

13 December 2006: THE EUROPEAN PARLIAMENT VOTES ON THE FINAL ADOPTION OF REACH. THE REGULATION WILL ENTER INTO FORCE ON JUNE 1st 2007.

REACH (Registration, Evaluation and Authorization of Chemicals), the new EU regulation on chemicals, is considered the most ambitious policy to protect the environment for 20 years. After three years of intense negotiations, Council and Parliament have now reached a compromise. The final REACH text, adopted by the Council on December 18th 2006, was published in the Official Journal on December 30th 2006. The regulation will enter into force progressively from 1st June 2007.

REACH will replace around 40 existing EU Regulations and Directives. The new regulation aims at **improving the protection of human health and the environment through a better identification of the properties of chemical substances without threatening innovation and competitiveness of the EU chemicals industry.** It will provide a single system of chemicals regulation to harmonize and centralise proceedings in order to facilitate the domestic market.

Once in force, REACH will require **producers and importers to register all chemical substances produced or imported above a total volume of 1 tonne per year.** The registration covers some 30,000 chemical substances in use today over a period of 11 years. For more hazardous substances (substances that cause cancer, infertility, genetic mutations or birth defects...), industries will have to submit a substitution plan to replace them with safer alternatives.

REACH gives greater responsibility to industry

The regulation transfers the burden of proof regarding testing and evaluation of the risks of chemicals from the authorities to industry.

Manufacturers and importers should manage the risks from chemicals, provide safety information (properties and uses) and inform customers about the hazardous nature of certain substances in consumer goods.

REACH creates a new Chemicals Agency

REACH creates a new European Chemicals Agency (ECHA), to be established in Helsinki, which will be responsible for the registration and authorization processes. The Agency will act as the central point in the REACH system: running of necessary databases, coordination of evaluation of hazardous chemicals. It will ensure a flow of information about the risks of substances throughout industry and to consumers.



Contrary to a Directive, the REACH regulation will apply to the 27 Member States of the European Union immediately as soon as it enters into force without any adoption of national law.

For additional information on products affected by REACH, exemptions, proceedings and SGS services regarding REACH, you can consult previous SafeGuards 080/05 (DECEMBER 2005)



The Regulation (EC) N° 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of chemicals (REACH) and Directive 2006/121/EC of the European Parliament and of the Council of 18 December 2006 amending Council Directive 67/548/EEC (relating to the classification, packaging and labelling of dangerous substances) were published in the Official Journal on December 30th 2006.



REACH will enter into force on 1 June 2007 instead of 1 April 2007, as previously announced.

THE REACH STEPS

10 October 2006 - Vote of the European Parliament's Environment Committee (Brussels)

Two main principles were reintroduced:

- ◆ The mandatory **substitution** allowing the substitution of hazardous chemicals (the most toxic substances) in consumer goods whenever this is economically and socially acceptable and if stimulating innovation in Europe.
- ◆ The **duty of care** principle ensuring that producers and importers of chemicals take responsibility for the safety of their products when the risks can be "reasonably foreseen".

13 December 2006 - Final adoption of REACH in second reading by the European Parliament (Strasbourg)

The main points of the compromise are:

1- Registration of substances

- ◆ The **Chemical Safety Report** (CSR) is not required for the tonnage band of 1-10 tonnes /year but this condition may be reviewed 7 years after the entry into force of REACH.
- ◆ The **registration deadline for the tonnage band > 1.000 tonnes /year** is extended from 3 to 3.5 years.
- ◆ The **data protection** is extended from 10 to 12 years.
- ◆ The requirements for **tests regarding toxicity for reproduction** (Annex VIII section 8.7) will be reviewed 12 years after the entry into force of REACH.
- ◆ The requirement for chemical safety reports for substances of very high concern (substances which are carcinogenic, mutagenic, toxic for reproduction) produced or imported in amount of less than 10 tonnes per year has been shortened from 11 years to 7 years.

2- Authorization of hazardous substances

- ◆ The **substitution** principle: there will be an obligation for producers to submit a substitution plan to replace hazardous substances with safer alternatives. Where no alternative exists, producers will have to present a research and development plan.
- ◆ It will be decided after six years whether **endocrine disruptors** should be included in a list of substances which can only be authorized if no alternative exists and socio-economic benefits are proved.

