20/06/2023

# ASMoR Comments on the WSP Essential use report – Policy options for REACH authorisation and restriction processes

ASMoR acknowledges the importance of the analysis of different policy options for REACH in the WSP report on "Supporting the Commission in Developing an Essential Use Concept". ASMoR supports the objective to make restrictions/authorisations more efficient, less burdensome, and more predictable to enhance the level of protection of human health and the environment when the use of a substance presents an unreasonable risk. However, we believe that the current proposed approach and broad application of the essential use concept (EUC) will ultimately result in an equally burdensome process for managing chemicals and fail to address existing challenges. ASMoR has identified several aspects that would need a more in-depth discussion to achieve a more efficient chemicals management.

## Challenges with current proposed application of the EUC

We understand that, currently, risk management under REACH is perceived to be too slow. The WSP report reflects on this in Section 9, "the essential use concept is intended (…) to speed up decision-making, therefore increasing the rate of restrictions of the most harmful chemicals so that risks to human health and the environment can be addressed as efficiently as possible, without the delays caused by the complexities in the current processes." (emphasis added). It is, however, noteworthy that after the preparation of a comprehensive report on the EUC, the report does not conclude that the EUC will speed up decision-making. 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 would be simpler and more efficient for authorities. However, this has largely not been the case.

While the report is silent about EUC truly speeding up decision-making, it recognises in the case study on "Lead in alloys under the Restriction of Hazardous Substances (RoHS) Directive" (see p. B38 ff.), and particularly in the sections "Challenges" and "Timing and procedures", that the evaluation of essentiality could:

- Be a heavy, granular and data-intensive assessment process;
- Not be cheaper than a RoHS-derogation-process;
- Be constrained by low responses during stakeholder consultations;
- Be unbalanced due to a lower participation of SMEs, if the process would be comparable to RoHS;

- Not be more predictable than a RoHS derogation process, and;
- Timewise require 12 to 15 months, if optimisations are possible, or else last up to 20 months.

In the example on DEHP in medical devices under RoHS (p. B51 ff.) the report further, highlights that "[t]he highest [administrative] burden stems from the high number of requested exemptions (around 60 currently in progress)". If we consider that the Commission had the annual capacity to process approx. 60 applications for authorisation, this strongly supports ASMoR´s previous argument that the EUC will slow down chemicals management.

Besides, ASMoR is concerned that the proposed application of the EUC to all substances with a certain hazard classification would require authorities to review all applications for derogations. As presented in the case studies on RoHS (lead and DEHP), this would result in a significant workload, which could be avoided by exempting applications where authorities hold reliable information that the use is safe [1]. ASMoR believes this lengthy process may misdirect and slow down regulatory risk management rather than help speeding it up. Our main concern for this, lays in the detailed information related to all uses and potential sub-uses (utilisations[2]) of a substance that would be required for such an assessment. Each of these (sub-)uses has its specific characteristics regarding essentiality and suitability of alternatives, making the assessment even more complex.

Under policy option 2, the mentioned industry-driven authorisations of **individual applicability** are intended to "remain exceptional" compared to industry-driven derogations of **general applicability**. ASMoR wonders how, under the industry-driven derogations of general applicability, the essentiality assessment and the analyses of alternatives can ever be conducted efficiently for various utilisations? Encouraging upstream applications for efficiency was already a miscalculation for authorisation, and ASMoR does not understand how this will be any different with the EUC.

For example, a pipe made of an alloy containing an MHC classified as STOT RE by inhalation would not lead to MHC-related exposure/risk for consumers and professionals. Besides, assessing the essentiality and alternatives for the pipe is highly complex and burdensome as it would require all the different utilisations of the article to be considered, as essentiality and alternatives are specific to each utilisation. Furthermore, the use of the MHC in this pipe is just one of the countless uses of the MHC.

When looking at the negative impacts, one, however, needs to assess also potential future consequences. One example here is the discussed classification of silicon dioxide as STOT RE 1 by inhalation. This will turn the substance into an MHC and consequently its use will be banned at least for consumers. So will be also its applications, like for example silicone sealants,

[1] For further information please refer to the ASMoR position paper on Appendix C of the WSP Essential Use Report – Safe Uses.

