REACH Review

What is REACH?

REACH stands for Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (EC 1907/2006). This key EU legislation on chemicals aims to improve the protection of human health and the environment, promote alternative methods to animal testing as well as ensure the free circulation of substances in the internal market while enhancing innovation and competitiveness of the EU chemicals industry.

The four processes of REACH are the registration, evaluation, authorisation and restriction of chemicals:

- **Registration**: Manufacturers and importers of chemicals must identify and manage risks linked to the substances they produce and market. By 31 May 2018, all existing chemicals manufactured, imported or placed on the EU market above 1 tonne per year will have to be registered. Without registration, substances cannot be manufactured or imported into the EU.
- **Evaluation:** The information submitted to register chemicals can be checked by the European Chemicals Agency (ECHA). Member States evaluate substances for specific concerns regarding human health and the environment.
- **Authorisation:** This procedure ensures that the risks of substances of very high concern (SVHC, for example carcinogenic, mutagenic or reprotoxic substances) are properly controlled and that those substances are progressively replaced by suitable alternatives. Those substances may be listed on Annex XIV of the REACH Regulation and then companies need to obtain an authorisation to continue to use these substances.
- **Restrictions**: Restrictions on the manufacturing, use, or placing on the market of substances are designed to manage unacceptable risks to human health or the environment that are not addressed by the other REACH processes or by other EU legislation. EU countries or the European Commission may propose EU-wide restrictions.

How has REACH helped protect human health and the environment to date?

So far, the REACH **registration procedure** allowed gathering information on more than 17,000 substances. 65,000 registration dossiers of the main chemicals manufactured and used in the EU were submitted since 2010 and allowed the EU to build the most comprehensive database on chemicals in the world. It improved the protection of human health and environment through a better knowledge and risk management of chemical substances by industry.

As regards the **REACH authorisation** procedure, a recent study published by the Commission, shows substantial results. So far, 181 chemicals that can have serious effects on human health and the environment have been identified as such and 43 are included in the “REACH authorisation list”. This also means

that companies are progressively replacing them when suitable alternatives become available.

For example, the **substitution** of arsenic trioxide used for the production of traditional glass in the Venice area was triggered by the REACH authorisation requirement. The traditional glassmakers had to find safer alternatives to arsenic trioxide, while maintaining the quality of their glassware. Joint efforts have led to alternatives that cover 95% of the production and that have reduced workers' exposure. Moreover, this has also improved air quality in the region, as arsenic concentrations in the air have decreased substantially.

Finally, the **restriction procedure** has led, between 2012 and 2016, to banning or limiting further the use of 18 chemical substances, including groups of substances, benefitting directly to people's health and environment. As an example, the restriction of chromium VI in leather articles enabled an estimated 1.3 million people with chromium allergy to use leather articles and reduces the number of new cases of chromium allergy by approximately 10,800 per year.

Another concrete example is the restriction of the use of lead in the EU. Lead causes damage to the central nervous system and is therefore banned in jewellery since October 2013 and, in many other consumer products, since June 2016. In particular children are at danger as they might put products directly in their mouth. Thirteen million children below the age of 3 have today a reduced exposure to lead which will have positive long-term effects for their neurological development.

In addition, the restriction of groups of substances such as perfluorocompounds, protects the environment (and wildlife) as well as humans (exposed through the environment) from the risks associated with toxic substances that are persistent and accumulate in living organisms.

Can REACH be further simplified and what is the Commission proposing?

The second REACH review has identified a number of areas which could be further simplified, including information requirements, extended safety data sheets, the authorisation process and the requirements for substances in products. The Commission therefore proposes the following:

- **Improving compliance of registration dossiers:** data gaps in registration dossiers need to be addressed through improved compliance and evaluation procedures.
- **Simplification of the authorisation process:** authorisation is still a relatively new process under REACH that has faced challenges as it became operational and it needs to become easier and predictable for companies.
- **Ensuring a level playing field between EU and non-EU companies:** EU manufacturers are at a disadvantage compared to non-EU companies when producing products containing Substances of Very High Concern (SVHC) that are subject to authorisation. The Commission is looking into ways of addressing this disadvantage.

