

WHITE PAPER:

**The Registration, Evaluation, Authorisation and
Restriction of Chemicals (REACH) Regulations**

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1. List of Acronyms and Abbreviations

Abbreviation	Description
BMT	British Maritime Technology
CA	Competent Authority (REACH)
CSA/CSR	Chemical Safety Assessment/Chemical Safety Report
DEFRA	Department of Environment, Food and Rural Affairs
DNEL	Derived No-Effect Level
DU	Downstream User
EC₅₀	The concentration that induces 50 % of the relevant effect under defined conditions
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Chemical Substances
EU	European Union
GHS	Globally Harmonised System for Classification and Labelling
HSE	Health and Safety Executive (UK)
IUCLID 5	International Uniform Chemical Information Database version 5 – Software tool for compiling Registration Dossiers
LC₅₀	Lethal concentration causing 50% mortality under defined conditions
MSDS	Material Safety Data Sheet
NOAEL/LOAEL	No Observed Adverse Effect Level/Lowest Observed Adverse Effect Level
OECD	Organisation for Economic Co-operation and Development
OR	Only Representative
PBT	Persistent, Bioaccumulative and Toxic chemical substance
PNEC	Predicted No-Effect Concentration
PPORD	Product and Process Oriented Research and Development
(Q)SARS	(Quantitative) Structure Activity Relationships
RCR	Risk Characterisation Ratio
REACH	EC Regulation 1907/2006 on the Registration, Evaluation, Authorisation and restriction of Chemicals
REACH-IT	Web-Based system for submitting Registration Dossiers to ECHA
RMM	Risk Management Measures
SIEF	Substance Information and Exchange Forum
SME	Micro, Small and Medium Enterprises
SVHC	Substance of Very High Concern
TEG	Triethylene Glycol
vPvB	Very Persistent and Very Bioaccumulative chemical substance

2. Introduction

The new European Union (EU) regulation concerning the Registration, Evaluation, Authorisation and restriction of Chemicals, Regulation (EC) No 1907/2006, came into force in June 2007. It has major trade implications for chemical industries in Europe, and globally, but has potentially significant health and environmental benefits. Succinctly put, REACH says: “No Data, No Market”; without registering, and providing the information required, you cannot market a chemical substance within the EU (which, for the purposes of REACH, is extended to include the European Economic Area). This White Paper presents a review and discussion of “why” REACH is important; “what” REACH applies to, “who” REACH impacts, and reviews “Where, How and When” to respond to REACH.

2.1. What?

Under REACH, chemicals are split into three general categories: substances, preparations and articles; these are defined as follows:

Chemical substances... chemical elements or compounds on their own, e.g. argon, iron, triethylene glycol (TEG);

Preparations... mixtures of chemical substances that do not react to form a new substance, e.g. paints, lubricants, corrosion inhibitor products; and

Articles... objects for which their shape, surface, or design determines its function more than its chemical composition, e.g. aluminium cladding, a bearing, a fragrant soap.

REACH requires the registration of all “chemical substances”, whether they are individual chemicals, in preparations or articles. All new and existing substances that are manufactured or imported in a quantity of ≥ 1 tonne per year in the EU must undergo registration. Existing substances may additionally pre-register to take advantage of a phase-in period, during which the substance can continue to be marketed whilst the full registration process is completed.

For “articles”, substances only need to be registered if there is “intended release”, the substance released meets the 1 tonne per year threshold, and it has not already been registered in the same supply chain. A notification may be required if exposure to the substance cannot be excluded and the substance meets criteria for being of very high concern. **Further information on this definition can be found in Section 7.**

2.2. Who?

REACH applies to the EU and under the regulations specific obligations are given for the following actors within a supply chain (Article 3(8-13)):

Manufacturer... any legal entity manufacturing a substance, preparation or article;

Importer... any legal entity importing a substance, preparation or article from outside the EU; and

Downstream User... any legal entity other than the manufacturer or importer who uses a substance, preparation or article in the course of their industrial or professional activities.

For the first time in European chemical legislation Downstream Users (DUs) have obligations with regard to the safe use of chemicals. Because only legal entities within the EU can act in accordance with REACH, non-EU manufacturers will have to share their data with their importer(s) to allow them to complete registration activities, or appoint an Only Representative (OR), a legal entity within the EU who will represent the non-EU manufacturer and take responsibility for all obligations under REACH. **The responsibilities of different actors in the supply chain are further discussed in Section 3.**

2.3. Where, How & When?

Where: All REACH registrations are being dealt with by the European Chemicals Agency, Helsinki (ECHA) which was formed on 1st June 2007. In addition to ECHA, each Member State has a Competent Authority (CA). In the UK the CA is the Health and Safety Executive (HSE), who have set up a helpdesk to respond to queries (**See Section 5**).

How: Registrations need to be submitted via ECHA’s REACH-IT system in an XML format. Whilst any system can be used to generate the XML required, as long as it conforms to the REACH schema, the freely available IUCLID5 system offers a structured system to collate data and submit direct to REACH-IT. Whilst it is also possible to directly input pre-registration data into REACH-IT, this is not viable for full registration (**See Sections Error! Reference source not found. & 5.8**)

When: New substances must be register prior to being placed on the market, whereas any existing substance that is pre-registered between 1st June and 1st December 2008 can take advantage of a phase-in period, with staggered registration deadlines broadly based on volume and toxicity. The REACH phase-in timetable is detailed in Figure 1 (**also see Section 3**).

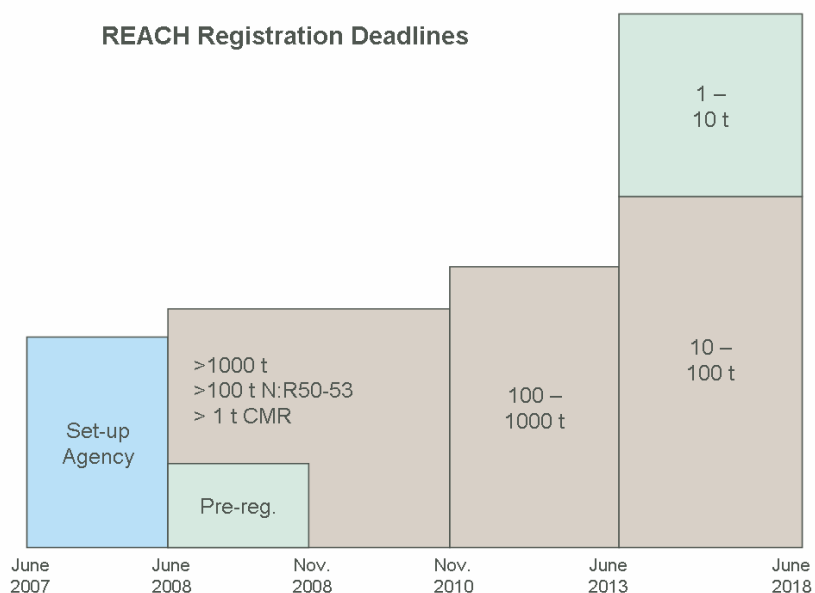


Figure 1 – Timetable for set-up of the European Chemicals Agency and the REACH phase-in period.

3. REACH Requirements

REACH is very wide in its scope, covering all chemical substances manufactured, imported, used as intermediates and placed on the market, on their own, in preparations or in articles. As with most legislation, there are exceptions; REACH does not apply in many cases where alternative controls are deemed adequate, including: waste,

medicinal products in their finished state (both human and veterinary), active substances for use in biocides, and radioactive substances. In addition, various categories of substances are exempt from registration, including: substances subject to customs supervision, non-isolated intermediates and some naturally occurring substances.

REACH classifies substances as either new or existing, where existing substances are generally substances listed in the European Inventory of Existing Commercial Chemical Substances (EINECS), and new substances are defined as any substance not on EINECS and which has not been manufactured previously. Any substance notified under the previous Notification of New Substances (NONS) Regulations will be deemed registered under REACH for the notifier only.

