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Environment and energy briefing from Burgess Salmon
published in the December 2010/January 2011 issue of
The In-House Lawyer:

Chemicals regulation update: live issues

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Chemicals regulation update: live issues



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A KEY MILESTONE IN THE IMPLEMENTATION of the REACH (Registration, evaluation, authorisation and restriction of chemical substances) Chemicals Regulation 1907/2006 (REACH) was the first registration deadline on 1 December 2010.

REACH

Registration was required by this date for:

- substances supplied at or over 1,000 tonnes per year per legal entity;
- R50/53 substances (eg hazardous to the aquatic environment) at or over 100 tonnes; and
- substances containing category 1 or 2 carcinogens, mutagens or reprotoxins (CMRs) supplied at or over one tonne per year.

Registration dossiers were arriving thick and fast at the offices of the European Chemicals Agency (ECHA) in Helsinki throughout October, but it is by no means clear that all, or even most, of those requiring registration were able to meet this first deadline. As of 8 November 2010, the ECHA reported that there has been 10,619 registrations and 554,291 classification and labelling notifications.

Some industries continue to voice extreme concerns at the possible practical effects of a significant failure to meet registration deadlines across Europe, with risks to business continuity high on the list of

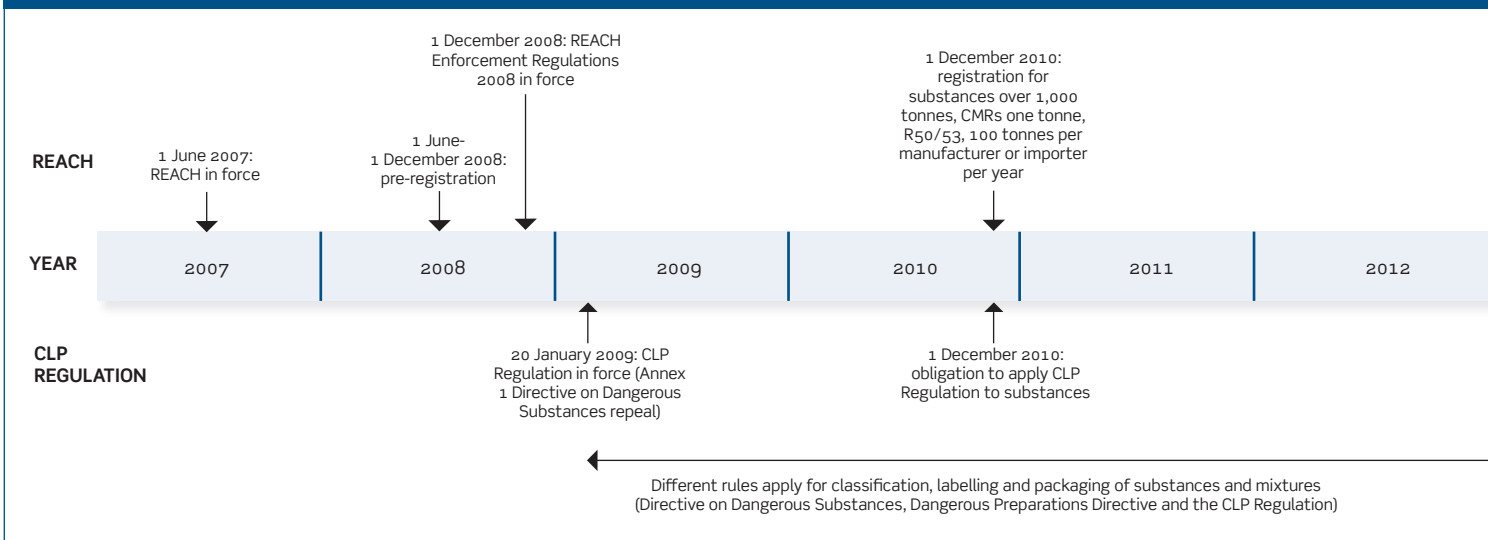
problems, as risks grow that suppliers of some key substances either cannot or will not continue to supply them to EU downstream users. Firms potentially affected by this kind of interruption to supplies may wish to track the progress of the Directors' Contact Group on the ECHA website, a high-level group of representatives from the European Commission, ECHA and industry trade bodies, set up to try and find practical ways to resolve some of the emerging difficulties in applying REACH.

A significant failure in the first registration process would also have widespread implications for contractual arrangements up and down complex supply chains, where businesses are already hard pressed to obtain all the information that they need from their suppliers to deliver compliance with REACH.

Another key development is the continued addition of Substances of Very High Concern (SVHCs) to the candidate list for authorisation under REACH.

Having substances on the candidate list for the much more restrictive and expensive authorisation procedure has both legal and practical effects. In legal terms, it imports immediate legal duties, such as the requirement to notify consumers on request about SVHC substances in articles. Other practical duties, such as changes to safety data sheets (SDS) and further notification requirements to ECHA, will

RECENT AND FUTURE TIMELINE OF CHEMICAL REGULATIONS



also come into play. In commercial terms, the importance of having substances on the candidate list, and liable to be added to the annex requiring authorisation to justify their continued use, raises the stakes. It will, in most cases, be difficult, restrictive and expensive to prepare the socio-economic analysis and other evidence necessary to justify the continued use of an SVHC substance. Meanwhile, customers may well conclude that whatever it says in REACH, they would prefer to avoid the substance and the product containing it, and the problems that go with it, hence the commercial pressure from a different kind of 'substitution'.

