Comments from the German Delegation following the WP-Meeting on Technical Harmonisation on 14 June 2023

Article 29(3)

From our point of view, supplying fuels in fuel canisters does not fall under the cases regulated in Article 29(3). In our opinion, this is covered by the new regulations on refill sales in Art. 35. Here, however, the corresponding regulations on the named hazard classes (Flam. Liq. 1/2, Asp. Tox. 1, etc.), would exclude supplying due to the hazard properties. In order to continue supplying fuels in canisters, a corresponding exception would have to be created.

Article 30(1)

We still consider the extension of the period from 6 to 12 months to be important in terms of feasibility for companies.

New section 1.2.1.6. in Annex I

We support the inclusion of the criteria in the appendix. However, our comment on the further inclusion of product identifiers in the relevant national languages from our last comment has not been included. We still consider this point to be important.

Article 48a

Of the two options presented in the steering questions, we prefer option b), since it is linked to the offer, regardless of which actor makes an offer. However, the reference to the DSA seems too narrow, since other horizontal EU regulations, such as the EU Product Safety Regulation, contain horizontal regulations for online sales, which partially modify the liability privileges according to the DSA. We therefore suggest a more general wording such as: *"without prejudice to other Union Legislation"*.

The proposed wording also leaves room for misinterpretation with regard to the placing on the market. It should be clarified that Article 48a refers explicitly to the offer phase and does not require proof that a

product has actually been dispatched to the customer. The term "making available" as a subcategory of "putting on the market" sometimes depends on the actual dispatch of the products in the case of distance sales (see Blue Guide p. 22). Accordingly, “making available” is specifically defined in Article 6 of the EU Market Surveillance Regulation. According to this, a product is deemed to have been made available for distance sale as soon as the offer is aimed at end users in the EU. The regulation for online sales in the CLP Regulation should therefore be congruent. This is ensured by our suggested wording *"Suppliers **offering** substances or mixtures **for sale** on the market through distance sales shall, clearly and visibly indicate in the offer the label elements referred to in Article 17"*. Alternatively, it is also possible to directly link the provision to the definition according to Article 6 of the Market Surveillance Ordinance.

Article 53(1a)

In principle, we support the specification and restriction of the empowerment basis for changing Annex I 1.6. Nevertheless, the level of ambition could be higher. In addition to the hazard and safety information, ingredients should always be included on the physical label for health and consumer protection reasons. Especially with regard to medical emergency advice, the quick identification of the ingredients in an emergency is of crucial importance. This is only guaranteed with a physical label. Ingredients must therefore be exempted from the empowerment to make them available exclusively in digital form. An additional extension to EUH phrases is supported, as these are important (consumer) information that must also always be present on the physical label.

Section 3.4 point (k) in Annex II

We continue to support the inclusion of Skin Sens. under point k). We had commented that STOT SE should also be included, but only categories 1 and 2. The hazard class STOT SE 3 should therefore be deleted.

Article 4(11)

The second option b seems preferable, but in the following modified version:

4(11) Substances and mixtures shall not be placed on the market from ***a country outside the EU*** *unless a supplier established in the Community,* ***who shall be indicated on the label****, acting in the course of an industrial or professional activity, fulfils the requirements set out in this Regulation with regard to the hazardous substances or mixtures in question.*

The regulation may only refer to substances and mixtures that are to be brought into the EU internal market from countries outside the EU. Only in such a case is a dealer based in the EU required. The previous version of option b does not make that distinction. Another argument in favour of option b is that a general ban on the placing on the market of substances and mixtures fits better into the previous system and the instruments of market surveillance. We therefore assume that a product that does not comply with the requirements of Article 4(11) could be prevented from being made available on the EU internal market by the market surveillance authorities or customs authorities. A supplier based in the EU would also have to be obliged to take corrective measures under the Market Surveillance Ordinance. However, it must be ensured that market surveillance authorities can identify which supplier is responsible for compliance with the requirements. The responsible supplier should therefore be named on the label.

Article 9(3)

We refer to our last written comment.

