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REACH and CLP: chemicals regulation issues for 2010

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THE REACH (REGISTRATION, EVALUATION, authorisation and restriction of chemical substances) Chemicals Regulation 1907/2006 (REACH) entered into force across the EU on 1 June 2007. UK enforcement of REACH is led by the Health and Safety Executive (HSE). The main purpose of REACH is to ensure a high level of protection of human health and the environment. It places duties on manufacturers, importers and downstream users of substances, preparations or mixtures and articles, when they are placed on the market.

SUMMARY

REACH achieves its aims through the registration of the majority of chemical substances, on their own, in preparations or mixtures, or in some case in articles (where the substance in question is intended for release). Registration dossiers, many of which are in preparation for 2010, will be subject to evaluation by the European Chemicals Agency (ECHA) in Helsinki, working with member state competent authorities. Substances of Very High Concern (SVHC) (see description on p29) may be selected for a Candidate List from which 'priority substances' may be required to have authorisation for their continued use. Authorisation is a rigorous, expensive and demanding process, requiring detailed justification for the continued use of the substances, such as socio-economic studies, or their substitution. REACH aims to deliver much more information to the users of chemicals already on the market and to drive the substitution of many problem chemicals by safer alternatives. This is reinforced by outside pressure from non-governmental organisations (NGOs) and others.

REACH also re-enacts the system of restrictions on chemicals from the Marketing and Use Directive (76/769/EEC) from 1976, which allows individual substances to be targeted by strict restrictions or bans.

Restrictions from this earlier Directive may be carried over into REACH, but firms cannot assume that exemptions will also survive the transition and these may need to be separately re-negotiated.

2010 will see some very significant milestones in the implementation of REACH and the related EU Regulation on Classification, Labelling and Packaging of Chemical Substances 1272/2008 (CLP Regulation). However, formidable difficulties must be overcome before many firms can be confident that they are managing the response to this new legislation fully and effectively.

REACH REGISTRATION

For those concerned with REACH, 30 November 2010 will see the first main registration deadline for substances over 1,000 tonnes, carcinogens, mutagens or reprotoxins (CMRs) over one tonne, and R50/53 substances very toxic to aquatic organisms over 100 tonnes, in each case per manufacturer or importer per year. Firms need to remember the key – no data, no market – rule in REACH:

'Subject to articles 6, 7, 21 and 23, substances on their own, in preparations or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.' (Article 5.)

In other words, if a substance requires to be registered under REACH and it has not been registered it may not be marketed in the EU. That is why, between 1 June 2008 and 1 December 2008, 65,000 companies rushed to meet the deadline and pre-registered some 150,000 substances. Where substances have been properly pre-registered, firms can take advantage of the phase-in timetable for full registration, which starts in 2010 for high-volume substances and CMRs or



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‘The German branch of Friends of the Earth, BUND, is understood to be planning a major information campaign for 2010 encouraging consumers to ask companies about the presence of SVHCs in articles.’

their equivalent. Where pre-registration has been missed, registration obligations will apply straight away. The HSE is investigating this as an enforcement issue as there have been several instances where firms have missed the pre-registration deadlines but are continuing to place substances on the EU market. If a substance needs to be registered before 1 December 2010, downstream users had to inform their suppliers of their uses by 30 November 2009.

Registration applications are accompanied by a full dossier of information on each substance. Downstream users must notify manufacturers and importers of their intended uses of a substance, while manufacturers and importers must then include that use in the relevant chemical safety reports and safety data sheets (SDS), having prepared or had access to the relevant exposure scenarios and studies, which they do through the Substance Information Exchange Forum (SIEF) and the registration dossier process. Once manufacturers or importers are notified of a use they can either:

- include that use on the SDS and register the substance;
- refuse to proceed to registration (for example on economic grounds) and cease to supply the substance; or
- register the substance but refuse to add the use to the SDS (for example if they think it is dangerous).

Rather than encounter this kind of stand-off, downstream users and their suppliers need to be identifying problems early and discussing their resolution. It is certain that supplier contracts will change to reflect REACH requirements.

