NOVEMBER 2021

Position paper supporting our response to the Open Public Consultation on the Targeted Revision of the Regulation on Classification, Labelling and Packaging of Substances and Mixtures (CLP)

The CLP Inception Impact Assessment (IIA) stipulates that the CLP Regulation together with the REACH Regulation on Registration, Evaluation, Authorisation and Restriction of chemicals are the key EU legislations on chemicals.
It should be acknowledged that the CLP Regulation has gone beyond its role of setting out the hazard classification of chemicals and how to communicate those hazards to consumers and workers. The CLP Regulation is now at the centre of a series of chemicals management pieces of legislation, in particular on risk management.
Hence, it is important to ensure its transparency and efficiency, avoid ambiguity, and have the best modalities for the involvement of all stakeholders, i.e., have clear roles/rules and boundaries.

This document provides a number of generic comments and a more detailed explanation of our answers to some of the questions raised in the Open Public Consultation (OPC) questionnaire where, due to the 'tick the box' format, it was not possible to give a proper explanation of some of the complexities involved.
We would ask that this document be read in conjunction with our official public consultation response. Thanks.

Generic comments

- **Preserve the scientific quality of CLP decisions:**

We would like to recall that the CLP fitness check drew attention to the fact that EU's knowledge base on chemicals including their properties, data on eco-toxicity of chemicals is unique in the world, allowing the EU framework to take science- and evidence-based decisions. Preserving this science and evidence basis, keeping up with scientific developments and ensuring capacity-building of all actors is crucial to ensure the revised CLP continues to meet its objectives.

In view of this, we would propose to:

- Clarify issues in the current CLP causing repeated discussions: e.g., the mixed nature of CLP when it comes to hazard and exposure (e.g., SCLs that include some element of exposure), standard vs. non-standard data, quality of human data, a clear framework to apply weight of evidence, all routes vs. specific routes classifications, substances specificities…identifying where additional guidance is needed/relevant.
- Separate the roles of those drafting guidance from those having to implement it when preparing/reviewing an Annex XV dossier.
- Reach a better (ideally common) view on the use of 'precaution' (precaution to be applied when data is lacking or when there are uncertainties).
- Ensure capacity building of RAC and all stakeholders ("Manual of Decisions"-like for elements of horizontal nature, or short videos posted on ECHA's website on "in RAC, what are the dos and don'ts").

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- When the Commission assesses RAC opinions and concludes that it needs a second scientific review, there should be a scientific body (possibly ad hoc) that the Commission could refer the case to, to obtain a second opinion. It is difficult for RAC to look at the same topic with a fresh mind, when they had already adopted an opinion.

• Quality of the data used in CLP:

- Maximise the use of the data included in the REACH files.
- Clarify the use of standard vs. non-standard data. For example, for environment, standard species should be used if the chronic data set is complete to ensure a level playing field comparison.
- Ensure the same data quality/reliability requirements for REACH and CLP data when it comes to hazard identification. It cannot be that under REACH Evaluation, ECHA would find a data gap and require it to be filled by a standard GLP compliant study, when later for classification and risk management, RAC relies on the non-standard and non-GLP compliant study.
- Ensure the good quality of data/dossiers entering the CLH process by allowing ECHA to apply an accordance check that exceeds simple alignment with the Annex XV template.
  The accordance check could e.g.,:
  - Check if the Annex XV proposals have considered all the information available in the REACH registration dossiers.
  - Check if the Annex XV dossiers in general meet quality and relevance criteria
  - Check if Annex XV proposals are in line with the CLP legal text and guidance. If not have the possibility to highlight deviations.
  - Include a tick-box (yes/no) for the Dossier Submitter on the interaction with industry at the start.
  - Check if there are ongoing, conflicting regulatory process (e.g., CLH running in parallel with REACH Testing Proposal or requested Substance Evaluation, Dossier Evaluation update according to a MSC decision). If this is the case, ensure the RAC review may be put on hold until these processes are finalised.
  - Possibility to stop the clock in defined cases to ensure only high-quality dossiers go through to RAC.

