



Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Complying with REACH – A Guide for SMEs

Second Edition

SPRING
singapore

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To understand fully the obligations that you will have under REACH, we recommend that you consult the REACH website at www.echa.europa.eu, or the REACH legal text (EC 1907/2006).

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FOREWORD

The European Union (EU) enacted its regulation for the Registration, Evaluation, Authorisation and Restriction of Chemicals, or REACH, on 1 June 2007. The regulation has a significant impact on businesses that directly export or are part of the supply chain that export to the EU.

Singapore exported almost \$11 billion of chemicals and related products to the EU, accounting for 23% of total exports to that region in 2008. In addition, industries such as electrical and electronics, which are downstream users of chemicals, contributed 50% of total exports to the EU. REACH, therefore, affects a broad spectrum of our industry sectors.

Even before REACH came into force, SPRING has been working with the Singapore Chemical Industry Council to prepare Singapore companies to comply with REACH. Among these efforts is the publication of the first edition of this guidebook in 2007 to help our companies to understand what REACH is and what they need to do.

With the end of pre-registration period in December 2008, businesses now have to meet various registration deadlines in order to continue to export to the EU. They also need to manage REACH enforcement and communication down the supply chain. Meanwhile, rapid developments related to the different REACH processes have been taking place in the EU to ensure that businesses will be able to meet the various related timelines. To help companies keep up to date with REACH registration and to overcome difficulties they may face, we have updated this guidebook to include the latest developments of REACH and practical tips for companies who need to register their products or who may be involved with information exchange with their EU customers as part of REACH requirements. We have also included two case studies of companies involved with REACH registration and the proactive steps they have taken to ensure that they comply with REACH and are hence able to remain in the EU market.

I hope you will find the new edition of this guidebook just as informative and useful as the first edition. I also welcome you to join us in our seminars and workshops to keep abreast of REACH and be prepared to meet the requirements to stay competitive.



Png Cheong Boon
Chief Executive
SPRING Singapore





REACH - KEY ELEMENTS

REACH is a new regulation by the European Union (EU) which entered into force on 1 June 2007. It affects all businesses in the EU as well as those outside the EU with dealings in the EU market. If any of your products end up in the EU, either directly or indirectly, chances are they may be affected by REACH.

1.1

THE ABCS OF REACH

REACH – **R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **C**hemicals – is a Regulation which entered into force in the European Union (EU) on **1 June 2007** designed to reduce health and environmental risks caused by chemicals and promote the development of green chemicals.

WHAT DOES REACH INVOLVE?

Registration of chemicals in quantities of **one tonne per year and above** by manufacturers and importers of chemicals, chemical preparations and – in some cases - products containing chemicals.

Evaluation of registered chemicals to establish if the information submitted is compliant, whether further information is needed (dossier evaluation) and additional measures are required (substance evaluation) to ensure their safe use.

Authorisation of chemicals identified as substances of very high concern (SVHC) – chemicals that may cause severe health or environmental problems – before they can be made, imported or used in the EU market.

Restrictions imposed on the manufacture, import and use of high risk chemicals – chemicals which cause unacceptable risks to the health and environment and which need EU-wide action.

Classification and Labelling of all chemicals including those identified as hazardous in a standardised classification system.

Communicating hazard information posed by chemicals and methods to ensure safe use of chemicals. This requires communication on how chemicals are used up and down the supply chain by all actors in the chain.

WHO ADMINISTERS REACH?

The European Chemicals Agency (the Agency or ECHA) has been established to manage chemical registration and authorisation, carry out dossier evaluation, co-ordinate substance evaluation and restrictions on chemicals.

WHO ENFORCES REACH?

REACH is a Regulation that applies to all 27 EU Member States (MS) as well as Norway, Iceland and Liechtenstein (European Economic Area) (EEA). Each MS has its own competent authorities (CA) to enforce REACH within its borders. The enforcement includes areas such as pre-registration, registration, safety data sheets (SDS) for phase-in substances, communication with ECHA on details of the registration dossier, and articles. Similarly, each MS will have its own penalties for non-compliances, which include fines and penalties.

The key target groups for enforcements are manufacturers, importers, downstream users (DUs), distributors, and only representatives (ORs) appointed by non-EU manufacturers.

WHY DO WE NEED REACH?

Chemicals have always been regulated due to the strong potential link between chemicals and a wide range of diseases, including respiratory and bladder cancers, eye and skin disorders, and asthma.

Pre-REACH laws did not effectively regulate chemicals and foster the development of new chemicals. Based on the cut-off date of 1981, there are two groups of chemicals – existing and new. Existing chemicals (approximately 100,000 reported) required no testing before marketing. Only new chemicals were tested in a rigorous manner. As a result, little is known about the hazards of existing chemicals and the development of new chemicals was significantly hindered.

REACH not only dispenses with the distinction between existing and new chemicals, but also introduces efficient processes for evaluation and authorisation which speeds up the chemicals restriction process.

REACH replaces some 40 chemical regulations and creates a single system for the regulation of chemicals.

Other chemical regulations that are not centralised under REACH will continue to apply.

HOW DOES REACH PROMOTE GREEN SUBSTANCES?

REACH promotes the development of green substances – especially substances that are friendly to humans and the environment – in a variety of ways. For instance:

1. There are more exemptions for substances used for research and development than under previous chemical legislation.
2. Businesses are required to consider alternatives and substitutes when seeking authorisation for the uses of SVHC.
3. The availability of alternatives/substitutes will be considered in decisions to authorise uses of SVHC and to impose restrictions on these substances.

1.2

SUBSTANCES AFFECTED BY REACH

REACH does not only affect dangerous chemicals, but also substances made, imported and used in the EU market. REACH applies to both chemical substances on their own, as well as chemicals which are part of preparations and – in some cases – chemicals used in articles/products.

In other words, REACH applies to chemicals used in industrial processes and in day-to-day products such as detergents, paints, clothes, furniture and electrical appliances.

WHAT SUBSTANCES ARE EXEMPTED?

Some substances are generally exempted from the overall scope of REACH as they generally present low risks to health and safety such as water, oxygen, noble gasses and cellulose pulp. Also, substances which occur in nature such as minerals, ores and/or concentrates as well as cement clinker are excluded from registration as long as they are not dangerous or have not been chemically modified.

Others are specifically exempted from certain provisions.

The following are not regulated by REACH:

- Substances under customs supervision (i.e. are only transiting through the EU) unless there is processing or treatment
- Transport of substances in the EU
- Substances used exclusively in the interest of defence
- Substances used exclusively as non-isolated intermediates*
- Waste

* Non-isolated intermediates are transient substances that exist only at a point in time in a manufacturing process. They are not manufactured as chemicals and are not released/removed from the process in which they are created.

Certain substances are exempted from specific REACH procedures as they are already controlled by other regulations e.g. medicinal products and radioactive substances.

Polymers are currently exempted from registration and evaluation. The European Commission (EC) will reconsider this in the coming years. The basic constituents (the monomers), on the other hand, must be registered. This includes the bound (or reacted monomers).

There are also special rules relating to chemicals used for research and development.

A list of exemptions can be found in Annex IV and V (Exemptions from the Obligation to Register) of the REACH legislation. The other exemptions are described in Article 2 (Application) of the REACH legislation.

REACH AND YOUR BUSINESS

REACH has far-reaching effects because it not only regulates chemicals and chemical preparations but also products containing chemicals. As many products contain chemicals in one form or another, REACH affects most industries in the EU market.

WHO DOES REACH AFFECT?

REACH affects all parties – manufacturers, importers, distributors, retailers and users – in the supply chain for chemicals, chemical preparations and products containing chemicals in the EU.

Singapore businesses with presence in the EU are treated as EU businesses. As such, you must comply with all the obligations imposed by REACH. If you fail to comply, you will no longer be able to make, import, distribute or use your chemicals, chemical preparations or products containing chemicals in the EU.

Those who do not have presence in the EU but have dealings with the EU market should still be aware of the obligations imposed by REACH. Your EU customers will need to comply and they will turn to you for help, information and advice. If you are unable to help your customers comply, they may be forced to look for new suppliers/business partners.

HOW WILL REACH AFFECT MY BUSINESS?