ENFORCEMENT ACTION

The REACH Enforcement Regulations 2008 have now been in force for some time, and it is expected that 2010 will see an increase in HSE and other authority enforcement actions, particularly with companies that have missed pre-registration and registration deadlines but have continued to place substances on the market.

SIEFs and consortia

A SIEF is a forum to help registrants who intend to register the same substance, identified by the pre-registration process. SIEF participants are required to react to requests for information from other participants and to provide other participants with existing studies on request.

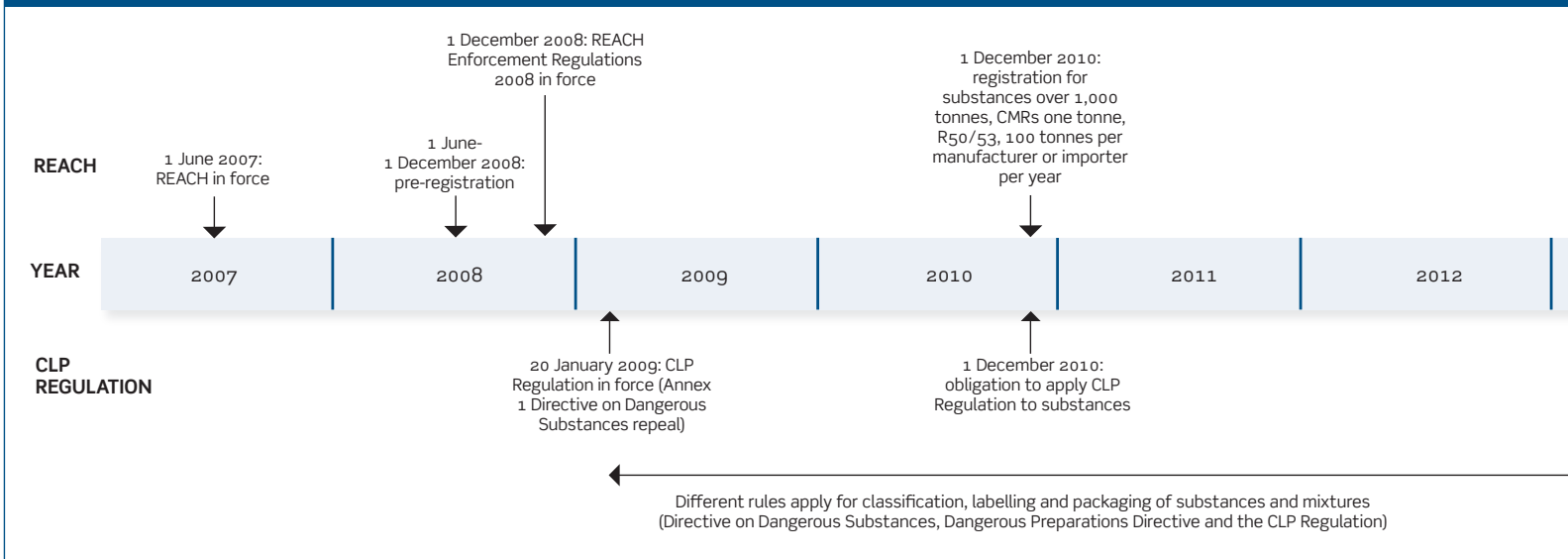
Potential registrants are required to:

- obtain missing information for their registration dossiers from other SIEF participants;
- act collectively in identifying further studies that will be required to comply with registration requirements;
- make arrangements to perform the identified studies; and
- agree on classification and labelling.

All of this is intended to lead to a single joint submission for the registration of each substance.

Within each SIEF, the lead registrant is the co-ordinator of the registration process for that individual substance, acting with the agreement of other assenting registrants. The lead registrant has to submit the joint submission dossier for phase-in substances. Typically, the lead registrant will be a manufacturer or importer who is caught by the first REACH registration deadline in

RECENT AND FUTURE TIMELINE OF CHEMICAL REGULATIONS



2010. Therefore, in many cases, the role has been taken on by some of the larger manufacturers and importers to get the job done, and to prevent interruptions in the supply and availability of individual substances.

