



HEAL comments on CARACAL 43 proposals for reform of REACH authorisation and restriction (Doc. CA/03/2022)

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The Health and Environment Alliance (HEAL) welcomes the opportunity to provide comments on the Commission's thoughts regarding **potential options for amendments of the REACH Regulation in order to reform the REACH authorisation and restriction processes.**

We thank the Commission's transparent outlining of the different options considered so far in the reform process and we support the objective of a targeted reform at the service of increased health and environment protection and more efficient and effective processes.

GENERAL COMMENT

Independent of the options proposed, **we regret that the document fails to provide details about the Commission's thoughts regarding the consideration of grouping in a reformed system for restrictions and authorisations.** The grouping approach is piece and parcel of the future of chemicals regulations and it will allow overall more efficient, coherent, and protective chemicals management, promoting a more efficient use of existing data and reduced reliance on animal testing. We urge the Commission to fully integrate it in moving forward in this process.

Overall, although we appreciate the difficulty of the REACH reform exercise and the many challenges to deliver on the promises of the Chemicals Strategy for Sustainability, **we still fail to understand how the Commission plans to link the discussion of the reform of the authorisation and restriction processes on the one hand, and that on the extension of the generic risk assessment and on the development of the concept of essential use(s) on the other hand.** The latter two concepts are being developed and assessed through separate studies and processes, and yet they will be instrumental to the delivery of reformed REACH restriction and authorisation processes. A meaningful stakeholder contribution to Commission proposals regarding the latter reform will require a full overview of how those different processes are being linked with each other.

PROPOSED CHANGES TO THE CANDIDATE LIST

The proposal to expand the use of the candidate list is a positive step forward. We already particularly welcome the following:

- The **automatic SVHC identification** for substances for which a **harmonized CLP classification exists** in order to save time and resources from the Member States Committee (MSC);

- The introduction of a **dynamic link between CLP and the candidate list** for automatic updates of the hazard properties of classified substances in the latter;
- The introduction of **information provision requirements for registrants and downstream users (DUs)**, with obligations of regular updates, including information on alternatives, at the service of prioritisation for future risk management measures. When it comes to the requirements for **additional information on use(s) and exposure(s)**, we would welcome more details on the link between this new step at candidate listing with existing requirements upon registration. We believe that this information is necessary and must be **delivered primarily at the registration stage**.
- The introduction of an **initial notification and annual “fee” for SVHCs** in the Candidate List in order to incentivise substitution;
- The **obligation for DUs to provide proof of SVHC information provision and fees’ payment** to enforcement authorities;

We would like more clarity on the **consequences of the proposal to demonstrate the ELoC for hazards other than CMR, ED, PBT, vPvB, PMT and vPvM**. In particular, we would welcome **guarantees that this proposal will maintain the candidate listing option opened for those chemicals** that may hold the ED, PBT/vPvB, PMT and vPvM properties but might not yet have a related CLP classification. This is particularly important considering that hazard classification under CLP is a slow process, slower than candidate listing, and that we can expect a CLP high workload for the ECHA risk assessment committee (RAC) in the coming future.

In the view of maximizing the added-value of the candidate listing step, we would also welcome the addition of a **legal deadline for the introduction of risk management measures once a substance is listed on the candidate list**.

POLICY OPTION 1

This is currently our most favoured option as a basis for a reformed system. Although we understand that most of the proposed changes currently relate to authorization, we believe that this option should also foresee a reform of the restriction process through article 68.1 in order to make the use of the restriction tool easier and more efficient for Member States.

3.2.1: In terms of speeding up the prioritization and inclusion of substances in annex XIV

We welcome the proposed aim, but we have several questions regarding the measures put forward:

- **As for removing the MSC opinion from the annex XIV recommendation**, we doubt that this is the most useful and efficient measure at this time. In our view, it is much less the MSC involvement and proceedings that are currently jamming the system, but rather the delays that come from the Commission’s own procedures. We would therefore recommend the Commission to make proposals to speed up its own decision-making cycles, with e.g. the introduction of a deadline for annex XIV updates, or through making the annex XIV update automatic based on a simple majority support from the MSC.
- **As for the proposal to introduce a new consultation tied to the addition of new requirements linked to candidate listing**, we currently do not see the added-value that this

could bring to the process and rather fear this might slow down the prioritisation exercise based on the existing information.

3.2.2: Application for authorisation phase

We welcome the proposals that aim to simplify the application process and strengthen incentives for substitution. We support comments raised by colleagues from ChemSec and ClientEarth during the CARACAL-43 meeting about the need to further develop active incentives for companies to provide more and better information about substitutes in a way that really delivers.

3.2.3: Evaluations of applications for authorisation

While we support proposals to integrate a formal completeness/conformity check procedure, we are wary about the real-life implications of the proposal to include advice from the Forum on enforceability. While the forum should be available for consultation, the development of restrictions should not be tied to its advice. Guarantees should be introduced that the consultation of the Forum cannot be used to block the development of restrictions in the future.

3.2.6 Restriction process

- 3.2.6.1 Restriction process under article 68.1

In our view, **the current restriction process under article 68.1 would still benefit simplifications in the objective of making the use of this tool easier for Member States** by reducing the burden of proof placed on them when they wish to introduce a restriction on a (group of) chemicals.

Because the process is currently very slow, **the introduction of legal deadlines for the presentation of a restriction proposal should also be considered:** 1) a maximum deadline between the introduction of a RMOA and the Commission proposal for decision and 2) a maximum deadline between the publication of the final ECHA committees' opinion and the Commission proposal for decision.

- 3.2.6.2 Restriction process under article 68.2

In our view, the option to use the **restriction tool under article 68.2 should be opened to Member States** in addition to the Commission.

Furthermore, we are concerned to read that the **Commission is proposing that “[t]he impact assessment will evaluate costs and benefits of integrating the horizontal essential use concept in REACH and, on this basis assess how the essential use concept could be combined with the concept of safe use.”** (p.15) In order for the essential use concept to deliver as promised in the Chemicals Strategy for Sustainability, it is necessary that its development remains independent from considerations on safety. Considerations on safety are relevant for articles throughout their lifecycles, but this is different discussion than that on the development of the concept of essential use (which aims to guide overall chemicals management).

POLICY OPTION 2

Although we welcome the efforts to achieve greater efficiency and simplicity in the current system through this proposed option, we have multiple concerns that make it difficult to support it in the current form.

First, under this option, **we still see the need to include a reform of article 68.1 restrictions** in a way that makes their use easier and less burdensome for Member States to use, when they do have a concern about a (group of) chemicals.

Second, the provisions to introduce derogation requests under this option raise a number of concerns. This is partly due to the multiplicity of entry points for the introduction of such requests, which we find confusing when the purpose of the reform is to simplify the system. This also has to do with the very large leeway granted to the European Commission to introduce such derogation proposals at a very early stage in the system, without the scrutiny of either relevant ECHA committees or Member States. This appears especially critical when the achievement of increased health and environment protection through authorisation and/or restriction will require much better reflection on, and accounting of, safe alternatives in the future. However, discussing requests for derogations upstream without involving all relevant actors will prevent in-depth exchanges to change the status quo. The REACH reform must precisely strengthen this step by strengthening the critical review and oversight of derogation requests. ECHA's scientific committees and Member States are likely better equipped than the Commission alone to collect and share information about alternatives to be considered for discussion at this stage.

POLICY OPTION 3

We are not in favour of this option. In our view, the removal of the authorisation chapter would be detrimental to the substitution efforts of chemicals of concern, and therefore run counter to the objective to strengthen the REACH regulation for increased health and environment protection.