REACH affects your business in many ways. For instance:

- Your goods may need to be registered or authorised before they can be imported into the EU market.
- You may need to find substitutes or alternatives for the substances in your goods which have REACH restrictions imposed on them. This may occur when your EU customers may find it too inconvenient to register or seek authorisation for those substances.
- You could face cost increases as your EU customers may pass on some of their compliance costs to you.
- You may need to set up systems and processes to provide information to your EU customers so that they can register or seek authorisation for your goods.

Please refer to **REACH and Singapore Manufacturers and Exporters** (Page 28) for more information on how REACH impacts Singapore manufacturers and exporters.

WHY DO I NEED TO PAY ATTENTION TO REACH?

REACH has **shifted the responsibility** of identifying health and environmental risks caused by chemicals and ensuring their safe use **to businesses**.

Under the older chemical legislations, public authorities were largely responsible. REACH represents a radical shift in approach to regulating the manufacture, import and use of chemicals in the EU.

Unlike traditional chemical legislation, which is mostly limited to manufacturers and importers of chemicals, REACH imposes obligations on all parties in the European supply chain. As such, even if a party is non-European, they are still subject to REACH obligations. Most notable is the obligation imposed on DUs (businesses that use chemicals) to ensure their use is covered in the registration. This registration of use is done by the party filing the registration (i.e. the EU importer or EU producer of the substance).

In a nutshell, REACH now holds businesses responsible for:

- Declaring the use of chemicals.
- Assessing the risks of chemicals.
- Ensuring the safe use of chemicals for these uses.

EU businesses that do not comply will not be allowed to manufacture, import, distribute or use chemicals (on their own, in preparations or as part of products) in the EU market.

These businesses will be looking for suppliers and business partners who can help them comply in order to minimise business disruption.

HOW MUCH DO I NEED TO KNOW ABOUT REACH?

Singapore businesses with presence in the EU will need to know everything about REACH intimately. The REACH obligations and processes are detailed in this guide to help you comply.

Singapore-based manufacturers and exporters need to understand REACH obligations and processes. Understanding REACH helps you to assess the impact of REACH on your business – especially in terms of the systems and processes you need to set up in order to help your EU customers comply or determine if you need to be involved with REACH compliance directly.

The more you know about REACH, the higher the chances of ensuring that your goods can be made, imported, distributed and used in the EU market.

You may also find that REACH presents new business opportunities to those who can comply or are able to navigate REACH processes.

HOW DO I REGISTER MY CHEMICAL SUBSTANCE?

Under REACH, all manufacturers and importers of chemicals in the EU must submit information on the properties and potential risks of their substances. This information must then be registered in a central database maintained by the ECHA.

This means that businesses outside the EU must provide their EU-based importers with detailed information about the substances that they supply or use in their products. However, this may result in potential conflict with the need to protect sensitive business information.

WORKING TOGETHER WITH YOUR ONLY REPRESENTATIVE

It is important to ensure that you select the right OR as they would be seeing you through your registration, performing duties related to registration and possibly assisting you with future imports of new products to the EU.

An OR with good knowledge on the practical handling of your goods would be able to:

- Fulfil all REACH obligations on your behalf.
- Help your EU customers fulfil their REACH obligations.
- Keep an inventory of goods imported and sold in the EU.
- Keep confidential information away from competitors and customers.
- Be a sustainable business partner for now and the future.

Once you have appointed an OR, inform your EU supply chain of the appointment.

1.4

GETTING HELP WITH REACH

SPRING Singapore's Export Technical Assistance Centre (ETAC) helps local exporters learn and get ready for compliance with REACH requirements.

AWARENESS PROGRAMMES

If you are new to REACH, you may attend the awareness programmes such as seminars and training workshops that ETAC organises. You can also learn more about REACH at www.spring.gov.sg/etac.

QUALITY AND STANDARDS E-ALERT SERVICE

As the REACH regulation is constantly evolving, local exporters need to be kept up-to-date on the latest changes and developments in their overseas markets to stay ahead of the competition.

Contact etac@spring.gov.sg to be included in our mailing list and receive updates on the development of standards and technical regulations for importing countries.

CONNECTIONS

If you need one-on-one help to understand REACH, ETAC can connect you to REACH consultants.

REACH consultants can help you to:

- Understand your REACH obligations.
- Carry out laboratory testing on your substances/articles.
- Draw up documentation and dossiers required by REACH.
- Review and implement classification/labelling.
- Prepare and update risk assessment.
- Educate your staff, suppliers and customers about REACH.
- Set up databases to collect information needed by REACH.
- Provide technical expertise on manufacturing processes affected.

LABORATORY/CHEMICAL TESTING

You may need to send your products to test centres or laboratories for toxicological or ecotoxicological tests and analyses in order to obtain the information needed for your chemicals to be registered under REACH.

New tests and analyses must be executed according the prescribed guidelines and must comply with Good Laboratory Practice (GLP) or other international standards recognised by the EC or ECHA.

A list of GLP registered facilities in Singapore may be found on the SPRING website <http://www.spring.gov.sg/glp>.

For other laboratory or chemical testing, you may approach any of the accredited test centres and laboratories on the Singapore Accreditation Council's website <http://www.sac-accreditation.gov.sg>.

REACH WEBSITE

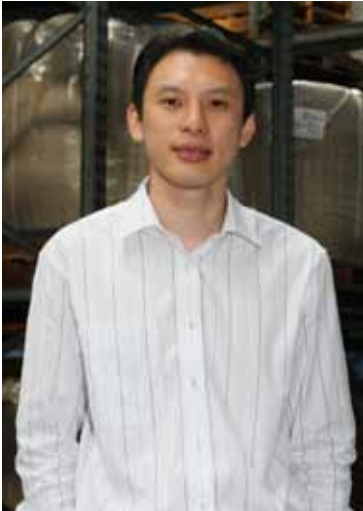
ECHA has set up a website to help businesses understand REACH and take the necessary actions to comply. On the website, you can:

Use the Navigator to understand your REACH obligations and identify the roles you play under REACH.

- Download guidance documents which explains the various REACH processes (e.g. registration, pre-registration, requirements for substances in articles etc.) and methods (e.g. classification, chemical safety report, etc.). These documents may be found at http://guidance.echa.europa.eu/guidance_en.htm.
- Get updates on the latest REACH developments (e.g. list of pre-registered substances, updates on the candidate list, revisions to the REACH legislations, public consultations, etc.).
- Find contact details of the ECHA helpdesk and various MS's helpdesks to get assistance with questions relating to REACH.

The REACH website is at <http://www.echa.europa.eu>.

REACHING FOR THE RIGHT PARTNER



**Mr Terence Tan, Sales Manager,
PrideChem Pte Ltd**

The right OR for you should understand your products and be effective in helping with REACH registration. Through plenty of research and speaking to several potential candidates, Singaporean company PrideChem found the perfect OR for their fit.

With 70% of its total revenue coming from the European market, complying with REACH is an important part of Singaporean company Pride-Chem's business. A manufacturer of copper oxide, which is used in the preservation of wood, PrideChem knows that in order to keep its business thriving in Europe, it must register its products in accordance with REACH.

The initiation to REACH however, can prove a little daunting, said PrideChem's sales manager Mr Terence Tan. "To be honest," he said, "I felt overwhelmed when I first heard about REACH and its requirements. I didn't understand what needed to be done."

So he turned to REACH seminars conducted by SPRING Singapore's Export Technical Assistance Centre (ETAC) and the Singapore Chemical Industry Council (SCIC). The seminars, said Mr Tan, were particularly helpful in his understanding of what REACH is about, its advantages and challenges. The seminars also helped him understand the importance of choosing a trustworthy OR to help PrideChem with its REACH registration in the EU.

"As a non-EU company, we are not allowed to handle our own REACH registration. So it is imperative that we have an OR who understands our products and who can effectively help in our registration," he said.



After speaking to several potential ORs from places as far away as Finland, Pride-Chem eventually settled on DHI Water and Environment, Inc, an independent research and consulting organisation from Denmark.

“What gives us confidence in our chosen OR is that they have a representative office in Singapore,” said Mr Tan. “That means we can call them whenever we need without having to take our time differences into account. It gives us a sense of security and assurance knowing that we can call or walk into their office in Singapore if something crops up.”

“As a non-EU company, we are not allowed to handle our own REACH registration. So it is imperative that we have an OR who understands our products and who can effectively help in our registration,”

CASE STORY 1 – PRIDECHEM PTE LTD



With REACH pre-registration now behind them, Mr Tan added that it turned out to be an easy, straightforward affair. “We only had to provide information on our products and the volume of what we intend to sell each year.”