• We need to make the best use of (already stretched) resources:

- Would it make sense to change the conceptual view on RAC's role in the classification system and have it organised differently? For example: the self-classifications are proposed by registrants and included in the registration dossiers. Instead of developing new Annex XV dossiers, RAC could rather act as a Review Committee giving advice on the quality of the assessment that has been carried out, indicating where it potentially deviates from the guidance (e.g., like what happens under a REACH Dossier Evaluation). This would permit to reallocate resources to address complexities in CLP (guidance, clean-up of inventory etc.)
- We need to ensure enough relevant expertise in RAC: every time new tasks are assigned to RAC the need to expand RAC's expertise to cover new areas shall be assessed. It should be stressed that the use of Working Groups has only recently started but it seems a way forward to increase the efficiency and allow for more in-depth discussions. It can be further recommended that these sub-groups are allowed to engage additional/specific expertise to also improve the efficiency on adopting opinions (e.g., the Working Groups

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would be built around demonstrated expertise, e.g., in classification; the Working Groups could form/adopt the opinion, which should only undergo a screening scrutiny by the members of RAC who are not experts in the field to prevent WG experts being outnumbered by experts in other fields, during the plenary discussion following the Working Group meetings).

- Identified expertise gaps can be filled by co-opting members (there is a need to change the limitation to have only 5 co-opted members), inviting advisers (not only by RAC members but also by ECHA), closer engagement with national/EU scientific committees (where relevant), involving industry experts with specific knowledge/expertise.
- Improve interaction with stakeholders at the start of the process (Annex XV drafting), setting up a prioritisation system: a publication of priority chemicals of concern can be used to stimulate better updates of self-classifications.
- Avoid disconnections between classification decisions and considerations of downstream consequences/impacts, as this may actually facilitate clear thinking about risk management and prioritisation of next actions.
- Ensure quality of the information handled in the context of CLP e.g., by a formal accordance check (see above).
- Ensure correct application of CLP/respective ECHA guidance by a transparent review process.

- **Need to ensure a level playing field:**

- Between types of materials (e.g., rapid transformation concept should be applied for all materials).
- Between substances (i.e., avoid that CLH assessments become dependent on the personality/engagement of RAC Rapporteurs).
- Over time (have some "Manual of Decision-like" mechanism, especially now that RAC's meeting minutes are very limited and hamper transparency).
- Between EU and outside the EU: keep in mind that companies implementing CLP also operate globally, hence avoid discrepancies and implementing endpoints not yet discussed at global level.

- **Links between CLP and other pieces of legislation:**

- Better understand/analyse/anticipate impacts due to links between CLP and downstream legislations. Eurometaux has developed a classification mapping tool that is available to allow companies to identify the other legislations that need to integrate the outcomes of a CLH process. The development of the tool was needed because there seems to be a disconnect between the forums/groups discussing classifications and the downstream consequences. This is hardly compatible with CLP being announced as being a core piece/key legislation in the CSS.
- While we support harmonization in general, we think the harmonization of DNELs, DMELs, and PNECs under the CLP regulation does not add value. These values are part of risk assessment, while the focus of the CLP regulation is on hazard classification. In some cases, different values justifiably have different protection goals in specific sectoral legislation, e.g., consumers vs. workers. Furthermore, under the REACH regulation, there is already a legal duty by industry to adopt these values jointly by joint registration where possible and to keep these values up to date. A harmonization process under the CLP regulation will likely lead to a more time-consuming and burdensome process

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- **Better Regulation**

In 2019, the CLP Regulation was adapted to Article 290 of the Treaty on the Functioning of the European Union (TFEU) on delegated acts. We would like to recall that under the Better Regulation guidelines, an impact assessment is required for delegated acts that are "likely to have significant economic, environmental or social impacts".
In addition, currently the Commission does not submit future delegated acts for a public consultation prior to their adoption, therefore limiting public consultations to the single one organised by ECHA ahead of its RAC meeting, that does not take socio-economic impacts into account. Submitting draft delegated acts for a public consultation would potentially address this knowledge gap, while enhancing transparency in line with the Better Regulation principles.
Moving forward, we would therefore encourage the Commission to assess whether an impact assessment is necessary for each delegated act under the CLP and, to the very least, publish draft delegated acts for a 4-week public consultation on the 'Have Your Say' webpage prior to their adoption.