The timetable for existing substances (also termed phase-in substances) defines a pre-registration period (1st June 2008 and 1st December 2008) and registration deadlines which are mainly dependant on the tonnage threshold of the substance(s), and to some degree their classification (Figure 1 & Table 3). The timetable will ensure that all existing chemicals are registered by 1st June 2018.

The Commission will review the scope of the Regulation five years after entry into force, with the potential to significantly alter the requirements of the chemical industry to conform to regulations.

Table 1 – REACH implementation timelineDEFRA –<http://www.defra.gov.uk/environment/chemicals/reach/pdf/reach-timetable.pdf>

2007	Entry into force of REACH.	1 June 2007
2008	Article 28 – pre-registration of phase-in (existing) substances manufactured at ≥ 1 tonne per annum.	1 June to 30 November 2008
2009	Article 28(4) – European Chemicals Agency publish list of pre-registered substances on website.	By 1 January 2009
	Article 58(3) – European Chemicals Agency’s first recommendation of priority substances to be included in Annex XIV (list of substances subject to authorisation).	By 1 June 2009
2010	Article 117(1) – first of 5-yearly Member State reports to Commission on the operation of REACH.	By 1 June 2010
	Article 23(1) – registration provisions for phase-in substances for CMR (cat 1 or 2) and toxic (R50/53) over 1 tonne + per year, and other substances over 1000 tonnes per annum.	1 December 2010
2013	Article 23(2) – registration provisions for phase-in substances of 100 tonnes or more per annum.	1 June 2013
2018	Article 23(3) - registration provisions for phase-in substances of 1 tonne or more per annum.	1 June 2018

3.1. EU manufacturers

EU manufacturers must first decide whether it will be commercially viable to register each substance under the new REACH legislation. If a decision is reached to discontinue manufacturing a substance(s), these manufacturers are advised to contact their customers with this information, if they have not done so already. Regardless of the decision concerning full registration, all manufacturers and importers are being urged to pre-register all substances on their inventory. Pre-registration will allow a company to continue manufacturing or importing a substance in the EU until the relevant full registration deadline (see Figure 1 and Table 3).

A major hurdle facing EU manufacturers is the expertise and resources required to conduct the REACH registration process. Missing the pre-registration or full registration deadline for a substance could be disastrous, especially for SME's that rely on a single

or very few products in the market. Therefore EU manufacturers must ensure they have fully identified their responsibilities regarding pre-registration and registration and planned to act accordingly.

3.2. Non-EU Manufacturers

Non-EU manufacturers must also decide whether it will be commercially viable to register each substance under REACH. Non-EU manufacturers, however, may not directly register a substance and must appoint a legal entity within the EU to carry out the REACH process. Non-EU manufacturers therefore have two options, they can arrange for each importer to conduct registration, or they can appoint an EU-based third party to act as their “Only Representative” (OR). The latter option is generally more attractive, because non-EU manufacturers will retain control over the registration process and avoid having to disclose confidential business information to importers and other DU's. A registration by an OR will also cover all supply chains for the substance entering the EU, whereas if an importer of the substance conducts registration, this applies to one supply chain only.

3.3. Importers

Importers of substances into the EU may have a role in the registration of a substance. As non-EU manufacturers are not permitted to carry out the registration process, their importers can conduct registration on their behalf. However, registration of substances requires significant resources and expertise, which an importing company may not have at their disposal. In order to protect their business, importers should seek assurance from their suppliers regarding the continuation of their intent to export substances into the EU in light of the introduction of REACH legislation.

3.4. Downstream Users (DU's)

For the first time in European chemical legislation, REACH imposes obligations on Downstream Users (DU's). A DU must ensure that they only use substances consistent with the usage scenarios (or exposure scenarios) from both the occupational exposure and the environmental exposure scenarios listed on the new REACH compliant Material Safety Data Sheet (MSDS). DU's should therefore ensure that their suppliers intend to both pre-register and register the substances used in products and that all identified uses will be incorporated into the registration dossier (and thus the MSDS). DU's may

also be asked to contribute to the generation of exposure scenarios, which requires expertise and a considerable amount of resources (**see Section 5.7**).

4. REACH Preparations

The sections that follow review in more detail what needs to be done to meet the obligations of REACH and what may be involved for the various processes. The requirements for companies outside of the EU are discussed along with what REACH means to Downstream Users.

4.1. Chemicals covered by REACH

Although REACH concerns both new and existing substances, it is the ~30,000 existing substances on the EU market produced in quantities above the 1 tonne per year threshold that are of immediate concern. These substances must now be “phased-in” to the new regulations, a process that will run until 2018. Phase-in substances need to be “pre-registered” between 1st June and 1st December 2008. Failure to pre-register an existing substance will rule out manufacturing, importing and thus marketing that substance in the EU until full-registration has been conducted. After pre-registration, the phase-in substances will be assessed over time, and submission of a completed registration must be made before the deadlines set by ECHA (Figure 1). These deadlines are tiered, and occur in November 2010, June 2013 and June 2018. Each deadline is dependant on the annual volume of the substance manufactured or imported as well as the classification of the substance. **A detailed synopsis of the REACH process of registering a substance can be found in Section 5.**

REACH not only applies to manufacturers in the EU, but will also affect non-EU companies exporting products into the EU. Although non-EU companies will have no direct obligations under REACH, they must ensure that their chemicals are registered by an EU legal entity. This can be achieved in two ways:

- The importing company in Europe can register the substance for that single supply chain (this may be an EU registered sister company or subsidiary), or
- The non-EU company can appoint an Only Representative to register the substance on their behalf, which will cover all supply chains into the EU.

More information on the obligations on REACH for non EU companies can be found in Section 1 & 3.2.

4.2. Gearing up for pre-registration

As of the 1st June, pre-registration is the immediate concern for companies affected by REACH. Pre-registration is free, i.e. there is no fee payable to ECHA, and the process requires only limited data and information on the pre-registrant and the chemical substance, however it is not a no cost option, with resource costs and the implications of membership of Substance Information and Exchange Fora (SIEFs) to be considered (**see Section 5.2**).

In order to be ready for pre-registration, companies should consider the following:

- Am I obliged to register any substances under REACH?;
 - Any EU company manufacturing or importing a substance in a quantity ≥ 1 tonne per year will need to register.
- Know your chemical inventory;
 - Make sure that you carry out a thorough check of your chemical inventory so that you are aware of the identity and quantity of all the substances that you manufacture or import.
- Prepare your pre-registration dossier;
 - Ensure that you have appropriately qualified and experienced personnel to prepare the pre-registration dossier using IUCLID 5, or via manual input of data into REACH-IT.
- Monitor pre-registration developments;
 - You can monitor the number of pre-registrants for your substances via REACH-IT indicating the numbers to be involved in cost and data sharing.

Once a substance has been pre-registered after 1st June 2008, a pre-registrant may update the registration with any further accompanying information, but may not alter the substance identity.

4.3. REACH-IT

REACH-IT is the internet-based system for which all registrations and notifications should be submitted to ECHA. Pre-registration was complicated by problems with REACH-IT, the web-based portal system to be used for all pre-registrations and registrations, which are described below. REACH-IT was intended to be a quick and hassle free system for submitting all pre-registrations, registrations and notifications required under the REACH regulations. It was, however, evident from late 2007 that there were some serious problems with the development and evaluation of this system, which caused growing concern amongst Member States and industry, evident in industry media.

REACH-IT was intended to be developed in three stages, with the final version facilitating the REACH registration process, including company sign-up, pre-registration (including bulk submissions), dossier submission, pre-SIEF information, messaging and fee calculation.

Concerns were initially raised by Member State officials in November 2007, who were not confident that the system would be ready in time, to which ECHA responded using phrases like “the project is more complex than originally expected” and “the Agency may have to put in risk management measures should the developers fail to deliver the system on time” (Chemical Watch Issue 3). ECHA were, however, still confident that a system containing all the primary capabilities required for the pre-registration phase would be delivered on time.

During April 2008, less than 2 months prior to the system going live, a pilot trial of the new system “did not go well” (Chemical Watch Issue 7). It is believed that submission of bulk IUCLID 5 export files caused REACH-IT to crash. However, ECHA were still undeterred and vowed that “REACH-IT has to be ready; the alternative would be a nightmare”.