In the meantime, PrideChem is being included in the Substance Information Exchange Forum (SIEF). “This forum,” explained Mr Tan, “will see plenty of debate with the bigger industry players providing and sharing data on the pre-registered chemicals before the registration deadline.” He added that PrideChem’s registration deadline of November 2013 gives the company ample time to put all its requirements in place.



Currently, PrideChem’s OR is handling its entry into SIEF and the process has been smooth sailing. That’s why, Mr Tan reiterated, it is important for Singaporean companies like PrideChem to find a dependable and effective OR. His advice: “Do your research, talk to the ORs, ask lots of questions and make sure there is a contract to safeguard both you and your OR. Then do your homework, attend REACH seminars and know what needs to be done for REACH. That way, your OR will know that you mean business.”



REACH OBLIGATIONS

REACH obligations are only imposed on businesses in the EU. These obligations will depend on the roles that businesses in the EU play in the supply chain. It is important for you to understand the different roles and determine if they apply to you or your EU customers.

2.1

CHEMICAL MANUFACTURERS AND IMPORTERS

Most REACH obligations are directed at manufacturers and importers who make or import chemicals into the EU market. Manufacturers from non-EU countries are not directly responsible for any action under REACH. However, they can nominate an only representative (OR) established within the EU to carry out the required registration of substances imported into the EU if needed. EU importers within the same supply chain are then relieved from their registration obligations because they will be regarded as downstream users (DUs) of the appointed OR.

Under REACH, EU chemical manufacturers, importers or non-EU manufacturers who have appointed ORs must:

1. Register chemicals or chemicals in preparations made or imported in quantities of one tonne and more every year.
2. Obtain authorisation to use or place on the market substances of very high concern (SVHC) that are listed in Annex XIV.
3. Comply with restrictions on substances related to their use, placing on the market or bans. These are listed in Annex XVII.
4. Submit classification and labelling of the following type of substances based on the EU's Classification and Labelling (CLP) Regulation, regardless of their registration deadline:
 - a. Those which must be registered.
 - b. Those classified as dangerous.
 - c. All other substances placed on the market (regardless of their tonnage) which may not fall within the REACH regulation.
5. Communicate the hazards posed by substances and the ways in which they can be safely used down the supply chain.

Further details may be found in the ECHA guidance document on Registration.

2.2

DOWNSTREAM USERS OF CHEMICALS

Downstream users (DUs) refer to any party that uses chemicals in the EU:

- to make preparations (e.g. paints, glues and detergents).
- as part of industrial processes (e.g. oils, lubricants and antifoams).
- as part of your profession (e.g. cleaners).
- to produce articles/products (e.g. toys and cars).

Under REACH, DUs in the EU must:

1. Ensure that they do not place any substances which are not registered in accordance with REACH in the EU market. Hence, products should only contain substances which are :
 - a. produced/imported by the supplier in amounts below one tonne per year, or
 - b. exempted from registration, including those that have been pre-registered and have a later registration deadline, or
 - c. have already been registered.
2. Ensure their uses — how they use the chemicals — are made known to ECHA via the registration filed by the EU manufacturer or EU importer of that substance. REACH empowers DUs to make their uses known to suppliers so that they can be included in the known uses of chemical safety assessment (CSA) carried out by chemical manufacturers and suppliers.

DUs who wish to keep their certain user information confidential may report these directly to ECHA and prepare a downstream user chemical safety report for such chemicals used in quantities of one tonne and above every year.

3. Follow instructions in the safety data sheet (SDS) received and note the exposure scenarios which will be attached to some SDS.

4. Communicate new information up the supply chain on hazardous properties of chemicals and any information that casts doubt on the risk management measures recommended by the supplier.
5. Apply the risk management measures for dangerous substances identified on the supplier's SDS.
6. Communicate the hazards posed by chemicals and ways in which they can be safely used down the supply chain.
Information to be provided include:
 - a. Hazards, safe conditions of use and appropriate risk management advice for preparations through a SDS.
 - b. Content of certain very dangerous substances that are candidates for authorisation exceeding a concentration of 0.1%weight/weight (w/w) in the articles they produce.
7. Obtain authorisation to use or place on the market SVHC that will be eventually listed in Annex XIV if the use has not yet been authorised by ECHA.
8. Comply with restrictions on substances in relation to their use – placing on the market or to ban. These are currently listed in Annex XVII.
9. Review the classification of their products and accompanying SDS as the classification and labelling of some substances may have changed **(for formulators)**.

Further details may be found in the ECHA guidance document for Downstream Users.

2.3

PRODUCERS AND IMPORTERS OF ARTICLES

Producers and importers of articles refer to any party that makes or places articles containing chemicals (e.g. cars, textiles and electronic chips) in the EU market.

Under REACH, producers and importers of such articles must:

1. Register chemicals in articles when the following conditions are met:
 - a. One tonne or more of a chemical, as a component of the articles, will be placed in the EU market every year.
 - b. The chemical in the articles will be released under normal conditions of use.
2. Notify ECHA about substances present in the article when the following conditions are met:
 - a. The article produced/placed in the EU market contains substance which is included in the candidate list for authorisation, **and**
 - i. The substance is present in the article produced/placed in the EU market in quantities of one tonne or more a year.
 - ii. * The substance is present in the article above the concentration of 0.1% (w/w).

For substances included in the candidate list before **1 December 2010**, notifications to ECHA must be done before **1 June 2011**.

* Substance concentration threshold applies to articles as produced or imported, it does not relate to the homogenous materials. Dissenting views on the application of the 0.1% threshold to the entire article have been notified from six Member States (Austria, Belgium, Denmark, France, Germany, and Sweden). Exporters to these States are advised to contact the respective Member States REACH helpdesks to seek clarification on this interpretation prior to export.



For substances included in the candidate list on or after 1 December 2010, producers and importers of articles must notify ECHA six months from the date that the substance has been placed on the candidate list.

3. It is important to note that notification is not required when:
The producer or importer of an article can exclude exposure to humans and the environment during the use and disposal of the article. The substance has already been registered for that use.
4. Register SVHC when directed by ECHA. After receiving the notification, ECHA will determine if the substances need to be registered. If the use of the substance has not already been registered, ECHA will require the producer or importer of the article to register.

Further details may be found in the ECHA guidance document on Requirements for Substances in Articles.

2.4

DISTRIBUTORS AND RETAILERS OF CHEMICALS

REACH Obligations for distributors and retailers of chemicals are similar to that of importers or downstream users (DUs) depending on their role within the supply chain.

Under REACH, distributors must:

1. Communicate safety information on chemicals throughout the supply chain outlined in Title IV of the REACH legislation.
2. Gather information needed by chemical suppliers to prepare chemical safety reports (CSRs) including information on:
 - How chemicals are used by their customers.
 - How chemicals are distributed in the EU market.
 - Potential hazards of identified uses of the chemicals.
 - New information on the hazardous properties of chemicals.
 - Risk Management Measures for hazardous chemicals.
3. Pass relevant information on chemicals to customers and DUs including:
 - The SDS provided by suppliers.
 - Information on ES provided by suppliers.
 - New information on hazardous properties of chemicals.

2.5

COMPLIANCE TIMELINE

Since the REACH entered into force on 1 June 2007, all businesses have to comply with the regulation. As it is impossible for all businesses to register all chemicals by 1 June 2007, deadlines for registration of most chemicals entering into the EU market have been spread over **11 years**.

REACH enters into force

1 June 2007

REACH enters into force. ECHA is established to manage chemical registration and authorisation, carry out dossier evaluation, co-ordinate substance evaluation and impose restrictions on chemicals.

Registration of New Chemicals

1 June 2008

ECHA opens its doors. All **new chemicals** must be registered before they can enter the EU market.

Pre-Registration of Phase-In Substances

1 June 2008 to 1 December 2008

Existing chemicals must be pre-registered so that they can be phased-in later. Pre-registration allows businesses to continue manufacturing, importing, using and placing in the market existing substances until the registration deadline is reached.

Businesses who submit data on pre-registered chemicals during this time are included in the Substance Information Exchange Forum (SIEF).

