

# Delphic HSE Solutions Ltd

All your Business Needs for Health Safety and Environmental Support



# REACH

**Delphic HSE Solutions Limited**

**“Only Representative” Service**

**For Non-EU Companies**

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# Implications of the REACH Regulation

## A Practical Guide

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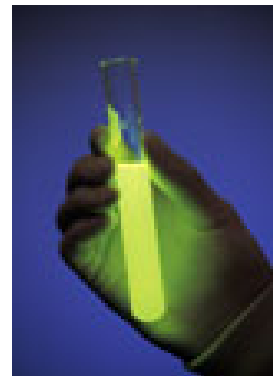
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## Introduction

REACH, the European Union Regulation for the **Registration, Evaluation, Authorization and Restriction of Chemicals** came into force on 1<sup>st</sup> June 2007.

REACH fundamentally alters the way in which all Chemicals are regulated and, given the global nature of the regulatory process, may well prove to be a blueprint for other countries: already China is looking at the possibility of introducing similar laws.

This document gives some background to the REACH Regulation and outlines how REACH is expected to work. REACH establishes the European Chemicals Agency (ECA) which is a new EU body that will administer the Regulation, and until the ECA starts work in June 2008, no-one will know for certain how things will operate.



## REACH in Outline

REACH is radical, but it is also very simple. The fundamental principle underlying REACH is that if a company manufactures chemicals in the EU, or if anyone wants to import chemicals into the EU, then they must :

- ◆ Know what those chemicals are used for
- ◆ Know what the effects on man and the environment will be
- ◆ Provide an assessment of risk to the authorities to demonstrate that any risks are known, understood and manageable.

***In short they must take responsibility for their actions.***

Behind that simple idea is a piece of legislation that is 849 pages long, with another 700+ pages covering standard methods for determining physico-chemical, toxicological and environmental properties. This replaces over 40 existing pieces of legislation.

## Why REACH?

The Pre-REACH position with regard to chemical regulation in Europe was mixed. New chemicals were subject to rigorous examination, whilst the great majority of "existing" chemicals are still unknown quantities as far as their potential adverse effects are concerned. They only came under investigation when something went wrong. Examples are lead from additives in petrol adversely affecting children's learning ability, asbestos from insulation, automotive components leading to mesothelioma, vinyl chloride causing liver tumours in PVC workers and many more.

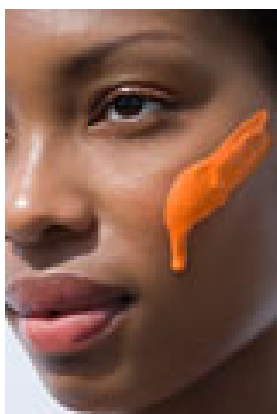
The responsibility for working on existing chemicals was delegated to the member states, each state taking the lead on a small number of compounds. This response to increasing public and political concerns about the safety of chemicals was, however, largely ineffective. Despite much time and effort, none of the reviews, started in the 1990s, were completed. Clearly the situation was not sustainable, and it was agreed that a new way of dealing with the regulation of chemicals was needed.

The process began with the chemicals white paper, a comprehensive consultation document, published on 27<sup>th</sup> February 2001. Following extensive consultation, the REACH regulation was the result, finally agreed on 30<sup>th</sup> November 2006, a mere five years and nine months

## REACH Overview

The first thing to note is that REACH is a Regulation. A Regulation becomes Law in each member state shortly after it is published in the Official Journal of the EU. It becomes Law as written, with no further implementation or interpretation by the member states and it comes into force in all member states at the same time. A Regulation is truly a pan-European piece of legislation: REACH came into force on 1<sup>st</sup> June 2007.

REACH replaces over 40 existing EU Directives. Much of the detail regarding the test methods for determining toxicity and physico-chemical properties remains unchanged. What is new however, is the emphasis on **risk-based assessment** instead of prescriptive data generation. This brings in a more interactive process of discussion with the regulators, so that if a scientific case for a particular course of action (or no action) is justified, then that can be pursued. The EU legislation on cosmetics was the first legislation that introduced the concept of professional risk assessment to ensure public safety: REACH extends that principle to all chemicals. It is now the responsibility of the manufacturer to assess risk and to demonstrate that the chemicals made or imported can be used safely, and that ultimate disposal will not pose a risk to health or the environment.