Complementary information or clarification vs. the questionnaire

Questions	**Additional feedback**
1	None
2	Should the question not have triggered a yes/no answer? How can this information be used as it may (also) differ depending on the type of products?
3	None
4	Industrial and professional users may require different types of labels. For the consumer, identifying the information they absolutely need to understand may be difficult due to the amount of information. The label should at least keep the label elements that are crucial for the safe use of products. Further information, such as additional hazard, safety and precautionary advice, product composition and use, and the respective translations into other languages should be kept in the digital format. Duplicate information coming from other regulations could also be mentioned in the digital part. On the other hand, it would be useful for some types of consumer products to give enough emphasis to end-of-life (e.g., recycle) and risk related information (e.g., like the existing 'do not throw batteries into the fire' and 'recycle')
5	None
6	None
7	It should be a combination of options. i) crucial information (e.g., pictograms, hazard statements, safe use instructions) in the form of a printed label displayed at the store, ii) stickers with essential information that the consumers can attach to the refilled bottle and iii) more information accessible via scanning of a QR code). For those not having access to smartphones, printed leaflets could also be made available

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8	Labels may be relevant for risk management (like the present indication on batteries warning to not throw the battery into an open fire and to bring them to the recycling point at their end of life)
9	None
10	If products already have specific labelling requirements according to EU Regulations that complement CLP (e.g., pharmaceuticals, food additives, cosmetics as outlined in Article 11 of the EU CLP), we would like to propose that those remain subject to those regulatory regimes to avoid confusion with labelling obligations from CLP. However, to keep a level-playing field, we would support the view to cover endpoints not in focus of those regulations (e.g., environment) by CLP labelling.
11	With regard to question 2, we would like to stress that as for toxicity data generation, economic assessments like Willingness to Pay require a stringent methodology and documentation to ensure they reflect the actual WTP consumers would be prepared to endorse. The way question 2 is formulated does not provide any indication on the methodology that is followed and may not provide replies that can be further used.
12	Please see our paper uploaded under question 50
13	While we agree with the importance of addressing adverse effects mediated through the endocrine system, we believe this can be better and more rapidly addressed through existing legislation such as REACH that can regulate the use of these chemicals and ensure communication on safe use. Making use of existing legislation to "flag" modes of actions instead of 'effects' should also be considered as policy options to address the issue + recall that as the CLP revision will take place before the UN GHS discussions, there will be inconsistencies between the EU, and global classification and transport frameworks, which will impact the international level playing field and affect hazard communication for chemicals traded worldwide, like metals and inorganics. Reiterate that we recommend that any proposal to add new hazard classes and/or to amend existing ones should first be discussed under UN GHS, before modifying the CLP, so as to minimise possible divergences from the UN GHS global standards. While this does not preclude the EU from taking the lead and developing criteria; proposing new hazard classes at UN GHS level subsequent to their implementation in CLP may entail the risk that the final GHS criteria for these classes would differ from what has been implemented in the EU, with the result that the CLP and related guidance may need to be modified again (generating unnecessary costs and burden)
14	None
15	We believe that the introduction of a second category creates complexity and may generate confusion. According to the WHO definition a substance is or is not an ED. If the information provided is not conclusive, there should be no classification. If it is decided to go for a second category, transparency and clarity should be built in to reflect the degree of uncertainty in the data/evidence for chemicals classified as ED Category 2. We support the inclusion in the criteria of a summation of the three elements of the WHO Definition, where all three elements have to be met by an endocrine disruptor: (1) it shows an adverse effect in an intact organism or its progeny; (2) it shows endocrine activity;

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	(3) the substance has an endocrine disrupting mode of action, i.e., there is a biological consequence between the endocrine activity and the adverse effect. For Category 2, it could be added: A substance is classified in Category 2 for endocrine disrupting properties for human health when there is evidence of an adverse effect, which is a consequence of the endocrine activity, and where the evidence for the causative link of (3) is not sufficiently convincing to place the substance in Category 1. Further work is needed to provide clear guidance. We also would like to emphasise that applying the endocrine disrupting classification on metals is not straightforward. Metals occur naturally, and some metals are essential elements. They may therefore naturally have a role in the endocrine system. Dedicated guidance is needed to ensure that metal-specific properties are considered correctly in endocrine disruptor assessments. The metals sector is consulting with various experts in the field to develop such guidance and prepared to provide this guidance to the EU Commission for consideration once it is finalised (second half 2022, outcomes of an expert panel available on request).
16	May disrupt hormonal system of humans
17	Annex XIII of REACH indicates that the PBT criteria do not apply in the same way to metals and inorganics. Indeed, the more a metal/inorganic is persistent, the less it is released hence of lower hazard. Also, the bioaccumulation potential of metals and inorganics requires care given the homeostatic control mechanisms of organisms making the BCF inversely related to the exposure concentration. For those reasons metals and inorganics were exempted from the PBT assessment/criteria as presently applied suggesting a case-by-case assessment when relevant. As a consequence metals and inorganics should remain exempted from the CLP.
18	None
19	None
20	None
21	None
22	None
23	An extension of the hazard assessment for the environment to the terrestrial compartment for classification purposes should only be considered if it would provide proven additional value in respect to the goals of hazard classification for the environment. So far, for metals, data demonstrate that the expression of toxicity at equivalent loading is higher in aquatic than in soil media, therefore challenging the added value of a potential extension. An ECETOC study came to the same conclusion for organics. Hence, we question the relevance of the development of such a parallel terrestrial classification system under GHS or CLP - which is the same conclusion reached by the OECD when the issue was raised in the nineties. Moreover, in the exceptional case a specific substance or group of substances were to demonstrate higher terrestrial than aquatic effects, this would be picked up under the risk characterisation of REACH, to demonstrate safe use for the terrestrial compartment.

