Brussels, 26/11/2021

Ad-hoc **CA/11/2021**

**Ad-hoc Meeting of the CAs for the REACH and CLP Regulations (CARACAL) on**

**CLP Revision**

 **6 December 2021 09:30 – 17:00**

**Webex meeting**

**Concerns: CLP revision: Labelling**

**Agenda Point: 4**

**Action Requested: Competent Authorities and observers are invited to comment on the document and the discussion points put forward. Written comments should be sent by 10 January 2022 to:****GROW-CARACAL@ec.europa.eu**
**ENV-CARACAL@ec.europa.eu**

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**CLP revision: Labelling**

# Introduction

This document serves as a basis for discussing labelling issues related to the CLP revision at the upcoming ad-hoc CARACAL meeting on 6 December 2021.

Several findings of the 2019 Fitness check on chemicals (SWD(2019) 199 final/2) identified that the current hazard communication and labelling provisions could be further improved:

*“The communication of hazards to consumers via pictograms and labels can also be improved e.g. labels overloaded with information and difficult to read with some duplication of certain information due to overlaps in legal requirements or because of the need to include hazard statements in all EU languages”.*

Two different studies have been launched in this area during 2021, namely the CLP revision impact assessment study[[1]](#footnote-2) (“CLP impact assessment”, see topics 1. to 3.) as well as the study on the simplification and digitalisation of labels on chemicals (“Digitalisation study”, see topic 4.). Both studies are operating on a similar timeline and are supposed to provide relevant findings and potential solutions to the problems related to labelling.

The following topics are covered in this paper:

* Labelling of small items
* Labelling of chemicals supplied to consumers without packaging
* Format of the label (e.g. multilingual labels, font size, contrast)
* Digitalisation

CARACAL members and observers are invited to provide their views on the questions outlined under heading 5. and to send their comments by the DDL which will be communicated during the meeting.

# CLP labelling of small items

The appropriate labelling of small items is one of the frequently raised questions in enforcement of the labelling provisions in CLP. The [inception impact assessment](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12975-Revision-of-EU-legislation-on-hazard-classification-labelling-and-packaging-of-chemicals_en) of the CLP revision provides that the Commission will assess the impacts of introducing additional tailored labelling rules for situations where there is not enough space on the packaging to comply with all existing labelling requirements. [The public consultation of the CLP revision](https://ec.europa.eu/eusurvey/runner/TargetedCLPRevision2021?surveylanguage=en) contains specific questions (e.g. CLP labelling of pens Q8).

As digitalisation of certain labelling information is one of the possible solutions, this topic is linked to heading 4..

The Commission tasked the contractor to look into this issue in the CLP impact assessment and to analyse different options to address the practical difficulties for duty holders to comply with the current obligations and for authorities to enforce them. At the same time, the contractor for the Digitalisation assesses policy options and their impacts for providing certain labelling information digitally.

CARACAL discussed CLP labelling of certain small items on several occasions (*e.g.* on writing instruments or lighters) and concluded that as CLP currently stands, those items are substances or mixtures in a container to which CLP labelling applies and to which currently no derogation applies (*e.g.* a derogation from labelling requirements for special cases under Section 1.3. of Annex I to CLP)[[2]](#footnote-3). Hence, the applicable legal provisions under CLP in this regard are Article 29(1) and (2), read in combination with sections 1.5.1. and 1.5.2. of Annex I to CLP. ECHA Helpnet endorsed a decision tree to facilitate the application of Article 29(1) and (2), read in combination with sections 1.5.1. and 1.5.2. of Annex I to CLP (see annex to this document).

One comment of the public consultation to the CLP revision regarded CLP labelling for articles that contain explosive substances or mixtures (such as ammunition) used by the defence sector. The matter requires further examination.

It has been argued that current labelling exemptions under CLP do not provide practical solutions for an effective labelling hazard communication for certain small items. To what extent the current exemptions are not fit for purpose will need to be assessed.