New Classification, Labelling and Packaging (CLP) Regulation enters into force

20 January 2009

The new EU regulation (EC) No 1272/2008 on classification, labelling and packaging of chemical substances and mixtures replaces Title XI (Classification and Labelling Inventory) of the REACH regulation.

The new CLP regulation is in line with the EU's implementation of the Globally Harmonised System (GHS) and affects all substances and mixtures regardless of tonnage manufactured or imported into the EU. It is directly applicable to:

- Manufacturers and importers of substances or mixtures
- Distributors
- Retailers
- Users of chemicals

Safety data sheet requirements from GHS are implemented in REACH. Classification, labelling and packaging requirements from GHS are implemented in the new EU CLP regulation.

Classification/Labelling Notification Deadline for Substances

30 November 2010

All businesses must submit the classification and labelling for all substances (either substances or substances in preparations)

- regardless of tonnage that are classified as dangerous,
- that require REACH registration to ECHA before 1 December 2010.

They are exempted if the classification has already been submitted for substances registered before 1 December 2010.

The new classification and labelling of substances must also be communicated within the supply chain; including an updated SDS.

Mixtures need only to be classified and labelled in 2015.

1st Phase-In Substance Deadline

30 November 2010

Registration deadline for manufacturers and importers of:

- Substances in quantities of 1,000 tonnes and above.
- Carcinogens, mutagens and substances toxic to reproduction (CMR category 1 and 2) above one tonne/year.
- Substances classified as very toxic to aquatic organisms (R50/53) above 100 tonnes.

1st Notification of SVHC in Articles Deadline

1 June 2011

For substances which have been included in the candidate list **before 1 December 2010**, producers and importers of articles must submit notifications to ECHA before **1 June 2011**.

For substances which have been included in the candidate list on **or after 1 December 2010**, producers and importers of articles need to notify ECHA six months from the date that the substance was placed on the candidate list.

2nd Phase-In Substance Deadline

31 May 2013

Registration deadline for manufacturers and importers of chemical substances in quantities of **100 tonnes and above**.

Classification and Labelling of Mixtures in Supply Chain

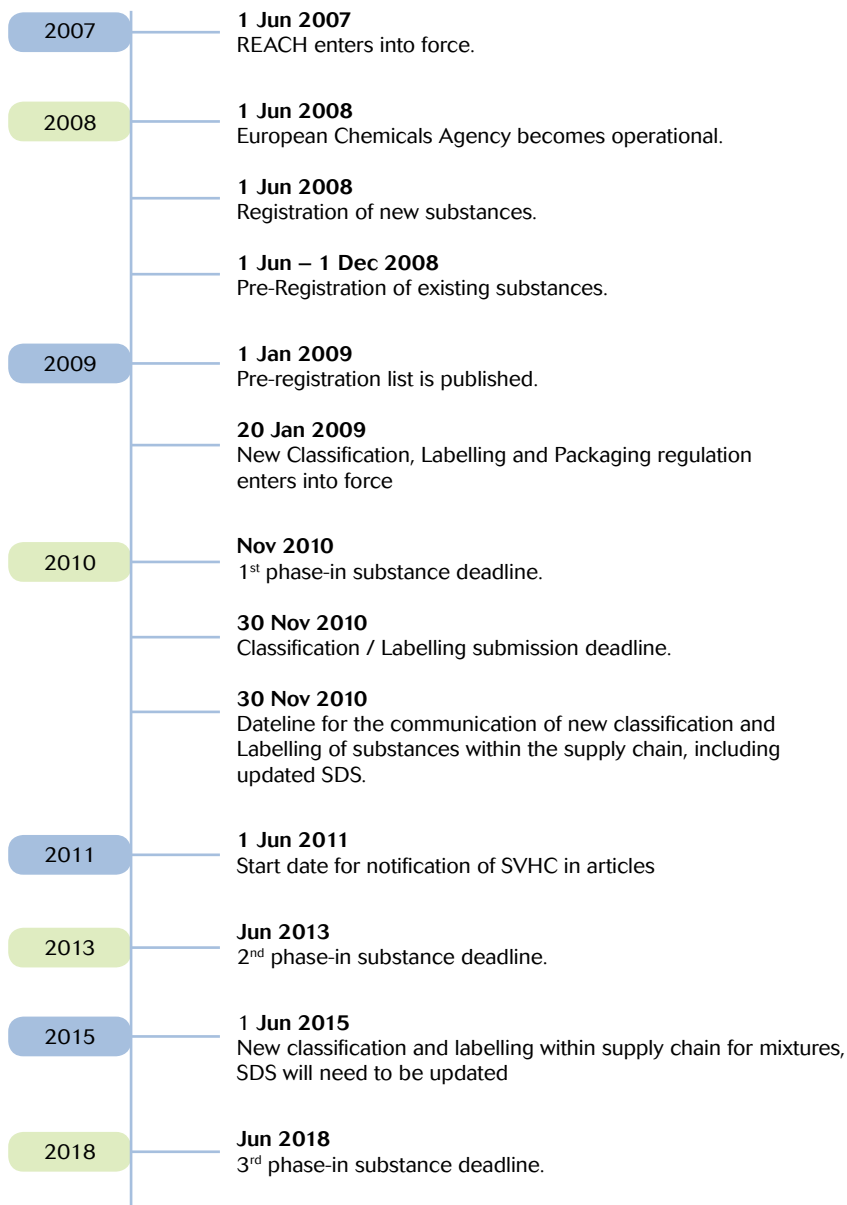
1 June 2015

New classification and labelling within the supply chain for mixtures and SDS will need to be updated

3rd Phase-In Substance Deadline

31 May 2018

Registration deadline for manufacturers and importers of chemical substances in quantities of **one tonne and above**.





REACH AND SINGAPORE MANUFACTURERS and EXPORTERS

REACH affects Singapore manufacturers and exporters whose products end up on the EU market are affected by REACH. Although REACH is only enforceable within the EU, suppliers to the EU may be required to provide necessary information to support REACH compliance.

Essentially, your role is to help your EU customers comply with REACH so that your products can continue to be made, imported, distributed and used in the EU. You will also need an effective communication system to ensure that information is transmitted quickly and accurately throughout your EU supply chain.

3.1

8 WAYS TO ASSIST YOUR EU CUSTOMERS

1. Understand the REACH obligations and processes so that your EU customers do not need to labour over explaining them to you. The more you understand, the more you will be able to help your EU customers to comply.
2. Monitor the products and volume of your shipments to the EU market. The chemicals in your products may need to be registered when they reached certain export thresholds. Alert your EU customers or your OR immediately.
3. Check with your EU customers if your products require registration under REACH. If so, provide them with the information which they need for registration. Should you decide to register your own products, you may do so by appointing an only representative (OR) established in the EU.
4. Avoid using substances of very high concern (SVHC) in your products as your EU customers may have to seek authorisation – a process which they may find too troublesome. If you must use such substances, make it easier for your customers to seek authorisation by providing them with all the information they need.
5. Avoid using high risk chemicals in your products or else they may be subject to REACH restrictions. Your EU customers may be blocked from using your substance and forced to switch to other products.
6. Classify and label your chemicals – especially those classified as dangerous – using classification systems accepted in the EU. In this way, the information can be easily passed on to your EU customers.
7. Set up communication channels with your EU customers so that they can communicate information easily and quickly to you. Have systems in place so that you can act swiftly on the information you receive.
8. Monitor REACH developments closely to keep track of chemicals in your products which may be subjected to restrictions or may need to be registered/authorised.

3.2

WORKING WITH EU CHEMICAL IMPORTERS

Your EU importer must comply with REACH obligations in order to import chemicals, chemical preparations and products containing chemicals into the EU. Your role is to help them comply so that your products can be imported into the EU and arrive in the hands of your EU customers.

To help them comply, you may have to:

- Provide all the information necessary to comply with REACH. e.g. chemical composition, labelling, classification, hazards, uses and safe handling methods for your products.
- Carry out tests on your products or produce chemical safety reports (CSRs) on chemicals.
- Prepare and supply safety data sheet (SDS)
- Change your formula or find substitutes for substances in your products that are subject to restriction or authorisation.
- Share the business costs of registration.

You may want to appoint an OR in the EU as a go-between. This way, you can avoid passing sensitive or confidential business information (CBI) to your EU importer. For further details, see the REACH process checklist on Working with your Only Representative.

