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From:	Commission services
To:	Antici Group (Simplification)
Subject:	Discussion paper – Drafting suggestions on provisions on labelling of 10ml packages

Disclaimer: this document aims to support the technical discussion on the Proposal for a Regulation amending Regulations (EC) No 1272/2008, (EC) No 1223/2009 and (EU) 2019/1009 as regards simplification of certain requirements and procedures for chemical products (COM(2025)531).
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PROVISIONS ON LABELLING OF 10 ML PACKAGES

This paper aims at clarifying the labelling rules for hazardous substances or mixtures supplied in packaging of less than 10 ml. It provides an overview of the current rules, the changes introduced by Regulation (EU) 2024/2865 (section 1), some resulting inconsistencies (section 2) and the additional changes proposed in the Chemical Omnibus (section 3).
In addition, the paper draws a comparison between those labelling rules and those on Child-Resistant Fastening and Tactile Warning, following a question by a MS during the last AGS meeting (Appendix I).

1. Provisions introduced by Regulation (EU) 2024/2865

Regulation (EU) 2024/2865 (Revision) broadened an existing derogation from labelling requirements for packages with content not exceeding 10 ml laid down in Regulation (EC) No 1272/2008 (CLP Regulation).
In particular, for such packages, new section 1.5.2.4.1 of Annex I allowed to:

- **Omit label elements** for the R&D substances and mixtures, **provided that the inner packaging is contained within the outer packaging that has all labelling information** in accordance with Article 17 (point (a) of section 1.5.2.4.1) – no change in content compared to the derogation in CLP Regulation before the revision.
- **Omit label elements** for substances or mixtures that **do not require any EUH statements** and **are not classified** in any of the hazard classes laid down in the list (point (b) of section 1.5.2.4.1). **The provision does not require outer packaging.**[1]
- **Omit label elements** for substances and mixtures that **are not classified** in any of the hazard classes laid down in the previous point but **do require EUH statements, provided that the inner packaging is contained within the outer packaging that has all labelling information** in accordance with Article 17 (point (c) of section 1.5.2.4.1).

Points (a) and (c) thus made a derogation conditional to the presence of an outer packaging bearing all labelling information requested in Article 17.
Point (b) does not request an outer packaging – provided that the substance or mixture in question **does not require any EUH statements and is not classified in the following hazards**:

- acute toxicity, any category;

[1] This is an extension which was part of the impact assessment developed for the revision of CLP. See Impact Assessment, description of policy option 2c, e.g. in table 17, section 8.1, page 50, SWD(2022) 435 final

- specific target organ toxicity – single exposure, categories 1 and 2;
- specific target organ toxicity – repeated exposure, any category;
- skin corrosion, category 1, any sub-category;
- serious eye damage, category 1;
- respiratory sensitisation, any category;
- aspiration hazard;
- germ cell mutagenicity, any category;
- carcinogenicity, any category;
- reproductive toxicity, any category;
- endocrine disruption for human health, any category;

The co-legislators did not include skin sensitisation on this list. The inclusion, however, was subject to political discussions and was analysed during negotiations. It was concluded that the addition of skin sensitisation (and other milder hazards that were subject to discussion) would undermine the purpose of 10 ml derogation as it would eliminate from its scope a number of products for which this derogation was designed.

Therefore, in accordance with the provisions of the Revision, substances and mixtures in packaging with content less than 10 ml that are classified as skin sensitisers (but are not classified in any other hazards that are listed above and do not need EUH statement) **can profit from the derogation laid down in point (b) of section 1.5.2.4.1,** and hence label elements from the packaging can be omitted accordingly.

2. Resulting inconsistencies in Section 1.5.2.4.2 of Annex I to CLP Regulation

The Revision did not take into account existing section 1.5.2.4.2 of Annex I to CLP Regulation. This section lays down certain exceptions from the derogation provisions in sections 1.5.1.2 and 1.5.2.4.1.

Section 1.5.1.2 requests hazard pictograms, the product identifier and contact details of the supplier on the label of the inner packaging, whereas section 1.5.2.4.2 (as a derogation from section 1.5.1.2) only requests product identifier and certain hazard pictograms, without any indications when this derogation should apply and which requirement should prevail. At the same time, as explained above, point (b) of section 1.5.2.4.1 allowed the omission of all labelling elements from the (inner) packaging, while section 1.5.2.4.2 requests product identifier and certain hazard pictograms on the label of the inner packaging.

