

REGNET ENVIRONMENTAL SERVICES

REACH SUPPORT SERVICES

The following provides a brief overview of the newly adopted European Union REACH regulation (Registration, Evaluation, Authorisation and Restriction of Chemicals) and why it is important for all companies, including those that do not sell product into Europe, to develop a strategic plan to minimize the impact of the new regulation. The experienced professionals of RegNet Environmental Services (RegNet) are well positioned to assist industry understand the implications of REACH and to develop the various documents required for registration. The target audiences for this overview are individual companies/facilities. RegNet has developed a separate brochure that describes its management support services for REACH consortia.

Background

The European Union's REACH regulation has grabbed the attention of the global chemical industry as this new regulatory system is the most ambitious ever put forward. The fundamental objective of REACH is to obligate manufacturers and importers of chemicals to take responsibility for assessing the safety of the chemicals they manufacture, evaluate downstream uses, and as needed, proscribe safe handling practices.

For US-based facilities, examining the contrast between REACH and the Toxic Substances Control Act (TSCA) helps to understand the significance of REACH. Under TSCA, any company in the US may legally manufacture (or import) a substance as long as it is listed on the TSCA Inventory and there are no specific regulatory restrictions. TSCA does not require companies to obtain any approvals to manufacture or distribute substances. Prior to REACH, the system in Europe was similar to TSCA.

Under REACH, each facility (or more precisely "legal entity") that manufactures or imports a substance has an obligation to register the substance with the European Chemicals Agency (ECHA). Downstream processors and users are only to use substances that have been registered by their supplier. Registration requires the submission of a dossier that contains information (including robust summaries) on the chemical, physical, environmental and toxic properties of the substance as well as information on exposure and guidance for safe use. Additionally, for substances manufactured or imported in excess of 10 tonnes per year, registrants must submit a chemical safety report (CSR) which is to present a detailed summary of the environmental and human health hazard properties of the substance, together with an assessment of exposure and risk.

Without Appropriate Strategic Planning, REACH Could Impose Significant Economic Impact on Facilities, Including Those Outside the European Union

Companies are likely to experience significant economic impact by failing to consider the potential business implications of REACH, whether or not the facility is located in the European Union (EU). For example:

- REACH will drive companies that process chemicals to reduce the number of suppliers. EU-based processors that have heretofore imported substances from outside the EU may find it no longer cost-effective to import their raw materials into the EU. REACH imposes on importers the same (or arguably greater) obligations than facilities that manufacture the substance in the EU. As such, the burden on EU importers is lessened if they purchase from domestic sources. Non-EU facilities that want to continue to ship products to the EU will need to develop a strategic framework that will support the continued importation.
- Non-EU companies that do not export to the EU might mistakenly assume that REACH does not impact them. To the contrary, a US facility selling product to another US facility for example, may find it difficult to continue to source their product if their customer's product is destined for the EU. As multinational companies strive for global formulas and to limit the number of products sold on a world-wide basis, REACH is likely to be the common denominator. Companies whose products are not REACH compliant may soon find difficulties distributing their product to other regions, and perhaps domestically as global companies may prefer global suppliers.
- REACH potentially imposes a competitive disadvantage on companies that have a lesser interest in a particular substance in contrast with larger producers. Typically, firms with the greatest interest in a particular compound possess the most data. While REACH requires competitors to share the data they possess, REACH allows the data holder to recover the costs associated with past data generation, the preparation of the chemical safety report and other registration materials. REACH dictates these costs are to be "fair and non-discriminatory;" nonetheless, for some facilities the costs will be prohibitive and drive them to exit certain businesses.
- Another consequence of REACH that has not been widely recognized is the potential impact that various exposure guidelines and hazard classifications recommended by the European industry will have on facilities outside the EU. These guidelines will become *de facto* industry standards; as such it will be incumbent on non-EU facilities to consider these standards in developing their own product stewardship programs.

Strategic Planning and Compliance Initiatives to Address REACH

Companies should give strategic consideration to the specific regulatory requirements alongside their business goals and objectives to assure that the costs of REACH are manageable as well as to limit lost business due to intended or unintended consequences. Many consultants tend to approach these issues from a "by-the-book" perspective; RegNet's goal is not only to assist its clients achieve compliance but to do so by taking the best advantage of the regulatory requirements to promote the client's business interests. This is particularly germane to the use/exposure scenarios in the CSR and the somewhat complicated issues associated with data ownership and cost-recovery. RegNet has been developing strategic approaches to help companies (consistent with their individual

objectives) assure that they are not asked to pay for more than they have to, and for data rich clients, to maximize generating revenue in recognition of past expenditures.

A mainstay of RegNet's work over the past 20+ years has been addressing hazard assessments and the integration of use/exposure reviews into risk assessments, including working with EPA and other regulatory agencies to improve outcomes. The underpinnings of these activities are directly translatable to REACH. Also, RegNet professionals are very familiar with IUCLID 5 and other REACH-IT software necessary for REACH registration. RegNet has already developed several IUCLID dossiers for its clients and others are under development.

RegNet Support Services for REACH

RegNet's mission is to provide the most efficient, cost-effective, quality service to our clients. To accomplish that goal, we tailor our efforts to provide clients with the services they desire to achieve their objectives.

RegNet is headquartered in Washington, DC and has a partner office in Brussels, Belgium. RegNet's experienced professionals and alliances are unique among the many firms claiming to provide REACH compliance services. RegNet has also established a REACH Advisory Committee consisting of current and recently retired chemical industry professionals that are very active in addressing REACH. Bios for RegNet's key REACH strategists are available.

For individual corporations considering RegNet for REACH support services, we recommend an initial scoping session (conducted under a confidentiality agreement, with no associated professional fees) for the purpose of understanding the specific client needs. If the results of the scoping phase suggest that RegNet may be able to strategically assist the client, we would anticipate preparing a phased proposal, which would include the conduct of a REACH Impact Assessment. Undertaking these tasks on a phased approach should allow the client to decide whether RegNet's capabilities are suitable to meet the client needs. The proposal will typically include the preparation of an internal road map and schedule for REACH compliance.

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