# CLP labelling of chemicals supplied to consumers without packaging/ re-fill sales

At a number of occasions CARACAL discussed on the best means to provide hazard communication for substances, mixtures and articles supplied in bulk or in refill systems (see below). In principle certain bulk/re-fill chemicals sales are valued for their reduced environmental footprint (*e.g.* less packaging) and are promoted in the context of some EU policies. On the other hand, they should comply with the human health and environmental objectives of CLP.

[The public consultation of the CLP revision](https://ec.europa.eu/eusurvey/runner/TargetedCLPRevision2021?surveylanguage=en) contains a specific question on CLP labelling of substances/mixtures supplied in bulk (Q7).

It should be kept in mind that this issue concerns supplies to consumers only, since supplies of chemicals between professionals, including for unpackaged chemicals, are covered by REACH (see recital (49) of CLP[[3]](#footnote-4)). For assessing the different policy options, it is necessary to differentiate between the following situations:

1. Chemicals supplied to consumers without packaging (*e.g.* fuels at filling stations pumped directly into the fuel tank of a vehicle) for which CLP labelling on the recipient vessel is highly impractical and of little added value because it is likely that consumers are sufficiently familiar with the hazards or unlikely to have noteworthy exposure;
2. Re-fill chemicals that could be filled in re-usable packaging for which CLP labelling is in principle possible and desirable because of their hazardous properties.

## Chemicals supplied to consumers without packaging (*e.g.* fuels)

Recital (49) of CLP provides that chemicals supplied to the general public should normally be packaged. Unpackaged chemicals can be supplied to the general public "in exceptional circumstances". CLP consequently addresses this scenario specifically in Article 29.

Article 29(3) of CLP foresees that “when a hazardous substance or mixture referred to in Part 5 of Annex II is supplied to the general public without packaging it shall be accompanied by a copy of the label elements in accordance with Article 17”. However, Part 5 of Annex II currently contains only one item: “ready mixed cement and concrete in the wet state”.

To provide legal clarity, it is necessary to understand weather more substances should be included in Part 5 of Annex II or whether the legal provisions need to be amended.

An example of chemicals supplied to consumers without packaging are fuels. CARACAL discussed CLP labelling of fuels in 2016, see [Doc. CA/05/2015](https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/60e26f95-a990-4008-a168-0e38e0140599/details), which was the outcome of the CARACAL sub-group on labelling and packaging issues.

For fuels, there was agreement that the placing on the market occurs at the moment of filling the fuel tank or container (*e.g.* a jerryjar). Therefore, CLP labelling requirements do not apply to the fuel pump itself, but to the fuel. In this context, the fuel can indeed be considered as unpackaged. In practice, fuel is currently not labelled in full compliance with CLP.

**Various options to improve hazard communication on fuels**:

* Bring fuels into the scope of Article 29(3) CLP by its inclusion in Part 5 of Annex II (option discussed in CARACAL in 2016, see Doc. CA/05/2015): If included in Part 5 of Annex II, a copy of the label elements would need to be provided to the general public at the point of sale.
* Amend Article 29(3) CLP to allow the provision of a sticker. This option was discussed in CARACAL in 2016 (see above). Within CARACAL, it was recognised that many filling stations are for self-service and that it would be sufficient to make a sticker with the correct label elements available at the fuel pump. It would be left to the consumer to take/use the sticker. Therefore, self-service filling stations would not be required to verify that every customer uses the sticker on their receptacle/jerrycan, but they would be required to at least make the sticker available. In practice, many filling stations nowadays have a CLP label put on the pump.

However, CARACAL agreed at the time that any potential new requirements should be very well justified and that it should first be confirmed that there is indeed a problem (*e.g.* divergent approaches to the application of CLP requirements to filling stations across Member States). Consultation with selected poison centres confirmed that there have indeed been some incidents with fuel, although the overall incidence and severity is unknown;

* Provide for a labelling derogation under Article 23 of CLP: The situation of unpackaged substances or mixtures to consumers is specifically addressed in Article 29 in response to recital 49. However, in principle, labelling derogations could also be addressed via Article 23. This pathway would have the advantage of being able to address the case of filling stations more specifically rather than just indicating that the general public should be provided with a copy of the labelling elements.

