

Our position

Input into the Guidance on the Revision of the Classification, Labelling and Packaging Regulation

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €3 trillion in 2019, directly supports more than 4.8 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

Executive summary

In view of the draft Guidance for the revised Regulation for the Classification, Labelling and Packaging (CLP), the following insights and recommendations aim to help make the implementation of the CLP a success for business, the environment, and human health:

- The increase in font size and line spacing poses several challenges both for business and the environment, due to larger labels, increased use of materials for fold out labels, as well as more waste in the process due to label updates.
- More flexibility in the application of the formatting rules will be needed, and further guidance on how information is displayed, and/or if certain information can be omitted.
- Better use of digital labelling options may also need to be considered in the fold-out label, among others.
- A more detailed and clearer breakdown specifying the transitional periods applicable to each provision would be welcome.
- Clarification of the advertising provisions and adapting the rules to the evolving advertising landscape is recommended.

Introduction

The Revision of the Classification, Labelling and Packaging (CLP) Regulation, proposed by the Commission on 19 December 2022 and agreed on 5 December 2023, following the interinstitutional negotiations, aims at ensuring a well-functioning single market for chemicals and a high level of protection for human health and the environment. The goal of the Revision was to ensure that more information about chemical hazards is identified and communicated, whilst modifying and simplifying certain labelling obligations.

In view of the upcoming Guidance on the CLP, this paper aims to provide constructive feedback and recommendations specifically related to Labelling and Advertising. This paper will focus on the impact that the font size and line spacing increase will have on businesses, including packaging sustainability choices, while also providing potential solutions to mitigate these challenges. It also addresses the updated CLP advertising provisions, and the limited detail provided in the regulation, for which further clarification is needed, taking account of the ever-evolving advertising landscape.

1. Labelling

a) Challenges in implementing font size increase

Key impacts of the font size increase

The increment in font size will require some of our members to transition from Plant Printed (in-house) to Pre-Printed (third-party provider) labels, leading to the following consequences:

- **Additional complexity in operations:** Increased font size will lead to the use of fold-out labels, where not previously used, to fit all the information in more than one language. Ensuring the right label is used on the right packaging is complex, what is automatized today, would now need to be checked manually, placing an extra burden on the Labelling and Packaging team in production and blending plants. This will also add complexity into production planning due to the different sizes of packaging units.
- **Sustainability issues:**
 - Increased carbon footprint: more deliveries with smaller quantities of labels will be needed instead of less frequent larger deliveries with generic labels. Currently, one generic label which is plant printed (in-house) can be used for hundreds of catalogue references (SKU). This means the plants order this reference in very large quantities in big reels because it is broadly used along a catalogue. By moving to fold out labels, there will be a need to have a different label for each of the references, so deliveries and the number of label reels ordered will multiply.
 - Increase in material use: with more pages needed, more material will be used (not single-page labels as before, but fold-out ones). As described above, using unique pre-printed labels for each article, rather than blank generic labels for in-house printing, will increase material used, and therefore increase the number of unused and/or redundant labels. Not only this, but these new labels are not recyclable as they are printed on a specific plastic material. This will dramatically increase the amount of labels going to waste.
- **Slowed down process of the label update:** It can **take up to three months** to obtain new labels from the third-party provider, due to the lag in order and print time. Changes to labels due to CLP are frequent and this additional step in the process would significantly **slow down the process of the update** for all new CLP requirements in the future.

- **Increased inventory management and costs** stem from the necessity to maintain surplus product inventory due to minimum production quantity requirements, which are associated with minimum blending quantities. Consequently, **overproduction** becomes necessary to meet the demands of diverse markets or clusters, particularly when accommodating various languages on labels, with the new requirement of enlarged font sizes preventing producers from fitting all the information on a single label. This reliance on external agencies significantly **amplifies costs** compared to in-house plant-printed labels, including notable increases in labour costs, transportation expenses, and the need for printing new labels.

Increased font size leads to increased packaging

Moreover, in considering how to implement the CLP font size changes, several cases demonstrated the practical impossibility of doing so without enlarging the packaging dimensions. Many of our members' products (eg detergents) are below 1 litre and vary in shape, making it impossible to fit the larger font size text and their current labels. The new line spacing requirements exacerbate this challenge, as does the failure to take into account all other text requirements on the packaging:

- Products being subject to multiple regulations that impact the label, such as the Detergents and Biocidal Product Regulations. (Future legislation such as the Packaging and Packaging Waste Regulation (PPWR), Green Claims Directive, extended fragrance allergen requirements and the Digital Product Passport QR code will compound this issue)
- Countries requiring 2 or 3 national languages on the pack, such as Belgium, Finland, and Malta.
- Countries that require additional local market compliance text such as Bulgaria (identification of all packaging materials), France (mandatory disposable charters), Greece (name of the manufacturing plant), Italy and Spain (recycling instructions).

