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REACH is Here

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After many years of publicity, negotiations, and preparations REACH is now a reality. REACH entered into force on 1 June 2007. Some duties may not apply for several years but others come into effect immediately. Do you know which duties will affect you and when? Whilst the REACH Regulation is agreed there are still many uncertainties to deal with; for example, how REACH applies to you, your suppliers and customers, the interpretation of the legal text, and guidance not being completed yet. This is a quick summary of the key elements that may affect you now or in the near future and key issues of concern.

Why REACH is important to you

- REACH will impact chemical use and supply in the EU and wider
- Withdrawal of substances from the market is inevitable; is this going to happen in your supply chain?
- Greater information generated by REACH will affect your liability
- Imports into the EU; importers and customers will require help (scientific, technical etc)
- Any legislation of the size and scope of REACH will provide opportunities as well as threats. There will be benefits as well as costs. Don't get into a 'bunker mentality'; take advantage of the opportunities and benefits.

Key Messages

- REACH entered into force on 1 June 2007: it will affect your business either directly or indirectly. If a substance (on its own, in a preparation, or in an article) you use or import or manufacture requires registration failure to do so will mean that it should be withdrawn from the market and/or manufacture stopped.
- Registration of 'phase-in' substances (existing substances listed on EINECS, the European Inventory of Existing Chemical Substances) is staggered over 11 years (2007-2018), depending on quantities manufactured or imported per year per manufacturer or importer: make sure you understand whether this applies to your business, and what information you will need to provide accordingly for registration.

- Registration and other REACH costs will be finalised in an EU Regulation by 1 June 2008. It is likely that there will be reduced fees for joint registrations, and SMEs.
- The pre-registration period, 1 June – 30 November 2008, is for manufacturers and importers wishing to take advantage of the later deadlines for 'phase-in' (existing) substances to make a pre-registration to the new European Chemicals Agency in Helsinki – this is not necessarily a straightforward process, start gathering the information now.
- If you fail to pre-register your substance(s) within the period above, you will not be able to register them using the staggered 'phase-in' periods, but will instead have to register them straightaway to be able to continue manufacturing them or placing them on the market.
- There are new requirements for manufacturers/suppliers to provide information down the supply chain (Safety Data Sheets), from 1 June 2007: make sure you are familiar with these to be able to comply.

Timing

REACH entered into force on 1 June 2007 as the start of a process that is planned to last at least 11 years and possibly appreciably more. The principle milestones concerning the various registration deadlines over the next 11 years are summarised below:

- **1 June 2007:** REACH entry into force;
- **1 June 2008 – 30 November 2008:** Period for pre-registration by manufacturers and importers (registrants) of the phase-in substances they intend to register according to the various phase-in deadlines. In general terms phase-in substances are those listed on EINECS (the European Inventory for Existing Chemical Substances);
- **30 November 2010:** Registration deadline for registrants supplying a pre-registered phase-in substance above 1,000 tonnes per year, or a CMR cat.1 or 2 substance above 1 tonne per year, or an R50-53 substance (PBT/vPvB) above 100 tonnes per year;
- **31 May 2013:** Registration deadline for registrants supplying a pre-registered phase-in substance above 100 tonnes per year;
- **31 May 2018:** Registration deadline for registrants supplying a pre-registered phase-in substance above 1 tonne per year.

Actions Now

Whilst the precise actions to be taken now will depend on each individual company and their substances and supply chains they may include:

- Identifying substances for pre-registration by you (in general terms those you manufacture or import)
- Identifying substances you want to ensure that your supplier will pre-register (in general terms those you depend on for your business)
- Researching alternative substances, suppliers and/or processes for those substances that may be vulnerable to withdrawal from your supply chain
- Putting in places plans to introduce new, and update existing, safety data sheets (SDS)
- Developing an inventory of your substances and their supply chains
- Identifying the implications of REACH for your business
- Identifying information that you consider to be confidential (a next step will be to see whether this information can be protected under REACH)
- Following developments on issues where uncertainty remains (e.g. requirements for substances in articles)
- Improving communication up and down the supply chain (i.e. talk to your suppliers and customers about how to address the consequences of REACH as effectively and efficiently as possible)

Pre-registration

Prior to the Registration process starting for phase-in substances, there is a pre-registration period from 1 June – 30 November 2008, during which 'pre-registrations' of substances that companies (manufacturers or importers) intend to register are submitted to the European Chemicals Agency (ECHA). Based on this information all potential registrants, and potentially downstream users, will form a Substance Information Exchange Forum (SIEF), to share data and associated costs in producing a single hazard data-set for the substance.

Why is Pre-registration so Important?

