FINLAND:

Helpex-Q&A on CLP labelling of nicotine pouches

Typically, nicotine pouches are sold in a low cylinder shaped, disc-like container that fits in a pocket. The low side part of the container makes it difficult to fit the hazard label to the side of the package. Typical diameters for the containers vary between 50 to 72 mm. Correspondingly, the actual available space on the side of the container available for fixing the label is typically limited to 9-16 mm x 157-226 mm (height x perimeter) with corresponding area of 1413-3616 mm2, whereas the height of the smallest compliant hazard pictogram (10 mm x 10 mm) is 14 mm. This has led to most manufacturers placing the hazard label on the bottom of the package.

Nicotine is classified as hazardous substance under the CLP Regulation and nicotine puches fall under the CLP Regulation, which requires hazardous mixtures to be labelled in accordance with that Regulation. Nicotine pouches which do not contain tobacco are not currently regulated under the Tobacco Directive.

CLP article 31(1) states: “Labels shall be firmly affixed to one or more surfaces of the packaging immediately containing the substance or mixture and shall be readable horizontally when the package is set down normally.”

CLP article 31(4) states: “The shape, colour and the size of a hazard pictogram as well as the dimensions of the label shall be as set out in section 1.2.1 of Annex I”

Article 29 states:
“1. Where the packaging of a substance or a mixture is either in such a 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 first subparagraph of Article 17(2) shall be provided in accordance with section 1.5.1 of Annex I."

From Annex I 1.5.1. Exemptions from Article 31 [(Article 29(1))]:
“1.5.1.1. Where Article 29(1) applies, the label elements mentioned in Article 17 may be provided in one of the following ways: (a) in fold-out labels; or (b) on tie-on tags; or (c) on an outer packaging.
1.5.1.2. The label on any inner packaging shall contain at least hazard pictograms, the product identifier referred to in Article 18 and name and telephone number of the supplier of the substance or mixture.”

Article 29 of CLP or Annex I section 1.5.1. do not specify the requirements for placement of fold-out labels or tie-on tags. Additionally, there are no specification on where the label on inner packaging mentioned on section 1.5.1.2. of Annex I should be placed.

Guidance on Labelling and Packaging (Version 4.2 – March 2021) states “The CLP Regulation does not foresee any separate provisions for tie-on tags or foldout labels. Both types of label must meet the same performance standards as any other “normal” label”. However, the same Guidance also states: “ It may be impossible for the label to be read horizontally when the package is set down normally or the label elements are of insufficient size and spacing as to be easily read. In this situation the label elements defined in CLP Article 17 may be provided either on: fold-out labels; or tie-on tags; or outer packaging.”

By our current interpretation, placing the hazard label on the bottom of the package is forbidden by CLP regulation irrespective of whether Article 29 is applied or not, and the lid defines the top of the

package. Some retailers argue that this is not the case, since in some cases the nicotine pouch packages are sold with them being set on a shelf on their narrow side with the “top” of the package facing the customers. Others argue, that as the package is small and such a shape that it is impossible to meet the requirements of Article 31, they can use the exemption in Article 29 of CLP and place a fold-out-label on the bottom of the package. It is clear, that in all cases where the package is such that it is possible to comply with (all) the provisions of Article 31, the label on the bottom of the container does not comply with CLP regulation, since the label must be "readable horizontally when the package is set down normally" in accordance with Article 31(1). However the cylindrical containers in question are very low in height which leaves room for divergent insights when it comes to interpretation of the legal text.

1. How should "readable horizontally when the package is set down normally" as stated in Article 31 of CLP should be interpreted in this context? Does the label on the bottom of the nicotine pouch package fulfill these criteria?

2. Does the label on the top of the nicotine pouch package (on the lid/closure) comply with Article 31?

3. Should Article 29(1) be applied for this type of packaging considering the fact, that the height of a 10 x 10 mm hazard pictogram is 14 mm, whereas height of the label in case placed on the side of the container is typically from 9 to 16 mm?

4. In case Article 29(1) applies, should the hazard label comply (fully or partially) with Article 31? Can tie-on tags and/or fold-out labels be placed on the bottom of the package? How about the minimum label elements specified in section 1.5.1.2 of annex I? Based on which considerations?

5. Can the label be affixed to the side of the package in a way that it breaks when the package is opened?

Final reply:

Placing the hazard label on the bottom of a package does not fulfill the criteria of CLP article 31.

To fulfill the criteria of CLP article 31, the hazard label should not be placed on the top of the package, especially if the top is completely removable.

Article 29(1) of CLP can be applied for a typical nicotine pouch package (low cylinder shaped, disc-like container where the available space on the side of the container available for fixing the label is typically limited to 9-16 mm x 157-226 mm (height x perimeter)).

The current text of Article 29 does not require that the conditions of Article 31 are followed. Therefore, there is currently no explicit legal obstacle to place a fold out label on the bottom of a package of this kind. However, article 31 of CLP should be applied as far as possible.

The label should not be affixed to the package in a way that it breaks when the package is opened.

Hellenic Republic

ΑΑΔΕ
Independent Authority
for Public Revenue (IAPR)

Independent Authority for Public Revenue
Directorate General
General Chemical State Laboratory
Directorate of Energy, Industrial and Chemical Products

Athens, 26.10.2023

1. Amendment 2 (**Recital 2)**: «*Substances containing more than one constituent are not **intentional** mixtures».*
   Comments: The term **intentional** mixture is not defined in article 2 of CLP.

2. Amendment 3 (**Recital 2 a (new))**
   Comments: We do not agree. The claim concerning the *renewable botanical origin* is not supported by generally accepted scientific evidence. This also constitutes a discriminatory treatment for the rest of the mixtures. Besides, CLP does not distinguish mixtures according to their origin.

   Also, the last sentence of the amendment, states that *"the Commission should assess the social and economic impact on micro and small enterprises*". Such an assessment is taken into account when legislative restrictions on use are put in place. CLP sets harmonized criteria for the classification of substances and mixtures. It does not impose restrictions from placing a substance or a mixture on the market. Therefore, the reference to social and economic impact is not relevant and should not be included in the text.

3. Amendment 18: **Article 1 – paragraph 1 – point -1 (new)** (Reg. CLP. Art.1.1): "*The purpose of this Regulation is to ensure a high level of protection of human health and the environment **including the promotion of alternative methods, for assessment of hazards of substances and mixtures**,…".*

   Comments: The phrase in bold refers to REACH Regulation and it is out of the scope of CLP Regulation. Test methods Regulation is an implementing Regulation of REACH.

4. Amendment 20: **Article 1 – paragraph 1 – point (2)(b)**, (Reg. CLP, art.2 (1) point 38a (new)):

   Comments: On the definition of refill, we support the text of the Council Mandate with the addition of the phrase in bold (**which fulfils the requirements on packaging set out in Title IV):**

'refill' means an operation by which a consumer or a professional user fills a packaging **which fulfils the requirements on packaging set out in Title IV,** with a hazardous substance or mixture offered by a supplier in the course of a commercial activity, whether in return for payment or free of charge.

5. Amendment 21: **Article 1 – paragraph 1 – point (2)(b),** (Reg. CLP, art.2 (1) point 38a (new)):

Comments: We support the text of the Council Mandate, with the addition of the phrase in bold:

'refill station' means a place where a supplier offers to consumers or professional users hazardous substances or mixtures that can be acquired through refill, either ~~manually or~~ through automatic or semi-automatic equipment, **according to Annex II paragraph 3.4.**'

6. Amendment 22: **Article 1 – paragraph 1 – point 2 a (new)**, (Reg. CLP Article 3(1)(2a)):

"…***Gender differences*** *with regard to the susceptibility to chemicals shall be taken into consideration, where relevant."*

Comments: Classification and labelling under CLP refers to human health and the environment generally and not to specific category of the population as for specific gender. This is out of the scope of CLP. It is not possible to have a discrimination between genders in CLP.

7. Amendment 23 : **Article 1 – paragraph 1 – point 4**, (Reg. CLP Article 5(3)(1)) *:*

Comments: If a text on MOCS is reintroduced, we support the wording of art. 5.3., in the working document st10912/2023, with the addition of the reference to Annex I (proposed initially by the Commission).

"A substance containing more than one constituent, in the form of an individual constituent, an identified impurity or an additive for which relevant information referred to in paragraph 1 is available, shall be examined using the available information on those known constituents as well as on the substance itself, **unless Annex I lays down a specific provision**".

8. Amendment 24**:** **Article 1 – paragraph 1 – point 4,** (Reg. CLP Article 5(3)(2))

Comments: We prefer the reference to paragraphs 3.5.3.1, ….4.2.3.1 rather than to paragraphs 3.5, …4.2 (as proposed by the EP), because it is more precise. Furthermore, the terms 'endocrine ***disrupting property*** *for human health*' and 'endocrine ***disrupting property*** *for the environment*, are also used in the relevant delegated act for the new hazard classes.

9. Amendment 106: **Article 1 – paragraph 1 – point 4 a (new),** (Reg. CLP, Article 5. 3a (new):

«3a. Paragraph 3 shall not apply to substances containing more than one constituent of ***renewable botanical origin*** *that are not chemically or genetically modified, ….».*

Comments: We do not agree. Exemptions to the classification rules that are not scientifically supported may cause a general pattern of stakeholders requesting exemptions for any other substance or mixture. There is no scientific justification for the proposed exemption. Products of botanical origin may contain substances CMR, ED, PBT, vPvB, PMT, vPvM etc.

Furthermore, as ECHA supported at the technical meeting about MOCs (on 12.06.2023): *"To provide conclusive evidence that exemptions are warranted, there are several factors that need to be considered. Data provided needs to conclusively demonstrate the mode of action which prevents the constituent exerting an adverse effect when present in the substance.*

If a mixture contains a carcinogenic substance at a low level it may not express the effect in an animal study on the mixture due to the lowered statistical power. Effects far below the detection limit of the assays are of concern. It would be questionable use of test animals as too low dosing of the constituent in the whole substance implies that lack of an effect can be due to an inability to detect the effect(s)".

This EP amendment presupposes that paragraph 3 of Article 5 will be reinserted in the text. In this case, we consider as appropriate the text of article 5(3a),(3b),(3c) of the document st10912/2023, as scientifically supported. That working document introduces the possibility for exempting some substances containing more than one constituent from the "mixture-rule" classification based on specific criteria, like strong scientific data to decide case-by-case (e.g. antagonistic effects, statistical power with in a study on the substance as a whole, proof of no release of the constituent from the matrix), or under specific procedure, e.g. via RAC mandated by COM based on Art 77(3)(c) in REACH.
(see also our comments on amendment 116)

10. Amendment 45: **Article 1 – paragraph 1 – point 13**, (Reg. CLP, Article 31(3)):

Comments: We support the Council Mandate which includes the phrase: "*They shall be formatted in accordance with section 1.2.1 of Annex I."*

"3. The label elements referred to in Article 17(1) shall be clearly and indelibly marked. They shall stand out clearly from the background and they shall be of such size and spacing as to be easily read. They shall be formatted in accordance with section 1.2.1. of Annex I".

