**EEB comments on the CARACAL document CA/03/2022 on potential options to reform REACH Authorisation and Restriction processes**

### Introduction

The EEB welcomes the opportunity to provide comments on the European Commission’s proposal with potential options to reform REACH Authorisation and Restriction processes (Doc. CA/03/2022).

We welcome the reforms that will speed-up the elimination of hazardous chemicals and reduce releases and exposure of people and the environment.

The REACH revision offers an opportunity to:

**Clarify the legal text** on issues such as the definition of uses and of intermediates to introduce follow up regulatory measures and to establish stricter deadlines.

**Speed up the regulation of hazardous chemicals**: by extending the fast-track restriction route (Art 68.2) to additional hazard categories and professional uses and by opening this route also to member state competent authorities; by adding additional SVHC categories; by incentivizing the restriction of groups of chemicals; and by establishing strict deadlines to each process.

**Promote substitution at an early stage** for example by introducing downstream users (DU) notification of uses, market analysis and alternatives as well as fees for use of SVHC and restricted chemicals and **support frontrunners.**

**Simplify the system**: by applying the essential use concept to reduce the number of applications for authorisation and derogations for restriction; by reducing authorisation to one route, only for downstream users and individual or collective application for similar uses; and by changing the trigger of restrictions from demonstrating unacceptable risk to justifying high concern.

**Increase information on uses, alternatives and emissions**: through DU notification of SVHC; empowering authorities to request missing information (e.g. uses, emissions, etc); mandatory authorisation process when not enough information is available to determine if a use should be restricted; labelling, monitoring and reporting requirements for all derogated uses of restrictions.

Below we provide comments on the different options outlined in the CARACAL CA/03/2022).

**3.1.- Candidate list**

**Future role**

We support the new role of the candidate list as it will allow mapping of industrial use and end-uses, alternatives, and key performances, as well as support company innovation and substitution efforts. We note that this should not undermine the obligations of industry to provide information on exposure, use, volumes, etc at the registration phase which needs to be strengthened.

We welcome that the candidate list becomes a tool to gather more advanced information on uses of substances of very high concern and their possible alternatives. We support the establishment of notification obligations, including updates and annual fees, by registrants and downstream users (DUs) of candidate list substances. In addition, an obligation to perform an annual substitution plan following the successful [TURA](https://www.mass.gov/guides/about-the-toxics-use-reduction-act-tura-program) model should also be established to reduce the use of SVHC and incentivise substitution.

The budget acquired through the annual fees should primarily support substitution activities, including market surveys and a Safe and Sustainable by Design (SSbD) and a substitution support network to be created under the Chemicals Strategy for Sustainability (CSS).

We do not agree that the information on uses of substances of very high concern (exposure, emissions, waste management) and their alternatives should replace the need to amend the registration requirements. Use and exposure information of all chemicals should be provided at the registration stage. The candidate list notification should support gathering more detailed information from downstream users of SVHC that would build on the existing registration information and allow a better understanding of uses, markets and alternatives.

**Inclusion of substances in candidate list**

We agree with establishing an automatic process for including CLH substances in the candidate list. However, the document does not clarify what would happen with the current SVHC identification process for identifying PBT/vPvB substances under REACH. If CLH is established as a pre-condition for SVHC identification, the process of candidate listing for PBT/vPvB substances would not be simplified, on the contrary, the time needed for their SVHC identification and candidate listing would become much longer which is contradicting the aim of the CSS to simplify and speed-up risk management. Therefore, we propose to maintain the current REACH SVHC identification process for PBT/vPvB substances under REACH. In addition, a similar procedure should be established for EDCs and PMT/vPvM substances (based on the criteria of the new CLP hazard classes, without the need for an Equivalent Level of Concern (ELoC) assessment. The current SVHC identification process by MSC is fast and efficient. Adding C&L as an additional, mandatory step before SVHC identification and candidate listing would delay further risk management of these SVHC by an additional 3 - 7 years. In addition, RAC would be overloaded even more, if ED, PBT/vPvB and PMT/vPvM assessment become their responsibility.

