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Revision of the CLP Regulation

Ahead of the Trilogue discussions, Cefic would like to share its assessment of the co-legislators' positions and highlight some outstanding concerns of the EU chemical industry.

The EU chemical industry supports the goals of the Chemicals Strategy for Sustainability (CSS): ensure the chemicals are produced and used in a way that maximises their contribution to society including achieving the green and digital transition, while avoiding harm to the planet. As CLP is a cornerstone of the EU chemical legislation, revising CLP means changing the foundation of one of the most comprehensive chemical legislations in the world. Changes to CLP will immediately cascade down to REACH, to product-specific EU legislation (e.g., cosmetics, biocidal and plant protection products, etc.).

The negotiations on the CLP revision should be concluded before the European elections, to offer predictability to the industry and ensure the necessary coherence with the provisions of the CLP delegated act published in March 2023.

Below you will find an overview of the key points and analysis of the co-legislators' positions (European Commission Proposal, Council position , European Parliament – EP - position):

1. Font sizes and formatting rules (Annex I Part I Section 1.2.1.4-Table 1.3 and 1.2.1.5)

While understanding the need to regulate the font sizes for the labels to ensure legibility, especially for small consumer packaging, the proposed increase will have considerable cost and operational impacts. It will make current label sizes unusable for the majority of products, thus reduce the number of languages that can be placed on one label and hence, require operational changes, while significantly increasing the costs of re-designing and re-printing labels (for one of the largest chemical companies, the impact will be in the range of €60 million). These consequences and impacts were not sufficiently examined in the Commission's impact assessment, that did not evaluate any specific font size option nor quantified the associated costs.

None of the positions currently on the table are acceptable.

The best way to address the font size would be starting from the ECHA guidance (1.2 mm for all packaging sizes), which is an option considered in the Commission's targeted impact assessment: in effect, CLP would 'legalise' a practice already recommended by ECHA and not regarded as posing legibility issues.

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- *we ask the co-legislators to work on a solution that will reflect the above values.*

For other formatting rules as specified for section 1.2.1.5, we support the Council proposal that changes some overly stringent provisions from the Commission proposal (deleting the need to print the labels with white background and distance between the lines) as it is more workable to the chemical industry.

- *we support the Council proposal on section 1.2.1.5.*

2. Grouping for the purpose of harmonised classification (Art 37 (2) and Art 37 (1) (3a))

We appreciate the goal of faster decision making related to grouping, however this should not come at the expense of scientific evidence. The grouping of substances for the purpose of applying the same harmonised classification to each substance in one group must rely on clear scientific data, consider differing properties from substance to substance and use the same methods as those applied under the REACH Regulation (for consistency). Therefore we support the outcome of European Parliament position because it is clearer in its reference to REACH compared to the Commission or Council proposals.

- *we support the European Parliament position on Art 37 (2).*

We disagree with European Parliament position that grouping should be used as a default in CLH (harmonised classification and labelling) process rather than individual substances as CLH should focus on the hazardous properties of the substances and their quantities. For example, a single substance with CMR (carcinogenic, mutagenic and reprotoxic) properties produced at high volume and used in different sectors should be prioritised over groups of substances with a less severe hazard profile, possibly used in smaller quantities. As referred to in the Chemicals Strategy for Sustainability, focusing on the most hazardous substances (in the uses that lead to exposure) is more protective.

- *we do not support the European Parliament position on Art 37 (1) (3a).*

3. Multi-constituent substances (MOCS) (Art 3 (a) (new))

We believe that Parliament's focus on exempting substances of renewable botanical origin that are not chemically or genetically modified is not scientifically justified as it treats a specific class of substances differently from other types of substances. Classification provisions should apply to all the chemicals in the same way (regardless of whether they are of botanical origin or not) and be based on availability of the data. Hence, we support the Council proposal to delete the provisions on MOCS for all chemicals with the review clause in 4 years followed by possible legislative action.

- *we support the Council position on MOCs.*

4. Label updates (Art 30 (1) and (2))

The new CLP Regulation proposal requires labels to be updated within 6 months in case a new hazard class or a more severe classification needs to be assigned to a substance or a mixture, or when new supplemental information on the label is required, and 18 months for all other cases. We would like to point out that the additions proposed by Council are not in line with

Article 15 (4) of CLP that already covers that those provisions apply for every actor in the supply chain (manufacturers, importers and downstream users) – not only original supplier/classifier. We note that complex value chains involve several mixture formulators downstream and thus require multi-step supply chain communication. It is also inconsistent with current practices (18 months for all actors) which have proven adequate to allow re-design, re-printing of labels and re-labelling of packages. Hence, we support the Commission proposal indicating that the timeline indicated for label updates should apply for every actor in the supply chain.

- *we support the Commission's position regarding the timing of label updates.*

5. Green Claims (Article 48, after § 2)

We believe that Green Claims should not be part of CLP but should be dealt with the Green Claims legislation (which is currently going through Parliament and Council). The Commission's proposals on Empowering Consumers for the Green Transition (amending the UCPD) and the Green Claims Directive are intended to be the main legislative texts defining the rules on environmental claims. To ensure regulatory coherence and legal certainty, it is important that environmental claims remain regulated by those two pieces of legislations. In addition, CLP text Art. 25 (4) already regulates that statements such as 'non-toxic', 'non-harmful', 'non-polluting', 'ecological' or any other statements indicating that the substance or mixture is not hazardous or any other statements that are inconsistent with the classification of that substance or mixture shall not appear on the label or packaging of any substance or mixture. For this reason, the approach of the Commission / Council is the preferred way forward.

- *we support the Commission and the Council positions and we not to support the EP amendment.*

6. Classification and Labelling Inventory (CLI) (Article 41 and 42(1))

We do not support the Parliament amendment stating that the most protective classification shall prevail in case notifiers/registrants cannot come to an agreement on the CLI entry as classification should be based on the available data to the notifier and depends also on its impurities/additives. Wrongly overclassifying the substance may have several consequences under other regulations. In addition, there is no possibility for ECHA to verify whether a more severe classification is duly justified by solid data or not, paving the way to potential misinformation prevailing in the inventory.

- *we do not to support the Parliament amendment adding that the most protective classification prevails in case notifiers do not come to an agreement on classification.*

We do not support the deletion of the provision as included by Commission for Art 42 (1) that specifies that the name of the notifier as submitted to Classification and Labelling Inventory (CLI) will not be published if the notifier duly justifies why such publication is potentially harmful (position of the EP). In fact, this can undermine potentially sensitive confidential business information (CBI) for some businesses. We note that Article 77 (2) (e) to REACH regulates the establishment of the inventory and the proposed deletion of the parliament

contradicts the provisions in Article 119 (1) to REACH that regulates the information that should be made publicly available in electronic format.

- *we do not to support the Council's position and the Parliament amendment deleting the right to claiming confidential business information.*

7. Fold-out labels (Art 32 (6) and Annex I 1.2.1.6)

We do not support the Parliament amendment for Art 32 (6) requiring that for fold-out labels, the front page should be in the all official languages of the Member State. Thiscauses additional administrative burden for industry and complicates further the supply chain distribution. In some cases, it actually makes the fold-out labels useless. The Council proposal for Annex I Section 1.2.1.6 where the it states that abbreviation of the language (country code or language code) for all languages that are used in the inside pages is more workable and provides flexibility for different types of packaging.

- *we do not to support Parliament amendment requiring to have the national languages of the member state on the front page of the fold-out label. We support the Council proposal.*

8. Child Resistant Fastening (CRF) (1a in Part 3 of Annex II point 3.1.1.1.)

We believe that the Child Resistant Fastening (CRF), used to ensure a higher level of safety of a consumer product, should not be extended to serious eye damage cat. 1 hazard class. This extension would lead to a majority of daily-use detergents (dish-washing, laundry) to be equipped with a child-resistant closure, which does not match the real risk incurred. While a very wide range of detergents are classified as eye cat 1, only 5% of exposure to detergents cause eye discomfort or injury. Moreover, only 1% of eye exposure to daily detergents and cleaning products are classified as severe i.e., permanently damaging according to the WHO poison severity score. As several Poison Centers have pointed out, this would be counter-productive as people would most likely leave the packaging open. Therefore we support the Commission and Council position not to extend CRF to this hazard class. Alternatively Parliament's proposal could be limited for serious eye damage cat 1 only at extreme pH values ≤ 2 or pH ≥ 11,5.

