ASMoR's recommendations to avoid a sweeping application of the Essential Use Concept render EU regulatory decision-making less efficient

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

1. General considerations

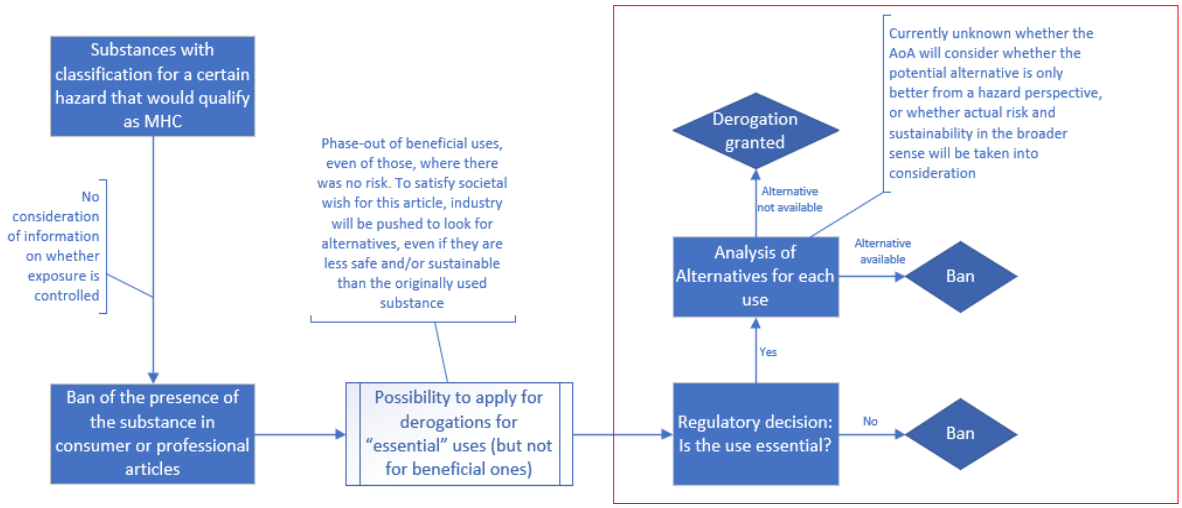
In the Chemical Strategy for Sustainability ('CSS'), the Commission committed to define criteria for essential uses to ensure that the **most harmful chemicals** ('MHCs') *"are only allowed if their **use is necessary** for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health"*. These criteria are meant to *"guide the application of essential uses in all relevant EU legislation for both generic and specific risk assessments"*. ASMoR welcomes that in a recent **paper submitted to CARACAL** (CA/03/2022), the Commission clarified that it will *"assess how the essential use concept could be combined with the **concept of safe use**"*. The present paper focuses on the workload triggered for authorities by having to assess applications for all essential uses and also reflects on how the combination with the safe use concept could enhance regulatory efficiency.

ASMoR recommendations

- ASMoR believes that applying the EUC in a sweeping fashion to all substances with a certain hazard classification would **risk slowing down regulatory risk management** rather than speeding it up, because assessing *all* essentiality claims for an extremely large number of substances would represent an extremely granular, complex, and therefore lengthy process.
- ASMoR recommends that the Commission **prepares a realistic assessment for the EUC**, carefully weighing up all the hurdles the process would encounter.
- ASMoR recommends that instead of a sweeping application of the EUC, **a substance is deemed an MHC only where the regulator has decided in the RMOA phase** (which could be started based on *inter alia* hazard considerations) **that the only risk management option that can tackle the risk effectively is a broad restriction with exceptions for uses demonstrated to be essential or safe only**.
- An **early screening process (RMOA)** could help define an appropriate scope and generic derogations, which would lighten the workload that might otherwise arise if all applications for derogations had to be fully assessed in a complex process, that would in many respects resemble the current authorisation system and is likely to become unmanageable for industry and authorities.

Our understanding of the Commission's original proposal on the essential use concept ('EUC') in the CSS is that the **EUC would be applied in a sweeping fashion** to all substances with a certain hazard classification, as presented in Figure 1 below. The present paper will cover the area in red, focusing on the workload triggered for authorities by having to assess applications for all essential uses.

Figure 1.



