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The Alliance for Sustainable Management of Chemical Risk

Study on "Strengthening the role of substitution planning in the context of REACH and other EU chemicals legislation"

ASMoR welcomes the Commission's study to strengthen the role of substitution planning in the context of REACH and other EU chemicals legislation. We would like to provide feedback to the questions raised during the first workshop held on Friday 1 March 2024.

Question 1. Refining the Problem Definition. The background paper identifies 5 primary challenges with the current REACH substitution regulatory framework and/or its implementation that is hindering the replacement of hazardous substances with safer, more sustainable and feasible alternatives.

- *Please offer additional insights or experiences on these challenges particularly with regard to the current regulatory framework and its implementation. Does this experience differ based on experience with substitution or substitution planning requirements under different regulations or with different sectors/product types (e.g., REACH RoHs, biocides)?*
- *What challenges/additional problems with the current regulatory framework are missing?*

ASMoR generally agrees with the five primary challenges outlined in the background paper, however, we would like to offer additional insights on 'regrettable substitution'.

The term 'regrettable substitution' is often used when a substance is replaced with an alternative that has the same or comparable risk profile or with a risk profile less known or less tested. While this is only one type of regrettable substitution, the concept needs to be defined more broadly.

Regrettable substitution is not only the substitution of a substance or a technology by an alternative that may actually pose similar or higher chemical risks, but also the substitution by alternatives that may be unsustainable from a lifecycle (or footprint) perspective, taking into account energy consumption, sourcing resource efficiency or may lead to loss of performance and/or decreased life expectancy of the product.

Such regrettable substitutions do not result in added value for human health or the environment in particular when the hazardous substance is being used safely, i.e. without exposures that would lead to a risk. Instead, they may lead to issues in their own right. These issues may potentially be regrettable for consumers, lead to dire consequences if the alternative does not provide the same functionality in health and safety applications, impede industry innovation or even hinder the European Union's ability to meet its strategic policy objectives.

Several examples illustrate how substitution can be regrettable from a sustainability perspective. These are included in Annex.

We would furthermore like to emphasize that substitution planning should focus on specific uses, considering factors like risk, exposure, and impact, and done only when existing Risk Management Measures (RMMs) are inadequate. It is crucial that decisions on substitution should not solely rely on a hazard-based approach; instead, they should be based on thorough risk assessments for each use case. The scope of EU substitution initiatives should be limited to substances already banned, restricted, or subject to authorization, avoiding recommendations for freely available substances to respect regulatory boundaries. Furthermore, government-funded research in substitution should prioritize substances where

risks are not adequately managed by existing RMMs, rather than simply focusing on hazardous classifications.

Question 2. Validating objectives of the substitution framework. The background paper outlines 4 primary objectives (along with sub-objectives) of a substitution framework to advance policy goals under REACH. These objectives are important to clarify and prioritize as they will serve as criteria used in the study to evaluate the merits of policy options focused on the use of substitution planning.

- *Are these the right set of objectives? What's missing? Should any be removed?*
- *There are likely trade-offs across the options. If you had to prioritize 3 objectives for a substitution framework, what would they be?*

Building on our initial response to Question 1, we advocate for a broader focus on avoiding 'regrettable substitution,' particularly across various policy objectives and with an emphasis on sustainability. We encourage the study to build on the work of the OECD in this regard.[1]

Objective 1 calls for a speeding up of substitution and innovation. Firstly, we disagree that these two processes are always interlinked, and that substitution would automatically be innovative. Secondly, we caution against politically prioritizing speed over the development of the best solutions. A framework centred solely on speediness may increase burdens on companies and authorities without necessarily fostering optimal outcomes. Instead, we propose a more flexible approach that allows for individualized strategies and appropriate timelines for substitution.

