

Frequently Asked Questions on REACH

1. What is REACH?

The new European law on chemicals, REACH Regulation (EC) No 1907/2006 concerning Registration, Evaluation, Authorisation and Restriction of Chemicals, entered into force on 1 June 2007.

The aim of REACH is to improve the protection of human health and the environment through the better and earlier identification of the properties of chemical substances. At the same time, innovative capability and competitiveness of the EU chemicals industry should be enhanced. The benefits of the REACH system will come gradually, as more and more substances are phased into REACH.

The REACH Regulation gives greater responsibility to industry to manage the risks from chemicals and to provide safety information on the substances. Manufacturers and importers will be required to gather information on the properties of their substances, which will help them manage them safely, and to register the information in a central database. The European Chemicals Agency will act as the central point in the REACH system: it will run the databases necessary to operate the system, co-ordinate the in-depth evaluation of suspicious chemicals and run a public database in which consumers and professionals can find hazard information.

The Regulation also calls for the progressive substitution of the most dangerous chemicals when suitable alternatives have been identified.

2. What is the effect of REACH on the existing chemicals legislation?

REACH shall repeal the following regulations:

- The Dangerous Substances and Preparations (Safety data Sheets) Regulations, 2002, (L.N. 393 of 2002) transposing Directive 91/155/EEC, with effect from 1 June 2007.
- The Dangerous Substances (Notification) Regulations, 2001, (L.N. 318 of 2001) transposing the Annex of Directive 93/105/EC, with effect from 1 June 2008.
- The Dangerous Substances (Risk Assessment) Regulations, 2002, (L.N. 40 of 2002) transposing Directive 93/67/EEC, with effect from 1 August 2008.
- The Dangerous Substances and Preparations (Restrictions) Regulations, 2003, (L.N. 346 of 2003) and The Asbestos Products (Labelling) Regulation, 2001, (L.N. 60 of 2001) transposing Directive 76/769/EEC, with effect from 1 June 2009.

3. What is the scope of REACH?

It applies to all chemical substances which are manufactured, imported, placed on the market or used within the European Community, either on their own, in a preparation or in an article.

Generally excluded from the overall scope of REACH are radioactive substances, waste & substances of low risks (e.g. water). Other substances occurring in nature (e.g. minerals) are not required to be registered as long as they are not chemically modified. There are also exemptions from large parts of REACH for substances in food and medicinal products because those are regulated in specific legislation. Non-isolated intermediates are fully exempt from REACH while isolated intermediates will have to be registered. Polymers are for the time being also exempted from registration and evaluation.

4. Are Medicinal Products exempted from REACH?

When a substance is used in a medicinal product within the scope of either Regulation (EC) No 726/2004 on Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency or Directive 2001/82/EC on the Community code relating to veterinary medicinal products or Directive 2001/83/EC on the Community code for medicinal products for human use the substance does not have to be registered under the REACH Regulation for that use.

Accordingly, it is in the interest of manufacturers and importers of substances which may be put to pharmaceutical-related uses to be aware if their own legal entity or their clients actually use the substance to produce pharmaceuticals covered by this legislation, since in that case they will not have to register or obtain authorisations, at least for the quantities of the substance used in this way.

The exemption does not distinguish between active or non-active ingredients as it applies to any substance "used in medicinal products". Excipients used in medicinal products are therefore also exempted from registration. Note however that quantities of the same substance may be used for other uses than pharmaceuticals, so those quantities are not exempted. Only the quantities of the substance used in medicinal products are exempted from the registration obligation and REACH authorisation.

5. What does registration of substances entail?

Registration requires producers and importers to obtain relevant information on chemical substances produced in or imported to the EU market in quantities of 1 tonne or more per year (*-30,000 substances*). It involves submitting a Technical Dossier containing information on the substance and information on how to effectively manage the risk entailed by using it; the type of information mainly depends on the tonnage.

Quantities of 10 tonnes or more per year additionally require the submission of a Chemical Safety Report (CSR) to document the safety assessment of the substance.

Failure to register means that the substance cannot be manufactured or imported.