Contact your importer and discuss how you can help them comply with REACH. They will appreciate your efforts and continue to be your loyal customers.

3.3

WORKING WITH EU PRODUCT IMPORTERS

EU product importers will rely heavily on you to comply with REACH as they are likely to have little knowledge of what your products contain.

To help your EU product importer comply with REACH, you may have to:

- Provide information on the chemicals contained in your products.
- Advise the importer on whether your chemicals must be registered.
- Disclose SVHC and hazardous substances in your products.
- Inform the importer of the chemicals that will be released from your products under normal use conditions.

You need to provide your importer with all the information necessary to comply with REACH or else they might play it safe by switching to suppliers who are ready and able to do so.

You may want to appoint a representative in the EU as a go-between. This will help you to avoid passing sensitive or CBI to your EU importer. For further details, see the REACH process checklist on Working with Your Only Representative.

3.4

COMMUNICATING WITH YOUR EU DOWNSTREAM USERS AND DISTRIBUTORS

Downstream users (DUs) of chemicals are usually not required to register the substances that they use. However, the registration of these substances by their manufacturers and importers will affect them in a number of ways, namely:

1. Substances that are not registered in accordance with REACH are not permitted for use or placement in the market.
2. Classification and labelling of some substances may have changed under REACH, thus impacting formulators using such substances.

Instructions in the revised or extended SDS received must be followed. To help your downstream users and distributors comply with REACH, you have to:

- Inform them if you will be carrying out registration of your products.
- Ensure that chemical information is updated and effectively communicated between downstream users and distributors. Eg. SDS, hazards posed by the chemicals and ways they can be safely used.

These efforts are critical to ensure that your products can be imported, distributed and used in the EU. Consider the following:

- DUs have a right, under REACH, to make their uses known to their suppliers. If you are responsible for carrying out chemical safety assessments (CSAs), you must make sure this information reaches you so that you can include these uses into your CSA. If you fail to do so, your chemical may not be permitted for use the EU.
- DUs may learn something new about the hazardous properties of the substances in your products. If you are responsible for producing the SDS, you must ensure this information reaches you and revise your SDS to comply with REACH. After your SDS is revised, you must ensure that the new SDS is passed on to your downstream users and distributors.

Delays in communication or action on information communicated may cause your products or your EU customers to violate REACH regulations. This could hurt your business in the EU.

DOING IT THEIR WAY



Mr Seah Cheong Leng, Director,
EPChem International Pte Ltd

Rather than employing an OR, EP Chem International Ltd has taken REACH into its own hands by setting up a legal entity in the United Kingdom.

As a pioneer in natural wax products, Singaporean company EPChem International Pte Ltd sees its products reaching as far as the United States and Europe. For instance, candles sold in shops like Walmart, Target and Ikea all contain components supplied by EPChem. Similarly its wax-derived components and products are used in everyday objects such as fibre optic cables and matchsticks worldwide.

When REACH was introduced in 2007, EPChem began receiving requests from its customers asking the company to ensure its products are REACH-compliant. “REACH is still very new and, in many ways, unknown,” explained EPChem’s director Mr Seah Cheong Leng. “Our customers want to make sure that the products we supply them are REACH-compliant so that they won’t have to deal with any REACH-related processes when they import them.”

To find out more about REACH and understand its requirements, Mr Seah and his team began attending REACH seminars organised by SPRING Singapore and talking to its Europe-based customers and associates who had experience with REACH.

Armed with the knowledge gleaned, the company then decided to set up a legal entity in the United Kingdom to handle its REACH registration independently. “We did our research and decided that it made more sense

for us to do it ourselves rather than use an OR,” explained Mr Seah. “Whether or not we use an OR, we still need to provide the information needed to fill up the pre-registration and registration forms. The OR merely serves as a conduit between us and the governing body. ORs can also be expensive, so we weighed the costs and found it was the same as our flying to the EU to do the work needed.”

The company has since pre-registered their wax and wax-derived products, including some mineral-based polymers. Mr Seah said the process was relatively straightforward and only involved filling several forms. Given that EPChem’s pre-registered products have a natural base (i.e. food, plant or mineral) with mild chemical components, Mr Seah said the company is confident that they will meet REACH requirements easily and be granted registration.



The company is currently waiting for news on when they can start to register their substances.. This could happen in the next seven years. In the meantime, EPChem is keeping abreast of REACH news so that it constantly understands any implications the regulations may have on its business.

To find out more about REACH and understand its requirements, Mr Seah and his team began attending REACH seminars organised by SPRING Singapore and talking to its Europe-based customers and associates who had experience with REACH.



REACH PROCESSES

These are the processes that must be followed in order to comply with REACH. Singapore manufacturers and exporters need to be familiar with them regardless of whether they are directly involved with registration or to assist their EU customers.

Most of these processes require information which you need to supply to or obtain from your EU customers. You may also want to be responsible for parts of these processes (e.g. preparing safety data sheets) to create value for your EU customers.

4.1

LATE PRE-REGISTRATION

Potential registrants who manufacture or import a phase-in substance in quantities of one tonne or more per year after 1 December 2008 for the first time can submit a late pre-registration.

However they must do so:

at the latest 6 months after manufacturing or importing a substance above 1 tonne per year

and

at least 12 months before the relevant phase-in substance registration deadlines

4.2

REGISTRATION OF SUBSTANCES

All **manufacturers and importers in the EU** must register substances and substances in preparations made in or imported into the EU market in quantities of one tonne and more every year. This also includes **only representatives (ORs) established in the EU and appointed by a manufacturer, formulator or article producers** to fulfil the registration obligations of importers.

Producers and importers of articles/products must register substances in articles if the substance is:

- present in quantities of one tonne or more every year, and
- intended to be released from the article.

Downstream users (DUs) are not obligated to register substances. But they must work with their suppliers to ensure that the uses of the substances are incorporated in the risk assessments done by the registrant. The substances should be used within the exposure scenarios developed by the registrant.

DUs who wish to keep certain user information confidential may choose to report these directly to ECHA.

DEADLINES FOR REGISTRATION

REACH distinguishes between phase-in and non phase-in substances. The former are existing chemicals which can be **pre-registered**. The latter are new substances or any substance that is not considered as a phase-in substance.

REGISTRATION OF NON PHASE-IN SUBSTANCES (NEW SUBSTANCES)

Substances that do not fulfil the criteria of phase-in are called non phase-in substances.

Non phase-in chemicals must, as of **1 June 2008**, be registered before they can be made, imported or used in the EU market. This has been referred to as the no data, no market principle.

REGISTRATION OF PHASE-IN SUBSTANCES (EXISTING SUBSTANCES)

To give businesses ample time to gather information on substances and register them, the deadlines for registration have been spread over 11 years for businesses that have **pre-registered the** phase-in substances.

Phase-in substances are defined in Article 3(20) of the REACH legislation. In a nutshell, the following substances are considered phase-in:

1. Substances listed on the European Inventory of Existing Chemical Substances (EINECS).
2. Substances already produced at least once in the EU but not placed on the EU market by that business in the 15 years before REACH entered into force.
3. Substances that were considered polymers under Directive 67/548/EEC, but which are since the 7th amendment of 67/548/EEC no longer considered to be polymers.

Pre-registration allows businesses to continue manufacturing, importing, using and placing in the market existing substances until the registration deadline is reached.

Phase-in substances that are not pre-registered and non phase-in substances will not enjoy the phase-in deadlines spread over 11 years. Instead, these substances have to be registered before they can be made, imported or used in the EU market.

1. Pre-Registration Deadline

Pre-registration of existing chemicals (phase-in substances) completed between **1 June 2008 – 1 December 2008**.

There is no need to submit the technical dossier for the substance at this stage. Pre-registration involves submission of:

- Identity of the substance
- Identity of the potential registrant
- Projected date of registration
- Tonnage manufactured or imported

Businesses which manufacture or import a phase-in substance in quantities of one tonne or more per year after 1 December 2008 for the first time can submit a late pre-registration.

2. Phase-In Registration Deadlines

The deadlines for registering chemicals depend on the tonnage and the hazard of the chemicals.