- **Enhancing enforcement** by national authorities, including import controls by customs authorities.
- **Coherence** by clarifying the interface between REACH and the worker protection legislation (OSH) as well as with waste legislation.
- **Supporting compliance by SMEs:** There are concerns about the vulnerability of SMEs. The Commission requests ECHA and Member States to step up their efforts to develop tailored guidance and support instruments focused on the needs of SMEs to help them comply with the REACH requirement.

I am an entrepreneur. How does REACH affect my company?

In line with "the polluter pays principle", REACH shifted the burden of proof to industry, making it responsible for the safety of chemicals along the supply chain.

To comply with the regulation, companies must identify and manage the risks linked to the substances they manufacture and market in the EU. They have to demonstrate to ECHA how the substance can be safely used, and they must communicate the risk management measures to the users. REACH requires new forms of cooperation among companies, enhancing communication along the supply chain, as well as developing tools to guide and assist companies and public authorities in its implementation.

Companies also need to comply with the requirements resulting from the evaluation, authorisation and restriction chapters of REACH.

How do costs and benefits of REACH compare?

The main direct costs for companies incurred under REACH so far are associated with registration and the communication of information along the supply chain. These are estimated at €2.3-2.6 billion for the first two registration deadlines. The estimated scale of potential benefits for human health and the environment are estimated at €100 billion over 25-30 years (since the entry into force of REACH).

The Commission assessment of the first ten years of REACH acknowledges the costs related to its administration and the impact on companies, especially on SMEs. This is why it adopted and encourages further measures to help companies comply with REACH requirements such as ECHA and Member States tailored guidance and support instruments for SMEs.

What has been the effect of REACH on the internal market and in the competitiveness and innovation of EU industry? What does the Commission envisage?

REACH aims to ensure the free movement of chemicals in the internal market, as well as to promote the competitiveness and encourage innovation, by for example facilitating the development of safer chemicals to replace hazardous substances. While REACH has further harmonised the internal market for chemicals, its effects on the competitiveness and innovation of EU industry are complex and depend on other factors, such as global market trends. The

actions proposed by the Commission will further improve the implementation of REACH, easing compliance by companies and ensuring that EU manufacturers do not face competitive disadvantages.

What is the public perception of chemicals in Europe?

The Commission ran a Eurobarometer survey on the public perception of chemicals at the end of 2016. Europe's citizens are concerned about being exposed to hazardous chemicals in their daily life and REACH responds directly to these concerns. The perception of chemical safety has improved in the last 10 years, although the perceptions of safety vary also between Member States and citizens will need further reassurance.

- 44% of EU citizens consider that safety of chemicals contained in products has improved in the last 10-15 years.
- They also have more confidence in products manufactured in the EU compared to those imported from outside.
- The main sources of information used by the public to get such information are product labels and media.

What are the overlaps identified by the review between REACH and other EU legislation dealing with chemical risk?

The REACH Review did not identify major incoherencies between REACH and other EU legislation. Some inconsistencies have already been addressed in the past years on the interface between REACH and POP and REACH and ROHS, while others are still requiring attention.

Although there are some synergies between REACH and the Occupational, Safety and Health (OSH) legislation, efforts are needed to address the diverging ways in which the two Scientific Committees, (RAC and SCOEL), provide opinions on workplace exposure limits.

The issue of determining when recycled materials cease to be waste and become subject to REACH again is being tackled in the context of the Circular Economy.

Can the role of the European Chemicals Agency evolve in the implementation of REACH?

The European Chemicals Agency (ECHA), founded in 2007, has a key role in the successful implementation of all REACH processes. ECHA hosts the world's largest database on chemicals and enables an easy online access to chemical safety data. Efficiency has improved over time both within ECHA and how ECHA works with Member States and other stakeholders.

ECHA has built-up a significant competence in chemicals management and is expected to become a European and global reference centre for the sustainable management of chemicals, capable of serving the implementation of other EU legislation should the Commission make a proposal to this effect.

What can REACH help to achieve at a global level?

The implementation of REACH positions the EU as a global frontrunner towards achieving the 2020 World Summit on Sustainable Development Goals. REACH concretely implements the SDG target “to achieve by 2020 sound management of chemicals throughout their life cycle and of hazardous waste in ways that lead to minimization of significant adverse effects on human health and the environment”.

For More Information

Press release

Chemicals and the Environment

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