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The world of Reach, year IV

The European REACH Regulation[1] (originally made up of more than 850 pages!) dated December 18, 2006 entered into force on June 1, 2007. Pursuant to this Regulation, chemical substances as such, used in the preparation of a mixture, or contained in an article in quantities of 1 tonne or above per year must now be registered with the European Chemicals Agency ("ECHA") created specifically for this purpose (it now employs hundreds of persons)[2].

REACH is a constantly evolving system. It has already been modified, adapted or complemented by a dozen of regulatory instruments. The most recent changes were introduced by a Regulation of May 20, 2010 published in the Official Journal of the European Union on May 31, 2010[3]. Such Regulation modifies the requirements governing the preparation of safety data sheets that any supplier of a chemical substance or product containing a chemical substance must hand over to its contracting partner or direct intermediary.

REACH concerns virtually all businesses, whatever their size or sector of activity. Indeed, REACH applies not only to manufacturers but also to importers, sellers, downstream users and companies based outside the European Union that export products to the EU market. The latter must appoint an EU-based representative that will perform the obligations before the ECHA.

Failing to register a substance in the conditions and within the timelines set forth under the REACH Regulation will render illegal the manufacture and marketing of such substance and articles and products containing such substances, and eventually lead to stiff criminal penalties and sanctions.

REACH also created a specific authorization procedure for substances that are of a very high concern for human health and the environment.

This new system was completed in 2008 by a Regulation of the European Parliament and of the Council on the classification, labeling and packaging of substances and mixtures (so-called "CLP Regulation")[4], the main objective of which is to align the European Union system of classification, labeling and packaging of chemical substances and mixtures to the Globally Harmonized System (GHS) agreed upon at the UN level. Pursuant to the CLP Regulation, companies are now liable for the classification of their products[5].

The two aforementioned Regulations have implemented a brand new system of registration, authorization, classification, labeling and packaging under which companies that produce, import, market or use a chemical substance (either directly, in the form of mixtures or incorporated in an article) are responsible for assessing and managing the risks associated with such substance. This responsibility used to mainly lie with the administrative authorities of the various EU Member States.

The REACH and CLP Regulations will be implemented in stages through 2018, according to the level of risk for human health or the environment associated with the relevant substance and the tonnage marketed by companies.

The year 2010 is a pivotal year for this implementation process. Indeed, the ECHA expects more than 25,000 registration dossiers to be submitted before December 1, 2010 and more than 2 million classification and labeling notifications to be made before January 3, 2011.

In order to spread the submission of registration dossiers over time, the REACH Regulation provided for a first pre-registration phase, from June 1 to December 1, 2008. Only companies that pre-registered their substances were granted extended deadlines for the registration of their complete dossier, through 2010, 2013 or even 2018, for certain substances. Substances that were not pre-registered at the end of the pre-registration phase may no longer be manufactured or marketed within the European Union unless they successfully go through the standard registration phase. Companies and corporate officers that do not respect this prohibition will be liable for heavy criminal penalties and sanctions.

During this 6-month pre-registration phase, the ECHA received 2.7 million dossiers on 143,000 substances from 65,000 companies!

Such radical changes in the management of chemical substances naturally have a substantial impact on companies.

First, companies must now manage the registration and/or authorization phase(s) for all substances they directly manufacture, sell, import or use as well as for all substances incorporated into the products they manufacture, sell, import or use.

As several companies are likely to use the same substance(s), the REACH Regulation introduced a set of rules imposing cooperation between companies through the formation of so-called Substance Information Exchange Forums ("SIEFs") for the submission of a single joint registration dossier.

This system can, however, create major difficulties at several levels: the protection of sensitive data, compliance with competition and antitrust legislation, tax repercussions (notably with respect to the sharing of costs that can be considerable) and even the accounting treatment of expenses incurred within the SIEFs or the consortiums set up to comply with the cooperation obligation imposed during the registration phase!

Companies must also be very careful with the consequences associated with the new liabilities vested upon them pursuant to the REACH and CLP Regulations and other legal and regulatory texts implemented by the various Member States to adapt their internal legislation:

- A permanent scrutiny of all safety problems relating to the chemical substances they use, by acquiring knowledge on said substances and, as the case may be, conducting trials;
- The assessment and the spontaneous amendments to the classification of non-harmonized substances and correlative modifications to the labeling of the concerned products;
- The constant update of the scientific data relating to the substances they use, both for the ECHA and for the recipients of the products, through modifications to the safety data sheet and the labeling of said products;
- The permanent obligation to substitute substances of very high concern with substances that are less dangerous for human health and for the environment, when these exist;
- The adaptation of their contracts and general terms of sale to remind their contracting parties of their own risk information and management obligation vis-à-vis their own contracting partners throughout the supply chain, up to the end consumer;
- The adaptation of the "*document unique d'évaluation des risques professionnels*" (single occupational risk assessment document), that must be made available to all employees, to take into consideration any change on the classification of chemical substances and the risks associated therewith;
- The adaptation of the delegations of powers and authority granted within companies to include and cover new tasks and liabilities imposed by the REACH and CLP Regulations;

to name but a few!

The REACH Regulation does not provide for any sanction other than the prohibition to manufacture, sell or import substances that are not validly registered with the ECHA or that did not obtain the specific, required authorization for substances of very high concern. As such, REACH follows the "no data, no market" principle.

It is up to EU Member States to enforce REACH and determine appropriate sanctions. In France, breach of the REACH and CLP Regulations are punishable by a maximum fine of 75,000 Euros and a maximum prison sentence of two years for individuals, and by a maximum fine of 375,000 Euros, possibly coupled with additional sanctions such as the temporary or definitive closure of sites or prohibition to do business, for companies. In comparison, the maximum prison sentence is six years in the Netherlands, two years in the United Kingdom and one year in Poland.

Numerous administrative agents are empowered to carry out controls, notably agents from the *Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes* (General Directorate for

Competition Policy, Consumer Affairs and Fraud Control – a Directorate that is under the authority of the Finance Minister), the *Directions Régionales de l'Industrie de la Recherche et de l'Environnement* (Regional Boards for Industry, Research and Environment that are responsible for inspecting classified sites and facilities), the labor inspection administration and Customs.

Hundreds of controls were announced at the beginning of the year 2009, notably to check manufacturers' and importers' compliance with the pre-registration obligation and the use of safety data sheets. The number of controls should drastically increase after December 1, 2010, this date being a milestone in the implementation process set by the REACH Regulation.

We have now really moved into the World of REACH, with the precautionary principle in the background since both the REACH and CLP Regulations expressly refer to it. This principle is therefore no longer a French exception, as it used to be when the Environmental Charter – which expressly mentions this principle – was incorporated into the French Constitution in 2005.

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[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] A few substances are exempt from REACH or from the registration procedure.

[3] Commission Regulation (EU) No 453/2010 of May 20, 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the registration, evaluation, authorization and restriction of chemicals (REACH).

[4] 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.

[5] The CLP Regulation provides for a harmonized system of classification and labeling of certain substances. Companies may not deviate from this classification and are required to use certain defined hazard symbols (pictograms) and corresponding warning phrases. On the other hand, companies are liable for the classification and labeling of mixtures and non-harmonized substances.

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