



EU ENVIRONMENTAL UPDATE

**The International Environmental Practice of Sidley Austin LLP**

Sidley has been advising clients on significant environmental matters throughout the world for decades. This work has included due diligence for multinational transactions, advising companies on the environmental risks and requirements associated with doing business in Europe, the United States, South America and Asia, advising clients regarding the environmental aspects of international trade, and assisting clients with the design and implementation of environmental management systems. The group's experience also extends to product stewardship issues, including restrictions on product content, packaging, labeling and disposal. Sidley advises clients on compliance with a variety of international environmental treaties and participates in advocacy on international environmental issues, representing clients on matters such as the EU's waste management legislation and the REACH initiative on chemical controls, U.S. Federal programs such as TSCA and those administered by the Consumer Product Safety Commission, and State programs in the U.S. that impose product content, recycling and communication requirements (including California's Proposition 65).

**To receive future copies of EU Environmental Update via email, please send your name, company or firm name and email address to Cristina Menendez at [cmenendezruiz@sidley.com](mailto:cmenendezruiz@sidley.com).**

This **Sidley Update** has been prepared by Sidley Austin LLP for informational purposes only and does not constitute legal advice. This information is not intended to create, and receipt of it does not constitute, a lawyer-client relationship. Readers should not act upon this without seeking advice from professional advisers.

*Attorney Advertising - For purposes of compliance with New York State Bar rules, our headquarters are Sidley Austin LLP, 787 Seventh Avenue, New York, NY 10019, 212.839.5300 and One South Dearborn, Chicago, IL 60603, 312.853.7000. Prior results do not guarantee a similar outcome.*

**European Parliament and Council Adopt New Legislation on Dangerous Substances and Mixtures**

In December 2008, the European Parliament and Council adopted a Regulation on the classification, labeling and packaging of substances and mixtures (CLP Regulation).<sup>1</sup> Between now and 2015, it will entirely replace the current EU rules under the Dangerous Substances Directive (67/548/EEC) and the Dangerous Preparations Directive (1999/45/EC). Modeled after the UN's Globally Harmonized System (GHS) of classification and labeling, the CLP Regulation is also the last major piece of legislation in the modernization of the EU chemicals program that resulted in the Regulation on the registration, evaluation, authorization and restriction of chemicals (REACH). Companies need to consider how the CLP Regulation may require changes to the classification, packaging and labeling of hazardous substances and mixtures they have placed on the EU market, and the amendments it makes to the safety data sheets (SDS) requirements.

**Global Harmonization of Chemical Classification under the UN's GHS**

The GHS defines health, environment and physical hazards and divides them into classes. In line with the GHS' building block approach that allows some choice between classes and categories of classifications, the EU has adopted all hazard classes of the GHS, but not all categories. Also, unlike the GHS, the CLP Regulation includes classification and labeling criteria for ozone depleting chemicals. Other UN members will similarly choose which GHS hazard classes and categories to implement. It is an open question, therefore, how much harmonization of chemical classifications will be achieved, which was the aim of the GHS in order to facilitate international chemical trade.

As a general matter, the CLP Regulation harmonizes the classification, labeling and packaging rules for substances and mixtures, and obliges companies to (self-)classify based on available information. Generally, the CLP Regulation applies to all substances and mixtures supplied in the European Community, except when other more specific

<sup>1</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF>.

Community legislation is relevant, such as the Cosmetics Directive (76/768/EEC) or the Medicinal Products Directive (2001/83/EC). Companies should verify which legislation will affect them, according to the product in question.

The CLP Regulation continues the basic EU chemical law principle that companies must, in the absence of harmonized classification, self-classify substances and mixtures before placing them on the EU market. Self-classification requires the evaluation of available information and identification of the appropriate classification, but there is no requirement for new test data. Companies must notify the European Chemical Agency (ECHA) of their classification and labeling decisions under REACH. ECHA is expected to issue more guidance on this subject in 2009.

### **The CLP Regulation and REACH**

The CLP Regulation complements REACH by taking over certain provisions regarding the notification of classifications and the creation of a classification and labeling inventory. Self-classified substances that are notified to ECHA and harmonized classifications at Community level will be published in this inventory. The aim is to ensure that all substances are classified in the same manner. If they are not, notifiers are to agree on a consistent classification.

There are some differences between the scope of REACH and the CLP Regulation. For example, REACH is generally concerned with the registration of hazardous and non-hazardous substances, mixtures and articles imported in quantities over one ton per year, whereas the CLP Regulation is concerned only with hazardous substances and mixtures, but in any specific quantity. Therefore, even if a company imports or markets a (hazardous) substance in quantities of less than one ton a year, it may have to comply with the CLP Regulation's classification, labeling and packaging requirements.

### **The CLP Regulation Compared with the Dangerous Substances Directive and the Dangerous Preparations Directive**

The CLP Regulation implements wide-ranging changes from the Dangerous Substances Directive and Dangerous Preparations Directive. It contains new hazard classes, and changes category criteria (e.g., cut-off values), which may result in a different classification for certain substances. It introduces new toxicity end-points and changes others.

Moreover, due to changes in cut-off values and calculation methods, the Commission predicts that more mixtures will probably be classified under the new system. These changes in classification rules will also result in changes to SDS's, product labeling, shipment labeling and new pictograms and phrases.