During early May 2008, ECHA started to concede that REACH-IT was not going to be able to perform all of the functions intended by 1st June 2008, bulk pre-registration, would just not be possible, and temporary measures would have to be put in place to submit notification of substances for Product and Process Oriented Research and Development (PPORD) and registration of new substances. Towards the end of May

the reduced version of REACH-IT was “looking good” (Chemical Watch 19 May 08), only for final tests by ECHA in late May to identify “significant problems” (Chemical Watch, 27 May 08).

However, these problems were ironed out within three days and REACH IT went live on the 1st June 2008, albeit with a severely reduced capability than originally intended. Although ECHA and the contractors developing REACH-IT may be red faced from the media circus surrounding REACH-IT, the system is up and running and industry have begun signing up, pre-registering phase-in substances, notifying substances and registering new substances, with almost 5000 submissions in the first week. In late July 2008, the REACH-IT tool for bulk submission of pre-registrations went live. This was a huge relief for pro-active companies that had used IUCLID 5 to prepare bulk registration files for their chemical inventory in advance of REACH-IT being implemented by ECHA. At the time of publishing this document, there were still temporary measures in place for submitting full registrations and PPORD notifications.

4.4. Uncertainties regarding phase-in process

Substance Information and Exchange Fora (SIEFs) will be formed after pre-registration, and are essentially groups of pre-registrants of the same substance. The purpose of each SIEF is to facilitate data sharing for the purpose of registration, thereby avoiding the duplication of regulatory testing (especially tests involving animals), and to agree on the classification and labelling of the substance consistent with the new Globally Harmonised System (GHS) for classification and labelling. SIEFs appear to be a good idea in theory, intending for all the pre-registrants of a substance to work together. However, in practice the smooth running of SIEFs will be very difficult to facilitate. Firstly, there are no official rules on how the SIEF should be organised and run, which may lead to potential disagreement among SIEF members about the approach a SIEF should take towards registration.

All members of a SIEF must be “in agreement” that the substance(s) each member plans to register is actually the “same”. There is guidance on determining the identity of a substance, but ECHA have not defined “chemical sameness” (REACH Implementation Project 3.10). It is conceivable that in the interest of gaining a market advantage, a SIEF member may look to exclude certain members of a SIEF by disagreeing on the identity of the substance a competitor wishes to register. There is, however, a provision for an

excluded SIEF member to launch an appeal for the data required, where ECHA will make the final decision whether to allow the excluded SIEF member access to shared data.

The use of suitable Quantitative Structural Activity Relationships (QSARs) is positively encouraged in REACH, where data gaps exist. In addition it is believed that the ECHA will positively support the use of evidence-based toxicology which makes better use of available data as presented by Hoffmann and Hartung¹.

Choosing the most appropriate regulatory tests for use as a key study in SIEFs is likely to be a cause of disagreement among members. If two different values for the same endpoint exist, carried out in compliance with the same regulatory guidelines, how will the most appropriate study be decided? The obvious answer is to use all such studies and apply the weight-of-evidence approach, but this may not be the view of all members of a SIEF. REACH does suggest that “all available data” on a substance be included in the registration dossier. But would this result in 10 identical studies on the same substance being used and the registration costs for all 10 studies being shared? It is doubtful that many registrants would have the resources to apply this thinking to every required regulatory test. At the 2008 Chemical Notification Conference in Washington DC (September 2008), industry delegates from major global chemical companies stated that they would not be buying “all available data” for dossiers, and that the financial infrastructure for SIEFs is going to be an extremely complex ordeal, with no guidance, management or support from the regulators currently available.

It would appear that some level of study selection will have to occur. In this selection stage it would seem in the spirit of REACH, that the worst case test results should be used, however this may present a serious business risk to some pre-registrants who may want to use their own data showing the substance to be least toxic. It is also conceivable that “product sabotage” may occur. A company could research the components of their competitor’s product to find species that are highly sensitive to a component. If these data then become available, a registrant would seem to be obliged under REACH to update the risk assessment in their dossier. The new data may result

¹ Hoffmann and Hartung (2006) Toward an Evidence Based Toxicology. *Human and Experimental Toxicology*, 25 (9): 497-513.

in a risk assessment showing potential impact for the environment, and requiring more stringent control on the use of the substance, potentially driving the competitor's substance from the market.

The issue here is with "data becoming available", and whether ECHA expects all registrants to respond to this data immediately. If registrants are expected to respond to every new piece of data, a new market in finding indicator species very sensitive to particular substances may evolve.

4.5. Non-EU Companies and Only Representatives

Whilst companies outside of the EU may not act as registrant for substances they export to the EU, they will not be able to market the substances in the EU unless they are registered. Only a legal entity within the EU must register, so either the non-EU company's clients, the importer(s) must act as registrant(s) or an Only Representative (OR) needs to be appointed. The OR, understanding the uncertainties facing non-EU manufacturers, must play a significant role in assessing and addressing concerns regarding confidentiality.

With respect to long-term operations, consistency, and fidelity of data and the dossier control, ORs are not allowed to go out of business, and are required to live ad nauseam, or at a minimum through the registration period extending to 2018. If a non-EU manufacturer has to change OR for any reason, fees for updates to the registration will be payable to the ECHA as detailed in Regulation 340/2008 on Fees and Charges under REACH. The standard fee is €1500, with reduced fees for medium (€1050), small (€600) or micro (€150) enterprises. Generally, it is in the manufacturer's interest to obtain an OR that has a good record of interaction with the EU chemicals agencies, that is financially secure, and has a proven track record in chemical regulatory affairs.

4.6. Downstream Users and REACH

Downstream users (DUs) have specific obligations under REACH and will also have to consider the impact and business risks that the Regulations will present. Once a substance has been registered, a DU may only use the chemical(s) in a product in ways prescribed on the new REACH format MSDS. Therefore a DU must ensure that their supplier(s) are planning to incorporate all of their uses of a particular product in the risk assessment and ultimately the registration. It should be the responsibility of the supplier

to conduct due diligence activities to ensure all customers' uses will be included in the registration; however this is simply not the current practice in many industries. Many suppliers are not proactively contacting their customers, even though they are advising customers that contact them that they expect support in developing exposure scenarios for their uses.

There is no doubt that some manufacturers that are unable to absorb the costs associated with REACH compliance will decide to terminate the production and marketing of certain substances. It is essential for downstream users to identify with their suppliers where substances or products may change or be withdrawn from the market. Where manufacturers continue to produce and market substances, additional costs to DUs are likely to arise through suppliers transferring the cost of REACH compliance down the supply chain, which may act as an opportunity for suppliers to generally review their pricing structures.

The potential loss of substances from the market will be a serious issue for a company's operations if the substance is not easily substituted. The actual number of chemical substances or products that will be withdrawn from the market due to REACH is difficult to predict, whether at the pre-registration or full-registration deadline. Those substances most likely to be affected are those that have lower value, are sold to niche markets or are produced in higher volumes but with low profit margins. In addition, registration may prove to be onerous for substances if there is limited test data available for completing the registration process. It is essential for DUs that have not had any contact from their supplier regarding REACH to open dialogue themselves, in order to identify any business risks through chemical product withdrawal from the market as early as possible prior to the pre-registration deadline.

DUs are therefore urged to open dialogue up and down the supply chain, and seek commitments from their suppliers regarding REACH registration commitments. Suppliers that buy in some components of products need to also seek such commitments from their suppliers. It is also worth checking the status of your suppliers and the commitments to pre-registration and registration they have from their suppliers.

In early 2008, BMT conducted research on chemical suppliers to the offshore exploration and production industry, to assess their preparations for REACH, the results of which

are summarised in Figure 2. Where these suppliers were manufacturers of substances, their commitments to pre-registration and full registration were generally acceptable, with nearly all planning to pre-register substances, and many also committing to full registration. However, where the suppliers externally sourced components for their chemical products, there was a distinct lack of similar commitments sought from up the supply chain, i.e. their suppliers. Less than 14 % of chemical companies had sought commitments for pre-registration from their suppliers, and only 9 % had sought similar commitments for full-registration, which is concerning considering how soon the pre-registration period closes.