An automatic process between CLH and SVHC identification should be established in both directions. Both processes for identification of hazardous substances should be maintained as they have different roles and prompt different regulatory processes and obligations. CLH classification should prompt automatic SVHC identification and SVHC substances should be prioritised for harmonised classification.

Regarding the options to demonstrate Equivalent Level of Concern (ELoC) (similar procedure to Article 59) the EEB considers it should not be limited to “other hazards than” CMR, ED, PBT, vPvB, PMT and vPvM but also remain a safety net for substances with evidence of CMR, ED, PBT, vPvB, PMT and vPvM properties which do not fulfil the article 57 a-e criteria, but which are considered to be an equivalent level of concern, such as quasi PBT/PMT chemicals or substances identified to meet a number of different (potential) concerns e.g. a carcinogen cat. 2 that is also a reprotoxicant cat. 2 and a skin sensitiser.

**Other elements that are missing:**

* Require only a qualified majority for identifying SVHC by the MSC to avoid a few or even one member state blocking the identification of certain substances.
* In case of intervention by the European Commission (COM), if a SVHC is not unanimously agreed by MSC, the time between ECHA’s opinion and COM’s decision should not exceed 6 months.
* Require timelines within which to include all harmonised CMRs in the Candidate list (under article 59).
* Expand the list of properties that should be identified as SVHCs and substituted e.g. immunitoxicants or neurotoxicants.
* Promote assessment of groups of chemicals for the candidate list to increase efficiency and avoid regrettable substitution.
* All CMRs, PMT/vPvMs and EDCs should be treated as non-thresholds by default, similar to PBTs and vPvBs.
* Introduce a maximum strict time frame for entry into force of risk management measures after inclusion in the candidate list.
* An annual substitution plan should be required from manufacturers and users of candidate listed substances.
* Need a clear mandate to ECHA to order market surveys.
* Need to link the fees with the SSbD and substitution network committed by the CSS.

**3.2. POLICY OPTION 1. Keep the authorisation process, with clarifications and simplifications**

**3.2.1. Prioritisation and inclusion of substances into Annex XIV**

We agree that the actual process to prioritise and include substances into Annex XIV could be improved and speeded up if DUs provided information on their uses and alternatives through a notification process.

In relation to the additional changes proposed in the document we consider that Member states should keep a mandate in the recommendation process. Once ECHA and the MSC agree on the recommendation for inclusion of SVHCs in Annex XIV, these should be added directly to Annex XIV. There is no need for the Commission to further scrutinise the recommendations once MSC has already agreed to this. In case the Commission keeps its responsibility in the inclusion of SVHCs in Annex XIV, we support the addition of a deadline for the Commission to include SVHCs in Annex XIV.

***Other elements that should be taken into account***

REACH requires ECHA to recommend SVHCs to be included in annex XIV at least once every two years. We consider that this timeframe slows down the system while ECHA has demonstrated that, in practice, lower time frames are feasible. We therefore recommend that:

* The consideration for the workload of ECHA- as currently allowed by Article 58.3, should be eliminated since it may encourage prioritising substances with fewer uses and users rather than substances with a higher number of uses; thus, more problematic for human health and the environment. SVHCs should be prioritised for phase out regardless of ECHA’s capacity optimisation.
* Implement a regular, annual process instead of recommendations provided “at least every second year” as currently required by Article 58.3.

In addition, we consider that cumulative effects of SVHC should be considered for prioritisation.