We note and welcome that the Commission is considering combining the EUC with a **Concept of Safe Use (CoSU)**. The present paper firstly reflects on what the CSS originally seemed to outline as reform proposal.

2. Possible EUC challenges based on the experience with REACH Authorisation

Some stakeholders perceive that **chemicals risk management is currently too slow**, arguing that generic bans of substances with a possibility for applications for derogations for essential uses would be more efficient (i.e., a faster and simpler process). ASMoR recalls that the reasoning was similar when introducing the REACH Authorisation process – it was thought that the process would place the burden on industry and be simpler and more efficient for authorities. However, this has largely not been the case (please see the Info-box 1 below). As a result, the **Commission is currently rethinking completely the role of Authorisations** as part of the ongoing REACH review.

Info-box 1. Lessons learnt from the REACH Authorisation process

The 2018 REACH Review concluded that Authorisations are meeting their objectives; however, their implementation should further gain in efficiency and aim to further reduce administrative burden and business uncertainty for companies applying for Authorisation, in particular for SMEs. The authorisation procedure was deemed "too heavy and inflexible", imposing a "heavy burden" on both companies and authorities.

ASMoR believes that a **sweeping application of the EUC would risk slowing down regulatory risk management** rather than speeding it up. Having carefully studied the Commission background paper developed in preparation for the workshop on the reform of the REACH authorisation and restriction system held on 12 November 2021 and the list of weaknesses of the Authorisation system revealed therein, we believe that very similar issues would arise if generic bans with the possibility for derogations for essential uses were to be implemented. For instance:

- **"Upstream applications"** covering several hundreds of downstream users' claims for essentiality of their uses could turn out to **be problematic**, as the applicants will in practice have limited insight and knowledge regarding all the uses of a certain substance and the impact along all product supply chains as well as its possible alternatives at downstream level. Moreover, where downstream users will apply individually for derogations, this could create a **multitude of repetitive individual applications for similar uses** of sometimes very small quantities of substances.
- The **type and amount of information required** to assess essentiality of a use and to analyse alternatives for those uses *(please see chapter below)* could be a **challenge for SMEs**, which often do not have the knowledge or capacities in generating the required information (e.g., dependence on suppliers, technological choices of their clients, toxicological information, socio-economic analysis, etc.).
- The type and amount of information to be submitted, the complexity of the aspects to be considered in the decision making and the possible diverging views on what is deemed essential and what not *(please see chapter below)*, could be a major **challenge for companies and authorities,** potentially leading to controversies, court cases, and subsequently considerable delays in the decision-making, with the associated uncertainties for companies. The main reasons could be:
    - The **EUC is based on the concept of "uses".** However, a use can embed a multitude of different sub-uses (called "**utilisations**"), which all have their own characteristics in terms of why they may be essential, but also in the suitability of alternatives.
    - Detailed information for uses will be important to determine essentiality, not only for applicants but also for authorities. **Assessing the essentiality for all utilisations** should the EUC apply in a sweeping fashion to all substances with a certain hazard classification is ***de facto*** **impossible**.
    - For the essential uses where authorities will be considering whether alternatives are feasible, another factor that may prove critical is the **acceptable loss of performance**. The alternatives may not provide the same level of performance, which in some cases may be acceptable but in others may result in severe problems, e.g., for the safety of equipment, product durability or energy efficiency.
    - Reducing a specific production to essential applications only may result in **loss of the entire production** because of economic reasons – no matter how essential the "rest" would be.

3. Complexity of the essentiality assessment

The application of a general ban for *all* MHCs with derogation possibilities for essential uses would lead to the need for authorities to assess *all* essentiality claims for an extremely large number of substances.

This would require an **extremely granular, complex, and therefore lengthy assessment**, putting an enormous burden on authorities and would run counter to the Commission's objective of simplifying

the procedure. Even for uses where authorities have reliable information that they are safe, they would still need to assess whether they are essential as well.