11. Amendment 116: **Article 1 – paragraph 1 – point 29 a (new),** (Reg. CLP, Article 54a (new)) (Review Clause):

"No sooner than [insert date six years after the date of entry into force of this Regulation], the Commission shall present a report to the European Parliament and the Council regarding the evaluation and classification of substances of renewable botanical origin containing more than one constituent referred to in Article 5(3a)"

Comments:

We do not agree, with extending the period to six years, nor with replacing the word «by» of the text of the Council Mandate with the phrase «no sooner than». This is a very sensitive issue, concerning the protection of human health and must be thoroughly examined **as soon as possible** in the light of scientific progress.

As we have already mentioned, we do not agree with the proposed by the Parliament Article 5(3a), therefore we do not support the discretionary and scientifically unsubstantiated reference to the *"substances of renewable botanical origin".*

During the examination of the proposal some Member States claimed that there are scientific reasons for which, in particular, essential oils should not be classified as CMRs, even though they may contain a CMR component in a concentration above the concentration limit that would result in a mixture being classified as a CMR, under the general rules of CLP for the above mentioned hazard classes.

For reasons of flexibility and compromise, and in order to give these MS the opportunity to scientifically support their arguments, we could accept the 4-year transitional period specifically for essential oils, provided that the above-mentioned MS and/or stakeholders involved:

- will present within 4 years scientific evidence to substantiate their claims .
- will provide scientific research tests to isolate CMR, ED etc. substances from an essential oil, either during the production process or from the final product, and
- the European Commission will evaluate the submitted data. The outcome of the evaluation may be accompanied by an appropriate legislative proposal.

12. Amendment 94: **Annex II – paragraph 1 – point -1 a(new)**, (CLP- Annex II – Part 3 – Section 3.1.1.1):

We disagree to add the "***serious eye damage category 1"*** among the classes that shall bear child-resistant fastenings for the following reasons, expressed already by industry and other M-S :

- Consumer products used many times a day (e.g., hand dishwashing detergents) would bear a CRF. Consumers in order to save time might not close at all the packaging or might transfer the products to another container without CRF. This can have exactly the opposite effect concerning the safe use that the CRF advocates.
- the possibility to cause serious damage to eyes, during management with hands of the above-mentioned products is limited in comparison with other products that are classified as "skin corrosive category 1". Moreover, investigation conducted by different Poison centers in EU (MAGAM II) indicates that serious eye damage is very rare using this kind of products.
- the application of the CRF to the above-mentioned products could lead the industry to stop producing "concentrated low volume products" in order to reduce packaging, as these products shall bear CRF. This is against the Chemical Strategy for Sustainability and the circular economy. Therefore, the packaging cost for SMEs may be increased, without any benefit to the protection of human health.

13. Amendment 96: **Annex II – par. 2,** (CLP- Annex II – Part 3 – Section 3.4 – point b)
Comments: We support the Council Mandate.

14. Amendment 97: **Annex II – par. 2,** (CLP- Annex II – Part 3 – Section 3.4 – point b(a))
Comments: We agree with the EP amendment as it is consistent with our position.

15. Amendment 98: **Annex II, second paragraph,** (CLP-Annex II–Part 3–Section 3.4 – point k (iv(a))
Comments: We agree with EU parliament addition as it is consistent with our position.

16: Amendment 99: **Annex II, second paragraph**, (CLP-Annex II, Part 3, Section 3.4., point k(v(a))
Comments: We support the Council Mandate, i.e., the exemption of skin sensitization, any category and not only of category 1(1A and 1B) as it is proposed by the EP.

17. Amendment 100: **Annex III – paragraph 1 a (new),** (CLP- Annex VI)
Comments: We agree with EU parliament addition as it is consistent with our position.

ITALIAN COMMENTS

Block 1 MOCS: we prefer the Consilium text expressed on 30 June where it was added the article 54a (even if we do not find it in the document 14625/23 on 24 October 2023). The proposal of article 54a represents a reasonable approach to manage all kinds of MOCS without exclude in a prior way, without scientific base, some of them. The timing of 4 years, indicted in article 54a, appears sufficient to elaborate an impact assessment, to discuss relevant and complex technical aspects and, in parallel, to elaborate an appropriate legislative proposal on scientific base by Commission.

Block 2 CLH procedures: we share the indication on the prioritisation for the group, where possible on scientific bases and the reference to the annex XI 1.5 of the REACH regulation. Anyway this should be indicated also for the CA/COMM and not only for the companies.
In other words:
- we agree with EP AM9 (recital 18) and AM51
- the impact of the AMs 52 and 101 should be aligned. Below in the table we proposal a modification for the row 166a (AM52) of the document 14625/23. The part added is the same of the AM101

		EP	Consilium	Italian proposal
166a		*'Whenever considered scientifically justified and possible by a competent authority or the Commission, proposals for harmonised classification and labelling shall prioritise groups of substances rather than individual substances. '*		*'Whenever considered scientifically justified and possible by a competent authority or the Commission, proposals for harmonised classification and labelling shall prioritise groups of substances rather than individual substances.* ***In the case of a proposal for harmonised classification and labelling of a group of substances, those substances shall be grouped together based on clear scientific criteria (as specified in REACH Annex XI (1.5)), including structural similarity and similar evidence-based hazard profiles***

We agree with EP AM55 (timing of twelve months for COMM). Please, delete the words "or mixtures": are a typo (row 177 of the table of the document 14625/23).

We do not support the AM60 because if divergences exist do not necessary means that some of self-classifications are wrong. We do not believe that doing prevail the most protective self-classification as more appropriate it is a correct choice. Indeed, the classification of a substance is based on the data availability of the notifier and often they depend on the presence of impurities and additives in that substance.

Block 3 access to justice: we deem that for the access to justice there are specific legislations, for this reason in our opinion it is not necessary introduce other disposition in the CLP regulation. So we are not agree with amendments 64 and 65.

Block 4 Environmental claims: we do not support the AM102 of the PE, because the Directive 2005/29/EC is under revision. In addition, in our opinion other part of a packaging labelling different from the CLP labelling requirements ("hazard labelling") are out of the scope of CLP regulation, thus it is not necessary to legislate on it..

Block 5 Child-resistant fastenings: concerning the AM 94 an Italian control poison center has underlined that on its experience, cases of accidental exposure to substances classified as eye damage 1 do not cause irreversible damage, consequently imposing the Child-resistant fastening for these kinds of product would have the paradoxical consequence of lowering the warning level towards other products with more severe hazardous that currently need Child-resistant fastenings. Indeed, citizens will be more inclined to leave products open, even those that present a real risk as skin corrosive products, and this situation would be extremely dangerous. For this reason we do not support the AM94.

Block 6 labelling: concerning the AM46 of the PE, in our opinion the writing in front page of the fold out label the information in all MS's languages, where the product is put on the market, it would be null and void what the fold-out labelling represents: a first alert of the product hazardousness both when it is not possible affix a label on the packaging and when the company chose this kind of label to group more languages . It should be underlined that the fold-out has to respect the same format requirements established for a minimum labelling (font size , interlines set up in section 1.2.1.6 of the annex 1) so this AM appears not feasible. So we do not support the AM 46

Concerning the minimum font size of the of the labelling, even if we support referring to the character's size in mm, we do not agree with AMs, 89 and 90. We have already shown in previous Consilium meetings that increasing the size of characters for more bigger label affixed on big package (50-500L, >500L) do not improve the readability. Concerning the AMs 87 and 88 we are in favour because they are the same reported on the the Consilium proposal. In general, for all the other formatting rules (e.g. line-spacing between two rows) we support the Consilium proposal.

Block 7 Refill station: we do not support the AM98 of the EP. In order to improve the use of the refill system and to limit the use of packaging, in our opinion it would be opportune not to extend further to the eye irritant products the list of the products for which should not be possible the refill operation, otherwise the target to reduce plastic package would be nullified.

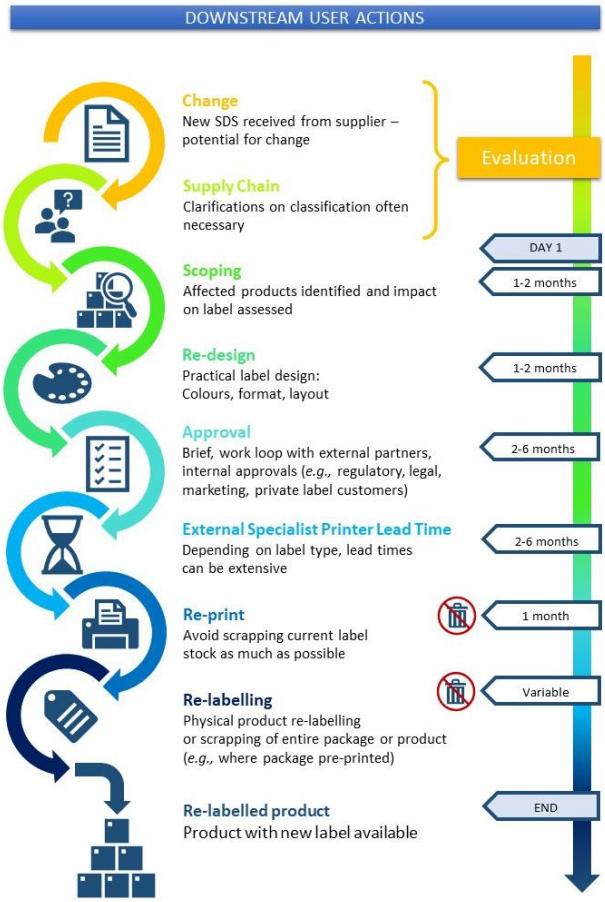
Block 8: *other Amendements*

- AM82 an AM83 EP on **transition period** of article 61 of the CLP. We support the opinion of EP to distinguish the application date of the CLP new rules for substance and mixture. So, for this aspect, we support AMs EP. Anyway, we let's seize the opportunity to request again more time especially for the mixtures. Please, remember that it is in parallel the updating of the labelling as consequence of the 2023/707 regulation (new criteria Eds HH/ENV, PBT vPvB PMT vPvM). In the table below we try to summarize the situation and the Italian proposal.

		Substance	*Substance already on the market*	*mixtures*	*Mixture already on the market*
Article 61	Comm/ Consilium	18months	42 months	18 months	42 months
	PE	18 months	42 months	24 months	48 months
	IT proposal	**24** months	**42** months	**36** months	**60** months

- At the end, even if the EP does not propose Amendments on the "**Updating information on labels**" set up in the **article 30 paragraph 1**, we continue to receive from companies' side concerning analysis on the feasibility of the timing proposal especially for the mixtures. So, we need to continue putting under your attention the enterprise's difficulties. Please, see the fig.1 that shows the necessary time to update a label (especially for formulators of several mixtures when receive a communication of an updated label from its supplier).