Deadline	Substance
30 Nov 2010	Substances in quantities of 1,000 tonnes and above
	Carcinogens, mutagens and substances toxic to reproduction (CMR category 1 and 2) above 1 tonne/year
	Substances classified as very toxic to aquatic organisms (R50/53) above 100 tonnes
31 May 2013	Substances in quantities of 100 tonnes and above
31 May 2018	Substances in quantities of 1 tonne and above

Businesses which have pre-registered become part of the **Substance Information Exchange Fora (SIEF)**. Through the SIEF, businesses can find other registrants of the same substance, share testing data and appoint a party to register the chemical on behalf of all registrants (lead registrant).

Late pre-registrants will also be able to benefit from the deadlines set out for pre-registered substances and also participate in the SIEF.

OTHER DUTIES OF THE REGISTRANT

COMMUNICATION WITH DOWNSTREAM USERS

For registrants to complete a registration dossier, they must ensure that information on the current uses and risk management measures of the DUs supplied to are available.

As of 1 June 2007, suppliers of a substance or preparation are required to provide a SDS to all DUs and distributors supplied to as soon as the substance meets one of the following criteria:

- Classified as dangerous
- Is persistent, bioaccumulative and toxic (PBT) or very persistent very bioaccumulative (vPvB) in accordance with Annex XIII of the REACH regulation
- Is included in the candidate list of substances which may be subjected to authorisation under REACH

A substance supplier could be requested at any time by their customer to provide a SDS. Therefore it is highly recommended that suppliers prepare and make these SDS available.

Apart from SDS, a supplier may also need to provide other information on the registration of the substance supplied to all DUs and distributors. This required information would include:

- The registration number (if available) for substances. If the product is a preparation, the registration number for each ingredient contributing to the classification of the preparation should be included.
- Details of the granted authorisation if the substance is subject to authorisation, or the relevant information if the authorisation has been denied.
- Details of the restriction.

CLASSIFICATION AND LABELLING NOTIFICATION

Registrants must electronically notify ECHA of the classification and labelling information related to **all** substances intended for registration before 1 December 2010.

For substances registered before **1 December 2010**, the classification and labelling will be reported in the registration dossier. Hence, there is no need for a separate notification to ECHA.

In addition, the classification of all other substances placed on the market or manufactured need to be notified regardless of their volume.

SUBSTANCE INFORMATION EXCHANGE FORAS

Substance Information Exchange Foras (SIEFs) are formed by companies intending to register the same substance. They may exchange information and work on activities such as agreements on the classification and labelling of the substance. SIEF activities are not governed by ECHA, but left to industry players.

Activities within the SIEF ultimately lead to a joint submission of each substance with minimum animal testing and cost to ECHA. Companies will then submit their own registrations to ECHA tapping on this joint submission.

Businesses that have pre-registered their substances and are preparing for registration are advised to be involved in the most appropriate SIEF for their substances as soon as possible. This will enable them to be well prepared to meet the various registration deadlines on time.

Failure to obtain a valid registration by the various deadlines will result in a loss of business within the EU market.

ECHA and the European Chemical Industry Council (CEFIC) have published some SIEF tips to help clarify the requirements of SIEF participants and ensure best practices among industry stakeholders. These tips may be downloaded from the ECHA and from the CEFIC website.

JOINT REGISTRATION

To avoid duplicate submission of information during registration, REACH requires that businesses with the intention of registering the same substance appoint a lead registrant. This **lead registrant** will submit all the information that should be shared with the joint registrants of the same SIEF.

- Registrants are required to jointly submit the following:
 - Hazardous properties of the substance
 - Its classification and labelling
 - Testing proposals (if any)
 - Chemical safety report (CSR) (optional)
 - Guidance on safe use (optional)
- The lead registrant has to submit his registration dossier first. The other registrants covered by this joint submission will be identified in this dossier.

The other registrants will then have to submit their own registration dossier containing as a minimum, the information they need to submit separately.

Businesses may choose to opt out of joint registration if:

- The costs of joint registration are too excessive.
- The business disagrees with how the lead registrant interprets the information submitted to ECHA.
- The business will have to disclose confidential information which would lead to substantial commercial losses.

Such registrants would be required to submit an explanation for opting out along with their dossier submission. Such submissions will not be entitled to reduced registration fees and nor receive higher priority for evaluation.

DATA-SHARING BY REGISTRANTS

REACH has several provisions to facilitate the sharing of data between registrants. The aim is to reduce the need for unnecessary testing especially vertebrate animal testing and duplicate testing of the same substance. This will help to lower the cost to industry. The SIEF is a platform for registrants to share such animal testing data. Registrants are expected to share the cost of these test data

PRINCIPLES OF DATA-SHARING PROCEDURES

Pre-Registered Substances

Businesses that have pre-registered their substances from 1 June 2008 to 1 December 2008 or have submitted a late pre-registration can share data through the SIEF.

All Other Substances

Potential registrants of non phase-in substances or phase-in substances that have not been pre-registered must lodge an inquiry with ECHA before registration. They must do so even if they have the full set of data for meeting the information requirements under REACH.

The inquiry involves the submission of an inquiry dossier. The process involves informing ECHA to check if existing data on the substance is available. ECHA can then advise if the registration should proceed. ECHA will also help to initiate data sharing among potential and previous registrants.

Further details of data sharing procedures may be found in the following ECHA guidance documents on:

- Registration, Chapter 2: Data Sharing Procedures:
- Data sharing

REGISTRATION REQUIREMENTS

Registration of a substance involves preparing and submitting a **Registration dossier** electronically to ECHA. It consists of two main components:

- i. Technical dossier
- ii. Chemical safety report (CSR)

A **technical dossier** must be submitted for all substances subject to registration obligations.

For chemicals in quantities of **10 tonnes and above** per year **that are dangerous**, a **CSR** must be submitted together with the technical dossier.

For chemicals in quantities of **100 tonnes and above** per year, registrants should not conduct tests to get information required under Annexes IX and X. Instead, you should include a testing proposal in the registration dossier. ECHA will review the proposal to see if it is adequate. This helps to reduce unnecessary animal testing.

Registration Dossier	Tonnage of Substance
Technical Dossier	Substances in quantities of 1 tonne and above
+ Chemical Safety Report (if substance is dangerous)	Substances in quantities of 10 tonnes and above
+ Testing Proposal (if Annex IX or X is missing)	Substances in quantities of 100 tonnes and above

THE TECHNICAL DOSSIER

The **technical dossier** contains information on the registrants, the properties and classification of a substance; known uses and guidance on safe use of the substance.

The depth of information required – set out in Annex VI-XI – depends on the tonnage made available in the EU market.

CHEMICAL SAFETY REPORT

The CSR should contain:

- Findings of the chemical safety assessment (CSA)
- Exposure scenarios developed as part of the CSA (if relevant)
- Risk management measures identified in the CSA (if relevant)

REACH requires CSAs to be carried out for substances in quantities of 10 tonnes and above.

If the substance is dangerous or has PBT or vPvB properties, the CSA should include known uses of the substance, including the downstream uses which have been communicated to the manufacturer/importer.

The CSA process involves:

- a. Identifying the hazards and assessing the risks caused by every known use of the substance.
- b. Developing exposure scenarios (ES) – scenarios where the substance may be exposed to humans and the environment – for substances which are:
 - Classified as dangerous
 - PBT
 - vPvB
- c. Developing risk management measures (RMMs) for the ES – ways to control the risks when the substance is exposed to humans and the environment.

TESTING PROPOSAL

The testing proposal outlines how the substance can be tested to ensure it is safe to use. REACH requires testing proposals to be submitted instead of carrying out immediate testing to prevent unnecessary animal testing or duplicate testing.

REGISTRATION PROCEDURES

Registrants must submit a registration dossier in the format prescribed and pay the relevant fees.

REGISTRATION FORMAT

The registration dossier must be submitted electronically using IUCLID 5 (International Uniform Chemical Information Database) format. This is the tool for chemical data collection which can be used for preparation of dossiers. It uses internationally harmonised formats for reporting data which are accepted by regulatory authorities within the Organisation for Economic Co-Operation and Development (OECD). IUCLID 5 can be downloaded, free-of-charge from <http://iuclid.eu>.

REGISTRATION FEES

Fees and charges under REACH registration procedures are published by the EC (Commission Regulation EC 340/2008)

These fees, which range from 1,200 Euros for substances of 1 tonne, to 31,000 Euros for substances of 1,000 tonnes and above, apply at the start of registration of chemical substances on 1 June 2008 and to all businesses – both EU and non-EU.

Payment for substances that qualify for pre-registration is only required upon registration with ECHA, which occurs after December 2008.