## REACH Aims

The main aims of the REACH regulation are:

- ◆ To transfer responsibility for the assessment of risk from the regulatory authorities to the manufacturer / importer in the EU
- ◆ To ensure that there is an adequate flow of information from the manufacturer / importer to users down the supply chain to enable them to handle and use the material safely
- ◆ To ensure that information flows up the supply chain to the manufacturer / importer so that how the chemicals are being used is accounted for when assessing risk

### Cost Control

There are a number of subsidiary ideals to REACH, some directly related to the main aims such as the substitution of active chemicals by alternatives of lower toxicity. Cost control is an essential element of the REACH Regulation. This is achieved by the formation of consortia of manufacturers, importers and users to share not just existing data, but also the development of new information (and associated costs) as required. REACH also aims to reduce, as far as is possible, the use of animal testing. Testing of formulated cosmetics has been banned by law in the UK since 1995 and the testing of finished products in the EU was outlawed by the 7<sup>th</sup> Amendment to the Cosmetics Directive. REACH is built to some extent on the experiences gained from Cosmetics regulation in the EU.



### Data Sharing

In order to carry out any risk assessment, there is a need for information on the hazards associated with the material in question and these data, together with information on exposure, form the basis of the risk assessment. One of the reasons for the introduction of REACH is that, for many existing chemicals, there are few that have comprehensive toxicological data and even fewer for which environmental information is available. One of the aims of REACH is to ensure that these data gaps are filled as far as it is necessary to do so, in order for the risk assessment to be carried out. All chemicals produced in quantities greater than 10 tonnes per year are subject to a risk assessment before they can be legally sold within the EU, with responsibility falling on Manufacturers and Importers. Generation of appropriate data is a significant aim of the REACH Regulation.

However, it is also a stated aim of REACH that the amount of testing, and animal testing in particular, should be minimized. This is addressed in the first phase of the REACH Regulation, as soon as the ECA becomes operational on 1<sup>st</sup> June 2008. The mechanism for achieving this end comes in two parts, the first is pre-registration and the second is the mandatory sharing of information in the Substance Information Exchange Fora (SIEF) which are the first projected activities that will need to be undertaken under REACH. These are described on page 5 in the section on data sharing.

### Pre-Registration

REACH applies equally to new and existing chemicals produced or imported in quantities greater than 1 tonne per year per manufacturer or importer. For new chemicals the process is straightforward and a dossier must be submitted containing all of the relevant information, as well as a risk assessment if required. For existing chemicals however, and there are a lot of these, the chemicals themselves are already on the market and in use. It is acknowledged in the Regulation that, from a practical standpoint, it is not feasible to require that all registrations must be completed on the day that REACH comes into force, nor is it possible to remove chemicals from use until they have been registered. It would not be physically possible to generate and assess all of the data and it would cause economic collapse if 90%+ of the chemicals in use in Europe were withdrawn overnight.

To overcome these difficulties the concept of Pre-Registration is built into the REACH Regulation. If a manufacturer or importer pre-registers their chemicals with the ECA then they can continue to sell those chemicals within the EU until they are fully registered.

*Pre-Registration enables manufacturers / importers to take advantage of an extended time span in which to complete the registration process.*

The timescale for the completion of registration is dependent on the properties of the substance and the annual tonnage that is either manufactured or imported into the EU. The timetable is shown below.