- **First duty for most under REACH**
- **Vital for all**
- **Applies to 'phase-in' (existing/EINECS) substances**
- **EU Importers: have to pre-register ingredients in preparations**
- **EU Manufacturers: have to pre-register the substances they manufacture**
- **Applies to substances in articles 'intended to be released'**
- **Applies to intermediates subject to registration**
- **Downstream Users: have to ensure the substances supplied to you and on which your business depends are registered up the supply chain to reduce any threat of substance withdrawal**
- **Consequences of failure to pre-register**
 - Possible withdrawal of the substance from the market
 - Early registration as a non-phase-in substance which may be impossible for many
 - Uncertainty
 - N.B. Downstream users are able to publish through the Agency their need for a substance if it is not on the list of pre-registered substances

Summary

- **Timing? 1 June 2008 – 30 Nov 2008**
- **Why?**
 - To allow phase-in substances to take advantage of the phase-in deadlines
 - To enable all registrants of the same substance to prepare a single hazard data-set
- **What information needs to be provided?**
 - Substance name
 - Potential registrant details (or 3rd party representative)
 - Deadline for registration
 - Similar substances (for read-across).
- **How?**
 - Agency publishes list of all those pre-registering substances on its website
- **Then?**
 - Pre-SIEF (to identify whether the pre-registrations are really of the same substance or whether one SIEF in practice has to be broken down into several smaller ones)
 - Start of the SIEF (Substance Info Exchange Forum); can also include DUs and other non-registrants. The SIEF has a duty under REACH to share data and prepare a single hazard data-set.
 - Normally a consortium will be formed which is the legal construct for managing the data sharing process i.e. there will be contracts between the participants governing how it will work.
 - A hazard data-set will be agreed per substance (opting out is possible in some cases).
 - Each registrant makes their own registration at the appropriate deadline.

	Manufacturer	Importer	Downstream User
Pre-registration	<ul style="list-style-type: none"> • Any substances that you manufacture that need to be registered? • What volumes per year of substances do you need to register? • Any isolated on-site or transported intermediates that need to be registered? 	<ul style="list-style-type: none"> • Assess whether the volumes of substances imported on their own or in preparations or in articles (intended to be released) meet registration thresholds. 	<ul style="list-style-type: none"> • Check that your supplier(s) is/are going to register substances that you use – especially any that are essential to your continued business. • Ask your supplier(s) to treat certain uses as ‘identified uses’. Some uses you will want to keep confidential in which case you may have to carry out your own chemical safety assessment for that use

	<ul style="list-style-type: none"> • Check with your downstream users about the uses of the substance that they would like you to treat as 'identified uses' and subject to an assessment to identify how they can be used safely (chemical safety assessment). 		<ul style="list-style-type: none"> • If any substance supplied may not be registered (i.e. withdrawn from the market in due course), identify alternative substances, processes or suppliers. An option may be to manufacture or import the substance yourself. • Identify the relative importance of substances, and plan for feasible alternatives, possible future restrictions, or their possible removal from the market.
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N.B. A pre-registration of a substance will mean that it will normally be registered later and placed on the market. However this will not be the case if:

- the pre-registration has been made by another DU who only wants to make sure that he will be allowed to import or manufacture the substance until the end of the transition period (3, 6, 11 years) in case no other suitable supplier is available
- a manufacturer or importer only pre-registered a substance in order to use up the registration period for phase-in substances and to market the substance until the end of this period without having the intention of marketing the substance in the longer term.

Safety Data Sheet (SDS)

One of the first parts of REACH to have practical effect will be the requirements for SDS. REACH introduces some changes which will enter into force on 1 June 2007. The immediate changes can be summarised as:

- SDS now have to be provided for PBT (persistent, bioaccumulative, and toxic) and vPvB (very persistent, very bioaccumulative) substances and preparations containing these substances in concentrations $\geq 0.1\%$
- exposure scenarios, if prepared up the supply chain for a substance, should be annexed to the SDS
- the format for SDS is slightly changed (sections 2 and 3 change order)

Making any changes required by 1 June 2007 is unrealistic and this is recognised by most if not all EU member state competent authorities. It is the author's view that the enforcement authorities are unlikely to take any enforcement action over any purely administrative change (i.e. change of order of headings 2 and 3 - after all how many prosecutions do you see over SDS which are poor and probably illegal?). If you have a reasonable plan to update the SDS

as and when appropriate (e.g. when other changes need to be made as a result of REACH, by a rolling plan of action) there should not be a problem. The timescale should be kept reasonable e.g. brought fully up to date within 2 or 3 years. You should however have a system in place to check whether the new SDS requirements (e.g. immediately for PBTs, vPvBs, later for 'substances of very high concern' (SVHCs), as CSAs come on stream) apply and if they do to prepare and supply the SDS accordingly.

Substance in Articles (SIA): Latest News

REACH requires substances intended to be released from articles to be registered the same as other substances on their own or in preparations. However, there is considerable debate between the authorities and stakeholders on exactly what these requirements mean, in particular, how an article is defined. This debate is important as there are some widely used 'products' which may fall into the definition of article or be treated as preparations; for example, are adhesive tapes articles or preparations which are 'contained' on tape? Another example is whether a printer ink cartridge including ink is an article or whether the cartridge is an article and the ink should be treated as a preparation. The latter interpretation would certainly add clarity. A further issue is whether an article is the object as imported or the parts of which it is made; for example is a pair of jeans an article or should it be broken down into the material, the zip, and buttons. The REACH text does not make this clear and many influential parties are arguing that an article should be homogeneous. This latter interpretation would have major ramifications for industry.