In addition, when asked about which parties would be involved in generating exposure scenarios, the responses were highly variable, with many suggesting that DU's will be involved. There was, however, no evidence to suggest that this information has been communicated to customers, who may need time to arrange resources to carry out this process.

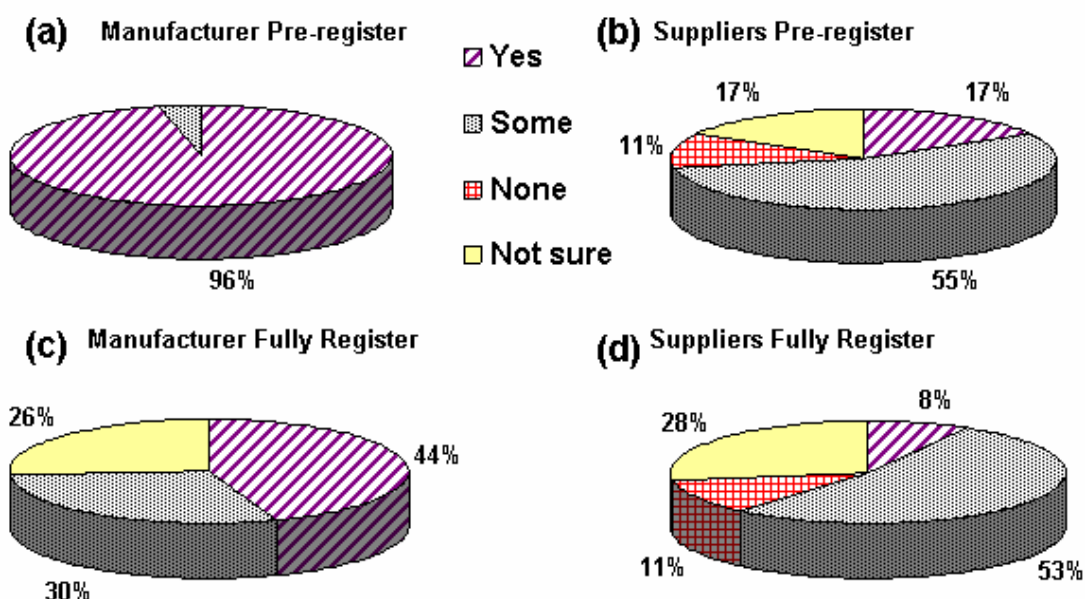


Figure 2 – Results of BMT's Research into the Readiness of Petrochemical Suppliers for REACH (continued overleaf).

(e) Who will Generate Exposure Scenarios



Figure 3 – Results of BMT’s Research into the Readiness of Petrochemical Suppliers for REACH (continued).

5. REACH Process

5.1. Pre-registration

Pre-registration affords manufacturers and importers the opportunity to benefit from the extended registration deadline and to continue "business as usual" after 1st December 2008.

Pre-registration is critical if a manufacturer or importer wishes to continue marketing a chemical in the EU. Failing to pre-register a substance will result in manufacturers, importers and DUs having to suspend all activities associated with a substance until full registration is completed. It should be noted that if a company is not actively involved in manufacture or importing of a substance until after the pre-registration deadline, they may conduct "late pre-registration", but must still meet the conditions of the full registration process.

There is no fee for pre-registration so it is therefore recommended that suppliers pre-register all of their substances, thus securing at least two years further marketing until the first registration deadline. Pre-registration will however have a resource cost and require SIEF interaction, however it makes sense for companies to pre-register in most cases, whether they intend to complete full registration or not.

Pre-registration can be carried out by a natural or legal entity within the EU, who may pre-register as many substances that require registration. Non-EU manufacturers may not act as a registrant directly, but can appoint an EU importer or an Only Representative from the EU to carry out registration activities on their behalf.

The process for pre-registration requires the pre-registrant to electronically submit a brief set of information about a substance to ECHA. This information includes:

- Substance identity;
- Pre-registrant identity, including a contact name and address;
- The envisaged registration tonnage band and deadline;
- Potential substances for data read-across; and
- An indication if the registrant is willing to act as a SIEF facilitator.

There are certain situations where double pre-registrations are required, i.e. DUs should pre-register as well as the manufacturers/importers. ECHA has recommended that DUs should pre-register re-imported substances (Article 2.7c), recovered substances (Article 2.7d), monomers in polymers (Article 6.3), and substances intended to be released from articles (Article 7.6), because the requirement for DUs not to register (as detailed in the various REACH Articles) are only valid when a full registration for the substances exist, and suppliers are likely to have only pre-registered by 1st December 2008. Whilst various trade associations and representative bodies are campaigning to have these extra pre-registration burdens removed, the current guidance is for DU's to pre-register in addition to their suppliers in these cases.

5.2. Substance Information and Exchange Fora (SIEF)

REACH provides for the formation of Substance Information and Exchange Fora (SIEFs) aiding the sharing of data among potential registrants of each substance, as well as allowing Downstream Users and other stakeholders (termed "Data Holders") who have information on the substance that they are willing to share in exchange for fair financial recompense.

SIEFs will be formed for each pre-registered substance after ECHA publish a list of all pre-registrants for each substance, which is due on the 1st January 2009. All pre-registrants are mandatory members of the SIEF, whereas data holders are not

mandatory members of a SIEF, but are encouraged to share any data or information they hold.

The main aims of a SIEF is to facilitate data sharing for the purposes of registration, thereby avoiding the duplication of data generating activities, and to agree on the classification and labeling of substances. A SIEF is not a legal entity or a consortium, but a forum to share data and information on a substance and SIEF participants are free to organise themselves as they see fit to fulfill their obligations under REACH.

5.3. Consortia

Members of a SIEF may wish to use a more structured and legally binding model, such as a consortium, to discuss their substances and share data. A consortium, in this instance, is a more organised and formal method of co-operation between parties, which may include either a signed agreement, the adoption of operating rules or reference to an agreed set of general rules. It is important to realise that a consortium is a separate entity to the SIEF, but shares the same obligations, as all potential registrants are mandatory members of the SIEF.

Formation of consortia may prove very useful for the smooth running of the data sharing, cost sharing and preparation of further testing proposals processes that are essential to completing registration. A SIEF may have more than one consortia e.g. for each tonnage level or for different industry sectors. This setup will still facilitate data sharing between consortia, but each consortium within the SIEF can focus more on their specific requirements for registration.

5.4. Classification and Labelling

If a substance is to be registered, or meets the criteria for classification as dangerous, and is placed on the market on its own, or in a preparation above a specific concentration limit, the registrant must electronically notify ECHA with information related to its classification and labeling (REACH Article 113). This must be completed by 1st December 2010 for substances already on the market, or as soon as he puts the substance on the market for the first time after 1st December 2010.

5.5. Technical Dossier

A Technical Dossier is one component of the registration dossier and will always be required for a substance regardless of the tonnage threshold. The dossier contains information on the intrinsic properties of a substance and includes: the identity of the manufacturer/importer; the identity of the substance and information on its manufacture and use; classification and labelling; guidance for safe use; robust study summaries for intrinsic properties of the substance; an indication as to whether any of the information on the intrinsic properties of the substance have been reviewed by an assessor; and, further testing proposals (if relevant). If the substance falls in the ≥ 1 tonne per year but < 10 tonne per year threshold, the Technical Dossier shall also contain general exposure related information for the substance.

5.6. Further Testing

Once all available data and information on a substance are gathered, the SIEFs and consortia must identify "data gaps" against the REACH data requirements. Depending on the nature of missing data, a testing proposal may have to be prepared and submitted to ECHA for approval. Potential registrants within the SIEF and consortia must agree on one member performing the studies on behalf of the others. All participants who require the missing information are required to contribute financially to the data costs.

5.7. Chemical Safety Report

The investigation into the adverse effects a chemical may have on human health and the environment is termed the "Chemical Safety Assessment" (CSA) in REACH, which will be documented as a "Chemical Safety Report" (CSR). The CSA of a substance will include the following steps:

- Physicochemical hazard assessment
- Human health hazard assessment (DNEL)
- Environmental hazard assessment (PNEC)
- Persistent, bioaccumulative and toxic (PBT) and very persistent, very bioaccumulative (vPvB) assessment.