### REACH Timetable

Date	Activity	Tonnes
1 Jun 2007	REACH Comes into Force	
1 Jun 2007	European Chemical Agency formed	
1 Jun 2008	European Chemical Agency becomes operational	
1 Jun 2008	Registration of New Chemicals begins	
1 Jun 2008	Start of Pre-Registration for existing chemicals	
1 Dec 2008	End of Pre-Registration	
1 Jan 2009	Publication of Manufacture and import information on EU Database	
1 Feb 2009	Beginning of SIEF formation	
1 Dec 2010	Registration Deadline	
	High Volume Substances	>1,000
	Persistent, Bioaccumulative, Highly toxic to the Environment	>100
	Carcinogens, Mutagens, Toxic for Reproduction	>1
1 Jun 2013	Registration Deadline	
	Medium volume substances	>100
1 Jun 2018	Registration Deadline	
	Low volume substances	>1

### Pre-Registration Information

The information required at pre-registration, for all substances manufactured or imported into the EU in quantities greater than 1 tonne per year is as follows:

- ◆ Name of chemical substance
- ◆ EINECS number
- ◆ CAS number (or any other identity code)
- ◆ Name and address of registrant
- ◆ Name of contact person
- ◆ Envisaged deadline date for registration
- ◆ Tonnage band.

This information will be submitted to the ECA by means of a software download that is available free of charge from the ECA website. The information will be entered into a database, known as IUCLID 5, which will form the basis of the entire registration process.

***The importance of the pre-registration process and the 6-month window from 1<sup>st</sup> June to 1<sup>st</sup> December 2008 cannot be over emphasized.***

If manufacturers and importers wish to make use of the extended deadlines for the completed registration process they must pre-register their substances; if they do not, and the window is missed, then the chemicals that they produce or import will be classed as "new" and will be subject to the full registration process before they can be legally sold. In short, they will have to be withdrawn from sale until a registration is completed.

### Sharing Data, The Substance Information Exchange Fora (SIEF)

The sharing of information and costs is not a new idea; industries have been generating data in response to regulatory requests in both Europe and the USA for many years. The EU have learned from the experience with existing chemicals that cost-sharing is an emotive issue and those companies who have generated data should not be disadvantaged commercially by the REACH requirement for data sharing. On 1<sup>st</sup> January 2009, one month after the closure of the pre-registration window, the ECA will publish, on its website, information on all of the chemicals that have been pre-registered and the contact details of the companies associated with each substance. The intention is that those with an interest in each chemical get together to exchange information and compile the registration dossier jointly, sharing costs equally and as all are involved in assessment of the existing data, minimizing the likelihood of duplicate studies.

There are some rules in the REACH Regulation that cover the formation and functioning of a SIEF and the subsequent submission of registration documents. These will not be tested until January 2009 at the earliest so there is no indication of how effective they will be. However the basic rules, as an indication of how data sharing is *supposed* to work, are shown below.

### Operation of a SIEF

- ◆ Data submitted to a SIEF shall be given freely and costs may then be shared in a manner agreed by all parties; if agreement cannot be reached on cost sharing, costs shall be shared equally. In cases of dispute the ECA will arbitrate if necessary
- ◆ All sources of data are acceptable: published papers, internal reports, read-across from other related compounds, Qualitative/Quantitative Structure Activity Relationship (QSAR) data etc. providing that it can be scientifically justified
- ◆ Existing data do not have to have been generated subject to Good Laboratory Practice (GLP) and / or Quality Assurance (QA) checks for it to be acceptable
- ◆ New data generated for registration purposes shall be according to OECD Test Guidelines and subject to GLP
- ◆ If animal testing is proposed, approval for the studies must be obtained from the ECA before the work is carried out. This is to cover the eventuality that some confidential information may be known to the ECA that provides information unknown to the SIEF and that could render the proposed test programme redundant. There may also be non-animal *in vitro* or *in silico* methods that would generate information acceptable to the ECA that had not been considered by the consortium involved in registration
- ◆ Costs of any new data generated shall be shared equally by all members of the consortium, in proportion to their obligation, based on tonnage
- ◆ The participants in a SIEF shall agree the classification of the substance
- ◆ It is anticipated that the major producer in a SIEF shall act as the lead organization, although this is not obligatory

As can be seen, there will be a lot of intra-industry co-operation and communication in relation to each SIEF, and it will be a time-consuming exercise on the part of those organizations or companies that are involved in the registration process. Time will tell whether the practicalities of co-operation match the theory as expressed in the REACH Regulation. It is not a new thing however, for the major EU Chemicals producers to act in response to legislation in this way. What will be interesting is to see how major importers, such as retailers react to their obligations under REACH. Exporters to the EU will need to ensure that their interests are represented by an 'Only Representative' if they are going to take responsibility for REACH registration away from their customers, the importers, who otherwise will have the responsibility under the REACH regulation for registration.