Fold-out labels:

While a potential suggestion from the Commission was to use fold-out labels (FOL) in such cases, our members' trials show they will not resolve the issue. Even though FOL can help, they are not suitable for all products due to their shape and small size. They often fall off and, in many cases, even the extra pages are not enough to contain all the text requirements linked to additional EU legislation and country requirements. Moreover fold-out labels lead to the following negative consequences.

1) Environmental impact: FOL come with an environmental cost. The legislation stipulates the FOL must not rip and must stay intact - necessitating the use of plastic. This is a backward step for some of our members. For instance, some of our members made significant progress in reducing the environmental impact of their packaging either by making the size smaller or in some cases, switching from plastic blister packs to paper. Overall, they are trying to reduce the use of plastic. Now to make the labels stick, they will be forced to use strong adhesive glue and to increase the weight of plastic labels (by introducing more pages); both of which contradict the strict recycling targets of 70% and 80% and packaging minimization of the PPWR. **The ultimate risk is to be forced to increase the size of the packaging in order to accommodate all the extra text.**

2) Higher cost

The use of FOL drives higher costs than standard, single-layer labels, due to the following factors:

- **Label Cost:** Multi-layer labels generally cost 3-5x standard labels.
- **Application of the Label:** The manufacturing process is more complex with multi-layer labels, as previously mentioned. Often the line must be slowed to permit the inclusion of the label, increasing production costs. In some cases, labels must be manually applied.
- **Scrap and disposal:** Increased disposal costs due to scraps generated during manufacturing plus the cost of glue and additional plastic pages (also an environmental burden).
- **Extended Producer Responsibility (EPR) fees:** Increased number and size of labels will have an impact on EPR fees and result in even higher penalties due to lower recyclability.

3) Significant time challenges

A major concern is our members' ability to meet the timing within the two-year framework of the legislation. They will require several months to review their entire portfolio and identify new technologies to deal with the changes, as already mentioned, both in the case of in-house and third party printing. They will likely need to modify their production lines – a minimum of 12 to 16 months for substantial line changes. Plus 2 more months for trialing the solution. Implementation of the solution typically takes at least 6 months from the design freeze.

Proposed solutions

- More flexible rules for labels on industrial sites for bigger packaging ≥ 50 L. If fold-out labels are used for packages stored at height, the worker will not be able to see the information properly.
- More flexibility on the new spacing rules and font for all packs. For bigger packaging ≥ 50 L, if the information is visible and easy to read the increased line spacing and font will not provide any added value. The way a person approaches a label for a 20L pack, 208L or 1000L is similar. The person gets closer to the pack instead of bringing the pack closer to them. In a similar way, the increased line spacing for smaller packs, even those $\leq 0,5$ L are only adding to the challenge to fit all the information on the pack and FOL will only mitigate and not solve the challenges for these types of packs.
- More flexibility on the use of digital labels and/or the DPP which is already under consideration for Detergents.
- Exemption on the font size increase for small packaging when it can be demonstrated that even a single language label or a FOL cannot contain all the information.
- More flexibility on how information is displayed on fold-out labels (original ECHA guidance applied, when there was more flexibility on font size and line spacing. New rules should take this into consideration), as it is clear the current rules will need to be updated to accommodate the new font size and line spacing requirements, and what goes on the front and back page of the FOL.
- Consider another 6 to 12 months for implementation.

b) Issues to be clarified

In addition, the future CLP Guidance should include the following aspects:

- A more detailed and clearer breakdown specifying the transitional periods applicable to each provision.
- Confirmation that the provision “the distance between two lines shall be equal or above 120 % of the font size” refers to the concept of the distance between the base lines of two adjacent/subsequent lines, i.e. “leading” in typography terms – number 6 on Annex 1.8.

2. Advertising

- a) Feedback on how to adapt CLP rules to all Advertising, including digital advertising.

A lot has changed in the world of advertising, with many people now consuming content online, in a variety of digital formats, and not via traditional paid media i.e., TV and radio ads, or even billboards. As such, any new rules on advertising, whether it be for CLP or other areas, need to take the new media landscape into account.

A plethora of new digital formats exist, besides the traditional ones (such as Connected TV, Newspaper/mags, Radio, among others), companies are using digital much more than traditional channels such as small/short Social Media ads, Podcast, Digital adverts that redirect shoppers to a landing page, and Programmatic (eg YouTube, digital displays – incl small banner ads) among others. Therefore, given the digital evolution of advertising, and the plethora of media formats has the Commission considered the following aspects?