There is no "one-size-fits-all" approach for substitution. Each case can be different and needs an individual approach and speed. It is very frequent that a specific substance cannot be replaced for all its uses/functions with just one another "universal substitute". In an efficient substitution-strategy one would need to look at all relevant combinations of the type "substance-use/function" and to develop adequate substitutes for all of these. Research and investment aimed at finding ''safer'' substitutes that do not hinder the achievement of the Green Deal objectives (es. circularity, lower emissions, energy efficiency requirements) require adequate time, resources, and funds. It's crucial to recognize that in some cases, after extensive research, no safer substitute may be found. Therefore, we suggest including provisions in the relevant legal framework for specific exemptions from the substitution requirements when substitution efforts do not yield expected results within a defined period of time (to be established by the Commission on a case-by-case basis).

We support Objective 2, especially its reference to "chemical risks." We believe the study should aim for a risk-based approach that considers exposure and safe use when assessing substances. Targeting uses of substances known to be safe for substitution can be inefficient and wasteful. Consequently, we challenge the problem definition's call to "minimise the use of and substitute the most harmful substances," as hazardous substances should only be substituted for uses where an unacceptable risk is identified. In our view, pushing for substitution of substances posing no risk diverts resources that could be better utilized elsewhere. The focus should be on what really matters: risk reduction.

We also endorse Objective 3. Investments should be promoted for chemicals that are strategically important for the EU's economic resilience and the Green and Digital objectives but have a high risk associated with their supply. We support the promotion of market opportunities for alternatives when these are proven safer, more efficient, in line with Green Deal objectives, and sustainably available. In this context, we encourage

[1] OECD (2021), Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternative, OECD Series on Risk Management, No. 60, Environment, Health and Safety, Environment Directorate, OECD.

the study to build on DG GROW's "Foresight for chemicals" report[2] published last year, as well as on other work on Critical Raw Materials.

If we were to prioritize the objectives outlined in the paper, we would prioritize the first three. In particular, objectives 1 and 3 are of importance to ASMoR. The focus of a substitution framework should be promoting innovation and supporting substitution procedures where necessary, rather than creating more regulation. The EU already has high standards to protect against chemical risks.

Question 3: Information needs to support speeding-up regulatory substitution timelines. Experience to date reveals that research, evaluation/testing and redesigning products/processes to support substitution takes time. How can early information on uses, exposure and alternatives speed up substitution of targeted hazardous chemicals in advance of regulatory requirements?

- *How can early discussion on alternatives be triggered and implemented and burden on companies, especially SMEs, be minimised? What information is needed or would be useful to support early substitution planning and how should it be provided?*
  - Please draw in experiences from use of substitution planning/regulatory programs in the EU and globally to the extent possible.

ASMoR advocates for proactive communication of potential regulatory concerns and their relevance for the EU's overall economy by Member State authorities at an early stage in the process. Establishing an agreement between Member State authorities on relevant results of screening assessments, Assessment of Regulatory Needs reports (ARNs), or Risk Management Options Analyses (RMOAs) conducted at an earlier stage would be beneficial. This approach would incentivize industries using the relevant substances to start gathering necessary information during the screening/ARN/RMOA procedures.

It's important to recognize the diverse spread of production, uses, and supply chains across Europe, with varying impacts and risk management conditions. Early communication of regulatory concerns would assist industries in preparing for portfolio changes, enhancing transparency, and predictability in regulatory processes. This proactive approach would result in more reliable data, speeding up the overall process and aligning with the Chemicals Strategy for Sustainability's targets.

To this end, early screening of safe uses of so-called 'most harmful chemicals' with a demonstrated lack of minimal exposure should be enough to warrant upfront exemptions from regulatory actions, particularly when safe use is already regulated through other legislation. This approach alleviates the burden on companies, particularly SMEs, and regulatory authorities, reducing the workload of evaluating alternatives and regulatory measures and in some cases prevents the unnecessary deterring of investments to secure the economic resilience.

Question 4. Legal/voluntary substitution planning requirements. Existing models demonstrate a range of required and voluntary uses of substitution planning.

