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|  | EUROPEAN COMMISSION  Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs  Consumer, Environmental and Health Technologies  **Chemicals**  **REACH**  Directorate-General for Environment  Green Economy  **Chemicals** |

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**21st Meeting of Competent Authorities for REACH and CLP (CARACAL)**

**29 – 30 June 2016**

**1 July 2016**

**Room 1D, Albert Borschette**

**Brussels**

**Concerns: Scope of Multilingual fold-out labels**

**Agenda Point: CLP session 6**

**Action Requested: For discussion and comments to** [**Elina.PIETILAINEN@ec.europa.eu**](mailto:Elina.PIETILAINEN@ec.europa.eu)**,** [**Maurits-Jan.PRINZ@ec.europa.eu**](mailto:Maurits-Jan.PRINZ@ec.europa.eu)**,** [**Fabienne.VAN-RAEMDONCK@ec.europa.eu**](mailto:Fabienne.VAN-RAEMDONCK@ec.europa.eu) **by …**

From the discussions in the previous CARACAL meetings and the comments received, it emerges that the majority of MS who have expressed their views is in favour of extending 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.

At CARACAL-20, the Commission services invited the delegations to comment on the conditions that should be considered in a possible extension of the scope of fold-out labels (Caracal document CA/05/2016). Answers were received from DK, DE, UK and NO as well as from AISE and DUCC (see the comments in Annex).

As a result, the COM services would like to present for discussion the following draft provision to be added to Article 29 (1) through Article 53 procedure, to be accompanied by ECHA guidance on the design requirements for the fold out labels:

* Amendment to first subparagraph for Article 29 (1)

*Where the packaging of a substance or mixture is either in such shape or form or is so small that it is impossible to meet the requirements of Article 31 for a label in the languages of the Member State in which the substance or mixture is placed on the market, the label elements in accordance with the firs*

* New second subparagraph for Article 29 (1)

*"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* …."

* Guidance on specific requirements

The Commission reminds CARACAL members that the latest version of ECHA's Guidance on labelling and packaging according to CLP (pending publication) contains a detailed description of the content, quality and design of fold-out labels with a particular emphasis on durability, readability and accessibility of information. It also specifies the labelling elements to be visible on the front page of the fold out label. Further requirements can be elaborated in ECHA guidance if needed.

