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Subject:	Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (CLP Regulation) - Annotations to the revised Presidency Compromise Proposal

Annotations to the Presidency Compromise Proposal

Document **ST 9689/23** includes a compromise proposal covering the entire CLP proposal, in the ordering of the Presidency clustering document.

The content of each sub-cluster is explained further below. Delegations also find below a number of steering questions from the Presidency ahead of the Working Party on 31 May.

Sub-group A1. Labelling obligations/exemptions

See changes or steering questions to Articles 23, 29, 30 and 31, changes in Annex I, and changes in Recital 7

Article 23(g)

As regards the definition of ammunition in Article 23(g), two delegations pointed out that it could be misleading to refer to Article 2(9). The Presidency therefore added a reference to Article 4(8) that regulates explosive articles.

Article 29

Editorial changes.

Article 30

The Presidency received a number of different suggestions for Article 30 on timelines for updating information on labels. After summing up these comments, the Presidency sees a preference for individual timelines for each actor in the supply chain, rather than setting cumulative timelines for the entire supply chain. In light of the summed-up comments, the Presidency also kept the number of months in both Article 30(1) and (2) as they stand. However, for reasons of clarity and symmetry, the wording in Article 30(2) has been aligned with that of Article 30(1) by adding 'by, or communicated to, that supplier'.

The Presidency re-introduced the 'undue delay' from the current CLP's Article 30(1) into both Article 30(1) and (2) in order to strengthen the wording.

Following the suggestion from one delegation, the Presidency also inserted more clear wording about the supplier 'of that substance or that mixture' in both Article 30(1) and (2).

Following questions from two delegations of whether the changes in Article 30(2) include changes in address or telephone number, the Presidency proposes to in both Article 30(1) and (2) change to 'classification or labelling' to cover changes to the label which do not derive from the classification.

As for Article 30(2a), two delegations commented on the requirements not being enforceable or not being sufficient. Two delegations also proposed a timeline for communicating the information. The Presidency proposes to strengthen the wording, but not to introduce another timeline.

Article 31

A number of delegations suggested to clarify the requirements on form and design for fold-out labels. Four of them suggested adding provisions in the legal text, particularly for the front page. In order to address the demands for guidance for fold-out labels, the Presidency will during the Working Party ask if delegations wish to add the following provision in a new section in Annex I:

1.2.1.6. 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;*
- *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;*
- *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.*

The Presidency's proposed wording for this new section is based on current guidance, but only limited to the front page. Compared to current guidance it also clearly includes UFI code on the frontpage, as was also suggested by one delegation.

The Presidency would however like to point out to delegations that the current guidance, and hence our proposed text, includes the signal word in all languages of the label that are used in the inside pages. This might imply a self-regulatory effect on the number of languages used, as signal word may take up space in case of numerous languages.

During the Working Party on 31 May, the Presidency will ask if delegations prefer to:

a) Not introduce requirements for the form and design of fold-out labels, but rather leave this to guidance.

b) Introduce requirements for the form and design of fold-out labels by inserting the proposed new section 1.2.1.6. in Annex I.

Table 1.3 in Section 1.2.1.4. in Annex I

As for the provisions on legibility, a number of delegations expressed support for using x-height in mm instead of pt in Table 1.3. The Presidency therefore proposes to amend Table 1.3 accordingly. The size in mm has mainly been set following the Commission's non-paper on legibility presented in the Working Party, in light of the impact assessment's conclusions about small font sizes and readability. However, compared to the Commission's non-paper, the Presidency proposes to decrease the font size for the largest packages, taking into account three delegations' concerns about costs and effects for the industry. In the Presidency's proposal, the minimum font size for the largest packages has therefore been decreased from 4,0 mm to 2,4 mm – meaning that the minimum font size is the same for the two larger packaging sizes in Table 1.3.

Section 1.2.1.5. in Annex I

Furthermore on legibility, and taking into account the concern from one delegation, the Presidency proposes to make the wording about line spacing in point (b) in Section 1.2.1.5. more flexible. This could also address concerns from other delegations about the size of the area needed for the mandatory label elements.

Section 1.5.2.4.1. in Annex I

Editorial changes in (b), after one delegation pointed out inconsistencies in how the categories within different hazard classes are referred to in the list. The numbering of the list will be aligned in the final stage.

Recital 7

Editorial changes to better reflect the relevant articles (i.e. Article 23(g) and Article 29(4b)).

Sub-group A2. Digital labelling

See changes in Articles 31 and 34, and in Recital 12

Article 31(1a)

In line with the comments from two delegations about the data carrier, the Presidency suggests deleting 'by consumers' to include any user.

Concerning the phrase next to the data carrier of more information being available online, one delegation proposed to add 'safety' and two delegations proposed using EUH-statements. Since the CLP Regulation regards hazard identification, the Presidency proposes to include the word 'hazard' in front of 'information'.

Article 34a(2)

Editorial change.

Article 34b(1)(a)

To clarify that all the labelling information shall be provided in one context, the word 'together' was included after suggestion from one delegation.

Article 34b(1)(c)

Regarding the time period for which the digital information shall be accessible, the Presidency changed it in line with a comment from one delegation that wanted to clarify that it cannot be shorter than 10 years and that the information must remain accessible for a longer time if that is required by other Union legislation.

Article 34b(1)(h)

Editorial changes in light of two delegations' requests for clarifications.

Article 53

As regards digital labelling, four delegations expressed concerns or questions about the empowerments in Article 53.

The Presidency sees a need to frame the empowerment a bit more and is working to find suitable suggestion for Article 53. The Presidency has not included any new changes to Article 53 in this compromise proposal, but will address this by the next Working Party.

Recital 12

Recital 12 has been amended to reflect a comment from one delegation of all suppliers being responsible for labelling requirements. In light of Article 25(3), one delegation also wondered about risks for label elements required in other Union acts being moved to the digital label. The Presidency believes that the revised Article 25(3) addresses these concerns, but clarified the issue further in Recital 12.

Sub-group A3. Refill sales

See changes in Article 2, changes or steering questions to Section 3.4 in Annex II and in Recital 15

Article 2(40)

As for the definition for *refill*, one delegation questioned the word 'container', and the Presidency therefore proposes to change it to 'package' since this is the concept used in the CLP Regulation. One delegation proposed to delete 'which fulfils packaging function' and one delegation proposed to change it to a reference to Title IV. The Presidency proposes to delete it, since this is already a requirement to be fulfilled according to Section 3.4 in Annex II.

One delegation proposed to delete 'in the context of a commercial transaction' since placing on the market also covers free offers. To reflect that the offer can be free of charge, the Presidency suggests changing it to 'in the course of an industrial or professional activity', since this wording is used in Article 4(11) and delimits the provision from applying to consumers.

Article 2(41)

As for the definition for *refill station*, one delegation proposed to delete it and only use the definition of refill from the proposal for the detergents regulation. The Presidency kept the definition of refill stations since specific requirements apply to those, but has included certain wording form the detergents proposal.

The Presidency also followed the suggestion from one delegation to change 'purchased' to 'acquired'.

Section 3.4. in Annex II

In general, the Presidency noted that two delegations requested more detailed provisions or reintroduction of the already deleted points. However, the Presidency still interprets the overall desire from delegations to be less granular provisions, so this has been the Presidency's overall line of reasoning. The Presidency also wants to stay careful not to step outside the scope of CLP.

In *point (a)*, two delegations suggested clarifying the obligation to label the refilled package, but the Presidency proposes to make that clearer in point (j1) instead. The Presidency also followed the suggestion of one delegation to clarify that the station can be provided with several labels.

In *point (b)*, several delegations had concerns related to the reference to Article 31. To accommodate these, the Presidency proposes to add the wording 'horizontally' from Article 31(1), limit the provision to paragraph 2 to 4 in Article 31, and to add that the requirements in Article 31 shall apply 'mutatis mutandis'. The Presidency also made an editorial change following one delegation's request to reflect that several labels can be affixed to the station. One delegation proposed to add a subparagraph entailing that the consumer should get a physical label attached to the package, and here the Presidency again refers to point (j1).

In *point (f1)* on risk mitigation measures, the Presidency has in the light of comments from two delegations changed the wording to 'as far as possible'. To try to accommodate one delegation's suggestion to add environment hazards in point (k), the Presidency has in point (f1) added 'and the environment'.

In *point (g)*, the Presidency has, after suggestions from two delegations, tried to clarify by changing 'routine' to 'maintenance'. The provision would entail that the supplier shall be available to take necessary measures to ensure that obligations within the CLP Regulation related to refill is fulfilled (e.g., that the package is labelled).

In *points (j1) and (j2)*, the Presidency rewrote the provisions to make them clearer, given a few delegations' other comments on Section 3.4.

As regards *point (k)*, the Presidency would like further guidance from the delegations about the list of hazard classes.

In their written comments on the list in (k), some delegations expressed support for including serious eye damage and skin sensitisation. Two delegations were however concerned about the possible inclusion of skin sensitisation, as it may affect refill sales for cleaning products. One delegation cited the same concerns for refill sales of detergents if specific target organ toxicity is included. One delegation expressed more general concerns for the effects of the current list for refill sales of detergents. Taking into account the need to strike a balance between promoting circularity and safety concerns, the Presidency has currently put both *skin sensitisation* and *specific target organ toxicity* in square brackets in its compromise proposal.

One delegation also wanted to include *explosive* and *oxidizing*. The Presidency did not at this stage include any classes suggested by a single delegation and also proposes not to include oxidizing as this would exclude bleach.

One delegation also wanted to include *aquatic toxicity cat 1 and 2*, and one delegation *aquatic acute* and *chronic*. The Presidency proposes not to include them as the list regards direct exposure for users, and other measures should be in place to i.e. avoid leakage. The Presidency also refers to its annotation for point (f1) as regards one comment on environment hazards.

In the very first sentence in (k), the Presidency also changed 'may' to 'shall' at the request of on delegation, and added 'differentiations'. The Presidency also streamlined the names in the list a bit more, but underlines that a general overview of the editorial coherence will be done when the list is stabilised.

During the Working Party on 31 May, the Presidency will ask delegations to signal their preferences for the content of the list in (k) – in particular for skin sensitisation and specific target organ toxicity.

Delegations are also invited to share any data or insights on potential implications of inclusion of certain hazard classes, in order for the Working Party to strike the right balance for the list in point (k).

Recital 15

One delegation proposed to add contamination and exceeding shelf life as examples. The Presidency proposes to add preventing contamination as an example of risk mitigation measures but considers that exceeding shelf life should be covered by the general requirements of the CLP Regulation.

Sub-group A4. Online sales

See changes in Article 48, and in Recitals 1 and 29

Editorial changes and changes to reflect the amended articles, e.g. the derogation for non-visual advertisement.

Sub-group B1. Rules on classification

See changes in Articles 6, 9 and 10

Article 6(3)

Editorial changes.

Article 9(4)

Following comments from three delegations, the Presidency deleted the last sentence, as it is not necessary and clarified in other parts. The Presidency also followed two delegations' suggestion to include a reference to Article 6(5) and changed mixture to plural as two delegations pointed out that multiple mixtures could be used in an interpolation.

Article 10

Editorial changes.

New sub-group B1a. Classification of forms

See changes in Articles 4 and 13

Eleven delegations commented on the Presidency's discussion paper on classification of forms. Six of them only had minor comments and five of them had more substantial suggestions.

In light of the written comments and discussions in the Working Party, the Presidency sees that there is general support for codifying the current practise when it comes to classification of forms of substances. The Presidency is however hesitant to amendments which are more far-reaching and where further analysis of potential implications could be needed, and therefore only proposes a slightly updated version of the text that was already presented in the Working Party.

The Presidency noticed some delegations' questions connected to Title II and harmonised classification. The Presidency has currently not proposed any amendment to this end, but to clarify that both self-classification and harmonised classification are based on the same set of criteria and general principles for classification, the Presidency could possibly propose an addition in Article 37(1) and 37(2). Such an addition could state that a proposal for harmonised classification shall be performed in accordance with relevant parts of Title II, and in addition follow the format set out in Part 2 of Annex VI and contain the relevant information provided for in Part 1 of Annex VI. The Presidency would however want to make sure that this reflects current practice and that there are no concerns for possible implications. During the Working Party, the Presidency will ask for the room's guidance on this matter.

Sub-group B2. MOCS

See changes or steering questions to Article 5(3), and Recitals 2 and 3

The Presidency thanks the delegations that submitted their preferences for the way forward (as presented in document ST 8705/23 and at the Working Party on 2 May).

In their written comments, two delegations favoured option A (deleting the derogation), three delegations favoured option B (explanatory part added to recital 2) and three delegations favoured option C (in Article 5(3) clarify the process and set conditions for the laying down of specific provisions in Annex I). One delegation preferred option A, conditioned that it would be combined with a specific derogation for UVCBs of biological origin. Two delegations were against general exemptions for certain groups of substances (e.g. UVCBs and essential oils) and considered that derogations should be based on a case-by-case scientific assessment.

Based on various input from delegations, the Presidency now proposes a combination of both option B (explanatory part added to recital 2) and C (in Article 5(3) clarify the process and set conditions for the laying down of specific provisions in Annex I).

In addition, Presidency could propose to include a transitional period to delay the date of application for the provisions in Article 5(3). The Presidency is currently looking into if this can be done by, for example, inserting a separate paragraph in Article 2 of the amending Regulation:

in Article 2, the following paragraph 2a is added:

'The provisions in Article 1(4) shall apply from [OP: please insert the date = the first day of the month following [30 or 42] months after the date of entry into force of this Regulation].'

Such a delay would allow more time for industry to adhere to the provisions, and the Commission to develop provisions for derogations in Annex I. The date of application for that provision could, for example, be 30 months or 42 months after the entry into force of the amending regulation. The former would entail that substances and mixtures placed on the market after the entry into force would have to fulfil Article 5(3) earlier than substances and mixtures which were already placed on the market. The latter would entail that all actors would have to fulfil the provisions at the same time.

As for other changes in Article 5(3), the Presidency changed an 'and' to an 'or', after one delegation pointed out that not all properties need to be demonstrated. The Presidency also added 'lack of (rapid) biodegradation' to its previous text in order to reflect two possible outcomes of the assessment of biodegradation: lack of rapid biodegradation or lack of biodegradation (when available data is scarce). Finally, the Presidency made a few consequential amendments to Recital 3.

During the Working Party on 31 May, the Presidency will ask for delegations' input on the described package solution on MOCS (i.e. a combination of both option B and C, possibly together with an extended transitional period) as a way forward.

Sub-group C1. New hazard classes

See changes in Articles 18, 36 and 37, and in Recitals 21 and 23

Article 18(3)

For consistency reasons and after discussions with the Commission, the Presidency has added the new hazard class endocrine disruption for human health in Article 18(3) point (b).

Article 36(1)

Editorial changes in the names of the new hazard classes for consistency.

Article 37(7) and (8)

Editorial changes to the names of the new hazard classes for endocrine disruption in order to align with the delegated act.

The Presidency has at this stage not included any new substantial changes in 37(7)-(8), but would like to highlight some of our takes from the presentation by the Commission at the last Working Party regarding ongoing assessments relating to identification of hazard properties of active substances within other legislations, such as the plant protection products and biocides regulations. The Presidency's previous amendments to prolong the cut-off dates have addressed the concerns of some delegations. However, they also entail that assessments which have been initiated but are not finalised before these cut-off dates will not be transferred to Annex VI of the CLP Regulation. The benefit of a harmonised classification of those substances will therefore not materialise.

The Presidency notes that it is possible to amend Article 37(7) and 37(8) further. By including an open-ended deadline, it would be ensured that all on-going assessments are transferred to Annex VI of the CLP Regulation when finalised. This might however affect the incentives to make the CLP Regulation the central piece of legislation to identify hazard properties of substances and mixtures.

During the Working Party on 31 May, the Presidency welcomes any additional input from delegations on Article 37(7) and (8), to get guidance if delegations wish to insert a more open-ended timeline.

Recitals 21 and 23

Editorial changes to the names of the new hazard classes för endocrine disruption in order to align with the delegated act. The references to recitals have been corrected.

Sub-group C2. Classification and Labelling inventory

See changes in Articles 40 and 42

Article 40(1)

After request from two delegations the Presidency added (g) and (h) in the subparagraph starting with 'The information referred to in (a) to (f)…'.

Article 42(1)

Editorial change to delete '3'. The Presidency also proposes clarifying the provision and deleting the last sentence as it is not necessary. One delegation suggested to include the date of the notification to help keeping the database up to date. The Presidency therefore inserted (d) with the date of the latest update of the classification and labelling.

Sub-group C3. Procedure for harmonized classification

See changes in Article 37 and Recital 19

Article 37(1)

Editorial change for more clarity.

Article 37(2a)

One delegation suggested clarifying that the Commission shall notify the Agency when requesting ECHA or EFSA to prepare a proposal for harmonised classification. The Presidency has the impression that this is the intention of the Commission and therefore suggests revising the text accordingly.

Article 37(3)

One delegation pointed out that the text should reflect the new procedure in Article 54(2). The Presidency therefore changed accordingly in Article 37(3) (as well as in Articles 24(2) and 52(2) in sub-group C4).

Recital 19

Correction of repetition mistake.

Sub-group C4. Other procedures

See changes in Articles 24, 52, 53 and 61

Articles 24(2) and 52(2)

One delegation pointed out that the text should reflect the new procedure in Article 54(2). The Presidency therefore changed accordingly in Articles 24(2) and 52(2) (as well as in Article 37(3) in sub-group C3).

Article 53(2) and 53a

Editorial changes and changes for coherence.

Article 61

Based on comments from delegations, the different references in Article 61(7) have been reviewed. Several articles do not entail any direct obligations that affect substances and mixtures already placed on the market. For these references, a deferred transitional period is therefore not motivated. Based on this, the Presidency proposes to delete references to these articles.

Cluster D. Poison centers

See changes in Articles 1 and 45, and in Part A, B, C and D in Annex VIII

Article 1(1)

The Presidency has included the suggestion by one delegation to specify the reference to Article 45(1b) and (1c).

Article 45

One delegation suggested to strike out the first 'effects' in paragraph 1b, and the Presidency has amended accordingly.

One delegation proposed to delete 'harmonised' when referring to information in Annex VIII, and the Presidency has amended accordingly with exception to the first full reference in paragraph 1.

Following the suggestion by one delegation and to align with paragraph 2, the Presidency has included a reference to paragraph 1 in paragraph 1c.

In paragraph 2 point (b), one delegation proposed to use current wording of the CLP, referencing to 'the Member State' instead of 'a Member State' to ensure that not any Member State within the Union has the possibility to request information for statistical analysis purposes.

In paragraph 3, one delegation proposed to add a reference to paragraph 2 in order to clarify the responsibilities that the appointed bodies have. The Presidency proposes to refer to paragraph 1 as that provision is considered more relevant for specifying the responsibilities of an appointed body.

Points 1.1, 1.2, 1.3, 1.4, and 1.5 in Part A, Annex VIII

A couple of delegations did not consider that distributors should have a retroactive responsibility from 1 January 2021 (point 1.1 and 1.2). One delegation proposed to add a reference to Article 45(1b) to clarify which distributors are responsible. As the amendments aim only to codify current practice, the Presidency proposes no amendments to the dates but to add a reference to Article 45(1b) in points 1.1, 1.2, 1.3, 1.4, and 1.5. The Presidency also deleted 'as changed' in point 1.5, following the suggestion from one delegation.

Section 3.1 in Part B, Annex VIII

Editorial change following the suggestion of one delegation.

Section 1.2 in Part C, Annex VIII

One delegation proposed to include contact information to the importer/distributor/downstream user if they are not the submitter, as some actors use consultants to fulfil this obligation. The Presidency proposes to include a reference to section 2.1 in Part A of Annex VIII, where importers, downstream users and distributors placing mixtures on the market are defined as 'submitters'.

Sections 2 and 3 in Part D, Annex VIII

Technical corrections.