3- Communication of information

A clause was added on the duty to inform the supply chain and the customers in a better way regarding the hazardous substances contained in consumer goods (presence of any chemical in an amount greater than 0.1% of the total product weight). The Commission must consider the possibility of establishing a European quality mark for chemical products.

4- Duty of Care

Manufacturing, import or placing on the market of substances must be done responsibly. Producers will have to collect data and relay recommendations about risk management along the distribution chain.

5- Animal welfare

REACH includes now the promotion of alternatives to the animal testing of chemicals. The objective is to avoid duplication of animal testing and use other tests than tests on vertebrate animals. To analyse toxicity to human beings, it is recommended to use alternative methods (to be validated by the Commission) such as in vivo procedures.

18 December 2006 - Adoption of REACH by the Council (Brussels)

Next steps

1 June 2007 - REACH enters into force

1 June 2008 - Helsinki Agency in operation

1 June 2008 / 30 November 2008 (12 to 18 months after the entry into force of REACH) - **Beginning of pre-registration of existing substances***. The pre-registration allows a registration grace period.

1 June 2008 - Beginning of registration of new substances*

1 December 2010 - Deadline for registration of substances in quantity > 1.000 tonnes /year, R50/53 in quantity > 100 tonnes /year, CMR (cat. 1 or 2) in quantity > 1 tonne /year

1 June 2013 - Deadline for registration of substances in quantity between 100 tonnes /year and 1.000 tonnes /year

1 June 2018 - Deadline for registration of substances in quantity between 1 tonne /year and 100 tonnes /year

* Existing substances: chemicals placed on the EU market between 1 January 1971 and 18 September 1981 and recorded in the European Inventory of Existing Commercial chemical Substances.

* New substances: chemicals placed on the EU market after 18 September 1981

REACH is now considered of vital importance for importers, producers and downstream users. Companies should now intensify their preparatory activities to be ready to fulfil their duties in time.



SGS DEVELOPS AN ORIGINAL OFFER OF SERVICES TO HELP CLIENTS TO MEET REACH REQUIREMENTS

To answer to the demand of its clients, the SGS group has anticipated for several years the implementation of the REACH regulation.

SGS offers a one stop shop service:

1. Our French laboratory (SGS Multilab Rouen) has developed **interactive software** to support clients in understanding the technical and regulatory aspects of REACH. This tool is the result of a partnership between SGS Multilab and the well-known French School of Engineers (INSA Rouen). The objective was to provide clients with guidelines to help them to optimise their strategy for compliance with the new REACH regulation. This software is a technical support for SGS experts: **the group can assist each client in its personal strategy for REACH, in identifying their obligations, checking data or defining testing needs.**

2. SGS performs all the tests mentioned in the REACH Annexes. **Physico-chemical, toxicological and ecotoxicological tests**, and measures of substances of high concern for health and ecosystems are already performed in its **GLP laboratories** (France, Germany...) according to the OECD guidelines. GLP (Good Laboratory Practise) is a required criterion for most of the tests.

SGS provides **testing capabilities that are at the technological forefront** by developing internal methods to meet industries' needs:

- ◆ Sustainable development, product strategy and biodegradability tests
- ◆ Proportioning of hazardous substances: CMR (Carcinogen, Mutagen, Toxic for reproduction)
- ◆ Ecotoxicological tests to measure the impact of products, materials and dumping in the ecosystems
- ◆ Assessment of interactions Environment /Health by HPLC/MS/MS and GC/MS/MS and ICP/MS

SGS provides **tests on different products** such as wood, textile, plastic, inks, pigments, metals, leather, paint...

3. **SGS provides training sessions** on REACH according to the client's issues (producers, importers, downstream users).

4. SGS provide clients **audit of products portfolio** and propose a methodology of work to meet REACH requirements.

Thanks to its **worldwide network**, its **technical and regulatory expertise**, SGS provides not only testing services regarding REACH but also training sessions, customized solutions and seminars on business topics.

For additional information, you can visit the SGS website about REACH www.sgs.com/reach.

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