EEB comments on the CARACAL Document CA/12/2022:
Study on the Possible Introduction of Additional Information Requirements on Uses and Exposures in REACH

Introduction
The EEB welcomes the introduction of additional information requirements on uses and exposures in REACH. The information provided in the registration dossiers on use pattern and tonnages is often incomplete, of low quality and not up-to-date, hampering the evaluation process and the implementation of risk management measures under REACH. We support implementation of all 4 proposed options in the revision of REACH. Our initial views and responses to the questions are provided below.

Answers to key questions for the impact assessment
1.1 Problem definition and the policy options

1) Do you agree that the improvement targets identified in Table 1 reflect the key problems as regards use and exposure data collected under REACH?

2) Would you be able to provide examples of instances where shortcomings in the available use and exposure data have created problems and/or had negative consequences?

3) If you think there are other problems with regard to use and exposure data under REACH that are not addressed by the policy options, please elaborate.

We agree that the targets for improvements identified in Table 1 reflect the key problems as regards use and exposure data collected under REACH. In addition, it would be useful if, for articles, information on the end of service life/waste stage is included to allow assessment of risks throughout the whole life cycle of the substance.

The lack of adequate use and exposure data is a general issue in restriction dossiers and of very high relevance for broad scope restrictions covering several chemicals and or several uses. This is repeatedly highlighted in the Annex XV dossiers and also in the opinions of RAC and SEAC. Recent examples include the restrictions of intentionally added microplastics or PFHxA.

The lack of up to date information on use and exposure hampers also the compliance check under REACH, as the hazard information requirements are dependent on the actual tonnage
band. Furthermore, the prioritisation of substances of very high concern on the candidate list for authorisation is dependent on up to date information on tonnage and use pattern.

1.2 Baseline (no policy change scenario)

4) How do you expect the baseline (no policy change scenario) to develop in the future? Do you expect the problems that the policy options seek to address will become more or less significant?

5) Do you foresee any specific instances (e.g. chemicals) in which a lack of high quality and comprehensive use and exposure data is likely to become a problem in the future?

6) Are there any other potential changes to chemicals legislation (including other potential revisions of REACH) that are likely to impact on the scale of the problem or the effectiveness of the policy options set out in this document?

The lack of high quality and comprehensive use and exposure data is already a big issue that has impacts on:

- Health and environment: Uses of hazardous chemicals that pose a risk to human health and the environment are not restricted or are allowed to remain in the market for long transitional periods due to the uncertainties regarding the quantities used. For example, in the case of PFHxA restriction, the lack of information on quantities used and resulting emissions from several uses (e.g. textiles, fire fighting foams, etc), obliged the dossier submitter to provide estimations that were later questioned by industry and resulted in SEAC not being able to conclude on the proportionality of the restriction for several uses and the proposal to support a wide derogation for all medical uses of PFHxA, despite only a few companies have asked for derogations for very specific uses and despite alternatives are available for a wide variety of uses.

- The lack of reliable information on uses and exposure also hinders the capacity to assess the reliability of CSR, as highlighted by ECHA. The most common compliance issues are related to exposure scenarios and several uses from different lifecycle stages linked to the same exposure scenario.

- The registration database is used by OSH professionals to guide their practices and recommendations, in particular in SMES. Lack of data or unreliable information on uses and exposure may lead to underestimation of risks or to poor risk management measures at workplaces, resulting in health and environmental impacts.

- Burden on authorities: as stated in the study the lack of adequate data in registration dossiers obliges authorities, when preparing restriction dossiers, to request this information through calls for evidence. Handling the information provided through these processes and assessing its reliability is very resource intensive, in particular as much contradictory information may be provided. Additionally, companies whose chemicals are under regulatory scope are reluctant to provide information.
The Commission intends to revise REACH with the introduction of the concept of essential use in authorisations and restrictions. This concept can be applied successfully only if reliable and up-to-date use and exposure information is available for the essential uses.