- *Should the regulatory use of substitution planning remain limited to provisions in current policy (e.g., its current role under REACH authorisations) or be extended to other applications (e.g., as a precondition for derogations from REACH restrictions)?*
- *How can voluntary use of substitution planning complement existing regulatory provisions supporting the substitution of targeted substances and uses?*

[2] European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Hafner-Zimmermann, S., Jagaciak, M., Kołos, N. et al., Chem4EU – Foresight for chemicals – Final report, Publications Office of the European Union, 2023, https://data.europa.eu/doi/10.2873/574731

ASMoR advocates for the regulatory use of substitution planning to remain limited to provisions in current policy, such as REACH authorisations. Substitution planning should not be extended to other applications as a precondition for derogations as sometimes substitution is impossible.

Substitution planning is a constant process in companies, which often already happens on a voluntary basis. There are different reasons for this, and regulatory requirements are only one of them. Others can be for example:

- internal policy of a company and/or its customers
- resource/energy efficiency
- economic considerations (eg price)
- (unwanted) dependency of supplier
- marketing reasons
- better handling of substances
- cheaper RMM
- improved properties/functions

Considering all these possible and different objectives of substitution, rather than considering how voluntary substitution planning could complement regulatory provisions, it would be more beneficial to investigate how regulatory mandated substitution planning could be complementary and supportive to industry's existing substitution planning processes.

Mandating substitution planning should be approached cautiously. It must be linked to clearly identified unacceptable risks. However, overly complex regulatory rules should be avoided, as:

1. Substitution planning is highly use-specific.
2. Authorities would need clear criteria to assess compliance with mandated substitution planning procedures.
3. It's currently unclear how regulatory authorities would define proof of compliance, especially when substitution is not feasible due to technical limitations, socioeconomic aspects, or regrettable substitution.

Listing substances for voluntary replacement will not increase European competitiveness but rather do the opposite. It undermines research into the application of substances for which substitution is considered. The European Commission should therefore have a plan to mitigate the risks of sidelining substances that are considered by the EU for substitution.

Question 5. Focus of the substitution plan. Considering both your reflections in advance of the workshop and the group's discussion in Question 4, how can substitution planning be most effectively and efficiently implemented?

- *Should individual companies create their own substitution plans? Is there value in pursuing an industry/use/value-chain wide substitution planning approach? Or a combination of both? Please draw in experiences from use of substitution planning in the EU and globally.*
  - If per company, how can the appropriateness of company-based substitution plans be exhaustively assessed without overstretching authority resources?
  - If industry/value-chain wide, how can joint plans be elaborated/co-ordinated? How can anti-competitive practises between companies be avoided; how can innovators best be protected; and how can confidential business information be managed?

ASMoR believes that substitution plans cannot be set by regulatory measures and regulators. Instead, relevant supply chain actors, with the best knowledge of the uses, are best positioned to set up substitution plans. Additionally, there are substances that cannot be replaced, due to their specific use, as previously

mentioned. Once it's established that substitution is not possible, the case should not be reopened, and the substance need not be included in future substitution plans unless proven otherwise.

We support the point that substitution planning, if implemented, must remain voluntary and be performed by the affected industry, and not the government. And there is no need that "company-based substitution plans be exhaustively assessed". A performance-based approach is a more efficient solution to the limited resources of industry and government.

In this case, based on experiences of cooperation schemes from different legislation, it would make sense to use these to support substitution. This could for example be the facilitation of cooperation platforms and communication within a supply chain and between similar supply chains with the objective to make substitution more effective and practically useful. It could be useful also to include R&D-centres and academia in such platforms. This approach has been successful in various areas, including cooperation in SIEFs under REACH, approval of biocidal active substances, development of biocidal product families, and applications of authorization under REACH.

Question 6. Who prepares, reviews and monitors implementation of plans? Existing models demonstrate various substitution planning structures and these vary whether the plans are mandatory or voluntary.

- *Who should be the actors involved in the preparation of substitution plans and how should decisions on their appropriateness be taken?*
  - Should the implementation of substitution plans be left to industry, or should there be continuous/periodic monitoring of the implementation and adjustment of the substitution plans over time?
  - How should third parties (alternative providers, NGOs, substitution centres, academia) be involved in the preparation and assessment of substitution plans and the monitoring of their implementation?
  - What role could periodic workshops take and by whom/how would those be managed?

