EEB and ClientEarth comment on the options to strengthen substitution planning in the context of REACH
18th October 2024

This document contains comments by the EEB and ClientEarth on the "policy options" suggested by the "Study on strengthening the role of substitution planning in the context of REACH and other EU chemicals legislation" as one of the measures that could accelerate safe substitution and enable efficient use of industry and authority resources. Our comments are based on the options presented in the background document, slides shared with the participants shortly before the "Workshop for substitution of targeted hazardous chemicals" (1 October 2024) and the presentations held during this workshop.

The Commission stated during the workshop that an impact assessment of the policy options would be performed by the consultants to complement the initial impact assessment of the REACH revision performed in 2022 that was supported by the Regulatory Scrutiny Board. **It is hence clear that the Commission uses this study to pave the way for deregulation in the context of REACH risk management. Given these high stakes, the flawed methodological design of the study and the way results of the study are communicated are unacceptable**:

- As for the study design, it neglects the current shortcomings in the implementation of REACH. The slow pace of substitution that indeed has to be observed is, in the first place, due to lack of compliance on the part of industry with the legal requirements of REACH, and due to lack of ambition in REACH implementation and enforcement on the part of authorities. Notably:
    - The information provided by industry in the context of registration does by no means meet the high regulatory standards of REACH ("all toxicological and ecotoxicological information that is relevant and available to the registrant"; "all identified uses"), thus depriving authorities of their prime information source to develop targeted and fit-for-purpose risk management measures.
    - The flow of information along the supply chains on SVHCs in articles is basically not happening, i.e. information desperately needed to drive substitution is missing and so is a potential source (via WFD/SCIP) for authorities to identify SVHC uses and better predict numbers of AfAs.

- The generous practice of the Commission when granting authorisations applied for by industry - almost ignorant of the applications' quality (more details below) - backs industry's business as usual strategy and misses out on sending stronger substitution signals.

These shortcomings must be acknowledged in the impact assessment when comparing the options with the status quo (baseline), otherwise it will not be possible to establish a robust evidence base for the evaluation, as required by the better regulation guidelines. We should remember that the 2017 REACH Review concluded that the authorisation process was fostering substitution although additional measures were needed to further promote substitution of SVHC.

- As for the communication, **the expected mechanisms and functions of the options are still unclear, and so is which policy options will be assessed (impact assessment) and how the results of this study will be taken forward by the Commission.** The workshop background document presented snapshots on three policy options, a fourth option combining all of them was also presented during the 2nd workshop. Additionally, Commission representatives stated that other options could also be assessed following the workshop discussions. In order to better contribute to the impact assessment, we would appreciate a clear description of which options are being considered, as well as an explanation of how the Commission intends to use the results of this assessment. The lack of transparency of this process hinders the capacity of authorities and stakeholders, including NGOs, to contribute.

Mindful of these limitations, we would like to submit the following comments.

In summary, the policy options presented have elements that can enhance the substitution of hazardous chemicals, such as ensuring early information on uses and alternatives both for authorities and along the supply chain or the creation of a substitution support center to provide technical and financial advice to SME.
However, the proposals that have been presented (in particular options 2,3 and 4) will add further complexity to the process, hinder substitution and delay the protection of human health and the environment from the risks posed by hazardous chemicals. In addition, there are methodological flaws in the study design calling into question the robustness of the impact assessment currently prepared.
Therefore, we encourage the Commission to assess the additional option that we are presenting below, explore simplifying and speeding-up the regulation of hazardous chemicals by implementing the Essential Use Concept, improving the information on uses and alternatives, supporting alternative providers and hastening Research and Innovation towards clean and toxic-free industries.

The information provided on the different options is insufficient to properly understand, evaluate and assess the different options.
The background document and slides provided shortly before the workshop, as well as the workshop presentations are extremely and vaguely concise and do not explain how the different options would be integrated in the current regulatory system, how and when authorities and stakeholders would be involved, which would be the timelines, how the options compare with the existing system, which would be the institutional setting of the substitution center that should be supporting all the options, etc. There is no description of what a targeted substance is. There is no clear explanation and criteria on how to define complex cases. The bullet points included in the slides to describe complex cases include so many possibilities (no safer, more sustainable and suitable alternatives available, critical/ necessary use, lower performance, higher price) that most uses could be considered complex. Therefore, the information provided is insufficient to provide an adequate assessment of the policy options that are being considered.

The problem definition on which the different options are based does not consider that the wrong implementation of the REACH authorisation is the root of the subsequent decision making problems for authorities.
As the European Court of Justice has ruled, the Commission and ECHA following its guidance, have wrongly implemented the authorisation chapter, by accepting upstream applications for authorisation with insufficient information on the risks of the uses applied for, and insufficient information on the lack of alternatives. These applications, while not complying with the legal requirements, have been assessed by ECHA Committees and afterwards have been granted authorisation.

