

A private sector view on REACH and competitiveness

2017 REFIT evaluation key to addressing outstanding obstacles

Executive summary

Members of the American Chamber of Commerce to the European Union (AmCham EU) are active stakeholders in the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH) and have experienced its procedures first-hand.

Over the past few years, the implementation of REACH has improved and to some extent become more predictable. The adoption of the Risk Management Option Analysis (RMOA) and of the Substances of Very High Concern Roadmap are the most visible signs of such improvements. Nonetheless, AmCham EU believes more could be done to guarantee REACH delivers on safety without jeopardising competitiveness and innovation in Europe. The 2017 REACH evaluation is the perfect opportunity to do so.

The impact of REACH on competitiveness is about much more than compliance costs. AmCham EU wants to illustrate in what ways REACH impacts competitiveness early on in the REACH evaluation process, to help frame the discussions going forward.

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AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €2 trillion in 2015, directly supports more than 4.3 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

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Introduction: What competitiveness is and what it means in the context of REACH

As stated in Article 1 paragraph 1 of the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation: ‘The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation’.

Explaining what impact REACH may have had on the competitiveness of European industry – whether chemical producers, users, or simply importers of finished articles into the European market – requires an evaluation of what the concept of competitiveness actually means. Many definitions of competitiveness exist, all differ slightly, but they revolve around: ‘the capacity to produce goods and services which respond to the demands of an international market, whilst at the same time allowing the citizens to enjoy a consistently rising standard of living in the long term’¹.

Most official definitions of competitiveness are drafted with countries or regions of the world in mind, eg, those of the World Economic Forum (WEF) and the Organisation for Economic Cooperation and Development (OECD). They also stress that competitiveness varies at different stages of economic development.

When looking at how these concepts could apply to the REACH debate, we must invariably focus on the competitiveness parameters which are linked to developed economies. Of the criteria set out by the WEF, those most relevant to the REACH debate include high-level education and training, efficient goods markets, the ability to harness the benefits of existing technologies, as well as the size of the market, both domestic and international².

AmCham EU has used the WEF competitiveness pillars listed above to extract the following factors of business competitiveness which are impacted by REACH:

- Predictability and investment security;
- Competitiveness is global: Europe v. the rest of the world;
- Innovation is much more than substitution.

Specific case studies from our membership can be found in the Annex of this paper.

Regulatory uncertainty caused by REACH can jeopardise long-term investments in Europe

The 2015 European Commission report on the *Single Market Integration and Competitiveness in the EU and its Member States*³ highlights that barriers to investment continue to exist in the EU. Hurdles include regulatory instability, unpredictability and overregulation that tend to impact longer-term investments in particular. The same report also stresses declining productivity growth in Europe as a

¹ Unites States Competitiveness Policy Council, 1992. Available [here](#).

² See WEF ‘pillars of competitiveness’ 5 through 10, available [here](#).

³ European Commission, Report on single market integration and competitiveness in the EU and its member states, 2015. Available [here](#).

key element that affects the EU's competitiveness. AmCham EU members find that the REACH Regulation contributes to these challenges.

Indeed, one of the main impacts REACH has on the competitiveness of companies active in Europe is the creation of legal uncertainty surrounding which chemical substances, or unfortunately groups of substances, will be targeted, when, and under which procedure, eg. candidate listing, Community Rolling Action Plan (CoRAP) list, Annex XIV, restrictions, etc.⁴ Global companies may lose competitiveness because of their inability to anticipate regulatory signals, sometimes contradictory or inconsistent, from different laws or Member States. Failing to anticipate which chemical substances can be used in a new range of products late in the product development cycle can cost millions, and in some cases much more.⁵

The current lack of predictability surrounding REACH means companies producing in Europe cannot be certain that a substance which is allowed now will be available for use in three, five or ten years – when a new product range is ready to go to the market, or even beyond that, during the product's life. For AmCham EU members whose manufacturing processes all use chemicals in one form or another, not knowing which substances can be used and for how long is not only expensive but also a deterrent to long-term investment. While AmCham EU acknowledges that information and knowledge evolve, and that predictability can never be complete, it believes improvements to the REACH processes should enable companies to reasonably estimate the level and timeframe on which they can expect a return on their European investments.