  Fig.1 timing need to modify a label, after the evaluation



In the following table, in yellow, we would like to propose a Italian amendment:

COMM	EP	Consilium	**IT proposal**

1. In case of a change regarding the classification and labelling of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in accordance with Article 25, the supplier shall ensure that the label is updated within 6 months after the results of the new evaluation referred to in Article 15(4) were obtained.		1. In case of a change regarding the classification ~~and~~ **or** labelling of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in accordance with Article 25, the supplier **of that substance or that mixture** shall ensure that the label is updated ~~within~~ **without undue delay and no later than** 6 months after the results of the new evaluation referred to in Article 15(4) were obtained **by, or communicated to, that supplier**.	1. In case of a change regarding the classification ~~and~~ **or** labelling of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in accordance with Article 25, the supplier **of that:** **i) substance ~~or that mixture~~** shall ensure that the label is updated ~~within~~ **without undue delay and no later than** 6 months after the results of the new evaluation referred to in Article 15(4) were obtained **by, or communicated to, that supplier;** ii) **that mixture shall ensure that the label is updated without undue delay and no later than 9 months after the results of the new evaluation referred to in Article 15(4) were obtained by, or communicated to, that supplier.**

- AMs 14 and 36 on **NAMs**:

  We do not support the AM14 (recital 33) while we support the AM36 with adequate evaluation and timing.

NOTAT

Ministry of Environment
of Denmark
Department

Drinking Water and Chemicals
Case No 2023-10726
Ref. MICGH/LIHAS
October 31 2023

Denmark's comments to the European Parliament's amendments to the Commission's proposal for revision of the CLP Regulation

Denmark thanks the Presidency for providing the opportunity to submit written comments from Member States in advance of the Trilogues. Denmark supports the Presidency's ambition to conclude negotiations on the CLP Regulation under the Spanish presidency of the European Council. Our written comments to the Parliament's proposal are set below, grouped under the eight clusters identified by the Presidency. Denmark reserves the right to submit further comments at a later stage in the Trilogues.

Block 1) MOCS and essential oils

The proposal from the Commission for the revision of the CLP-regulation aimed to codify the current practice on the classification of MOCS in articles 10(1) and 11(1). However, it has become clear that there are very different approaches to the classification of MOCS and that there is a broad interpretation of the current guidelines. With the proposal from the Parliament, certain MOCS substances will be permanently exempted from being classified. This is not something that Denmark can support, as it will lead to a weakening of the rules as they stand today. It remains the Danish interpretation of the CLP that all MOCS are covered by the CLP and that MOCS, including essential oils or substances of 'renewable botanical origin' should be addressed in accordance with the guidelines set out by ECHA.

One of the core principles of the CLP Regulation is that classification is based on scientific data and when the criteria for classification is met, a hazard class and a category is assigned to the substance. With respect to the wish to exempt all MOCS of 'renewable botanical origin' there is no relevant or scientific data yet presented that could lead to an exemption for the entire undefined and incredibly diverse group of substances.

Denmark notes that the Parliament's proposal in amendment 3 / Recital 2a puts forward socio-economic concerns. However, social and economic factors should not be considered when assessing the inherent hazardous properties of a substance that could lead to a classification. A classification is based on relevant and scientific data alone. The Parliament also suggests a review clause on MOCS, however Denmark is of the opinion that such a clause must set out a commitment to bring forward a legislative proposal on the matter of classification of MOCS.

Block 2) Procedure for harmonisation and notification

Denmark is generally positive with regard to the Parliament's proposals in Block 2, but notes the concerns raised by the Commission and other Member States at the last meeting of the Council Working Party on timelines. Denmark's reading of the Parliament's amendments is that the parliament seeks to streamline the process for harmonised classifications, whereby proposals for classification should prioritise groups of substances rather than individual substances (amendment 9,

52 and 101) and the timelines for the adoption of delegated acts (amendment 55). Denmark is flexible with regard to these points.

Denmark has sympathy for the Parliament's proposal that where registrants and notifiers disagree on classification, the most protective classification shall be used (row 200a). However, in practice such an approach may lead to scientifically unjustified classifications with no mechanism in place to resolve scientific disagreement. Therefore, if the Council should accommodate the intention of the proposal from EP, we would prefer that a mechanism for reaching an agreement on the classification is built into the regulation. We are flexible with regard to the precise formulation of this amendment, but believe that this proposal should be incorporated into the final CLP text.

Block 3) Right to request action and access to justice

Denmark welcomes efforts to improve transparency in the classification of hazardous chemicals, but has serious reservations about Parliament's proposal. Denmark cannot support Parliament's proposal, which would represent a significant interference with the day-to-day operations of our authorities.

The CLP Regulation does not prevent interested parties from bringing issues relevant for classification and risk management to the attention of the authorities. The proposal may even prove counterproductive as rigidly defined approaches to transparency could lead to problems with regard to self-incrimination, as this may discourage suppliers from engaging in early dialogue with authorities. It is also unclear what the reporting obligations set out in amendment 64 point 7 would entail for Member States.

The proposals on access to justice will also potentially lead to a significant increase in administrative costs for authorities. Decisions on the best process for addressing classification of substances should not be determined by concerns over litigation. Denmark is worried that the use of litigation could be abused and lead to backlogs in the classification process and an approach to classification guided by the fear of litigation instead of evaluation of scientific arguments.

Block 4) Environmental claims

Denmark would prefer to see the issue of environmental claims handled in the horizontal legislation proposed under the Green Claims Directive. If new rules on the use of green claims under the CLP Regulation are introduced, it is vital, that these rules do not have negative consequences for the use of ecolabelling, such as the EU flower or the Nordic Swan. As Denmark understands it, the Parliament's proposal respects this, and as such, we are able to show a degree of flexibility on this point.

Block 5) Child-resistant fastenings

Denmark has sympathy Parliament's proposal, which is designed to improve child safety. Initial feedback from our industry actors suggests that a significant number of daily household products will be affected by this proposal, necessitating new packaging. It is also unclear whether the proposed changes will have a positive or negative effect upon consumer behaviour, as complicated packaging may simply lead to products being transferred to alternative containers.

Parliament's proposal relates to a provision in Annex II, part 3. Article 53(1) empowers the Commission to adopt delegated acts amending the criteria for child-resistant packaging. Denmark suggests that the negotiating parties work towards a solution, whereby instead of adopting the

Parliament's proposal, the Commission and Member States agree to examine this proposal within the CARACAL forum.

Block 6) Labelling obligations + Minimum dimension of labels, pictograms and font size
Denmark does not support the Parliament's proposal on font sizes. Denmark has under the negotiations in the Council Working Group consistently raised the issue of font sizes and the resulting costs for businesses. While we agreed to the Council negotiating position, we would have preferred to have also seen minor reductions on the font sizes for smaller packages compared to the Commission's proposal. The Council negotiation position was a compromise we were though willing to accept, given concerns raised on readability by some Member States.

Taking the Commission's initial proposal as a starting point, which is of course broadly the same as the Parliament's proposal, feedback from Danish industry bodies suggests that the costs involved for the new proposed font sizes could add up to 50 million euros in initial costs, with annual ongoing costs of up to 50 million euros for Danish companies alone, as larger font sizes will require larger labels or fold-out labels. These costs are disproportionately high compared to the potential benefits – particularly for the larger packaging sizes. Broadly speaking, three options are open to suppliers, all with their own cost implications:

i) Use larger labels – Where suppliers print their own labels, suppliers may have to invest in new printers capable of printing larger labels, if they print labels themselves. Where suppliers instead purchase labels from third party label producers, prices will increase in line with the extra material needed for these larger labels.
ii) Use fold-out labels - Industry estimates suggest unit prices will increase eightfold per label and may also require suppliers to invest in new machinery to affix these labels.
iii) Reduce the number of languages on the label – This will have a knock-on effect on the marketing operations of suppliers, as the number of possible markets for each individual product will be reduced.

As such, Denmark strongly favours the compromise position set out in the Council negotiating mandate, which better balances the businesses costs and concerns on readability. If at all possible, we would also like to see reductions for the smaller font sizes – for instance from reducing the font size for the smallest packages to 1.2 mm and 1.4 mm for packaging of between 3 litres – 50 litres.

Denmark also favours the Council's negotiating position on the regulation of fold-out labels, which codifies ECHA's guidelines on front pages. Ensuring the most important information is readily available on the front page of a fold-out label will improve consumer safety. Council's proposal ensured that this was the case, whereas the proposal put forward by Parliament will mean that important information such as hazard pictograms and product identifiers can be placed on the inner pages of a fold-out label. Parliament's proposal on fold-out labels would codify rules on fold-out labels that are weaker than the ECHA guidelines. Denmark is flexible with regard to rules on the inner pages of fold-out labels, but prefers the position adopted in Council, as the logical ordering of labels is best dealt with via guidelines, where for instance linguistic concerns are easier to address.

Block 7) Refill stations:
Denmark remains in favour of the positions adopted by Council on refill sales, including the hazard classes determining which substances and mixtures may not be sold via refill. Council's position reflected lengthy discussions on this topic, resulting in a nuanced compromise that creates a workable system for refill sales. Labelling was a key issue in this regard, and Denmark regards it as important,

that the revised CLP clearly states that labels must be made available for consumers at refill stations, as set out in Council's negotiating position (row 358a).

Denmark has been made aware by the industry that adding eye irritation category 2 to the list of hazard classes that cannot be sold via refill, as EP suggests, would cause significant problems for the sale of detergents via refill stations.

In addition to this, we have also been alerted by industry actors about an emerging area of the refill market where the consumer buys a small container with a concentrated product to later dilute in a container at home. The concentrated products could be household detergents, cleaning products such as glass spray and dishwashing liquid. This form of refill could be affected by the rules for refill stations when the consumer needs to refill the small container with the concentrated product again. The concentrated product could possibly be excluded from refill stations as the mixture in the product is classified with one or more of the hazard classes mentioned in Annex II, part 3.

Denmark does not support the Parliament's proposed deletion of the rules relating to safety considerations for refill stations in Annex II, part 3.4 (rows 359-366), nor does Denmark support the Parliament's amendment requiring the supplier must be available on site to provide maintenance and reachable for immediate assistance, including emergency assistance. Denmark also prefers the definitions for refill set out in the Council Negotiation mandate (missing from four-column table, but Article 3, (38, 40 and 41).

Block 8) Other amendments

Online sales

Denmark notes that the Parliament has broadly speaking adopted the rules on online sales as they stood in the Commission's initial proposal. Council adopted various amendments on online sales, which Denmark believes have significantly strengthened the proposal, for instance with the addition of Article 4(11) and the reformulation of Article 48a.

It is of the utmost importance for Denmark that in the coming negotiations that the Council maintains its position on online sales as agreed upon in the Council negotiating mandate.

Non-Animal Methods (NAM) / Alternative methods

Denmark understands that the changes put forward by Parliament on non-animal methods, will not lead to a material change in the law as it stands today. As such, Denmark does not object to the proposals put forward by Parliament. However, if the proposals on animal testing will lead to a material effect upon the effectiveness of the classification system as non-animal methods are introduced, it is be necessary to assess the safety implications of the change. Non-animal methods must provide the same level of safety as animal testing. The issue of non-animal methods have not been considered in the impact assessment.

Timelines under Article 37

At the Working Party meeting of the 21st June 2023, Denmark raised a practical issue relating to timeframes in Article 37(7) in the Council's negotiation proposal, regarding the transfer of substances that have been included in the candidate list referred to in Article 59(1) of REACH for certain hazard classes to CLP annex VI. The Commission stated at the meeting that it would look into this issue, which we are now taking the opportunity to follow up on.

