as the body responsible for	BG:	BG:

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receiving information relating to emergency health response and preventative measures referred to in paragraph 1.’;	1b. Importers and downstream users placing on the market mixtures that are classified as hazardous on the basis of their health effects or physical effects, shall submit to the body or bodies appointed in accordance with paragraph 1 **or paragraph 1a** the harmonised information referred to in Part B of Annex VIII. IE: We suggest to use the wording ‘placing mixtures on the market’ instead of ‘placing on the market mixtures’ (this comment also applies to 1c and throughout Annex VIII). Editorial suggestion: ‘health ~~effects~~ or physical effects’ PT: 1b. Importers and downstream users placing on the market mixtures that are classified as hazardous on the basis of their health effects or physical effects, shall submit to the body or bodies appointed in accordance with paragraph 1**, the ~~harmonised~~ information** referred to in Part B of Annex VIII.	In case, the MS take advantage of the option to define the Agency and for the purpose of clarity for the notifiers. PT: As a follow up of the 5th April meeting, concerning the possibility to review the downstream user and distributor definitions, PT **does not** consider adequate to review these concepts as those are already consolidated in the chemicals legislation. We support MT suggestion and propose a revision of the text.

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1b. Importers and downstream users placing on the market mixtures that are classified as hazardous on the basis of their health effects or physical effects, shall submit to the body or bodies appointed in accordance with paragraph 1 the harmonised information referred to in Part B of Annex VIII.	FI: FI: rebrand > change the brand name IE: Editorial suggestion: 'health ~~effects~~ or physical effects' PT: 1c. Distributors placing on the market mixtures that are classified as hazardous on the basis of their health effects or physical effects, shall submit to the appointed body or bodies **the ~~harmonised~~ information** referred to in Part B of Annex VIII where they further distribute those mixtures in other Member States, or where they rebrand or relabel the mixtures. This obligation does not apply if the distributors can demonstrate that the appointed body or bodies already received the same information from importers or downstream users.';	BG: We believe that it creates an unnecessary administrative burden for: 1. the distributors who should notify and verify that the information has not already been notified by importers or downstream users in the different countries. 2. the competent authorities, they should exercise control over the compliance with this obligation, which would be difficult, given that the distributor is based in another Member States. We believe that a possible solution is: for a distributor who rebrands or relabels a mixture to notify his supplier – the importer or downstream user – who will accordingly supplement the notification provided by him. This will also avoid the duplication of information, since it concern a mixture with the same composition. EL: <u>Comment:</u> Although we believe that a distributor is a downstream user when he rebrands or relelabels the mixture and

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		therefore he is liable to submit information, we consider that this amendment is in line with our position (already included in the guidance of annex VIII) because it reaches the same result. In addition, the double notification for the same mixture is avoided, because there is no need for the above mentioned distributors to submit the relevant information if importers or downstream users have already submit it. This is the practice we already follow in the enforcement in our CA. FI: FI: proposed wording in line with the current CLP (Annex VIII part B 1.1) PT: We support MT suggestion and propose a revision of the text.
	FR: 1c. Distributors placing on the market mixtures that are classified as hazardous on the basis of their health effects or physical effects, shall submit to the ~~**appointed**~~ body	FR: Changes for consistency with subparagraph 1b.

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	or bodies **appointed in accordance with paragraph 1** the harmonised information referred to in Part B of Annex VIII where they further distribute those mixtures in other Member States, or where they rebrand or relabel the mixtures. This obligation does not apply if the distributors can demonstrate that the ~~**appointed**~~ body or bodies **appointed** already received the same information from importers or downstream users.'; 	How will distributors demonstrate that the appointed body has already received the information from their supplier (importers or downstream users)? It should be mandatory that each UFI matches with one notified composition. The notification is under the responsibility of the downstream user, who gives the UFI to the distributor.
1c. Distributors placing on the market mixtures that are classified as hazardous on the basis of their health effects or physical effects, shall submit to the appointed body or bodies the harmonised information referred to in Part B of Annex VIII where they further distribute those mixtures in other Member States, or where they rebrand or relabel the mixtures. This obligation does not apply if the distributors can demonstrate that the appointed body or bodies already received the same information from importers or downstream users.'; 	BE: ~~**(c) in paragraph 2, point (b) is replaced by the following:**~~	AT: It is unclear how a distributor in the role of a distributor can rebrand or relabel mixtures as this would classify him as a downstream user from an enforcement perspective.
	FR:	FR:

