

## VdMi position paper on the Revision of EU's REACH Regulation

*The EU's REACH Regulation in combination with the CLP Regulation are unique in such a form and extent worldwide. The collection of information on the hazard and potential risks from chemicals is a huge gain for protecting human health as well as the environment. Other countries already use REACH as a blueprint for their own chemical regulations.*

*The effectiveness of the regulations as well as the archived benefit for health as well as environmental protection are unchallenged. This huge success should be kept in mind when considering further steps, nor should the many – mandatory as well as also voluntary – contributions from industry be forgotten which made this success possible.*

*While there are several aspects that may be improved, VdMi would like to stress that these refinements are also considered possible within the given legal framework. Instead of tightening the legal framework with additional obligations and data demands, the already existing possibilities should be exhausted first.*

### **Extension of registration requirements: Risk of losing chemicals without benefit**

An extension of registration requirements especially burdens manufacturers of chemicals in the low tonnage bands. These may produce in this low tonnage band because they are an SME or because the chemical is used only in a rather niche application. In both cases, a loss of these chemicals looms. However, a huge variety of substances is basis for innovation and thus, a fundamental requirement for the aims of the Chemicals Strategy for Sustainability.

Additionally, extended information demands come at the cost of further animal tests which should never be required without even a hint for such hazardous properties.

Furthermore, there are already several safety values included in the current, conservative approach to assess hazards and safety. Thus, the introduction of specific mixture assessment factors (MAF) is not expedient and therefore, not necessary.

The extensions and unification of (electronical) safety data sheets should be treated carefully. A uniform data format leaves less options to communicate specific hazards. As a result, hazard communication might even suffer from such an alignment or an extreme large database for wordings is required which contradicts the concept of uniform wordings.

The proposal for a calculation of an "environmental footprint" for chemicals is not deemed feasible, nor helpful or expedient. The impact on the environment heavily depends on the application. With several and diverse applications for one specific substance, there is no way to determine a precise impact for the substance, only for a specific article the substance is used in. Thus, such ideas should not apply to substances or mixtures.

### **Extension of the restriction criteria:**

#### **No restriction based on non-intrinsic properties or without a defined hazard**

The extension of the SHVC criteria to include STOT classifications, or the new planned CLP hazard classes vPvM and vPvB which still need precise definition cannot be supported. A deviation from the GHS should be avoided at all costs to ensure a globally harmonized communication of risks and hazards and equal trading conditions. However, these categories in particular are inappropriate to trigger regulatory restrictions as they are based on substance unspecific, non-intrinsic properties which cannot be unified for all forms of a substance in case of specific target organ toxicity or lack a defined hazard in case of the two classes focusing on persistence (vPvB and vPvM).

**Revision of the evaluation process:****Already several measures running to further improve data quality**

The REACH Review in 2018 identified several aspects where data quality needs to be improved. However, we would also like to underline that despite these shortages, there was hardly any non-compliance with the registration obligations. Nevertheless, industry committed to improve the quality of registration dossiers. Additionally, ECHA adjusted their evaluation plan.

Due to these actions already applying today, more than 4500 dossiers were revised by industry since 2019. On top of that, many dossiers were updated due to the newly introduced separate registration of so-called nanoforms. Overall, there is a constant improvement of the registration dossiers. Further tightening is not necessary but only adds pressure to all parties.

**Revision of the authorisation process: A sure instinct is required**

While a simplification of the authorisation process would be highly welcome, the partially complex applications of chemicals should be treated with respective expertise. Closely linked to the approach of "one substance, one assessment" the necessary expertise to assess all applications of one chemical needs sufficiently detailed consideration.

**Contradictions to general aim of the Chemicals Strategy on Sustainability**

Many of the proposed actions threaten the variety of the chemicals available within the EU. This is a huge innovation barrier while innovations are strongly needed to enable the transition towards a pollution and emission free economy. Bringing the EU industry in a disadvantage contradicts the aim for further resilience towards trading conflicts in sensible applications like e.g. pharmaceuticals.

Besides, the proposed actions burden the industry with immense costs additional to the already spent amounts of money and resources to fulfill the REACH obligations as they are and further improve the data quality. Additionally, due to the linkage between classifications, registrations and other legislation, there are already many, partially confusing obligations in place. The manpower to keep track of all responsibilities is already a huge burden for SMEs in particular. More and more complex obligations and links between respective regulations only increase the burden and thus, is a huge disadvantage for EU's industry and will lead to a decreasing number of SMEs in the end.

However, as long as several important terms like 'essential use' or 'substance of concern' are not clearly described industry has no planning security and a full impact assessment for VdMi's members is not possible.

Therefore, VdMi promotes

- no turning away from the risk-based approach for evaluating chemicals and their applications
- no ban of chemicals without risk assessment, stakeholder participations, and cost-benefit impact assessments
- uniformly carried out enforcement within the EU and also strict application to all imports

**Contact:**

Verband der Mineralfarbenindustrie e. V.  
Dr. Heike Liewald

[liewald@vdmi.vci.de](mailto:liewald@vdmi.vci.de)

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