NEWS letter

helpdesk luxembourg
REACH & CLP
Un service du Luxembourg Institute of Science and Technology
En partenariat avec le Ministère du Développement durable et des Infrastructures et le Ministère de l'Economie

Thematic Issue "Registration" - *English Version*

# REACH Registration

**REACH* requires from companies, that substances on their own, in mixtures or in articles shall not be manufactured or placed on the market in the Community, unless they have been registered. The principle "No data, no market" (Title II, Art. 5).**

** Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), entry into force 1 June 2007*

## The registration procedure

**Manufacture or import > 1 t/a**

In order to manufacture or import a substance in amounts exceeding 1 tonne per year, the EU manufacturer or importer has to register the substance at ECHA (European Chemicals Agency).

**Inquiry**

Potential registrants have to inquire to ECHA, whether a registration has already been submitted for the substance in question. Pre-registered substances are listed on the ECHA website.

**Identify other registrants**

**Data exchange**

The Substance Information Exchange Forum is open to any company in order to exchange substance data with other registrants. In case there are several registrants for the same substance, REACH obliges registrants to jointly submit a registration (Art. 11).

**Preparation registration dossier with IUCLID**

The registration dossier is prepared with means of the IUCLID software, which is available via the ECHA website.

**Submission of registration dossier and chemical safety report**

After preparing the registration dossier, the registration is submitted to ECHA via the REACH-IT system. For substances manufactured or imported above 10 tonnes per year, a chemical safety report has to be submitted as well (Art. 14), in order to define conditions under which the potential risks arising from the substance and its use are adequately controlled.

**Updating duty of the registrant**

It is the responsibility of the registrant to keep the registration up to date.

### Definitions according to REACH (Art. 3)

- **Registrant:** Manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance.
- **Manufacturer:** Any natural or legal person established within the Community who manufactures a substance within the Community.
- **Importer:** Any natural or legal person established within the Community who is responsible for import.
- **Downstream user:** Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user.
- **Substance:** Chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substances or changing its composition.
- **Phase-in-substances:** Phase-in substances were already manufactured or place on the market before REACH's entry into force. The European Commission inventory consists of three independent inventories, namely EINECS, ELINCS and NLP.
- **Non-phase-in substances:** Substances that do not fulfil any of the criteria for phase-in substances are considered as non-phase-in substances. Normally, non-phase-in substances have not been manufactured in the EU before 1 June 2008. Since 1 December 2008, these substances must be registered immediately once placed on the market the first time > 1 tonne per year.

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## Substances to be registered

The registration obligation concerns substances on their own, in a mixture, and in certain cases substances in articles (Art. 7), which are manufactured or imported in quantities of more than one tonne per year. Basically, the registration of a substance must be submitted immediately, but for certain substances, so-called phase-in substances, transitional arrangements shall apply, providing they have been pre-registered before 1 December 2008 (Art. 23).

The REACH regulation shall not apply to:

- Radioactive substances (Art. 2(1a))
- Substances, which are subject to customs supervision (Art. 2(1b))
- Non-isolated intermediates (Art. 2(1c))
- The transport of dangerous substances and mixtures by rail, road, inland waterway, sea or air (Art. 2(1d))

Exempted from registration duty:

- Substances in human and veterinary medicines and in food or feedingstuffs (Art. 2(5))
- In Annex IV contained substances (Art. 2(7a))
- Substances that are included in Annex V (Art. 2(7b))
- Substances re-imported (the supply chain) (Art. 2(7c))
- Recovered substances (Art. 2(7d))
- Substances used in product and process oriented research and development (PPORD) (Art. 9)
- Polymers (Art. 2(9)), so far.



**Check your portfolio** to identify your substances subject to registration obligation!

**Have you ever done an inventory of the chemicals and articles you buy?**

**The REACH&CLP Helpdesk Luxembourg offers you its *REACH Excel Tool*,** which can help a company to gather relevant information to make an inventory of chemicals in the company.

***Download on www.reach.lu (Tools)***

### Who needs to register?

- EU manufacturer or importer of a substance, either on its own or in one or more mixture(s), in quantities of one tonne or more per year (Art. 6).
- EU producers and importers of articles: for any substance contained in those articles, if both the following conditions are met (Art. 7):
  - The substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
  - The substance is intended to be released under normal or reasonably foreseeable conditions of use.
- Only representatives established in the EU and appointed by a manufacturer, formulator or article producer established outside the EU to fulfil the registration obligations of importers (Art. 8).

