Journal of Business Chemistry

Commentary

REACh: A European chemicals regulation with global intersectoral consequences

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First of all what is the meaning of REACh? REACh stands for Registration, Evaluation, Authorisation and Restriction of Chemicals and is the new Chemicals Regulation of the European Parliament and Council which entered into force on June 1, 2007. The background of REACh´s coming into force is that our current European chemical system has a lack of information of the existing chemicals, which cover today more than 97% of the market. The current chemical system consists of more than 103,800 chemicals, round about 100,000 existing chemicals, so called EINECS (European Inventory of Existing Commercial Chemical Substances) and 3,800 "new chemicals", ELINCS (European List of Notified Chemical Substances). The impact on human health and environment of the EINECS chemicals has not been yet checked until today. REACh should close this gap by fulfilling the protection of human health and environment, the increase of transparency throughout the whole chemical supply chain, the transfer of responsibility from public authorities to the chemical industry, a harmonized system for EINECS and ELINCS, the substitution of hazardous substances and last but not least the avoiding of animal tests.

All actors along the European chemical supply chain have duties and responsibilities under REACh. Any European producer who manufactures a substance on its own, in preparations or articles in quantities of one tonne or more per year within the European Community is obliged to submit a registration dossier to the Agency. The polymers are exempted from REACh, but the monomers have to be registered. In case that a European manufacturer or agent imports chemical substances, formulations or articles in quantities of one tonne or more per year in the European Community, he has also to register under REACh.

In cases where substances/preparations/monomers are produced or imported in quantities of ten tonnes or more per year, the manufacturers or importers have to conduct a chemical safety assessment (CSA) and to create a chemical safety report (CSR). If manufacturers/importers are producing/importing hazardous substances/preparations, the manufacturers/importers have to create additionally an exposure scenario (ES). To ensure the safe use of chemical substances/preparations, downstream users are obliged to inform the producer/importer about the application and working conditions, so that the manufacturer/importer can create an individual chemical safety report or respective risk management measures. In case that a manufacturer will not add an application of one of his downstream users to his CSR, the downstream user has to register by himself under REACh. In case that the market participants will not fulfill the duties under REACh the consequence can be summarized with Art. 5 of the REACh Regulation: "No data, no market"!

At first view the Regulation´s definition may give the impression that REACh applies only to chemical raw materials and the chemical industry, but REACh´s impact is much larger. The next concrete example should demonstrate this. A producer of chemical raw materials supplies barium sulfate to a formulator. This formulator produces a formulation for coatings, which is sold to downstream users like the automotive industry, plastic industry, textiles, electronics etc. Each of the mentioned down-stream

users integrates the supplied formulation again in diverse applications and product lines. The intermediate or end product is again determined for the local market (European) but also for the export and therefore if some chemical raw materials will not be registered under REACh the whole supply chain has to be examined. Alternative suppliers (EU and Non-EU producers), substitutions of chemical raw materials or even new formulations have to be taken into account.

Although REACh is a European Regulation the consequences will be global. REACh will cause enormous costs, which have to be considered as an investment for future business. In case that the predicted REACh costs will surpass the margin, the result of a cost-benefit analysis will be: no registration. This means immediate streamlining of the product portfolio. A progressive streamlining of the product portfolio would happen in the case that a product will be registered, but the price increase is so high that it will cause a significant decrease in demand. A restructuring of the product portfolio would have dramatic consequences for many industry sectors all over the world – as it is primarily low volume specialties that are the engine for innovation (Research & Development).

Non-European producers have to ensure their business in Europe by choosing the right option for the registration. Non-Community manufacturers cannot register their substances/formulations/articles directly as REACh is a European Regulation and the obligation under REACh should primarily apply to European actors. There are three options for Non-European producers:

1. Importer
2. Legal Entity
3. Only Representative

In case that the importer will take care of the registration under REACh, the Non - European manufacturers have to take into account that the importer who will register will be the owner of the registration no. Then the Non-European manufacturer is completely dependent on his agent and cannot appoint another one. The second aspect is that the importer, who has registered a substance under REACh can use another supplier (if the substance identity is the same) and the first supplier, here the Non-European producer will be out of the market.

The second option which can be used by Non-European producers to maintain their business in Europe is a “legal entity” within Europe. A legal entity could be a daughter company in Europe, which could take over the responsibility for the pre-registration and the registration. Nevertheless resources and know-how are needed for REACh and as the REACh time schedule is quite short the know-how could not be first build up but has to be promptly available. Last but not least the Regulation offers Non - European producers a third option to ensure their business in Europe, namely to appoint a natural or legal person, so called "only representative" (Article 8) to fulfill their obligations under REACh. The advantage of an "only representative" is the flexibility and the independence which Non-European manufacturers maintain as they will own the registration no. An additional advantage is the higher protection of sensitive information – like Intellectual Property - and thus better control of know-how. By the way the Non-European producer can profit from an anonymous appearance in SIEF and consortia. EU manufacturers or EU importers can also appoint a fully responsible "third-party representative" to comply with the obligations under REACh.

REACh will definitely have important business effects: product portfolios – not only within the chemical sector – will be restructured, production locations may be shifted and REACh will have a significant influence on financial figures. In future the commercial due diligence for any Mergers & Acquisitions project will also comprise a REACh check of the whole company. The conclusion: REACh is a European Chemicals Regulation with global intersectoral consequences.