6. What is the difference between Phase-in & Non-Phase-in substances?

The phase-in substances and the non-phase-in substances are the two categories of substances that need to be registered under REACH.

Phase-in substances ("existing substances") (substances which have long been on the EU market) meet at least one of the following criteria:

- it is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) - <http://ecb.jrc.it/esis/>
- it was manufactured in the Community, or in the countries acceding to the EU on 01/01/1995 or on 01/05/2004, but not placed on the market by the manufacturer or importer, at least once in the 15 years before the entry of force of REACH, provided the manufacturer or importer has documentary evidence of this;
- It was placed on the market in the Community, or in the countries acceding to the EU on 01/01/1995 or on 01/05/2004, before entry into force of REACH by the manufacturer or importer and was considered as having been notified in accordance Article 8(1) of Directive 67/548/EEC but does not meet the definition of a polymer as set out in this Regulation, provided the manufacturer or importer has documentary evidence of this;

Non-phase-in substances are those substances requiring registration, which do not benefit from the transitional regime provided for phase-in substances under REACH.

7. What is the aim of pre-registration?

The objective of pre-registration is to facilitate sharing of data between registrants, where possible, in order to reduce unnecessary testing, especially on vertebrate animals, and to decrease costs for the industry.

For Non-Phase-in substances no pre-registration is required however for Phase-in substances the pre-registration phase will occur as from 1 June 2008 until 1 December 2008.

If a manufacturer or importer fails to pre-register a phase-in substance, he will need to register it before continuing manufacture or import.

A list of all pre-registered substances will be published on the website of the Agency by 1 January 2009. This list will facilitate the identification of potential registrants of the same substance for the purpose of data sharing.

8. What information needs to be submitted for pre-registration?

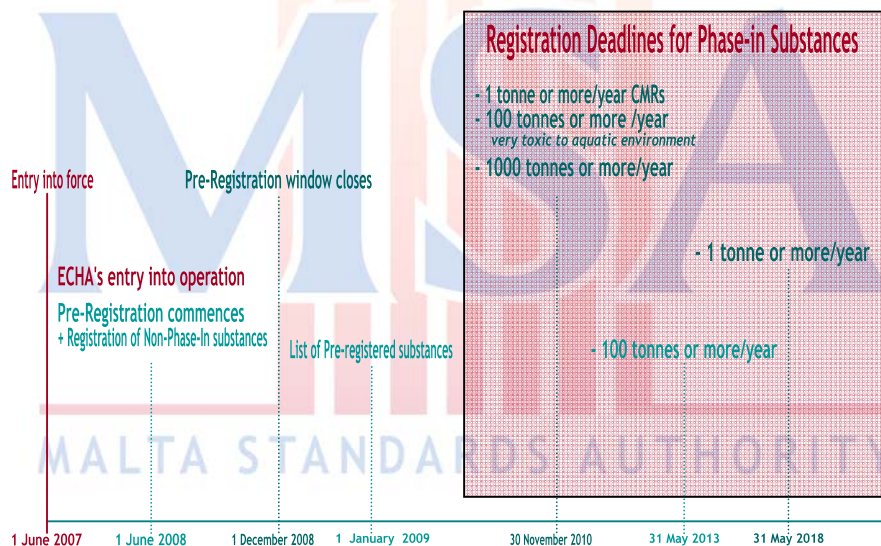
For pre-registration, potential registrant needs to submit to the ECHA only basic information on the produced/imported substance:-:

- ◆ *the registrant's name and contact details,*
- ◆ *the substance name by IUPAC-name (+ EINECS & CAS if available or other identity codes),*
- ◆ *the envisaged registration dead-line*
- ◆ *and the tonnage band within which he produces / imports the substance.*
- ◆ *The IUPAC-name of other substance(s) which may have relevant substance information to the one pre-registered.*

9. What are the Registration Deadlines?

For the registration of phase-in substances REACH provides for a phase-in scheme with staggered registration deadlines depending on the tonnage band and hazards of the substance. Following are the dates of the registration deadlines:

- 30 November 2010; or
- 31 May 2013; or
- 31 May 2018



To take advantage of such deadlines, phase-in substances will need to be pre-registered.