Guidance (RIP 3.8: Substances in Articles) is being developed which should:

- Provide the means for industry to identify which substances are (intentionally) released from an article and in what amount they are present in those articles
- Identify when action is needed by producers and importers of articles
- Set-out what action is subsequently needed: identify the use of a substance in production of an article up the supply chain, register, notify or no action

It is expected that the guidance will be finalised in June 2007.

European Commission Support – 'Navigator'

The European Commission is producing vast amounts of guidance to help industry cope with REACH. However this is likely to run into many thousands of pages and even then will often only be understandable to experts. This will be impossible for most companies to cope with. In recognition of this the Commission is developing a tool called 'Navigator'. This will ask a series of questions and according to the answers given direct you to the relevant parts of the guidance. This tool is not ready yet but should be helpful.

Guidance

The European Commission is funding a number of projects to develop guidance (known as RIPs – REACH Implementation Projects). This process started in 2004 and has involved stakeholders throughout. The legislative text leaves margin for interpretation on how to meet the requirements of REACH in several key areas. The RIP projects provide an important way for companies to understand what is expected of them to ensure compliance; however it must be noted that the RIPs are only guidance and there may be other ways to comply.

Summary of Progress on RIPs

The following projects have been finished:

- RIP 3.2-1A: Technical Guidance Document (TGD) on preparing the CSR (Scoping) & RIP 3.2-1B: TGD on preparing the CSR (Draft CSA)
- RIP 3.3-1: TGD on information requirements (Scoping)
- RIP 3.5-1: TGD on Downstream User requirements, preliminary study
- RIP 3.9-1: Preliminary study on Socio-Economic Analysis
- RIP 3.10: TGD on Identification and Naming of Substances in REACH
- RIP 4.4: TGD on the preparation of Annex XV dossiers

The projects are currently running or near completion:

- RIP 3.1: Guidance on Registration
- RIP 3.2-2: TGD on preparing the CSR
- RIP 3.3-2: TGD on information requirements
- RIP 3.4: TGD on data sharing
- RIP 3.5-2: TGD on Downstream User requirements
- RIP 3.7: Guidance on preparing an Authorisation Application
- RIP 3.8: Guidance on fulfilling the requirements for articles
- RIP 3.9-2: Guidance on carrying out a Socio-Economic Analysis
- RIP 4.1/4.2 Guidance on Dossier/Substance evaluation
- RIP 4.3/4.5: Guidance document on inclusion of substances in annex XIV and guidance document on priority setting for evaluation

One project is still to start:

- RIP 3.6: Guidance on Classification and Labelling under GHS

N.B. RIP 3 activities are aimed at industry and RIP 4 at authorities.

RIP 3.5: Downstream-User Requirements

A key RIP will be RIP 3.5; guidance for downstream users. This identifies DU obligations under REACH regarding use of substances, exposure scenarios, the information they should have available, and information to communicate up and down the supply chain.

The guidance will build on the experiences from an earlier scoping study, other ongoing activities and experience from the preparation of examples of exposure scenarios under RIP 3.2. The project includes 4 case studies where implementation of exposure scenarios and applicability of the guidance will be piloted. The acceptability of exposure scenarios to manufacturers/importers as well as to downstream users is crucial to the overall success of REACH and will be a crucial element of the work. Tools for simple and workable communication, especially on exposure assessment, risk management, and exposure scenarios (ES) must also be developed. It is expected that the guidance will be finished 3rd quarter of 2007.

Problem Areas

There could be some difficulties at the start of the REACH process with regard to pre-registration and the first registration deadline. It is possible (the author believes likely) that many phase-in substances will not be pre-registered by their potential registrant. The implication of failure to pre-register is that the registrant would be required to register the substance immediately otherwise they should be withdrawn from the market and/or EU manufacture stopped. Immediate registration would be a huge burden for most companies and is likely to mean that many substances are withdrawn from the market. Another problem for pre-registration is ensuring that the substance is correctly identified. If this is not done correctly it will have implications for the continued use and supply of such substances; the authorities will need to decide how they address such cases. The first registration deadline is only two years after the end of the pre-registration period. This is very little time for all registrants of the same substance to agree the hazard data set for the substance; this will require consortia to be established with legal agreements on how they operate, data and costs to be shared and possibly, non-animal, testing undertaken. It is possible (again the author would say likely) that many phase-in substances will not be registered to the deadline; in theory this would mean that they also should be required to be withdrawn from the market and/or EU manufacture stopped.

Conclusions: Act Now!

- Decisions are being taken now by many companies on how they will deal with the challenges posed by REACH
- You need to understand the potential implications of REACH (direct and indirect effects) for your business
- A key to making REACH work for you is to develop supply chain relationships; supplies may be at risk and customers may be at risk
- Identify and assess alternatives if there is the potential for substance withdrawal from your supply chain; alternatives can be substances, processes, or suppliers
- REACH needs careful management – put a system in place
- Most importantly at this time identify substances for pre-registration by you or your suppliers and make sure this action is taken