Importers will need to determine whether they are going to accept responsibility for REACH activities, or whether they will come to an agreement with their suppliers whereby the supplier will appoint an 'Only Representative' within the EU to carry out REACH registration for their products.

***If an 'Only Representative' solution is sought, Delphic HSE Solutions can assist the non-EU manufacturer by acting on their behalf and, by so doing, maintaining commercial confidentiality between manufacture and importer.***

## Exemptions from REACH

REACH only applies to substances made or imported in quantities of 1 tonne or more per manufacturer or importer per year for registration purposes. If the amount made or imported is less than one tonne of each individual substance per year per importer, then there is no obligation to register.

There are also exemptions for particular types of chemical. These are in general related to product groups that are already subject to their own strict regulatory requirements, such as food, pharmaceuticals, agrochemicals, radioactive substances and biocides.

- ◆ Polymers are not subject to REACH largely because such molecules are generally inert, however if free monomer is present at 2% or more, then the polymer is subject to registration by virtue of the monomer content. Also, although polymers are exempt from registration, any substances added to the polymer, e.g. plasticizers *may be* subject to registration if these additive substances are intended to be released; it is the polymer, not the plastic, or the product that is exempt.
- ◆ Cosmetics are exempt from REACH as far as *the human health implications are concerned*. Cosmetic products imported into the EU may contain ingredients that are not subject to the human health risk assessments required under REACH because these are already addressed in the Cosmetics Directive which requires that each product is assessed for safety by a qualified individual before the cosmetic can be placed on the market. The environmental effects of Cosmetic products are not subject to this professional assessment however, and these aspects *are* subject to REACH.

## Cosmetics

Any importer of cosmetic products that imports chemical substances that total over 10 tonnes per year will be required to register those chemicals that are present at a concentration that results in the formulation being classified or >0.1% (whichever is the lower) and to generate an environmental risk assessment. This is of particular relevance to retailers and other importers who bring into the EU items such as shampoos and hair care products. Many of these products can utilize similar basic ingredients. The total imported volume of some chemicals such as surfactants (Sodium Lauryl Ether Sulphate), cationic conditioning agents and so on across a wide range of goods may well exceed the one tonne limit, triggering the REACH registration process and environmental risk assessment for the chemical substances that exceed 10 tonnes.



In addition, the packaging of the cosmetics themselves, although considered articles, may contain substances that could be subject to REACH. It will be the responsibility of each importer to determine their obligation under REACH with respect to the goods that they import. In order to determine what obligations there are, an importer will need to know:

- ◆ The total tonnage of each product that they import per year
- ◆ The formulation of each product
- ◆ The weight of packaging
- ◆ The composition of packaging

It is the responsibility of the importer then to calculate the weight of each chemical that they import with each product / package. These will then need to be added to give the total amounts of each chemical that they have imported over the year, and if any single chemical substance totals 1 tonne per year or more, then that substance will be subject to notification and registration. Suppliers to the EU will need to be aware that these data are going to be requested by their customers. It will not be enough to simply state that there are no substances that exceed the 1tonne limit; each importer may well have several sources of the same chemical in a year and it is the total annual amount from all sources that will be important, not the amount involved with just one product from a single supplier.

If suppliers appoint an Only Representative however, there is no obligation on their customer (the importer) and no requirement to divulge confidential information to anyone other than their representative.