- **Limitations or exclusions in terms of both length and size of the ad?** i.e 3/6 seconds adverts; tiny banner ads)
- Confusion due to the addition of even more information on (often) small screens. Is there any concern that displaying all this information will **confuse rather than inform the consumer?**
- Has the commission considered adapting this requirement in line with OTC medication? i.e., a warning sentence and mention of the active driving the classification: ***'always read and follow the information on the product label'*** and ***'contains X'***. (see Annex 2.1)
- Does it only apply to ads that can lead to the conclusion of a 'purchase contract'? i.e., in store and online retail? If not, and it applies to all formats, does the commission plan to provide a list of formats?
- Are certain advertising formats included/excluded?

Proposed solution:

Our suggestion would be to consider how the pharmaceutical industry displays warnings: Pharma, another highly regulated sector, has strict rules when it comes to advertising, even for over the counter (OTC) medications. Advertising regulations for OTC across Europe can vary depending on the country. However, there are general principles that are commonly observed:

1. the ads should clearly include ***'Always read the label'*** or text along these lines

2. the name of the *active ingredient*
3. *'consult with your pharmacist'*.

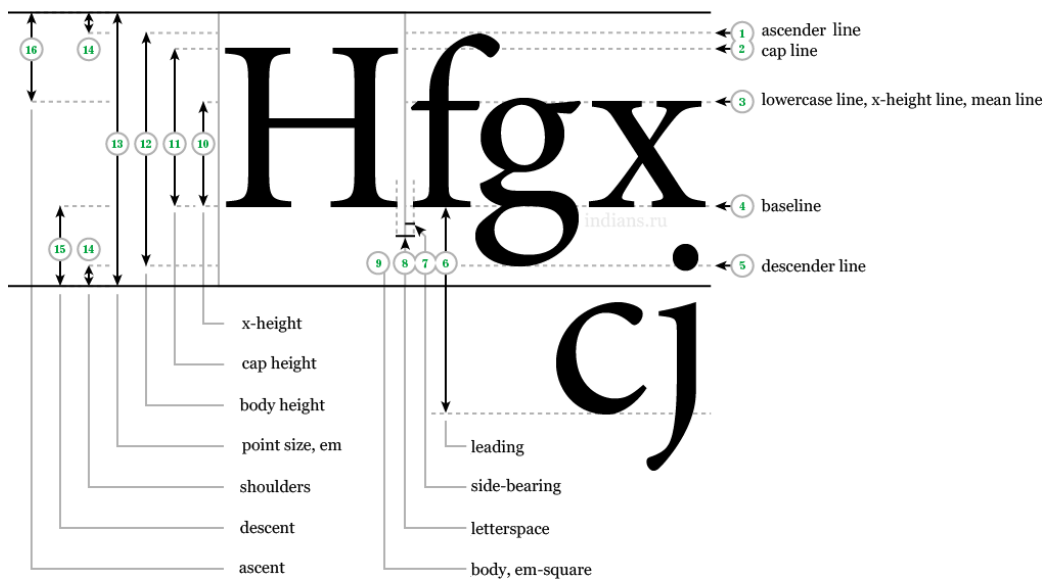
Therefore, we would suggest the CLP to take a similar approach (Annex 2.1)

Conclusion

In order to support the upcoming guidance on the CLP, the paper has provided insights, concrete examples and recommendations to mitigate the potential challenges resulting in the increase in font size as well as to make new CLP rules on advertising more adaptable. To ensure the successful implementation of the CLP Regulation, it is crucial to utilise the constructive contributions of stakeholders and to promote continuous collaboration.

Annex 1: Font size and labels

Font's measurement units



Annex 2: Advertising

1. Example of how the pharmaceutical industry displays warnings

ALLEVIA: OTC ANTIHISTAMINE

2. Label Elements – to be indicated in ads

Label Elements – to be indicated in ads

Signal words

- the relevant signal word in accordance with the classification of the hazardous mixture. **'Danger'** and **'Warning'** to indicate the severity of a hazard

Hazard Statements

- labels must also bear the relevant **hazard statements** describing the nature and severity of the hazards of the mixture.
- Annex III to CLP lists the correct wording of the hazard statements as they must appear on the labels.
- The hazard statements of one language must be grouped together with the precautionary statements of the same language on the label

EUH statements

- There are special rules that concern the labelling of certain mixtures with particular properties. The specific hazards are indicated using the supplemental **EUH statements** outlined in Annex II to the CLP Regulation.