## Re-fill sales

CLP specifies that labelling information must be legible and visible on the packaging. However, at the time of drafting CLP, the increasing trend of supplying chemicals in bulk was not yet anticipated. Therefore, it does not clearly address the specific case of “re-fill sales” involving consumers bringing an empty receptacle to the store and re-filling it with a product, *e.g.* a liquid soap, washing powder or paints. This may result in placing on the market without respecting the CLP requirements for labelling (no or incorrect label) and packaging (incompliance with specific packaging rules, *e.g.* child resistant fastenings or unsuitable packaging material), ultimately lowering the level of protection for health and environment.

This new trend of re-fill sales differs from the scenario described above for filling stations, because the consumer does not leave the shop with an unpackaged chemical. However, the chemical is ‘placed on the market’ unpackaged in so far as it is ‘made available’ (one of the ways to place on the market under Article 2 of CLP) to the consumer without packaging. Hence, it could be considered to fall under Article 29(3) of CLP. However, since the consumer is leaving the store with a packaged chemical, that provision is not entirely suitable. The practical problem is that, although packaged in the shop, it may be that the consumer buys it unlabelled or incorrectly labelled and/or packaged.

## The distributor can ensure compliance in different ways. For example, the refilling can happen via distribution machines that recognise specific receptacles ((*i.e.* with the correct label) and only allow the re-fill if the correct receptacle is used; in addition, it is also possible to consistently verify at the check-out whether the correct label is applied to the receptacle and whether the receptacle is fit for purpose. It could also be an option to limit re-fill sales to chemicals that are commonly used in households and pose a limited health risk, similar to the level of a typical detergent or cosmetic product.

Similar discussions are ongoing within the context of the Revision of the Detergents Regulation, where the Commission will examine re-fill sales in the impact assessment. In this area, the main issue relates to the requirement laid down in the Detergents Regulation that certain information must be legible and visible on detergents’ labels. It is often the case that this labelling requirement is not fulfilled in the refill sale of detergents as the product is sold in bulk and filled into empty containers that are either not labelled at all or bear the wrong label[[4]](#footnote-5).

**Various options to solve this issue**:

* Address in guidance how re-fill chemicals should be labelled;
* Introduce a specific provision in Article 29 for re-fill sales in the legal text on how to label (Article 29(3) CLP: one could think about adding an Article 29(3a) for re-fill chemicals or providing a derogation via Article 23);
* Introduce provisions in CLP to allow digital labelling solutions, *e.g.* put a QR-code on the packaging/label;
* Consider provisions in CLP or other legislation to ensure a safe handling of the refilling station (*e.g.* only staff can re-fill into suitable and labelled containers or apply labels to containers where necessary).

Similar options are currently being considered under the Detergents Regulation. It would be preferable to ensure coherence when it comes to re-fill sales between CLP and the Detergents Regulation.

# Aspects related to the format of labels

## Multi-lingual labels with a focus on fold-out labels

With regard to multi-lingual labels, the Fitness Check of the most relevant chemicals legislation (excluding REACH)[[5]](#footnote-6) concluded that:

*“evidence also indicates that labels can become overloaded with information e.g. too much text, too long and not meaningful chemical names to non-professional users making it difficult for downstream users and consumers to focus on the essential hazard information, thus reducing the effectiveness of hazard communication. Too much text included on labels, especially when this is required to appear in multiple languages, thus restricting the comprehensibility of the information.[[6]](#footnote-7) This could be overcome by increasing the use of digital tools to communication hazard information. 61% of respondents to SME panel consultation agreed or strongly agreed that providing information on chemical hazards to consumers should rely more on novel tools, such as QR-codes, apps and websites. Currently, however*, *the legal (mandatory) requirements do not incentivise the use of more innovative techniques and digital tools and when it happens, industry is using digital tools on voluntary basis”.*

The Commission is assessing the more specific rules on (multilingual) fold-out labels in CLP in the framework of the CLP impact assessment. The contractor is expected to assess this issue and to analyse different options for improvement.