Our Competent Authority informs us that it is currently only possible to submit dossiers regarding SVHC twice a year to ECHA. As such, we believe that the 6 month period after entry into force is too short, if all possible submissions are to be registered. Therefore, we suggest that the submission period is extended from 6 months to 12 months, unless the process for submission according to REACH is not altered, so as to avoid the duplication of assessment of hazardous substances. Similarly the 24-month period in Article 37(7) should be extended to 30 months and the 18-month period in Article 37(7a) should be extended to 24 months to take account of the extended submission periods. Denmark notes the Commission's remarks on the need for similar updates to paragraphs 8-11, which we also support.

[Background: As the classification guidance for the new hazard classes is not expected to be finalized before Q2 2024, it would be difficult for member states to submit CLH classification proposal before the new guidance is available. The SVHC process takes place twice a year (normally around February and August). The submission deadlines exist due to the need to connect the legal timelines prescribed in Article 59 of REACH (*Identification of substances referred to in Article 57*) with a meeting of the Member State Committee (MSC), should a case need to be referred to the MSC to strike an agreement, as happens quite often in the SVHC process. Without this connection, it could result in the legal timelines be exceeded in some SVHC cases, thereby leaving them open to legal challenge on a purely procedural matter. We refer to the following guide on the ECHA homepage for more information: https://echa.europa.eu/da/support/authorisation/substances-of-very-high-concern-identification]

Council of the European Union
General Secretariat

Interinstitutional files:
2022/0432 (COD)

Brussels, 07 November 2023

WK 14310/2023 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.:	ST 14625 2023 REV 1
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 BG, DE, DK, EL, FI, HR, IE, IT, NL, Pl, PT, SE, LV on the proposed amendments by the European Parliament

Delegations will find in the Annex the comments by Member States on the full text of the proposed amendments by the European Parliament on the CLP revision, as set out in document ST 14625 2023 REV 1

CLP Regulation

PT comments | 03.11.2023

1) **MOCS and essential oils (amendments 3, 19, 106, 24, 28 and 116)**

In our opinion, the Council's approach is a delicate balance and therefore should be maintained as much as possible.

2) **Procedure for harmonisation and notification (amendments 9, 52, 55, 101 and 60)**

In the Amendment 55, although we consider relevant to increase effectiveness of harmonized classification and labelling process, we have some doubts about the feasibility of the deadline foreseen for the adoption of delegated acts by the Commission (only 12 months after the publication of the opinion of the Committee for Risk Assessment).

In Amendment 55, we suggest removing the reference to mixtures since article 37 is only applicable to substances:

«*(...) shall adopt delegated acts in accordance with Article 53a to amend Annex VI by inclusion of substances ~~or mixtures~~ together with the relevant classification and labelling elements and, where appropriate, the specific concentration limits, M-factors or acute toxicity estimates in Table 3 of Part 3 of Annex VI*».

3) **Right to request action and access to justice (amendments 64 and 65)**

In principle, amendment 64 (addition of new article 43) seems to bring the opportunity for the submission of evidence in cases where hazardous properties of a substance or a mixture may not have been sufficiently considered in the classification or labelling process. However, we have difficulties understanding when this procedure applies. This new amendment should not be an opportunity to delay or to hinder the introduction of new entries in Annex VI. We would also like to note that the possibility for the industry to submit a CLH dossier already exists as well as the preparation of a CLH dossier by the CA. All stakeholders have the possibility to provide information on hazard properties during the consultation of a new hazard classification and labelling. We have therefore reservations regarding this amendment. Nevertheless, in case this amendment is considered as appropriate, we have the following concerns:

Regarding point 1 [«*1. Any natural or legal person, individually or in association, shall be entitled to submit substantiated evidence to competent authorities* (…)»], the human biomonitoring data and environmental monitoring data by itself are not related to hazard properties and should not be included in the same data package. Additionally, the hazardous property of a mixture is not assessed in the harmonization of classification and labelling process, as mixtures are not subject to CLH.

In that sense, we propose the following text:

«*1. Any natural or legal person, individually or in association, shall be entitled to submit substantiated evidence to competent authorities as referred to in Article 43 or the Commission, such as peer-reviewed studies~~, human biomonitoring data, or environmental monitoring data~~, on the hazardous properties of a substance ~~or mixture~~, or of substances ~~or mixtures~~, showing that hazardous properties of a substance ~~or mixture~~ or of substances ~~or mixtures~~ may not have been sufficiently considered in the classification or labelling process.*»

On the other hand, we don´t consider adequate to suggest REACH Regulation amendments in CLP revision process. Therefore, the following text should be removed:

«~~*4. Where the assessment has shown a wide dispersive use of and/or consumer exposure to the substance or mixture concerned, the competent authority or the Commission shall initiate a risk management process under Article 59, Article 69, or Article 68(2) of Regulation (EU) No 1907/2006. Where the assessment has shown a lack of information on the risk to health or the environment posed by a hazardous substance or mixture, the competent authority or the Commission shall require companies or any other relevant actor to provide more information, with a view to taking risk management measures under Title VI, VII or VIII of Regulation (EU) 1907/2006, where necessary.*~~»

Additionally, the development of an opinion in 6 months (by the Commission or the Competent Authority) seems to be too short, since the amount of information to be received is unknown.

On amendment 65 (regarding article-43a), the proposed text doesn´t seem to be necessary since transparency and access to justice is already implemented and regulated.

4) Environmental claims (amendment 102)

Regarding this subject, we consider that amendments on environmental claims should be made on sectorial and more adequate legislation.

5) **Child-resistant fastening (amendment 94**)

We would like to have more information about impacts on economic operators and about the products that would be covered by this obligation.

6) **Labelling obligations + Minimum dimension of labels, pictograms and font size (amendments 46, 87, 88, 89 and 90)**

Considering the amendment 46 (article 32 – paragraph 6), in the compromise text adopted by COREPER this paragraph was deleted and the content of the front page of the fold–out label was included in section 1.2.1.6. of Annex I. This new provision foresees the inclusion of all the information stated in article 17(1), except only paragraphs (f), (g) and (h) (the last one not mentioned in EP amendment). In that sense, we do not agree with the EP amendment, since almost all the mandatory information included in the label is in the front page of the fold-out label.

7) **Refill stations (amendment 98)**

We have concerns about the impact of this proposal and would like to have more information about the products that would be covered by this change and about the impacts on other environmental and sustainability policies (*e.g* reduction of waste or plastic).

CROATIAN COMMENTS ON THE EP AMENDMENTS

Croatia appreciates the possibility of providing written comments on the amendments of the European Parliament in the spirit of finding a compromise solution and finalizing the revision of the CLP regulation. Consequently, at this stage, we submit a position on individual proposals of the EP as follows.

EP amendment, Annex II, Part 3, Section 3.1.1.1.

HR has sympathy for the EP proposal in light of safety reasons for extending the requirement for a child-resistant fastening (CRF) to serious eye damage category 1.

Still, HR prefers the current CLP text and is not in favour of extending it to any additional hazards due to possible negative sustainability initiatives and possible other negative impacts. Furthermore, it should be highlighted that this issue is not covered by the impact assessment.

EP amendment, Annex II, Part 3, Section 3.4 , paragraph (k)

HR cannot support this EP amendment related to the addition of an eye irritation category 2 due to high number of detergents that would be exempted from the possibility to be sold at refill station.

EP amendment, Annex II, second paragraph, amending provision, numbered paragraph (3.4), second subparagraph, point (ba), line 358a

Croatia is in favour of this EP amendment.

(ba) a label is available at the refill station, free-of-charge for consumers in a self-adhesive sticker form to be affixed on the container used by the consumer. Where refill stations provide several substances or mixtures, labels should easily and clearly identify which substance or mixture provided at the refill station the labels correspond to;

Furthermore, HR believes that CLP regulation is not appropriate legislative act for regulating prohibition of the use of environmental claims.

General comment

HR prefers Council position for other EP amendments and could consider to be flexible after receiving clarifications due to some uncertainties related to current proposals as defined by the EP, especially related to MOCS.

Ministry of Economic Development and Technology
Republic of Poland

Warsaw, November 3, 2023

Non – paper by Poland on selected amendments to the provisions of Regulation (EC) 1272/2008, proposed by the European Parliament

In principle, Poland supports most elements of the current version of the revision proposal, which reflects and enhances the experience gained to date legal transparency in many aspects, including responsibility on labeling for platforms e-commerce, introduction of digital marking for some label elements, clarifications on certain concentration limits and increased clarity of the classification list and labeling (Classification and Labeling Inventory – so-called C&L Inventory). Nevertheless, at this stage of the EU decision-making process, we have identified some concerns in relation to selected amendments to the provisions of Regulation (EC) 1272/2008, proposed by the European Parliament.

Here are our main comments, observations and questions presented in accordance with thematic block followed the EP amendments:

Block 1 MOCS and Essential Oils: Amendments Nos. 3, 19, 106, 24, 28, and 116.

In case of substances containing more than one constituent (so called MOCS), in principle, Poland is against specific exemptions for substances of biological origin. This approach seems to have no substantive justification and is inconsistent with the precautionary principle. In case this proposal remains, due to the many tasks entrusted to the Commission, we agree to a 6-year review period for this solution.

Block 2 Harmonization and notification procedure: amendments 9, 52, 55, 101 and 60

In the case of amendment 52 (Article 37 – paragraph 1 – subparagraph 3 a (new), we point out, that the provision regarding the prioritization of group applications compared to those for a single substance should list all institutions that may prepare an application for harmonized classification, and not only the competent authorities of the Member States and the Commission.

With regard to amendment 55 (Article 37 – paragraph 5 – subparagraph 1), we believe that the deadline previously agreed in the Council for the adoption of a delegated act on the harmonization of labeling classifications should remain as "undue delay". In our opinion, the 12-month period for adopting a delegated act may be difficult or impractical to implement. Additionally, it is necessary to remove the word "mixtures" in the context of the inclusion of both substances and “mixtures” in Annex VI. The procedure applies only to substances.

+48 222 500 123
kancelaria@mrit.gov.pl
gov.pl/development-technology

Pl. Trzech Krzyży 3/5
00-507 Warsaw
Ministry of Economic Development
and Technology

We also support Amendment 101 (Article 37 – paragraph 2 – subparagraph 1), which concerns clear scientific criteria for proposals for harmonized classification for groups of substances.

In the case of amendment 60 (Article 41), Poland considers that in the case of two disputed entries in C&L inventory and lack of consensus between the registrant and the notifier, the proposed provision will lead to the use of a stronger classification without scientific justification. The classification should be adequate and consistent with the CLP criteria, rather than overly strict.

Block 3 - Right to demand action and access to justice: amendments 64 and 65. 4).

Regarding Amendment 64 (Article – 43 (new)), first of all, we would like to ask for a technical explanation. The entry states that "The following Article -43 is inserted:". Should we understand that the proposed provision is to be added under the current provision of Art. 43 of Regulation 1272/2008? In other similar cases, the phrase "is added" or "is replaced by" was used.