***Removing MSC opinion from the Annex XIV recommendation process?***

The Annex XIV recommendation process can be further simplified and streamlined. However, we don’t support removing the role of MSC entirely in order to maintain a democratic recommendation process and since this process is rather efficient. The main bottleneck of the process is the Commission's slowness in taking on board the MSC/ECHA’s recommendations. Automatic inclusion from ECHA’s recommendation to annex XIV or a short deadline imposed on the Commission is more important. We therefore recommend:

* Give mandate to ECHA to add substances to Annex XIV once the recommendation is supported by majority by the MSC.
* Require a maximum one-year time limit to the Commission for the inclusion of candidate list substances in Annex XIV in case the current system is maintained.
* Ensure that ECHA is resourced in order to be prepared for peaks in authorisation requests.

***Would you be in favour that in case new requirements linked to the Candidate listing to submit additional information would be introduced, only a simplified consultation is needed during the prioritisation process?***

Consultation is not needed in our view, ECHA needs to prioritise SVHC based on the available information. If not sufficient information is available, it should be part of the criteria for prioritising SVHCs.

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**3.2.2. Application for Authorisation phase**

**3.2.2.1. Requirements for applications**

We welcome the proposal to establish a clearer legal definition of uses applied for and exempted use, including the definition of intermediates, this is absolutely crucial. A definition of use applied for is needed in order to avoid too broad uses -that include several uses, for which exposure and alternatives’ information is not possible in practice.

We also welcome the proposal to develop a specific set of information requirements (“reporting standards”) for applications for authorisation, that should be included in the legislation as well as ensuring clearer guidance to applicants and ECHA Committees. We agree it would increase efficiency and to ensure legal certainty and predictability. In addition, up front information at the candidate listing stage will allow best practices to be established. This candidate list information would establish the minimum risk management measures (RMM) that applicants should have already implemented as a requirement for submitting an Application for Authorisation.

Regarding the question of who should be allowed to apply for authorisation, we consider that authorisation should not apply to manufacturers, only to users of SVHCs. Upstream or broad use applications should not be allowed. To simplify the process, joint applications by downstream users, which have shown already to work well, should be highly incentivized for similar uses and operational conditions.

**3.2.2.2. Better specification of information requirements**

We agree to incorporate the essential use concept in Authorisation and Restriction, as a filtering tool - i.e non-critical uses should not be allowed to apply for an authorisation or derogation of restriction. The upfront information provided by the new role of the candidate list would allow to identify non-essential uses. Essential uses of SVHC would follow the authorisation path, in order to guarantee that authorities have detailed information on who is using SVHC and in which quantities, detailed exposure and emission information, availability of alternatives and to establish strict RMM and operational conditions (OC).

We agree on the need to redefine the legal conditions that need to be fulfilled by the applicants in order to legitimise the Commission to grant an authorisation, including a clearer definition of the suitability of alternatives. Additionally, the option to eliminate the applicants’ need to submit a socio-economic assessment should be considered. The socio-economic assessment is very burdensome for applicants and the SEAC and too often not useful for the decision making as authorisation decisions are generally triggered by the availability of alternatives and credibility of the substitution plan. The process should be simplified to only one route to apply for authorisation. Information requirements should include only justification of critical/essential use, minimisation of emissions, lack of alternatives and a substitution plan.

The EEB supports clarifying the requirements for submission and evaluation of review reports, as they will facilitate the opinion making at RAC and SEAC, the discussions at the REACH Committee and the decisions by the Commission.

The ruling of the General Court on the lead chromate paints gives directions on the clarifications that are needed to be included in the legal text, such as limiting authorisations to specific downstream uses, etc.

We fully agree with the Commission that a gradual increase in the information requirements and submission fees for authorisation holders with every subsequent review report would incentivise substitution.

The EEB considers that the conditions for granting an authorisation should be clearly defined and equal to all actors that use or manufacture SVHCs. Favouring SMEs regardless of the volumes they manufacture/use undermines the protection goal of REACH.

Moreover, it is our belief that the authorisation process should be burdensome for companies to discourage continued use of SVHC and support frontrunners that provide safer products into the economy. The burden on SMEs could be eased through collective AfAs for the same or similar uses that establish common minimum RMM and OC. Existing experience with this kind of AfA has been positive.

