

A Priority Issue for Industry in 2010 and 2011 - *Classification and Labelling of Chemical Substances*

Large companies which need to register chemical substances, under the REACH (Registration, Evaluation, Authorisation and restriction of Chemicals) Regulation (EC) No 1907/2006, are aware of their obligations to classify and label their chemicals. However, smaller companies which manufacture or import substances in low tonnages are probably not yet aware that they have to prepare for the new classification, labelling and packaging Regulation, even though they are not subject to REACH.

The CLP Regulation (EC) No 1272/2008 on the Classification, Labelling and Packaging of substances and mixtures, implemented into national legislation by Legal Notice 214 of 2009, brings new obligations for suppliers of chemicals.

CLP is about the hazards of chemical substances and mixtures and how to inform others about them. It is the task of industry to establish what are the hazards of substances and mixtures before these are placed on the market, and to classify them in line with the identified hazards. In case a substance or a mixture is hazardous, it has to be labelled so that workers and consumers know about its effects before they handle it.

There are certain timelines for industry to classify and label their substances and mixtures in line with the CLP rules. Also, industry must notify hazardous substances and mixtures to a central inventory.

Classification and Labelling - From 1 December 2010, all suppliers placing chemical substances on the market have to classify and label their substances in accordance with the new criteria. From 1 June 2015 this also applies to mixtures produced from the substances. The classification according to the Dangerous Substance Directive (DSD) continues until 1 June 2015.

Notification – Manufactures and importers who place a hazardous substance on the market, on or after 1 December 2010, either on its own or contained in a hazardous mixture will have to notify the classification and labelling of the substance to ECHA, irrespective of its quantity. The obligation to notify will also apply to manufacturers and importers placing on the market a substance that is subject to registration under REACH. No further notification is required when the classification, in accordance with the CLP criteria, has already been submitted as part of a registration under REACH by the same manufacturer or importer. Downstream users, including formulators of mixtures, as well as distributors of hazardous substances and mixtures do not need to notify to the classification and labelling Inventory. This is because the notification of the respective substances should have occurred already at an earlier stage in the supply chain.

Classification and Labelling Inventory - ECHA will establish a classification and labelling inventory which will be accessible over the internet. This will include the notified classifications as well as classifications included in the registration dossiers submitted under REACH and the classifications that are harmonised at EU level.

Safety Data Sheets – An existing Safety Data Sheet (SDS) may require an update when a substance or mixture has been classified, labelled and packaged according to CLP and if new knowledge on hazards becomes available. After 1 December 2010 the

SDS shall contain the classification of a substance according to the Dangerous Substances Directive 1967/548/EEC, as transposed into national legislation by Legal Notice 306 of 2008 (as amended), and according to CLP. Until 1 June 2015 the SDS shall contain classification of a mixture according to the Dangerous Preparation Directive 1999/45/EC, as transposed into Legal Notice 10 of 2007 (as amended). However, if a mixture is already classified, labelled and packaged according to CLP, it shall also contain the CLP classification of the mixture. As from 1 June 2015 the substance and mixture classifications on the SDS shall be according to CLP.

Important CLP deadlines

- **1 December 2010** - Substances must be classified and labelled according to the CLP criteria
- **3 January 2011** - Substances which are hazardous or subject to registration and are placed on the market (Date of marketing) on 1 December 2010 must be notified
- **Ongoing** - Substances which are hazardous or subject to registration and are placed on the market after 1 December 2010 must be notified within one month
- **1 June 2015** - Mixtures placed on the market must be classified and labelled according to the CLP criteria

The helpdesk established within the Regulatory Affairs Directorate (RAD), at the Malta Standards Authority (MSA), offers support if a company needs clarification on its obligations. The RAD has produced information leaflets dealing with the CLP obligations. Furthermore the European Chemicals Agency (ECHA) has also published on its website an introductory guidance document on CLP (available in both English and Maltese), a guidance document on the application of the CLP criteria, a general leaflet and a first package of Frequently Asked Questions. Further material is under preparation, including a brochure explaining how to notify a classification to ECHA.

ECHA expects to receive several million notifications, most of them in November and December 2010. The ECHA IT team is currently implementing new features in the REACH-IT system. It is important that industry sends the notifications already in spring or summer 2010.