New sub-group B1a. Classification of forms

We can continue to support the proposal. However, we would still welcome a definition of the term "form of a substance". We made a proposal which unfortunately was not included.

Council of the European Union
General Secretariat

Interinstitutional files:
2022/0432 (COD)

Brussels, 19 June 2023

WK 8326/2023 INIT

LIMITE

ENT
MI
IND
ENV
SAN
CHIMIE
CONSOM
CODEC

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

NOTE

From:	General Secretariat of the Council
To:	Working Party on Technical Harmonisation (Dangerous Substances - Chemicals)
N° prev. doc.:	CM 3233/23
N° Cion doc.:	ST 16258 2022 ADD 1 - 8
Subject:	Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Revision) - Comments by DE, IE, LV, NL on the Revised Presidency Compromise Proposal

Delegations will find in the Annex a consolidated table with the comments by Member States on the full text of the Presidency's compromise proposal on the CLP revision, as set out in document ST 9689/23 REV 1.

LV COMMENTS

We are quite cautious about Article 35 Paragraph 2a Subparagraph 2. If we read this subparagraph together with Article 29 Paragraph 3 and Second subparagraph of Part 5 of Annex II, in our understanding fuel supply in jerrycans might be totally banned. Refill sales provisions laid down under Article 35(2a) do not apply to hazardous chemicals supplied in accordance with Article 29(3). However, Article 29(3) refers only to chemicals, that are mentioned in Part 5 of Annex II. And this particular part of the Annex refers only to mixtures, including the fuel, which is being filled directly into a vehicle. So, in other words, after you look onto these three norms systemically, it can be interpreted that derogation mentioned in Article 35(2a) is not applicable only to fuel and other mixtures that are being filled into jerrycans at filling stations and thus for such chemicals general refill sales provisions shall apply.

If we look into Point (k) of Part 3.4. of Annex II, we can easily see that mixtures cannot be sold at the refill stations for the general public if they are classified in such hazard classes as, for example, acute toxicity, aspiration toxicity, specific target organ toxicity etc. And now if you look at the safety data sheet for a diesel fuel (please find enclosed to this e-mail), that is being sold across the EU, in Section 2 you can see listed the same hazard classes, which were previously mentioned. In other words, the new CLP provisions can be interpreted so that fuel filling into jerrycans at the filling stations is totally prohibited. In this regard, we would like to seek some clarifications from both the COM and the PRES. And in or view this problem should be resolved not only from the refill sales perspective, but also from the labelling perspective, which we have raised several times during our previous WP meetings, for example, by broadening the scope of Part 5 of Annex II so, that it also covers the fuel that is being filled into jerrycans, which might solve both issues.

Written comments from the Netherlands on ST 9689/1/23 REV 1 following the Working Party Meeting on the 14th of June (CLP)

