



REACH, CLP and RoHS – Critical issues in Chemical Regulation for 2010

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"REACH is a key example of balance-striking between the three pillars of sustainable development: competitiveness, social and environment. REACH ensures a high level of protection of human health and the environment, while also playing an important role to encourage innovation, foster competitiveness and better enable enterprises meet essential demands of consumers"

Joint statement of European Commission Vice President Tajani and Environment Commissioner Potocnik, visiting the European Chemicals Agency, 25 March 2010.

2010 will see some critical challenges in the development and implementation of the REACH and CLP Regulations and the RoHS Directive. Whether or not the businesses coping with this legislation share the uplifting views of the European Commission, they will be affected by the legal and regulatory changes, and for some being sufficiently prepared is a matter of critical business risk.

REACH

The REACH chemicals Regulation 1907/2006 came into force on 1 June 2007 and covers the registration, evaluation and where necessary authorisation and restriction of chemical substances, on their own, in mixtures and in some case in articles. Key features of REACH are that it is based in the 'producer responsibility' of manufacturers, importers and downstream users for what they place on the market. Also key is the 'no data, no market' principle in A. 5 whereby if a substance requires registration and has not been registered, it may not lawfully be placed on the EU market. REACH is applied in individual EU Member States including the UK by national enforcement regulations, applied by Member State competent authorities.

Classification, labelling and packaging 'CLP' 'CLP' regulation

The Classification, Labelling and Packaging Regulation 1272/2008 will place obligations on manufacturers, importers and downstream users of substances and mixtures to classify substances placed on the EU market. The CLP Regulation imports most of the Globally Harmonised System 'GHS' for hazard descriptions and symbols. This will affect all substances subject to registration, including those intentionally released from articles. Substances and mixtures classified as hazardous have to be labelled and packaged according to the CLP Regulation.

A number of existing classifications – perhaps 3-5% - will change under these rules. In some cases, retesting will be required in order to record physical hazards (for example if substances are explosive or corrosive) under the new system. Manufacturers and importers and suppliers will need to comply with the new classification and labelling requirements.

Very importantly, new CLP classification and labelling can affect obligations under much other legislation, including the Seveso Directives, waste legislation, the RoHS Directive and the Volatile Organic Compounds Directive. Substances not previously within the scope of this other legislation may be brought in under the CLP Regulation.

For all substances subject to registration and for all substances classified as hazardous under the CLP, there will be notification obligations to ECHA regardless of the tonnage imported, and CLP inventory notification will be a very major obligation in some cases.

Compliance with the CLP Regulation is required for **substances** by 1 December 2010. For **mixtures** compliance is required by 1 June 2015. There are some transitional provisions for products in stock. Where substances are subject to CLP inventory notification and are 'placed on the market' after 1 December 2010, notification is required by 3 January 2011.

Firms needs to check and review arrangements for compliance with the CLP Regulation as a matter of some priority, especially in areas such as compliance with the new and revised requirements for Materials Safety Data Sheets. Although the CLP Regulation appears largely procedural, and although in the longer term there may be advantages for multinational operations in the worldwide standardisation of classification and labelling under the GHS system, in the short term the scope for mistakes and non-compliance is really very high.

REACH Registration Issues for 2010

The incoming European Commissioners Tajani and Potocnik have underlined that the 30 November 2010 deadline under REACH for registration of high volume chemicals and particularly hazardous substances is only a few months away. The estimate that 9,000 substances will be affected by this first 'phase-in' deadline – other industry sources estimate around 12,000 substances are affected.

The problem is that as at, for example 29 April 2010, the website for the European Chemicals Agency 'ECHA' showed that Lead Registrants had been appointed within Substance Information Exchange Fora 'SIEFs' for only 2,487 substances.

This kind of disparity has led some industry sources to warn of registration 'chaos' in November 2010, with up to 75% of substances failing to meet the first registration deadline, and continued supply to the EU market of key substances required for manufacturing processes becoming illegal. They warn that this could have some key adverse effects. These include essential uses of substances not being included in the registration dossiers under preparation (for example where the Lead Registrant only addresses uses as an Intermediate); loss of continuity of supply of product to manufacturing industry, and possible mass non-compliance, with impacts on procurement and supply chain arrangements.

Nobody yet knows for sure whether this is an issue like the 'Millennium Bug', predicted to bring computers to a halt on 1 January 2000, and somehow life will carry on for those affected. However, for effective contingency planning, many responsible industries are expecting considerable problems.

Authorisation, Substitution

The EU Commissioners also announced on 25 March that agreement had been reached on criteria for identifying persistent, bioaccumulative and toxic substances, or very persistent and very bioaccumulative substances. All available information is to be considered in what they refer to as a "weight of evidence" approach. Settling the criteria for 'PBT/vPvB' properties will be of practical importance to both registration and authorisation.