10. Who are the Downstream Users (DU) and what are their obligations?

Downstream users (DU) may be any industrial user of chemicals, whether formulators of preparations (e.g. paint producers) or users of chemicals such as oils and lubricants in other industrial processes or producers of manufactured articles such as electronic components. They are required to consider the safety of their uses of substances, based primarily on information from their suppliers, and to apply appropriate risk management measures. DU will need to communicate effectively with their suppliers, to get the information they need in the Safety Data Sheets (SDS) supplied to them. In particular they will have to check that their use(s) are “covered” by the SDS, i.e. that they use a substance within the conditions described in the exposure scenarios in the Annex to the SDS, and apply these conditions.

To get the relevant information, downstream users have the right to make their uses known to their suppliers so that the suppliers can include these uses in their chemical safety assessments as “identified” uses or pass the request on up the supply chain. A DU can also choose to keep his use confidential or decide to use a substance outside the conditions described in the exposure scenario(s) communicated to him. In these cases he will have to perform a Chemical Safety Assessment (CSA) developing the exposure scenarios for his intended uses and, if necessary, a refinement of the supplier’s hazard assessment. This obligation does not apply if the DU uses less than 1 tonne of the substance per year. However, a DU relying on the 1 tonne exemption still needs to consider the use(s) of the substance and identify, apply and recommend appropriate risk management measures.

11. How is the Evaluation procedure carried out?

There are two types of evaluation with different aims:

- Substance evaluation: the Agency in co-ordination with the Competent Authorities of Member States may investigate chemicals with perceived risks. This assessment may be used later to prepare proposals for restrictions or authorisation.
- Dossier evaluation: the Agency will do a quality check of the registration dossiers:
 - Compliance check with registration requirements; at least 5% of dossiers should be checked;
 - Checking of testing proposals: the aim here is to prevent unnecessary animal testing, i.e. the repetition of existing tests, and poor quality tests.

12. When are the Authorisation and/or Restrictions processes required?

Authorisation may be required for substances of very high concern.

The substances required to be authorised are substances which are:

- CMR: carcinogens, mutagens, substances toxic to the reproductive system (reprotoxic), category 1 and 2,
- PBT: substances which are persistent, bio-accumulative and toxic,
- vPvBs: very persistent and very bio-accumulative or of equivalent concern) &

- identified from scientific evidence as causing probable serious effects to humans or the environment, such as endocrine disrupters.

The authorisation system is intended to ensure that such substances will be progressively replaced wherever they cause unacceptable risks for human health and the environment or where there are no other reasons that justify carrying on using them.

If the use of a substance - on its own, in a preparation or in an article - poses unacceptable risks to health or the environment it may become subject to Community-wide restrictions. Restrictions can be decided either for the use of a substance in certain products, the use by consumers or even for all uses (complete ban of a substance).

13. In Malta what are the penalties applicable to REACH?

The penalties applicable are those prescribed in the Part IV of the Product Safety Act (Chapter 427).

14. What is ECHA?

[ECHA](#) is the acronym used for 'European Chemicals Agency'; the Agency is located in Helsinki (Finland) and it will manage the registration, evaluation, authorisation and restriction processes for chemical substances to ensure consistency across the European Union. These REACH processes are designed to provide additional information on chemicals, to ensure their safe use, and to ensure competitiveness of the European industry.

In its decision-making the Agency will take the best available scientific and technical data and socio-economic information into account. It will also provide information on chemicals and technical and scientific advice. By assessing and approving testing proposals, the Agency will minimize animal testing.

As from 1st June 2008 the Agency started to accept registrations.

15. Where can I find further information on REACH?

Further guidance can be found in the [ECHA website](#). The latter is a single point of entry for all information on REACH. It provides access to [technical guidance](#), frequently asked questions ([FAQs](#)), [software tools](#) and [helpdesks](#). In the ECHA website you will also find the latest updates on guidance, tools, data on chemicals and the Regulation.

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