In addition, the Digitalisation study assesses multilingual labels from a simplification and digital labelling perspective following the outcomes of the fitness check. Based on the outcomes of the interim studies which took into account replies from stakeholder interviews as well as literature research it can be summarised that:

* Business representatives explained that multilingual labels are used to achieve economies of scale;
* National authorities and consumer associations put in evidence that featuring multiple languages makes labels hard to read at the expense of communicating important safety and hazard information and that languages should be reduced to a certain number.

CARACAL discussed CLP multi-language labels in 2016, see [Doc. CA/05/2015](https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/60e26f95-a990-4008-a168-0e38e0140599/details) which was the outcome of a CARACAL sub-group meeting on labelling and packaging issues and [Doc. CA/52/2016 rev.1](https://circabc.europa.eu/ui/group/8a073cb6-03cb-4665-a866-4a17b17a6f60/library/df837828-906c-4dc3-a0ea-1094c64df840/details).

As a result of those discussions, the Commission proposed to extend the scope of fold-out labels beyond what is currently allowed in Article 29(1), that is, to allow more languages to figure in fold-out labels than those required by the MS in which the product is placed on the market. However, no agreement was found on the conditions to be applied (CARACAL-21).

The Commission services presented for discussion the following draft provision to be added to Article 29(1) through Article 53 procedure (now delegated acts procedure), to be accompanied by ECHA guidance on the design requirements for the fold out labels:

• Add a second subparagraph to Article 29(1) CLP:

*"Where in accordance with the second subparagraph of Article 17(2) the supplier uses more languages on its labels than those required by the Member State in which the substance or mixture is placed on the market, and the packaging is either in such shape or form or is so small that it is impossible to meet the requirements of Article 31, the label elements in accordance with Article 17(1) may be provided in fold out labels. The number of languages on the fold-out label shall be limited to 6.”*

• Consequently, there is a need to change Annex I, section 1.5.1.1 to read:

*"Where the first subparagraph of Article 29 (1) applies ….".*

• Address design requirements such as content, quality and design of fold-out labels with a particular emphasis on durability, readability and accessibility of information in ECHA’s guidance on labelling and packaging (completed).

It emerges from the DSR of CARACAL-21 that “members had diverging views on the maximum number of six languages” and expressed different concerns and alternative suggestions[[7]](#footnote-8).

**CARCAL discussions did not reach a conclusion on this topic**.

## Readability

CARACAL already discussed the need to set a minimum font size of labels, a topic closely related to the allowance of multilingual labels (see [Doc. CA/05/2015](https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/60e26f95-a990-4008-a168-0e38e0140599/details)), but did not reach a definitive conclusion on that issue, except from the insertion in ECHA’s labelling and packaging guidance of the following text concerning the readability of fold-out labels (see p. 44):

“*Readability is determined by the combination of font size, letter spacing, spacing between lines, stroke width, type colour, typeface, width-height ratio of the letters, the surface of the material and significant contrast between the print and the background*”.

CARACAL should discuss if this reference in guidance is sufficient or if further rules should be set either in guidance or in CLP.

# Digital labelling

## Digital labelling at EU level

The findings of the [Fitness Check of the most relevant chemicals legislation (excluding REACH)](https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1561530857605&uri=COM:2019:264:FIN) were that it is possible to better communicate essential information about chemicals to users (particularly consumers) and that the use of innovative digital tools on product labels could improve the communication.