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	Please consider to add two new subparagraphs: 1d. Distributors placing on the market mixtures, within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from [one year after the publication of this act]. 1e. By way of derogation from Section 1.4, if one of the changes described in Section 4.1 of Part B of this Annex occurs before [four year after the publication of this act], importers and downstream users shall comply with this Annex before placing that mixture, as changed, on the market.	Distributors should benefit from the same transitional provisions as manufacturers and importers
(c) in paragraph 2, point (b) is replaced by the following:	BE: **~~'(b) where requested by a Member State, the Commission or the Agency, to undertake a statistical analysis to identify where improved risk management measures may be needed.'~~**; ES: '(b) where requested by **the~~a~~** Member State, the Commission or the	BE: Information submitted is confidential and may be sensitive; this is why its access and use were very limited by the legislator. Statistical analysis are aiming at Poison Centres identifying particular trends in incident or adjust the focus of preventive actions, as described in point 2(a). Firms confidence could be lost if the Commission and the Agency are allowed to

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	Agency, to undertake a statistical analysis to identify where improved risk management measures may be needed.’;	get and use these information; even competent authorities do not have access to the detailed information received by Poison Centres. On the other hand, requests by the Commission or the Agency to Poison Centres to provide particular data would increase the burden on Poison Center and reduce their ability to focus on urgent medical demands and prevention of incidents. In addition, some Member States chose to keep running their national notification system in parallel of the ECHA Portal and information received are thus fragmented. BG: The current text should be preserved – the risk management measures are prerogative of the Member States. ES: In the text proposed, we see that "the Member State" has been changed from the current wording to "a Member State", in addition to adding the possible request by the Commission and the Agency. We do not

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		agree with changing "the" to "a" as it would imply that any Member State could request the information for statistical analysis purposes from the body designated by another Member State. Currently, only the competent Authority of the Member State may request such information from the body he has designated. In our opinion, such information should only be sent to the Competent Authority where the designated body is located or to a supranational institution such as COM or ECHA.
‘(b) where requested by a Member State, the Commission or the Agency, to undertake a statistical analysis to identify where improved risk management measures may be needed.’;		
(d) paragraph 3 is replaced by the following:	EL: We propose the addition of the text in bold: The appointed bodies shall have at their disposal all the information ***described in paragraph 2,*** required from importers, downstream users and distributors referred	EL: Comment: the meaning of the phrase *“the tasks for which they are responsible”* is very broad and undefined. According to paragraph 2, information may only be used:

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	to in paragraph 1c, to carry out the tasks for which they are responsible ’;	(a) to meet medical demand by formulating preventative and curative measures, in particular in the event of an emergency; and (b) where requested by a Member State, the Commission or the Agency, to undertake a statistical analysis to identify where improved risk management measures may be needed. IE: It’s important to include distributors, so that they have a direct obligation to notify the hazardous chemical mixtures they place on the market. This ensure that poisons centres have the information they need to provide an adequate emergency health response for all hazardous chemical mixtures. LT: Enforcement institutions do not have any access to the information that is submitted under article 45, because this information is confidential. However, for enforceability of the implementation of article 45 requirements, access to commercially non-sensitive information should be provided to