Subgroup	Instructies
A1 Labelling obligations/exemptions Annex I, section 1.2.1.4 Annex II part 5 (jerry cans)	NL: Regarding Annex I, section 1.2.1.4, we would like to thank the Presidency for revising the requirements for the larger labels as a way of compromise. We do still think that the new requirements would result in disproportionate costs for industry, simply because the larger minimum font sizes lead to the need of new and larger labels and most probably new printers. In general, we support the solution for the labels as proposed by Denmark in their non-paper. Additionally, we would like to take it further by opting for their proposed solution but allow smaller font sizes if the stated conditions are proposed. Regarding Annex II part 5, we support the proposal from Denmark with regards to the jerry cans.
A2 Digital labelling Article 53	NL: We are afraid that with the latest proposal, the possibility to amend the label elements by delegated act for digital labelling is too limited. We prefer the Commission proposal on the wording in this provision, that allows the Commission to amend the digital label elements to technical progress (in the light of the level of digital readiness among all population groups in the Union), while still taking into account GHS.
A3 Refill sales Annex II in A3 Section 3.4, point k	NL: Regarding the list under (k): we understand that 7 Member States were in favour of omitting Skin sensitisation from the list under K, and 7 Member States were against it. Again, we strongly believe leaving Skin sensitisation on the list will very much limit the options of products to be supplied by refill stations, so we regret that it has not been revised. As mentioned in the Steering note by the Presidency however, perhaps this list can be reviewed at a later moment since it can be amended by delegated act. NB: We have asked the CLS whether CLP is the suitable regulation to regulate the substances allowed/prohibited to be supplied by refill stations (Annex II, section 3.4 point k).
A4 Online sales Article 4(11) Article 48a	NL: Regarding article 4(11): we understand that the end result for both options is the same. We have a slight preference for option B. We would also like to note that the word "hazardous" is missing from the sentence under option A: it should be "hazardous substances or mixtures". Regarding article 48a: we follow the Commission's logic and opt for option b.
B1 Rules on Classification	-
B1a Classification of forms	-
B2 MOCS (Multi-constituent substances)	NL: We support the compromise proposal, however we would prefer to shorten the transition period. The transition period has been set to 42 months. While we understand that a longer transition period has been put in place to take into account the possible derogations, we are not in favour of allowing such a long additional transitional period, especially since it should already be current practice to classify according to these rules. *Outline of our considerations* *• The proposed approach by the Presidency and the Commission is in line with the existing CLP provisions regarding the identification of CMRs in mixtures and also in line with existing CLP guidance. From a toxicological point of view, multi-constituent substances are no different from mixtures. As such, existing CLP guidance on assessing CMR properties for mixtures already addresses multi-constituent substances in the same way.* *• The same applies to environmental fate properties: persistence, biodegradability, bioaccumulation and mobility for which data on the mixture/MOCS as a whole has*

	limited or no meaning, i.e. cannot be readily interpreted for the purpose of classification and labelling. *• For these hazard classes described in article 5.3 it is therefore necessary to look at the individual constituents in order to apprehend the full hazard potential of MOCS. It is not sufficient to only take the data on the substance itself into account (because data on the mixture/MOCS as a whole cannot be interpreted for the purpose of classification).* *• Essential oils and UVCBs are, in that light, no different from other MOCS (or UVCBs) and should therefore not be pre-emptively excluded from the proposed rules on evaluation of multi-constituent substances.* *• CLP by no means requires testing for the properties concerned. It is the responsibility of the entity placing on the market to classify the products based on all information available to them. For essential oils, in our view, this means it is crucial that the manufacturer has sufficient knowledge on the manufacturing process as well as on the composition including the (hazardous) constituents and their typical concentration ranges.* *• We do believe it is important that in cases where there is adequate and reliable scientific argumentation to not look at the individual constituents, derogation is made possible for the MOCS-rules. In that case, a scientific assessment should be made by the Commission and/or a scientific committee (RAC) that evaluates a derogation on a case-by-case basis.*
C1 New Hazard Classes	-
C2 Classification and Labelling inventory	-
C3 Procedure for Harmonised Classification	-
C4 Other regulatory procedures and entry-into-force	-
D1 Poison centres	-

IE comment to Article 4(11) CLP under subgroup A4, On-line Sales

IE thanks PRES for the work on Article 4(11) and the efforts made to reach a compromise text on this element.

With respect to the 2 options suggested by PRES in the annotations and steering questions paper ahead of the June 14th WP meeting, IE prefers option B as it the best option to avoid placing an obligation on the non-EU supplier, an obligation which cannot be enforced.

Having said that, our concerns remain as to how this could be enforced by EU CLP enforcement inspectors, although we acknowledge that this is a recognised issue and difficult to fully resolve in the current targeted revision of CLP.

Looking to the text of option B, to us, the fact that we are talking about products originating from outside the EU and placed on the market via on line sales is missing here and we would prefer if those elements were incorporated into article 4(11). In our written comments following the May 31st meeting, we provided options to PRES for this text. We again provide suggested text for your consideration, using option B as the basis, but incorporating the elements we feel are missing:

4(11) Hazardous ~~S~~substances and mixtures originating from outside the EU shall not be placed on the market via on-line sales unless a supplier established in the Community, acting in the course of an industrial or professional activity, fulfils the requirements set out in this Regulation with regards to the hazardous substances or mixtures in question.