**ANNEX**

**- Comments of MS as regards possible quality requirements**

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| **#** | **MS/ Obs.** | **CARACAL comment** | **COM response** |
| **Multi-lingual fold-out labels** | | |  |
|  | **DK** | As previously expressed the Danish CA is not in favour of extending the scope of fold-out labels. We believe that such labels should still be restricted to packaging that is either so small or has such a form that it is not possible to meet the normal labelling requirements. However, we are aware that a majority of the MS seem to be in favour of an extension of the scope.  Should a proposal be made for widening of the scope we see a need for placing **very firm requirements** as of when (under which conditions) fold-out labels can be used and of the design of the label (i.e. **the maximum number of languages, pages, format and readability**). A lot of work has been done under GHS in relation to labelling of small packaging’s and this work should be taken into account if an extension of the scope and new guidance is proposed. | The COM takes note of the DK concerns and consequently proposes a maximum number of languages to meet the requirements of Article 31, for which the exemption must be interpreted and applied in a restrictive way. Readability and accessibility of the information are indeed paramount and are addressed in detail in the proposed ECHA guidance. Other appropriate requirements can also be addressed via guidance. |
|  | **DE** | DE refers to its previous comments in which it support certain restrictions to the use of fold-out labels, in particular number of languages, pages/layers of the fold-out and a differentiation of application for consumer or professional products | The COM takes note of the DE concerns and consequently proposes a maximum number of languages to meet the requirements of Article 31, for which the exemption must be interpreted and applied in a restrictive way. Readability and accessibility of the information are indeed paramount and are addressed in detail in the proposed ECHA guidance. Other appropriate requirements can also be addressed via guidance |
|  | **UK** | The UK welcomes the Commission’s proposal to amend Article 29(1) to allow for a broader scope for the use of fold-out labels and support the intention to provide additional guidance.  However, while the fold-out labels should meet the requirements for quality, durability and readability, we would caution **against being too prescriptive in listing the requirements or restrictions** with regard to the design, style and contents of the label itself in the supporting guidance.  While the guidance can prescribe **what label elements and language codes should appear on the front/back pages**, the order of languages (i.e. alphabetical), and the label elements expected to be seen on each inner page, the label format (Article 1.5.1 of Annex I merely states ‘fold-out’ labels so book, window or accordion style etc. are all acceptable) should be determined by the supplier depending on the substance or mixture being placed on the market, its hazardous properties, the intended market (i.e. the number of MS in which it will be placed on the market) and the number of official languages involved. Limiting the number of languages and/or pages may inhibit the options open to the supplier.  The need to meet both the quality and readability requirements may, in any case, place practical restrictions on what can be achieved by suppliers given the extra costs involved of producing a fold-out label. | The COM takes into account the concerns of the UK in relation to guidance and considers that quality requirements can be set in an ECHA guidance, which allows sufficient flexibility to meet the needs of specific product types and packaging as well as markets. However, based on the comments received, COM proposes to limit the number of languages, in order to meet the requirements of Article 31. |
|  | **NO** | In addition to the possible restrictions mentioned in the document, NO suggest considering requiring that **certain information**, including the hazard pictograms, **must be included on the outer page of fold-out labels**. We will also repeat that Norway proposes **the number of languages to be restricted**. Many languages makes it more difficult for the user to locate and read information in the national language. Enforcement inspectors also points out that these restrictions should be implemented in the regulation and not in the Guidance. It is not possible to enforce text in the Guidance. | The COM takes note of the NO concerns and consequently proposes a maximum number of languages to meet the requirements of Article 31, for which the exemption must be interpreted and applied in a restrictive way. Readability and accessibility of the information are indeed paramount and are addressed in detail in the proposed ECHA guidance. Other appropriate requirements can also be addressed via guidance |
|  | **AISE** | A.I.S.E. welcomes the Commission’s proposal to allow for a broader scope regarding the use of fold-out labels and to amend the article 29.1of the CLP Regulation accordingly. As for possible quality requirements or restrictions in relation to fold-out labels to be inserted either in Annex II of CLP or in ECHA guidance:  A.I.S.E. insists on the fact that **sufficient flexibility** should be allowed to Companies in order to adapt to various product types and packaging and to potential future markets. The use of multi-lingual fold-out labels is economically essential for niche products that have a relatively slow turnover and are sold in multiple countries. Many SMEs rely on such products and do not have the possibility to manage multiple Stock Keeping Units (SKUs).  Besides these considerations, there is no limitation on the number of languages allowed for ‘regular’ (non fold-out) labels. Companies have been providing multi-country information via multi-lingual labels for many years while contributing positively to safety and protection of users. Therefore, A.I.S.E. believes that **the limitation of the maximum number of languages for fold-out labels is not justified for safety considerations**. In practice, according to the draft update of ECHA guidance on Labelling and Packaging, the amount of information required on the front page of fold-out labels is already limiting the number of languages to be used in such labels.  **Likewise**, we are of the opinion that there is no need to add further restrictions on **the number of pages or the format** of the fold-out labels, as long as these comply with the labelling requirements of the CLP regulation.  Furthermore, we would like to stress that some information relating to the quality and design of fold-out labels, as well as readability principles, were already included in the recent draft update of ECHA guidance on Labelling and Packaging, with the definition of the elements to be visible on the front page, the label being firmly affixed etc., therefore we do not see what could be the objective of further limitation in the format with regards to the safety of users. | The Commission takes note of AISE's comments concerning the potential benefits of multi-lingual fold-out labels.  The Commission considers that if requirements are set in ECHA guidance, sufficient flexibility can be foreseen to meet the needs of specific product types and packaging as well as markets. The Commission proposes to limit the number of languages in order to meet the requirements of Article 31. |
|  | **DUCC** | DUCC welcomes the Commission’s proposal to broaden the scope of Article 29(1), to make it clearer that these can be a valid way to implement the requirements of CLP Articles 17, 31 and 32. The importance and value of such labels has already been amply expressed both in feedback from DUCC and other industry stakeholders, but also in previous CARACAL documents from the Commission.  We re-iterate our earlier comments that these labels should naturally **be subject to quality and readability requirements**.  However DUCC consider it **inappropriate to specify arbitrary fixed limits on the number of languages or pages, or restrictions on forma**t. **Industry should be allowed the flexibility** to design labels which meet the needs of their supply chain, whilst always being subject to the overriding principle that they should be clear, legible, easy to use and sufficiently durable for the lifetime of the product. In light of the large number of factors involved this can only be judged on a case-by-case basis. | The Commission takes note of DUCC's comments concerning the potential benefits of multi-lingual labels.  The Commission considers that if requirements are set in ECHA guidance, sufficient flexibility can be foreseen to meet the needs of specific product types and packaging as well as markets. The Commission proposes to limit the number of languages in order to meet the requirements of Article 31. |
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