Position Paper on regrettable substitution

The Alliance for Sustainable Management of Chemical Risk (ASMoR) is an alliance of 30 members that share a common position on the Essential Use Concept (EUC) in EU chemicals policy.

Published in October 2020, the EU Chemicals Strategy for Sustainability (CSS) aims to provide, amongst others, a chemical framework to support the transition to a circular economy. The CSS introduces a toxic-free hierarchy that would trigger substitutions to support chemicals that are safe and sustainable by design and could enter toxic-free lifecycles. To increase the pace of substitutions, the Inception Impact Assessment of the upcoming revision of REACH Regulation[1] suggests introducing generic restrictions for the most harmful chemicals, which would only allow derogations for 'essential uses'. The ASMoR strongly believes that such a hazard-based approach to chemical management would risk promoting substitutions that would be regrettable with respect to various policy objectives and in particular sustainability.

As the Commission is in the process of defining the term 'essential uses' and its scope of application within EU chemical policy, we would like to share our views on substitution and how to avoid that the regulatory system promotes regrettable substitution.

[1] Inception Impact Assessment of the revision of REACH Regulation to help achieve a toxic-free environment, p.3

January 2022

To avoid an increase in the instances of regrettable substitution, the ASMoR recommends that the Commission:

- adopts a risk-based approach when assessing substances;
- adopts a **life-cycle approach** when comparing substances or technologies to be substituted;
- considers a **broader set of environmental, social and economic implications;**
- considers the **compatibility** of a substitution decision **with other policy goals**, including those of the EU Green Deal, of the European Digital Strategy and of the Industrial Strategy;
- ensures a **targeted application** of **restrictions** as well as of the Essential Use Concept (**EUC**).

A standardised consideration of the impacts of substitutions carried out in Risk / Regulatory Management Option Analyses (RMOAs) could support this approach. To encourage proactive generation and provision of information on assessments of alternatives by industry, authorities should reassure industry that this data will be taken into account during the RMOAs.

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, triggering incoherence within the different goals of the regulatory framework, such as the European Union's greenhouse gas reduction ambitions or the transition to a circular economy.

In the CSS, the Commission claimed that the objective is that substitution should be "safe and sustainable".[2] However, generic risk management does not take into account whether there is actual exposure and risks. Therefore, it would trigger systematic bans of substances even

[2] Chemicals Strategy for Sustainability, p. 3

where they are safe for use. The market would be pushed to use alternatives, regardless of whether these alternatives are less sustainable.

We anticipate that application of the EUC as provided for by the CSS would likely accelerate this trend as hazard-based bans on non-essential uses will require switching to alternative substances without taking into account lifecycle considerations and socio-economic aspects such as availability and cost. Introducing generic restrictions for substances based on hazard only with possible derogations for essential use would generate uncertainties in the market, which in turn might precipitate regrettable substitution. In addition, even in case of essential uses, the market may shift to less sustainable alternatives to avoid stigmatisation and the difficulty of obtaining a derogation.

Avoiding regrettable substitution

There are many reasons to consider substitution and the decision to substitute should be informed by well thought-through and documented analyses of alternatives. This should include a comprehensive comparison of substances or technologies to be substituted with their potential alternatives on an equal footing covering their entire lifecycle. Moreover, chemicals facing the threat of substitution are currently used in highly strategic applications such as sustainability technologies, aerospace and defence.

The recently published OECD Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternatives provides a general approach and criteria for the selection of safer chemical alternatives. In Chapter 5 of that Guidance, the OECD provides an outlook on how to integrate the analysis of what would be chemically safer with sustainability considerations.[3] In line with those guidelines, our Alliance recommends that the analysis conducted to designate safe and sustainable alternatives should also consider a broader set of environmental, social and economic factors as well as the compatibility of the decision with overall EU policy goals, such as decarbonisation, digitalisation and the transition to a circular economy.

The analysis of alternatives should, therefore, involve a lifecycle approach to products and substances, which would take into account the sustainability attributes or trade-offs from cradle to cradle, including raw material extraction, manufacturing, use and end-of-life management.

Moreover, each industry sector could conduct an analysis of alternatives, including impact of substitution, in preparation of a Risk / Regulatory Management Option Analysis (RMOA). This would allow authorities to assess or at least screen where a generic restriction may cause regrettable substitution or have other negative impacts. Such RMOAs could help identify the appropriate risk management option. For chemicals that have a wide ranging effect comparable to that addressed by the Montreal Protocol, i.e. that there is an unacceptable risk from continued use of the substance that cannot be addressed by a more targeted risk management measure, a restriction could be put in place with the potential to apply for

[3] OECD Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternatives, 2021, p.45

derogations only for essential uses. Using the EUC in this more targeted fashion would help avoid regrettable substitutions that would occur when using the alternative broad application of generic restrictions.

Conclusion

If the generic restrictions with the sole possibility of derogations for essential uses were to be automatically applied on the basis of hazard classifications, it would lead to the substitution of products either considered beneficial or even 'essential' for consumers and professionals with less sustainable and durable materials. To avoid such an increase in the cases of regrettable substitution, the Alliance strongly recommends that the Commission adopts a life-cycle approach and considers a broader set of environmental, social and economic factors as well as the compatibility of the decision with other policy goals, including those of the EU Green Deal or those of the European Digital Strategy. A targeted application of restrictions as well as of the EUC would avoid these regrettable substitutions. A standardised consideration of the impacts of substitutions carried out in the RMOA could support such an approach.

ANNEX I – Examples where substitutions can be regrettable from a sustainability perspective

The examples provided in this Annex are to showcase how purely hazard-based substitution can lead to impacts that are regrettable from a sustainability perspective. The examples are not limited to areas, which would be directly impacted by generic restrictions for articles used by consumers and professionals.

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.

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.

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.

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.

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.

ANNEX: List of Members of the ASMoR

1. ACEA – European Automobile Manufacturers' Association
2. AmCham EU
3. BeST - Beryllium Science & Technology Association
4. Cerame-Unie – The European Ceramic Industry Association
5. CETS – European Committee for Surface Treatment
6. CI - Cobalt Institute
7. ECGA – European Carbon and Graphite Association
8. EFCC - European Federation for Construction Chemicals
9. EGMF - European Garden Machinery Industry Federation
10. ETRMA – European Tyre and Rubber Manufacturers' Association
11. Eurobat
12. EUROFER - European Steel Association
13. Eurogypsum
14. Euromines
15. EXCA - European Expanded Clay Association
16. FEC - Federation of European manufacturers of Cookware and cutlery
17. FEICA - Association of the European Adhesive & Sealant Industry
18. FEPA - Federation of European Producers of Abrasives,
19. FPE - Flexible Packaging Europe
20. Fluoropolymers Product Group
21. Glass Alliance Europe
22. ICDA - International Chromium Development Association
23. IFRA - International Fragrance Association
24. ILA - International Lead Association
25. IMA-Europe
26. the Lead REACH Consortium
27. Nickel Institute
28. Orgalim
29. PVthin
30. RECHARGE
31. SME United
32. UNIFE -

January 2022

33. WSM – German Steel and Metal Processing Industry Association
34. WVMetalle