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		enforcement institutions to check if a notification according to the UFI code indicated in the label is submitted to the appointed body and available to poison centres.
'3. The appointed bodies shall have at their disposal all the information required from importers, downstream users and distributors referred to in paragraph 1c, to carry out the tasks for which they are responsible.';	EL: We agree	
(25) Article 50 is amended as follows:		
(a) in paragraph 2, point (b) is replaced by the following:		IE: Enforcement inspectors can experience issues in being able to verify as to whether a product with a UFI has been notified via the ECHA PCN or not. We suggest that consideration be given to identifying a means whereby this information can be provided to NEAs by ECHA.
	IT:	

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Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting suggestions** **AT, BE, BG, DE, DK, EL, ES, FI, FR, , IE, IT, LT, NL, PL, PT, SI, SK**	**Questions, comments and justifications of drafting suggestions** **AT, BE, BG, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK**
'(b) provide competent authorities with technical and scientific guidance and tools on the operation and implementation of this Regulation and provide support to the helpdesks established by Member States under Article 44.';		
(b) the following paragraph 3 is added:		
'3. Where the Agency acts as an appointed body in accordance with Article 45(1a), it shall put in place the tools necessary to provide access to the information to the relevant appointed body or bodies of the appointing Member State to fulfil their tasks with regard to emergency health response and preventative measures.'		
Changes to Annex VIII in D1	EL: We agree	
(1) Part A is amended as follows:		

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(a) Section 1 is replaced by the following:		
'1. Application	ES: *Suggestion 1:* 1.1 Importers~~,~~ **and** downstream users ~~and distributors referred to in Article 45(1c)~~ placing on the market mixtures for consumer use, within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2021. **Distributors referred to in Article 45(1c) placing on the market mixtures for consumer use, within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from [indicate application date].** *Suggestion 2:* 1.1 Importers, downstream users and distributors referred to in Article 45(1b) and (1c) placing on the market mixtures for consumer use, within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2021.	ES: According to the current text, distributors do not have the obligation of submitting information to the appointed bodies. We have concerns related with the Commission proposal, because it seems that the obligation would apply to distributors retroactively. We think that distributors would have to comply with the obligation no earlier than the application date of the reviewed text. If this paragraph is not modified according to suggestion 1, we propose suggestion 2 in order to add clarity we suggest to include also a reference to the new Art. 45(1b). PT:

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1.1 Importers, downstream users and distributors referred to in Article 45(1c) placing on the market mixtures for consumer use, within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2021.	ES: *Suggestion 1:* 1.2. Importers~~,~~ **and** downstream users ~~and distributors referred to in Article 45(1c)~~ placing on the market mixtures for professional use, within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2021. **Distributors referred to in Article 45(1c) placing on the market mixtures for consumer use, within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from [indicate date].** *Suggestion 2:* 1.2. Importers, downstream users and distributors referred to in Article 45**(1b) and** (1c) placing on the market mixtures for professional use, within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2021.	ES: See previous comment
1.2. Importers, downstream users and distributors referred to in Article 45(1c)	ES:	ES:

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placing on the market mixtures for professional use, within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2021.	1.3. Importers, downstream users and distributors referred to in Article 45**(1b) and** (1c) placing on the market mixtures for industrial use or mixtures with an end use not subject to notification within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2024.	To add clarity
1.3. Importers, downstream users and distributors referred to in Article 45(1c) placing on the market mixtures for industrial use or mixtures with an end use not subject to notification within the meaning of Section 2.4 of Part A of this Annex, shall comply with this Annex from 1 January 2024.	ES: 1.4. Importers, downstream users and distributors referred to in Article 45**(1b) and** (1c) having submitted information relating to hazardous mixtures to a body appointed in accordance with Article 45(1) before the dates of applicability mentioned in Sections 1.1, 1.2 and 1.3 and which are not in accordance with this Annex, shall for those mixtures not be required to comply with this Annex until 1 January 2025.	ES: To add clarity
1.4. Importers, downstream users and distributors referred to in Article 45(1c) having submitted information relating to hazardous mixtures to a body appointed in accordance with Article 45(1) before the	ES: 1.5. By way of derogation from Section 1.4, if one of the changes described in Section 4.1 of Part B of this Annex occurs	