However, of much more immediate concern to many industries is the Commissioners' firm political support for rapid expansion of additions Substances of Very High Concern 'SVHC's on the REACH 'Candidate List'. The two EU Commissioners agreed a roadmap for adding 106 priority SVHC substances to the existing 29 substances by 2012, and they called on Member State competent authorities to add more. That comes much closer to the demands of the environmental NGOs and their 'Substitute it Now!' or SIN list, with some 356 substances, while many industry sources say that as many as 3,500 substances are well known and formally listed as having CMR characteristics.

The practical effects of this are very wide indeed. When a new substance is proposed for identification as a SVHC under REACH, this results in public consultation and an opinion by a Member State Committee of ECHA before it is actually added to the Candidate List. But for the most part, the specific characteristics of the substance, as carcinogenic, mutagenic, reprotoxic, endocrine disruptive or of equivalent effect, are not seriously at issue, as many substances are already on other lists as having these characteristics. The difference

is that even preliminary consideration under REACH will trigger both formal notification obligations, and commercial pressure from customers and consumers for substitution. Many customers and consumers will not wait for the formal operation of the legal provisions of REACH, but will simply apply commercial pressure for that problem to be avoided. Further down the line, substances may be selected for prioritisation and for inclusion on an Authorisation list (REACH Annex XIV), which will mean that users have to undergo a lengthy and expensive process to justify their continued use, if they are able to do so.

To all this, environmental NGOs and indeed EU Member State governments may respond that that is the point of REACH, it is supposed to apply pressure for substitution of chemical substances with adverse effects with safer alternatives. It is the pace of change, the unpredictability and the timescales for delivering substitute substances that are going to cause acute problems for many major industries.

SVHCs and consumer rights to know

Article 33 of REACH provides that –

"Any supplier of an article containing a [Candidate List] substance ... in a concentration greater than 0.1% by weight ... shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance."

We can reasonably expect this obligation to gain increasing prominence as for example some environmental NGOs such as the German Friends of the Earth 'Bund' encourage consumers to ask questions under these 'right to know' provisions about SVHC substances in articles. For many practical purposes, industry will need to be able to get access to this kind of information for substances on the Candidate List and for substances nominated by EU Member States as possible future 'candidates' on the 'register of intentions'.

Enforcement

Reach Enforcement Regulations are now in place, with the HSE as principal enforcement authority in most cases. Non-registration where the November 2010 deadlines are missed could become a significant enforcement policy issue. The HSE is also participating in the REACH-EN-FORCE 1 and 2 projects across the EU, checking pre-registration and registration and Safety Data Sheets against the 'no data, no market' rule. The next step is likely to be targeted inspection campaigns.

Supply chain compliance

Significant businesses which are well advanced with their REACH implementation planning report that they have now moved well beyond the initial stages of sending out supplier questionnaires about REACH to suppliers, and are now busily engaged considering competing IT packages capable of delivering better targeted and more specific information across the supply chain. Contract revisions are under way to point up suppliers' responsibilities for REACH compliance, and as always, good two way communication up and down the supply chain is the key to successful joint working.

RoHS directive revisions

The Restriction on Hazardous Substances 'RoHS' Directive 2002/95/EC applies as from 1 July 2006 to the following substances in electrical and electronic equipment –

- Lead
- Mercury
- Cadmium
- Hexavalent chromium
- PBB (polybrominated biphenyls) and PBDE (polybrominated diphenyl ethers)

where the quantities exceed stated maximum concentration values.

There are, currently, some important exclusions from the scope of this Directive, including military equipment, and the means of transport, including aerospace equipment, some of which includes and uses the key RoHS target substances.

Changes are under active negotiation at the European level which could greatly widen the scope of the Directive and even apply 'open scope' rules with no limitations. Such changes are expected to have very wide implications for industries currently enjoying scope exclusions, and like REACH authorisation provisions, are likely to result in greater pressure, both legal and commercial, for the advancement of substitution, and for temporary derogations or exclusions while affected industries adapt.

For example, the aerospace industry may lose the benefit of current exemptions, and some key aerospace applications of substances covered by the RoHS Directive, such as lead and hexavalent chromium, would be covered by the restrictions in that Directive.

This in turn could result in tensions or even conflicts with international airworthiness regulations, which in some cases require results that (at present) only restricted substances can deliver.

Further information

At Burges Salmon LLP our key chemicals regulations experts have been closely involved with the REACH Regulation through two and a half years negotiation, and have worked with a range of industries, trade associations and several governments on key aspects of the implementation of this and related legislation.

We can provide the back up that companies need to understand their obligations under this important legislation, to work effectively with their supply chains and regulators, to have in place the contracts and documentation that they need, and to resolve problems and handle enforcement actions. We have in-depth experience of delivering senior level training and briefing on this legislation as required.

For further information about REACH, CLP or chemicals regulation issues, please contact:



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