

Registration, Evaluation, and Authorization of Chemicals (REACH)



No data, no market . . .

Recently passed legislation by the European Union (EU) will require all businesses that manufacture or formulate chemicals in member states, or that import or export chemicals or formulations into member states, to meet sweeping new requirements for the registration of all affected chemicals. The legislation aims to transfer to industry the responsibility for generating, gathering, and assessing data that define chemical hazards. *Without registration, it will not be possible to continue doing business in the EU.*

Manufacturers, formulators, and importers of chemical substances, in a quantity greater than one metric tonne per year, are required to register each of those substances with the new European Chemicals Agency. The registration process requires gathering and developing sufficient information on each substance to complete a dossier outlining the properties, uses, safe handling, and hazards associated with those substances.

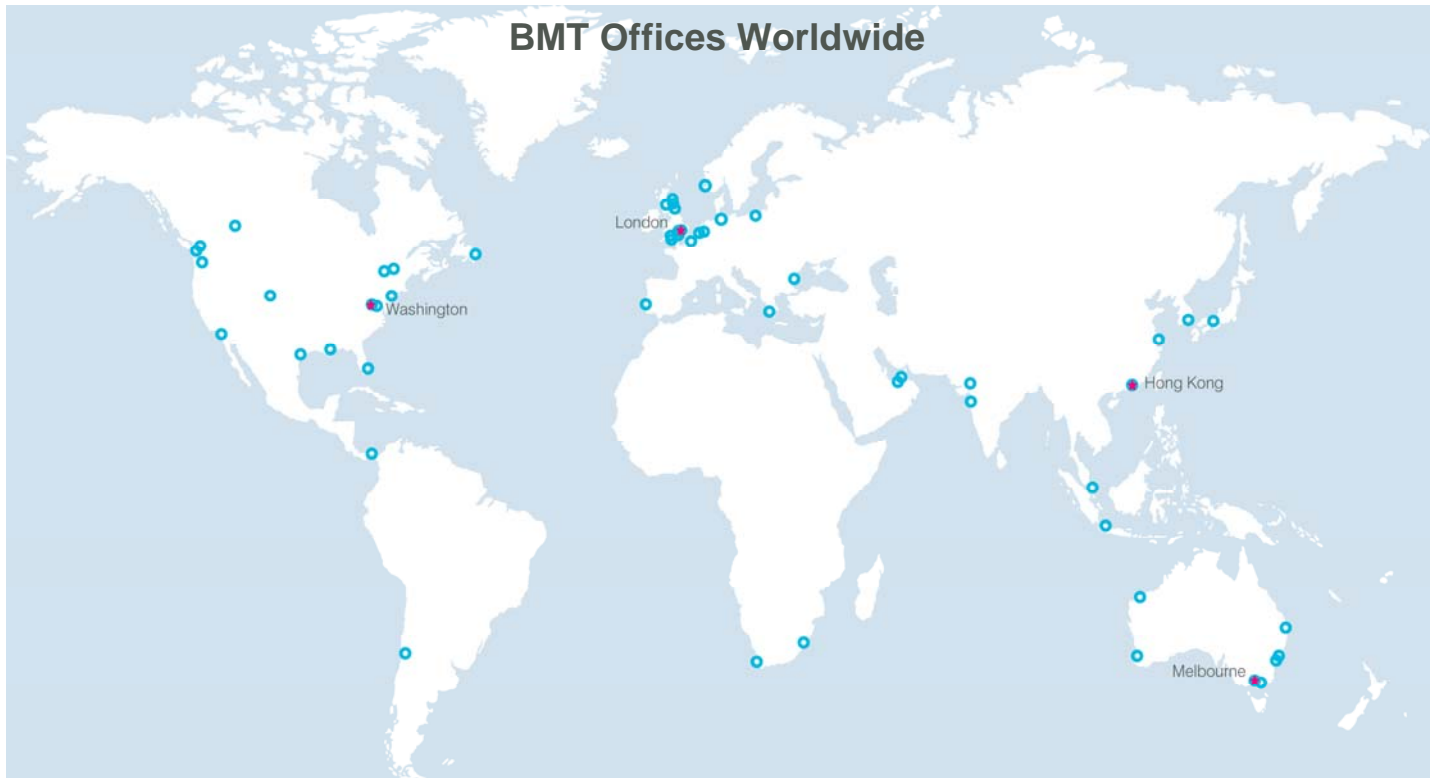
Data requirements vary according to the annual quantity of the substance that is manufactured, formulated, imported, or exported. Below 10 tonnes, data requirements are mostly physico-chemical in nature. Above 10 tonnes, significant toxicological and ecotoxicological data are required, which could necessitate extensive laboratory data development. Examples include:

- Mutagenicity and carcinogenicity.
- Acute and chronic toxicity.
- Teratogenicity.
- Acute and chronic toxicity to aquatic ecological receptors.
- Acute and chronic toxicity to terrestrial ecological receptors.
- Toxicity to benthic organisms.
- Toxicity and teratogenicity to avian receptors.
- Biodegradation and bioaccumulation.

Affected substances (about 30,000 of them) must be pre-registered by December 2008 in order to take advantage of the regulation's "phase-in period" toward full registration. *Failure to pre-register will deny you the advantages of the phase-in period, and could entirely prevent you from doing business in Europe.*

Companies that export affected substances into the EU will require a legal entity - known as an

“only representative” - within the EU to serve as an agent and register substances for the European market.



BMT REACH Services

BMT has offices around the globe and can help affected manufacturers, importers / exporters, suppliers, and downstream users meet these requirements. We can assist you to:

- Assess your chemical production or usage portfolio.
- Assure timely pre-registration of affected substances by the December 2008 deadline.
- Gather existing physico-chemical, toxicological, and ecotoxicological data.
- Perform gap analyses against the full suite of registration requirements.
- Develop a strategy to fill data gaps.

Where multiple companies produce or import / export the same affected substance(s), the EU authority encourages the formation of consortia in order to limit, where possible, the adverse effects to test animals that might be imposed by multiple toxicological testing regimes, and to streamline data submittals.

BMT can facilitate consortia formation and operations, maintain confidentiality of commercially sensitive information among consortia members, and coordinate laboratory testing. Working within the structure of consortia, members would share the cost of toxicological testing, thereby reducing the financial burden on each individual member.

For non-EU based operations, we can also act as your EU agent through our European offices.

For more information, or to discuss how BMT may assist in meeting your REACH requirements, please contact any of the following:

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