



ASMoR Comments on Appendix C of the WSP Essential Use Report – Safe Uses

ASMoR appreciates that WSP included Appendix C in its Report “Supporting the Commission in Developing an Essential Use Concept”. We, however, feel that the Appendix neither fully reflects established facts nor contributions made by ASMoR and its Members during the consultation. We have prepared this note to complement Appendix C. We hope that it will be a good basis for further discussion and progress on this important topic.

Uses of most hazardous chemicals can be safe

The WSP report suggests that it is a mere ‘opinion of some industry representatives’ that uses of what is now called “most harmful chemicals” can be safe. As the quote from an article written by eight members of the German Federal Institute for Risk Assessment BfR demonstrates (see textbox at top of page 2), the concept of safe use of hazardous substances is an established fact. The quote shows that the naming of chemicals as “harmful” is misleading, as the exposure and risk component are not considered. In a different part of the WSP report, it reads as if derogations from restrictions had so far been granted only based on socio-economic considerations. In reality, the risk assessments conducted by authorities under REACH and prior to REACH have often used other regulatory means than bans because safe use could be ensured in that manner. In other cases, exemptions or derogations have been granted based on an assessment that the use did not pose a risk and that it would therefore not have been proportionate to ban the use or adopt other risk management measures.

The consequences of discarding the possibility of safe uses for the quality of the impact assessment contained in the WSP report are grave. Even if WSP was not responsible for providing advice on possible exemptions or derogations for safe uses, it should have covered the impact that banning safe but non-essential uses will have – not only on the economy, but on society. Where uses are demonstrated to be safe, a ban of the use cannot be considered to be a proportionate measure. There would be no benefits that could even begin to outweigh the societal costs.

“it is trivial yet important to clearly distinguish between hazard, exposure and risk, as only the latter provides information on whether something is harmful (i.e. actually causes harm) or not. Amalgamating the terms “hazard” and “risk” leads to conceptual misunderstandings, with the consequence of fostering muddled conclusions and perceptions. For example, [...] the fact that chemicals with hazardous properties can cause harm does not mean that they indeed do so at all doses or by all exposure routes. It would, therefore, be wrong to conclude that just because a chemical has hazardous properties it is a threat to human health (as partly insinuated in the public discussion as well as the CSS and SWDs). If this were so, many of our everyday foods (e.g. coffee, soy products, chocolate, many vegetables, meat, alcohol or sugar) as well as widely used natural substances (e.g. essences, oils, soaps) and chemicals or products (e.g. stainless steel, cosmetics, jewellery) would be deemed unacceptable for use.

[...] The understanding that chemicals with hazardous properties can in principle be used safely has been one of the cornerstones of modern developed societies, in fact of civilisation as such.” (emphasis added) “Source: Herzler, M., Marx-Stoelting, P., Pirow, R. et al. The “EU chemicals strategy for sustainability” questions regulatory toxicology as we know it: is it all rooted in sound scientific evidence?. Arch Toxicol 95, 2589–2601 (2021). <https://doi.org/10.1007/s00204-021-03091-3>”.

The correct scope of the safe use / essential use debate

The perspective of ASMoR and its Members on the scope of the safe use / essential use debate is not reflected in the report. A large part of Appendix C of the WSP report reflects on whether industry claims that all professional and industrial uses, use as intermediates or low volume uses could be considered to be safe. The argument made by ASMoR and its Members has been very different.

Contrary to what WSP states in Appendix C, the CSS did not proclaim “the objective to phase out all non-essential uses of the most harmful chemicals”. The essential use concept was merely proposed to be applied to consumer uses. Furthermore, it could also be applied to a certain extent to professional uses, if the level of protection is not at least equivalent to that of consumers. The CSS also made other suggestions for the enhanced protection of workers from MHCs (see e.g. pages 10 and 11 of the CSS).

In its comments in the consultation, ASMoR has remained true to the proposed vision of the CSS and commented within that scope. ASMoR objects to extending the scope of the Essential Use Concept to industrial uses and suggested the limitation of its scope to some professional uses. While the overall aim should be to achieve full safety of workers at the workplace, risk management at workplaces under EU Workplace Legislation (OSH) accepts that sometimes full safety cannot be achieved and that the best achievable risk management at workplaces is more appropriate than to ban the use of substances as such. Applying the Essential Use Concept to REACH risk management at industrial workplaces and most professional workplaces would undercut OSH principles.