To minimise the burden on smaller firms, reductions for registration are as follows:

- 30% for medium companies
- 60% for small-sized companies
- 90% for micro enterprises

To check if businesses (both EU and non-EU) qualify for the reduced fees under REACH, they would need to refer to the European Commission recommendation 2003/361/EC concerning the definition of micro, small and medium-sized companies.

COMPLETENESS CHECK AND INVOICING PROCEDURES

The completeness check process comprises two distinct sub processes:
Technical completeness check – for registration dossiers, updated registration and process oriented research and development (PPORD) registrations
Financial completeness check – for dossier types where a fee is required

ECHA will undertake the completeness check of a registration dossier within three weeks of the submission date or within three months of the relevant deadline. If the dossier is incomplete or fee payment is missing, ECHA will inform the registrant before the expiry of the given period.

Otherwise, the dossier is treated as complete and the businesses in the EU can begin or continue to manufacture and import the substance.

Once registration is complete, the REACH IT system at ECHA will automatically assign a registration number to the registrant for the substance concerned and a registration date which will be the same as the submission date.

4.3

DOSSIER AND SUBSTANCES EVALUATION

There are two main evaluation tasks undertaken by ECHA
They are:

- i. Assessment of registration dossiers – includes examination of testing proposals and compliance check of registrations
- ii. Assessment of substances

REGISTRATION DOSSIER EVALUATION

This evaluation is done by ECHA.

Dossiers are checked for compliance to ensure that the **required information (e.g. safety assessment is suitably documented in chemical safety reports) is available and sufficient**. If any information is found lacking, ECHA will ask the registrant to provide more.

Information from the dossier evaluation will be used for prioritising substances for further evaluation and added to the European Community rolling action plan.

If the registration dossier contains a testing proposal – which is required for chemicals in quantities of 100 tonnes and above – ECHA will **evaluate the testing proposal** to ensure that reliable and adequate data is produced, as well as determine if further testing needs to be carried out.

All proposals involving animal testing will be scrutinised as REACH aims to minimise the use of animal testing.

SUBSTANCE EVALUATION

Substance evaluation is carried out by ECHA and the competent authorities (CAs) of each EU Member State (MS).

The evaluation aims to clarify any concerns that a given substance may pose a risk to human health or the environment. Therefore, all registration dossiers submitted for the same substance are – as far as relevant – examined together. Any other relevant information available is also taken into account.

Substance evaluation does not focus solely on substances but also on break-down products. It takes into account suspicion from structural alerts/similarities to other substances of concern.

ECHA and MS will use the information from the dossier evaluation to propose substances to be added to the European Community rolling action plan for substance evaluation and for preparing an Annex XV dossier for the purpose of identification of SVHC, restriction, and harmonised classification and labelling.

When the substance evaluation is completed, ECHA, together with MS, may decide to:

1. Impose restrictions on uses of the substance.
2. Require authorisation for use of the substance.
3. Harmonise the classification or labelling of the substance.
4. Pass on the information to other authorities to take action.

Further information on how ECHA and the MS CAs will perform the various evaluation tasks is found in the ECHA guidance document on dossier and substance evaluation.

4.4

AUTHORISATION OF SUBSTANCES

Substances of very high concern (SVHCs) will gradually be included in Annex XIV. They cannot be placed on the EU market or used after a date has been set (i.e. sunset date) unless the company is granted an authorisation. The SVHC list and sunset dates are maintained by ECHA.

Authorised substances need not be registered substances. The quantity of substances made, imported or used is also irrelevant. The authorisation system is intended to ensure that SVHC are progressively replaced.

SUBSTANCES OF VERY HIGH CONCERN

SVHC – mainly chemicals which cause severe health or environmental problems – are candidates for authorisation. The effects of these substances are very serious and often irreversible. SVHC are first identified and put on a candidate list and gradually included in Annex XIV (List of Substances subject to Authorisation). The candidate list for authorisation is updated regularly and is found on the ECHA website.

Criteria to identify potential SVHC's are:

1. CMR category 1 and 2.
2. PBT substances as set out in Annex XIII.
3. vPvBs substances as set out in Annex XIII.
4. Any other substance identified and backed by scientific evidence as being equally dangerous to human health or the environment (e.g. endocrine disruptors).

PARTY TO APPLY FOR AUTHORISATION

REACH spells out who has to obtain authorisation for the use of substances listed in Annex XIV:

1. Manufacturers and importers must obtain authorisation to make, import and use such substances.
2. DUs using Annex XIV substances must obtain authorisation to use or place on the market if the use has not yet been authorised by ECHA. If the use is already authorised, DUs need only notify ECHA of their use of an authorised substance.
3. Importers of articles containing SVHC do not need to obtain authorisation, but they will need to notify ECHA if their article contains a substance on the candidate list.

APPLYING FOR AUTHORISATION

To obtain authorisation, the party seeking it must show that the risks associated with use of such substances are adequately controlled or that the socio-economic benefits from their use outweigh the risks.

APPLICATION REQUIREMENTS

The party seeking authorisation must:

1. Specify the use for this authorisation and document control of risk in a CSR.
2. Investigate safer alternatives or technologies and attach the analysis to the application. If substitution is possible, include a substitution plan.
3. Include a socio-economic analysis where alternatives exist or if adequate risk control of the substance cannot be demonstrated.

DEADLINE AND APPLICATION FEES

Applications for authorisation must be submitted **at least 18 months before the sunset date of the use of each substance**. An application fee will be imposed by ECHA.

GRANTING OF AUTHORISATION

Authorisation will be granted for a **specific use** for a **limited period of time** if:

1. The applicant can show that the risk to human health and environment can be adequately controlled (e.g. when the risk is negligible); or
2. The socio-economic benefits outweigh the risks and there are no suitable alternatives or substitutes.

All granted authorisations will be reviewed after a certain time limit which is set on a case-by-case basis.

All uses must be authorised unless they are specifically exempted. Generally, exemptions (e.g. use in medical products) are granted only because the use is regulated by some other legislation.

4.5

RESTRICTIONS ON SUBSTANCES

Restrictions will be imposed on substances that cause unacceptable risks to health or the environment. Annex XVII of the REACH Regulation contains the list of all restricted substances and the uses which are restricted.

Existing restrictions set out in the Marketing and Use Directive (76/769/EEC), e.g. the ban on asbestos and restrictions on the uses of certain azo-dyes, have been carried over to REACH in Annex XVII.

TYPES OF RESTRICTIONS

Restriction may be imposed on the manufacture, import and use of:

- The substance itself.
- Preparations which use the substance.
- Products containing the substance.

Restriction may be in the form of:

- Limits on the concentration/amount of substances.
- Limits on certain or all uses of the substances.
- Outright bans on the substances.

Check the ECHA website to find out which substances have been considered for restriction and the type of restriction.

4.6

CLASSIFICATION AND LABELLING OF SUBSTANCES

SUBMISSION OF CLASSIFICATION/LABELLING

Under REACH, businesses must submit classification/labelling information in accordance to the new EU regulation on classification, labelling and packaging of chemical substances and mixtures (CLP) to ECHA for the following substances:

1. Substances that must be registered under REACH.
2. Substances that are classified as dangerous even if they are or placed on the markets (e.g. imported) or manufactured in quantities below one tonne. This includes dangerous substances under pre-REACH Directive 67/548/EEC.

Submission of classification and labelling information of substances which are excluded from REACH, but not excluded from the CLP regulation must also be submitted to ECHA.

DEADLINE FOR SUBMISSION OF CLASSIFICATION/LABELLING

All businesses should submit the classification/labelling for their substances by **1 December 2010**, unless they have already been submitted as part of substance registration.

HARMONISATION OF CLASSIFICATION/LABELLING

ECHA, together with EU MS, will harmonise the classification and labelling with priority for the following substances:

- Carcinogens
- Mutagens
- Substances toxic to reproduction
- Substances toxic to respiratory sensitisers
- Any other substance identified on a case-by-case basis.

Businesses are also required to make efforts to harmonise classification and labelling for all other substances.

GHS has been adopted by the EU under the new regulation on classification, labelling and packaging of substances and mixtures (EC 1272/2009). This new regulation is also commonly known as the CLP Regulation. Businesses will need to use the CLP regulation to classify/label their substances under REACH.