As for substantive comments, we absolutely do not support changes that impose new obligations on Member States, especially those that were not analyzed in the impact assessment, which is crucial in this case. We also believe that the only authority that is able to scientifically analyze the evidence is the RAC Committee.

Block 4 - Environmental claims: amendment 102.

We do not submit any comments.

Block 5 - Child-resistant closures: amendment 94.

Poland supports the position of the European Commission and the EU Council. In our opinion, the scope should remain in line with the current text of the draft CLP regulation, without extending the requirements to include additional classes of threats. Amendment 94 (Annex II ‑ Part 3 ‑ Section 3.1.1.1) is acceptable in terms of protecting human health, but may cause a disproportionate burden on industry. According to estimated data received from the detergent industry, new requirements may occur be covered by approximately 50% of the detergent product portfolio. Packaging with closure protecting against opening by children will be subject to attestation, i.e. testing and assessment product in terms of compliance with applicable technical standards in this area. This this type of research is carried out by accredited laboratories, which will most likely significantly increase costs of producing a wide group of final products, including everyday products. Due to the current conditions, entrepreneurs may be burdened with additional economic costs, leading to the breaking of important links in value chains, or even to termination of the economic activity of SMEs.

Moreover, there is a high risk that with this legal measure environmental objectives may not be achieved. Consumers most likely using fluids on a daily basis dishwashers will replace newly designed packaging, i.e. in case of integrated one - with a secure closure, and in case of regular ones - with easier dosing. Therefore, during the filling process

+48 222 500 123
kancelaria@mrit.gov.pl
gov.pl/development-technology

Pl. Trzech Krzyży 3/5
00-507 Warsaw
Ministry of Economic Development
and Technology

ordinary containers may result in increased emissions of chemical substances/mixtures to the sewage system or directly to surface water in situ. Widespread use of child-resistant closures in detergent products would be counterproductive to industry's efforts to make it safe and sustainable, in line with the ambitions of the EU Green Deal, because it can prevent reuse and refilling of the packaging. It would also carry packaging recycling implications because CRF closures are often not accepted in sorting plants, which leads to their burning or landfilling.

Block 6 - Labeling obligations, minimum size of labels, pictograms and size fonts: amendments 46, 87, 88, 89 and 90

Poland prefers the EU Council amendment regarding the minimum font size in Annex I (section 1.2.1.4). Poland supports the position of the Commission and the EP on the contrast of labels in Annex I [(section 1.2.1.5(a)]. In our opinion, there seems to be a requirement to print the label text in black disproportionate and inconsistent with the product identifier which forms part of the label, in accordance with Annex I 1.2.1.5 (according to Article 17(1)), but may appear in the form of a product logo or trademark.

Poland supports the EU Council amendment regarding line spacing in Annex I, (section 1.2.1.5, paragraph (b)), which will improve the readability of the text. The Poland supports the EP amendment adding section 1.2.1.5.a - regarding the introduction of the order of official EU languages on the label.
Poland supports the EU Council amendment to include format requirements fold-out labels. It draws attention to the fact that by imposing a minimum size font, the use of this format may become impossible to implement in practice. Poland supports the position of the EU Parliament on transitional periods (Article 61 CLP and art. 2 of the revised regulation), which allows for additional time to implement changes mixtures.

Block 7 - Refill stations – amendment 98

In the case of Amendment 98 (Annex II - Part 3 - Section 3.4. - point k - point iv a (new), we believe that the change introduced is too far-reaching. Under the current provisions make no sense of the "Refill sales" solution. We suggest leaving only serious eye damage cat. 1, but we are open to discussion regarding removal the EP proposals from the CLP text in this regard. Extension of the ban on bulk sales to include a hazard class - eye irritation category 2, seriously would limit the ability to sell many detergent products and would have a negative impact for environmental purposes (consumers are not able to fill it with the selected liquid unit packaging).

Block 8 – Other amendments

During the work in the ENVI Commission, it was also decided to extend the provisions of Art. 48 CLP regulation by adding a point on the prohibition of using environmental claims in regarding substances and mixtures classified as hazardous. In our opinion, this change falls outside the scope of the CLP Regulation. Poland expresses doubts whether the provisions regarding the declaration proposed by the EP environmental issues, do not fall outside the scope of the CLP Regulation. Environmental statements and

packaging sustainability principles are already included as part of the Circular Economy Action Plan. Moreover, it currently is pending directive on empowering consumers in the transformation process environmental protection and the directive on the justification of environmental claims, which is aimed to protect consumers and businesses from the so-called "greenwashing" and to enable consumers making informed on purchasing decisions based on reliable claims and labels environmental. It is important to have environmental statements and principles for sustainable development packaging were regulated by dedicated regulations to ensure legal consistency. Additionally, prohibiting or restricting the use of environmental claims may have a negative impact on the industry actions towards a more sustainable and pro-ecological production.

Poland in principle supports the position of the Commission and the Council on updating the label according to Art. 30 (1 and 2). However, changes have been made to Annex I in the tables showing the relevant requirements for font sizes used on labels, and update deadlines labels are not satisfactory.

Mandatory increase in font sizes and spacing requirements introduced on the labels seem virtually impossible to implement. After changes, the current label sizes will become unsuitable for most products, especially for larger packages with a capacity above 50 L. New solutions may also limit the number of official languages that can be used on one label. They will also generate additional redesign costs and label printing. Poland believes that this issue should be discussed further in order to improve the proposed requirements.
We are wondering if it is possible at this stage to add a new range for packaging up to 1L – e. g. 1 mm and to reduce the minimum font size to 1.2 mm for packaging up to 3 lL

Moreover, Poland asks the Presidency for considering to extend the necessary period to update the label and packaging from 6 months to at least 12 months. Even more so the Poland requested it several times, and during the last G07 meeting (June 21 2023) supported the German delegation in this respect. In its justification, we think that the proposed time to update the labels is technically unfeasible for the industry. Entrepreneurs need sufficient time to decide whether to continue implementing after the classification change product for sale, and if so, the text placement on the project should be re-planned on the level of a graphic design, re-plan logistics activities and entire industrial production.

We would like to draw your attention to the amendment 61, referring the provisions of art. 42 of the CLP regulation. The European Parliament proposed to change the classification and labeling list publicly available free of charge and online accessible in a user-friendly format. We are wondering how one should determine “a user-friendly format” in practice and we are asking question whether it is necessary to introduce such a provision in the legal act.

We thank Presidency for the its efforts in negotiations with the EP and we are open to further discussion.

+48 222 500 123
kancelaria@mrit.gov.pl
gov.pl/development-technology

Pl. Trzech Krzyży 3/5
00-507 Warsaw
Ministry of Economic Development
and Technology

LV Comments on ST 14625 2023 REV 1

Thank you very much for WP Technical harmonization (CLP revision) fruitful meeting held on 23 October 2023. By this we would like to kindly provide some written comments regarding the proposed amendments by the European Parliament to the proposal for a regulation amending the regulation No. 1272/2008 (CLP). Please find the comments below.

1. **Amendment 34**: The amended text of Subparagraph 2 of Article 6(3) can be misinterpreted. From the amended text one can understand that this specific subparagraph applies to plant protection products (within the regulation (EU) 1107/2009) and biocides (within the regulation (EU) 528/2012) only. Although, the initial intension was to cover a wider range of mixtures.

2. **Amendment 64**: The newly introduced Article 43 Right to request action from competent authorities and the Commission might stand against existing clear and transparent harmonization processes. Currently there are provisions settled under Article 37 Paragraph 6 of the CLP regulation, which provides sufficient legal protection. Additionally, it is also unclear what is the purpose of including Article 43(5) provisions relevant to REACH in the CLP regulation. Furthermore, we believe that the newly introduced Article 43 will also severely and unnecessarily increase the administrative burden for Member State CLP competent authorities.

3. **Amendment 65**: The introduced Article 43a Access to justice is rather unclear and in our view it is unnecessary. The provisions settled under Article 43a should be covered by the Market surveillance regulation and/or by the Green Claims Directive Proposal (COM(2023) 166 final), and not the CLP regulation. Especially, if the introduced text is being viewed in light of the scope and purpose of the CLP regulation, that is provided under Article 1.

Sweden has the following comments on the EP amendments;

Provisions on classification of multi-constituent substances, Article 5(3)

- EP amendment 3, 19, 106, 24, 28 and 116

The idea behind the provisions in the original proposal of the Commission was to codify current practice on the classification of substances containing more than one constituent according to Articles 10(1) and 11(1) and current guidance on the application of the CLP criteria. Hence, the issue of classifying these substances were not considered in the impact assessment of the original proposal from the Commission. During Council negotiations, it became apparent that there were diverging views on what was current practice and that the guidelines had been applied differently by relevant actors.

The CLP Regulation is a central legislative act in the area of chemicals, with the purpose of identifying hazardous properties of substances and mixtures via hazard classification. **One of the core principles in the Regulation is that the classification should be based on relevant and scientific data and a certain hazard class and category is assigned when the classification criteria in CLP is met**. It is crucial that this principle is upheld in order to ensure that the purpose of the Regulation is not undermined. There is no legal basis for considering social or economic impacts within the context of the Regulation.

There is currently no available scientific data that justifies the introduction of a general exemption for all substances from renewable biological origin containing more than one constituent from the proposed classification rules in Article 5(3). This article states that data for the individual constituents of the MOCS should normally be used as the basis for hazard identification of CMR, endocrine disruption for human health and the environment and the persistent, bioaccumulative and mobile properties of a MOCS. The introduced exemption is therefore discrepant to the premises on which the CLP Regulation apply. Additionally, there is no evidence justifying a differentiation between substances of renewable biological origin containing more than one constituent and other substances containing more than one constituent why the introduction of special provisions for the first mentioned may lead to unfair and distorted competition.

In order to properly regulate the classification of MOCS and to ensure a procedure that is fit for purpose, there is a need for more scientific data to assess the suitability of classification rules for MOCS and if there is evidence to justify specific exemptions from these rules based on agreed criteria. **Sweden therefore strongly favours the Council position to introduce a review clause obliging the Commission to present a report on the issue and to keep status quo regarding the classification of MOCS for now.**

The adoption of the general approach in the Council depended specifically on Member States finding an agreement on the issue of MOCS. Certain Member States wanted to go in the direction of the EP amendments, whilst some wanted to further clarify the Commission proposal, entailing all MOCS should be classified similar to mixtures for CMR, endocrine disruption for human health and the environment, and for persistent, bioaccumulative and mobile. By maintaining status quo and introducing a review clause to ensure the Commission shall assess current practice as well as provide scientific data for any provisions when it comes to the classification of MOCS, a compromise could be found. Sweden notes that the

mandate is delicate and believe flexibility within the scope of the adopted Council mandate could be a way forward. For example, it could be possible to elaborate on specifying what the Commission report should include as a minimum, as well as the proposed time frame. Additionally, the use of substances and mixtures is regulated in separate legislative acts, such as the Cosmetics Regulation, where it is possible to introduce provisions specific to that area of use on a risk-based approach.

