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Regulatory challenges
REACH Regulation in 2017 and beyond

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Abstract Europe remains one of the most highly regulated regions in the world with ever stricter and more complex legislation. This article looks at the REACH Regulation and its impact on business within the EU including considerations for mergers, acquisitions and restructuring within organisations.

INTRODUCTION

Regulation and good governance is an essential part of modern society, and no more so than in the EU. Regulating at EU level in areas such as competition, trade and the internal market builds a level playing field that creates opportunities for business, workers and consumers. It also protects the health and safety of citizens, consumers and workers; and in the chemicals sector we have seen over recent years a common EU legislative framework come into force, replacing or aligning the laws of different Member States.

The principle behind the REACH Regulation (1) follows this ideal - it is intended to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals.

REACH applies to all chemical substances, not only those used in industrial processes but also in our day-to-day lives, for example in cleaning products, paints as well as in articles such as clothes, furniture and electrical appliances. Therefore, the regulation has a very broad impact throughout the EU.

REACH places the burden of proof on companies. 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 (European Chemicals Agency) how the substance can be safely used, and they must communicate the risk management measures to the users.

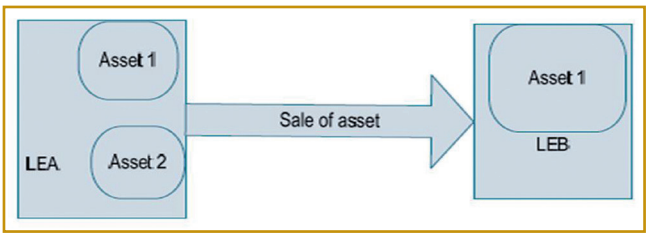
If the risks cannot be managed, authorities can restrict the use of substances in different ways. In the long run, the most hazardous substances should be substituted with less dangerous ones.

With the final June 2018 deadline for registration of phase-in substances under REACH fast approaching, we're now well into the final lap of what has been a Regulatory marathon of Olympic scale. Whilst many businesses will now be well-practised and efficient in preparing and submitting dossiers for substance hazard and risk characterisation in order to complete registrations, there is the potential for ongoing risks in the constantly changing economic and political environment.

TACKLING COMPLIANCE AS PART OF MERGERS AND ACQUISITIONS

Nowadays changes within organisations are an ever present part of corporate development activity. On a daily basis we hear about restructuring of companies through mergers, asset sales, joint ventures and many other variations. Companies are constantly reviewing the structure that best serves them at any point in time, which may result in outsourcing parts of their business, absorbing them again into previous structures or creating new divisions or corporate entities. All these changes are in response to economic trends, market demands or corporate strategy. Their aim is to improve efficiency of the individual units, profitability of the production process or to achieve growth, and these business priorities present regulatory obligations – such as REACH registration – which can be challenging to manage in this non stable business environment.

ECHA acknowledged the issue of company mergers and acquisitions in 2010 (2) when they implemented an option to change the Legal Entity as well as allowing the transfer of registrations under specific conditions. Even though trading of REACH registrations is forbidden, it has been allowed when accompanied by the transfer of an asset. However a problem can arise when a company is selling only a part of its business – for example a chemical production site.



Where the sale of such a facility is made to a different company (legal entity B), but the selling company (legal entity A) retains production in other locations, the substance registration is not valid for both sites. Under these circumstances the respective companies will need to negotiate which of them can benefit from the registration. The legal entity not benefiting from the registration will need to submit a new substance registration.

The other side of this issue materializes when the selling company agrees to transfer its registration together with an asset. This solution seems to be logical as long as the selling company does not decide to relaunch the production of the same substance at a later point in time, or the buyer decides not to integrate the production site it has acquired into its existing corporate structures (i.e. it creates a new legal entity). In this case both companies would be obliged to obtain a new registration.

The area of asset sales, mergers and takeovers can be complex and it is worth remembering that ECHA provides helpful guidance on the implications arising from legal entity changes under REACH (3).

