Verband der
Chemischen Industrie e.V.
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CONSULTATION ON CLP DRAFT TEXT

VCI Position on "Proposal for a revision of the Regulation on classification, labelling and packaging of chemicals (CLP)"

Summary of key points - Additional information and detailed assessments of the EU Commission's drafts in the following document

General comments

- **Amendments in CLP Regulation concern several regulations**: The legal consequences of the proposed changes for other chemical regulations, like REACH, biocides or cosmetics regulation, must be considered and are often far-reaching. Furthermore, the impact assessment[1] lacks in significance as it does not take into account a large part of the consequential costs caused by the CLP revision.

- **Missing harmonisation with UN GHS:** The unilateral introduction of the new hazard classes in the EU via delegated act[2] in parallel to the start of discussions about introduction of those hazard classes into the UN GHS will result in a transition period of several years with non-harmonised requirements in the EU and the rest of the world.

Multi-constituent substances

Multi-constituent substances will lead to legal uncertainties for substances and mixtures. The proposed definition of the term multi-constituent substance is not aligned with the requirements on substance identity under REACH. Currently the substance definition[3] under CLP and REACH includes necessary additives and impurities from the production process. A new definition only creates confusion and is not needed.

Harmonised Classification and Labelling (CLH)

The Commission intends to streamline and facilitate the CLH process, which is supported in general. However, we share a critical view on the following changes:

- **Substances or substance groups:** We have objections against the harmonised classification of groups of substances. Transparent and scientifically sound criteria for grouping of substances should be used. Otherwise, grouping may lead to unjustified classification of a substance in a group, if the scope is not well defined.

[1] Impact assessment report -Commission Staff Working Document (SWD(2022) 435)

[2] Delegated Regulation amending Regulation 1272/2008 as regards hazard classes and criteria, https://environment.ec.europa.eu/publications/clp-delegated-act_en

[3] Substance according to REACH Art. 3(1) and CLP Art. 2(7): "substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used […]"

- **Automatic Classification for new hazard classes**: It is agreed that substances with the new hazard classes should be given priority in a harmonised classification. However, we strongly disagree that substances listed under
  - the REACH SVHC candidate list as Endocrine Disruptors for human health or environment or PBT/vPvB,
  - Regulation (EC) No 1107/2009 (PPPR) and Regulation (EU) No 528/2012 (BPR) as Endocrine Disruptors for human health or environment or PBT/vPvB,

  should automatically receive a classification under Annex VI of CLP.
- **Initiation of CLH:** In case of a CLH proposal initiated by the Commission itself, the initiator and the assessing party will be identical. Thus, we see a risk of inadequate political pressure, e.g. politically motivated substance bans, on a process that should be purely science based.

Labelling

- **New requirements for labels**: With new requirements in labelling formatting, especially for the adapted font sizes the Commission is creating a heavy administrative burden and significant practical hurdles without any recognizable benefit for hazard communication.
- **Digital Labelling**: We support the introduction of digital labels. However, the presented introduction for digital labels on a voluntary basis offers little incentive to actually introduce them widely. The use exclusively on a digital label is only permitted for supplementary information and regular labelling is still mandatory for core elements. This duplication of most information removes the opportunity to improve clarity of label information that digital labels could provide.
- **Fold-Out labels**: The use of fold-out labels should be further facilitated as they are enabling the free movement of goods between EU countries and are also beneficial for non-native speakers in the member states.

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Background

The Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures ('CLP Regulation') regulates the classification, labelling and packaging of chemicals and implements the Globally Harmonised System (GHS) of the United Nations (UN) in the European Union (EU). The GHS serves as an internationally consistent basis for classification, labelling and packaging. The primary objective of the CLP Regulation is to inform actors in the supply chain about potential adverse effects of substances and mixtures by classifying them and labelling them appropriately based on this classification.[4]

The revision of CLP Regulation was announced by the Chemicals Strategy for Sustainability[5] as a key part and adopted on 14 October 2020. The Union has overall been successful in creating an efficient single market for chemicals. Some weaknesses in the CLP Regulation described below prevent consumers, companies, and authorities from fully benefiting from protection against the dangers posed by hazardous chemicals. In the opinion of the EU Commission, however, there are some gaps in relation to hazard communication and the identification of hazards of substances and mixtures, which are to be addressed with the present draft. Although certain chemicals and articles may pose risks to human health or to the environment, their hazards are not always properly identified and communicated. The main driver behind this issue are inefficiencies in the procedures for assessing and classifying hazards. Appropriate hazard classification determines, among others, the appropriate labelling and packaging of the chemicals in the supply chain, in particular to protect workers, consumers and the environment, but also to enable the single market to function properly. Furthermore, the Chemicals Strategy for Sustainability identifies imported chemicals and online sales as a particular challenge and priority area for action. Many chemicals sold online in the EU and placed on the EU market, especially those sold by actors established outside the EU, do not meet the legal requirements. Chemicals classified and labelled incorrectly result in consumers not being properly informed about the hazards, which ultimately leads to incorrect use, storage or disposal.

