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Latest developments concerning the Reach and CLP regulations

So-called REACH Regulation 1907/2006^[1] and CLP Regulation 1272/2008^[2] marked an important milestone in the evolution of EU law on chemical substances. The objective of these Regulations is to gain a better knowledge of chemical substances used within the EU in order to ensure a higher level of protection of human health and the environment.

The focal point of the REACH Regulation is the creation of a process of registration of all chemical substances used within the territory of the European Union: as such, all chemical substances manufactured or imported in quantities of 1 ton or more per year per company must be registered in a database. Another fundamental aspect of this Regulation concerns the sharing of data by and among industrials and the limitation of testing on vertebrate animals. The placing on the market and the use of certain substances can be subject to authorization.

The CLP Regulation imposes on manufacturers of substances and mixtures the obligation to classify, label and pack their products in accordance with certain requirements so as to inform the users of the inherent hazards of the relevant substances or mixtures.

These two Regulations are constantly evolving to adapt to the technical evolutions and improve scientific knowledge.

The beginning of 2012 has been marked by the adoption of a series of texts that amended or completed these two regulations.

Eight new substances added to Annex XIV to the REACH Regulation

As exposed above, pursuant to the REACH Regulation the chemical substances of very high concern are

subject to authorization. Such substances are listed in Annex XIV. A substance included in Annex XIV may no longer be used or marketed, unless the manufacturer, importer or user is granted an authorization by the EU Commission.

A Regulation dated February 14, 2012^[3] added eight substances^[4] to the list set forth in Annex XIV to the REACH Regulation.

Pursuant to this new Regulation, the applications for authorization pertaining to these eight substances recently included in Annex XIV must be filed with the European Chemicals Agency ("ECHA") before August 21, 2013 and February 21, 2014, depending on the substances.

The so-called sunset dates, i.e. the date on which a substance may no longer be placed on the market and used without authorization, range from February 21 to August 21, 2015, depending on the substances.

As such, manufacturers, importers and users of any of these eight substances must remain vigilant and, as the case may be, file an application for authorization with the ECHA as soon as possible.

Publication of the first European classification and labeling inventory

On February 13, 2012, the ECHA published the first European inventory for the classification and labeling of chemical products^[5].

The inventory compiles information for more than 100,000 chemical substances and provides a classification thereof.

It will be valuable help for industrials wishing to classify and label their substances and mixtures as per the requirements of the CLP Regulation.

Publication of a new Candidate List of substances - Opinion of the French Ministry of Ecology

So-called "candidate" substances are substances of very high concern that may be included over time in Annex XIV to the REACH Regulation: the registration of such substances on the Candidate List of substances is therefore a first step towards authorization.

Candidate substances can continue to be freely placed on the market until their inclusion in Annex XIV.

Yet, the registration of a substance on the Candidate List of substances has a number of consequences.

In December 2011, the ECHA published an updated Candidate List that now contains 73 substances^[6]. On this

occasion, the French Ministry of Ecology recalled the obligations imposed on the suppliers of articles incorporating such substances^[7].

Suppliers of an article that contains a substance included in the Candidate List above a concentration of 0.1% weight by weight (w/w) must provide the recipients^[8] of such an article with sufficient information to ensure safe use/handling, including at the very least the name of the relevant substance.

They are also required to provide such information to consumers within 45 days from receipt of a consumer's request for information.

When the substance included in the Candidate List is present in an article in an amount totaling more than 1 ton per year and in a concentration above 0.1% weight by weight (w/w), the manufacturers or importers of this article must notify the ECHA of the presence of such substance within six months as from the date of inclusion of the substance on the Candidate List, unless the substance is already registered for that use. This obligation became effective on June 1, 2011.

Inclusion of new substances in Annex XVII to the REACH Regulation

Annex XVII to the REACH Regulation lists the substances subject to restrictions.

Some substances, on their own, in mixtures or in articles, pose risks to the health or the environment that are not adequately covered by other provisions of the REACH Regulation. Therefore, the manufacture, use and placement on the market of such substances are subject to specific restrictions or prohibitions.

A New Regulation^[9] adopted on February 9, 2012 completed Annex XVII to the REACH Regulation by adding new CMR (carcinogenic, mutagenic, or toxic for reproduction) substances.

As such the REACH Regulation is aligned with the CLP Regulation that had already been amended^[10] for inclusion of these CMR substances.

This new Regulation shall become effective on June 1, 2012.

Manufacturers, importers and users of chemical substances classified as CMR must consequently ensure that their use of such substances (on their own, in mixtures or in articles) is not restricted or prohibited under this new Regulation.

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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] [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.
- [3] [Commission Regulation \(EU\) No 125/2012](#) of February 14, 2012 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council, published in the OJEU on February 15, 2012.
- [4] Diisobutyl phthalate, diarsenic trioxide, diarsenic pentaoxide, lead chromate, lead sulfochromate yellow, lead chromate molybdate sulphate red, tris (2-chloroethyl) phosphate and 2,4-dinitrotoluene.
- [5] [Consult the inventory](#).
- [6] [Consult the Candidate List of substances](#).
- [7] Opinion of the Ministry of Ecology to economic operators on the obligation to provide information on the substances contained in articles, as per the requirements set forth in Article 7.2 and 33 of Regulation n°1907/2006 REACH, published in the Official Journal on February 17, 2012. The list of the 73 substances included on the Candidate List of substances is attached to the Opinion.
- [8] It is specified that the term “recipients” means industrial or professional users and distributors, not consumers.
- [9] [Commission Regulation \(EU\) No 109/2012](#) of February 9, 2012 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) as regards Annex XVII (CMR substances), published in the OJEU n°L37 on February 10, 2012.
- [10] The CLP Regulation was amended by [Regulation 790/2009](#), published in the OJEU n°L235 of September 5, 2009.

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