SVENSKT NÄRINGSLIV
SWEDISH ENTERPRISE

Response to the public consultation on the targeted revision of REACH

We thank the European Commission for the opportunity to provide comments to the public consultation on the revision of REACH. The Confederation of Swedish Enterprise welcomes the European Commission's Chemical strategy for sustainability and a revision of REACH that addresses the previously identified issues.[1] This combined with a strong and coordinated enforcement across the union will protect consumers, environment and ensure a level playing field and competitiveness for business.

Swedish Enterprise wishes to make the following input and proposals to the REACH public consultation:

- Chemicals are essential to society and are used in almost all products to deliver specific functions or features. A safe handling of chemicals to ensure a high level of protection to the environment and to human health is essential and necessary.
- Given the broad use of chemicals we emphasize the need for impact assessments made with a holistic view that look at the potential effects for the whole value chain. Such assessments must include all actors, from the chemical industry to downstream users such as article producers and consumers.
- A strong and coordinated enforcement across Member States need to be at heart of the policy framework.

The current REACH revision is an opportunity to further improve the framework by making it more efficient, consistent, and coherent with other EU product safety and environmental legislations while maintaining the core parts that make REACH the most comprehensive regulatory framework in the world.

Swedish Enterprise wants to especially stress the following key issues in the revision:

- New data requirements must bring added value to existing registrations.
- REACH is not the right carrier for information on environmental footprint, although the data availability is important.
- Information on use and exposure must fulfil a clear purpose and be used only for those substances facing a regulatory restriction or policy development.
- A mixture assessment factor (MAF) must be differentiated and targeted to those substances that are identified as risk drivers.
- Digitalized supply chain communication is supported but must also include a discussion on which information to communicate to which user.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0116&from=EN

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- The authorization and restriction procedures must be streamlined to ensure as targeted regulations as possible taking all available regulatory tools into account and minimizing the need for exemptions.
- The coherence between REACH and other policies (RoHS, IED, SPI, different OSH directives etc) must be improving and maintained to avoid double regulation.
- Enforcement must be improved and coordinated across EU to ensure safety of products entering EU and a level playing field.

Section I Registration

Information on substances marketed at the lowest tonnage level

Any new data requirements need to be clear, well justified and bring added value to the data already generated today. New data requirements must also support and allow innovation. Therefore, we urge the European Commission to ensure that any extended data requirements are proportionate to the risks that they are set out to reduce and is only required and generated if there are value for risk management. This is especially valid for low tonnage substances, polymer registrations and information on exposure data, as increased data requirements do not necessarily lead to better protection of people and the environment, due to the low exposure. Any new data requirement must be carefully assessed with respect to impacts on especially small and medium sized enterprises, as well as downstream users along the value chains.

Animal testing must always be the very last resort, and the revision of registration requirements should be taken as an opportunity to significantly accelerate acceptance of alternative non-animal testing methods. We call on authorities and regulatory agencies to make every effort to identify where animal-based testing may not be necessary while maintaining a high level of protection, and to evaluate where predictive and validated New approach methodlogies (NAMs) can deliver the safety information expected under REACH. With the right focus on NAMs quicker innovation with high safety for health and environment can be achieved, also for low volume substances.

Information on environmental footprint

We agree with the Commission concerning the importance of information that can support environmental footprint assessments. However, REACH legislation is not fit for this information requirement as REACH is primarily designed for assessing hazards and controlling risks for substances and mixtures. Since the same substance can be used in many applications and value chains, and be produced by different registrants, a registration requirement on environmental footprint would create a very complicated framework, that is not fit for purpose.

The need to provide environmental footprint data for substances shall instead be driven by the value chains and uses and is preferably initiated by market requirements.

Information requirements on use and exposure

We agree that further improvement of the communication on uses and exposure is necessary. However, additional requirements should be designed in a way that avoid unnecessary administrative burden. The reporting needs to fulfil a clear purpose and thereby be limited to those substances that might face regulatory restriction or policy development and produced above a certain volume threshold. Any regular reporting should be limited to the identity of hazardous substances used and detailed information on use and exposure should only be requested if needed for developing regulatory measures. A harmonised web-based reporting is highly preferred.

Introduction of a Mixture Assessment Factor

With the introduction of a Mixture Assessment Factor (MAF) the Commission seeks to address risks from exposure to unintentional mixtures of different chemicals. However, data has shown, that only in a limited number of cases environmental levels of chemicals point to a potential combined exposure risk that cannot be addressed by applying current assessments and regulatory regimes.[2]

Therefore, we would like to emphasize that in order for a MAF to be relevant:

- Differentiation shall be made between environmental exposure and human health, as well as using different sized MAF depending on data available.
- An effective (regulatory) approach should be as targeted as possible, rather than applying a generic one-size-fits-all approach.
- Introduction of a generic approach like a MAF needs a detailed impact assessment. The consequences for the value chain must be thoroughly assessed.
- Use of a MAF shall be based on a tiered approach where presence of data always shall outweigh a general MAF.

Simplifying communication in the supply chain (options for improving SDS, including harmonized electronic formats)

Over the past decade, industry – with support from ECHA, Member States and the Commission – has put considerable effort into investigating and developing approaches & tools to implement high quality extended Safety Data Sheets (eSDS). To address outstanding issues the following elements are essential:

- Digitalize the communication flows
- Improve the communication flow along the supply chain
- Define minimum requirements for exposure scenarios
- Consider the needs of the receiver of safe use advice (via eSDS)
- Improving and fine-tuning of existing methodologies for defining safe use info for mixtures
- A digital solution must always support easy transmission and translation of SDS, within EU and between other regions.