[2] From 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:
"REACH authorisation is based on the concept of "uses". In reality, a use as applied for can embed a multitude of different sub-uses (called "utilisations" in authorisation decisions), which all have their own characteristics in terms of applied risk management measures, but also in the suitability of alternatives."

although in these products, silicon dioxide is inextricably bound in the polymeric matrix and cannot be inhaled. At the same these products have high environmental and social benefits. While they enable a more efficient building insulation with energy savings of up to 60% and a significant extension of the life span of buildings, they also allow quick fixes of smaller damages in bathrooms or kitchens performed directly by the inhabitants. Would the latter not be possible due to a hazard-based ban, such fixes could be only performed by professional companies. Considering the related costs and limited availability of professionals, one can expect that appearing damages will not be treated as fast as before. They will evolve and cause a more structural damage until finally a professional is contracted.Under paragraph 10.5.5 of the report on the "information to be provided to prove that a use is essential for society" it is stated that "the burden of proof will ultimately have to fall on the (group of) stakeholder(s) with an interest in the use, as only these stakeholders will have the insights needed to demonstrate criticality for the functioning of society, necessity for health/safety, and the absence of alternatives." ASMoR would like to point out that in the above example of the pipe, the producer of the pipe will not be able to do the essentiality and alternatives assessment for the different utilisations of the pipe. Furthermore, the report recognises in the case studies on RoHS that requests for derogations are relatively scarce and limited to larger businesses. All this does not support the assumption that industry-driven derogations of general applicability will be the rule and industry-driven derogations of individual applicability only an exception. The current authorisation process was based on a comparable misassumption that originated from the expectation that upstream applications would be the rule. While this is no longer the case, mainly due to the overwhelming demand for details coming from committees, authorisation caused notably more workload for industry and authorities, an impact we would also expect for the EUC. In addition, ASMoR finds it is unrealistic for such stakeholders to prove with absolute certainty the absence of an alternative for a safe use of an MHC as it is scientifically impossible to prove a negative. Instead, following an inconclusive assessment of alternatives, a third party claiming that an alternative exists should be the only one required to bear the burden of proof.

## ASMoR's recommendations for a more efficient risk management process

ASMoR believes the current scope of application of the EUC is too broad to make the regulatory management process simpler and more efficient. However, a more targeted application of the EUC in combination with derogations for safe uses could be a way forward for a workable reformed risk management process

### *Art. 68(1) restrictions*

A strong leaver for a reform and simplification is Art. 68(1). Its revision should target a better shared workload between authorities and industry. This could be achieved by creating a screening procedure, based on clear and defined criteria applicable in general, that accounts for information provided by industry at an early stage, i.e., before a specific regulatory route is decided upon. Based on the screening, authorities could target their risk management activities to uses/sectors/products where it has not been demonstrated, according to the general criteria mentioned beforehand, that risks are sufficiently controlled. This would considerably reduce the workload for the authorities, who would no longer have to bear the

sole burden of proof in demonstrating the existence of a community-wide unacceptable risk. If this approach would not be workable, a restriction according to Art. 68(2) could still be triggered.

An early screening and scoping procedure could be also helpful when deciding to apply an Art. 68 (2) restriction or not. It could help better target the regulatory intervention and, as such, reduce the workload that might otherwise arise from a broad restriction and the large number of subsequent applications for derogations. These would have to be assessed in a heavy process, which would in many aspects resemble the current authorisation system, and is likely to become unmanageable for industry and authorities.

