REACH AND GLOBAL CHEMICALS REGISTRATION
One stop shopping solution for global registration of your chemicals

In many countries across the globe, chemical substances are required to be registered by manufacturers and importers. In the European Union (EU), all imported or manufactured chemical substances above a quantity of one tonne per year are subject to registration under the REACH regulation. Similar registration requirements and regulations also exist for other markets. In several countries such as Canada, the United States, Australia, Korea, China and Turkey, notification is also mandatory for new chemicals on the market. We can help you stay up-to-date with these rapidly changing global requirements.

As experts in chemical management based in the EU, DHI is fully versed in the requirements of the EU REACH Regulation. However, as we assist many of our clients in their business outside of the EU, we have acquired experience with regard to regulations in other markets. Below are some major markets where we have assisted our clients in compliance with the national chemicals regulation.

USA
New chemical substances must be notified in accordance with the US Toxic Substances Control Act (TSCA) section 12(b). A notification must contain detailed documentation of the substance identity and an agreement with the Chemicals Abstract Service (CAS) in order to obtain a correct CAS name and number. Available toxicological information need to be collected and used as basis for a registration dossier, though authorities may require additional information.

CLIENT
- Manufacturers
- Formulators
- Importers
- Downstream users
- Distributors

CHALLENGE
Meeting country- and region-specific requirements for the registration of chemicals

SOLUTION
Using our in-depth, global knowledge of human and environmental toxicology to:
- Mine data, perform QSAR and assist in the registration of chemicals with authorities
- Perform ecotoxicological tests in compliance with OECD Guidelines
- Obtain offers and monitor testing at contract research organisations and analytical laboratories to meet data requirements
- Comply with obligations under market specific regulations, including REACH regulations; New Chemicals Substance Notification in China (China REACH); and the United States Toxic Substances Control Act (TSCA)

VALUE
- Tailored and cost-efficient registration of chemicals
- Up-to-date compliance with regulatory requirements for relevant markets
- Expert compilation of data and documentation
- Professional monitoring and validation of tests
- Assistance with the authorisation process from beginning to end

We have successfully submitted chemical registrations and have helped companies meet legal requirements worldwide by taking care of all technical and administrative services. © Shutterstock / Markus Pfaff
We offer one-stop shopping solutions for your chemical registration needs, including:

**TECHNICAL AND SCIENTIFIC SERVICES:**
- Data-gap analysis and data evaluation
- Adaptation of data requirements: Literature, read-across, QSAR, waiving and including scientific justification
- Test strategy, testing proposals and test monitoring
- Ecotoxicity testing in DHI lab
- Compilation of documentation in IUCLID and other region-specific formats for registration
- Chemical Safety Assessment (CSA) and Chemical Safety Report (CSR)
- Submission and follow-up on registration dossiers

**SUPPLY CHAIN COMMUNICATION AND REGULATORY SUPPORT**
- Exposure scenarios
- Safety Data Sheets (SDS) in more than 50 languages
- Extended Safety Data Sheets (eSDS) for mixtures
- GHS and CLP classification, labelling and notification

**STRATEGY AND MANAGEMENT SERVICES**
- Scientific support on strategic decisions regarding registration
- Substance Information Exchange Forum (SIEF) facilitation and management
- Only Representative services
- Administrative services

**CANADA**
New substances must be notified according to the New Substances Notification (NSN) Regulations. A notification requires evaluation of available toxicological and ecotoxicological data and a fixed list of data requirements. We have successfully used QSAR modelling to bridge data-gaps in a notification to the Canadian authorities.

**REPUBLIC OF KOREA**
The Korean chemicals regulation, also known as K-REACH, has tonnage based data requirements similar to the European REACH Regulation. Substances must be registered jointly by the manufacturing and importing companies of the same substance. We offer Only Representative services for non-Korean companies through our cooperation with the Korea Institute of Science and Technology (KIST).

**SWITZERLAND**
Switzerland is not a member of the EU or the European Economic Area (EEA) and all new substances must be notified, registered and/or declared in Switzerland before they are placed on the market. This is so even if they are already registered in the EU under REACH. Substances have to be registered according to the Swiss Ordinance on Protection against Dangerous Substances and Preparations (Chemicals Ordinance; ChemO, SR 813.11, 4th Revision).

**CORE DATASET FOR WORLDWIDE REGISTRATION**
Data requirements for registration of chemical substances across the industrialised countries tend to be similar. Global chemical suppliers should consider to establish a core dataset for use in different registration regimes. Ownership of data is critical as access to studies by Letter of Access obtained for EU registration normally does not allow data to be used for registration outside the EU.

**RUSSIA**
Manufacturers or importers of chemical substances have to comply with the requirements of the Russian Register of Potentially Hazardous Chemical and Biological Substances (Rospotrebnadzor). Notification requires a broad range of toxicological and ecotoxicological information, which is decided and evaluated on a case-by-case basis by the Federal Services. The Russian legislation requires that the registration is renewed after a certain period, usually three years.

**AUSTRALIA**
The Australian Chemicals Registration Scheme (NICNAS) requires that the manufacturer or importer of existing and new substances include a set on toxicological and ecotoxicological data points in the registration dossier. The data requirement is tonnage dependent.

**WORLDWIDE REPRESENTATION**
DHI has offices in 30 countries worldwide. Our core competence in chemicals regulation is based in our head office in Denmark where the staff includes experts with German, French, Chinese and the Turkish language as their mother tongue. With this diversity, our local DHI offices are able to liaise between our experts and regional authorities in matters related to registration/notification. In addition, our service include supplying safety data sheets in compliance with national regulation of more than 50 markets worldwide and in national languages including Chinese, Japanese, Russian and Hebrew.

Contact: REACH - reach@dhigroup.com
For more information, visit: www.tox.dhigroup.com