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The nuts and bolts: EU's chemical regulation touches all parts of a product

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The European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation has been described as one of the most complicated pieces of legislation in the world. The regulation, which went into force June 1, 2007, is more than 800 pages long and took seven years to pass. It represents the laws governing chemicals in every member state in the Union harmonized into one and encompasses hundreds of thousands of chemicals.

REACH governs three major things:

1. Substances, which are essentially chemicals.
2. Mixtures, which are combinations of two or more chemicals.
3. Articles, everything else in the world that is a physical object.

The first two items are easy to understand, but it is the third item that has company executives across the world losing sleep. An article under REACH is defined as "an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition" (Article 3(3)).

To understand the magnitude of what this means, it is helpful to understand what "once an article, always an article" means. This phrase relates to a September 2015 ruling by the European Court of Justice that clarified the definition of an article. The new definition includes all of the components that make up an assembled article, and not just the finished product. Under the new ruling, any article containing more than the 0.1% threshold for a listed "Substance of Very High Concern" (SVHC) must be disclosed to the European Chemicals Agency (ECHA) and the public.

The 2015 ruling has had a tremendous impact on supply chain compliance. Instead of evaluating finished products, companies must dig down deep into their supply chains to determine if any of the components (i.e., articles) that make up the finished product (also an article) contain substances or mixtures that are on the SVHC Authorisations List and need to be disclosed to the ECHA.

"So imagine I manufacture washing machines," said Travis Miller, general counsel at Assent Compliance Inc. "If one nut in that washing machine has a plating with a chemical that has been identified as an SVHC, then I have to disclose that information to the ECHA. And if I sold a thousand of those machines in Europe before I disclosed the information … then I have to take back all of those machines over something as small as a nut."

For companies deep in the supply chain, the compliance burden has become great and the risks even greater. Manufacturers that make components used in iPhones or automobiles, for example, risk getting "designed out" of those products by some of the largest companies in the world, if they are unable to provide clear and concise information regarding the substances present in the manufacturing process. Once a company has been designed

out of a process, they are rarely, if ever, designed back in.

To make matters even more interesting, the ECHA tends to make additions to the substance candidate list every six months. There are several evaluations that a substance must go through before it is added to the Authorisations List, but nevertheless, waiting to learn if a product may lose access to the European market because of a dangerous substance within its components is a nerve-wracking process. That process has slowed down in the last few years, as the workload became very high and EU member states and nongovernmental organizations criticized the process for being too slow, too biased toward manufacturers of SVHCs, or guilty of stifling more versatile, safer alternatives to dangerous substances.

One side effect is that companies that provide due diligence solutions have experienced a marked increase in queries, as manufacturers and processors choose to contract the work out, instead of hiring entire teams to perform the work internally.

Shifting responsibility

The origins of REACH lie in the events of the latter parts of the 20th century when workers or consumers were more exposed to hazardous chemicals in events such as factory fires and spills, and ongoing research into carcinogens like asbestos. Attempts to trace potentially hazardous chemicals to their sources resulted in time-consuming and often unfruitful investigations through global supply chains and deep into unregulated territory.

At the time, most current EU member states had laws that resembled the model used by the United States and reflected in the Toxic Substances Control Act of 1976. Under this model, substances were approved for commercial use until proven dangerous, after which they were subject to heavy regulation and sometimes removed from the market entirely. That meant government agencies had data on only a small fraction of the many substances being commercially sold every day.

In order to better protect the health of the population and the environment, member states came together to propose a model wherein companies would be required to register with a governmental body the substances in their products and any data they had regarding the safety of the chemicals. REACH arose out of these negotiations.

On the far side of the Atlantic, the passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (also known as the new Toxic Substances Control Act) in 2016 changed the way the U.S. Environmental Protection Agency regulated chemical substances. The act added an evaluation and risk assessment requirement that moved closer to REACH requirements, while also keeping the government largely responsible for evaluating and regulating chemical substances. REACH places the responsibility on companies to register substances used in their products, instead of relying on the government to find and test each and every substance with potential harmful effects. Both approaches, REACH and the New Toxic Substances Control Act, represent a tightening of the legislation governing chemicals and other hazardous substances in the face of global supply chains with increasing complexity.

Takeaways

- The EU's Registration, Evaluation, Authorisation and Restriction of Chemicals regulation (REACH) is one of the most complicated regulations in the world and affects any company selling products in Europe.
- The definition of "article" under REACH forces supply chain managers to dig deep into their global value chains to determine the presence of any substance or mixture that may affect their business in Europe.