

REACH and the polyester processing industry

Introduction

The chemical industry in Europe is to a large extent governed by European law. In 1967 the first European Directive was put into force regulating the classification, labelling and safe handling of dangerous substances. Since then more than 40 regulations and directives have been issued on various aspects of the risks associated with handling chemicals. Some of the most important directives are as follows:

Directive 67/548/EEC: Classification, Packaging and Labelling of Dangerous Substances.

Directive 88/379/EEC: Classification, Packaging and Labelling of Dangerous Preparations.

Council Directive 98/24/EC: Protection of Workers of the risks related to chemical agents at work.

Council Regulation 793/93/EC: Evaluation and Control of the Risks of Existing Substances.

New legislation

In 2000 it was felt that the current legislative framework for chemicals had to be updated and streamlined. Therefore, in 2001, the European Commission outlined its strategy for ensuring a high level of chemicals safety and a competitive chemicals industry through a system for the Registration, Evaluation and Authorisation of Chemicals - the REACH system.

The REACH system is based on seven objectives that need to be balanced within the overall framework of sustainable development:

- Protection of human health and the environment
- Maintenance and enhancement of the competitiveness of the EU chemical industry
- Prevention of fragmentation of the internal market
- Increased transparency
- Integration with international efforts
- Promotion of non-animal testing
- Conformity with EU international obligations under the WTO.

At the time of publication, REACH is not yet operational and the legislative process is still on-going. REACH will come into force in all EU countries from June 1st 2007.

REACH explained



REACH : Registration, Evaluation and Authorization of Chemicals

Registration

Registration is the basis of REACH. Manufacturers and importers will be required to gather information on the properties of their substances - which will help them manage them safely - and then submit the information in a registration dossier to a central data base. This is called the Chemical Safety Report (CSR). Under REACH approximately 30,000 different substances will have to be registered. The CSR also contains the material safety data sheet (MSDS).

The MSDS used for the transfer of information in the present system will continue to be used in REACH. An MSDS is a well-understood and internationally accepted tool for the communication of information on chemical hazards, risks and risk reduction measures. MSDS will be used as the primary communication tool for information developed under REACH.

Registration will involve providing information on the intrinsic properties and hazards of each substance (such as physicochemical, toxicological and ecotoxicological properties).

In the registration a listing of the identified uses of the substance must be provided. An assessment of risks for human health and the environment has to be made and adequate risk management measures have to be described.

Evaluation

There are two types of evaluation:

Dossier evaluation will be conducted to check proposals for testing on animals and ensure that unnecessary animal testing is avoided.

Substance evaluation can be performed when there is reason to believe that a substance may present a risk to human health or the environment (for example, because of its structural similarity to another substance or for other reasons).

Both evaluations will be performed by competent authorities in the Member States.

Authorization

All substances of very high concern will be subject to authorization. Authorizations apply to particular uses of the substance in question and will be granted if it can be shown that risks from the proposed use can be adequately controlled.

The authorization decision will take possible substitution plans into account. Examples of substances that will be subject to authorization are:

- CMRs (carcinogenic, mutagenic or toxic to reproduction), category 1 and 2 (according to Directive 67/548/EEC).
- PBTs (persistent, bio-accumulative and toxic) and vPvBs (very persistent, very bio-accumulative) substances (R 50-53).
- Substances identified as having serious and irreversible effects to humans and the environment, such as, for example, endocrine disrupting substances (substances disturbing the body's hormone system).

Substances, preparations and articles

REACH distinguishes between substances, preparations and articles. In the REACH proposal a **substance** is a chemical element or a compound composed of chemical elements. In the European substances data base (EINECS) approximately 100,000 substances are registered and catalogued. From this list around 30,000 substances will have to be registered within the REACH proposal.

For the time being, polymers (according to the current European definition) are exempt from registration. However, the raw materials for the polymers have to be registered. Most unsaturated polyester resins are polymers dissolved in styrene monomer. However, certain unsaturated polyester resin backbones might not be considered as polymers under this definition and will have to be registered as a substance.

A **preparation** is a mixture or solution, composed of two or more substances. Typical examples are paints, polyester resins in their commercial form, and printing inks. In a UP resin formulation several additives may be present, such as thixotropic agents, accelerators, UV stabilizers, etc.

An **article** is an object composed of substance(s) and/or preparation(s) which during production is given shape, surface or design; determining its end use function to a greater degree than its chemical composition does.

Within REACH only substances will have to be registered. When considering a preparation, the required information has to be gathered for all individual substances used. Articles do not have to be registered. However, if an article contains substances, which are intended to be released during the use of the article and which are classified as dangerous substances, a notification to the Chemical Agency has to be made.

Responsibilities within REACH

REACH addresses manufacturers, distributors, importers and downstream users.

Manufacturers produce substances. **Importers** import substances from non-EU countries, and **Distributors** only store or market a substance. **Downstream users** make industrial or professional use of chemicals. Some of them mix chemicals to make preparations (such as inks), others use substances or preparations to make articles (everything from pens to cars), or use them in their operations (such as CD-manufacturers who use degreasing agents to clean their machines).

The vast majority of the REACH requirements apply directly to manufactures and importers of substances. They will supply data on the properties of their chemicals, develop chemical safety assessments and implement risk management measures.

Downstream users will be supplied with safety information about the chemicals they purchase and should follow them when handling the chemicals. They will also need to make sure that their customers (e.g. other industries and consumers) have all the information necessary to use their products safely. When a chemical is to be used in a way not covered by the original registration, the new uses or risk reduction measures will have to be reported to the Agency if the volume is higher than 1 ton. Distributors must also ensure that safety information is provided with the substances they sell.