## Registration deadlines

For pre-registered phase-in substances following registration deadlines apply:

- 1 December 2010: > 1000 t/a, CMR Substances > 1 t/a, Very toxic to aquatic organism > 100 t/a.
- 1 June 2013: 100-1000 t/a
- **1 June 2018: 1-100 t/a**

Chemical substances that are manufactured in quantities of over **one tonne up to 100 tonnes per year**, or imported from non-EU countries, and already pre-registered, are subject to the REACH registration deadline 31 May 2018. A chemical safety report (CSR) is in this case only necessary when more than ten tonnes per year of the substance are manufactured or imported. The data request results from Annex VII and VIII of the REACH regulation.

### Support for REACH Registration deadline 2018

- ECHA Webinars **REACH 2018**
- http://www.echa.europa.eu/reach-2018


**REACH Excel Tool**

*Identify the status of your company for every purchased chemical or article and related obligations like REACH registration.*

*A simple and functional tool, in MS EXCEL format, to collect and analyze your data.*

*An interactive Guide with questions and hyperlinks to relevant documents to help you entering your data and **famliliarise with basic REACH obligations.***

**The registration dossier:** The registration dossier consists of a variety of substance information submitted by a registrant for a substance electronically with the IUCLID Software. The dossier is divided in two parts:

**1. The technical dossier (*IUCLID*)**, that has always to be submitted for all substance for which there is an obligation to register.
Depending on the manufactured or imported quantity of a substance, the registration dossier shall include certain information (Art. 10), including:

- Identity of the substance and of the manufactures or importers
- Information on the manufacture and use(s) of the substances
- Classification and labelling of the substance
- Guidance on safe use of the substance
- Robust study summaries of the information and in some circumstances testing proposals

The information requirements and possible adaptations are set out in the Annexes VI to XI of REACH.

**REACH requires the submission of information on:**

- Physicochemical properties
- Mammalian toxicity
- Ecotoxicity
- Environmental fate, including abiotic and biotic degradation

**Testing proposals:** Registrants must submit a testing proposal when they conclude that alternative methods cannot fill an information gap, for meeting the higher-tier studies of the Annexes IX (> 100 t/a) and X (> 1000 t/a) of REACH (Art. 12). Third parties can submit scientifically valid information and studies that address the relevant substance and hazard endpoint as covered in the testing proposal within 45 days (Art. 40).

**2. The Chemical Safety Report:**

Registrants who manufacture or import a substance at **ten or more tonnes per year** must conduct a **chemical safety assessment** according to Art.14 of the REACH Regulation, to define the conditions of use under which the risk can be controlled. A chemical safety assessment iincludes a risk assessment for human health, for the environment, and a PBT/vPvB* assessment and the results of the chemical safety assessment are documented in a chemical safety report (CSR), which is submitted as part of the registration dossier to ECHA (Art. 10). The general provision for the chemical safety assessment and the development of chemical safety reports are listed in Annex I (Art. 10). The *Chesar Tool* supports registrants herewith.

**Data Sharing:** Companies, who want to register the same phase-in Substance, will join a **Substance Information Exchange Forum**. (SIEF). Here, data can be exchanged on substance properties in order to avoid repetition of studies (Art. 29). See also: Implementing regulation *Implementing regulation (EU) 2016/9*.

## Duty to keep registration up to date:

It is the responsibility of the registrant to update his registration when needed. According to Article 22, the registrant must immediately inform ECHA or update his dossier upon its own initiative or due to decisions by ECHA or the Commission, when new relevant information regarding the substance or the registration is available.

## SME and Fees:

Before a company classifies itself as SME (small and medium enterprise) it should be informed in advance of the relevant EU-definition. The Commission Recommendation 2003/361/EG serves as a basic for determining the correct size of enterprises. In opposition to standard companies, reduced fees apply to SME. The fee regulation can be found *here.* It is important to notify the correct size, since a false statement, in addition to difference for the full charge (Art. 74), is subject to an administrative fee. Each registrant is responsible for the validity and correctness of his statements in the registration dossier. Only after the invoice was paid on time (Art. 6, 7, 17, 18) and all the necessary information has been submitted (Art. 41), a dossier is considered complete. ECHA may then issue a registration number for the corresponding substance.

## Further information and support?

- **REACH&CLP helpdesk Luxembourg:** *www.reach.lu*
- **ECHA guidances:**
  - Guidance on registration
  - Guidance on identification and naming of substances under REACH and CLP
  - Guidance on data sharing
- **ECHA Website:** section registration / section REACH 2018

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** PBT/vPvB: persistent, bioaccumulative, toxic / very persistent and very bioaccumulative*