The inception impact assessment of the initiative on **Simplification and digitalisation of labels on chemicals** states that the main objective is to *“increase the effectiveness of communicating essential information on chemicals, including safety and product use-instructions, in order to further reduce the impact of harmful chemicals on health and the environment. The means of simplifying and streamlining information and introducing the use of digital tools for parts of the labels will be explored to fulfil this objective”.* The baseline scenario to be used as benchmark against which policy options will be assessed will reflect the current state of labels on products, under the CLP, Detergents and Fertilising Products Regulations.

It should be noted that the labelling requirements in CLP are established within the framework of GHS. There are, consequently, some limitations to provide CLP label information only digitally. The discussion also needs to consider that GHS is itself exploring the matter of digitalisation, albeit in a more global framework context.

Policy options in line with the following scenarios will be looked at in terms of improving product user outcomes through labelling:

 Simplifying information, *e.g.* by aligning labelling information (relevant to the CLP and Detergents Regulations only).

 Changing the way in which specific information is currently provided (*e.g.* from the physical label to digital means; relevant to the CLP, Detergents and Fertilising Products Regulations). Such change should happen gradually, taking into account scientific and technical progress as well as consumer behaviour.

The Commission tasked a contractor to carry out an impact assessment study on this initiative, which includes a state-of-the-art **behavioural experiment**. That experiment tested consumers’ behaviour using three different treatments: no-label, a status-quo label and a simplified label (with a QR-code) for two different products relevant to CLP labelling: a detergent and a glue). The experiment was conducted with just over 4000 participants in four Member States: Germany, France, Romania and Greece, throughout September and October 2021. The preliminary findings of the experiment show that the status quo label (reflecting the current on-pack labelling practices) and the simplified label (containing a QR code with mandatory product information) perform equally well for the communication of hazards and precautionary measures.

Based on these first study results as well as preliminary results from the stakeholder survey, below is a first skeleton of options to be assessed (depending on the final study outcomes, these might be subject to change; reference to “regulations” means CLP and the Detergents Regulation):

* **No new policy actions (baseline):** no change, *i.e.* also no rules at all on e-labelling;
* **Non-legislative measures: Physical labels and voluntary use of e-label**: all labelling requirements on physical label would remain. A framework set out in a Commission guidance document would address the possible use of digital labelling;
* **Revision of the labelling rules in the regulations**:align the two regulations and address inconsistencies **on the physical label only**;
* **Revision of the labelling rules in the regulations, introducing optional digital labelling**: All requirements for the physical label would remain. A framework set up within CLP would regulate the optional use of digital labelling, *i.e.* to provide the *option* to move certain labelling requirements on the e-label only;
* **Revision of the labelling rules in the regulations, introducing optional/mandatory digital labelling**: Most relevant requirements for the physical label would remain. A framework set up within CLP would regulate the optional/mandatory use of digital labelling, *i.e.* to provide the option *to move further labelling requirements* on the e-label only;
* **Revision of the labelling rules in the regulations, providing for** digital labelling only in specific cases (to be kept in mind for products which currently do not bear a label at all).

Regarding the means of digital labelling or the general rules on the digitalisation of labels (format, accessibility, technical requirements, etc.), the Commission is currently reflecting internally how this could best be done.

# Questions

1. ***CLP labelling of small items***

a1) Do you think certain small items containing mixtures deserve additional derogations from CLP labelling? If yes, please indicate why and which categories/products/hazard classes should be covered. In your reply please be mindful of the GHS requirements.

a2) Should the labelling exemption in Article 23 of CLP and subsequently under Section 1.5.2.4. of Annex I to CLP be extended to certain small items (e.g. writing instruments) and if yes under which conditions (e.g. depending on the hazard classes)?

a3) Do you think that Article 23 of CLP (derogations from labelling requirements for special cases) should be expanded? If yes, for which products/hazard classes?

a4) Do you consider that CLP should introduce a digital labelling option for those products (see last bullet in heading 4)? If yes, which information should be provided electronically?