Below is an overview of some of the aspects[1] that would need to be considered in *each* case where the use of an MHC is claimed as essential:

Info-box 2. Selection of aspects to be considered in the EUC assessment raised in Belgian MSCA Caracal paper of 17 March 2020

In terms of scope:

- Ethics, philosophy and values: How to justify different benefits and impacts of the ban on different persons or groups? Are there values that conflict with the ban?
- Economy, employment, public services, well-being, sustainable development: Which are the impacts on income, employment, GDP, SDGs, (human development index), etc.?
- Sociology-anthropology, symbolic, cultural: Which are the social practices associated with a use? Which social representations are associated with a use?
- Politics: Can the ban raise conflicts, and how can they be solved?
- Techniques, logistics: How is the ban propagated/compensated into the downstream users and transport/distribution chains? Does the ban impact the resilience of society to environment or health crises, by disrupting specific value chains? Are there major impacts on energy, communication, transport?
- Life cycle analysis: Can the alternatives have negative systemic impacts on society at any stage of their lifecycle?
- Law, fundamental rights: Does the ban impact any of the values of the EU?

In terms of process:

- Industry to bear the burden of proof within a fixed timeframe.
- Essentiality assessment needs to involve society: use of specific participatory methods
- A specific committee is to be created in order to practically set the framework for discussion and participation, and to summarize the diversity of views and worst cases realistic scenarios that emerge from there.
- Time-limited nature of the assessment, which would lead to a regular need for re-assessment of derogated uses.

4. Analysis of Alternatives: the need to avoid regrettable substitution

In each case where an article with the functionality delivered by a substance with the hazard classifications in question is deemed essential, a proper Analysis of Alternatives (AoA) would need to be prepared and reviewed by authorities. Informed substitution would therefore have to be thoroughly considered in every case, in order to avoid regrettable substitution. *"Regrettable substitution"* is here understood not only from a chemicals management perspective, but also from a broader sustainability perspective (prevention of climate change, circular economy, etc.). If the generic restrictions with the

[1] Selection of elements raised in Belgian MSCA Caracal paper of 17 March 2020.

sole possibility of derogations for essential uses were to be automatically applied on the basis of hazard classifications, this would lead to the substitution of products either considered beneficial or even 'essential' for consumers and professionals with less sustainable and durable materials. Please see the info-box below for an example.

For more considerations and examples, please see our position paper on regrettable substitution. A

Info-box 3. Regrettable substitution example: 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.

targeted application of generic bans with the possibility for derogations for essential uses would reduce the risk of regrettable substitutions.

5. ASMoR proposed solution

A broad application of a ban on all substances with a certain hazard classification in **all consumer, professional articles and potentially even in industrial uses** with a need to apply for derogations for essential uses will create an **insurmountable burden on authorities**, as they would be spending significant resources on assessing the essentiality of uses, many of which are safe. Based on experience from other regulatory areas, we expect that applications will be numerous, and it will not be possible to process them in a timely fashion. This will have an enormous **negative effect on the European economy.**

Already today we observe this for example for biocidal products. The authorisation process for biocidal products and the approval of biocidal active substances has a huge backlog. Due to the complexity of assessing chemicals in combination with their uses, many authorities are overwhelmed by the workload and are not able to finalise an assessment in the foreseen timeframes. The same applies to authorisations under REACH.