By 14 January 2010 lead registrants had been appointed for 2,249 substances, so there is still a very long way to go before the first registration of substances in 2010. There are really significant problems in the manageability of this process, with some SIEFs containing several thousand members, and some large firms that have 'volunteered' to be lead registrant now stuck with the responsibility, between now and 2018, for co-ordinating data sharing arrangements and preparation for the substance registration process between large numbers of more or less co-operative SIEF members. Anyone who knows how difficult it is to get a committee to make critical decisions can begin to imagine the practicalities of getting several thousand SIEF members in a position to make key decisions on the registration of individual substances, particularly where this involves expenditure and co-operation on sharing information with a value.

In many cases practical co-operation is being advanced through informal consortia, which are not a REACH requirement but are a more practical commercial response to making co-operation and data sharing work. Some of those who have signed up to off-the-shelf consortium agreements are

finding that they have not allowed for all of the commercial considerations that apply to individual businesses and industries.

Alerting supply chains

In some cases even well-organised downstream users still have a very long way to go to ensure that their supply chains are well informed about REACH obligations and are able to deliver the information that will keep them within the EU in compliance with REACH. Despite all of the questionnaires, prompting and reminders, the number of small and medium enterprises who have scarcely heard of REACH is surprising, and this is going to put the compliance by larger firms further up the supply chain in question. One response in 2010 is likely to be new contractual provisions placing further obligations on suppliers.

AUTHORISATION AND SUBSTITUTION: SVHCs AND CONSUMER 'RIGHTS TO KNOW'

This remains one of the biggest problem areas within REACH and one where major developments can be expected in 2010. SVHCs are substances that are:

- CMRs;
- persistent, bioaccumulative or toxic (PBT);
- very persistent very bioaccumulative (vPvB); or
- of equivalent concern, such as endocrine disrupters or R50/53 substances (toxic to aquatic organisms).

There are currently 29 SVHC substances on the candidate list for authorisation, with

more added in January 2010. Acrylamide has not been included pending a legal challenge. The presence of some of the substances on that list is already causing critical business continuity problems for some industries in securing the supply of substances essential to the manufacture of articles, or working out whether to try to support the continued authorisation of those substances for continued use under REACH, or to arrange for their substitution by safer alternatives.

However, this is only the beginning of a longer process. The NGO 'Substitute it Now!' (SIN) list cites 267 such substances and many industry lists count some 3,500 substances that are CMRs. For example, one declarable substances list contains known CMR substances, those listed as vPvB or PBT under the OSPAR Convention (formed in 1992 by the Oslo and Paris Conventions), Montreal Protocol on Substances that Deplete the Ozone Layer, Stockholm Convention on Persistent Organic Pollutants, and other restricted substances. More must to be done, either to justify continued use of SVHCs through the authorisation process, which is lengthy, difficult and expensive, or to substitute such substances with safer alternatives, which is what REACH is designed to achieve. Either course can have big implications for companies concerned.

For substances already on the candidate list, provisions of REACH are already in force, which will require that from 2011 EU and European Economic Area producers or importers of articles must notify ECHA if

(Based on European Chemicals Agency chart)

1 June 2013: registration for substances over 100 tonnes per manufacturer or importer per year

1 June 2018: registration for substances over one tonne per manufacturer or importer per year

2013

2014

2015

2016

2017

2018

1 June 2015: CLP Regulation to apply to mixtures (few exceptions)

Substances and mixtures classified, labelled and packaged under CLP Regulations

their article contains a substance on the candidate list above 0.1% (weight by weight (w/w)) and if the substance is in produced or imported articles above one tonne per year per company.