The consequence is that new ranges of products or manufacturing sites will not be built in Europe (see case study 2 from the pharmaceutical industry and 4 from aerospace). This is the most critical risk to the competitiveness of the EU and its industry. When a company's latest cutting edge products are not made in a certain region, the plants in this region do not benefit from the same investments, and therefore, over time will become less competitive than those in other regions. This competition is valid even for manufacturing sites within the same company.

Europe v. the rest of the world: Has REACH boosted investments in Europe?

Market access, investment & innovation

Market access is a key consideration for investors. REACH has created very expensive regulatory market barriers with no equivalent in the world. While this obstacle does not discriminate between substances manufactured in Europe and imported ones, REACH compliance costs are often too high for small and medium enterprises (SMEs), which are critical to EU innovation clusters, or for new chemical substances in small volumes which may not be able to provide a return on this initial investment.

Manufacturing in general and chemistry in particular are part of Europe's economic future. Chemicals enable the development of new materials and new technologies to meet new societal needs. As mentioned above, the EU chemical industry is increasingly a high-added value sector that is at the core

⁴ The recent trend by EU authorities to propose Restrictions with a very broad scope, which are open to interpretation is a worrying trend. The example of the proposed restriction for carcinogenic, mutagenic, or toxic for reproduction substances (CMR) in textiles is illustrative in this sense. A restriction of 286 substances, in an unknown number of uses, with various possible detection limits will be impossible to implement, and therefore will never send a clear message to the market. For more on this, please see the [joint-association paper](#) co-signed by AmCham EU.

⁵ Investment in high volume chemicals can cost billions of euros over decades.

of Europe's competitiveness and innovation. As such, REACH has an impact which goes far beyond this sector alone.

Energy and resource efficiency, modern healthcare and transport, the digitalisation of the economy and all the investments that go with this evolution of our society, none can happen without the chemical industry. Innovation relies on local networks and innovation hubs and the chemicals industry is intrinsically part of both. Without chemistry competitiveness as a whole would suffer.

Addressing the myth that having to comply with REACH in Europe provides a comparative advantage in other regions of the world

Despite REACH being the most demanding chemicals legislation in the world, multinational companies must still comply with all relevant legal obligations in the jurisdictions in which they operate. Even when requirements in other parts of the world such as China or the United States appear to impose similar EU REACH requirements, in practice these are very different. Chemicals laws in different jurisdictions around the world set out different testing requirements and prioritisation criteria.

For global companies, including the members of AmCham EU, complying with REACH in the EU is expensive and there is no guarantee that additional requests for testing or reporting will not occur in other jurisdictions of the world. REACH can even be detrimental to competitiveness when it is not enforced properly. EU REACH restrictions which are not enforced are a de facto competitive advantage to noncompliant European and third country industries. See case study 1 from the tyre sector in the Annex.

Innovation and REACH: The debate should be about more than substitution

REACH has had one positive impact on innovation management: it has pushed companies to systematically identify and prioritise which substances they are not interested in producing or using in the future.

That being said, the current policy debate around chemical substitution and REACH is too often unconstructive. Regulators feel that substitution is most likely to occur when it is mandated by regulatory change and industry feels its efforts are not recognised since these may need to be kept secret to comply with competition policy requirements. For example, the chemical composition of products is sensitive information among competitors.

Innovation for the private sector is market driven, and is about meeting customer and consumer needs faster than the competition does. Regulatory compliance efforts seldom help private sector entities innovate. Safety and compliance are non-negotiable for American corporations, as they serve as a licence to operate. Compliance requires constant effort, but has little to do with the forward-looking perspective of innovation.

REACH compliance requires specialist knowledge and in-house expert competence. One of the negative indirect impacts of REACH on innovation is that company expert staff, which includes research and development (R&D), process improvement, and product testing experts, is mobilised for compliance efforts associated with REACH rather than for the R&D priorities they were hired for. Following the Commission's *Report on Single Market Integration and Competitiveness*, this misallocation of R&D resources should become an issue for EU regulators.