The implementation of substitution plans should be left to industry and should in the end be based on economic considerations. The entire supply chain should be involved with a multi-disciplinary approach with input from relevant industry experts, regulatory authorities, and other involved parties. This ensures that plans consider various aspects, from R&D and financial considerations, to regulatory and sustainability concerns.

To address the multidisciplinary nature of substitution procedures, third parties can be included in plan preparation and assessment. Authorities can facilitate dialogue with relevant stakeholders by organizing regular thematic workshops, ensuring involved third parties have the necessary credentials and experience with the specific supply chains under consideration.

About ASMoR:

The Alliance for Sustainable Management of Chemical Risk (ASMoR) is an alliance of over 30 corporations and trade associations who have joined together around their common position on the Essential Use Concept in EU chemical legislation and the common goal to ensure that safe uses of hazardous substances remain permitted. ASMoR also takes joint positions on the broader reform of chemical risk management.

Annex: Examples where substitutions can be regrettable from a sustainability perspective

Example 1: Cobalt in hydrodesulfurization catalysts

Cobalt is employed in solid-state hydrodesulfurization catalysts at oil refineries to remove undesired elements in fuels. Iron could be used to substitute cobalt. Nevertheless, substitution by iron would require each refinery to employ ten times more catalyst than the current cobalt-based techniques, implying major changes in the process equipment, higher energy usage, more waste generated, and a massive increase of costs.

Example 2: Lead used in copper alloys

Lead is added in copper alloys to improve their machinability, but bismuth could also be used to achieve this goal. However, the substitution of lead by bismuth would have an impact on recycling of copper alloys, as copper alloys with lead are fully recyclable. Conversely, bismuth cannot be separated easily from the copper in the smelter, making bismuth “a single use” material requiring new primary material for alloying. In addition, the substitution of lead by bismuth would affect resource efficiency, since it will entail an increase in demand for bismuth, which is an inefficient by-product of lead mining. To produce 1 tonne of bismuth, 30 to 100 tonnes of lead need to be produced. This would exacerbate the possibilities to source bismuth, as it is already considered as a critical raw material in the EU.

Example 3: HHPA and MHHPA

Both phthalic acid anhydrides are classified as respiratory sensitiser, cat. 1. In an industrial setting they are used in a fully automatised and highly controlled process as monomers for the manufacturing of polymeric isolation-layers directly on generators, which produce clean electric energy from water and wind. Due to the nature of the production process, exposure for workers can be excluded, nevertheless measures like special filters and protection equipment are used additionally. As the substances are only present during the chemical reaction during the production process, neither consumers nor the environment is at risk. A common alternative for isolation-material outside the EU is a type of sophisticated tar, which, however, is significantly less energy-efficient. Banning HHPA and MHHPA in the EU would mean that the market would shift to more use of the alternative sophisticated tar, leading to less energy-efficiency overall, while not increasing safety.

Example 4: Chromium trioxide in coating

One of the key advantages of using chromium trioxide to produce hard (functional) chromium coatings is that once the coating has worn down, it can be re-plated. A good example of this is in the gas and oil exploration sector. Helical rotor pump components can be up to 8m long and need a uniform, wear resistance coating. These components can operate hundreds of metres below ground so they must function reliably as the cost of removing several hundred metres of piping can be extremely expensive, time consuming and lead to unnecessary waste. Once the coating has started to degrade (this can be after three months to three years use, depending on soil conditions and the fluid being extracted), the rotor pump components can be removed and re-processed to produce brand-new components. Suggested alternative coatings cannot easily be re-processed and therefore new components are required from the start using more natural resources, more energy and lead to more waste.

Example 5: Lead solders

Without an assessment of actual risks the RoHS Directive pushed for the substitution of lead solders in a broad range of electrical and electronic equipment. Within a short timeframe industry was generally able to shift to alternatives, but exemptions still exist in critical industries where substitution is not feasible. While

at first sight, this appears to be a successful case of hazard-based substitution pressure the case is more complex:

- The alternatives presented a number of concerns in terms of their performance compared to lead solders.
- A commonly used alternative was a tin/silver/copper solder, which however required higher temperatures in the production process, leading to considerably higher energy consumption of the production process.