Managing the patchwork

Tim Becker, chief REACH officer at **REACHLaw**, advises on critical aspects for chemicals companies to ensure REACH and CLP compliance post-2010

2010 was the year of major compliance deadlines for chemicals manufacturers and importers under the EU's REACH and Classification, Labelling & Packaging (CLP) Regulations, with fixed dates on 30 November and 1 December 2010 and 3 January 2011. Some 25,000 REACH registrations and 3.1 million CLP notifications have lifted the implementation process to the next level; the EU authorities have plenty to enforce now and chemical users need to be sure that they source from compliant suppliers, whereas the next deadlines are already looming.

It is easy for companies to get lost in the jungle of REACH and CLP compliance these days, but it is not a good time to be doing so. Building up and maintaining a compliant organisation is a key necessity for all affected companies and should preferably be part of an integrated global regulatory compliance approach.

Have you done your homework?

Virtually every chemicals company operating in the European Economic Area (EEA) market should have already made considerable efforts in order to comply with the REACH and CLP Regulations. The task list has been rather straightforward so far. The first step should have been an internal assessment in your company to map, for your raw materials sourced and products sold:

- Whether they qualify as substances, mixtures or articles
- Whether you are a manufacturer, importer, distributor, downstream user (including formulators) and/or other actor in the supply chain, established within or outside the EEA
- Certain parameters determining REACH & CLP obligations, such as annual volume information, hazard classification, uses and properties triggering an exemption

In a second step you should have been able to determine your responsibilities in relation to your suppliers and customers and should have taken the necessary action, such as:

- Pre-registration of existing substances by 1 December 2008
- Registration of high volume and certain very dangerous substances by 30 November 2010
- CLP classification and labelling of substances by 1 December 2010 and notification by 3 January 2011
- CLP notification of certain substances in mixtures by 3 January 2011
- Update of safety data sheet (SDSs) for substances and mixtures, with limitations, according to the revised REACH Annex II by 1 December 2010

From 2011 onwards, chemicals companies are facing a much more fragmented situation in terms of REACH and CLP compliance, which they should strive to get under control for the sake of business continuity. Figure 1 illustrates the various current issues with regards to compliance.

A myriad of scenarios

There is nowadays a great variety of possible compliance or non-compliance scenarios (Figure 2). The first substances have been registered, but many others have not yet been. Substances could have been erroneously registered as intermediates under strictly controlled conditions. Different versions of REACH-compliant SDSs for substances and mixtures may be provided down the supply chains, depending on the registration status and classification of the substance or the applicability of transitional provisions allowing continued use of 'old' SDSs.

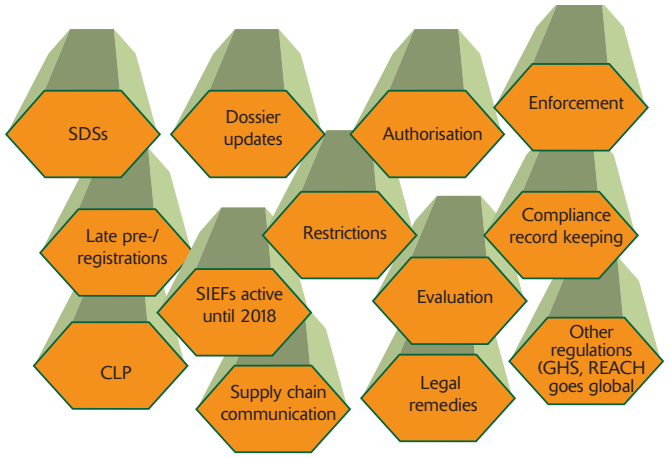

Figure 1 - REACH & CLP compliance issues after 2010

In addition, substances placed on the EEA market these days may be REACH-compliant but not CLP-compliant, for example because notification to the European Chemicals Agency's (ECHA's) Classification & Labelling Inventory was omitted for a hazardous additive imported in volumes below 1 tonne/year. Hazardous substances placed on the EEA market need to carry labels according to CLP, whereas mixtures may still be labelled according to the 'old' Dangerous Preparations Directive (DPD).

Hence, determining whether a product is 'compliant' with REACH and CLP is very complex. This makes it particularly difficult for downstream actors, who are reliant on registrations, SDSs or labels from manufacturers or importers. One supplier may be compliant, another not. Mixtures are even more difficult to assess, because the compliance status relates partly to the mixture as a whole, with regard to SDS and labelling, and partly to the component substances, with regard to registration and CLP notification compliance.