It follows that ASMoR and its Members have taken the following position: Where the essential use concept is rolled out for consumer uses, safe uses should be exempted upfront (where the safety is demonstrated) and the possibility for derogations upon application should be possible not only for essential uses, but also for safe uses, where the safety was not possible to be demonstrated in the phase when the restriction was being developed.

Defining 'safe use' in the context of MHCs

WSP did not note any proposed definition of 'safe use' in literature or in the consultation. The underlying concept of the calls for exemptions for safe uses is that uses that do not pose a relevant risk should not be covered by the bans. As WSP reflects, the calls for exemptions for safe uses led the Commission to consider whether "exclusions or derogations from restrictions could also be envisaged on the basis of minimal exposure". ASMoR would be willing to contribute to a definition, be it of 'safe uses' or of 'uses leading to minimal exposure'.

As part of the VVA study on the Generic Risk Approach, the following draft definition was put forward: "a derogation and/or authorization may be granted if industry proves that the exposure/emissions throughout the whole life cycle of the substance are absent or minimal AND there are no suitable alternatives that are acceptable from the standpoint of environment and health."

ASMoR welcomes the development of such a definition, but has objected to two aspects:

1. The scope of the definition should be limited to the scope of the restriction. The CSS proposed the Essential Use Concept to be applied to better protect consumers and, where necessary, professionals from exposure to substances with certain hazardous properties and the environment from releases of certain hazardous substances that result from the consumer and relevant professional uses. Therefore, the definition of what constitutes minimal exposure should not be extended beyond this scope. This means that for human health endpoints within the scope of the CSS' Essential Use Concept the (lack of) exposure of the consumer / professional user of the substance / mixture / article matters. For the environmental endpoints covered by the scope, the resulting release to the environment matters. Production and recycling stages would fall outside the scope for human health endpoints. Here, OSH would be applicable.
2. Where the consumer's (or, if relevant, professional) use of a substance is safe, the derogation should be granted regardless of alternatives that may or may not be available. Otherwise, a rather complex Analysis of Alternatives would need to be conducted even though safety of the continued use is established. This would not seem to be the best use of scarce resources of regulators (and industry) that should focus on addressing uses that lead to unacceptable risks.

Conclusion

Chemicals are key drivers in our life and for those with a hazardous profile the risk they may pose needs to be controlled adequately. Not all consumer and even less professional uses of most hazardous substances (MHC) pose a risk to human health and to the environment. Some uses of such substances can be safe and a priori excluded from such an assessment.

In our view the report gives a solid basis for a more in-depth discussion, how the EUC can be transposed from a theoretical concept into something that works in practice. We see a need for the Commission to initiate a sufficiently wide consultation to discuss the findings of the report. In line with the Commission's commitment to better regulation, this discussion process should be followed by an impact assessment.

Such a discussion process is even more important, because for example in Appendix C it is clearly stated:

"The decision on whether 'safe' uses should be allowed in addition to essential uses is not considered under scope of defining the horizontal essential use concept or setting the policy options for implementation. Rather, it is being considered separately by the Commission who is assessing the grounds for exclusions from restrictions under individual pieces of chemicals legislation."

This conclusion points at a very important aspect that was not covered by this report. This gap needs to be filled urgently and industry – and other interested stakeholders – should be given the opportunity to contribute to a "safe use" definition, beyond what was already done as part of the VVA consultation on GRA.

If the inclusion of "safe use" is not considered and this gap is not fixed, ASMoR believes that this will risk causing irreparable damage to the EU's interests by removing safe and beneficial uses from the EU market, including those that are contributing to achieving the key objectives of the Green Deal and the CSS. In an era where chemicals are key factors in our lives, especially given the challenges we currently face, and are building blocks of our society for health protection, low carbon solutions, energy efficiency technologies, and products, food, the risk of phasing out substances that can be used safely, is irresponsible.

ANNEX: List of Members of the ASMoR