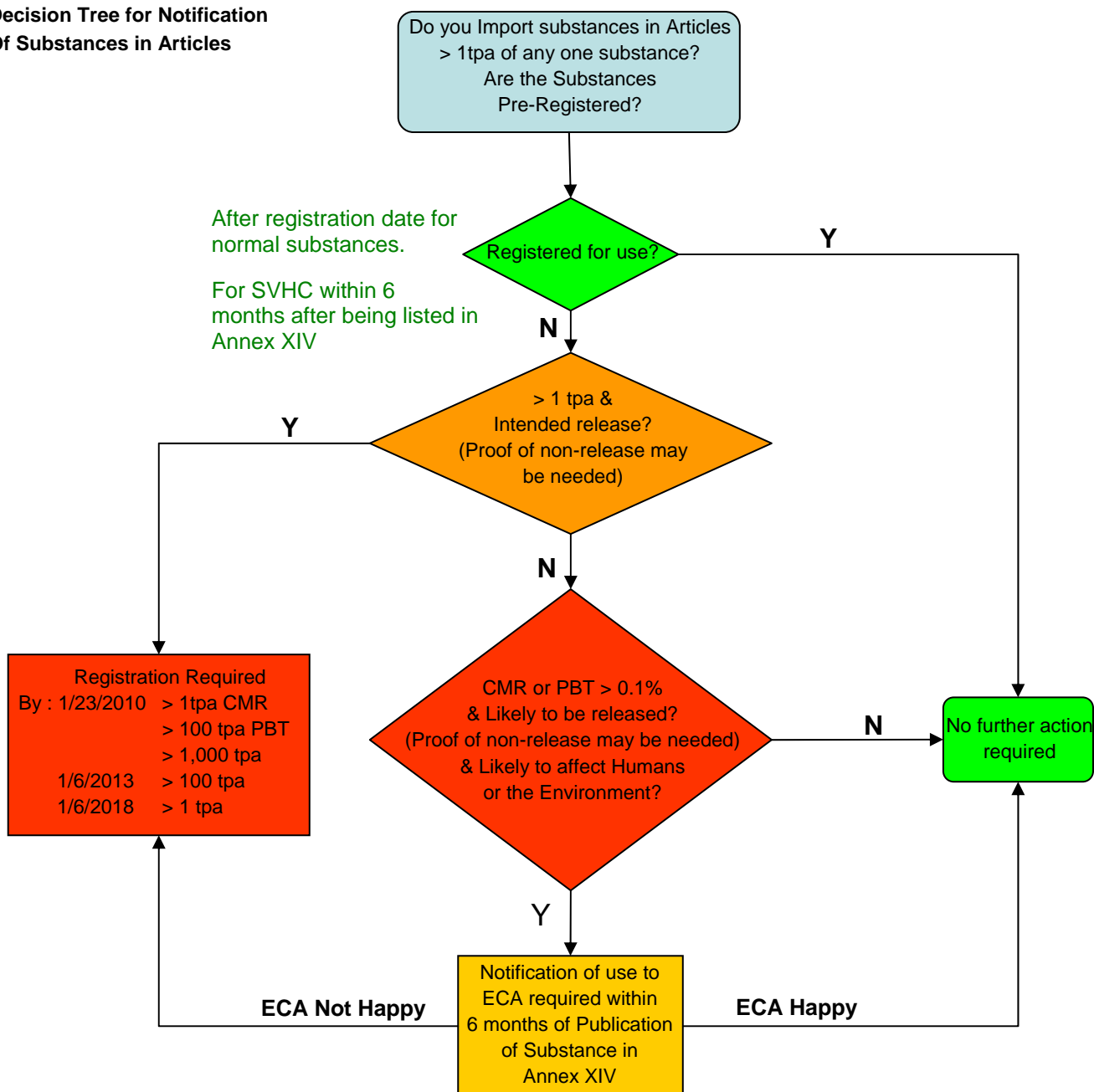
**Delphic HSE can maintain confidentiality and ensure regulatory compliance for non-EU Cosmetic suppliers.**

## Registration

In order to register a chemical – and remember REACH applies *only* to single chemical substances, no matter how they enter the EU – a registration dossier must be submitted to the ECA. The information that is required is related to physico-chemical properties, mammalian toxicology and environmental effects. For a cosmetic import, the human health effects are not required. There are sections in the REACH Regulation that detail the various pieces of information that must be addressed when submitting a dossier. It is the job of the ECA to ensure that all these headings have been addressed, by checking the completeness of each registration dossier before it goes on for detailed assessment. It must be stressed that REACH is not a box-ticking exercise in the sense that all tests must be completed before a registration can be approved. That was one of the failings of the old system that led to the development of REACH; if a certain test had not been done then a registration was rejected, irrespective of whether the test was relevant or not. Under REACH it is important that each phase referred to in the regulations is addressed, but that may simply be by giving a scientifically valid reason why a particular piece of work is not necessary or inappropriate in a particular instance. This again, is related to the aim of avoiding unnecessary work and costs.