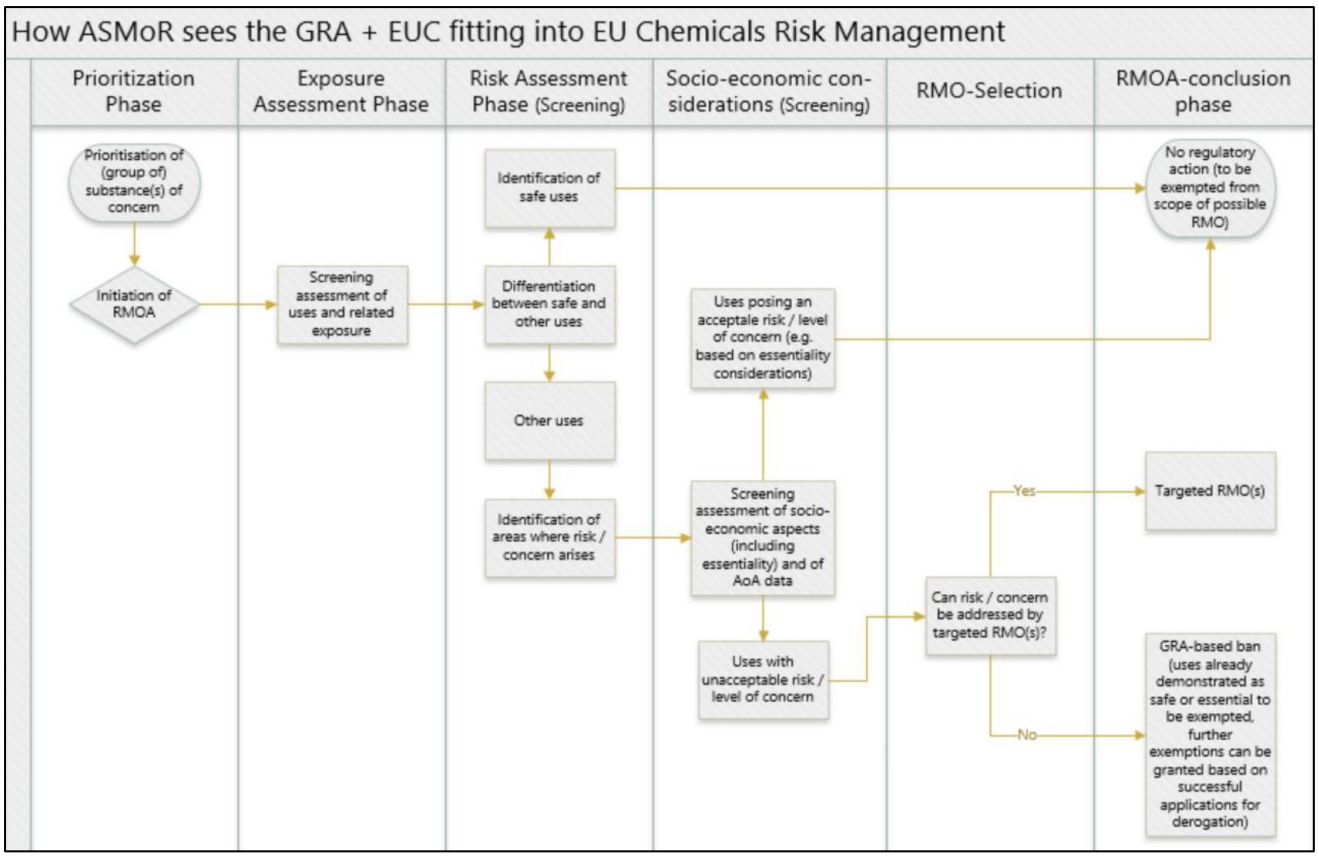
### *Authorisation*

The inception impact assessment of the Commission already concluded, "[t]he authorisation procedure is too heavy and inflexible". We agree that if the current authorisation regime should continue to play a role, it would need to become simpler and more streamlined.

In the background paper for the workshop on the reform of the REACH Authorisation and Restriction System, the Commission stated that "[f]ollowing the experience with chromium (VI) substances, no other SVHC with a similar widespread use has been recently added to Annex XIV". Keeping this precedent in mind, an idea from the SVHC Roadmap could be picked up, i.e., to select only 'relevant' substances. Such a relevancy assessment could be reviewed by the ECHA Member State Committee. To enable the use of authorisation also for substances with widespread uses, it would be worth considering creating the option of including only specific uses of substances within the authorisation scheme (e.g., those where there is a substitution potential in the near to mid-term future). Unlike the GRA, this reformed authorisation would stand a better chance to promote meaningful substitution. Due to its rigid hazard-based focus the GRA would even have the tendency to push towards regrettable substitution (please see ASMoR's reaction to the WSP report on this topic here).

## Conclusions

ASMoR believes a proportionate regulatory risk management option should not be determined solely based on hazard. Instead, we recommend conducting an early RMOA to efficiently identify regulatory needs and for those uses with a regulatory need, the best risk management option to address it. RMOAs are flexible and do not require the same level of detail that more formalised processes (e.g., authorisation or assessment of essentiality claims) trigger. RMOAs will thus help to prioritise and define an appropriate scope, reducing the workload and burden on the authorities and directing their attention and resources to relevant areas. This would truly improve protection of human health and the environment through faster, simpler, and more flexible processes and would avoid the unnecessary assessment of numerous and complex essentiality claims that would need to be conducted by authorities for all uses, including for uses known to be safe.




ANNEX: List of Members of the ASMoR