

## 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 €3.7 trillion in 2022, directly supports more than 4.9 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In view of the draft Guidance for the revised Regulation for the Classification, Labelling and Packaging (CLP), the following insights and recommendations aim to help make the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 (FOL), 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 FOL, 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 Revision's goal 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.

## Labelling

### Challenges in implementing font size increases

#### Key impacts of the font size increase

The incremental increase in font size will require some AmCham EU 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 FOL 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 automatised today would 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.

- **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 that is plant printed (in house) can be used for hundreds of catalogue references. 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 FOL, they will need 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 FOL). 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. Furthermore, these new labels are not recyclable as they are printed on a specific plastic material. This will dramatically increase the number of labels going to waste.
- **Slowed-down label update process:** 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 to update all new CLP requirements in the future.
- **Increased inventory management and costs:** These 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 increases 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 demonstrate the practical impossibility of doing so without enlarging the packaging dimensions. Many AmCham EU members' products (eg detergents) are below one 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 subject to multiple regulations that impact the label, such as the Detergents and Biocidal Product Regulations. In addition, future legislation such as the Packaging and Packaging Waste Regulation (PPWR), Green Claims Directive, extended fragrance allergen requirements and the Digital Product Passport (DPP) QR code will compound this issue.
- Countries that require two or three 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 (FOL)

While a potential suggestion from the Commission was to use FOL in such cases, AmCham EU members' trials show these labels 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 FOL lead to the following negative consequences:

- **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 AmCham EU members. Some companies 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. To make the labels stick, they would be forced to use strong adhesive glue and increase the weight of plastic labels by introducing more pages, both of which contradict the strict 70% and 80% recycling targets and packaging minimisation set out in the PPWR. The ultimate risk is to be forced to increase the size of the packaging in order to accommodate all the extra text.
- **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 three to five times more than standard labels.
  - **Label application:** 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:** There are increased disposal costs due to scraps generated during manufacturing plus the cost of glue and additional plastic pages. These are 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.
- **Significant time challenges:** A major concern is AmCham EU 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 two more months for trialling the solution. Implementation of the solution typically takes at least six months from the design freeze.

## Proposed solutions

- More flexible rules for labels on industrial sites for packaging larger than 50 L. If FOL 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 packaging larger than 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 20 L pack, 208 L or 1000

L 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 smaller than 0.5 L are only adding to the challenge to fit all the information on the pack. 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 FOL. The original European Chemicals Agency guidance – which had more flexibility on font size and line spacing – should be applied. 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.
- Another six to 12 months for implementation.

## 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, ie ‘leading’ in typography terms – number 6 on Annex 1.8.

## Advertising

### 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 instead of via traditional paid media, ie TV and radio ads and billboards. As such, any new rules on advertising, whether it be for CLP or other areas, need to take into account the new media landscape.

Companies are using digital formats (such as small and short social media ads, podcasts, digital adverts that redirect shoppers to a landing page and programmatic ads like YouTube and digital displays, including small banner ads) more than traditional channels (such as connected television, newspapers, magazines and radio). Given the digital evolution of advertising and the plethora of media formats, the Commission should consider the following:

- Limitations or exclusions in terms of both length and size of the ad, ie 3/6 seconds adverts and tiny banner ads;
- Confusion due to the addition of even more information on often small screens. Is there concern that displaying all this information will confuse rather than inform the consumer?

- Has the Commission considered adapting this requirement to be in line with over-the-counter (OTC) medication? This could include a warning sentence and mention of the active ingredients driving the classification such as: ‘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’, ie in store and online retail? If not, and if it applies to all formats, does the Commission plan to provide a list of formats?
- Are certain advertising formats included/excluded?

## Proposed solution

The Commission should consider how the pharmaceutical industry displays warnings. The pharmaceutical industry, another highly regulated sector, has strict rules when it comes to advertising, even for OTC medications. Advertising regulations for OTC vary across Europe. However, general principles are commonly observed:

- The ads should clearly include ‘Always read the label’ or text along these lines;
- The name of the active ingredient; and
- ‘Consult with your pharmacist’.

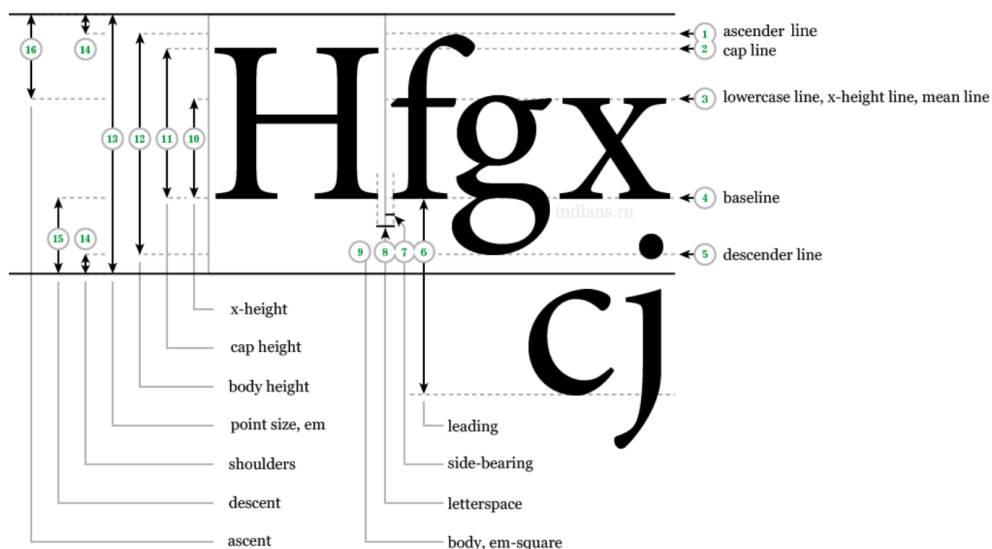
Therefore, the CLP should take a similar approach (Annex 2.1).

## Conclusion

In order to support the upcoming guidance on the CLP, this paper has provided insights, concrete examples and recommendations to mitigate the potential challenges resulting from 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 promote continuous collaboration.

## Annex 1: Font size and labels

Font’s measurement units



## Annex 2: Advertising

Example of how the pharmaceutical industry displays warnings.

### ALLEVIA: OTC ANTIHISTAMINE

The advertisement for Allevia OTC Antihistamine includes the following elements:

- Text: "TARGETS YOUR ALLERGY"
- Text: "Contains fexofenadine"
- Text: "Always read the label"
- Image: A silhouette of a head with a brain, and a small image of the Allevia product box.

Labels identifying the highlighted text:

- Active ingredient (points to "Contains fexofenadine")
- Warning sentence (points to "Always read the label")

## Annex 3: 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.

