The CLP Regulation: Don't wait until December 2010

Regulation (EC) No 1272/2008 on the Classification, Labelling and Packaging (CLP) of chemical substances and mixtures, which implements the UN Globally Harmonised System (GHS) at EU level, entered into force on 20 January 2009.

The deadline for implementing the new system is 1 December 2010 for substances (coinciding with the first registration deadline for phase-in substances), and 1 June 2015 for mixtures.

Does that means that companies can wait until December 2010? Unfortunately not. For several reasons, as described below, action is needed now and certainly before 1 December 2010.

CLP compliance schedule

The CLP Regulation will gradually replace the current rules of Directives 67/548/EEC for dangerous substances (DSD) and 1999/45/EC for preparations (DPD) during a transition period ending on 1 June 2015, when both Directives will be definitively repealed.

This means that all substances and preparations ("mixtures" under the CLP) will need to be "classified", "labelled" and "packaged" according to the CLP after that date. In the meantime, and without prejudice to the possibility to resort to early implementation of the CLP Regulation rules as described below, the DPD and the DSD will continue to apply, as follows.

Substances

The "classification" provisions in the DSD will continue to apply until 1 June 2015 and classification in accordance with the DSD will be required until that date. However, the classification provisions in the CLP Regulation will start to apply as from 1 December 2010, and manufacturers and importers are required to ensure that substances are classified in accordance with both the old and new classification systems during the period 1 December 2010-1 June 2015. In other words, manufacturers and importers will have to ensure "double" classification from 1 December 2010 until 1 June 2015.

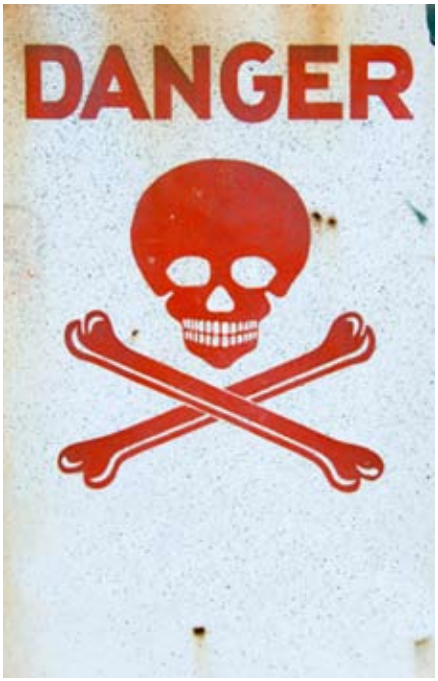
The "labelling" and "packaging" provisions in the DSD will continue to apply until 1 December 2010, after which they will be repealed and definitively replaced by the labelling and packaging rules in the CLP Regulation. This means that implementation of the labelling and packaging rules in the CLP Regulation will have to be ensured from that date.

Mixtures

The "classification", "packaging" and "labelling" rules of the DPD will remain applicable until 1 June 2015, after which only the CLP Regulation rules will apply. As will be further explained below, suppliers are allowed to implement the new classification, labelling and packaging rules already now, in which case the DPD rules would not apply to them, including classification.

In addition to the above, there are several other aspects of the CLP that are already applicable today.

Double classification of substances to meet the old and new rules will be required from 1 December 2010 to 1 June 2015



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DSD Annex 1 deleted

Annex I to the DSD has now been deleted and transferred to the harmonised classification and labelling entries in Annex VI of the CLP (Table 3.1), with Table 3.2 providing the corresponding GHS-based classification and labelling. This means that today, Annex VI of the CLP is the applicable reference for EU harmonised classification and labelling that must be used by companies when classifying and labelling their substances/preparations.

The problem is that for some entries, the harmonised classification and labelling in Annex VI are not identical to those in the previous DSD Annex I. Companies should verify the status of the classification and labelling of their substances and preparations under Annex VI and, if this different from that in Annex I, amend current product labels and safety data sheets. As the CLP is a Regulation, Annex VI is directly applicable in all the Member States and companies may not invoke national provisions implementing Annex I of the DSD to avoid consideration of Annex VI. However, they could seek advocacy efforts and possible legal remedies to correct discrepancies flowing from the new Annex VI entries.

30th and 31st ATP to DSD Annex I

The transfer of Annex I entries to Annex VI does not include the 30th and 31st amendments to technical progress (ATP) of the DSD, which were adopted before the entry into force of the CLP Regulation. This has created confusion among operators as to the status of these ATPs due to the deletion of Annex I following the entry into force of the CLP Regulation.

