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Eurocolour's comments on the essential uses approach

According to the Chemicals Strategy for Sustainability, the concept of essential uses should be applied in all relevant EU legislation for both generic and specific risk assessments. The integration of the concept in REACH is one of the key components of the ongoing reform of the restriction and authorisation processes under REACH. In particular, the criteria for essential use should be used for making decisions on authorisations and on whether or not derogations to restrictions would be justified for a particular use. Additionally, the implementation of the essential uses concept is to be considered in the generic risk management approach (GRA).

The mentioning of the REACH framework and of the GRA seems to indicate, in both cases, that an actual risk assessment should take place before or in parallel to the application of the essential uses concept. This is, however, not the case, and is an extreme change in the chemical evaluation system.

In general, any approach which considers hazard alone as a deciding parameter should be evaluated carefully. That does not mean that this approach is always unnecessary or impracticable: The chemical industry is very much aware of the intrinsic hazard of some chemical properties and of the necessity of a prompt intervention. A recent example of a successful approach is the restriction of CMRs in textiles: it was quite clear that the risk from these substances is unacceptable, and the chemical industry collaborated with the authorities to define a framework allowing a precise and easy to implement ban. Additionally, thanks to the definition of a clear scope (relevant substances for the application), the restriction process was completed in a short time without losing in completeness or efficacy.

The key point of the example above is that it is quite possible to start from pure hazard information to develop suitable restrictions, but this process needs to be adapted, any time, considering the relevance of other specific information, which may differ from case to case.

On the contrary, the more generic a hazard-based approach is, the higher is the probability of an overcautious assessment (worst case) of substances or groups of substances with potentially significant und unjustified consequences. From this point of view, the essential uses concept presents various problematic aspects:

- The concept of essential uses looks at all chemicals (and their properties) as if all of them would remain the same during their life cycle; this is an extreme oversimplification, which can lead to results in contrast with the goal of achieving improved safety. Especially, it can cause the ban of long-established and proven as safe substances, which would be a "regrettable ban".
  In particular, many chemical substances will react during their application and change their properties, or even be completely consumed, so that the final products will show none of the potentially concerning characteristics of the starting materials. This reactivity aspect is totally overlooked by the approach, and this would affect substances for which evidence of no risk in final articles would be overruled by the initial screening.

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- A further contribution to an overestimation is the inclusion of respiratory sensitizers as a hazard class at the same level of CMRs and EDs. Unlike the other properties covered by the concept, this endpoint is linked to a very specific exposure path and, in many cases, to a specific form of the substances: the hazard is often due to the status of the pure substance as a powder, but, through the application process, the powder will dissolve in an appropriate medium or encapsulated in a matrix and no longer be available in respirable form in any subsequent stage of its life cycle. Additionally, as described above, chemical reactions could take place and completely eliminate the hazardous properties.

- Finally, as mentioned, other hazardous properties could be linked to a quite specific exposure or form of the substance, which can be relevant only in a very limited number of cases. Here, the specific cases should be the target of a regulatory action, and not the total applications field; again, this result can only be achieved by refining the first hazard-based screening.

In conclusion, the essential uses approach might look like a faster and more efficient way, especially for legislators and authorities, to evaluate /assess very harmful substances, but is, as a standalone instrument, too ambitious. By bringing together many different hazardous properties as a starting point and focusing on the substances as such, independently from any considerations on their specific life cycle, it could become a quite dangerous tool and cause the elimination of safe and useful substances together with the originally targeted ones.

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About Eurocolour:

Eurocolour e. V. is the umbrella association for the manufacturers of pigments, dyes, fillers, frits, ceramic and glass colours, and ceramic glazes in Europe