Online sales, Article 4(10)

- No corresponding EP amendment

Sweden considers that the proposed amendments relating to Article 4(10) and (11) in the Council general approach should be introduced in the Regulation. The purpose is to ensure that substances and mixtures cannot be placed on the market unless they comply with the CLP Regulation as well as clarify the obligation of actors outside the EU to ensure that there is a responsible supplier within the Union who shall fulfil the provisions of the CLP Regulation in order to avoid the situation where consumers become importers.

Refill stations, Article 35(2a) and section 3.4 in Annex II

- EP amendment 48, 96, 97, 98, 99

Sweden considers that the provisions on refill stations in Article 35(2a) and section 3.4 in Annex II should be limited in accordance with the Council general approach in order to ensure that the provisions does not go beyond the scope of the CLP Regulation as well as regulate aspects which are of relevance with regards to the purpose of the Regulation.

Sweden supports EP amendment 48 as it corresponds to Article 35(2a), second subparagraph in the Council general approach.

Sweden is flexible on EP amendment 96 as the purpose of the amendment seem to align with the amendment of point 3.4 (b) in Annex II to the Regulation in the Council general approach.

Sweden is concerned that EP amendment 97 may imply that consumers take on the responsibility regarding the labelling of a refilled container. Such approach would be disproportionate and contrary to the obligations of the CLP Regulation, where the suppliers carry the responsibility for labelling of substances and mixtures placed on the market.

Sweden is flexible on EP amendment 98 and 99 but can conclude that the inclusion of the hazard class "Eye irritation, cat 2" may lead to the exclusion of several substances and mixtures from being provided via refill stations.

Right to request action

- EP amendment 64

Sweden considers there is no need for EP amendment 64 as current requirements in the Regulation, together with market surveillance, sufficiently ensures that substances and

mixtures are classifications correctly and that action can be taken in the event of non-compliance.

Sweden also notes that there is a need to differentiate between the purpose of different chemicals legislations, where the CLP Regulation aims at identifying and communicating hazardous properties of substances and mixtures whilst the Reach Regulation aims at regulating risks from substances and mixtures via authorizations, restrictions and prohibitions.

Access to justice

- EP amendment 65

Sweden considers there is no need for EP amendment 65 as there is already legislation in place to sufficiently ensure the right to access to justice, i.e. via Regulation (EC) No 1367/2006.

Fold-out

- EP amendment 39, 44, 46, 91

Sweden considers that EP amendment 39 and 46 would be disproportionate and contrary to the aim of allowing the use of fold-out labels which is to ensure flexibility. The EPs proposal to include both hazard and precautionary statements in all languages of the Member States where it is placed on the market, would mean that a large amount of information have to fit on the front page whilst lacking important information such as the hazard pictogram. Sweden considers it sufficient to regulate the front page of a fold-out label in line with current guidance and in accordance with Section 1.2.1.6 in Annex I in the Council general approach.

Sweden supports EP amendment 44 as it corresponds to Article 31(1) in the Council general approach.

Sweden is flexible on EP amendment 91 as long as the provision includes an objectively enforceable criterion.

Format requirement, Article 31(3) and Section 1.2.1.4 and 1.2.1.5 in Annex I

- **EP amendment 87. 88. 89. 90**

On the basis of experience from market surveillance, Sweden considers there is need to regulate legibility in terms of font size, contrast and spacing in order to ensure that relevant actors can understand hazard information on labels and packages of substances and mixtures.

Contrast has been regulated in Article 31(3), but the impact assessment and experience from market surveillance has shown that this has not been sufficient. In the proposal from COM, only the background color is regulated. To make the provision on contrast clear and enforceable, Sweden considers it important to regulate the color of the text in line with Section 1.2.1.5 in Annex I in the Council general approach. Sweden is flexible on font size and spacing.

IE Written Comments following Tech Harm meeting to discuss European Parliament amendments to CLP on October 23rd 2023

Please find below the IE comments on the following amendments:

Amendment 2:
It is not technically correct to say '*Substances containing more than one constituent are not intentional mixtures'.* These are not mixtures at all – either intentional or unintentional. Our preference is it is best to refer to them as substances.

Amendment 3:
We note recital 2a relates to relates to the "essential oils" matter discussed previously at Council see comment re same in this briefing paper.

Amendment 7:
In relation to digital labels, the proposal focuses on label elements that are allowed to be provided in a digital format only but doesn't mention the elements that should be provided on both the physical and digital labels. We suggest that the Unique Formula Identifier, the hazard statement, the precautionary statement, and the signal word, should be on the digital label as well as remaining on the pack. This is to ensure that people with a visual impairment who cannot read the pack label, and who rely on software to read a digital label, have access to this essential information.

Amendment 10:
With respect to the insertion '*Interested parties should be given the opportunity to comment where appropriate',* we seek clarity as the purpose of these comments and in what context that they would be made and to whom would such comments be sent**.** Perhaps the intended purpose of the comments in this proposed amendment could be reflected on.

The ability of COM to administratively adopt a delegated act within 12 months of the publication of the RAC opinion in all cases needs to be considered and this amendment may need further reflection.

Amendment 11:
While we can agree if during the course of activities an incomplete notification etc. is identified by ECHA that ECHA could have the ability to remove the notification after notifying the notifier, if this is translates into a duty on ECHA to review the inventory, we would question how feasible is it for ECHA to review the inventory and remove incomplete, incorrect or obsolete entries. We would also question as to whether it is an appropriate use of ECHA's resources. This would be a very significant piece of on-going work for ECHA. We are also mindful that there is an onus on notifiers to update their notifications within 6 months after a decision to change the classification and labelling of a substance has been taken, in addition to providing reasons for divergences. We suggest that consideration be given to not putting this obligation on ECHA to ensure that that inventory does not contain incomplete, incorrect or obsolete entries and that the responsibility to ensure the entries are up to date and complete remains with the notifiers.

Amendment 19:
We note that the EP proposes to delete the definition for multi constituent substance. We support maintaining this definition in the Regulation.

Amendment 20:
We continue to support the definition for 'refill' as outlined in the EU Council negotiating position of June 30th 2023 *('refill' means an operation by which a consumer or a professional user fills a packaging with a hazardous substance or mixture offered by a supplier in the course of a commercial activity, whether in return for payment or free of charge).*

Amendment 21:
We continue to support the definition for 'refill station ' as outlined in the EU Council negotiating position of June 30th 2023 ('*refill station' means a place where a supplier offers to consumers or professional users hazardous substances or mixtures that can be acquired through refill, either manually or through automatic or semi-automatic equipment'*).

Amendment 22:
We are of the opinion that it is not necessary to state *Gender differences with regard to the susceptibility to chemicals shall be taken into consideration, where relevant,* as this is something that is already taken into account and is inherent within a hazard assessment.

Amendments 23 – 25 and other amendments thereafter relevant for substances with more than one constituent (MOCS)
We are open if others wish to have further discussions on how/whether substances with more than one constituent (MOCS) can/should be addressed within the Regulation. While our preference is for the position taken in the Council negotiating position of June 30th 2023, some flexibility could be provided to EP here in the spirit of compromise.

Amendment 32 (note this is indicated in the paper as number 106 but it appears that it should be amendment number 32);
Notwithstanding our comment above in relation to Amendments 23-25 and other amendments thereafter relevant for substances with more than one constituent (MOCS), we are reluctant to include exemptions for any particular substances or groups of substances from the provisions in relation to MOCs without scientific justifications, if such provisions will be included in CLP. We are of the opinion that further discussions would need to be had on the scientific justification for such an exemption. However, some flexibility could be provided towards EP if required to secure Council position in other parts of the text.

Amendment 35:
We query the reasoning for the newly inserted text in article 6(4) and why this differs in principle from the similar text in Article 6(3).

Amendment 55:
Concerning the 12-month timeline we query the onus that the adoption of a delegated act within 12 months of the publication of the RAC opinion places on the Commission in all cases and we consider that this may need further reflection (similar to observation on amendment 10 above).

The inclusion of mixtures here is not correct because mixtures classification is not harmonised and is not included in Annex VI in the same way as substances.

Amendments 58 and 59:
The reasoning for the addition '*and without needing to acquire new data or new studies being necessary'* is not clear and we would welcome further reflection/clarity.

Amendment 60:
While we see the reasoning for this amendment, we would be reluctant to support the proposed amendment to article 41. This article concerns self-classification by industry and having a requirement that *In case where notifiers and registrants cannot come to an agreed entry because of divergences about the level of scientific evidence supporting a classification and labelling of the same substance, the most protective classification shall prevail* goes somewhat towards harmonised classification and labelling, which is a separate process of CLP. This provision would also be difficult to enforce.

Amendment 63:
Our comment above relating to amendment 11 also applies to amendment 63.

Amendment 64:
We have serious reservations as regards the EP's proposal to insert article -43 regarding the right to request action from Competent Authorities and the Commission and we are of the opinion that this requires further in-depth discussion as on the face of it, it appears to go against the existing open and transparent processes for consultation and engagement.

There are set consultation periods during the development of a harmonised classification and labelling proposal during which all interested parties can submit information and comments that can be considered during the later decision making phases for the CLH. We would have concern that the EP proposal here could interfere with, or compromise, the decision making processes under RAC. It could also inadvertently result in substance classifications remaining in a cycle of ongoing discussion and uncertainty.

It is important to highlight that within CLP there is already a provision whereby if a company has information that disputes the harmonised classification of a substance, they can request a Competent Authority to prepare a classification and labelling proposal for that updated classification, so that part of the EP proposal is not needed in that regard (Article 37(6).

The proposals around enforcement in -43(3) are not clear, especially as to who is the non-compliant duty holder in this case. However when it comes to compliance/enforcement, this is a matter for Member State Authorities.

Overall, there are parts of the proposal that overlap with processes already in place under both REACH and CLP and for which Competent Authorities and ECHA have the relevant obligations and remit (e.g. ECHA's role in checking REACH registration dossier compliance under dossier evaluation). This EP proposal now risks undermining and circumventing those processes.

We are mindful that the amendment of CLP was always intended to be targeted and to focus on the key elements that arose from the Commission's fitness check, in particular on identifying hazards, better hazard communication and addressing legal gaps and ambiguities. This proposal from the EP goes beyond that targeted revision. Also it was not part of the initial impact assessment which is important.

Amendment 65:
Following on from our comments above regarding amendment 64, we also have concerns as regards amendment 65 on access to justice. We are of the opinion that further in-depth discussion on this proposal would be required amongst Member States and the Commission.

Amendment 75:

While we do see the reason behind this proposal, we question the proposed addition of … *the development of criteria for immunotoxic and neurotoxic substances….*to article 53. The hazard criteria for these hazard classes are not yet included in CLP and it is not expected that the EU will present them to the UN GHS until the end of 2024. This inclusion in CLP presently may be premature and not yet required.

We do note the link between this proposed amendment and amendment 77.

Amendment 81: (note this is indicated in the paper as number 116 but it appears that it should be amendment number 81);
Our comment here relates to previous comments on amendment 32 and we are of the opinion that this needs further reflection.

Amendment 87:
We support 1.4 (x-height in millimeters)

Amendment 88:
We support 1.8 (x-height in millimeters)

Amendment 89 and 90;
We are of the opinion that the proposed amendments could lead to difficulties for industry with respect to printing labels. Alternatively, we support 2.0 (x height in millimeters), as proposed in the EU Council negotiating position of June 30th 2023.