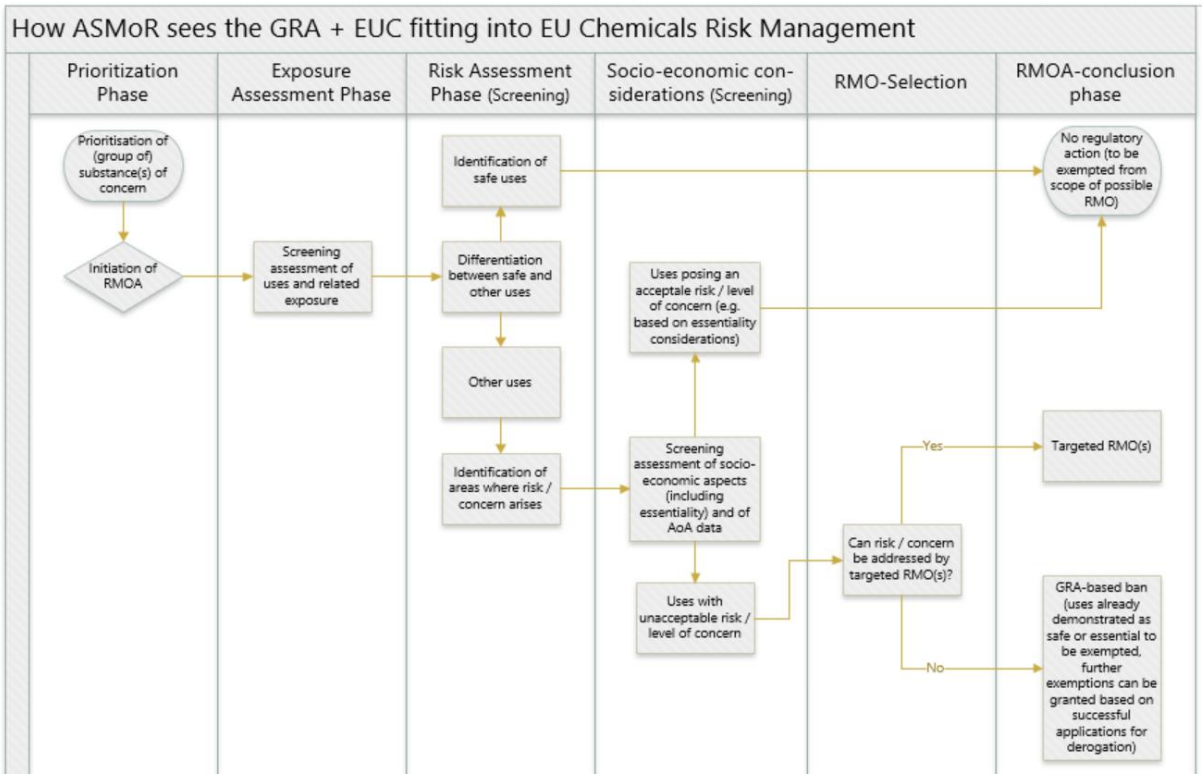
In light of all the above considerations, ASMoR recommends that the Commission **prepares a realistic assessment for the EUC**, carefully weighing up all the hurdles the process would encounter, before considering it a panacea for regulatory efficiency.

To avoid that the EUC creates a process which would overburden businesses and authorities (and would in fact defy the purpose of the EUC in the first place), ASMoR proposes **not to apply the EUC in a sweeping fashion to all substances with a certain hazard classification**. According to ASMoR members, it should be considered whether **Art. 68(1)** could be revised in a way that would simplify the process by creating a **screening procedure** that allows to take into account information provided by industry at an early stage, i.e. before one or the other regulatory route is decided upon. This would allow to share the work better between authorities and industry. In this context, we welcome that the Commission recognises that also under the reformed restriction regime derogations can be granted by authorities. The only way to avoid the excessive workload brought on by the handling of applications for derogations of essential (and safe) uses is by making good use of the possibility to **appropriately determine the scope of restrictions and include generic derogations.**

ASMoR recommends that in the **Risk / Regulatory Management Option Analyses (RMOAs) phase** (which could be started based on *inter alia* hazard considerations), the risk / concern is assessed. If there is a risk or concern (based on exposure considerations), authorities would consider which RMO could effectively tackle the risk. Only if **no proportionate targeted option exists**, then the **generic restriction** with **essential use derogations** would be applied to that group of substances. For an illustration of our approach, please see Figure 2 below.

In line with this approach, a substance would be deemed an MHC only where the regulator has decided that the only risk management option that can tackle the risk is a broad restriction with exceptions for uses demonstrated to be essential or safe. This would limit the scope, as all MHCs will be under the generic risk approach (GRA), but the **definition of the MHC would not be based on hazard alone** but on **identification as relevant.** In this way, the concept of MHC would align with that of SVHCs. To be treated as SVHC under REACH, a substance need not only be classified for certain hazardous properties. The substance has to be specifically identified as SVHC by inclusion in the Candidate List. And as per the SVHC Roadmap, authorities aim to only include 'relevant' substances with the hazard classification in the Candidate List.[2] Such a **relevancy assessment** could be reviewed by the ECHA Member State Committee not only for SVHCs but also for substances that are under consideration of being identified as MHC.

Figure 2. How ASMoR sees the GRA and the EUC fitting into EU Chemicals Risk Management



[2] We note that in the abovementioned CARACAL-paper (CA/03/2022), the Commission is considering whether to automatise the inclusion of substances on the Candidate List. We advocate against this change, as is further detailed in our comments on said CARACAL paper.

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