1. ***CLP labelling of mixtures supplied in bulk / re-fill sales***

b1) Is there a concrete issue in the lack of CLP labelling for certain mixtures provided to consumers (*e.g.* divergent Member States approaches on fuel, accidents with fuel products)?

b2) In cases of lack of concrete issues and/or practical impossibility and unenforceability to label certain substances/mixtures supplied in bulk, should CLP exempt them from labelling, or, alternatively, introduce obligations to label only digitally or via other means?

b2) For re-fill chemicals, should additional specific rules be introduced in CLP on how to label those products (stickers etc.)? Should CLP introduce digital labelling options for those products?

1. ***Multilingual labels / Font size***

c1) Should CLP allow multilingual fold-out labels in addition to the official language(s) of the MSs where the substance or mixture is placed on the market? Should CLP define some conditions such as setting up a maximum number of languages? Instead, should CLP introduce the possibility to provide the labelling information in additional languages digitally?

c2) Do you think the introduction in CLP of provisions for minimum format requirements (e.g. font size, contrast) for labels is needed instead of the current CLP guidance?

1. Please provide your views on the different proposals outlined under heading 4. on digital labelling.

Annex

# CLP labelling of small items





1. Technical and scientific support to the Commission’s impact assessment for the revision of the Regulation on classification, labelling and packaging of substances and mixtures (CLP). [↑](#footnote-ref-2)
2. DSR CARACAL -27 on writing instruments: <https://circabc.europa.eu/ui/group/8a073cb6-03cb-4665-a866-4a17b17a6f60/library/f3bf68dd-c0d6-440b-a802-e163ea3b7fba/details> [↑](#footnote-ref-3)
3. Recital (49): *In general, substances and mixtures, especially those supplied to the general public, should be supplied in packaging together with the necessary labelling information. The supply of appropriate information between professionals, including for unpackaged substances and mixtures, is ensured by Regulation (EC) No 1907/2006. However, in exceptional circumstances, substances and mixtures may also be supplied to the general public unpackaged. Where appropriate, relevant labelling information should be supplied to the general public by other means, such as an invoice or bill*. [↑](#footnote-ref-4)
4. Another potential issue with the refill sales of detergents results from the definition of "manufacturer" provided in the Detergents Regulation (“manufacturer means … any person changing the characteristics of a detergent or of a surfactant for a detergent, or creating or changing the labelling thereof, shall be deemed to be a manufacturer”). As any person changing the label of detergents is deemed to be a manufacturer under the Detergents Regulation, the refill sale of detergents could lead to a situation where a retailer or (in a more extreme scenario) even a consumer, changing the label of a detergent sold in bulk is deemed to be its manufacturer, and therefore responsible for placing that detergent on the market. [↑](#footnote-ref-5)
5. SWD(2019) 199 final/2, p. 53. [↑](#footnote-ref-6)
6. 1st FC Study p. 24 and p. 70; see also Annex III, Section 7.3; Case Study 5; see also1st FC Study workshop report p. 12-13; see also Study supporting the Evaluation of Regulation (EC) No 648/2004 (Detergents Regulation) p. 77-79, p.106. [↑](#footnote-ref-7)
7. See [CARACAL DSR 21](https://circabc.europa.eu/ui/group/8a073cb6-03cb-4665-a866-4a17b17a6f60/library/93c2cac3-f5da-44ef-bc7c-63cf90fa089e/details): “One member indicated that more languages can be beneficial, another favoured fewer languages and yet another, joined by one observer, preferred focusing on quality and readability rather than specifying a number of languages. While two other members expressed that they were in favour of a limitation of languages, an observer considered a maximum number of languages not to be justified. He underlined the importance of multi-lingual fold-out labels for niche products and intends to provide examples of fold-out labels to the group. A member enquired whether the local language should be on the outer page of the package. One member asked for further specification when fold-out labels can be used and expressed concern about fold-out labels that become detached. Another member favoured a simpler approach and suggested that a minor amendment to Article 29 would be sufficient to allow for more languages (i.e. by including a reference to readability in Article 29). Another member insisted on the importance to take the discussions at GHS level into account.” [↑](#footnote-ref-8)