Annex I of the Dangerous Substances Directive (which contained harmonized classifications) has been deleted as of 20 January 2009 and its classifications have been transferred to a new list in Part 3 of Annex VI of the CLP Regulation. Due to the timing of the legislative process, the 30th Amendment to Technical Progress (ATP) Directive (2008/58/EC) and the 31st ATP Directive (2009/6/EC) to the Dangerous Substances Directive are not yet included in the CLP Regulation.

### **Harmonization of Classifications at Community Level**

The CLP Regulation gives Member State authorities the power to propose harmonized classifications. Manufacturers, importers and downstream users may also do so, but cannot propose amendments to existing harmonized classifications without the support of a Member State. The procedure for Member State authorities and companies to propose harmonized classifications to the ECHA Risk Assessment Committee is similar, though the CLP Regulation contains more extensive rules on the procedure, format, methodology and information required for a harmonized classification proposal compared with the current rules.

## Transition Period Requirements

The CLP Regulation repeals the Dangerous Substances Directive and the Dangerous Preparations Directive as of 1 June 2015, and provides a transition period until then for companies to adjust to the new system. The transition period runs until 1 December 2010 for substances, and until 1 June 2015 for mixtures. To assist companies, the CLP Regulation contains a translation table in Annex VII for converting Dangerous Substances Directive classifications into CLP Regulation classifications. Further, the CLP Regulation amends the rules on SDS set out in REACH, to bring the SDS rules into line with the CLP transition periods. The tables below provide an overview of the changes to the classification, labeling, packaging and SDS requirements for substances and mixtures.

### For Substances

<u>Date</u>	<u>Classification</u>	<u>Labeling and Packaging</u>	<u>Safety Data Sheet</u>
20 January 2009 - 30 November 2010	DSD classification required. CLP classification optional.	DSD labeling and packaging rules apply, unless also classified according to CLP, in which case only CLP labeling and packaging rules apply (not DSD).	DSD classification must be given in the SDS. If classified according to CLP and DSD, then must include DSD classification <u>and</u> may include CLP classification.
1 December 2010 - 31 May 2015	DSD classification required <u>and</u> CLP classification required.	CLP labeling and packaging only, but under Article 61(4), substances classified, labeled and packaged in accordance with DSD and placed on the market before 1 December 2010 do not have to be relabeled and repackaged in accordance with CLP until 1 December 2012.	DSD and CLP classifications must both be included in the SDS.
From 1 June 2015 (DSD repealed)	CLP classifications required.	CLP labeling and packaging required.	CLP classifications must be given in the SDS.

CLP: CLP Regulation (EC) No 1272/2008.

DSD: Dangerous Substances Directive 67/548/EEC.

DPD: Dangerous Preparations Directive 1999/45/EC.

**For Mixtures**

<u>Date</u>	<u>Classification</u>	<u>Labeling and Packaging</u>	<u>Safety Data Sheet</u>
20 January 2009 – 31 May 2015	DSD classification required. CLP classification optional.	DPD labeling and packaging rules apply, unless also classified according to CLP, in which case only CLP labeling and packaging rules apply (not DPD).	DPD classifications must be given in the SDS. If the mixture is classified according to CLP <u>and</u> DPD, then must include DPD classification and may include CLP classifications.  But, if the mixture <u>and</u> its constituents are all classified according to CLP, then the SDS must include CLP, DSD and DPD (as applicable) classifications for the mixture and its components.
From 1 June 2015 (DPD repealed)	CLP classifications required.	CLP labeling and packaging only, but under Article 61(4), mixtures classified, labeled and packaged in accordance with DPD and placed on the market before 1 June 2015 do not have to be relabeled and repackaged in accordance with CLP until 1 June 2017.	CLP classifications must be given in the SDS.

CLP: CLP Regulation (EC) No 1272/2008.  
DSD: Dangerous Substances Directive 67/548/EEC.  
DPD: Dangerous Preparations Directive 1999/45/EC.

**For more information about the issues discussed in this update, or Sidley’s EU law practice more generally, please contact one of the following lawyers:**

**Laurent Ruessmann**  
Brussels  
+32.2.504.6464  
lruessmann@sidley.com

**Christopher L. Bell**  
Washington, DC  
+1.202.736.8118  
lbell@sidley.com

**Roger R. Martella, Jr.**  
Washington, DC  
+1.202.736.8097  
rmartella@sidley.com

BEIJING BRUSSELS CHICAGO DALLAS FRANKFURT GENEVA HONG KONG LONDON LOS ANGELES NEW YORK SAN FRANCISCO SHANGHAI SINGAPORE SYDNEY TOKYO WASHINGTON, D.C.  
[www.sidley.com](http://www.sidley.com)

*Sidley Austin LLP, a Delaware limited liability partnership which operates at the firm’s offices other than Chicago, London, Hong Kong, and Sydney, is affiliated with other partnerships, including Sidley Austin LLP, an Illinois limited liability partnership (Chicago); Sidley Austin LLP, a separate Delaware limited liability partnership (London); Sidley Austin, a New York general partnership (Hong Kong); Sidley Austin, a Delaware general partnership of registered foreign lawyers restricted to practicing foreign law (Sydney); and Sidley Austin Nishikawa Foreign Law Joint Enterprise (Tokyo). The affiliated partnerships are referred to herein collectively as Sidley Austin, Sidley, or the firm.*