Changes in legal entity are usually associated with two types of costs: access to the jointly submitted substance dossier – so called Letter of Access (LoA) - and fees paid to ECHA. In many cases a company acquiring an asset will need to pay again for the full value of the LoA - within a data sharing agreement (SEIF Agreement) it is usual for a company who ceases production not to be entitled to reimbursements. If the company decides to relaunch production usually they have to pay again the full fee for the LoA. This is especially true when there is a change in the legal entity structure. Administrative fees payable to ECHA for changes in legal entity are detailed in the Fees Regulation (4) and this includes reductions available for SMEs. It is important to underline that a substance affected by a change in legal entity may require a new REACH registration and placing on the market will not be possible until this registration is in place, which will be the most important aspect for a business.

The issue becomes more complicated when it involves large chemical companies that have very often been highly involved in the REACH registration process since the beginning and may have acted as Lead Registrant (LR) submitting a dossier on behalf of other companies in a Joint Submission. The transfer of the role of LR is another important aspect of the REACH Registration process. According to the provisions of the Regulation, as well as the contractual agreement between the co-registrants (SIEF Agreement), it is not permitted for a party to resign from the role of LR without transferring the role to a new candidate. Whilst this is a relatively straightforward process, for less active groups of co-registrants there are often no candidates for this role. In this case the LR has to retain the role until a new candidate is found.

It is worth noting that a company which has ceased production of a substance will need to continue to follow the instructions of ECHA in order not to face additional costs related to the registration of this substance. In addition, an LR who no longer manufactures a substance and omits to inform ECHA, for example, about an asset transfer, risks facing additional costs if, in the meantime, ECHA issues a decision related to compliance checks, substance evaluation or a testing proposal. However, this issue has finally been picked up by the new ECHA guidance on data sharing (5) that was issued in November 2016, with minor amendment in January 2017 – six years after the first registration deadline. It describes how to appoint a Lead Registrant even in the event where no candidates are present: "*In case of a lack of a volunteer to be the Lead Registrant, as a last resort even a lottery is an option*". But this would be allowed only if all the other parties agree to such a choice and also agree to be bound by the result.

COMPLEXITY OF MULTIPLE REGULATIONS

The development of the EU's chemicals framework has been continuous and has been built on the experiences obtained and the approaches developed – so called 'learning by doing'. Currently work is ongoing to assess how to regulate nanomaterials, endocrine disrupters and hazardous polymers not only within REACH, but more widely within the pesticide and biocide sectors and more will follow suit. The EU Commission is also working on a new Circular Economy Action Plan which will assess the interaction between waste, products and chemicals legislations in order to facilitate the traceability of chemicals in the recycling process and limit unnecessary burden for recyclers and to promote more recycling. And finally there is the task of creating an EU strategy for a non-toxic environment which is foremost in the 7th Environment Action Plan (7EAP) (6).

All these regulatory obligations, besides the main goal - to ensure the safe use of chemicals - are linked with a very high cost of implementation. A problem appears when a substance produced by a legal entity has different applications which fall under different legislations.

A substance registered under the REACH Regulation can also fall under the scope of regulations, such as the Biocidal Products Regulation, Cosmetics Regulations, Wastes Directive, Food and Food Contact Regulations. In this situation the costs associated with regulatory compliance become a very important factor in assessing the profitability of the production and marketing of the substance. In many cases it leads to a situation where a very good substance, from the point of view of efficacy and technical properties, can be excluded from a specific use due to the fact that the cost of regulatory compliance is too high – especially if it is only used in low volumes. Another problem that arises is when companies seek alternative solutions – by claiming different modes of operation (activity) of the substance. In this way they try to cut the costs of regulatory compliance, but the risks related to the "unintended" use of the substance may not be properly investigated and confirmed to be safe. This can lead to the situation where false expectations for the risk and hazard assessment of the substance are made which in turn can lead to incorrect implementation of risk management measures, leading to potentially damaging outcomes for business, workers and consumers.

A legislative framework such as REACH requires the regulation of chemical substances at an EU level, however verification that companies are in compliance operates at a national level and is enforced through local regulations. This can result in enforcement actions that vary significantly from country to country and is an outcome that goes against the ambition of harmonized EU regulation.

CONCLUSION

The complexities of the changing regulatory landscape within the EU will continue to challenge companies to ensure regulatory compliance. The impact of legislation such as REACH on companies going through changes including mergers, acquisitions and corporate restructuring should not be overlooked; failure to consider it could have major consequences on companies wishing to do business within the EU market.
The introduction of further instruments to promote the removal of hazardous substances at source will ensure that those of us who are product stewards will not be short of things to do and the marathon described above may have in fact only just started.

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