**Additional issues for consideration:**

Authorisation also needs to apply to exports of substances outside the EU and to ensure a level playing field, no exemptions for authorisation of imported articles should be possible.

The authorisation procedure as established today is not adequate for recycling processes and recycled materials. It should be amended.

**3.2.3. Evaluation of applications for authorisation and opinion making**

The EEB supports the proposal to formalise the procedure for completeness/conformity check as it would clarify and make the procedure more predictable. A process to sort out AfAs for essential uses needs to be added, for example by including an opinion of MSC or a vote by the REACH Committee after the candidate listing.

We consider that the proposal to consult the Forum on the enforceability of the summary of the proposed conditions set out in the Opinions of the Committees would add additional burden for authorities and add complexity to the process as well as further slow it down. An assessment of the causes of the difficulties encountered by enforcement authorities is needed before adding a new procedural step to authorisation. For example, whether the difficulties are due to the lack of clarity of the conditions imposed, existing capacities and/or lack of resources of the enforcement authorities, etc.

We consider that the RAC members assessing AfAs have sufficient hand-on experience on the implementation of the conditions they are advising to establish. The Forum would need to incorporate OSH experts from different member states and be changed into a formal Committee delivering opinions. Moreover, the goal of authorisation is the phase out and substitution of SVHCs, if enforceability becomes a prerequisite, less SVHCs would be regulated and phased out in Europe, undermining the protection goal of REACH.

Currently ECHA does not evaluate confidentiality assessments of the AfAs and it is up to the applicants to decide what information should or should not be made public. We consider that a new requirement to ECHA is needed to oblige the Agency to check confidentiality claims of AfAs, similarly but much stricter than the provisions set in the registration chapter (for registered chemicals) since these are no ordinary chemicals but substances of very high concern for which exceptional use permit may be granted.

**Additional issues for consideration:**

All effects should be considered by RAC when describing and assessing the risks, not only the reason for inclusion in the candidate list as SVHC.

Annex I has its limits because it does not provide for a clear wording to be used by RAC to do a “qualitative assessment” of the risk for non-threshold substances. The wording currently used “RMM and OC are adequate in limiting the risk" in RAC opinions is very weak. Annex I or Article 60 should introduce more appropriate wording. Overall, chemicals such as EDCs or carcinogens and mutagens, should be considered non threshold SVHCs and treated equally than PBTs and vPvB chemicals.

**3.2.4. Decision making process**

The document includes a proposal to prolong the time for preparing a Commission proposal, e.g. up to 6 months. Prolonging the time for the Commission to prepare its decisions means prolonging the use of SVHC by applicants. If the changes suggested before by the EEB are implemented, the number and complexity of the applications will be highly reduced, and therefore the Commission should be able to decide faster. The legal text should be amended to:

* Establish a strict deadline of 3 months for the Commission to decide on the authorisation applications;
* When the Commission does not decide within a 3 months’ period, the starting date for the authorisation should be considered the sunset date set in Annex XIV.

**3.2.5. Review of granted authorisations**

The EEB welcomes the proposal to clarify grounds for the review of granted authorisations under Art. 61(4) as it is really needed!

**3.2.6.1. Restriction process under REACH Art. 68.1**

The options presented in the document do not consider any major changes to the restriction process under ART 68.1. Although it is a straightforward process, it is also extremely burdensome for authorities. A major bottleneck of this process is the European Commission as it delays regulatory decisions for years.