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24	To fulfil its communication aims, classification requires the unambiguous identification of the hazard of a chemical and to relate its properties to well-defined categories. To this end we need well-defined and agreed ways to interpret the available data/evidence. It is proposed to focus first on the methods to generate the information and define the boundaries/cut-offs for these endpoints as well as defining the impact of suggested cut-offs, before adding a new hazard class. Also to minimise divergences and avoid decreasing the efficiency of classification at global level, we ask that any proposal to add new hazard classes and/or to amend existing ones is first discussed under UN GHS auspices. Divergence from the UN GHS global standards will strongly affect hazard communication for exported EU manufactured chemicals as the classification of substances may differ from local classification and due to the intro of new hazard classes be stricter and misaligned with what the local rules would require. This would increase the classification burden rather than strive towards harmonisation.
25	To fulfil its communication aims, classification requires the unambiguous identification of the hazard of a chemical and to relate its properties to well-defined categories. To this end we need well-defined and agreed ways to interpret the available data/evidence. It is proposed to focus first on the methods to generate the information and define the boundaries/cut-offs for these endpoints as well as defining the impact of suggested cut-offs, before adding a new hazard class. Also, to minimise divergences and avoid decreasing the efficiency of classification at global level, we ask that any proposal to add new hazard classes and/or to amend existing ones is first discussed under UN GHS auspices. Divergence from the UN GHS global standards will strongly affect hazard communication for exported EU manufactured chemicals as the classification of substances may differ from local classification and due to the intro of new hazard classes be stricter and misaligned with what the local rules would require. This would increase the classification burden rather than strive towards harmonisation.
26	None
27	None
28	It should be clarified that metals and inorganics can't be reformulated as can be done for organics. However, alloying may result in reduced releases hence reduced hazard which can be measured by tests like the Transformation Dissolution protocol (for the ENV endpoint) or Bioelution tests.
29	While we see a possibility for this option to bring in more consistency and relevance in the Annex XV proposals it requires that sufficient and adequate resources be foreseen to ensure the quality/transparency of the ensuing Annex XV drafting and CLH discussions (e.g., ECHA staff, ECHA Committees, guidance). This is in order to be able to reach the communication and protection target, and not simply an increase in the number of classified substances. It also necessitates ensuring that Commission can continue to exert its discretion when evaluating the RAC opinions and preparing the ATP entries, beyond fulfilment of the classification criteria. In particular, we call on the Commission to be in a position to consider the need to classify chemicals via all exposure routes, when scientific evidence is available for one of these routes only. This is particularly important for CMRs where uses shall be considered. The cumulation of hazard-based, automatic restrictions or