AmCham EU would also like to stress that certain breakthrough technologies are not being investigated to their fullest extent in Europe because of uncertainties surrounding the regulatory regime that will affect them. An example of this includes nanomaterials, the fear being that they will be regulated in an overly cautious manner under REACH. This simply means that R&D and market deployment efforts will be undertaken outside of Europe.

A further impact REACH has on innovation is that REACH-related costs make it is relatively less interesting to sell small-volume specialty chemicals in Europe, and that these are increasingly being developed in other regions of the world. Downstream users are therefore penalised, having limited access to substances that cannot usually be substituted easily, potentially threatening business continuity.

The cost of registration dossiers and letters of access means that accessing the European market for chemicals requires capital upfront. While this may be fully appropriate for high or medium tonnages, as a high return on investment is expected, it can be hard to justify for SMEs and larger companies alike who sell just a few tonnes a year.

This means small volume substances which may be of added value in the future will increasingly be developed in innovation clusters outside of Europe. These new substances will only be available on the European market once they have reached a certain maturity and market penetration. This may have a knock-on effect for downstream users as well who will only be able to use these new substances later on in the innovation cycle, compared to other regions.

AmCham EU believes that this economic fact will impact the competitiveness of the EU chemicals industry as well as its entire manufacturing sector. Therefore it should be at the forefront of EU regulators' minds as they assess REACH in their 2017 Evaluation.

Conclusion: Competitiveness is about much more than compliance costs

The Commission's own *Cumulative Cost Assessment of the EU Chemical Industry*⁶ illustrates that the total direct cost of chemicals legislation on the sector is on average 2% of the sector's turnover, which represents 12% of value added, or 30% of gross operational surplus.

These costs undoubtedly impact the profitability of the chemicals industry. In parallel, the Commission's assessment of the benefits of chemicals legislation⁷ paints a positive picture. When taken together, these reports seem to show REACH delivers. It is important to ask however whether it could do the same at lower costs for industry, and eventually society.

Whereas REACH compliance costs are significant, and should not be disregarded, the issue of REACH's impact on competitiveness has much more to do with the predictability of the regulatory regime, how it compares to other regions of the world and whether it encourages innovation.

⁶ Full report available [here](#).

⁷ Full report available [here](#).

It is time to pause and assess how to make necessary adjustments. REACH has significant shortcomings, and AmCham EU hopes these will be discussed, and proposals made to address them as part of the 2017 Evaluation.

AmCham EU members look forward to further discussion and a constructive evaluation over the next year to help improve this Regulation.

ANNEX: REACH and competitiveness case studies from AmCham EU members

Case study 1

Lack of enforcement of REACH restrictions gives foreign production a competitive advantage v European-based production.

Example from the tyre sector, 2010 polycyclic aromatic hydrocarbon (PAH) restriction in tyres.

The lack of enforcement of REACH and its restrictions greatly impacts the competitiveness of EU based manufacturing. An illustrative example is in the tyre sector and the related Annex XVII restriction of PAHs in their oils.

Compliance with this restriction mobilised huge amounts of R&D and testing resources in the oil, polymer and tyre companies producing in Europe, including American ones. The tyre industry has estimated that this restriction costs them over €100 million. This granted a first competitive advantage to producers from other regions of the world importing their finished products into the EU. These producers, without having made this investment, benefitted from the R&D of the European industry and a new supply of compliant oils.

A second competitive advantage is granted to non-compliant actors in that they continue to have access to the European market without having made the necessary investment to meet the new REACH related obligations. After the 2010 REACH restriction, the tyre industry ran its own testing campaign (more information [here](#)) to check the compliance of tyres on the EU market. Over 10% of tyres were not compliant with the restrictions and this 10% represented exclusively cheap imports from outside the EU.

De facto, non-compliant actors who have not had to pay REACH compliance costs are given a competitive advantage over those who are compliant.

Case Study 2

R&D and manufacturing sites not being built in Europe because of the uncertainty around REACH authorisation

Example from the pharmaceutical sector

Aprotic solvents⁸ are on the Substances of Very High Concern (SVHC) list and may soon be prioritised and added to Annex XIV. Such a move could very well create a disincentive to move new pharmaceutical manufacturing to the EU.