NOTIFICATION OF CLASSIFICATION/LABELLING CONFLICTS

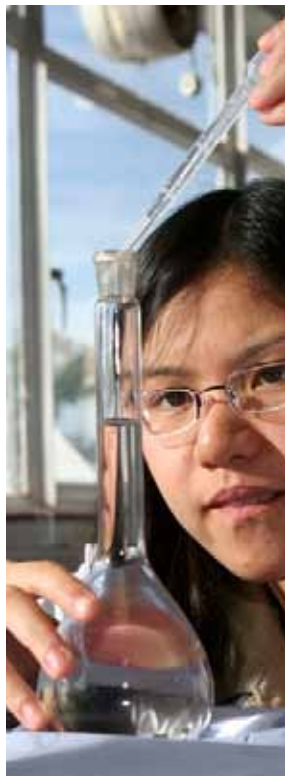
As classification/labelling is based on submissions by the industry, there may be cases where classifications/labels differ. DUs are required, under REACH, to notify ECHA when their classification/labelling is different from that registered by their suppliers.

4.7

COMMUNICATION IN THE SUPPLY CHAIN

All EU parties in the supply chain have a duty to communicate hazard, use and risk information on substances throughout the supply chain. This has an impact on non EU participants of that supply chain. The REACH obligations in Title IV - Information in the Supply Chain are extensive.

All information must also be made available to all parties in the supply chain – including workers who might be exposed to substances in their course of work – for at least 10 years.



COMMUNICATION REQUIREMENTS FOR SUBSTANCES ON THEIR OWN OR SUBSTANCES IN PREPARATIONS

Suppliers of chemical substances and chemical preparations are responsible for preparing and communicating hazard, use and risk information on the substances down the supply chain to their customers, who in turn must provide them to their customers if required.

Such information is to be included in the registration dossier.

DOWNSTREAM USERS

DUs of chemicals who export their products to the EU will have to work with their suppliers to ensure that the chemicals have been identified and registered.

KEY INFORMATION TO COMMUNICATE

The following information must be communicated/exchanged throughout the supply chain:

1. Alignment of uses covering different life cycles of the substance (based on the Use Descriptor System) between the manufacturer/importer (M/I) and his DUs. This will enable the M/I doing the registration to collect the identified uses needed for the registration dossier.
2. Any information that helps DUs manage the risks associated with the substance (risk management measures) and key risks associated with the substance for all known uses (exposure scenarios). This information will be included in the chemical safety report submitted by the M/I during registration (if required). DUs may also play a role in developing exposure scenarios and include these in their CSR if they intend to carry out CSAs on their own.
3. Any new information on hazardous properties of a substance.
4. Any information that casts doubt on the RMMs recommended by the supplier.
5. Details on whether the substance is subject to authorisation or restriction under REACH.
6. SDS – Hazard, use and risk information to be consolidated into the headings as per Annex II (Guide to Compilation of Safety Data Sheets). If a SDS is not required for the substance, any format can be used as long as the key information is communicated.

Further details on the Use Descriptor System can be found in the ECHA guidance document on information requirements and chemical safety assessment – chapter R12: use descriptor system

SAFETY DATA SHEETS

Pre-REACH, suppliers of chemicals were required to produce SDS under the Safety Data Sheets Directive (91/155/EC). The SDS is a well-understood and internationally accepted tool for the communication of information about chemical hazards, risks, and risk reduction measures.

All the obligations under the Directive are now carried over to REACH under Title IV with some minor changes. The general rule is that SDS are required for any substance classified as:

- Dangerous
- PBT
- vPvBs

Annex II (Guide to Compilation of Safety Data Sheets) lists the 16 headings of information required in a SDS.

For substances requiring a CSA, information provided in the SDS must be consistent with the CSA. The relevant exposure scenarios must be annexed to the SDS.

If you are currently responsible for producing SDS, you should continue to do so and pay special attention to these additional obligations imposed by REACH.

All parties in the supply chain must make sure that they use the information derived in the CSA to compile the SDS to ensure consistency.

COMMUNICATION REQUIREMENTS FOR ARTICLES

In general, REACH does not require communication in the supply chain for articles. This mainly applies to articles containing substances intended for release.

NOTIFICATION OF SUBSTANCES IN ARTICLES

Suppliers of **articles** containing chemical substances must notify ECHA if the substances present are:

1. In quantities of more than 1 tonne per year, per manufacturer/importer; **and**
2. in concentrations above 0.1% weight/weight (w/w); **and**
3. listed on the candidate list for authorisation.

Notification is due six months after the substance is placed on the candidate list.

ARTICLES WITH INTENDED RELEASE OF SUBSTANCES

Suppliers of articles containing chemical substances must communicate within the supply chain if the substances present are:

1. SVHC listed on the candidate list for authorisation; **and**
2. in concentrations above 0.1% w/w.

Such suppliers are required to provide safe-use information of those substances to industrial users of those articles.

Should consumers request information about substances present in the article, suppliers are to provide the information within 45 days of the request.

If the substance is not intended for release, suppliers of articles need only provide sufficient information to industrial and professional users to allow safe use of those articles.

ASSESSING COMMUNICATION OBLIGATIONS WITHIN THE SUPPLY CHAIN

Article suppliers to the EU should:

- i. Monitor the SVHC candidate list for authorisation as it is updated regularly.
- ii. Communicate to their suppliers the presence of SVHC in concentrations of > 0.1%w/w.
- iii. Conduct a chemical analysis if unsure of the type of substances present in the article.



REACH CHECKLISTS

These checklists highlight the key activities which industry stakeholders of REACH have to engage in to comply with REACH.

Singapore manufacturers and exporters can use them as a guide to develop checklists for their REACH preparation or complement the activities of the EU customers. Where possible, we have highlighted some of the activities which may involve overseas manufacturers/ exports (overseas suppliers).



5.1

CHECKLISTS BY ROLES

These checklists are prepared according to the roles of each industry stakeholder. An industry stakeholder may have one or more roles depending on their business activity in the EU.

MANUFACTURERS AND IMPORTERS OF CHEMICALS CHECKLIST

Checklist for EU manufacturers and importers of chemicals (including preparations containing substances).

CREATE LISTS

1. Based on the composition of your products, draw up an inventory of substances and the tonnage made or imported into the EU. Include new substances which are made/imported as of 1 June 2008.
2. Make a list of customers and suppliers and match them to the substances that made/imported.

ASSESS NEED FOR REGISTRATION

3. Identify substances which require registration, i.e. substances that are:
 - made/imported into the EU market over one tonne/yr; and
 - not excluded or exempted from registration.
4. Determine what information is needed to be included in the registration dossier based on the manufactured or imported tonnage per year per legal entity (eg: chemical safety reports and chemical safety assessments).
5. Use the **Substance Registration Checklist** as a guide on the steps to register substances (if substance registration is required).
6. Use the **Working with Your Only Representative (OR) Checklist** as a guide if you are intending to appoint an OR to carry out the registration on your behalf.

ASSESS NEED TO PREPARE SAFETY DATA SHEETS

7. Identify substances or mixtures which require safety data sheet (SDS), i.e. any substance or mixture classified as:
 - Dangerous
 - PBT
 - vPvBs

In some specific cases, an SDS for preparations which are not classified as dangerous will also need to be supplied upon request.

8. Use the SDS Checklist as a guide to preparing SDS. EU businesses may ask overseas suppliers to prepare SDS to comply with the REACH requirements.
9. Prepare the SDS as required by REACH under Article 31 (Requirements for Safety Data Sheets) and supply them to downstream users and distributors.

CLASSIFICATION AND LABELLING

10. Notify ECHA of the classification of all substances intended for registration under REACH and all other dangerous substances.
11. Ensure that substances and preparations placed on the EU market are eventually classified and labelled according to the CLP regulation (EC 1272/2009) and the relevant deadlines.

ASSESS NEED FOR AUTHORISATION

12. Check if the substances in the products are listed in Annex XIV (list of substances subject to authorisation) or are on the candidate list for authorisation. EU businesses may need the help of overseas suppliers to identify or declare the presence of such substances.
13. Decide if there is a need to apply for authorisation for any uses of substances listed in Annex XIV.

ASSESS NEED TO COMPLY WITH RESTRICTIONS

14. Identify substances which have restrictions imposed on them. EU businesses may need the help of overseas suppliers to identify these substances.
15. