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From:	General Secretariat of the Council
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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) - Presentation and examination of partial compromise proposals from the Presidency - Annotations and steering questions

Delegations will find in the Annex the annotations and questions by the Presidency, which relate to the new Presidency's compromise text of the CLP Revision, as layed out in document ST 8697/23.

The new compromise proposal will be discussed at the Working Party meeting of Technical Harmonisation (Dangerous Substances – Chemicals) on 2 May 2023.

ANNEX

Annotations to the Presidency's Partial Compromise Proposal

Document ST 8697/23 includes a partial compromise proposal covering sub-groups A3 and A4, cluster B, and sub-groups C1 and C3 of the Presidency's clustering document.

The content of each sub-cluster is explained further below.

Sub-group A3. Refill sales

See changes in Articles 2 and 35, in Section 3.4 in Part 3 of Annex II, and in Recital (15)

A considerable number of delegations have highlighted the importance of ensuring that refilled packaging fulfils the labelling and packaging requirements in the CLP Regulation. Some delegations also suggested to include a definition of refill sales, while others asked for clarification regarding what is regulated, or which requirements apply to refill. A few delegations wanted to clarify who is responsible for ensuring that the requirements are fulfilled. A considerable number of delegations highlighted that the requirements are ambiguous or unclear, some pointing out they may be difficult to enforce. One delegation indicated that some requirements in the proposal regarding refill sales might be outside the scope of the CLP Regulation. One delegation asked for a clarification with regard to the difference between sales of substances and mixtures via refill stations and sales via bulk.

In light of this, the Presidency is suggesting a clarified and streamlined approach to the requirements on refill sales based on the following:

For legal clarity, two new definitions of refill and refill station are included in Article 2, inspired by the definitions in the packaging and packaging waste proposal.

In Article 35(2a), a clear exemption is included to clarify that the provision on refill does not apply to hazardous substances or mixtures that are supplied to general public in bulk. The references to Titles III and IV are moved into clearer provisions in the Annex.

In Section 3.4 of Annex II, the chapeau is simplified with a clear reference to the supplier being responsible for ensuring that the requirements are fulfilled.

In letter (a) and (b) of Section 3.4, editorial changes have been made to clarify the requirements, including that additional requirements apply to the labelling of the refill station.

Following the criticism on their granularity and/or ambiguity, letters (c) to (f) and (h) to (i) have been merged into a combined letter (f1) stating that risk mitigation measures need to be applied to ensure that the exposure of humans is avoided or minimized. Elements of the original letters have been moved into recital (15) so that they can form the basis of future guidance on relevant risk mitigation measures. Elements of letter (h) has also been merged into a clarified letter (g) to address a number of practical questions posed by delegations.

Letters (j1) and (j2) clearly state that the refilled packaging shall fulfil the labelling and packaging requirements in the CLP Regulation, as was indicated by earlier references to Titles III and IV in Article 35(2a).

In letter (k), which references the kind of hazardous substances or mixtures that cannot be supplied via refill sales, the Presidency has taken note of considerable requests for including “eye damaging” and “skin sensitizing”. The Presidency did not include any suggestions for additional hazard classes that were only supported by a single delegation.

Sub-group A4. Online sales

See changes in Articles 4, 48 and 48a and in Recitals (1), (29) and (30)

In Article 4, a number of delegations want to introduce an explicit obligation for the actor outside of the Union to appoint a responsible representative, some with references to similar concepts in other Union legislation, while a few delegations consider it unclear how such an actor shall be appointed. The Presidency therefore suggest strengthening the wording in Article 48 to clarify that any actor established outside the Community who wants to place substances and mixtures on the market must ensure that a supplier within the Union has ensured that the requirements in the CLP Regulation are fulfilled. The drafting for this includes reverting to the current paragraph 10 while instead introducing the obligations in a new paragraph 11. Following the request of a delegation to clarify that this is also applicable to online market places, additions have been made in recital (1) and (30), and references to other Union legislation which apply to distance sale, in particular online sales, are included to provide the greater picture (also of relevance in relation to Article 48a).

In Article 48, a number of delegations asked for the deletion of the requirement to indicate the hazard class as they saw little added value and risks for confusion. A few delegations have however asked for supplemental label elements set out in Annex II, among other things pointing out that mixtures which are only labelled pursuant to Article 25(6) do not have to be labelled with pictograms, hazard statements or signal words. The Presidency notes that different terms are used for this information throughout the CLP Regulation, e.g. “statements”, “supplemental hazard statements”, “additional hazard statement”, and “supplemental hazard information”. Since the information in question is in the form of EUH-statements (European Union Hazard Statements), the Presidency proposes to use the wording EUH-statements for clarity about what is sought.

In relation to Article 48, a number of delegations have pointed to the difficulties of fulfilling the requirements for non-visual advertisement, e.g. indicating pictograms in radio commercials. The Presidency proposes to introduce a new paragraph 3 with derogation for non-visual advertisement. Following the request of one delegation, the wording “safety and protection of the human health” is included in recital (29).

In Article 48a, a few delegations have raised the need for clarifications of "clearly indicated". The Presidency has included suggestions on clarifying that the label elements should be indicated visibly and within the offer. Following questions about the interlinkage with the DSA and the GPSR, clarifications have been made in recitals (1) and (30).

Sub-group B1. Rules on classification

See changes in Articles 2, 6, 9(4) and 10(4)

In Article 2(38), two delegations asked for a revision of the proposed definition of ATE since ATEs are not equal to criteria but they are numerical values.

In Article 6, paragraphs 3 and 4, two delegations have requested alignment with the names of the new hazard classes in the delegated act, while another has requested the re-introduction of 'of this Title' after 'chapter 2' for clarification and to be in line with the current text in CLP.

In Article 9(4), a few delegations have expressed scepticism or at least the need for clarification of the text on integrated bridging principles and Weight of evidence. One delegation has pointed to contrasts with text in the GHS for classification of mixtures and that the new provision is in practice limited to the selection of the suitable reference mixture in the case that more than one possible reference mixture is available. Another delegation considers that when using bridging principles, simultaneously with the weight of evidence approach and using expert judgement, it should be clarified that the most protective scenario for the human health and the environment should be considered. As a response, the Presidency has suggested to clarify that, when applying the bridging principles, a weight of evidence determination may be applied to select the most suitable similar tested mixture for decision on classification when more than one similar tested mixture is available.

In Article 10(4), two delegations have expressed concerns that allowing for the setting of a specific concentration limit (SCL) for all substances in Annex VI that do not have an SCL would also allow for the setting of an SCL for substances where RAC consciously decided to not set one. One delegation proposed that the generic concentrations limit should be added in entries on Annex VI when RAC has concluded that it is applicable for a substance and one delegation would like to have clarification if SCL or ATE should be set by the manufacturer, importer or downstream user when SCL or ATE is not given in Part 3 of Annex VI for a substance. To address these concerns, the Presidency proposes to remove the last part of article 10.4, to keep the wording as in the current provision and to ensure that no specific concentration limit is allowed to be set when there is a harmonised classification. The Presidency does not suggest further changes but points to Annex VI, 1.1.2.3 where it is stated '*Where no specific concentration limits are given in this Annex for a certain category, the generic concentration limits given in Annex I must be applied for the classification of substances containing impurities, additives or individual constituents or for mixtures. If harmonised ATE values are missing for acute toxicity the correct value has to be established by using the available data.*'

As part of the discussions on sub-group B1, the Presidency would like to open a discussion on the issue of classifications of certain forms as set out in document WK 5466/2023.

Sub-group B2. MOCS

See changes in Articles 2(7a) and 5(3)

In light of a number of delegations highlighting a definition of 'multi-constituent substance' as unnecessary while a considerable number of other delegations are expressing doubts about its clarity and interplay with the ECHA guidance for identification and naming of substances under REACH and CLP, the Presidency suggest removing the definition in Article 2(7a).

Following the deletion of the definition, the wording 'multi-constituent substance' in Article 5(3) has been replaced with the phrase 'a substance containing more than one constituent'.

A few delegations have expressed questions or concerns with the derogation 'unless Annex I lays down a specific provision' at the end of the first subparagraph of Article 5(3). In order to present a suitable compromise proposal, the Presidency would need guidance from delegations on their preferred way forward.

Given the questions about the derogation, would Member States:

a) want to remove the wording '*unless Annex I lays down a specific provision*' altogether.

b) want to keep the Commission's current non-specific approach, with an explanatory part in recital (2) giving examples of the criteria that could be applied in these specific provisions:

'Specific provisions could be provided into Annex I on the basis of adequate and reliable scientific argumentation. Such derogations would be needed for cases where using data on constituents and calculation rules would result in a less appropriate classification of the complex substances than by using data on the substance itself. This could be the case for example when a complex substance contains only structurally similar constituents or when there is proof of antagonistic effects among constituents. When necessary, an opinion of the Risk Assessment Committee should provide an assessment of the scientific argumentation.'

c) want to clarify the process and set conditions for the laying down of specific provision in Annex I, through an explanatory paragraph mimicking the EP rapporteur's AM19:

'When the criteria set out in this paragraph is not suitable for a certain substance containing more than one constituent, the Commission shall, in light of all relevant information on the concerned substance, use the procedure referred to in Article 53 to amend Annex I to lay down specific provisions.'

Given the multitude of scenarios that might be relevant, the Presidency sees limited room in laying down tailored specific provisions for all scenarios as part of this ordinary legislative procedure.

Sub-group C1. New hazard classes

See changes in Articles 36 and 37

In article 36(1), full stops have been removed after the given section number of each of the listed hazard classes following a request from a delegation.

In Articles 37(7) and (8), two delegations have expressed concerns about ongoing assessments within other legislative acts not being covered by the provisions and propose either to delay the cut-off date or delete the cut-off date. Along the lines of the proposal by one delegation the Presidency suggests delaying the cut-off-date to address those concerns and propose to add a deadline for the Commission to adopt such delegated acts. The Presidency also deleted the phrase 'with derogation' in Article 37(8) since one delegation pointed out that an active substance can be approved as a biocidal active substance without the need for a derogation, if the substances is considered as having endocrine disrupting properties only with regards to the environment.

Sub-group C3. Procedure for harmonised classification

See changes in Article 37

In Article 37(2a), two delegations suggested to add 'the proposed classification' to the information required in a Registry of intention which reflects the current practice today.

In Article 37(5), one delegation noticed that a statement in the current CLP text was missing and considered this text important to reintroduce.