Recently, two pharmaceutical companies made the decision not to move the manufacturing of two new pharmaceuticals to the EU because of concerns these solvents would become unavailable.

⁸ Dimethyl formamide, dimethyl acetamide, and N-methyl pyrrolidone.

Although pharmaceuticals themselves are exempted from REACH, the law has an impact on this industry. If these solvents are placed on Annex XIV, EU-based pharmaceutical manufacturers would not be able to use them unless they invest time and resources in applying for authorisation. They also need to be willing to risk building manufacturing sites that may become valueless when the first review period expires, ie, if they may receive authorisation the first time, but not the second time. In contrast, non-EU manufacturers can make these drugs outside of the EU using these solvents and import them into the EU.

Case Study 3

REACH leads to wasted R&D efforts and a disincentive to invest in Europe.

Example from the plasticisers industry

Of the approximately 30,000 plasticisers assessed for plasticising properties over the last 70 years, there are now about 50 REACH registered plasticisers available in the EU commercially. Of these, five are major, high-volume, general-purpose products bringing highly-cost effective performance and in sufficient volumes to meet the market demand. These are the result of major investments in research, development, manufacturing, distribution, applications testing and a tough market selection process over many years based on performance, availability, price and health and environmental safety. They bring tremendous benefits to society in a wide array of applications.

Despite extensive regulatory evaluations for some of these substances, there seems to be a regulatory obstinacy to target them. This means there is no, or limited, predictability for the future of these substances, and that future product investment to reach capacity and enhance competitiveness will not take place in Europe.

In addition, non-EU producers who are not subject to REACH will invest outside the EU, most likely in products which have been less extensively evaluated by regulators, or even those which are subject to phase-out in Europe. This will decrease the cost structure of non-EU producers versus EU producers, thereby decreasing the latter's competitiveness.

The overall effect of REACH's obstinacy is to decrease the competitiveness of the EU plasticiser industry and to disincentivise innovation and investment. This means a reduction in the availability of high-performance and cost-effective plasticiser products in European society, with no improvement to human health and environmental protection.

Case Study 4

How uncertainty associated with REACH can impact the bidding process

Example from the aerospace industry

The aerospace industry is characterised by developing and producing highly-reliable and certified components for aeroplane models that might be produced for over forty years. These components are so strong that if they were made for cars, they would be expected to last a million miles. This long-term production planning is not compatible with repeated Authorisation applications and is negatively impacting the competitiveness of metal treatment processes in Europe. Indeed customers in the

aerospace industry expect to be able to receive parts for decades. At the moment, REACH Authorisation is incompatible with this legitimate business expectation.

REACH Authorisation introduces a significant factor of uncertainty in the future production capabilities of European sites, undermining their competitiveness within a global supply chain. This uncertainty will discourage investments and ultimately impair job creation, as well as technology and skills' development in Europe.

Case Study 5

Impact on REACH on R&D cycles

Example from the petrochemical industry

Industry innovates, that is its mission. Regulatory developments can however impact companies' innovation efforts accelerating R&D activities in some fields and their substitution strategies in others.

However, it must be stressed that the signals received from regulations in the chemicals field must be counterbalanced by the need to comply with other technical regulations. Replacing one chemical substance with another is a very complex exercise and may easily require 5-10 years. In addition, the replacement of a substance in a mixture may require the reformulation of the mixture itself.

In the additives business, the commercialisation of a new substance passes through several stages, which include design of the molecule, lab testing, bench testing, engine testing, field testing, substance registration, etc. The process takes well over 5 years and costs several million euros, without counting the costs associated with new manufacturing facilities.

The uncertainty over the outcome and duration of a RMOA, CoRAP listing, the move from the SVHC list to Annex XIV, means the planning of the above activities is extremely challenging. It may even stop some new molecules from coming to market. If the time from inclusion on the SVHC list to the phase out 'sunset date' is shorter than the commercialisation process of a new component, this component will never be sold on the EU market.