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dates of applicability mentioned in Sections 1.1, 1.2 and 1.3 and which are not in accordance with this Annex, shall for those mixtures not be required to comply with this Annex until 1 January 2025.	before 1 January 2025, importers, downstream users and distributors referred to in Article 45**(1b) and** (1c) shall comply with this Annex before placing that mixture, as changed, on the market.'; IE: Propose to change text to 'before placing that changed mixture, ~~as changed~~,'	
1.5. By way of derogation from Section 1.4, if one of the changes described in Section 4.1 of Part B of this Annex occurs before 1 January 2025, importers, downstream users and distributors referred to in Article 45(1c) shall comply with this Annex before placing that mixture, as changed, on the market.';		
(b) Section 2.1 is replaced by the following:		
'2.1 This Annex sets out the requirements that importers, downstream users and distributors referred to in Article 45(1c) ('submitters') placing mixtures on the market shall fulfil in respect of the		

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submission of information so that appointed bodies have at their disposal the information required to carry out the tasks for which they are responsible under Article 45.';		
(c) in Section 2.4., first subparagraph, the following point (6) is added:		
'(6) 'composition conforming with a standard formula specified in Part D' means a composition which includes all the components listed in one of the standard formulas referred to in Part D of this Annex, where those components are present in the mixture in concentrations within the ranges specified in that standard formula.';	EL: We agree	
(2) Part B is amended as follows:		FI: FI: Does this come after 1.1? It should be clearly indicated.

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(a) the following Section 1.1a. is inserted:		
'1.1a. Name and product description of standard formula or name of fuel		
For mixtures with a composition conforming with a standard formula specified in Part D, the name and product description of the relevant standard formula as indicated in that Part shall be included in the submission.		
For fuels listed in Table 3, the name of the fuel shall be provided as indicated in that table.';		
(b) in Section 3.1, the third paragraph is replaced by the following:	ES: 'Components which are not present in a mixture shall not be notified. However, if ~~the~~ **those** components are notified as part of an interchangeable component group in accordance with Section 3.5. or their concentration has been submitted as a range of percentages in accordance with	

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	Sections 3.6. or 3.7, they may be notified if it is certain that they will be present in the mixture at some point in time. In addition, for mixtures with a composition conforming with a standard formula specified in Part D for which the composition is notified in accordance with Section 3.6, first indent, components listed in the relevant standard formula shall be notified even if the component is potentially not, or not permanently, present in cases where the indicated concentration range in Part D includes 0 %.’;	
‘Components which are not present in a mixture shall not be notified. However, if the components are notified as part of an interchangeable component group in accordance with Section 3.5. or their concentration has been submitted as a range of percentages in accordance with Sections 3.6. or 3.7, they may be notified if it is certain that they will be present in the mixture at some point in time. In addition, for mixtures with a composition conforming with a standard formula specified in Part D for which the		

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composition is notified in accordance with Section 3.6, first indent, components listed in the relevant standard formula shall be notified even if the component is potentially not, or not permanently, present in cases where the indicated concentration range in Part D includes 0 %.’;		
(c) the title of Section 3.6. is replaced by the following:		
‘3.6. Mixtures with a composition conforming with a standard formula’;		
(d) in Section 3.7., the first row of Table 3 is replaced by the following:		
‘Fuel name / Product description’;		FI: FI: Added to the end of the list?
(e) in Section 4.1, the first paragraph, the following indent is added; :		
		IT:

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		We would like to ask some clarification or examples on these possible "other changes" in the guidance
'- when there are other changes to a mixture placed on the market which are relevant for the emergency health response referred to in Article 45';		
(3) Part C is amended as follows:		
(a) Section 1.2. is replaced by the following:		
'**1.2 Identification of the mixture, submitter and contact point**		
Product identifier		
Complete trade name(s) of the product including, where relevant, brand name(s), name of the product and variant names as they appear on the label, without abbreviations or non-alphanumerical symbols and enabling specific identification of the product.		

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Unique Formula Identifier(s) (UFI)		
Other identifiers (authorisation number, company product codes)		
In case of group submission, all product identifiers shall be listed.		
Name and product description of standard formula or name of fuel		
Standard formula name and product description as specified in Part D (where applicable)		
Fuel name as specified in Table 3 of Part B (where applicable)		IE: Include also contact details for the importer, distributor or downstream user placing the mixture on the market, if they are not the submitter. In relation to IE's comment above that the contact details of importers, distributors or downstream users placing the mixture on the market if they are not the submitter be

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		added to Part C, section 1.2, IE notes that agencies submitting information on behalf of importers, distributors or downstream users have sometimes been listed as the duty holder on the PCN. This could make it difficult for National Poisons Information Centres to locate information on a mixture. For example, if staff are told by a caller who doesn't have access to the UFI that the product is a PVC primer with company X branding, but company X hasn't been listed as the duty holder, staff won't be able to find the information on that product. In a perfect world the UFI would be known but in reality people sometimes attend hospital without the original container or with a photograph of only the front of the container or the label is damaged, so the UFI isn't always known
Contact details of the submitter and contact point		
Name		

CLP proposal – table for MS comments following Presidency clustering

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/ removing/ adjusting/ merging/ splitting cells and rows. This would hinder the consolidation of your comments.

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Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, , IE, IT, LT, NL, PL, PT, SI, SK**	**Questions, comments and justifications of drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK**
Full address		
Telephone number		
E-mail address		
Contact details for rapid access to additional product information (24 hours/7 days). Only for limited submission.		
Name		
Telephone number (accessible 24 hours per day, 7 days per week)		
E-mail address’;		
(b) Section 1.4. is replaced by the following:		
‘1.4. **Information on the mixture components and interchangeable component groups**		
Identification of the mixture components		

PUBLIC

Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, , IE, IT, LT, NL, PL, PT, SI, SK**	**Questions, comments and justifications of drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK**
— Chemical/trade name of the components		
— CAS number (where applicable)		
— EC number (where applicable)		
— UFI (where applicable)		
— Standard formula name and product description (where applicable)		
— Fuel name (where applicable)’;		
Name of interchangeable component groups (where applicable)		
Concentration and concentration ranges of the mixture components		
— Exact concentration or concentration range		
Classification of mixture components		
— Hazard classification (where applicable)		

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Commission proposal (following PCY proposed clustering, WK 1216/2023)	**Drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, , IE, IT, LT, NL, PL, PT, SI, SK**	**Questions, comments and justifications of drafting suggestions AT, BE, BG, DE, DK, EL, ES, FI, FR, IE, IT, LT, NL, PL, PT, SI, SK**
— Additional identifiers (where applicable and relevant for health response)		FI: FI: This is in italics in the original regulation
List according to Part B, Section 3.1, fifth subparagraph (where applicable) ’;		
(4) Part D is amended as follows:		
(a) In section 1, the first row of the tables with standard formulas for cement are replaced by the following:		
[please refer to the tables in point (4)(a) of Annex III of the Commission proposal]	BG: (b) In section 2, the ~~two~~ first row~~s~~ of the table with standard formula for gypsum is replaced by the following **two rows:**	BG: Technical correction – if the first two lines are replaced, the line with the three columns – Component name, EC № and Concentration - will disappear.
(b) In section 2, the two first rows of the table with standard formula for gypsum is replaced by the following:		

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[please refer to the table in point (4)(b) of Annex III of the Commission proposal]	BG: (c) In section 3, the ~~two~~ first row~~s~~ of the tables with standard formulas for ready mixed concrete are replaced by the following **two rows**:	BG: See comment on letter b) FI: FI: Please combine the two cells listing the classes of Standard Formula 1
(c) In section 3, the two first rows of the tables with standard formulas for ready mixed concrete are replaced by the following:		
[please refer to the tables in point (4)(c) of Annex III of the Commission proposal]		
Recitals relating to D1	EL: We agree	
(26) Pursuant to Article 45(1) of Regulation (EC) No 1272/2008, appointed bodies in the Member States are to receive relevant information relating to emergency health response submitted by importers and downstream users placing on the market	EL: We agree	