- *we support the Commission and the Council positions and we not to support the Parliament amendment.*

9. Right to request action from Competent Authorities and Commission (Art 43)

As there is already a public consultation mechanism foreseen in harmonised classification and labelling (CLH), there is no need for parallel processes that might create duplication and confusion. Hence we do not support the amendment from the Parliament in this sense.

- *we do not support the Parliament position calling for a right to request action.*

Annex I

European Commisison	Council	European Parliament
Font sizes Annex I Part I Section 1.2.1.4-Table 1.3 and Section 1.2.1.5		
Not exceeding 3 litres: 8 pt *Greater than 3 litres but not exceeding 50 litres: 12pt* *Greater than 50 litres but not exceeding 500 litres: 16pt* *Greater than 500 litres: 20pt';*	*Not exceeding 3 litres: **1,4 (x-height in millimeters)*** *Greater than 3 litres but not exceeding 50 litres: **1,8 (x-height in mm)*** *Greater than 50 litres but not exceeding 500 litres: **2,0 (x-height in mm)*** *Greater than 500 litres: **2,0 (x-height in mm)***	*Not exceeding 3 litres: **1,4 (x-height in millimeters)*** *Greater than 3 litres but not exceeding 50 litres: **1,8 (x-height in mm)*** *Greater than 50 litres but not exceeding 500 litres: **2,4 (x-height in mm)*** *Greater than 500 litres: **3,0 (x-height in mm)***
The text on the label shall have the following characteristics: (a) the background of the label shall be white; (b) the distance between two lines shall be equal or above 120 % of the font size; (c) a single font shall be used that is easily legible and without serifs; (d) the letter spacing shall be appropriate for the selected font to be comfortably legible. For the labelling of inner packaging where the contents do not exceed 10 ml, the font size may be smaller than indicated in Table 1.3, as long as it remains legible for a person with average eyesight, where itis deemed important to place the most critical hazard statement and where the outer packaging meets the requirements of Article 17.	The text on the label shall have the following characteristics: (a) **printed in black on a white** ~~the~~ background ~~of the label shall be white~~; (b) the distance between two lines shall be **appropriate for the selected** ~~equal or above 120 % of~~ the font size **to be easily legible**; (c) a single font shall be used that is easily legible and without serifs; (d) the letter spacing shall be appropriate for the selected font to be ~~comfortably~~ **easily** legible. For the labelling of inner packaging where the contents do not exceed 10 ml, the font size may be smaller than indicated in Table 1.3, as long as it remains legible ~~for a person with average eyesight~~, where it is deemed important to place the most critical ~~hazard~~ statement, <u>such as hazard statement or EUH statement,</u> and where the outer packaging meets the requirements of Article 17.'	Same as COM and (3a) In Annex I, part I, the following section is added: Section 1.2.1.5.a For multilingual labels, the languages shall be ordered
Grouping Art 37 (2) and Art 37 (1) 3a (new)		
Manufacturers, importers or downstream users of substances may submit to the Agency a proposal for harmonised classification and labelling of those substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, provided that there is no entry in Part 3 of Annex VI for such substances in relation to the hazard class or differentiation covered by that proposal.	Manufacturers, importers or downstream users of substances may submit to the Agency a proposal for harmonised classification and labelling of those substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, provided that there is no entry in Part 3 of Annex VI for such substances in relation to the hazard class or differentiation covered by that proposal.	Manufacturers, importers or downstream users of substances may submit to the Agency a proposal for harmonised classification and labelling of those substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, provided that there is no entry in Part 3 of Annex VI for such substances in relation to the hazard class or differentiation covered by