Art 68.1’s efficiency in reducing emissions and exposure to hazardous chemicals should be improved by:

* Explicit that the goal of restriction is to minimise emissions of hazardous substances.
* Reducing the burden of proof placed on authorities to demonstrate “unacceptable risk” by replacing it with the requirement to **demonstrate that there is a high concern** that needs to be addressed on a Community wide basis (e.g. non classified substances like dioxins in baby nappies, microplastics, mobile chemicals, immunotoxicants, etc.). The high concern could be justified through a risk or a hazard assessment using a more precautionary approach.
* Introduction of:
  + The essential use concept (consideration of the criticality of the use and the availability of alternatives) as cut-off criteria for accepting derogations and establishing transitional periods.
  + Mandatory authorisation process when not enough information is available to determine whether the use is still non-avoidable. This is to avoid continued use of the substance, without risk management and ensure the non-availability of alternatives.
  + Derogations should be conditioned to a justification of compliance with REACH obligations (registration, DU notification of SVHC, etc) and other legal obligations (OSH, water, waste, etc.).
  + Labelling, monitoring and reporting requirements as well as mandatory risk management measures and fees for all derogated uses. Fees should be based on hazard properties and tonnage use.
* Establish an obligation for the Commission to publish the reasons for not meeting its existing legal requirement to present the proposed restriction to be voted, within 3 months from ECHA’s final opinion. Additional consequences of decision delays should be established, such as the direct discussion at REACH Committee of the original proposal by the dossier submitter.
* Establish a deadline for authorities to present a restriction proposal since the publication of the assessment of regulatory needs (ARN, formerly called RMOA).
* The restriction proposal should not exceed a specific number of pages. A word limit should be provided also for contributions in public consultations.

**3.2.6.2. Restriction process under REACH Art. 68.2**

The EEB fully supports the proposal to extend Art 68.2 to further hazard classes and uses as part of the CSS commitments in order to phase out the most harmful substances in products for consumer and professional uses as a means to speed -up the elimination of hazardous chemicals in consumer products. However, we are concerned that the REACH consultation does not mention PMT and vPvM chemicals. The Commission should ensure that these classes of chemicals are also included in the revision of Art 68.2.

Moreover, the current implementation of article 68.2 is not exempted from loopholes. The granting of derogations for example lack of criteria or scrutiny, opening the door for unjustified derogations. Article 68.2 should therefore be amended as well in order to improve the process and introduce clear criteria for derogation acceptance.

The EEB is deeply concerned with the proposal to combine considerations on “safe” uses with the essential use concept. Safe use is the “business as usual” risk-based approach that should take into account the whole life-cycle of chemicals, including circularity. Adding this approach would not only generate additional complexity but most importantly, would undermine the essential use concept. A clear definition of Essential use is key to make the process efficient, make sure that only the essential use cases are discussed, and to keep the incentive for substitution. Also, critical uses should be substituted if alternatives are available.

**3.3. Policy Option 2: Merge the authorisation and restriction processes**

The proposal to merge or create an articulation between Authorisation and Restriction could simplify the process to ban hazardous chemicals in the EU. However, the final aim should be to eliminate as swiftly as possible the use and exposure to toxic chemicals, in particular SVHCs.

Therefore, continued use should be allowed only for essential uses, for a limited time and under conditions that allow monitoring, reporting and enforcing strict risk management measures that reduce releases. A yearly fee on the quantity of the restricted chemicals allowed to be used should be established to pay for the authorities’ enforcement costs.

The proposal laid out in option 2 of this document, would result in facilitating the continued use on SVHC by allowing for wide upstream and sectoral derogations, reducing the scrutiny of expert committees and member states and removing the incentives to substitute of the existing authorisation process.

**3.3.2. Restriction process under REACH Art. 68.2**

**3.3.2.1. Restrictions following GRA**

See comments to 3.2.6. Restriction process under REACH Art. 68.2 and comments on the proposal to allow companies/groups of companies to request broad derogations in our comments below.

**3.3.2.2. Restrictions for SVHC on the Candidate list for industrial and/or professional and/or consumer uses**

We understand that under this option the Commission would prioritise SVHC for restriction based on ECHA’s opinion and a stakeholder consultation. The Commission could propose derogations and allow industry to request further derogations after adoption of the restriction and include them as amendments to the Annex XVII entries. ECHA Committees wouldn’t give an opinion on the derogations proposed by the Commission.