On December 19, 2022, the European Commission published its proposal for the new hazard classes and, at the same time, the proposal for a revision[6] of the CLP Regulation which this document addresses and comments on.

In addition to general comments on the amendments to the CLP regulation in regard to new and changed requirements for classification, labelling and packaging of hazardous substances and mixtures, VCI will provide concrete detailed assessments of the provisions in the following part.

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[4] CLP-Regulation,

Article 1 (1): The purpose of this Regulation is to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and articles [...].

[5] Chemicals Strategy for Sustainability, Communication from the Commission, Brussels, 14.10.2020 (COM(2020) 667 final), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2020%3A667%3AFIN

[6] Proposal for a revision of the Regulation on classification, labelling and packaging of chemicals (CLP), COM(2022) 748 final, 19.12.2022, https://environment.ec.europa.eu/publications/proposal-clp-revision_en

No compliance with UN GHS on the horizon

The potential disharmonisation with GHS caused by the introduction of the new hazard classes via a separate delegated act[7] will bring major challenges for the entire chemical industry and will lead to trade barriers and legal uncertainties. We would like to emphasize again that we strongly object to the unilateral introduction of the new hazard classes and question the necessity of their introduction in CLP, as laid down in detail in our consultation feedback to the Delegated Act.[8] It is of utmost interest for industry to maintain the harmonisation achieved and not to disregard the work of the UN GHS Expert Committee by unilaterally introducing new hazard classes without consulting the UN. The UN GHS discussions and an agreement on the "potential hazard issues and their presentation in the GHS" need to take place before a final introduction into EU CLP. However, an outcome of these discussions cannot yet be estimated and a deviation from the GHS system for several years or even permanently is to be feared, which is contrary to the fundamental concept.

Multi-constituent substances

The introduction of the so-called 'multi-constituent substances' according to Article 2, which were previously referred to as 'more than one constituent substances' (MOCS), will cause many problems for the chemical industry and therefore needs clarifying explanations and clear delimitations to the currently applicable substance definitions under CLP and REACH. Newly introduced provisions under Article 5(3) set the rules for classification of the multi-constituent substances which are intended to follow in general the rules of mixture classification. The provisions on relevant information on the individual components, but also on the overall substance, which must be used for classification, are specified there. The inclusion of identified impurities and additives here causes problems with existing substance definitions that urgently need to be resolved.

The current practical definitions of substances under REACH – mono-constituent, multi-constituent or substances with 'Unknown or Variable composition, Complex reaction products or Biological materials' (UVCB), like petrochemicals, in Annex VI Section 2, supplemented by guidance[9] – are well established and have been a cornerstone throughout the chemical industry for many years. The CLP amendments should not formally pre-empt the REACH revision and the harmonisation between the two regulations should by all means remain in place.

There is no need to introduce a new definition of multi-constituent substance for the purpose of clarifying classification rules. A simple statement like "toxicological and environmental properties of constituents (to be defined) or impurities and additives (>10 % (w/w)), e.g. stabilizers, have to be considered in the classification and labelling of any substance and mixture placed on the

[7] Delegated Regulation amending Regulation 1272/2008 as regards hazard classes and criteria, https://environment.ec.europa.eu/publications/clp-delegated-act_en

[8] VCI input to the public consultation, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13578-Hazardous-chemicals-updated-rules-on-classification-labelling-and-packaging/F3348921_en

[9] 'Guidance for identification and naming of substances under REACH and CLP', ECHA, Version 2.1, May 2017.

market" could resolve the potential gap. In conclusion, the substance definition ('mono-constituent') and 'multi-constituent substance' should be aligned between REACH and CLP. The introduction of the definition should be withdrawn due to the many potential problems.

Harmonised Classification and Labelling (CLH)

Substances or substance groups: We advocate for clear scientific criteria for grouping of substances going into a harmonised classification and labelling. The allowed grouping criteria should be clearly defined as established under REACH. In addition, each member of a group should be identified via its CAS number, or other numeric identifier. Grouping based on mere structural similarity or reactive groups, especially when group members are not clearly identified and validated with respect to the assessed hazard, may lead to inadequate worst-case classification. Furthermore, missing identification of group members leaves responsibility for correct identification and classification of substances with the industry. This will necessarily result in deviating classifications and is exactly in contrary to harmonised classification.

