# REACH (Registration, Evaluation, Authorization and Restrictions of chemicals)

REACH is the EU regulation governing the placement on the market of chemical substances. It is an acronym for the "registration, evaluation and authorization of chemicals and has been in force in all EU Member States since June 1, 2007. It also applies in Iceland, Lichtenstein and Norway.

This page is for Pakistani exporters to Europe, particularly SMEs, in identifying their obligations under REACH so they can take the necessary steps to ensure compliance with this regulation.

## 1. Basic Information

## a. Registration

In general, REACH requires the registration of chemical substances manufactured or imported into the EU in quantities exceeding 1 metric ton per year. This requirement applies per substance and per manufacturer/importer. Registration applies to chemical substances as such, in preparations (also called "mixtures") and, under certain conditions, to articles (finished products) incorporating those substances.

REACH assigns the obligation to register on the EU based manufacturer or EU based importer. Non-EU and EU based companies may also appoint an "only representative". Registrations are submitted to the European Chemicals Agency (ECHA) through the IUCLID website (<a href="http://iuclid.eu/">http://iuclid.eu/</a>).

REACH exempts a limited number of chemical substances and uses from registration. Specifically, these exemptions apply to:

- Chemical substances imported into the EU or manufactured in quantities below 1 metric ton:
- Chemical substances used for research and development;
- Waste;
- Chemical substances whose uses are covered by other EU legislation such as medicine and food products;
- Pesticides and biocides;
- Polymers (however, monomers included in polymers must be registered); and,
- Companies that had notified chemical substances under previous EU legislation (Directive 67/548/EEC).

Annex IV and V of the REACH regulation lists a number of other chemical substances exempted from REACH. The list includes minerals, ores, cement clinkers, crude oil, coal and coke; on the condition that they are not chemically modified.

#### b. Evaluation

There are two aspects to the REACH evaluation process, dossier evaluation and substance evaluation. ECHA is mandated to perform a compliance check on at least 5% of the dossiers submitted for registration. This evaluation focuses on completeness and quality of information. ECHA will request further information from registrants that fail to provide sufficient information.

For substance evaluation, each year ECHA and the EU Member States select a number of chemical substances for placement on the "Community Rolling Action Plan", commonly known as "CoRAP", for further evaluation. They focus in particular on those that are manufactured/imported in large quantities and which are persistent and bio-accumulate. Each Member State has a designated agency that performs the evaluation; it is not performed by ECHA. Chemical substances placed on the CoRAP may eventually be subject to authorization or restriction.

The Corap list is published on the ECHA website. See Corap list.

#### c. Authorization

Pakistani companies that wish to export or use within the EU chemical substances identified as a "substance of very high concern" (SVHC) must ensure that a use-authorization has been obtained. The policy objective of this requirement is to ensure adequate control and progressive replacement of these substances.

U.S. companies concerned about whether a product requires an authorization should review the "<u>candidate list</u>" and the <u>"authorization list</u>" (REACH Annex XIV). The candidate list identifies the chemical substances the EU is considering requiring use-authorization. Companies that need to apply for an authorization may visit the following website for further information: <u>See applications</u> for authorization.

The REACH authorization process does not apply to imported articles. However, importers of articles containing Candidate List substances have certain legal obligations. See the <u>quidance on substances in articles</u> for the obligation to notify ECHA and the duty to communicate safe use information.

#### d. Restriction

Restriction is another means under REACH that allows the European Commission to control the use of dangerous chemical substances circulated within the common market. Any chemical substance on its own, in a preparation or in an article may be subject to EU-wide use restrictions that limit or prohibit its production or use.

Chemical substances subject to restrictions can be found in REACH Annex XVII. The following link will direct you to the ECHA webpage with the most up-to-date information on chemical substances subject to restriction: restriction page.

## 2. Other Important Information

## a. May 31, 2013 Registration deadline for phase-in substances

31 May 2013 is the deadline for the registration of all phase-in substances manufactured or imported in the EU in quantities above 100 metric tons per year. Companies have to submit a registration dossier to the European Chemicals Agency (ECHA) with information on the properties, uses and safe handling of their chemicals.

The registration deadline for all phase-in substances manufactured or imported in the EU in quantities 1 metric ton/year is in 2018.

See ECHA website for more information on the submission of registration dossiers: <a href="http://echa.europa.eu/2013">http://echa.europa.eu/2013</a> en.asp

## b. REACH Review

On February 19th, 2013 the European Commission published the first review of the implementation of REACH. The review focuses on the functioning of ECHA; reports on the experience gained from the functioning of the regulation; confirms that the basic legal text will not be amended; and, a indicates that the annexes to the regulation need to be altered to better facilitate the registration of nanomaterials. Further information can be found on the <a href="Commission webpage">Commission webpage</a> on the REACH review.

## c. CARACAL

Competent Authorities meetings on REACH implementation (CARACAL) are held at least twice a year and bring together the Commission, ECHA, Member States and a number of stakeholders including non-EU countries

## 3. Assistance & Further Information

## a. Representatives and Business Service Providers

# Dartways (SMC-Pvt.) Limited

No. 6, Street # 32/1, Sector F-8/1

Islamabad - Pakistan

Phone: +92 51 226 1487

Fax: +92 51 228 0581

email: dartways@dartways.com

## b. Guidance & Legislation

ECHA has produced a number of <u>quidance documents</u> to help companies determine their REACH obligations and comply with the legislation. In addition, ECHA maintains a webpage containing answers to frequently asked questions. <u>See REACH FAQs</u>.

Pakistani exporters may also submit questions to the ECHA helpdesk (free of charge).

In addtion, ECHA maintains the following webpage containing links to the REACH regulation (as amended), court-rulings by the European Court of Justice and other relevant legislation. See REACH legal texts.

## c. Relevant EU Websites

- European Chemicals Agency
- DG Enterprise
- <u>DG Environment</u>