SVENSKT NÄRINGSLIV
SWEDISH ENTERPRISE

Reply to IIA on revision of REACH

We thank the European Commission for the opportunity to provide comments to the Inception Impact Assessment (IIA) 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 makes the legislation simpler and more efficient. 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.

The Confederation wishes to make the following input and proposals to the IIA:

- 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 necessary.
- Given the broad use of chemicals we would like to stress 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.
- REACH is the most comprehensive regulatory framework aiming at securing safe use of chemicals, but chemicals are also regulated in several other legislations. To simplify the legislation, make it more efficient and to avoid overlaps with other legislation in combination with a strong and coordinated enforcement across Member States is the way forward.
- The current REACH revision is an opportunity to further improve the framework by making it more efficient, consistent and coherent with other pieces of EU product safety and environmental law by
    - bringing added value to new data requirements
    - using digitalised supply chain communication
    - simplify the authorisation and restriction procedures
    - improve and maintain policy coherence between REACH and other policies (RoHS, Ecodesign, IED etc)
    - An essential use concept must facilitate decision making in authorization/ restriction process
    - improved and coordinated enforcement to ensure safety of imports entering EU

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Bringing added value to the current requirements

Any new data requirements need to be clear, well justified and bring added value to the data already generated today. New data requirements should support and allow innovation. Furthermore, the revision of registration requirements is an opportunity to significantly accelerate acceptance of alternative non-animal testing methods. Therefore, the impact of new data requirements on animal welfare should be part of the European Commission's Impact Assessment.

With the introduction of a Mixture Assessment Factor (MAF) the Commission seeks to address risks from exposure to unintentional mixtures of different chemicals via our surroundings or the environment. In this context we would like to highlight that:

- 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.
- A MAF should not duplicate existing regulatory requirements.

Using digitalized supply chain communication

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 up and down 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

Simplify the authorization and restriction process

Any clarification and simplification that the European Commission may provide to the authorisation process to increase predictability of action is very welcome. Better targeting the type of information and format needed by ECHA's scientific committees will improve the assessment of the application and understanding of current situation. Providing additional opportunities for applicants to exchange with the committees is another way to remove uncertainties and clarify questions raised by the committees during the opinion making process.

We also welcome the reflection launched on the interface between authorisation 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 when it comes to restricting substances. At the same time, the process should be as efficient as possible for both the

regulators and industry, specifically also with regards to exemptions or derogations. Authorisation only applies to the use of the substance in the EU, whereas Restrictions also apply to imports of substances, mixtures and articles. For global manufacturers in many sectors we prefer a system that is equally applicable to import and production in the EU and provides the same prohibitions and exemptions to all companies. Article producing industry needs to be able to continue to produce products using chemicals in a level playing field with non-EU countries. Therefore, a REACH Restriction rather than authorisation is the preferred instrument to regulate chemicals. Restriction at least sets equal conditions for the chemicals content of EU-manufactured and imported products alike and therefore also supports higher quality of material streams. Therefore, REACH restriction and authorisation should be better harmonized.

While the proposal made to develop a national authorisation process and enforcement for smaller applications may have practical advantages, we see a big risk with this. We believe that it is important to keep REACH harmonized across all EU member states and aim to further guarantee a level playing.

In principle, the reform of restriction procedure would benefit from streamlining of processes to improve information gathering, allowing for a better exchange between involved parties to have a common understanding on the needed regulatory action, practical implementation and required derogations. Grouping criteria need to be understood and applied in the same manner by all stakeholders throughout different REACH processes.

Extending the scope of the generic risk assessment in article 68.2 to professional user would have significant impact for the industry. The use of CMR-substances should of course be minimized but the risk for professional users should not be equated with that of consumers. Professional users are covered by workers legislation put in place to control risks. Any extension of article 68.2 should be subject to an impact assessment considering alternative approaches such as a strengthening of workers health legislation.

Improve and maintain policy coherence between REACH and other policies

Double regulation (POPs, REACH, RoHS, Industrial Emissions Directive (IED), etc.) should be avoided and resolved. Before deciding on the REACH authorisation 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.

We strongly question inclusion of environmental footprint information in REACH. Even though we agree it is an important issue it is better addressed in other legislation. Double legislative instruments shall be avoided. This being said, we welcome the supporting study that the European Commission will launch which will look into the environmental footprint information and how it may be integrated under REACH. The goal to include such data under REACH needs to be clarified, the assessment needs to be fully consistent with parallel initiatives namely “safe and sustainable by design” criteria and not duplicate other

work/databases or methodologies that are available elsewhere (PEF, ISO standards on LCA, carbon footprint databases, etc.).

An essential use concept must facilitate decision making in authorization/ restriction process

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:

- It must facilitate decision-making in authorization restriction process, in line with the Chemicals Strategy for Sustainability.
- It needs to be scientifically based and only implemented where an unacceptable risk is identified or where adequate control cannot be guaranteed.
- It has to be based on transparent and predictable methods, done on a case-by-case analysis, and involve discussions with stakeholders from both industry and civil society.
- Decisions on Essential Use should be made by a politically accountable body that is empowered to take both decisions and responsibility beyond existing scientific or regulatory committees (RAC, SEAC, CARACAL).
- The alignment with international trade agreements must be secured.

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