We conclude that it is an incorrect approach as structurally similar substances can have different behaviour and effects. Therefore, the assessment of similarity must be based on a review of all available data on the substances' physico-chemical, ecotoxicological and toxicological properties. This review must include a Weight of Evidence assessment across all relevant criteria for the hazard in question. Such an approach will help avoid over-classifying and over-regulating substances based on 'presumed' hazards.

Initiation of CLH: We take a critical view of the Commission's right to initiate the CLH process itself, since the initiator and the assessing instance are now identical. According to the amendments in Article 37(1) the Commission may now ask the ECHA or the EFSA to prepare a proposal for a harmonised classification and labelling. Furthermore, ECHA's independence in assessing CLH proposals initiated by the Commission (I.e. annex XVII dossiers created by themselves commissioned by the Commission) may be questioned. This may also result in politically motivated substance bans through the "back door" at the initiative of the Commission, including groups of substances. In our view there is no need to change the right of initiation of the procedure. The bottleneck of the CLH process is the capacity of the scientific risk assessment committee (RAC), not the lack of regulatory bodies entitled to submit a proposal. Speeding-up the process could more easily be achieved by providing adequate resources to RAC. Following the amendments to Article 37(5), there is no longer clarity on whether or not the EU Commission must review if a proposed harmonised classification and labelling is appropriate, which was a final assessment step after receiving the RAC opinion in the process.

Automatic Classification for new hazard classes: We strongly disagree with the new provisions regarding the new hazard classes, laid down in Article 37(7+8), that substances listed under

- the REACH SVHC candidate list (according to REACH Article 59(1)) as endocrine disruptors for human health or environment or PBT/vPvB,

- Regulation (EC) No 1107/2009 (PPPR) and Regulation (EU) No 528/2012 (BPR) as endocrine disruptors for human health or environment or PBT/vPvB,

should automatically receive a classification under Annex VI as Endocrine Disruptor Cat. 1 or PBT/vPvB. The processes involved are not the same and the criteria against which classification was made under the previous regulations may differ from the final criteria under CLP. We would like to emphasize that a harmonised classification, based on the assessment and criteria agreed on, into the aforementioned hazard classes must be the prerequisite for further measures in downstream and horizontal chemical legislation and also for the inclusion on the SVHC candidate list under REACH. The reasons are the differences in the involved processes and the level of details in the assessment. Usually, a CLH dossier is discussed in several RAC meetings until the RAC adopts its opinion. The Member State Committee (MSC), on the other hand, in most cases deals with an SVHC dossier in only one meeting. In addition, the two committees have very different membership compositions, as the RAC consists of formally independent experts, while the MSC consists of delegated representatives of the member states. During discussions in the MSC, the MSC member of the member state that submitted the dossier defends the dossier. For this reason, the MSC's referral of SVHC dossiers is less independent than that of the RAC in case of CLH dossiers. Therefore, we conclude a much less intensive and scientific evaluation of the SVHC dossier takes place in the MSC. The timelines of participation for external stakeholders are also lower because a public consultation on a SVHC dossier is shorter (45 days) than that for a CLH dossier (60 days).

Labelling Rules

In our view, the rules for the labelling of substances and mixtures should be simplified and flexibility in formatting should be maintained instead of adding more requirements to them. This is also true for the new fixed deadline of six months for updating labels because of new or changed classification of substances and mixtures, which is not adequate in our opinion.

Furthermore, we advocate clear transitional periods for sell-off, so that substances and mixtures that are appropriately labelled under current law do not have to be relabelled before sale, which would lead to enormous costs throughout the industry.

New label requirements

We would like to object to the further amendments in Annex I Section 1.2.1.4 and 1.2.1.5. The new minimum font size requirements are an example of how regulations continue to tighten without relying on practical "best practices" from the chemical industry, as for many current labels, implementation is not possible without high effort. Instead of the unreasonable additional requirements for physical labels, it would have made sense to simplify the use of

digital labels, also in line with new initiatives such as the digital product passport[10] or the battery passport. Today companies can design product labels for a group of several countries and thus streamline warehousing and logistics. From a practical point of view the proposed minimal print sizes space requirements even for one language may exceed the available space on a label or on even the whole packaging. Some, often rather small, countries have more than one official language (e.g. Belgium) and could no longer be served with the same product.