		that proposal. **In the case of a proposal for harmonised classification and labelling of a group of substances, those substances shall be grouped together based on clear scientific criteria (as specified in REACH Annex XI (1.5)), including structural similarity and similar evidence-based hazard profiles.**
None	None	**Whenever considered scientifically justified and possible by a competent authority or the Commission, proposals for harmonised classification and labelling shall prioritise groups of substances rather than individual substances**
MOCS Art 3 (a) (new)		
'3. A multi-constituent substance containing at least one constituent, in the form of an individual constituent, an identified impurity or an additive for which relevant information referred to in paragraph 1 is available, shall be examined in accordance with the criteria set out in this paragraph, using the available information on those constituents as well as on the substance, unless Annex I lays down a specific provision. /…/	Deleted, with the review clause in 4 years followed by possible legislative proposal	**(4a) in Article 5, the following paragraph is added: "3a. Paragraph 3 shall not apply to substances containing more than one constituent of renewable botanical origin that are not chemically or genetically modified without prejudice to the application of Regulation (EU) No 1107/2009 1a or Regulation (EU) No 528/2012.**
Label updates Art 30 (1) and (2)		
1. In case of a change regarding the classification and labelling of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in accordance with Article 25, the supplier shall ensure that the label is updated within 6 months after the results of the new evaluation referred to in Article 15(4) were obtained.	In case of a change regarding the classification ~~and~~ ***or*** labelling of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in accordance with Article 25, the supplier ***of that substance or that mixture*** shall ensure that the label is updated ***without undue delay and no later than*** ~~within~~ 6 months after the results of the new evaluation	In case of a change regarding the classification and labelling of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in

	referred to in Article 15(4) were obtained ***by, or communicated to, that supplier.***	accordance with Article 25, the supplier shall ensure that the label is updated within 6 months after the results of the new evaluation referred to in Article 15(4) were obtained.
2. Where a change regarding the classification and labelling of a substance or a mixture is required other than that referred to in paragraph 1, the supplier shall ensure that the label is updated within 18 months after the results of the new evaluation referred to in Article 15(4) were obtained.	Where a change regarding the classification ~~and~~ or labelling of a substance or a mixture is required other than that referred to in paragraph 1, the supplier ***of that substance or that mixture*** shall ensure that the label is updated ***without undue delay and no later than*** ~~within~~ 18 months after the results of the new evaluation referred to in Article 15(4) were obtained ***by, or communicated to, that supplier.***	In case of a change regarding the classification and labelling of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in accordance with Article 25, the supplier shall ensure that the label is updated within 6 months after the results of the new evaluation referred to in Article 15(4) were obtained.
Green claims Art 48, after § 2		
None	**None**	**2a. The use of environmental claims as defined in Article 2, point (o), of Directive 2005/29/EC shall be prohibited for substances and mixtures which are classified as hazardous due to their germ cell mutagenic, carcinogenic, toxic to reproduction, endocrine disruption for human health or the environment, persistent, bioaccumulative and toxic (PBT), very persistent, very bioaccumulative (vPvB), persistent, mobile and toxic (PMT), or very persistent, very mobile (vPvM) properties;**
Classification and Labelling Inventory (CLI) Article 41 and 42(1)		

Where the notification in Article 40(1) results in different entries on the inventory referred to in Article 42 for the same substance, the notifiers and registrants shall make every effort to come to an agreed entry to be included in the inventory. The notifiers shall inform the Agency accordingly.	Where the notification in Article 40(1) results in different entries on the inventory referred to in Article 42 for the same substance, the notifiers and registrants shall make every effort to come to an agreed entry to be included in the inventory. The notifiers shall inform the Agency accordingly.	Where the notification in Article 40(1) results in different entries on the inventory referred to in Article 42 for the same substance, the notifiers and registrants shall make every effort to come to an agreed entry to be included in the inventory. The notifiers shall inform the Agency accordingly. **In case where notifiers and registrants cannot come to an agreed entry because of divergences about the level of scientific evidence supporting a classification and labelling of the same substance, the most protective classification shall prevail.**
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***;	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~~***;	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~~***;
Fold-out labels Art 32 (6) and Annex I Section 1.2.1.6		
None	**The front page of the fold-out label shall include at least the following elements:** **i. name, address and phone number of supplier(s);** **ii. nominal quantity of the substance or mixture in the package made available to the general public, unless this quantity is specified elsewhere on the package;** **iii. the product identifiers in accordance with Article 18(2) for substances and Article18(3)(a) for mixtures in all languages of the label that are used in the inside pages;** **iv. where applicable, hazard pictograms;** **v. where applicable, signal words in all languages of the label that are used in the inside pages;** **vi. where applicable, the unique formula identifier, unless printed or affixed on the**	**Where the** label elements referred to in **Article 17(1) are provided by means of a fold-out label, *the front page shall contain at least the information provided in accordance with Article 17(1)(e), (f) and (g) in all official languages of the Member State where the product is put on the market* along with a reference to the additional information provided on the inside page or pages**.