It has now been clarified that the harmonised classification and labelling provisions introduced by the 30th and 31st ATPs are inapplicable with the result that:

* Companies have no legal obligation to apply the "new" classifications introduced by the ATPs, although they can do so to avoid

that national authorities then question that different self-classification new entries,

✱ Companies cannot apply revisions or deletions of Annex I "old" entries that were introduced by the ATPs but not yet reflected in Annex VI of the CLP.

The Commission has now submitted a proposal for the first ATP to the CLP Regulation, which includes the entries in the 30th and 31st ATPs and which should be finally adopted by June-July of this year.

2010 deadline applies to all Substances

Although companies are only required to classify, label and package their substances using CLP classifications from 1 December 2010, it is important to realise that this deadline applies not only for substances that require registration on 1 December 2010, but for all substances that are being placed on the market in the EU, regardless of tonnages and whether they are phase-in or non phase-in substances! In connection to this, the CLP has also deleted with immediate effect Title XI of REACH on the "classification and labelling inventory" and transferred an amended version of these provisions under Chapter 2 of Title V of the CLP Regulation itself.

The amendments are of minor importance – except that they bring benefits for article producers and importers who are exempted under the CLP rules from classification and labelling inventory notification and for substances and preparations covered by sector specific EU legislation, to which the the CLP Regulation does not apply at all. But many companies may not have realised that the obligation to notify the new CLP classification and labelling of substances by 1 December 2010 also applies to all substances placed on the EU market that are classified as "dangerous" ("hazardous" under the CLP), not only those that require registration by that date!

This will seriously affect manufacturers of low volume substances and importers of either substances and preparations classified as dangerous, but also large companies that are currently concentrating their scarce resources on the registration of the substances subject to the first registration deadline.

Importers of preparations are particularly vulnerable to non compliance. Unless they are accorded access to compositional information, they have no other option than to rely on the classification and labelling provided by the exporters. The due diligence they should exercise may include a request for positive assurance that the classification is accurate and an indication of the dangerous substances in the preparation that trigger classification.

Early implementation of the CLP

As indicated above, companies are only "required" to classify, label and package their substances and mixtures using CLP classifications from 1 December 2010 and 1 June 2015 respectively. However, the CLP Regulation allows companies to use the CLP classification on their labels and safety data sheet already today, provided that they continue to "classify" the substances also in accordance with the DSD until 1 June 2015. In other words, the supplier would still be required to ensure "double" classification, i.e. classification in accordance with both the DSD and the CLP Regulation. There is no such condition for classification of mixtures, which can therefore be classified, packaged and labelled in accordance with the new rules in total replacement of the DPD rules.

'The CLP Regulation requires expert consideration today'

Early implementation of the CLP classification and labelling remains a supplier's decision. However, it may present advantages in a number of cases and companies should consider assessing the expected impact of the new rules to determine if this is the case with their substances and mixtures.

✱ First, companies may consider early implementation each time the shift to the new system appears to be a straightforward exercise. Early implementation could allow them to focus future efforts on more complicated regulatory compliance challenges, including REACH.

✱ Early implementation of the new system may also be an interesting option to pursue where this could result in a lower or more suitable level of classification and labelling of substances and preparations. The new classification and labelling rules for substances with CMR hazards provide a good example in this connection. The current system does not allow suppliers to specify the relevant route of exposure that causes the hazard. If ethanol was to be classified "carcinogen 1" on the basis of epidemiological data relating to ethanol consumption by the oral route, the required labelling does not allow them to specify that carcinogenic effects are restricted to exposure via the oral route/ingestion. This is now possible under the new system, if available hazard data exist showing that the other routes of exposure do not contribute to the hazard.

✱ Finally, the new classification and labelling rules for mixtures also appear to offer good potential to reduce the current level of hazard classification. This may well be the case with untested mixtures. Under the current rules, untested mixtures should be classified and labelled on the basis of data on their ingredients, by application of the "conventional method". This method has been criticised as leading in most cases to over-precautionary/conservative classifications (and labelling). Although this principle is maintained in the new CLP system, its application has been restricted to cases where read across from similar mixtures is not possible, albeit with certain exceptions, for example for carcinogenic, germ cell mutagenic or reproductive toxic substances (CMR) substances. In other words, the CLP Regulation gives clear precedence to the use of data on similar mixtures using "'bridging principles", as well as expert judgment and weight of evidence, with the conventional method being the last resort.

For all these reasons, the CLP Regulation should not be stored on shelves as next year's compliance duty, but requires expert consideration today.

For further information contact Mayer Brown

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