Amendment 92
We
Amendment 94
We could support the proposed amendment to add serious eye damage cat 1 to this provision on child resistant fastenings. To note CRF is the one that is enforceable.

However, as a general comment, we note that with respect to the EP proposed amendments to Annex II part 3 section 3.1.1.1 and section 3.2.1, amendments to these sections were not part of the original Commission proposal and so their impacts would not have been assessed. This may require further reflection.

In relation to the proposal that has been made to extend the requirements for Child Resistant Fasting (CRF) and Tactile Warning of Danger (TWD) to consumer products classified as Eye Category 1 (Severe Eye Damage), industry has pointed out that such an extension would mean that many daily use consumer products (e.g. hand dishwashing detergents) would require a CRF and a TWD.

We are surprised that these types of products are classified as Eye category 1 and wonder if they are being classified correctly. The Dutch Poisons Information Centre recently reviewed the assignment of Eye Category 1 to detergent mixtures notified via the PCN database and found differences in the classification of similar detergent mixtures, with some products being classified as Eye Category 1 while others are not. They stated that “These inconsistencies could stem from formulation differences but also from variations in classification methods, where the ‘calculation method’ seems to be overly conservative.”

It makes sense to us that products that can cause severe eye damage should require a CRF and TWD. However, before introducing such a requirement the classification method for Eye Category 1 should be reviewed and improved if possible. Industry could also work towards aligning the classification of comparable products, possibly with support from the relevant trade associations.

Amendment 95

We could support the EP proposed amendment to add further hazard classes to this provision on tactile warnings, particularly the addition of serious eye damage cat 1, but are of the opinion that further discussion may be required as to the exact hazard classes that need to be added.

Amendment 97

We consider that the proposed amendment regarding a requirement that self-adhesive labels be available at the refill station may be too restrictive. We prefer that the means by which the requirements on hazard communication in the form of labelling be left more open and be met by the supplier for each refilled package, without the need to be so prescriptive in the legal text.

Amendment 98

We could support the proposed amendment to add serious eye damage cat 1 to this section but question the need to also add eye irritation cat 2. The addition of eye irritation cat 2 may result in the inability to provide certain mixtures via refill, whereby it is the intention to do so e.g. detergents.

2nd November 2023

Written comments of the Netherlands on the Amendments adopted by the European Parliament on the proposal for the CLP revision

Comments in line with the agenda of the Council Working Party on 23-10-2023.

MOCS and essential oils: amendments 3, 106, 116

We do not support the amendments by the European Parliament on MOCS and stand by the Compromise Proposal of the Council.

We do not support the amendment as proposed by the European Parliament to include a general derogation for so called substances of *renewable botanical origin* (amendment 106). This is not a term that is used in any (chemicals) legislation and we are of the opinion that it is a questionable and ambiguous term that should not be used in the CLP Regulation.

We are not in favour of a general derogation at all because we believe the correct method to assess substances with more than one constituent is by its constituents, and derogations should be done on a case by case basis, where there is sufficient data to exclude a substance of these rules.

We do not support amendment 3 (recital 2a new) and 116 (article 54a), concerning the review of the rules for substances containing more than one constituent that are of *renewable botanical origin*. Regarding amendment 3, we do not believe the Commission should assess the social and economic impact on micro and small enterprises. CLP is science-based and socio-economic impacts should not be assessed within CLP. Amendment 116 proposes a review period of 6 years – we believe this should be shortened to 4 years.

We stand by the Compromise Proposal, i.e. to table the provisions on *substances containing more than one constituent* and have a review period of 4 years for the Commission to assess all information and data on these substances and provide a new legislative proposal. We believe this would be a good compromise on this matter.

Grouping of substances: amendments 9, 52, 101

We do not support the mandatory prioritisation of the classification of groups of substances over individual substances (amendments 9, 52). The option for grouping exists and we believe it is up to the dossier submitter to decide whether they have the capacity and the available data to submit a CLH Harmonised Classification & Labelling for a group; their decision is usually also dependent on the proposed classification and impact of the CLH, rather than merely tackling more substances.

In amendments 9 and 101, we would like to see the last part of the last sentence deleted: "including structural similarity and similar evidence-based hazard profiles", meaning we would propose to end the last sentence after "based on clear scientific criteria". We find the sentence to be too limiting and would rather not specify the underlying criteria for grouping in the provisions or recitals; we would propose to just stick to the reference made in amendment 101 to REACH Annex XI.

Commission adopts delegated acts within 12 months to include substances in Annex VI: amendment 55

We cannot support amendment 55. We do not believe a 12 month period works with the current procedure in place as regards to the delegated acts for Annex VI. Currently, the Commission gathers RAC opinions over a specific period to then discuss these in CARACAL, where industry has the option to comment and provide additional relevant information. It would not be efficient to discuss and publish single RAC opinions or organise ad hoc meetings solely for the discussion of a couple substances/RAC opinions.

We do, however, understand the reasoning behind the provision and would therefore propose a period of 18 or 24 months.

Entries in the C&L inventory: amendment 60

We do not support amendment 60 because we do not necessarily believe that this provision would lead to the most accurate C&L. There are cases where notifications are unjust and we also believe companies could take advantage of this provision to outrule the competition, e.g. notify a substance that you hardly use in your products and classify it as a severe hazard class. We believe that the provisions proposed regarding the divergence in notifications is sufficient to tackle the underlying problem.

Right to request action and access to justice: amendments 64 and 65

We do not support the proposed amendments. We understand that valuable information should be shared and taken into account, however, we find it important that the information is relevant, useful and of quality. There are procedures in place where data and information can be submitted already, i.e. public consultations, and we do not think it is necessary to amend CLP to include a right to request action. We believe that if there is a concern about a substance or existing CLH, individuals, companies and NGOs are able to contact competent authorities or their institutes already.

Additionally, we are of the opinion that it should be up to the Competent Authorities to decide upon which substances to take on for harmonised classification and labelling themselves, also taking into account other pressing substances and capacity.

Regarding paragraph 3 of the proposed article -43: this paragraph seems out of place here and is about the non-compliance of a product in regards to existing CLH; procedures are set in place to take enforcement measures already.

The administrative and judicial procedure in amendment 65 would mean a high increase of costs and capacity, moreover, having the obligation to assess and report every single submission of information would take up a lot of time, while in most cases, it would only take a few minutes to properly assess whether or not the data or information is relevant and of quality.

Environmental claims: amendment 102

In principle, we support the amendment on the prohibition of environmental claims for CMR, ED, PBT/vPvB/PMT/vPvM substances. We do question whether CLP is the suitable legislation for this.

Additionally, we wonder if this amendment is in line with the Green Claims Directive and the Empowering Consumers for the Green Transition Directive. We understood that in the ECTG, there is a reference to an evalution being made in 5 years which mentions the possible prohibition of environmental claims for products containing hazardous substances.

Child-resistant fastenings: amendment 94.

We are not able to support amendment 94 at this time. While we do think that, in principle, it makes sense that products that can cause severe eye damage are fitted with child-resistant fastenings, there is conflicting information on the actual benefits of child-resistant fastenings for these type of products. Therefore, we believe it is necessary to have more information on the costs and benefits before implementing this requirement.

We would propose to replace amendment 94 by an obligation of the Commission to assess the necessity for a provision to require child-resistant fastenings for the packaging of products

classified for Serious eye damage category 1 by conducting an impact assessment. This would then possibly result in a delegated act to amend annex II.

Label elements – front page of fold-out label: amendment 46

We do not support the amendment to require the Signal Words, Hazard Statements and Precautionary Statements in all languages on the front page of the fold-out label. We believe this requirement would negate the purpose of the fold-out label, since this information (in all languages) would not all fit on one page.

We very much prefer the Compromise Proposal, that requires the minimum safety information about the substance or mixture on the front page.

Minimum dimensions of labels, pictograms and font size: amendments 87, 88, 89, 90

We are not in favour of amendments 87 to 90 that lays out minimal font, pictogram and label sizes.

Our opinion is to adhere to the status quo and do not include new provisions on minimum label, pictogram and font size. However, as a compromise, we would like to stand by the Compromise Proposal.

Refill stations: amendment 98.

We do not support amendment 98 to include eye irritation category 2 and skin sensitisation category 1 to the exclusion list for refill sales.

We believe that refill has the potential to reduce packaging waste and find it important that a right balance should be made between facilitating more sustainable sales forms and the protection of the consumer.

Considering the fact that refill will often be used for cleaning products that contain biocides that will meet the criteria under eye irritation cat 2 and skin sensitisation cat 1, we believe we should look at the risks involved by allowing substances classified as skin sensitisation and eye irritation to be supplied by refill stations – and we think this small risk can be accepted in light of the purpose of the circular economy and supplying chemicals through refill.

We believe it would be a considerable limitation for refill stations if skin sensitisation and eye irritation is excluded. Consumers will be informed of the hazards by the label on the refill station and on the container. Some consumers will already be aware of their sensitivity to certain substances, and skin sensitisation is normally an effect that disappears when there's no more exposure. Regarding eye irritation category 2, a lot of consumers will be aware of this property and exposure would result in reversible effects where in most cases washing the eye thoroughly is sufficient to prevent further irritation.

As a compromise, we would support the Compromise Proposal.

Other comments in order of amendments.

Weight of Evidence: amendment 5 and 38

We do not support these amendments, which add an additional sentence to recital 4 (amendment 5) and article 9 paragraph 3 (amendment 38). The amendment is unnecessary, since the application of Weight of Evidence is already mentioned and thus applicable, and in addition, the way it is written does not take into account where there is a designated Tiered Approach included in the criteria.

Amendment 12: the change of "certain" to "all" in the sentence <u>all information notified to the Agency's classification and labelling inventory should be made publicly available, free of charge.</u>

We are uncertain what is meant by "all" information – would this also include confidential information? That would be in conflict with the following sentence that says without prejudice to the protection of commercial interests.

The use of the term new approach methods/NAMs, e.g. amendment 14, 36

The European Parliament uses the term new approach methods/NAMs in quite a few amendments. This term is however not legally defined. Also, we believe the amendments often mean to use non-animal test methods, while NAM's can include animal testing too.

Gender differences: amendment 22

This amendment includes an additional sentence in article 3 paragraph 1: *"Gender differences with regard to the susceptibility to chemicals shall be taken into consideration, where relevant."* We do not believe this sentence should be included in this very paragraph. And while there are no separate classifications for genders, data on gender differences is already included in the assessment. We believe this sentence should be included in Annex I, Weight of Evidence, and would like to propose to move the sentence there.

Test data on mixtures: amendment 34

The addition of Plant protection products and Biocidal products in article 6, paragraph 3, sub 2 might be confusing here, and we suggest rewriting the paragraph to make clear that it concerns evaluating positive data on PPP and BP on one hand and positive data on CMR/ED on the other hand, and not just PPP and BP in general.

Evaluation of mixtures: amendment 35, article 6 paragraph 4.

We cannot support this amendment. CLP states that the mentioned data for biodegradation, bioaccumulation, persistence, mobility and aquatic toxicity is not reliable with regard to the mixture as a whole. That data should not be used.