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mixtures that are hazardous based on their health or physical effects. Distributors are not required to submit such information. In certain cases of distribution across borders from one Member State to another, or where distributors rebrand or relabel mixtures, the absence of such submission obligation causes information loss for the appointed bodies which may prevent them from providing adequate emergency health response. To address this situation, an obligation to submit information relating to emergency health response should also be introduced for distributors, where they further distribute hazardous mixtures in other Member States or where they rebrand or relabel hazardous mixtures.		
(27) Pursuant to Article 45(3) of Regulation (EC) No 1272/2008, appointed bodies are to have all the required information available to provide adequate emergency health response. The Agency already set up and maintains a Union level Poison Centres Notification portal, and established, developed and maintains a database containing information relating to	BE: **~~(28) In addition to the Member States' appointed bodies, the Commission or the Agency should be able to use the information relating to emergency health responses for the purpose of carrying out statistical analysis. That would usefully~~**	BE: See comment on Article 45(2)(b). If complementary information on the use of substances submitted as part of registration under Regulation (EC) No 1907/2006 are needed, the CLP regulation is not the appropriate regulation to collect such

PUBLIC

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emergency health response to assist some Member States in complying with that Regulation. Therefore, the Agency would be in a position to fulfil the task of receiving that information. To reduce administrative burden for Member States and take advantage of economies of scale, Regulation (EC) No 1272/2008 should provide for the option of appointing the Agency as a body responsible for receiving the relevant information, should a Member State wish to do so.	~~**complement information on the uses of substances submitted as part of registration under Regulation (EC) No 1907/2006, while enabling a better prioritisation of substances to be subject to harmonised classification and labelling under Regulation (EC) No 1272/2008 and feeding into the risk management processes under Regulation (EC) No 1907/2006, and potentially under other Union acts.**~~ EL: We agree	information. A revision of the REACH regulation is more appropriate for this purpose.
(28) In addition to the Member States' appointed bodies, the Commission or the Agency should be able to use the information relating to emergency health responses for the purpose of carrying out statistical analysis. That would usefully complement information on the uses of substances submitted as part of registration under Regulation (EC) No 1907/2006, while enabling a better prioritisation of substances to be subject to harmonised classification and labelling under	EL: We agree	

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Regulation (EC) No 1272/2008 and feeding into the risk management processes under Regulation (EC) No 1907/2006, and potentially under other Union acts.		
(31) Apart from providing industry with technical and scientific tools on how to comply with Regulation (EC) No 1272/2008, the Agency should also provide competent authorities with such tools, for example databases, in order to foster implementation. Regulation (EC) No 12727/2008 should more in detail set out the Agency's remit in this regard. Furthermore, the Agency, acting as a body appointed by a Member State competent authority for receiving information for emergency health response, should provide the relevant national appointed body of that Member State access to that information.	EL: We agree	
(34) Annex VIII to Regulation (EC) No 1272/2008 provides for harmonised information relating to emergency health response and preventative measures to be received by appointed bodies, and sets forth the general	EL: We agree	

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

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(36) Regulation (EC) No 1272/2008 should therefore be amended accordingly.	BE: End BG: End DE: End DK; End EL: End ES: End FI: End SK: End IE:	BE: End BG: End DE: End DK; End EL: End ES: End FI: End SK: End IE:

CLP proposal – table for MS comments following Presidency clustering

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/ removing/ adjusting/ merging/ splitting cells and rows. This would hinder the consolidation of your comments.

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	End LT: End NL: End PL: End PT: End	End LT: End NL: End PL: End PT: End
	IT: End SI: End	IT: End SI: End
	AT: End	AT: End
	FR: End	FR: End