This proposal would maintain and transfer the most problematic cases under the current system (e.g. upstream applications or broad uses and sectoral derogations to restrictions) directly to the Commission without assessment by RAC and SEAC. The scrutiny would necessarily be lower as it would be performed solely by the Commission.

Where the Commission had the power to take the final decision under set conditions, it now has the power to do the first and only assessment of the situation, without limits. This proposal would increase the discretion of the Commission, reduce scrutiny by authorities, experts and stakeholders and hinder the aim of REACH to eliminate/substitute all SVHCs as it would facilitate broad and sectoral derogations.

**3.3.2.3. Applications for derogations (common to GRA restrictions for professional and consumer uses and industrial uses of SVHCs).**

This proposal would allow companies/groups of companies to apply for authorisation/an individual derogation from the ban/restriction after adoption of a restriction by the Latest Request Date. The process to evaluate these requests would be similar to the current Authorisation process, including an opinion by ECHA Committees and vote by the REACH Committee.

We understand that the decisions to allow the continued use of the SVHC would apply not only to the applicants but also to any downstream user within the use. This is a single or a group of companies could trigger an authorisation for a whole sector, similar to the current “upstream” applications.

This process would facilitate the continued use of SVHC as it extends the authorisations to all companies using the chemicals, not only to those applying for authorisation and disincentivize substitution. The difficulties to assess these AfAs/derogations would be the same as for the current upstream applications.

An alternative option would be to facilitate collective AfAs for the same uses that establish common minimum RMMs and OCs, as mentioned in previous sections, existing experience with this kind of AfAs has been positive.

**Further considerations:**

We are concerned with the proposal to transfer the most problematic and resource consuming AfAs (upstream applications) and broad derogations to restrictions to the Commission without opinions of RAC and SEAC. This would save resources only if a much lighter level of scrutiny than today (already so low that it is problematic) is applied. We do not understand the logic behind the proposal that the most complex (upstream) AfAs are to be handled by the Commission itself, but individual, easier cases go through RAC and SEAC. If experts are supposed to help with complexity then the complex cases should go through them. This option should be rejected as it would allow for upstream AfAs and would allow one company to trigger authorisations for a whole sector. Authorisations need to be kept nominative.

An alternative option that would accelerate the elimination/substitution of all SVHCs would be to automatically include SVHC in annex XVII and in XIV, allowing time-limited continued use for essential uses through an application for authorisation. This would ensure transparency on which companies are allowed to continue using/emitting these chemicals and in which conditions.

In addition, we consider that the following changes to 68.2. are needed:

* Open this fast-track restriction route also to member states.
* Review of the actual derogation process.
* Inclusion of a compulsory work plan with deadlines.

**3.4. Policy Option 3: Remove the authorisation title from REACH partially**

We understand that the proposal under this option is to remove the Authorisation title although retaining the Candidate List that would serve as a tool to prioritise actions under REACH (restriction proposals) and non-REACH processes (OEL and BAT setting).

We completely oppose this option as either OEL setting or declaring the use of a SVHC as not being BAT would not result in the swift elimination or substitution of SVHC. The limitations of OSH legislation were one of the main reasons to adopt REACH back in 2006 and the Authorisation process has shown to be a very effective tool to reduce use and exposure to SVHCs at the workplaces. As the document highlights: declaring the use of a SVHC as not being BAT would not have the same impacts of Authorisation, as this would take place as part of the periodic BREF review work programme under the IED, and the final permit decision depends on local authorities, which adds potential lack of harmonisation throughout the EU. In addition, the ambition of the IED to write negative BATs applies to *hazardous* substances (IED annex III point 2), and thereby goes much beyond SVHCs; however, its approach is much less systematic than that of REACH.