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	bans, and excessively severe SCLs, constitute roadblocks for the objectives of the EU's Green Deal which may more systematically be identified and removed by the Commission and ECHA. This option may help in addressing the issue of "keeping up to date with the science" if it includes the possibility to revise existing CLH cases when new data become available that could change the existing classification (including a given category, exposure route, or SCL). This option should also entail the possibility to raise and evaluate the impacts of the proposed classifications, with more clarity on the effects at downstream legislation level Harmonised classification should remain focussed on legal requirements (BPR) and what matters from a perspective of endpoints (CMR). The remaining endpoints should be left to registrants with ECHA acting as an auditor reviewer like all other registration sections. This would increase industry's responsibility of and make better use of ECHA's and national authorities' resources.
30	Eurometaux could support one scientific derivation of a scientific basis that can then be used in different pieces of legislation. In these pieces of legislation, the feasibility and socio-economic aspects can be taken into account before setting a limit value.
31	None
32	The present system of Annex XV classification reviews by RAC is highly burdensome, not effective and cannot be challenged on its scientific credibility. A publication of priority chemicals of concern can be used to stimulate better updates of self-classifications and may allow RAC and Member States to refocus their role to that of a review group in charge of assessing the classifications and thus to permit reallocation of resources to address complexities in CLP (guidance, clean-up of inventory, enforcement). Low concern would not only mean "low hazard" but rather complete data sets reviewed and concluded on with care.
33	Improvement of files should not be hampered by costs/fees
34	None
35	ECHA should change the system the way that the companies can remove notifications when applicable.
36	Cases are mainly with outside EU and companies operating globally. Still, we would plea for a simplification of labels to remove duplicate information on the label that would originate from different regulations. In this way, the relevant information will be easier to find by the user and will also result in the reduction of administrative cost and regulatory burden for companies and facilitate the competitiveness for EU chemicals industry.
37	None
38	Hazard labels should keep as a minimum those label elements that are important for the safe use of products. Elements like additional hazard, safety and precautionary advice, product composition and use and the respective translations into other languages could be kept in a digital format. Harmonization of digital communication via a common EU framework would lead to clearer hazard communication and awareness of the safe use of products.
39	Safety of products is compromised when non-compliant products enter the market

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40	None
41	None
42	Online sales are a complex issue but most relevant priority. Not all online platforms are the same. Some are very legitimate with strong reputations and take responsibility for the products that are sold (e.g. online stores). Others are legitimate with strong reputations but do not take such responsibility for the products that are sold (e.g. online auction sites). Other are not legitimate in either sense and can be transitory and mobile.
43	None
44	None
45	If products have already specific labelling requirements according to EU regulations that are complementary to CLP, then they should remain subject to that regulatory regime to avoid confusion with labelling obligations from CLP. Those questions concern the products that are out of scope of the CLP Regulation and they are entirely regulated by other legislation (medicines, cosmetics, food, etc.). It should also be noted that the real impact from CLP hazard classifications and new hazard classes is related to so-called 'automatic link to bans' and risk management measures that are triggered by some classifications in REACH and other sector legislation (e.g., use of CMRs category 1 in consumer products, Seveso, etc.). The CSS states that the Commission intends to introduce more 'generic restrictions' driven by the hazard classification of substances or mixtures, which will lead to more bans and restrictions. These consequences should carefully be considered in the impact assessment for the proposed new classes. We propose to include the possibilities to decouple the automatic link between CLP and other legislations and/or to require a downstream legislation to include the consideration of specific exposure potential before risk management is envisaged, to prevent non-proportional measures (e.g., Seveso for massive metals)
46	If products already have specific labelling requirements according to EU Regulations that complement CLP (e.g., pharmaceuticals, food additives, cosmetics as outlined in Article 11 of the EU CLP), we would like to propose that those remain subject to those regulatory regimes to avoid confusion with labelling obligations from CLP. However, to keep a level-playing field, we would support the view to cover endpoints not in focus of those regulations (e.g., environment) by CLP labelling.
47	Expanding the PCN notification obligation from mixtures to substances would not bring any added value on safety for human health and environment perspective as the information on the substance(s) is already available in the ECHA substance information tool. This would lead to duplicating information in C&L inventory, PCN tool and REACH databases. The C&L inventory would require a clean-up before it can be considered as 'sufficient' to fulfil the objective.
48	None
49	We would like to raise some concerns regarding this questionnaire. The applicability of some questions was unclear, or the formulation of the provided replies did not allow to bring

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	in nuances. We were also expecting to see some questions related to the items identified along the CLP Fitness Check process. Finally, scientific opinions increase their robustness and credibility if they can be challenged. Such possibility already exists for testing proposals, dossier and substance evaluations but not for classification proposals. As a result, contested scientific opinions are brought to the table at policy level, where they do not belong. For quality and consistency, we therefore recommend setting up a science appeal potential, at ECHA's level, like it exists for ECHA evaluation decisions by the Board of Appeal
50	This file

ABOUT EUROMETAUX

Eurometaux is the decisive voice of non-ferrous metals producers and recyclers in Europe. With 500,000 employees and an annual turnover of €120bn, our members represent an essential industry for European society that businesses in almost every sector depend on. Together, we are leading Europe towards a more circular future through the endlessly recyclable potential of metals.

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