Each hazard assessment (human and environmental) will be conducted following the same three steps; evaluation of the data, classification and labelling, and derivation of exposure and effect levels (see Figure 2). Full guidance on conducting the CSA can be found in REACH Implementation Project 3.2.

The physicochemical hazard assessment will be used to aid the human health and environmental hazard assessment and also to support the classification and labelling scheme to be adopted by the SIEF. This assessment will focus on properties such as explosivity, flammability and oxidising properties of chemical substances.

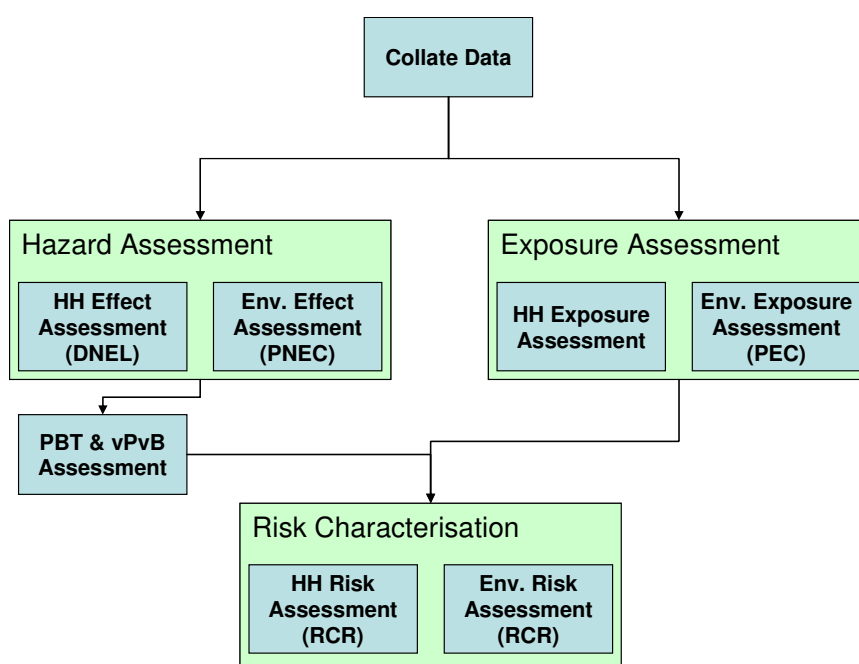


Figure 4. Schematic diagram of the Risk Assessment Process for Human Health and the Environment

The human health hazard assessment will be used to derive a Derived No-Effect Level (DNEL). The DNEL is an exposure level below which unacceptable effects are unlikely to occur, and is based on a series of assessment steps using the available toxicity data on a chemical substance. Appropriate toxicology endpoints, such as the No Observed Adverse Effect Level (NOAEL) or the Lowest Observed Adverse Effect Level (LOAEL), are considered and an assessment factor applied based on the amount and quality of data available. The assessment factor is designed to allow for uncertainties,

with a higher assessment factor being used where there is greater uncertainty (e.g. only few data available).

The environmental hazard assessment will be used to derive a Predicted No-Effect Concentration (PNEC), a value similar in principle to the DNEL but for environmental receptors. The PNEC is defined as a concentration below which adverse effects are unlikely to occur and is from available information on toxicity to species from relevant environments. A PNEC for a particular environmental compartment (fresh water, marine, soil, sediment) is derived from the endpoint data from ecotoxicological tests on relevant species, such as the concentration causing 50 % mortality under defined conditions (LC_{50}) for short-term studies or the No Observed Effect Concentration (NOEC) for long-term studies. Appropriate assessment factors are used to account for uncertainties such as extrapolating from laboratory to field and from a few species to whole ecosystems. The methodology and assessment factors vary depending on the environment being assessed, for example the assessment factors for the marine compartment are higher than for freshwater, due to the higher biodiversity in marine ecosystems, producing a broader distribution of species sensitivity.

The CSR must also include an assessment against the criteria for Persistent Bioaccumulative and Toxic (PBT) and very Persistent, very Bioaccumulative (vPvB). These criteria can be found in REACH Implementation Project 3.2. PBT and vPvB substances in the environment are of great concern. The persistence of a substance reflects the potential for long-term exposure of organisms but also for the substance to reach the marine environment and to be transported to remote areas.

After carrying out the hazard and PBT/vPvB assessments, if a chemical substance meets the criteria for classification as dangerous in accordance with the Dangerous Substances Directive (67/548/EEC) or is assessed to be PBT or vPvB, the CSA must also include a full exposure assessment, including the generation of exposure scenarios and conducting risk characterisation to compare the estimated exposure with the DNEL and PNEC.

An exposure scenario (ES) is required for each identified use and will follow the following stepwise process:

1. Identification of uses and processes
2. Description of manufacturing or use processes
3. Development of a “tentative” ES
4. Assessment of exposure and risks
5. Risk Characterisation
6. Definition of the “final” ES
7. Development of Annex to the SDS

Identification of the uses and associated processes is pertinent to manufacture, formulation and end use of substances. Although not a legal requirement, registrants (whether manufacturers, importers or DUs) are urged to be proactive and identify all the uses of the substance throughout the supply network and communicate these. Alternatively, if a DU wishes to keep their “use” of a substance confidential, an individual exposure assessment can be submitted to ECHA by the DU.

Before drafting a tentative ES, it is advisable for the registrant to document a description of the manufacturing or use process that will form the basis for the tentative ES. From this documentation, emission pathways during the relevant life cycle steps of the substance can be considered. The relative magnitude of exposure during each of these steps will determine the contribution of each step to the ES.

The tentative ES should be used as the basis for conducting an exposure estimate and risk characterisation for the purpose of assessing whether risks are adequately controlled. As a minimum, a tentative ES should encompass the Tier 1 exposure model data requirements described in REACH Implementation Project 3.2.

The assessment of exposure and risks uses the information in the tentative ES to estimate exposure and the level of risk which then feed into the risk characterisation process. After making a more detailed assessment of the levels of exposure, certain processes in the life cycle of a substance, preparation or article may require a separate ES. The assessment of risks will also be used to determine the appropriate risk

management measures (RMM's) that should be communicated and adopted for the safe use of a substance.

Risk characterisation is the quantitative assessment of the likelihood that adverse effects will occur to man or the environment due to exposure to a substance. The Risk Characterisation Ratio (RCR) compares the results of the exposure assessment and the effects (toxicology) assessment for each human health and environmental end-point. Risk characterisation is the calculation of the PEC/PNEC ratio for environmental end-points and the exposure/DNEL ratio for human receptors.

Where an $RCR < 1$, there is deemed to be no immediate concern based on the data and models used for this chemical substance and application. If the $RCR > 1$ there is potential for impacts to occur, and further data (to reduce uncertainty) and/or risk mitigation measures (to reduce exposure) should be considered.

The final ES will be defined when it has been demonstrated that under the specified operational conditions and RMMs, risks are adequately controlled. The final ES is only valid for the substance(s) and the process(es) that have been assessed. The final ES will then be consolidated to include all the relevant information needed by a DU to identify the uses covered by a registration and the appropriate RMM for safe use. The format for all information requirements in a REACH compliant MSDS can be found in Article 31 of the REACH regulations.

Once the Chemical Safety Report is complete, updated and extended Safety Data Sheets should be prepared.

5.8. Registration Submission

After completion of the Technical Dossier and the CSR in IUCLID format, the Registration Dossier must be submitted to the ECHA via REACH-IT prior to the relevant full registration deadline. Once submitted, ECHA will send the registrant a unique submission number. A completeness check is conducted as part of the dossier acceptance. Once registration is complete, ECHA assigns a registration number, to be displayed on all Safety Data Sheets. Within 30 days of the submission date the ECHA will notify the relevant Member State competent authority (e.g. the Health and Safety Executive in the UK), that the registration has been submitted and that all the relevant

information relating to the registration is available on the ECHA website. Once complete, a registration is valid until the need for a registration update (**see Section 5.10**).