For REACH the requirements for registration start at 1 tonne per year. It is recognised however, that a large amount of potentially dangerous materials may be brought into the EU as a component of articles each year. As a result of this, there is a requirement that if a substance of very high concern is present in an article at greater than 0.1%, there is an obligation to notify the presence of the substance to the ECA. A decision tree for substances in Articles is shown below. No further action or obligation exists at this stage, although in the future the ECA may require a full registration.

## Decision Tree for Notification Of Substances in Articles



## Registration Dossiers

The registration dossier comprises several parts. The first is the Chemical Safety Report – required for all substances made or imported in quantities >10 tonnes per year. In this document a manufacturer / importer must assess the safety of the chemical in respect of all identified uses. All stages of the life cycle must be addressed, from manufacture to ultimate disposal and including an assessment of all notified uses of the chemical in question. The uses are identified by those downstream in the supply chain who have an obligation under REACH to inform their supplier of the ways in which the particular chemical substance is used. In this way the manufacturer can take account of all uses of the chemical when assessing exposure and hence risk.

The chemical safety report contents are given in detail in Annex 1 of the regulation. One of the fundamental requirements is that the chemical safety assessment “shall be compiled by people with the appropriate competence and training”. This is a task that cannot be delegated to just anyone. At present Cosmetic Safety assessments are carried out by people competent and trained at assessing human health risks. Under REACH, environmental risks will need to be assessed and it may not be the case that an individual will be competent at assessing environmental risks just because they have the experience needed to assess health risks.

It is permissible to use information from any source in the compilation of the chemical safety report, providing that it can be scientifically justified. Sources such as data on similar compounds – read across – structure / activity data and so on are all permitted. The steps of a chemical safety assessment shall include:

- ◆ Human health hazard assessment
- ◆ Human health hazard assessment of physicochemical properties
- ◆ Environmental hazard assessment
- ◆ PBT and vPvB assessment

Inherent in these assessments will be the generation of exposure scenarios that reflect all uses of the substance and also an estimation of the exposure that will result during those scenarios.

Combining the hazard and exposure information into a risk assessment is the final stage. This of course, will vary in detail on a case-by-case basis and it is not intended that there should be a one-size-fits-all model for risk assessment. It is the responsibility of the manufacturer to establish the criteria that they use for their risk assessment. Only necessary information is required: it specifically states in the Regulation that “When information is not necessary in accordance with Annex IX, this fact shall be stated under the appropriate heading of the chemical safety report...” It is essential to realize that the entire process is an iterative one and not prescriptive. The intention of REACH is not to promote a lot of unnecessary testing that will place burdens of cost on the chemical industry. The aim is to ensure that those who manufacture chemicals (or import them into the EU) know and understand the properties of those chemicals and the risks involved in their use. Responsible chemical manufacturers have in fact been doing this in relation to their products for many years, a good example being the Responsible Care programme that began in Canada and is now adopted by many chemical companies around the globe.

## What REACH Means for Importers

The implications of REACH are much simpler for manufacturers of chemicals within the EU than they are for importers of preparations and articles.

The first difficulty lies in the fact that manufacturers outside the EU may be reluctant to divulge the content of their products. This is understandable as the formulation represents the investment and commercial advantage of the manufacturer. Under REACH however, it is the importers responsibility for ensuring compliance, not that of the non-EU supplier of the goods. If for example, a major retailer in the EU imports a range of goods from manufacturers outside the EU then the retailer is responsible for the totality of the chemicals that are being imported, not just the amount of chemical being imported per product. A retailer may for example, bring in several hundred different types of products during a 12-month period. Each of those may contain potentially a number of common ingredients; sodium lauryl ether sulphate for example, may be found in shampoo, bath and shower gels, toothpaste, household cleaners, washing up liquid, car cleaning products and so on. In any one product-range it is possible that the amount of SLES imported may be below the one tonne per importer per year amount that triggers a REACH obligation, but if the total amounts of SLES that are bought into the EU across the range of imports are considered, it may be that a single retailer may be importing SLES in the 100 tonne per year range, if not into the thousands.

