Ad-hoc Meeting of the CAs for the REACH and CLP Regulations (CARACAL) on CLP Revision

6 December 2021 09:30 – 17:00

Webex meeting

Concerns: CLH Prioritisation - Commission’s Right of Initiative to Introduce CLH Dossiers

Agenda Point: 2

Action Requested: Competent Authorities and observers are invited to comment on the document and the discussion points put forward. Written comments should be sent by 10 January 2022 to:

GROW-CARACAL@ec.europa.eu
ENV-CARACAL@ec.europa.eu
CARACAL@echa.europa.eu
1. PURPOSE OF THE PAPER

This paper concerns an action under the Chemicals Strategy for Sustainability regarding the introduction of the Commission’s right of initiative to propose harmonised classifications under Title V, Chapter I (Establishing harmonised classification and labelling of substances). It also explores the possibility to introduce a roadmap for the prioritisation of substances. COM welcomes any views from CARACAL on the proposed options.

2. BACKGROUND AND CONTEXT

According to the findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) "a number of stakeholders, for instance, have expressed concerns with respect to the pace of the harmonised classification processes in contrast to the processes of self-classification by industry" and that "the Member States’ capacity to prepare harmonised classification dossiers is limited, [...] (...). Moreover, the workload is unevenly spread between Member States’ competent authorities, with just a few Member States carrying the majority of the burden". Furthermore, the Fitness Check recognises that "given the high number of substances that need to be assessed and the resources and the time that such an assessment requires, this [substance-by-substance] approach has its limits in terms of the overall efficiency" [italics added].

The Chemicals Strategy for Sustainability sets forth that the Commission will ensure that CLP is the "central piece of hazard classification and allows the Commission to initiate harmonised classifications". This action is closely related to the one substance, one assessment approach.

In its inception impact assessment, the Commission states that it will examine the need to introduce a mandate to request ECHA to develop new harmonised classification and labelling dossiers, as well as to introduce a prioritisation mechanism for harmonising the classification of certain chemicals.

In addition, also the public consultation of the CLP revision contains specific questions related to COM’s right of initiative (see questions 29, 32).

3. OPTIONS

3.1. Prioritisation mechanism handled by ECHA

The proposal of introducing a prioritisation mechanism under CLP for the assessment of CLH dossiers intends to increase effectiveness and a proper allocation of resources in line with the priorities. Hereinafter the general principles are provided that the

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Commission would like to discuss for the mentioned prioritisation mechanism. To be noted that this mechanism should complement the prioritisation that is currently stated in Article 36 of CLP, - which is in any case likely to be amended by the introduction of the new hazard classes.

- Dossier submitters (MSs/companies) *indicate* their intention to submit a CLH dossier in ECHA’s registry of intentions at least [X] months in advance (to be considered if this should become obligatory or stay as voluntary step);

- ECHA will screen the registry of intentions for new CLH proposals on a regular basis.

- ECHA publishes/proposes on a regular basis a prioritisation of the CLH intentions based on the following criteria, and taking account of the capacities of RAC to process CLH dossiers (the below list is only indicative and will be further developed in due time with Member State Competent Authorities):
  
  - Hazard class and category (e.g. prioritisation of EDs after the adoption of the criteria or Cat. 1 higher priority than Cat. 2 etc)
  - proposal for a group of substances
  - Tonnage (the higher the tonnage the higher the priority; based on information from REACH dossiers)
  - Exposure (e.g. consumer exposure, widespread dispersive uses, based on information provided in the relevant REACH dossier)
  - Number of registrants (the more registrants, the more likely that the classification is disharmonised)

- ECHA submits the proposed prioritisation programme to Commission for discussion in CARACAL and confirmation;

- CLH intentions not included in the prioritisation programme should be considered of low priority and should be parked for in a pool for further prioritization.

### 3.2. Introduction of COM’s right of initiative

The proposal of introducing a Commission right of initiative for the submission of CLH proposals intends to address shortcomings identified in the Fitness check (see above). Hereinafter, the general principles are provided that the Commission would like to propose for the introduction of the mentioned right of initiative for CLH dossiers.

In consideration of ECHA’s substance screening and discussions in RIME+, ECHA should draw a list of substances (or group of substances) that warrant a harmonised classification based on the above criteria provided in section 3.1.
Where no competent authority volunteers to propose a CLH dossier for those substances (e.g. no intentions to submit a CLH proposal is provided in the registry), the option for the Commission to mandate ECHA to develop such a dossier should be introduced in CLP.

Procedural steps:

- ECHA publishes regularly a list of most hazardous substances fulfilling agreed criteria not already harmonised
- Commission discusses the list with MSCAs (for instance in RIME+) on how to best address the concerns identified (e.g. by grouping some entries) and invites them to indicate if they wish to submit a CLH dossier (new entry in register of intentions)
- In case no MS volunteered for the identified substances, COM may mandate ECHA to develop a CLH dossier;
- ECHA prepares the dossier and starts the public consultation;
- As of the public consultation, the dossier follows the usual procedure (Art. 37 CLP).

Note: In line with the current provisions of Article 36(2) and 36(3) both the prioritisation mechanism and the Commission’s right of initiative would not apply to substances covered by Regulations (EC) No 1107/2009 and (EU) No 528/2012, where a mechanism for aligning the processes for hazard identification according to CLP and the sectorial risk assessment has already been put in place.

4. BENEFITS AND COSTS

4.1. Prioritisation mechanism handled by ECHA

- There will be a guarantee that Union resources (in ECHA, Member States industry, and COM), which are by nature limited, will be spent in line with EU priorities;
- Result: Increase in the number of high priority substances subject to harmonized classification
- Estimate of additional resources for ECHA: Need for assessment;
- CLP practitioners will also benefit from an increased visibility in terms of substances of higher priority for harmonised classification.

4.2. ECHA screening - CLH dossier initiated by COM

- ECHA has a good, EU-wide overview and is hence in a good position to identify the Union-wide most hazardous substances;
• CLH system will become more effective and become better as COM could concentrate on the most hazardous substances and group of substances screened by ECHA;

• ECHA already performs such screening exercise including for EDs, BPTs, to a lesser extent for PMTs, hence this implies very minor additional costs for ECHA.

5. **Questions for CARACAL**

1) What are your views on the options outlined under Sections 3.1 and 3.2?

2) Do you think that the proposed options would improve the current CLH system in terms of efficiency and effectiveness?

3) How could ECHA coordinate/interlink the screening exercises under 3.1. and 3.2.?

4) Do you think also PPP and BPR substances should be subject to Section 3.1 and 3.2.? Why?