Showing compliance

Considering the complexity of assessing compliance with REACH and CLP requirements, it is equally challenging for companies to show compliance to customers, enforcement authorities or Customs. Companies are required to keep in-house compliance records. These are to be shown to EEA enforcement authorities upon request but both Regulations are quite vague about the extent of the record-keeping obligation.

Basically all relevant information on the fulfilment of a company's REACH obligations should be stored. According to feedback received from inspections so far, authorities place great value on a coherent record-keeping system that is based on the REACH principles (such as per legal entity and substance) and major parameters triggering the different obligations (such as classification, volumes and uses). Setting up such a system requires an advanced understanding of the REACH and CLP regulatory framework.

By contrast, the communication tools to be used by suppliers of hazardous substances and mixtures vis-à-vis their customers are well-defined. A SDS according to REACH Annex II needs to be provided to professional customers and a hazard label

according to CLP Title III or the DPD on the packaged substance or mixture must be supplied to all customers, including consumers. Suppliers should ensure that these tools are correct and up-to-date.

There is no legal basis to ask a supplier for 'REACH compliance certificates', documents issued by ECHA, pre-registration numbers or even registration numbers for non-hazardous substances. Suppliers are therefore advised to have a consistent approach as to what information they are willing to communicate to customers and how, beyond what is strictly required under REACH and CLP, in order to show compliance in the supply chain.

Managing change

An important aspect for maintaining a REACH- and CLP-compliant organisation is to monitor continuously and react appropriately to changes that may occur all over the place. A major potential source of such changes is your own business. Each time you switch suppliers, get new customers, substitute raw materials, formulate new products, increase volumes imported or produced, carry out M&A activities, etc., you need to assess the impact on REACH and CLP and take further action.

Another important subset is changes to the regulatory requirements, such as amendments to the law or guidance. ECHA has recently published updated versions of the guidance on registration and for intermediates, considerably tightening the conditions for intermediate registrations. Even though such guidance is not legally binding, it is applied by authorities and usually becomes industry standard, so you had better follow it.

Furthermore, third parties may ask you to take further action in terms of REACH and CLP compliance. ECHA may request further information from the registrant, if a dossier it checks is deemed non-compliant. National inspectors may visit your premises and order you to correct deficiencies observed, the Lead Registrant may claim a further cost share for additional testing or new information may become available, suggesting a different classification from that used so far.

Company actions to accommodate those changes may be of a regulatory nature, such as new registrations, updates of dossiers, chemical safety reports, SDSs, labels or applications for authorisation. Other such actions may be of a more commercial nature, such as changing suppliers or substances or discontinuing certain activities.

Compliance strategies

Companies have different options in various respects to ensure compliance with regulatory requirements. The decision on the path to take depends to a great extent on the criticality of certain raw materials and products on one hand and the individual company philosophy on the other. In terms of REACH compliance, a company may, for example, choose:

- To register early, source only from registered suppliers or register itself instead of being dependent on others

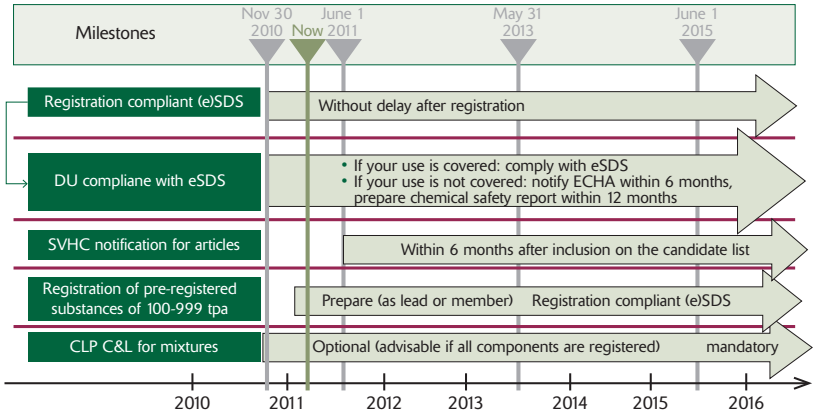

Figure 2 - Compliance & non-compliance scenarios under REACH & CLP

- To work based on 'worst-case' assumptions with maximum obligations or build a strong case to justify a position involving minimum or no obligations
- To take 'over-compliance' measures to be on the safe side
- Between proactive or reactive approach regarding dossier updates or supply chain communication
- To substitute substances of very high concern with less hazardous substances, if alternatives are available
- To outsource regulatory compliance functions to service providers

In any case, companies are advised to include appropriate clauses in contracts with suppliers and customers, as they are efficient means to mitigate risks and clarify roles and responsibilities of the parties in relation to each other.