For importers therefore, there is a complex requirement to know exactly how much of all chemicals, across all product ranges, they are bringing into the EU. From each supplier therefore, a retailer will need to know:

- ◆ How much product they buy on a year-by-year basis from each non-EU supplier
- ◆ What the formulation is of each product that they buy so that they can calculate the total amount of each chemical substance that they import across all product ranges.

**It will not be enough for a retailer or other importer of multiple products to obtain reassurance that none of the ingredients will require REACH registration from a supplier, as this will not address their overall obligation.**

## Information Flow and The Safety Data Sheet

REACH is not only concerned with identifying the properties of chemical substances that enter the European Market, but it is also concerned about the supply of information about those properties up and down the supply chain.

The means of achieving this objective is the Material Safety Data Sheet (SDS) which is a regulatory requirement for all single substances and preparations that are classed as Dangerous according to the EU Classification system. These sheets have been in use for many years and their 16-section format has become a global standard adopted in many countries around the world. The aim of the current sheets is to identify hazardous properties, to advise on the safe handling of the chemicals concerned and also to give basic first aid advice in the event of an accident or spillage. REACH introduces some minor typographical changes to the SDS, with the reversal in order of sections 2 and 3, but the major changes relate to the risk and exposure information that will form a fundamental part of the information in an SDS and which were not included previously. Exposure scenarios, depending on the use of the substance, will be incorporated into the data sheet that, along with information on hazard, will enable an element of risk assessment to be incorporated into the SDS. Of course these new format sheets can not be produced until the new information required by REACH becomes available from 2010 onwards, so it is not yet clear what the new sheets will be like. It is probable that for some chemicals that have many different uses, a different SDS will be required for each use.

Not all substances and preparations require a SDS by law. If the product is not classified, is not subject to (or in the case of a preparation, does not contain substances subject to) a workplace exposure or control limit, and if there are not substances contributing to the classification of the product, then a SDS is not a legally-required document. It is common practice in many companies however, for a SDS to be required for all products entering premises and this requirement may be expected to continue, and expand, after REACH becomes fully implemented.

Articles are also not subject to the need to supply an SDS. There is however, a requirement under REACH for the presence of substances of very high concern that are present in articles to be notified down the supply chain to recipients of the article. If an article contains any substance that is classed as carcinogenic, mutagenic or toxic to reproduction or is persistent, bioaccumulative or highly toxic in the environment, and is present in an article at >0.1% by weight, then the presence of that substance must be notified to recipients in the supply chain and also, on request, to consumers. The name of the chemical substance must be given together with sufficient information to enable the article to be used safely.

**Delphic HSE can assist with the production of REACH-Compliant Material Safety Data Sheets and advise on communication of risk by other media as required.**



### Action Required!

At this stage in the REACH process and until 1<sup>st</sup> June 2008, companies should be concerned about the process of information gathering. Knowledge of the chemicals manufactured and imported is essential and if it is not readily available systems must be established whereby this information can be obtained. It is essential that downstream users of chemicals inform their EU based suppliers of the uses that they are making of chemicals, in order that these uses can be taken into account during the registration process.

It is also essential that downstream users make known to their suppliers that they wish to continue using chemicals. It has already been made clear by some major suppliers that they will not be supporting their entire product portfolio with registration, taking the opportunity to concentrate on core products from which they generate the biggest profit margins. Ensuring continuity of supply will be a significant part of the information exchange process up and down the supply chain. The time to pre-registration is getting shorter by the day. The 2008 deadline is coming!