CLP REGULATION

The EU Regulation on Classification, Labelling and Packaging of Chemical Substances 1272/2008 (CLP Regulation) came into force on 20 January 2009. It implements the internationally agreed Globally Harmonised System of Classification and Labelling of Chemicals (GHS), and will replace both the Directive on Dangerous Substances (67/548/EEC) and the Dangerous Preparations Directive (1999/45/EC) by 1 June 2015.

The obligation to apply the CLP Regulation to substances runs from 1 December 2010. There may be practical changes required to SDS, health and safety materials, and other information within companies that needs immediate review if this is not already in hand. Important notification requirements are due by 3 January 2011. The Health and

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Safety Executive has posted a new website page on the CLP Regulation, and firms with CLP Regulation issues are recommended to start by checking its application to their operations against that page.

Member state competent authorities and industries can propose the harmonisation of classification and labelling under the CLP Regulation, and the first such proposals have been received and are the subject of consultation on the ECHA website.

RoHS DIRECTIVE RECAST

The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Directive (the RoHS Directive) has been undergoing a very important recast or revision, with negotiations between EU institutions, resulting in a first reading agreement. It will affect a large number of industries.

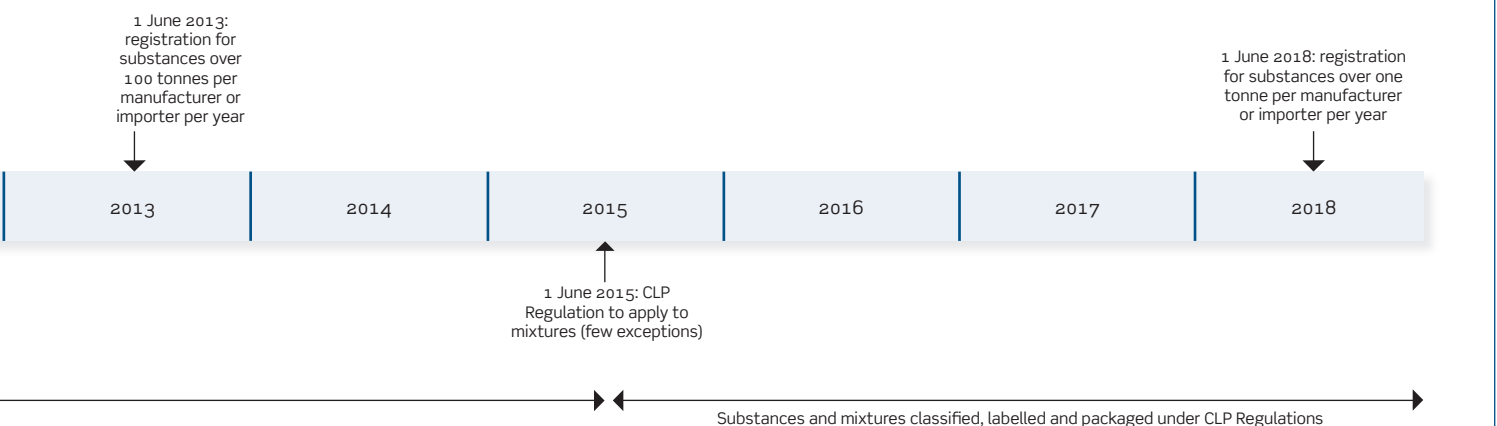
The RoHS Directive originally applied restrictions on the use of a limited list of six hazardous substances in electrical and electronic equipment, namely:

- lead;
- mercury;
- cadmium;
- hexavalent chromium;
- polybrominated biphenyl (PBB) fire retardant; and
- polybrominated diphenyl ethers (PBDE) fire retardant.

Many industries using these substances were nevertheless outside the scope of the RoHS Directive because of wide exemptions.

One likely outcome of the negotiations to recast the RoHS Directive may be to expand its scope, and to restrict the number and availability of exclusions. A case has been made to add both PVC (polyvinyl chloride) and BFR (brominated flame retardants) as newly banned substances. In addition, the RoHS Directive may become a 'Conformité Européene (CE) mark' directive, whereby

(Based on European Chemicals Agency chart)



industry will have to provide enhanced certification to justify its claims to be RoHS Directive compliant.

Each of these areas of negotiation and amendments to the RoHS Directive will affect a wider circle of industries and firms in different ways. The electronics industry has concerns about CE mark requirements. Renewable energy technology companies and generators are concerned about the application of the RoHS Directive to their industry. The aerospace industry is also very anxious about the effects of the recast RoHS Directive on the limited applications that it makes on some of the substances, for which there are few, if any, available substitute products with similar characteristics that meet aviation

and airworthiness quality and certification requirements.

Future progress of the concluding stages of the negotiations on the RoHS Directive needs to be watched closely.

OTHER RELEVANT CHEMICAL REGULATION

Other related proposals not dealt with here concern the regulation of:

- pesticides;
- plant protection products;
- biocidal products; and
- cosmetics.

Possible future legislation and concerns:

- endocrine disruptors;
- combination effects of chemicals; and
- nanomaterials.

For further information or advice on any aspects of chemical legislation or regulation affecting your business, please contact the author.

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William worked for two and a half years on the negotiations of REACH, with industry and trade associations, and has advised a wide variety of businesses and governments on aspects of its implementation.*