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Eurometaux response to the public consultation on the Inception Impact Assessment (IIA) on the Revision of CLP

Eurometaux welcomes the possibility to comment on the CLP Inception Impact Assessment.

A harmonised way of identifying and communicating hazards is crucial to ensure the safe use of chemicals at global, national and regional level. The metal/inorganic sector, producing and trading on a global scale, actively supports the UN GHS and the EU CLP that contribute to a well-functioning market and a high level of protection of human health and of the environment.

The CLP has been identified, alongside REACH, as a key legislation for a successful implementation of the Chemicals Strategy for Sustainability, hence the importance of its optimal functioning. The CLP Fitness check concluded in 2019 that the legislation delivered results as intended and is fit-for-purpose, but also draws attention to issues that need further improvement, such as simplification and burden reduction or areas that merit attention.

The fitness check also 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 CLP continues to meet its objectives.

The sector's comments on the CLP IIA and on the proposed policy options will also consider these issues to allow the EU chemicals legislation to deliver up to full potential.

- ***On the introduction of new hazard classes (such as endocrine disruptors) and corresponding criteria:***

The IIA indicates that the Commission sees a need for implementing new hazard classes in CLP. As the CLP revision will most probably 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. We recommend that any proposal to add new hazard classes and/or to amend existing ones should first be made 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).

More specifically, on the proposed new hazard classes:

- 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.

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- On the proposal to consider the development of a parallel **terrestrial environmental classification** system: an extension of the hazard assessment for the environment to the terrestrial compartment for classification purposes should only be considered if it would provide 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. 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 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. However, in case the EU nevertheless goes ahead with the development of such a terrestrial scheme, we propose that the learnings on how to conduct a proper hazard assessment for metals and inorganics should be considered from the start, as they are well documented from previous discussions and reviews.
- For **other hazard classes** like immunotoxicity, neurotoxicity, we question the added value of introducing hazard classes for modes of action like immunotoxicity and neurotoxicity that are adequately covered by existing hazard classes (STOT-SE and STOT-RE and toxicity to reproduction in the case of developmental neurotoxicity)
- For hazard classes like PBTs and PMTs), the possible impacts will be directly related to the criteria and their implementation and whether e.g., specificities of chemicals will be considered (e.g., PBT for metals/inorganics in REACH Annex XIII). We need to have commonly agreed criteria and international agreement is key in this context.
- It should however be noted that the real impact from CLP hazard classifications and these 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. It is also proposed 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).

- ***Clarify the obligations to classify mixtures and some complex substances:***

We further support the development of approaches supported by science to classify appropriately complex materials like alloys, UVCBs, inorganic matrix containing materials such as ceramics and frits, etc. and the related hazard communication. In view of the volumes of complex materials present on the markets and in society and the need to address their hazards properly, we would support a reference in the CLP legal text (and in Annex I) to frame the possible refinements of CLP.

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- ***Introduce the possibility to submit proposals for and set harmonised environmental and safety values for some substances:***

The benefit of deriving harmonised safety values under the CLP is unclear.
DNELs and PNECs belong to the hazard and risk assessment under REACH, and their derivation goes further than hazard identification & classification by considering e.g., assessment factors. DNELS and PNECs cover conditions that can be broader, more flexible but also actually occurring compared to the conditions required for a standard hazard assessment used for classification. Submitting proposals and setting harmonised environmental and human health safety values will further increase the burden on RAC, in addition to the need to assess more harmonised classifications as a consequence of the new hazard categories intended to be introduced in CLP. The legal relevance and additional workload for RAC should be considered in the impact assessment.

The introduction of limit values in the CLP may also lead to unintended consequences for the implementation of other legislation applicable to the sector, which could impact the effectiveness of the overall regulatory system for chemicals, as well as industry's competitiveness. Further clarifications on the trigger and scope would be welcomed to assess the impacts more specifically. In the Impact Assessment it should be properly assessed what consequences the introduction of limit values may have on other legislation (e.g., OSH).

In this respect, it should be ensured that the setting of limit values under CLP does not lead to 'automatic risk management measures', as the application of limit values normally needs to take into account feasibility and socio-economic aspects.

Moreover, updating a DNEL or PNEC/ERV via the CLH process when new relevant information becomes available will require more resources and time than the updating of a registration file. A CLP inspired process may therefore slow down the inclusion of the newest evidence and science rather than promote it.

- ***Introduce a mandate for Commission to request ECHA to develop new harmonised classification and labelling ('CLH') dossiers:***

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 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[1] where uses shall be considered. The cumulation of hazard-based, automatic

[1] As (i) many automatic bans and restrictions result from a harmonised classification, and for (ii) Specific Concentration Limit (SCL) values are derived based on data for one exposure route (e.g., inhalation) although it is not relevant for most of the uses of the chemical which are addressed in the subsequent (hazard- or CLH- based) risk management regulations (e.g., uses leading to oral or dermal exposure only)

restrictions or 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 that could change the existing classification (including a given category, exposure route, or SCL) become available.

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.

Finally, we wonder whether the current conditions for industry to submit a (re)classification dossier could not be made smoother. Such cases presently remain rare even if new evidence on hazards were to indicate such needs. The main reasons are the cumbersome process for updating/revising an existing classification (including convincing a Member State) but also because dossiers submitted by industry are not always considered exclusively on the basis of their scientific merits. This creates disharmony between classifications applied in the EU, where suppliers cannot deviate from the harmonised classification entry even if scientific evidence disagrees with the mandatory minimum classification, and other regions of the world, where science-based classifications shall be implemented.

- ***Introduce a prioritisation mechanism for harmonising the classification of certain chemicals:***

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).

- ***Promoting the scientific robustness and credibility of the assessments:***

Scientific opinions increase their robustness and credibility if they can be challenged. Such possibility already exists for evaluations but not for classification proposals. 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. Furthermore, this would prevent that scientific considerations are raised are debated at policy level as is presently often the case (e.g., CARACAL).

We are interested to contribute to the supporting study the Commission plans, to the development of policy options and scenarios as well as to the assessment of impacts of the various policy options.

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