5.9. REACH Compliant Safety Data Sheets (SDS)

It is a manufacturer's duty to provide a substance Safety Data Sheet (SDS) or other relevant safety information when an SDS is not required, to all DU's in the supply chain. SDS's include relevant information such as occupational exposure limit values, biological limit values, Derived No-Effect Levels (DNEL's), Predicted No-Effect Concentrations (PNEC's) and Risk Management Measures (RMM's). Existing SDS's need to be updated with the new information required by REACH and should also be disseminated down the supply chain, which may involve issues of translation into languages other than English.

5.10. Updating Registration Dossier's

It is a registrant's duty to keep the information held in the registration dossier up to date. There are three general situations where a registrant's dossier will require updating (Article 22(1)):

1. A registrant is required to update their registration dossier if any new information regarding a substance becomes available;
2. As a consequence of a decision made by ECHA or the Commission upon evaluation of the dossier, changes may be requested e.g. the inclusion of additional data;
3. If a registrant reaches the next tonnage threshold for a substance, an updated dossier will be required including all additional data for the new tonnage threshold.

5.11. Non Phase-in Substances

Non phase-in substances, or "new" substances, are not listed on the European Inventory of Existing Commercial Chemical Substances (EINECS) and will therefore not enter the transitional regime provided for phase-in substances. Non phase-in substances must be registered before they can be manufactured, imported or placed on the market in the EU, unless already notified under Directive 67/548/EEC.

To facilitate the data sharing stage of REACH, potential registrants of a non-phase in substance must submit an inquiry to ECHA, who will then notify inquirers whether there has been a registration of that (or similar) substance, or whether another party is in the

process of registering that substance. Where a substance has been registered for less than 12 years prior to the inquiry, then registrants of the non phase-in substance must provide financial recompense to the relevant data holder(s) from the previous registration for data used. Beyond 12 years from first registration access is free to the previous registration data. Where data gaps exist for a non phase-in substance, potential registrants are required to avoid testing on animals where possible by using the read-across approach or (Q)SAR models, if this is sufficient for the purpose of registration.

6. REACH Fees

To cover running costs of the ECHA, fees will be charged not only for submission of each registration (Table 4), but also for updates to registrations. The registration fee varies on a number of factors including tonnage, data submitted and the size of the registering organisation. A 25 % reduction is applied for joint submissions and further reductions are provided for medium (30 %), small (60 %), and micro (90 %) enterprises (as defined in 2003/361/EC²). A summary of the standard fees for registering substances are presented in Table 2.

Table 2 – Standard REACH Registration Fees³

Tonnage	Individual Submission (€)	Joint Submission (€)
1 to 10 tonnes	1,600	1,200
10 to 100 tonnes	4,300	3,225
100 to 1000 tonnes	11,500	8,625
Above 1000 tonnes	31,000	23,250

The standard registration fees in Table 2 and the reductions for smaller businesses (summarised above) are, however, just the tip of the iceberg. The draft document on fees³ also cover fees for registering intermediates and articles, fees for updating a registration, fees for requesting confidentiality for certain aspects of registration, fees

² Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (2003/361/EC)

³ (Draft Commission Regulation (EC) No 1907/2006 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

and charges for notifying ECHA of the intent to manufacture substances for research & development (PPORD), fees for applying for an Authorisation to use a substance, charges for reviewing an Authorisation, and finally fees for appeals to ECHA should a potential registrant disagree with any of their decisions regarding a registration dossier or other application.

With many of these fees running into thousands of euros, it is clear that the costs of REACH will stretch far beyond conducting the Risk Assessment and preparing the Registration Dossier. All parties planning to register products need to be well aware of this situation, when budgeting for REACH registration. An example of the other fees and charges ECHA are imposing under REACH presented in Table 3.

Table 3 – Other REACH fees and their price range³

Process	Individual Submission (€)	Joint Submission (€)
Fees for the update of a Registration Dossier	2,700 – 24,400	2,025 – 22,050
Fees for requesting confidential business information to be withheld from the public domain	1,500 – 4,500	1, 125 –3, 375
Fees and charges for PPORD notifications (including PPORD extensions)	50 – 1,000	N/A
Fees for Authorisation Applications (same charges apply for each review of an Authorisation)	50,000	Additional 37,500 per applicant
Fees for Appeals	2,200 – 6,600	N/A

7. Defining an Article

An article may be produced from natural or synthetic materials and substances or preparations may be added to an article to give it special properties. Many everyday objects are considered articles, e.g. electronic equipment, vehicles, furniture and toys. To determine whether an object fulfils the definition of an article under REACH a thorough assessment of an objects function and properties is required.

Clearly this can be a troublesome task as some articles are complex. Also, a decision must be made for substances or preparations enclosed in an object. Are they an

integral part of an article (e.g. the liquid in a thermometer) or not (e.g. aerosol in a spray can)? Finally, the determination of the function of an object may help in deciding whether the object is an article or not.

A multitude of criteria can be applied to an object to determine whether it is an article or not. The latest guidance provides a number of set questions and flowcharts to aid in this decision (REACH Implementation Project 3.8). Two examples below help to illustrate this process:

A wet wipe impregnated with cleaning liquid would be regarded as a substance/preparation on a carrier material. The function of the wipe is to remove dirt from surfaces, however the cleaning effect could still be achieved using the same preparation but with another wipe. If the wipe alone was used the cleaning effect is unlikely to be the same. Therefore, cleaning wipes in general should be regarded as a “special carrier material containing a preparation” and not an article.

A thermometer is an example of a substance or preparation being an integral part of an article. If the substance or preparation was removed from the article the empty thermometer would fail to show the temperature, rendering it useless. Also, the main function of the thermometer is to display temperature and not to deliver a substance or preparation. Finally, the thermometer would normally be disposed of still containing its substance or preparation content. This information leads to the conclusion that a thermometer (including the substance or preparation) is an article.

8. Authorisation and Restriction

8.1. Authorisation

Making a chemical substance subject to authorisation is intended to tighten the level of regulation for substances that are considered “of very high concern”. The requirement for authorisation ensures that the risks of using such a substance are either adequately controlled or justified on socio-economic grounds, having taken into account any available information on alternative substances or processes. Annex XIV of the REACH regulations will list substances subject to authorisation.

Once a substance is listed in Annex XIV, a manufacturer, importer or downstream user needs an authorisation to market or use such a substance on its own, in a preparation or

in an article. However, authorisation will not take full effect until a “sunset date” has been reached. The sunset date is the date beyond which any marketing or use of a substance will be prohibited, unless an authorisation has been granted. An application for authorisation should be submitted to the ECHA at least 18 months prior to the sunset date. The first “candidate list” of substances has been published for inclusion in Annex XIV (Table 4).

Table 4 – The first candidate list for Authorisation⁴

Substance name	CAS number	EC number
Anthracene	120-12-7	204-371-1
4,4'- Diaminodiphenylmethane	101-77-9	202-974-4
Dibutyl phthalate	84-74-2	201-557-4
Cobalt dichloride	7546-79-9	231-589-4
Diarsenic pentaoxide	1303-28-2	215-116-9
Diarsenic trioxide	1327-53-3	215-481-4
Sodium dichromate, dihydrate	7789-12-0	
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	81-15-2	201-329-4
Bis (2-ethyl(hexyl)phthalate) (DEHP)	117-81-7	204-211-0
Hexabromocyclododecane (HBCDD)	25637-99-4	247-148-4
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	85535-84-8	287-476-5
Bis(tributyltin)oxide	56-35-9	200-268-0
Lead hydrogen arsenate	7784-40-9	232-064-2
Triethyl arsenate	15606-95-8	427-700-2
Benzyl butyl phthalate	85-68-7	201-622-7

8.2. Inclusion of Substances on Annex XIV

Substances expected to become candidates for authorisation are likely to be classified as category 1 and 2 carcinogens, mutagens and substances toxic to reproduction (CMR's), persistent, bioaccumulative and toxic (PBT), and very persistent and very bioaccumulative (vPvB). Any other substances that are considered to give an equivalent

⁴ European Chemicals Agency Press Release, ECHA/PR/08/18

level of concern (e.g. endocrine disrupting chemicals) may also become candidates for authorisation.