This level of 0.1% (w/w) of a SVHC will also be the trigger for the very important duties in article 33 of REACH, which will give consumers the right to be told by the suppliers of articles whether they contain SVHCs at these levels. Much more will be heard about this consumer information aspect of REACH as the number of substances on the candidate list continues to grow. Public and NGO use of these consumer right-to-know provisions under REACH is likely to become much more actively used in the near future, and will result in greatly increased pressure to make sure that suppliers have access to far better and more reliable information on exactly what is in their articles. The German branch of Friends of the Earth, *Bund für Umwelt und Naturschutz Deutschland (BUND)*, is understood to be planning a major information campaign for 2010 encouraging consumers to ask companies about the presence of SVHCs in articles and reminding them of their rights to information under article 33 of REACH.

CLP REGULATION AND KEY DATES

The related CLP Regulation applies within the EU and complies with the United Nations (UN) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). It will result in major changes to the classification and labelling of substances (from 1 December 2010) and of preparations (from 1 June 2015). It will lead to the repeal from 1 June 2015 of the Directive on Dangerous Substances and the Dangerous Preparations Directive.

The CLP Regulation is about the hazards of chemical substances and mixtures (the new term for preparations), and the steps that have to be taken, mainly by industries, to inform others about them. The hazards of substances and mixtures have to be established before they are placed on the market, and they must be classified in line with identified hazards. Workers and consumers must be able to tell from the labelling what they need to know about any hazardous properties.

ECHA recommends that, to understand the CLP Regulation, businesses should develop

a company inventory of their substances and mixtures, including substances contained in mixtures. ECHA points out that much of this information may already have been collected for REACH. Training will then be needed for appropriate technical and regulatory staff within companies.

In practice, changes to classification and labelling provisions, although not controversial in itself, will imply changes to SDS and, in many cases, health and safety materials and information within companies. This is not related to the same tonnage bands and timetables as REACH so companies need to be engaging with this issue immediately.

The CLP Regulation came into force and repealed annex 1 of the Directive on Dangerous Substances on 20 January 2009. The obligation to apply the CLP Regulation to substances applies from 1 December 2010. The obligation to apply the CLP to mixtures will in most cases apply from 1 June 2015 (for some substances and mixtures other re-labelling and re-packaging deadlines may apply).

REACH INTERPRETATION AND PRODUCER RESPONSIBILITY

One of the main drivers behind the massive efforts expended on the negotiation of REACH, which took several years and resulted in the most comprehensive review of EU chemicals law since the Second World War, included the poor state of knowledge of the characteristics of the 30,000 or more existing chemical substances already on the market. Unlike new substances, these had not been studied, and their effects on their own and in combination were poorly understood. At the same time, very general public concern about chemical exposures led to support throughout the European Parliament, and the majority of EU member state governments voted for a tougher and more effective form of control.

One of the key differences about REACH as a piece of legislation is that instead of landing an under-resourced regulator with a complex set of tests to apply, it applies the principle of producer responsibility:

‘This Regulation [REACH] is based on the principle that it is for manufacturers, importers and downstream users to

ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.’ (Article 1.3.)

To be able to discharge their obligations under REACH, manufacturers, importers and downstream users need to know far more than before about the substances that go into what is placed on the market. The licence to place on the market is tied to the availability of sufficient information to allow safe use.

CONCLUSIONS

REACH and the CLP Regulation are now in force and require a major effort by companies to achieve compliance. However, some companies rightly say that compliance is almost the least of their problems with this legislation, which is really for them a matter of:

- business risk and business continuity;
- continued availability of substances and mixtures that are essential to their manufacturing processes or marketing of their products;
- coping with the huge structural pressures to substitute SVHCs with safer alternatives; and
- justifying the continued use of SVHCs through the authorisation process, with all the reputational risk involved in wider consumer rights-to-know becoming more actively used.

2010 will see major upheavals in REACH SIEFs and consortia as they prepare for the first tranche of substance registrations, tackle the first of the classification and labelling issues, and address the effects on their businesses of substances being added to the candidate list for authorisation. No one would want to minimise in any way all the other pressures on businesses, but – for those affected – REACH and the CLP Regulation need to be near the top of in-trays in 2010.

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