Focus on eSDS

In 2011 one of the first action points for companies having registered dangerous substances by 30 November 2010 is to update their SDSs 'without delay' following registration, in order to align them with the dossier, and enclose so-called Exposure Scenarios (ESs), describing the conditions of safe use that are relevant for downstream customers. The result is a so-called 'extended' SDS (eSDS).

Once the customer who is using the substance receives the eSDS, the clock starts ticking for him to assess whether or not his use conditions are covered by the ES. If his use is not covered, he may have to inform ECHA within six months of receiving the eSDS and carry out his own Chemical Safety Assessment within 12 months.

In terms of the next registration phase, the time left until the deadline of 31 May 2013 for existing substances manufactured or imported in quantities of 100 tonnes/year or more seems to be ample at a first glance. However, the data gaps to be filled through testing or alternative methods are likely to be considerably bigger than for the high volume substances registered in 2010.

Experience from the first deadline also shows that the preparation of Chemical Safety Reports was in many cases a much more resource-intensive challenge than initially expected. With

Figure 3 - Next deadlines for REACH & CLP

Product	Deadline	Classified	SCC	Pre-reg	Registration	CLP notification	eSDS	CLP label	Compliant
Substance	2010	Yes	No	Yes	Yes	No	Yes	Yes	Yes
Substance	2010	No	No	Yes	Yes	No	No	No	Yes
Substance	2013	Yes	No	Yes	No	Yes	No	Yes	Yes
Substance	2013	No	No	Yes	No	No	No	No	No
Substance	2010	Yes	No	Yes	Yes	No	No	Yes	No
Substance	2018	Yes	No	No	No	Yes	No	Yes	No
Substance	exempt	Yes	No	No	No	No	No	No	No
Intermediate	2010	Yes	Yes	Yes	Yes	No	No	Yes	Yes
Intermediate	2010	No	No	Yes	Yes	No	No	No	No

this in mind, major manufacturers of a 2013 substance cannot start early enough to assess the resources available for what is needed in terms of expertise, data and finance and advancing the formation of consortia with other major players, if deemed appropriate for the purposes of data, work and cost sharing.

Smaller companies with a later registration deadline are advised to check whether a 2010 registration is already available. In this case, there may be no reason to wait and an early registration may be advisable in order to get the marketing benefit associated with a registered substance.

Beyond REACH & CLP

The EU and the rest of the world are becoming increasingly regulated. REACH is prompting similar changes globally. CLP is only the transposition in the EU of the UN's Globally Harmonised System, which is being implemented also in many other countries worldwide.

REACH is prompting similar changes globally. A topical example is the Regulation on the Inventory & Control of Chemicals in Turkey, which foresees a deadline of 31 March 2011 for the notification of existing chemicals by manufacturers and importers. Exporters to Turkey may appoint a Turkish-based representative similar to the Only Representative in the EU for REACH notification.

Full and active compliance with REACH and CLP will certainly facilitate the adoption of other similar chemicals legislation, but differences necessitate sound knowledge of the regulation in question. Even the magnitude of new chemicals regulations represents only a small fraction of the evolving global regulatory framework. Global regulatory compliance is becoming a strategic issue for internationally operating chemicals companies affecting markets, investments, manufacturing processes and product portfolios.

Many companies encounter difficulties in keeping track of the new developments or lack the competencies and management processes in place to assess the business impact of regulatory changes in specific markets and to take the necessary action. It is therefore essential for larger chemicals companies to design and implement a global regulatory compliance function in their organisation.

Conclusions

After the major 2010 deadlines, REACH and CLP are presenting themselves as a continuous patchwork of compliance issues that deserve to be organised properly within your company. Putting a system in place and finding the right compliance strategy for your company requires a sophisticated understanding of the requirements.

You should be able to monitor and react to changes of your business and regulatory standards and answer to authorities and various industry players on compliance issues. In terms of REACH compliance, the preparations by leading manufacturers for the next registration deadline of 31 May 2013 should start as soon as possible to ensure timely construction of the joint registration dossier.

Another priority for 2011 is the generation of eSDSs for registered substances that are classified. Beyond REACH and CLP companies are urged to monitor and follow up on the fast changing global regulatory framework which may be relevant for their business, as part of an integrated compliance approach, possibly using external specialists who can provide the necessary legal and technical resources to manage global regulatory compliance.

For more information, please contact:
Tim Becker
REACHLaw Oy
Keilaranta 15
FIN-02150 Espoo
Finland
Tel: +358 40 7738 143
E-mail: tim.becker@reachlaw.fi
Website: www.reachlaw.fi