[2] Characterising chemical co-exposures in the EU to support a combined exposure assessment strategy, Arche Consulting & VITO, October 2021.

On additional information requirements on uses and exposures it is of outermost importance that the reporting system is workable, set a minimum quantity for reporting obligation, and is limited to the identity of the most hazardous substances. Detailed information on use and exposure should only be requested if needed for developing regulatory measures. Previously performed studies have concluded that systematically collecting these data will be labor intensive, face many limitations due to complexity of value chains as well as CBI concerns.[3]

Section II Evaluation

Changes to the provisions on the evaluation process

Swedish Enterprise agrees with the Commission that registration dossiers shall be correct and compliant and the initiatives to strengthen a zero-tolerance approach to non-compliance. However, the new system on revocation of registration numbers must include clear conditions and a sound legal process to ensure legal certainty for companies. It should also be used only as a last resort. Further important aspects are

- Right to be heard. Companies must have the rigth to be informed and heard before a decision on revocation is taken
- Possibility to appeal. Companies must be able to appeal a revocation decision before the ECHA Board of Appeal
- No retroactive effect of revocation. Revocation decisions must not have a retroactive effect. For downstream users the registration number must remain a clear indication that a substance has been legally placed on the market before the revocation date.

Section III Authorization and restriction

Including the concept of essential use in authorizations and restrictions

There are many fundamental questions and issues related to the essential use concept that need to be discussed and clarified, including an in-depth assessment of the benefits and consequences of the concept and its legal basis. When introducing an Essential Use concept into REACH, the following elements are critical:

- Decisions on Essential Use must be made by a politically accountable body that is empowered to take both decisions and full responsibility of the decisions.
- An essential use committee/body should include representatives of member states, European parliament, industry, civil society etc.
- The essential use concept should facilitate the decision-making in authorization/restriction process, in line with the Chemicals Strategy for Sustainability.
- It must only be implemented where an unacceptable risk is identified or where adequate control cannot be guaranteed.
- It must be ensured that a definition of essential use defined today does not restrict needed innovation of emerging and future technologies.
- The alignment with international trade agreements must be secured.

[3] Report issued by the Tonnage Information Task Force in view of Action Area 2.6 of the 2018 CSR/ES Roadmap, July 2016.

Reform of authorizations and restrictions

A revision of the authorization and restriction process that results in a regulatory system able to focus on regulatory measures for the most prioritized substances is very welcome. A future regulatory system shall focus on prioritized substances where the measures bring the most benefits and using the regulatory regime that is most targeted. We urge the Commission to ensure that the impact assessment clearly evaluates whether the proposed changes would allow to do so.

We support a candidate list as a prioritization tool for potential regulatory action, including for non-REACH regulatory measures. However, to make the candidate list workable and useful both for authorities and industry, chemicals should only be added when there is an identified need for regulatory action. In other words, the candidate list should not be a copy-paste from Annex VI of the CLP regulation via a dynamic link, as this would make the list unmanageable and watered down.

Furthermore, the SVHC proposals prepared by MS and ECHA should include a justification on the risks and the inclusion of the chemicals in the candidate list to have a predictability. Also, a removal process of chemicals should be introduced to allow the update of the candidate list when no further communication, nor regulatory actions is needed. Obtaining derogations/authorizations when safe use can be proven should always be an option.

Double regulation (POPs, RoHS, IED, SPI, different OSH directives etc) must be avoided and resolved. Before deciding on the REACH authorization route, it should be thoroughly evaluated whether other legislative tools are more efficient to reduce the risk of a substance. A careful evaluation regarding conflicting requirements must be done.

Other general improvements of the authorization/restriction process could be better targeting of the type of information and format needed by ECHA's scientific committees. Also, additional opportunities for applicants to exchange with the committees could remove uncertainties and clarify questions raised by the committees during the opinion making process.

We also welcome the reflection launched on the interface between authorization and restriction. The interaction between those processes deserves further improvements to ensure a coherent and manageable regulatory risk management measure. We strongly support the concept of a level playing field between EU and non-EU actors. Therefore, a system for authorization and restriction needs to apply equally to import and production in the EU. While the proposal to develop a national authorization process and enforcement for smaller applications may have practical advantages, we see a big risk that this will be devastating for the level playing field and the internal market.

At the same time, the process should be as efficient as possible for both the regulators and industry with regards to exemptions or derogations, and without compromising on risk assessment, use or exposure.

Generic risk management approach

Extending the scope of the generic risk assessment in article 68.2 to professional users would have significant impact for both industry and society that needs to be carefully assessed. While the use of CMR-substances should of course be minimized, the risk for professional users should not be equated with that of consumers, and can be addressed by other means, like for example by OSH legislation or extended training for professional users. Any extension of article 68.2 should be subject to an impact assessment considering alternative approaches such as a strengthening of workers health legislation and end use products possibly affected by the extension as for example corrosion protection, wood protection, heavy duty fixing, waterproofing etc.

Section IV Enforcement

Establishing a European Audit Capacity and Enhance the Enforcement of national controls, including stricter border controls

We strongly support an increased and harmonized format for enforcement. Enforcement and enforceability are critical to implement a regulatory measure and ensure it delivers on its objectives. It is essential to strengthen and formalize the role of the ECHA Enforcement Forum with a view on enforceability. The Impact Assessment should include an option for the Forum to assess enforceability based on defined criteria. This would help in identify gaps that need to be addressed before the restriction is enters into force.

This response has been produced in close cooperation with Swedish Enterprise´s member organisations.

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