## Conclusion

REACH came into force on 1<sup>st</sup> June 2007 and is a revolution in chemical regulation in the European Union. REACH applies only to EU Manufacturers and importers of chemicals into the EU, irrespective of how they are delivered to the market. Responsibility is placed on the manufacturer for assessing the risk associated with all aspects of the manufacture, use and disposal of chemicals in as far as they can affect human health and the environment. A risk assessment must be submitted to a new EU body, the European Chemicals Agency, which is established under REACH to police and administer the system. The requirements of REACH are to a large extent, already being met by the large European chemical manufacturers.

Cosmetics are exempt from the human health requirements of REACH, however the packaging and the environmental aspects of cosmetic use are subject to REACH and will be subject to registration and control. Cosmetic ingredients are, of course, considered as chemical substances and will be subject to REACH in its entirety.

It is imperative that manufacturers in the EU and importers of goods into the EU begin the process of information gathering as soon as possible and that the systems for ensuring that they have the information that they need are robust and in place before 1<sup>st</sup> June 2008. Those manufacturers and importers who pre-register their substances in the 6-month window between 1<sup>st</sup> June and 1<sup>st</sup> December 2008 can then take advantage of the extended time available to complete the registration process – up until 1<sup>st</sup> June 2018 for low volume, low toxicity substances. If the pre-registration window is missed, then the consequences can be severe; substances will be considered to be “new” chemicals and a full registration must be completed before the substance can be legally marketed in the EU. If this applies to a product already on sale then it must be withdrawn from the market until the registration is complete.

## Delphic HSE REACH Services

Delphic HSE Solutions Limited staff have been working on REACH since the publication of the EU Chemicals White Paper in 2001 and have been active across Europe and the Far East in presenting training seminars to Companies and Industry Associations. Presentations have been given in Hong Kong, Brussels and New York, as well as across the UK, on the requirements of the REACH Regulation giving us a breadth of experience in the new regulation. Also, as a result of our activities, we have developed a deep understanding of the needs of various industries from retail and clothing manufacturers to oil companies and mineral extraction.

Delphic HSE is therefore able to offer the services listed below to our customers who require professional and cost-effective assistance in meeting their REACH obligations.

### REACH Services Available

- 1. Data Gathering.** Using the Delphic HSE **REACH Obligation Tool** will give a simple cost-effective means of working out the annual volume of chemicals and hence the obligation to register
- 2. Pre-Registration.** Delphic HSE is already registered with the European Chemicals Agency as a user of the IUCLID 5 Database. We are therefore able and ready to act on behalf of clients to pre-register their chemicals in the 1st June to 1st December pre-registration window in 2008.
- 3. Information Exchange.** The first activity after pre-registration is the submission of information into the IUCLID 5 database in conjunction with other interested parties. Ensuring that information on use of chemicals is a part of the REACH risk assessment, is vital to business continuity for importers. Delphic HSE staff can liaise with other companies to ensure that all the relevant data are included in the assessment process and that commercial confidentiality is maintained.
- 4. Data Assessment.** The professional staff at Delphic HSE Solutions are experienced at the assessment and evaluation of complex toxicological data. Involvement of Delphic HSE Professionals will ensure that assessments are cost-effective and new data generation is only undertaken when necessary, saving time and testing costs.
- 5. Risk Assessment.** Risk assessment is central to the operation of REACH. Delphic HSE professional staff have between them over 150 years of experience in the evaluation of data applied to the risk assessment of chemicals.
- 6. Toxicological and Environmental Expertise.** When testing is required, rest assured that the involvement of Delphic HSE staff will ensure that the testing is carried out in a way that maximizes the value of the work. Not all testing facilities are the same and Delphic HSE staff are experienced in working with multi-functional teams to give the correct result at the right price.
- 7. Product Development.** Delphic HSE professionals have experience in industry and product development of a vast range of products. When it comes to having to find a substitute for a chemical that is no longer available, Delphic HSE can be a part of your research team and offer guidance on the properties of chemicals that may save you expensive reformulation costs later on.
- 8. Complaint Information Analysis.** Information feedback from the marketplace or the shop floor is a prime source of information on the properties of chemicals. It is also open to abuse by the making of false claims. Delphic HSE staff are experienced in the analysis of human and environmental data and often appear as expert witnesses in court cases.

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