Derogations based on voluntary substitution commitments open the door to de-regulation, hamper substitution, increase the complexity and workload of both companies and authorities, are impossible to enforce and create an unlevel playing field.
Policy options 2, 3 and 4 (the latter a combination of all options) propose to grant permanent derogations to allow companies to continue using hazardous chemicals based on voluntary commitments to substitute. Replacing the clear legal process established in the REACH restriction chapter with a voluntary process will:

- **Hamper substitution and innovation towards safer alternatives**. As expressed in several reports and by industry organizations during the two workshops on this topic, regulation is the main driver for substitution and innovation. Clear timelines allow predictability which is what companies are asking for to invest in safer alternatives. Introducing flexibility on regulatory timelines by allowing companies to decide (jointly and even individually) on the best moment for them to substitute hazardous chemicals will eliminate the pressure to substitute and innovate. Flexibility is at odds with predictability.
- **Add complexity to the process** as new steps would be added to the existing restriction process:
    - Deciding on a list of targeted substances (in all options)

    - Compiling information (all options)
    - Deciding which uses should follow which regulatory process (options 2, 3 and 4),
    - Deciding which uses could be derogated if industry commits to develop and implement substitution plans
    - Enforcing company substitution plans
- **Create an unlevel playing field** among users of the same hazardous chemicals as those considered “complex cases” would be allowed to substitute when they wish while others should comply with legal deadlines.
- **Deregulate imported articles** that follow under a complex case, as they would not be covered by any regulation, creating an unfair competition situation for EU based companies.
- **Open the doors to free riders**, in particular in option 2.
- **Hinder enforcement** as it will be very difficult to assess the compliance of a substitution planning commitment.

No timelines are included in the policy options.
It can be expected that adding new steps to an already lengthy process will add further delays. The impact assessment of all options shall include the time needed to regulate hazardous chemicals and should compare these with the existing timelines (on average it takes nine years to complete an authorisation and five years to complete a restriction process under REACH). Expected durations of each of the new steps should be included in the assessment together with the impacts on the environment and health due to the delayed regulation.

We welcome the proposals to generate the missing information on uses of hazardous chemicals and their alternatives early in the regulatory process, however additional information on risks, substitution pathways, etc. is unnecessary and will further delay regulation.
The policy options include proposals to enhance the collection of data on uses of hazardous chemicals including the **notification of use** and a **call for evidence to alternative suppliers**. Generating this information early in the regulatory process (e.g.) would reduce the burden on authorities when preparing restriction dossiers, as information on uses and alternatives would be already available and would support authorities to prioritize hazardous chemicals for regulatory action based on the essential use criteria.
However, the options also include a long list of additional information that should be compiled before deciding on regulatory action, such as information on risks of continued use, analysis of alternatives, substitution pathways, etc., that would require significant time to compile as well as efforts by companies, further delaying the already too long regulatory processes.

We support the creation of a substitution center to provide technical support, in particular to SME and authorities.

Substitution centers can support substitution efforts, for example by providing technical advice to identify safer alternatives, identifying financial aid to substitution and innovation efforts, trigger supply chain conversations, etc. However, we are concerned about the role of the substitution center as foreseen in the policy options presented by the Commission as it should enhance cooperation and development of substitution pathways while also monitoring their implementation and reporting on progress to regulators. We believe that these roles are not compatible.
The development of the policy options presented relies heavily on a substitution center that is nonexistent. The study to propose its structure and define its roles is not expected to finish before mid-2027. Without a clear understanding of the role, cost and financing of the substitution center it is not possible, in our view, to assess the impact of the different policy options presented.

We propose to assess an additional option that would maintain the actual system with the following changes:

- Ensure early generation of data on uses and alternatives with a strict timeline through a notification system. Downstream users should provide information on uses and alternative providers should submit data on their alternatives when a substance is either:
    - CLH-classified as belonging to the most harmful chemicals*
    - Included in Registry of Intentions for restriction
    - Candidate-listed as a SVHC
- The information generated would support authorities when preparing restriction dossiers or listing SVHC in Annex XIV.
- Enhance efficiency and effectiveness of the REACH risk management system by better combining the restriction and authorisation regimes; with a preference for broad scope (grouping) restrictions with only complex cases (for critical uses where the availability of alternatives is uncertain) sent to authorisation.
- Derogations from restrictions, and authorisations, should be based on the essential use criteria:
    - No derogations to restrictions, or authorisations, should be granted to non-essential uses
    - Time limited derogations could be granted to essential uses
- Together with the notification of uses, companies producing or using any of the most harmful substances would pay a yearly fee dependent on the production or use volume. This fee should increase overtime and support substitution activities, including the substitution support center.

This option would incentivize substitution by ensuring clear regulatory timelines (predictability for investments), increasing information requirements for users of the most hazardous chemicals and by including a fee for the continued use of hazardous chemicals.

***Defined in the Chemicals Strategy for Sustainability as: CMRs, EDCs, PBT, vPvB, PMT, vPvM as well as substances affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ.*