This challenge applies to very small packaging sizes which requires to be taken closer in our view making even smaller than 8 pt print easily legible and no stricter requirements are needed.

Furthermore, the new proposal up to 20 pt print size will also affect medium and large packaging. Even on 1000 litre containers (IBC), which are predominantly used within industrial settings, the CLP information at 20 pt print size may no longer fit within the available space. All products that are manually handled are within arm's length of the operator and at this distance print sizes of in the range of 10 to 12 pt are easily legible. Smaller packaging also requires to be taken closer making even 8 pt print easily legible. Legibility is not an argument to ask for up to 20 pt print size. Splitting of the same product into a multitude of language versions causes a plethora of negative impacts ranging from replacement of printers to accommodate larger sizes to larger warehouses for more product types up to increased waste due to expired shelf-life to name a few. Other requirements for the components of a label, which are listed in the Supplementary Information and which may result from other EU acts, for example the Biocidal Products Regulation, also lead to further problems with the new proposed minimum font sizes.

We therefore oppose the new formatting rules as they are impractical, expensive and of no benefit in terms of readability and hazard communication.

Digital Labelling

The long-awaited provisions on digital labels unfortunately bring very few benefits, as these may only be used in addition to the physical label (only supplemental labelling information according to article 25(3) may be omitted from the physical label). Especially regarding consumer products, the proposal should be amended to allow additional label elements to be omitted when digital labels are used. This would allow improvements to label clarity and provide more space to accommodate other proposed changes (e.g. font size). Further obstacles arise from a number of technical details and requirements set out in Article 34b, Sections 1 (a)-(j), 2 and 3. A more encouraging wording of the criteria in terms of use and benefits for a wider acceptance by industry would be supported by VCI.

[10]Article 8 – Product Passport in the "Proposal for a regulation establishing a framework for setting ecodesign requirements for sustainable products", https://environment.ec.europa.eu/publications/proposal-ecodesign-sustainable-products-regulation_en

Fold-Out labels

Based on the intention of the EU Commission to allow for a broader use of fold-out-labels, as stated e. g. in Recital 11, and in order to enable companies to take advantage of economies of scale, as stated in the Explanatory Memorandum, a more explicit wording is needed in Article 29 clarifying that the use of fold-out labels shall be allowed without limitation to the official language of one Member State where the substance or mixture is placed on the market.

Additional Comments

Label update deadlines for changed classification

We would like to object to the change of the current update requirements for labels to a fixed period of six months in Article 30 in case a substance or mixture needs to be assigned a new hazard class or a more severe classification, or if new supplementary information is required on the label. This timeline is too short and inconsistent with current practices which have proven adequate to allow re-printing of labels and re-labelling of packages in each step of the supply chain and not an unrealistic deadline for the whole supply chain. The current provision provides the needed flexibility. We also want to mention that a new or changed entry in harmonised classification and labelling has a transition period of 18 month which is a more realistic timeframe.

Classification and Labelling Inventory (CLI)

With the intended amendments the name of the notifier will be published for transparency reasons and justifications for a less severe classification have to be made. We do not support disclosure of company names, as third parties will utilize this information for market analysis and other commercial purposes. This might even endanger R&D activities and innovations by EU companies. In addition, lots of unnecessary communication along the supply chains will be triggered and further information requirements for the inventory will lead to more bureaucracy without beneficial effects. At least, the inventory needs to be purged from classifications which turn out to be evidently false. The proposed justification of deviation from the most severe classification in the inventory is not workable, as with each change of the most severe classification all justifications provided so far will become meaningless. Instead of increasing the administrative burden, the objectives of promoting transparency and knowledge on the hazards of substances can be achieved better by focusing the CLI on the harmonised C&L (Annex VI) and the joint C&L from REACH registrations. This information is of higher value than the notifications kept in the inventory database, which may already differ for the same substances and do not claim to be up-to-date. There is a high number of erroneous or obsolete classifications of substances, as well as diverging classifications for the same substance in the European Chemical Agency's classification and labelling inventory ('inventory), with almost 60% of companies having multiple notified classifications for a single substance, as stated in the explanatory

memorandum[11] of the current proposal. Additional (and extended) notification duties in Articles 40(1), 40(2) and 42(1) will bring no added value. The substance-wise check of each individual hazard class of each notification for divergence is time-consuming and will bring questionable results, which will be outdated anyway with the next submission of another notifier.

