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38. Meeting of Competent Authorities for REACH and CLP – CLP topics - written comments – Agenda item CLP 3

Document "AP_3_CLP revision - CARACAL-38_V2.pdf"

The DE-CA thanks the Commission for the opportunity to comment on the proposed changes to Regulation (EC) 1272/2008 (CLP Regulation) as part of the new chemical strategy. We appreciated that the Commission provided its concrete proposals regarding a future CLP revision in a power point presentation at CARACAL 38. However, it would be very helpful for a CARACAL discussion if the Commission could present documents that are more detailed and descriptive on the individual proposals, also well before the next CARACAL meeting. The timeline, as presented, is rather ambitious and the matter of the proposals of such grave nature that they require thorough examination and coordination of different experts at Member State level.

Being aware of the time constraints of preparing such documents, we request the Commission to provide CARACAL members with more detailed information regarding the outlined CLP revision. For example, the specifics of the approach to address a PMT hazard class that were presented at a scientific workshop may also be of interest to CARACAL.

As the Commission's presentation did not provide specific details in particular, we would like to comment in general on some of the points addressed by the Commission.

Please note that these general comments do not represent any finalised position from and have not yet been approved within the German Federal Government and the German Competent Authority. An agreed position can probably only be provided when more detailed proposals by the Commission are available.

1. **Inclusion of a mandate for COM to request ECHA to initiate, develop and submit a proposal for CLH dossiers**

The strengthening of the role of the ECHA Secretariat is problematic if the same persons who draft the dossiers also support RAC rapporteurs when assessing the dossiers. This allocation of tasks is already problematic in the restriction process.

2. **Harmonisation of human health and environment based safety values (e. g., PNEC, DNEL)**

In our opinion, Annex VI of the CLP Regulation is not the systematically correct place to accommodate said safety values, as they are not relevant for the classification and labelling of substances and mixtures.

3. **Prioritisation mechanism for substances subject to HCL and mediation possibility at EU level**

As the Commission has not specified how and at what level of the process such a prioritisation mechanism would be established, it is difficult to comment on that point. More information on the intended mechanism, especially concerning the aspect of mediation, would be very important.

4. **Inclusion of an additional opportunity for concerned parties to comment during the procedure for HCL**

The DE-CA agrees that in a number of cases when the proposed classification of substances (i.e. RAC Opinions) were intensively discussed at CARACAL level, a substantial delay in further processing took place. Therefore, we have sympathy for finding solutions that would avoid lengthy discussions after a RAC opinion has been finalised.

5. **New hazard class for ED for human health and one for the environment with a categorisation system for both**

As there are still doubts at expert level regarding the need of an additional hazard class for ED human health, we suggest to assess carefully whether such a hazard class is in fact required and, if so, how it should be designed.

6. **Assessment of the need for specific criteria for immunotoxicity and neurotoxicity, currently covered under 'Specific target organ toxicity' and 'reproductive toxicity', and their amendment if necessary**

On a technical level, according to our experts the existing hazard classes on specific organ toxicity adequately address the endpoints immunotoxicology and neurotoxicology. Therefore, no changes to the system would be necessary at this point. Besides, any changes to the harmonised UN-GHS building blocks in the CLP Regulation should be avoided.

7. **Assessment of the need to limit the labelling derogation for some products (e. g. cosmetics)**

Extending the scope of the CLP Regulation to other product groups that are currently not classified and labelled according to the CLP Regulation would mean that other downstream legislation that is linked to the classification will also start to apply to these products. It should be thoroughly examined beforehand whether the resulting consequences are aimed for, appropriate and necessary.

8. **Inclusion of the obligation for distributors to notify to the poison centres their mixtures classified as hazardous for physical hazards or for human health and the obligation of duty holders to notify substances / Clarification of the role of duty holders to notify to the poison centres their mixtures classified as hazardous for physical hazards or for human health**

We very much welcome any clarification regarding the roles of duty holders under Article 45. The current discrepancy between the views of some Member States and the Commission creates additional difficulties to those obliged to notify and weakens the common market.

9. **Obligation to periodically update CLP inventory notifications**

We support any actions that aim at increasing the data quality and the usefulness of the classification and labelling inventory. An obligation to periodically update the inventory may be suitable to increase the data quality and usefulness of the inventory. However, the real driver to increase the usefulness of the inventory would be to increase the number of agreed classifications.

10. **Clarification of responsibility for compliance for online sales / Clarification of responsibility for compliance for online sales by non-EU economic operators directly to consumers within EU**

A standardization and clarification of the provisions of Article 48 of the CLP Regulation, or a corresponding amendment to include clear regulations for online trading, is welcomed.

11. **Possibility of adapting [limiting] labelling requirements for mixtures supplied in certain forms (e. g. in bulk, very small containers like pens)**

The exceptions to labelling permitted in Article 29 and possibly Article 23 and Annex II should be updated and adapted to the current requirements, also taking into consideration the discussions currently taking place in HelpNet and the Forum.

12. **Clarification of how to apply the bridging principles for classification**

Clarification of the scope and applicability of the bridging principles is welcomed in principle. However, the bridging principles are part of the UN GHS building blocks of the individual

hazard classes and should therefore not be altered. The currently active mandate on the application of the bridging principles within the UN GHS workgroup for practical classification issues should be used to clarify these issues. It is envisaged that at the UN GHS level this workgroup topic will be chaired by the DE delegation.

13. **Remove the requirement for separate Commission legal acts when those are based on different empowerments**

It could be adequate and useful to amend the empowerment in Article 37(5) of the CLP Regulation to Annex VI Part 1 to allow the inclusion of new notes to substances listed in ATPs. However, further discussions about possible changes to the empowerment in Article 45(4) of the CLP Regulation are necessary.