Incomplete, incorrect or obsolete entries in the C&L inventory: amendment 63

We support amendment 63. In addition to the obligation of ECHA to inform the notifier of the deletion of their entry, we would like to propose to include a requirement to inform the Enforcement Authority of the country of registration of the notifier.

Adopting delegated acts to include NAMs and non-animal test methods: amendment 76

While we understand where this amendment is coming from, NAMs must first be accepted in GHS, after which implementation can take place in CLP. The building blocks of GHS do not provide the option to accept NAMs on an EU-level, since you implement the hazard classes with inclusion of their criteria.

COMMENTS OF BULGARIA

to the EP amendments to the Commission Proposal for the CLP revision

1) MOCS and essential oils: amendments 3, 19, 106, 24, 28 and 116.

Bulgaria supports the European Parliament amendment **19.**

Bulgaria supports the EP amendment **106.** We consider that introducing derogation for essential oils is the most appropriate way to address the need of clear and legally stable regulation for the sector**,** however the redaction of amendment **3 should be taken into account.**
We do not have problem with the usage of **"*substances containing more than one constituent of renewable botanical origin".*** The term is covering so-called "***natural complex substances"*** which is well defined by the ISO standard 9235:2021 on aromatic natural raw materials and EFEO-IFRA guidelines on substance identification and sameness of natural complex substances under REACH and CLP. ECHA Guidance for identification and naming of substances under REACH and CLP also addresses the term ***substances of biological origin,*** providing some examples (page 44-45 - UVCB sub-type 3, where the source is biological and the process is refinement).

Bulgaria **do not** support amendment **116.** We believe that a balanced, predictable and sustainable solution to the problem of the classification of essential oils have to be found, which will guarantee security for their production and use throughout the European Union in the long term. However, if it is retained we are not in favour of reducing the review period.

BG supports amendment **3** with the following redaction:

Scientific evidence on substances containing more than one constituent of renewable botanical origin shows that specific constituents considered in an isolated way can have hazard properties that might not be expressed in the substance as a whole.
Substances of renewable botanical origin are substances obtained from living plant, algae and fungi organisms, renewable on a human time scale (non-fossil sources). ~~*The Commission should review the identification and examination of substances containing more than one constituent of renewable botanical origin that are not chemically or genetically modified and are not covered by Regulation (EU) No 1107/2009 or Regulation (EU) No 528/2012. In the context of such review, the Commission should also assess the social and economic impact on micro and small enterprises.*~~

Comma is included after "*plant"* to be clear that the scope of substances containing more than one constituent of renewable botanical origin are obtained from **living plant** as well as from algae and fungi organisms. The third and fourth sentences relate to Amendment 116 and should therefore be deleted.

Bulgaria supports amendments **24 and 28** – but the two texts should be aligned, since the articles are analogous – in am. 24 after *Chapter 2* "*of this Title"* should be added and no changing of the numbering in Annex I, in am. 28 – *known* should go before *individual.*

2) Procedure for harmonisation and notification: amendments 9, 52, 55, 101 and 60.

BG supports amendments 9, 52 and101.

We **do not** support amendment 55. Including 'or mixtures' is not correct as the entries in Annex VI refer to specific substances/groups of substances but not to mixtures and we are skeptical about defining a timeframe for the adoption of delegated acts.

We **do not** support amendment 60. In case of differences in classification, the stronger will prevail instead of the scientific criteria.

3) Right to request action and access to justice: amendments 64 and 65.

Bulgaria **do not** support amendment 64 and 65. The provisions create unnecessary administrative burden for competent authorities. Regulation (EC) No 1367/2006 is directly applicable and reference to the act is superfluous.

4) Environmental claims: amendment 102.

We **do not** support amendment **102**. The Environmental claims is a horizontal issue and should be addressed by the proposed Green Claims Directive.

5) Child-resistant fastenings: amendment 94.

We **do not** support amendment 94. There is no impact assessment and the need for such regulation is not clear.

6) Refill stations: amendment 98.

We **do not** support the text, regarding "*eye irritation, category 2"*.

Comments by the Federal Republic of Germany regarding the motions of the EP in the framework of the CLP Regulation

Below please find our comments regarding the motions for amendment of the EP that we view critically. And we also reserve the right to submit further points in due course.

Specifically:

Recital 2, 2a 3; amendments 2, 3, 4

Regarding "MOCS" we strongly prefer the version adopted by Coreper overall, in particular due to the specific conditions in Article 5 (3) c). However, here too, we have expressed reservations that are still applicable regarding the planned exemption and the review request addressed to the Commission. The other amendments for which the EP asks should not be accepted.

Recital 12, 13; Amendments 7, 8

We suggest to draft a synthesis of the changes suggested by the Council and the EP.

Recital 4; Amendment 5 [Zeile 13 4-Spalten-Dokument]

The sentence inserted by the EP should be moved to an own recital. Recital 4 is connected to the bridging principles, which are laid down in Article 9(4). The EP insertion refers to the criteria for weight of evidence considerations in general, which is addressed in Article 9 (3). In the text proposed by EP, the part "Given that the application of criteria on the different hazard classes is not a always straightforward" should be deleted as it is ambiguous and bears the risk of watering down the strict requirements for the application of weight of evidence in Article 9 (3).

Recital 19, Article 37 (5); amendments 10, 55

The 12-month period to implement the comments of RAC is by far too short for the Commission. The Commission would have to draft and adopt ATPs significantly more frequently. This would also strongly restrict the current practice to discuss substances also in CARACAL. The reference in Article 37(5) is not correct either as Annex VI only regulates substances.

Recital 25; amendment 12

We reject this amendment. With a view to consistency regarding the statements on the protection of inter alia intellectual property, it should be still possible to present a substantial justification to hide the notifiers' identity for reasons of confidential business information (CBI) so that they do not have to be published in the inventory.

Recital 33, Article 1 (1): amendments 14, 18

We support the amendments in principle. However, the selected wordings in recital 33 (amendment 14) and Article 1 (1) (amendment 18) are not consistent. Reference should always be made to "New Approach Methodologies (NAM)". However, it should be generally pointed out that the CLP Regulation serves in principle to implement GHS not requiring a specific test methodology.

Recital 36a, Articles 50(3a), 50(3b); EP Amendments 16, 71

We support the additions proposed by the EP.

Article 2; amendments 19-21

Definitions of "refill" and "refill station" are necessary and meaningful. However, the aim should be to have the same definitions in the CLP and in the Detergents Regulation.

The definitions provided for in the Council's draft are more accurate in our view, therefore we do not support the amendments proposed by the EP, in particular also with regard to the differentiation according to gender.

Article 5 (3a); amendment 106

We reject this amendment. There is no scientific reason to exempt an entire group of substances (which is not even defined more closely) from the regulations governing MOCS. If exemptions from these regulations are considered necessary on a case-by-case basis, they should be regulated in the same way as in the Council Draft by special exemptions in Annex I.

Article 6 (3); amendments 33,34

We reject the EP addition to subparagraph 2. In the framework of the approval process for biocidal and plant protection products no negative test data shall be used for the non-classification of products (mixtures) and active substances (with several constituents) in view of the exemption criteria (CMR, ED). There is no reason why a different procedure should be applied in this classification process for (complex) substances and mixtures compared to the one applied in the framework of the REACH Regulation.

Article 17 (1), 17 (2); amendment 39

We reject the amendment because it would require a lot of information to be placed on the outside of the label which would significantly restrict the usability of folding labels.

Article 30(1)

We would like to point out that a period for updating of 6 months appears to be too short, in particular for complex value chains, in which several downstream users are involved. A period of 12 months would be considered adequate and viable for all parties.

Article 31(3); amendment 45

We reject the deletion proposed by the EP. It is not comprehensible why the reference to Annex I section 1.2.1 should be deleted.

Article 32(6); amendment 46

We reject the amendments proposed by the EP as they would significantly limit the usability of folding labels even more as a lot of information would have to be placed on the outside of the label.

Article 37(7); amendment 57

We reject the amendment of the EP. We view in particular the automatic transfer of PMT and vPvM substances critically as the criteria applied so far in the identification of such substances are not comparable with the new CLP criteria.

Article 41; amendment 60

We reject the amendment of the EP. It is doubtful whether it is always appropriate to apply the "most protective classification" if it is based e.g. on a minority opinion.

The regulations proposed elsewhere, which require that deviations have to be justified, should be sufficient in the case of diverging classifications. The requirement for justification would also be largely ineffective if an obligation to agree on the strictest classification was formulated at this point, since no deviations would be possible.

Article 45, 43a; amendments 64, 65

We strongly reject the amendments of the EP. According to our view there is no need to introduce such far-reaching rights for natural and legal persons. The proposed regulations would also cause considerable additional work for the authorities.

Article 48 (1), 48 (2); amendments 66, 67

The aim of the addition on the part of the EP - to facilitate better information for consumers - is acceptable to us. P103 ("Read label before use") is a similar regulation for which there are however no clear requirements currently as to when this information should be provided. We therefore recommend that reference is made to this P sentence instead of using a new wording.

Article 48 (2a); amendment 102

We do not support this amendment as it constitutes an automatic legal consequence of a classification. The CLP-Regulation should instead focus solely on the classification itself based on assessement of substance inherent properties. Legal consequences should be discussed elsewhere.

In this case the 'Circular Economy Action Plan' and in particular the 'Green Claims' Directive' seem appropriate.

Article 53 (1a); amendment 73

We prefer the formulation in the Council proposal and we consider the reference to the indefinite term "societal needs" necessary which was deleted in the Commission's proposal. The empowerment to extend the digital labelling by delegated legislation needs to be restricted to ensure congruence with GHS.

Article 53(2), 53(3), 53a(2), 53a(6); Amendments 75, 76, 78, 79,80

We are in favour of the deletion of the two paragraphs provided for in the Council draft and we reject in particular the additions of the EP. The development of the methodology is not a task of the UN but rather of the OECD; so this task is not helpful here. However, this does not solve the problem of the lack of structured method development, which is the basis for a risk assessment that can be used for regulatory purposes.

Article 53 (3a); amendment 77

We reject the addition to paragraph 3a. A deviation from GHS is thus not necessary here as the hazard classes immunotoxicity and neurotoxicity can still be easily reflected in the already existing hazard classes (in particular STOT and reproductive toxicity) until the consultations at UN level will be finalized.

Article 54a; amendment 116

We reject the review clause proposed by the EP. The review clause contained in the Council draft should remain.

Annex I.3.1.1.1; amendment 94

We view the obligation to provide child safety locks in connection with the hazard class "Serious eye damage, category 1" critically as many household products for daily use would be affected even though only very few reported incidents are classified as serious. Some poison centres even assume a higher exposition if the adaptation proposal were accepted as it has to be assumed that many consumers will as a consequence store the packaging unlocked. We thus support the positions of the Commission and the Council.

Annex I 3.4.b), k); amendments 96, 97, 98, 99

We prefer the wording as contained in the Council draft. This is in our view more consistent as far as the severity of the hazard and the selection of the exemptions is concerned. Regarding the possibility of exposure we would like to point out that the hazard class "Serious eye damage, category 1" poses major challenges for industry.