REACH for down stream users

A down stream user (DU) is defined as any natural or legal person, other than the manufacturer or the importer, who uses a substance - either on its own or in a preparation - in the course of their industrial or professional activity. Most polyester processing companies will therefore be considered to be DUs.

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The DU has to communicate with their supplier for which application they intend to use a certain product. These applications or processes are called 'identified uses'. The manufacturer of the product has to provide exposure scenarios and risk management measures for all identified uses. This information is put together in the new Material Safety Data Sheet.

For a DU the new MSDS will be a very important document as it not only provides the usual information that is currently detailed and supplied with every product; the new MSDS will also have a separate health and environment section in which all relevant information on identified uses, exposure controls and risk management measures can be found for the substance or product.

The DU has to follow the instructions for the safe use of the product as detailed in the MSDS.

Time frame

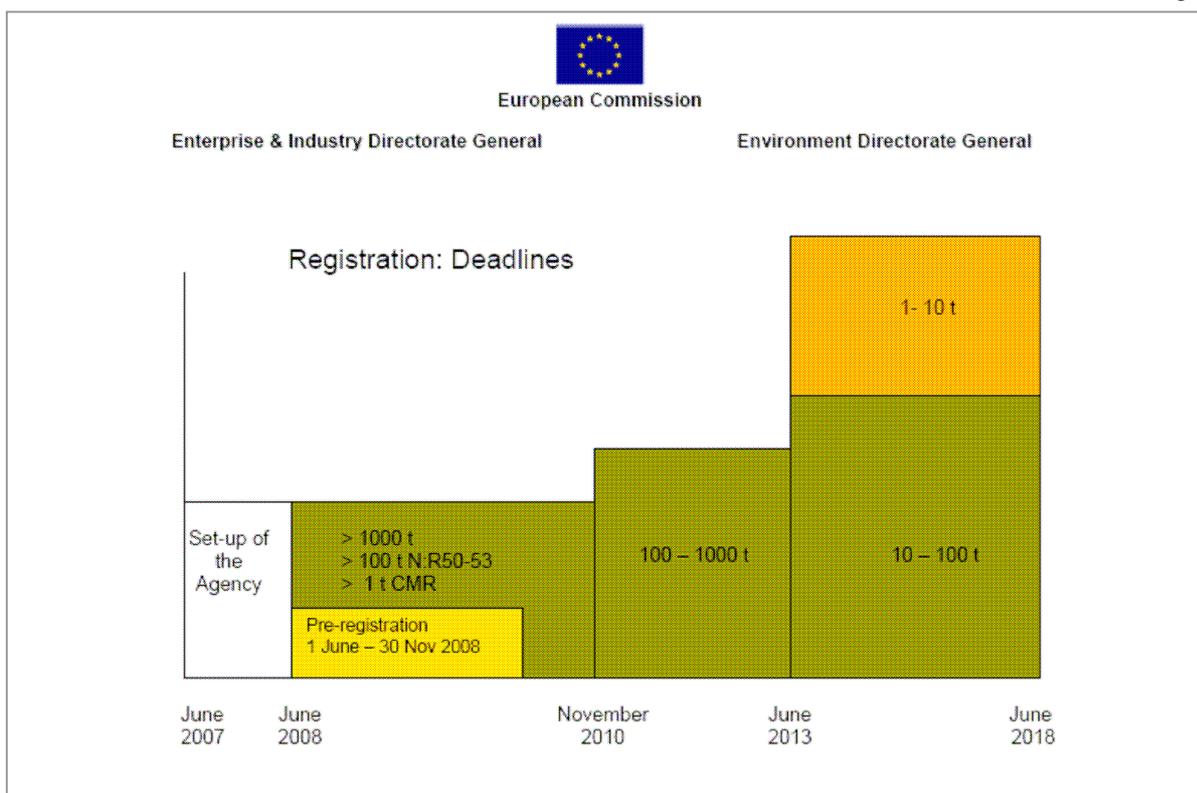
REACH will come into force in June 2007. From that moment on there is a distinct time schedule for the whole process. All so-called 'phase-in substances must be pre-registered in a period between 12 and 18 months after REACH comes into force. They must meet at least one of the following criteria:

- Listed in EINECS (European Inventory of Existing Commercial Chemical Substances)

- Manufactured in one of the current EU Member States at least once within the period of 15 years before the enforcement of REACH, but not placed on the market (e.g. intermediates, R&D substances)

When the pre-registration is completed in time, information about substances can be shared through so-called SIEFs, (Substance Information Exchange Forums). This will prevent a lot of unnecessary duplication during the registration process. The timing for the registration process depends on the properties and the production volume of the substances. Fig 1 shows the timetable for the whole registration process under REACH.

Fig 1



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What the UP Resin Industry is doing about REACH



The main UP Resin producers in Europe are organized through CEFIC and PlasticsEurope. The UPR producers are following closely the introduction of the REACH process, so they are prepared when REACH comes into force. The chemical industry, as a whole, participates in a vast number of REACH Implementation Projects, thereby ensuring that the implementation of REACH will be done in the best possible way and without creating an unnecessary administrative burden.

Through intensive communication with its downstream users, the UP Resin industry will make sure that the impact of REACH on the composites industry will be minimized without sacrificing the principles of REACH.

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