Once a candidate list is published, all interested parties (governments, NGO's, industry, etc) will be invited to submit comments by a specified deadline. These dossiers will then be reviewed to decide whether the substance(s) should be included in Annex XIV. Before ECHA sends its final recommendation to the European Commission, it shall make it publicly available on its website. ECHA will again invite all interested parties to submit comments within three months of the publication, in particular on uses which should be exempt from the authorisation requirement.

8.3. Applying for Authorisation

Full guidance on applying for an authorisation (REACH Implementation Project 3.7) is still under development and is due for release during 2008.

The application may be made by manufacturer(s), importer(s) and/or downstream users of the substance and may be made by one or several applicants, for one or several uses. In addition, a significant fee must accompany each authorisation application³ that vary depending on the number of applicants and uses. The application must be accompanied by an analysis of alternatives and where suitable alternatives are available, substitution plans including a timetable for proposed action by the applicant.

The application may also include a socio-economic analysis and a justification for not considering risks to human health and the environment in specific cases, where the benefits of the use far outweigh the identified risks.

8.4. Restrictions

In REACH, restriction is the process by which limitations are placed on the marketing and/or use of a particular substance. Putting restrictions in place will require the regulators to first establish the uses that currently exist, and which should be restricted, whilst considering whether safer alternatives are available. Substances subject to restrictions are detailed in Annex XVI of the REACH regulations.

Proposals for restrictions will be prepared by Member State Competent Authorities (e.g. HSE for the UK), adopting a similar format to the authorisation dossier. This dossier should demonstrate that there is a risk to human health and/or the environment that

needs to be addressed at an EU level. In addition a set of suggested risk management measures should also be identified. As with the authorisation procedure, interested parties will have the opportunity to comment on proposed restrictions.

Existing restrictions set out in the Marketing and Use Directive (76/769/EEC) will be carried over to REACH in a consolidated version into Annex XVII of REACH, to include currently restricted substances and new additions through REACH.

9. Impacts of REACH

The following sections examine some of the business, financial and market impacts that REACH may have. The manner in which REACH is being phased in for existing substances means that some impacts of the new legislation may take time to occur, and companies may be able to mitigate the impacts over the phase-in period. What is certain is that the regulation of chemicals has changed dramatically and that this will affect the market in many ways.

REACH is set to have a greater impact on SMEs than other producers. Larger chemical manufacturers and some well-prepared SMEs may, depending on the situation, even see REACH and its consequences as an opportunity; and if they conduct business properly and aggressively, it will be. For most SMEs, the degree to which REACH becomes a disaster or becomes an opportunity will directly relate to the degree to which the companies that are affected by REACH recognise its implications and respond in a timely way. Supply chain communication is critical.

Most of the chemical production worldwide currently depends on SMEs, and surveys conducted indicate that many SMEs are ill-prepared to deal with REACH. In a recent national awareness survey, the UK Department of Environment, Food and Rural Affairs (DEFRA) in the UK stated that “around a fifth (of SMEs) said they had heard of REACH, but only a quarter of these (5% of the total) professed to understand something about the regulation” (Chemical Watch, April 2008).

9.1. Business Impacts

The EU chemical industry currently encompasses about 30% of global chemical production, and is the 3rd largest manufacturing industry within the EU. Within Europe the industry employs around 1.7 million people, with up to 3 million jobs dependant on it.

In addition to the several leading multi-national corporations, there are approximately 36,000 SMEs, which represent 96 % of the number of enterprises and account for ~30 % of total chemical production⁵.

The main focus of REACH is undoubtedly protection of human health and the environment, with the new regulations placing the responsibility of hazard and risk assessment, and communication of information on industry. However, the massive costs and resources required to achieve REACH compliance, not only for manufacturers, but also downstream users, is likely to have large impacts on the future shape of the industry in the EU, and globally.

The direct cost of compliance with REACH, associated costs and market impacts have been the focus of a number of economic impact assessments conducted by various governments and their economic analysts, trade associations and management consultancy firms. Cost analyses indicate direct and indirect costs will be substantial and are difficult to assess a priori, but it is widely recognized that SMEs that operate on smaller profit margins and with smaller volumes will be potentially more affected financially, at least at the outset.

Yet there are other value factors to the equation that have potential impacts, both positive and negative, including the benefits of the regulation that relate to improved quality of life, or conversely the potential loss of jobs due to changes in the market. The positive benefits to society in terms of improved health and well being will not only be experienced within the EU; to the degree greater knowledge regarding health and environmental impacts of chemical substances becomes known, and 'green chemistry' supplants hazardous and toxic substances, it is believed that the cost of health care and incidences of disease will decline worldwide. At the same time, the short-term effect of REACH and its impact on jobs has been noted⁶, and the ripple effect throughout all industry and agriculture could be significant, especially if strict application of REACH occurs. However, the ongoing lobbying from trade associations and recent change in

⁵ European Commission Staff Working Paper "Regulation of the European Parliament and of the council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}.

⁶ BBC (2004) EU chemicals law sparks job fears, BBC News 16 November, 2004, 17:13 GMT, last viewed at website http://news.bbc.co.uk/2/hi/programmes/file_on_4/4016313.stm

Annex V of REACH and the guidance on registering has cast further uncertainty for industry who were already struggling to come to terms with their obligations.

The reality of pre-registration and registration will have its effects: some substances will be removed from the market and there is a potential that there simply are no readily available alternatives. With notable exceptions, the global chemical industry is generally widely valued and supported for its economic, social and environmental contributions to society. Now, industry players can be classified under two broad categories: long- or short-term thinking. Immediate costs, the difficulties of change, and temporary uncertainties crowd the minds of the short-term thinkers. The sustainability of the chemical industry, preservation of public health, and commitment to innovation motivate the long-term thinkers.

World exports of chemicals totalled more than €750 billion in 2006, and exceeded €1 trillion in 2007⁷ ⁸. In the United States, as in the EU, the chemicals industry continues to be the top exporting business, despite various disrupting events, and unusually high energy prices. The United States typically accounts for 11 % of the total world chemical exports, about €86 billion in 2006 and €105 billion in 2007. Direct chemical exports from the US to the EU that are likely to be impacted by REACH have been estimated at more than €9 billion, and accounting for 54,000 US jobs. Similar kinds of statistics apply to other parts of the Americas, especially Canada, Mexico, and the main trading countries of South America.

The global chemical market is complex and interlinked; world trade in chemicals reflects an intensely competitive struggle for markets by the producers in an increasingly global industry. The industry is experiencing a significant paradigm shift at present, reflecting maturation and saturation of markets in OECD countries, a shift in production of HPV chemicals to countries where labour markets and volume demand favour growth of those chemicals. Operations that continue or are new within Europe and North America require a shift towards chemical production in substances that are more specialised, in

⁷ U.S. Census Bureau (2008) FT900: U.S. International Trade in Goods and Services, available online: http://www.census.gov/foreign-trade/Press-Release/current_press_release/ft900.pdf, 2008; American Chemistry Council, Responsible Care/Economy/Chemical Industry Exports. see http://www.americanchemistry.com/s_responsiblecare/sec_members.asp?CID=1323&DID=4866

⁸ American Chemistry Council (2008) Responsible Care/Economy/Chemical Industry Exports. available online: http://www.americanchemistry.com/s_responsiblecare/sec_members.asp?CID=1323&DID=4866

areas that support life science, opto-electronics, IT & communications, advanced materials, aerospace and the like. New product areas in biotechnology have a much greater stake in agriculture, pharmaceuticals and food; similarly nanotechnology is becoming the new boom area for development and in all kinds of new products.

Product life-cycle and overall profitability generally depend on maintaining proprietary market share, which, at the end of life cycle for any individual product, erodes due to increased competition from similar or replacement products (sometimes from the same manufacturer, in which case market share is shifted). The impacts of REACH on profitability will undoubtedly affect the smaller, more marginal operations, especially start-ups that are most needy for capital. Thus, initially REACH may stifle rather than encourage innovation. REACH will most likely increase costs across the board, and may increase the trend toward mergers and acquisitions within the chemical industry.