1.3 Significant impacts - costs

7) Please assess the feasibility of each of the policy options. If you believe that some of them are not feasible, please elaborate on the reasons.

8) What would be the potential (one-off and recurrent) costs of each of the policy options for registrants?

9) What would be the potential (one-off and recurrent) costs of each of the policy options for Downstream Users (DUs)?

10) What would be the potential (one-off and recurrent) costs of each of the policy options for the authorities?

11) Are specific types of stakeholders (e.g. registrants supplying a specific type of a chemical or SMEs) that would face particular difficulties or costs due to the policy options?

12) If you believe that there is a potential for significant costs, is there any way the policy options could be adapted to reduce these impacts (e.g. exemptions from some requirements for low tonnage substances)?

We consider that all 4 policy options are feasible and urgently needed. Option 3 will have the highest costs for DUs. However, as stated in the study, DUs are already obliged to have an updated inventory of the chemicals they are using, including uses, and quantities under OSH legislation. Also other environmental legislations (IED, water, waste, air pollution, etc.) include similar obligations. SDS digitalisation would lower these costs. Additionally, the obligation to notify user information will also improve the data of on-site risk assessments, resulting in improved risk management at workplaces and consequently on cost savings for the companies and reduced health and environmental impacts. These benefits should also be considered in the impact assessment.

We strongly support option 4. Authorities should have the power to request company data needed to regulate chemicals, in particular information on uses and exposure. Competition law already grants the Commission power to request companies requesting to merge to send them information. This option would incentivise companies (applicants for authorisation, asking for derogations to restrictions) to be accurate in the data they provide and the arguments they make to justify their request. Also companies are more likely to respond to a personal and formal request from the Commission (or ECHA) than to contribute voluntarily and proactively to a public consultation.
We do not see an increase of potential costs for authorities, on the contrary, improved information requirements will lead to reduced costs due to reduced workload for authorities (ECHA and MSCAs) because of better availability of reliable and up to date use and exposure information.

1.4 Significant impacts - benefits

13) In your opinion, are the policy options likely to be effective in terms of ensuring that better quality, more comprehensive and up-to-date use and exposure data are collected?

14) Are the improvements in data availability likely to improve the control of chemical risk (human health and the environment)?

15) The study may provide several specific examples of instances in which the policy options would improve chemical regulation outcomes. These case studies may be instances where better data could have improved past regulatory management of chemical risk under REACH or hypothetical examples of potential future interventions for specific types of situations[1]. Are there any such examples (case studies) that you believe should be considered by the consultants?

16) Is there a potential for cost savings for companies due to better information and the reduction of information collection costs for the authorities?

Each of the proposed options will be effective in terms of ensuring better quality, more comprehensive and up-to-date use and exposure information in its own way. We propose to implement an annual reporting requirement on tonnages and use patterns, to keep use and exposure information up to date.

For examples of cases where better data could have improved regulatory management we refer to our comments in section 1.2.

Availability of better data will allow better risk management measures focussed at the problem areas and might contribute to cost savings for companies by avoiding regrettable substitution. Availability of better data will clearly contribute to cost savings for authorities due to reduced resources needed for the collection of information.

1.5 Other impacts

17) Would there be any distributional effects, e.g. an impact on burden sharing between registrants and downstream users?

18) Do you expect any other impacts due to the policy options, for example with regard to competition, competitiveness or confidential business information?
1.6 Conclusions

19) As noted in the text, the individual policy options (and their components) can be combined into different packages of measures. What would be your preferred package and why?

Our preferred package would be the combination of all 4 proposed options as the complete package will be most effective in improving the availability of reliable, relevant and up to date information on use and exposure, both from manufacturers as well as from downstream users. By implementation of the whole package, it will be possible to accelerate the implementation of risk management measures as well as improve the level of protection of human health and the environment.

[1] For example, a widely used solvent where the registrant has limited information on Downstream Uses, etc.