	inner packaging in accordance with point 5.3, Part A in Annex VIII of this Regulation; **vii. a reference to the full safety information inside the fold-out label in all languages of the label or a symbol to inform a user that the label can be opened and to illustrate that additional information is available on inside pages;** **viii. an abbreviation of the language (country code or language code) for all the languages that are used in the inside pages.**	
CRF 1a in Part 3 of Annex II point 3.1.1.1.		
"Packaging of whatever capacity containing a substance or mixture supplied to the general public and classified for acute toxicity, categories 1 to 3, STOT — single exposure category 1, STOT — repeated exposure category 1, skin corrosion category 1, shall be fitted with child-resistant fastenings."	**"**Packaging of whatever capacity containing a substance or mixture supplied to the general public and classified for acute toxicity, categories 1 to 3, STOT — single exposure category 1, STOT — repeated exposure category 1, skin corrosion category 1 shall be fitted with child-resistant fastenings."	**"**Packaging of whatever capacity containing a substance or mixture supplied to the general public and classified for acute toxicity, categories 1 to 3, STOT — single exposure category 1, STOT — repeated exposure category 1, skin corrosion category 1, **or serious eye damage category 1** shall be fitted with child-resistant fastenings."
Right to request action from competent authorities and the Commission (Art 43)		
		Right to request action from competent authorities and the Commission **1. Any natural or legal person, individually or in association, shall be entitled to submit substantiated evidence to competent authorities as referred to in Article 43 or the Commission, such as peer-reviewed studies, human biomonitoring data, or environmental monitoring data, on the**

		hazardous properties of a substance or mixture, or of substances or mixtures, showing that hazardous properties of a substance or mixture or of substances or mixtures may not have been sufficiently considered in the classification or labelling process. **2. The competent authorities or the Commission shall diligently and impartially assess the information submitted in accordance with paragraph 1, adding the evidence submitted to all other available evidence using a weight of evidence approach.** **3. Where the evidence submitted shows non-compliance with one or several of the requirements on the classification, labelling and packaging of substances and mixtures, enforcement measures shall be initiated in accordance with Article 47.** **4. Where the assessment has shown that the substance meets the criteria for classification in any of the hazard classes referred to in Article 36(1), the competent authority or the Commission shall initiate a process of harmonised classification and labelling. Where the assessment has shown a wide dispersive use of and/or consumer exposure to the substance or**

		mixture concerned, the competent authority or the Commission shall initiate a risk management process under Article 59, Article 69, or Article 68(2) of Regulation (EU) No 1907/2006. Where the assessment has shown a lack of information on the risk to health or the environment posed by a hazardous substance or mixture, the competent authority or the Commission shall require companies or any other relevant actor to provide more information, with a view to taking risk management measures under Title VI, VII or VIII of Regulation (EU) 1907/2006, where necessary. **5. Where the evidence submitted should have been included in the registration dossier submitted under Regulation (EU) No 1907/2006 but was omitted by the registrant, the enforcement measure shall be initiated under Article 126 of Regulation (EU) No 1907/2006 against registrants the registration of whom is non-compliant.** **6. The competent authority or the Commission, shall, within 6 months, inform the natural or legal persons referred to in paragraph 1, of its opinion on the evidence and concerns submitted under paragraph 1, and of**

		any steps it plans to take to address those concerns, providing the reasons for both the opinion reached and the steps proposed. **7. Competent authorities and the Commission shall publish an annual report on the requests received and how they have been dealt with.**