9.2. Cost of REACH Compliance

The main costs associated with a manufacturer or importer complying with REACH include the cost of generating regulatory data on the substance (physicochemical, toxicological and ecotoxicological), registration fees submitted to ECHA (see Section 7), and of course the cost of man hours or consultancy fees to facilitate this process.

Although it is likely that much of the cost of registering substances will be passed to customers through inflation of prices, it is still a large initial monetary outlay that some businesses will find prohibitive to continued business.

Costs for regulatory testing will vary considerably for REACH, depending on the amount of suitable data already available and the nature of the data gaps. Although the cost of regulatory testing varies depending on the testing laboratory and the chemical substance in question, "ball park" costs for obtaining all the data for each tonnage threshold are presented in Table 2. These costs come from general "price lists" from a number of BMT's approved testing laboratories.

It should be noted that the costs for this kind of work varies depending on the nature of the chemical substance, with the possibility of method validation and analytical support.

Table 5 - Cost of all potential studies required for a substance in each REACH tonnage threshold.

1-10 tonnes	10-100 tonnes	100-1000 tonnes	>1000 tonnes
€ ~75,000*	€ ~250,000*	up to €1, 260, 000*	Highly dependant on results of previous studies.

* Not all studies included in the above estimations will be required for all substances; it is highly dependant on the properties of the chemical substance in question. These requirements can be found in Annexes VII-XI of the REACH Regulation.

Basic registration fees for substances range from €1,200 to €31,000, depending on the type of submission (joint or individual) and the tonnage threshold of a substance, with a 30, 60 and 90 % reduction for medium enterprises, small enterprises and micro-enterprises respectively. In addition there are also fees for updating to a new tonnage threshold, for requesting confidentiality, research and development notifications and applying for authorisation for Annex XIV substances (**see Section 8**).

Using generic costs associated with data generation, the specific costs associated with registration submission and the cost of man hours required to achieve the above, it has been estimated that the costs imposed on EU downstream users of chemicals through inflated prices could reach over €5 billion, although such estimates have varied considerably.

9.3. Product Rationalisation

One inevitable outcome of REACH is that certain companies located both within the EU and the rest of the globe will have to rationalise the inventory of chemicals that they manufacture or export. The main reason for product rationalisation is simply that the cost of registering with REACH will not outweigh the benefits of continuing to market the substance in the EU.

Exactly how extensive such product rationalisation will be is unclear. Seeking assurances from suppliers regarding the continued supply of products after REACH has provided a mixed response, especially in the petrochemical industry. In a study by BMT, only 5 % of oilfield chemical suppliers manufacture all of the substances contained in their products, with 65 % manufacturing some and 30 % manufacturing none. This

means that only 5 % of the oilfield chemical industry has full direct control over the effects that REACH will have on their business (see Figure 2).

Of the substances these oilfield chemical suppliers manufacture, their commitments to REACH are reassuring, with >90 % committing to pre-registering the substances they manufacture. Concerning full registration of substances they manufacture, just under half have committed to fully registering all substances, with the remainder still undecided. This is not surprising considering the great consideration that must be given to commit to REACH, given the costs that will be involved.

There is, however, cause for concern regarding substances that oilfield chemical suppliers purchase in order to formulate their products. There does not appear to be adequate communication throughout the supply network to gain REACH assurances. Only 17 % of oilfield chemical companies that purchase component substances for their products have gained assurances for pre-registration of all substances, with 11 % having taken no action yet, and 17 % were unsure of the situation. The scenario is even more concerning for full registration, with only 8 % having sought commitments for full registration, the same 11 % yet to take any action and 28 % unsure of the situation.

Supply chain communications are essential for safeguarding business critical chemicals. Early identification of products at risk due to REACH will allow time for supplier or product substitution.

Another concern many companies are faced with is the performance of a product being compromised due to the active substance or other co-formulant no longer being available to, or viable for, the producer. This information may be very hard to acquire from the makers of products, and will most likely be identified after REACH deadlines have passed. One way risks can be identified is by assessing if a substance meets the Substances of Very High Concern (SVHC) criteria, and particularly those selected as candidates for authorisation (on Annex XIV).

9.4. Micro, Small, and Medium Enterprises (SMEs)

The European Chemicals Industry, although somewhat dominated by multi-national organisations, is also composed of thousands of SME's. The REACH registration fees (Regulation (EC) No. 340/2008), officially adopted in April 2008, recognise the financial burden of REACH compliance for SME's by providing reduced registration fees (**see**

Section 6). As most SME's usually deal with low volume chemicals, there is the added advantage of reduced data requirements and a later registration deadline for lower tonnage threshold chemicals. How this will work in practice though is unclear, considering that the data requirements for all tonnage threshold will have to be in place by November 2010, the >1000 tonne threshold registration deadline. The >1000 tonne threshold data requirements encompass all other tonnage thresholds (see REACH Annexes VII – XI). As there are no rules and little guidance on SIEF's, this may complicate their management until 2018 in several ways. A SIEF member in a lower tonnage bracket, such as an SME, may not want to part with the money required to buy the rights to use study reports until closer to their registration deadline, which may be after the 2010 deadline for the >1000 tonne group. This will complicate the "accounting" of the SIEF as every member is supposed to have paid "fair recompense" to the data holder, so in effect a small refund will have to be paid to all the SIEF members who have already paid for rights to the data. How this will be facilitated is unclear. In addition, an SME may hold data for the same endpoint that has been used by other SIEF members in a higher tonnage bracket. If the results of these studies are considerably different, it may lead to disagreements regarding which study should be used, and why.

9.5. The Positives

Although many players in the chemical industry see REACH as a huge financial burden, and question the reasoning behind the new Regulations, there will be some positives for the European chemical industry. Businesses that manufacture or supply chemical products should benefit from their customers knowing that their products are now safer and environmentally friendlier. As chemicals proven to be highly detrimental to human health and the environment will be phased out under REACH, this will promote innovation of new products that are friendlier to humans and the environment, and the general "greening" of chemistries.

There are certainly going to be business areas that benefit from REACH. The most obvious candidates are lawyers, consultants and regulatory testing laboratories. Lawyers are already benefiting from industries that have challenged the legality of REACH; for example in the USA, many companies approached the World Trade Organisation claiming that REACH was a barrier to global trade and should be abolished, a campaign that was quickly ended. Consultants are also likely to see a

growth in regulatory business thanks to REACH. Many smaller EU companies will not have the manpower or expertise to register chemicals and require the support of consultants, and non-EU companies with no EU legal entity status will be calling on consultants to act as their Only Representative. Finally, regulatory testing facilities which are already seeing their businesses grow from companies trying to address REACH data requirements proactively, will also see a significant rise in tests requested by industry based on data gap analysis during the SIEF stage of REACH. In addition, lucrative contracts will also be awarded to testing laboratories to meet the requirements of the further testing proposal submitted to ECHA as part of the registration dossier, which will consist of expensive and often long term tests on vertebrate animals.

10. About the Publisher

BMT is a leading multidisciplinary engineering, science and technology consultancy offering a broad range of services, particularly in the defence, energy, environment, and shipping and transportation sectors. BMT has over 1200 staff in 27 countries.

BMT Energy and Environment Division provides a comprehensive range of environmental consultancy and software services to clients in the oil and gas and renewable energy sectors, the construction, manufacturing and retail sectors, to national and local governments and to international donor agencies. Its 90 staff provide core services in environmental legislation, impact and risk assessment, management systems, auditing, training and capacity development, stakeholder consultation, social impact assessment, surveying, Geographical Information Systems, data management systems, sustainability, resource efficiency, chemistry, toxicology, software information systems, modelling and research.

BMT has a dedicated REACH Team, based in our offices in Aberdeen, London, Washington, Hong Kong and Melbourne with a wide range of relevant experience. The team offers comprehensive services to EU companies to support them in meeting their obligations under REACH, and can act as their EU third party representative.

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