3. Omnibus VI proposed clarification and fixing patches on 10 ml packages

The provisions proposed by the Omnibus VI with regard to 10 ml packaging build on the provisions introduced by the Revision, and aim at clarifying these provisions from one hand and removing identified legal contradictions from another hand.

a. Clarifications

For the sake of legal clarity, the Omnibus restructures the text as follows:

- groups the provisions that allow the omission of labelling requirements from the inner packaging provided that the outer packaging has a full labelling (as per points (a) and (c) of section 1.5.2.4.1 introduced by the Revision) into **point (a) and (b) of section 1.5.2.4.1**;
- moves the provision allowing the omission of labelling requirements without the need to have an outer packaging (as per point (b) of section 1.5.2.4.1 introduced by the Revision) **to a new section 1.5.2.4.3** in order to clearly distinguish cases where outer packaging is not required, thus providing more legal clarity to economic operators and enforcement authorities;

The scope of the hazard classes that are allowed for derogations remains the same as introduced by the Revision. So does the obligation remain to label the outer packaging of a pack of containers of less than 10 ml, where the volume of the content of the pack is more than 10 ml.

b. Fixing patches

In order to remove contradictory provisions, the Omnibus also:

- modifies section 1.5.2.4.2 by removing the reference to section 1.5.1.2 (as section 1.5.1.2 requires a broader list of label elements to be indicated on the inner packaging which was not supposed to be further narrowed).
- removes the inconsistency with the possibility to omit labelling, as the requirements of point (b) of section 1.5.2.4.1 were moved to a new section 1.5.2.4.3.
- includes reference to section 2.8 of Annex II (EUH208 statement) in sections 1.5.2.4.1 and 1.5.2.4.3, thus allowing substances and mixtures that require EUH208 (but **are not classified** under any hazards that are listed in point (b) of section 1.5.2.4.1) to profit from the labelling derogation laid down in **section 1.5.2.4.3**;

EUH208 statement is required by section 2.8 of Part 2 of Annex II when the mixture **is not classified as sensitising** but contains a sensitising substance in a certain concentration (which is lower than the concentration leading to the classification).

As mentioned previously, in accordance with point (b) of section 1.5.2.4.1 introduced by the Revision, mixtures in packaging with content less than 10 ml **that are classified as skin sensitisers** can profit from the derogation, and hence label elements from the packaging can be omitted accordingly.

At the same time, in accordance with point (c) of section 1.5.2.4.1 introduced by the Revision, mixtures in packaging with content less than 10 ml that are **NOT classified as skin sensitisers**, **but contain a sensitising substance** (in concentration lower than of what is required for classification of the mixture) **cannot profit from the derogation**, and would require the outer packaging with full labelling.

The provisions of the Omnibus VI are thus **seeking to correct that inconsistency without, however, changing the scope of hazard classes** not eligible for derogation, as agreed by co-legislators in the Revision.

Appendix I: Child-resistant fastenings, tactile warnings and labelling derogations

Part 3 of Annex II of CLP Regulation require **substances and mixtures supplied to general public**, which are classified in certain hazard classes (regardless of the capacities of the packages) to be fitted with child-resistant fastenings (CRF) and/or tactile warnings (TW).

The CRFs are required for the following hazards:

- acute toxicity, categories 1-3;
- specific target organ toxicity – single exposure, category 1;
- specific target organ toxicity – repeated exposure, category 1;
- skin corrosion, category 1;
- aspiration hazard (except for aerosols).

Specific provisions on CRF laid down for methanol in concentrations equal or more than 3% (classified, among other hazards, in **acute toxicity, category 4**) and dichloromethane in concentrations equal or more than 1% (classified as carcinogen, **category 2**).

All of the abovementioned hazards are also among the hazards mentioned in point (b) of section 1.5.2.4.1 with regard to 10 ml derogations. **Thus, the substances and mixtures that require CRF cannot profit from 10 ml derogations.**

Substances and mixtures falling under point (a) of section 1.5.2.4.1 can however be classified in any hazard classes, including the ones requiring CRF and TW. However, as point (a) grants a derogation only in cases where "substance or mixture is placed on the market **for supply to a distributor or downstream user for scientific research and development or quality control analysis**", these substances and mixtures **do not fulfil a requirement of "supply to general public"** and thus do not require CRF or TW.

The tactile warning is required for the following hazards:

- acute toxicity;
- skin corrosion;
- germ cell mutagenicity, category 2;
- carcinogenicity, category 2;
- reproductive toxicity, category 2;
- respiratory sensitisation;
- specific target organ toxicity, categories 1 or 2;
- aspiration hazard (except for aerosols);
- flammable gases;
- flammable liquids, categories 1 or 2;
- flammable solids;

Out of all these hazard classes only **flammable gases, liquids and solids are not covered by the list laid down by point (b) of section 1.5.2.4.1** with regard to 10 ml derogations. It is therefore possible for substances or mixtures classified as flammables, to derogate from labelling requirements if their content does not exceed 10 ml. However, in this case, **they would still have to bear a tactile warning in accordance with the requirements of Part 3 of Annex II** if they are supplied to the general public.