In order to reduce unnecessary bureaucracy, we are in favour of shutting down the C&L Inventory, as it is not a valuable information source for hazard classification and may even provide false and/or outdated information. Beyond this, the C&L inventory creates uncertainty as it distracts from the classification of the registration dossier which is based on sound scientific data generated in experimental studies.

Poison Centre Notifications

We welcome the fact that some legal gaps, for example the lack of a required notification of mixtures for distributors (relabellers and rebranders), have been closed. However, the new amendments that ECHA may be (after appointment by a Member State) the designated body to receive emergency information are not welcomed. This also applies to the intention to use the data provided by companies retrospectively for other purposes such as regulatory measures, which would give ECHA and the Commission further access to detailed information, for example on production in the Member States and chemical markets, which could be used for future risk management measures and enforcement actions not communicated so far. This information has been provided by companies solely for the purpose of emergency information and further usage should be avoided and is questionable from a legal point of view.

Online Sales

An equal level playing field for online sales, especially for imports of dangerous substances and mixtures by online stores from outside the EU, is supported. The requirement of a legal entity within the EU is intended to create higher compliance of online sales, but it is questionable from our point of view whether this will improve enforcement by the authorities.

Advertisement

With the proposal the commission intends to extend requirements for advertisement laid down in Article 48 for substances and mixtures with the signal word, the hazard class and the hazard statements. The consumer's access to relevant hazard information is already in place and there is a fear of being overloaded by too much hazard information. The consequence of the adapted

[11] From the explanatory Memorandum: "[…] Second, there is a high number of erroneous or obsolete classifications of substances, as well as diverging classifications for the same substance in the European Chemical Agency's classification and labelling inventory ('inventory), with almost 60% of companies having multiple notified classifications for a single substance."

Article 48 is that hazard pictograms and hazard statements would have to be provided in advertising directed at consumers, in magazines, on television, etc.

We suggest that the new and stricter amendments should only apply to substances and mixtures if the contract of sale can be concluded by consumers without viewing the label, as it is the case in the current version of the Article 48(2). This will guarantee a safe communication of hazards.

Further Delegated Powers

With regard to the extended rights set out in Article 53 of the draft, which further empowers the EU Commission to adopt delegated acts on the topics of digital labels, harmonised classification and labelling, animal free new approach methods (NAM), etc., we have a critical stance. Especially with regard to the new hazard classes that are to be introduced via a separated delegated act, the question of the Commission's powers remains open and is also discussed by member state competent authorities (MSCA), so that these authorizations in our view should be well-dosed. Also the delegated power to adopt delegated acts for a harmonised classification and labelling of the new hazard classes for a five year period is questionable, because further substances identified and added as ED on the SVHC candidate list could get a harmonised classification and labelling without any RAC involvement.

Weight of Evidence – Approach (WoE)

We advocate that the legal text ensures that if further high-tier information is available, it is taken into account and, in the example of mobility assessment, can override purely Koc-based conclusions through a weight of evidence (WoE) approach. While the legal text addresses this topic, we would like to raise a concern about the legal clarity of the current wording in Article 9, Paragraph 3. Thus, we would propose to make the following adjustments:

Article 9(3) referring to Annex I: […] Where the criteria cannot be applied directly to **all** available identified information, manufacturers, importers and downstream users shall carry out an evaluation by applying a weight of evidence determination using expert judgement and weighing all available information having a bearing on the determination of the hazards of the substance or the mixture […].

Generic concentrations limits, Acute toxicity estimates (ATE) and M-factors

New amendments and clarifications in Article 10 for specific and generic concentration limits where the presence of a hazardous substance as an identified impurity, additive or individual constituent leads to the classification of a mixture are supported. The further application of acute toxicity estimates for substances being classified as acute toxic below the ATE and M-factors concerning substances hazardous to the aquatic environment also find our support.

Refill stations

For environmental reasons, the use of refill stations should be significantly promoted for professional users as well as for consumers in order to save on disposable packaging. We therefore promote the introduction into CLP. However, from our perspective, Annex II section 3.4 sets a number of requirements for the operation of these refilling stations and some open questions about the scope of the Annex remain, which should be clarified. Fuels and fuel stations used extensively by consumers should not be covered by the scope of this new section of the Annex, although hazard classes such as flammable liquids etc. are to be excluded in the draft. In our opinion only severe hazard classes should be restricted for use in refill stations, while hazard classes such as STOT SE cat. 3 should be permitted there. In addition, the provisions on the containers used at the refill stations should be further specified so that in particular consumers are prevented from contamination with hazardous substances and overfilling of the containers is technically prevented for safe and practical use.

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