



Published on 1 December 2010 by **Jean-Luc Soulier**, Member of the Paris Bar jl.soulier@soulier-avocats.com

Tel.: +33 (0)1 40 54 29 29, + 33 (0)4 72 82 20 80

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Reach: a new milestone in the registration process of chemicals

Since several years, the EU authorities have been striving to improve the regulatory framework governing chemicals in order to gain a better knowledge of chemical substances used within the EU and to ensure a higher level of protection of human health and the environment. In this context, two main regulations have been adopted:

- The REACH Regulation^[1] creates a process of registration of all chemical substances used within the EU and provides for a system of authorization for the most dangerous substances. While the registration only applies to the manufacture or importation of chemicals (either directly, in the form of mixtures or incorporated in a product), other provisions of this Regulation impose new obligations on all actors of the supply/production/distribution chain of chemical substances.
- The CLP Regulation^[2] creates a system of classification, labeling and packaging of substances and mixtures and transfers to producers the responsibility of the classification.

The implementation of the REACH and CLP Regulations thus creates new obligations and places greater responsibility on industrial companies that must now assess their products, prepare and submit registration files, decide on the product classification and post the appropriate labeling. Because this is a gigantic work, the implementation process has been divided into several stages.

November 30, 2010 was an important milestone in the implementation process of REACH: it was the first deadline for registering certain substances that had been pre-registered in 2008, i.e.:

• The most hazardous substances, i.e. substances that are carcinogenic, mutagenic or toxic for reproduction manufactured or imported in quantities of 1 tone or more per year per company as well as substances very toxic to the aquatic environment manufactured or imported in quantities of 100 tones



or more per year per company,

• All substances manufactured or imported above 1,000 tones per year.

As of November 30, 2010, 24,675 registration files had been submitted to the European Chemicals Agency ("ECHA"). This step was of paramount importance because the failure to register a substance is heavily sanctioned: substances that were not registered may no longer be manufactured, imported or marketed within the European Union. In France, companies that breach such prohibition shall be subject to (i) administrative sanctions, i.e. a fine of 15,000 Euros maximum and a penalty of 1,500 Euros for each day of non-compliance (Article L.521-18 of the French Environmental Code) and (ii) criminal sanctions, i.e. a maximum fine of 75,000 Euros and a maximum prison sentence of two years (Article L.521-21 of the French Environmental Code).

Companies that failed to register their substances within the applicable timelines can still submit a registration file but they will not be authorized to manufacture, import or market the substances in question until completion of the registration process by the ECHA.

There are two further registration deadlines on June 1, 2013 and June 1, 2018 for substances produced or imported respectively in quantities of 100 tones or more per year per company or in quantities of 1 tone or more per year per company.

In parallel, the producers of substances were also required to notify the classification, labeling and packaging of their products in accordance with the requirements of the CLP Regulation before December 1, 2010. For substances placed on the market after that date, notification is due no later than on January 3, 2011. This notification obligation applies not only to the substances that ought to be registered by the aforementioned November 30, 2010 deadline but to all chemical substances, including those produced in lesser quantities.

It should be noted that for mixtures, the deadline for the notification of the classification, labeling and packaging as per the requirements of the CPL is set on June 1, 2015.

- [1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of December 18, 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency.
- [2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of December 16, 2008 on classification, labeling and packaging of substances and mixtures.

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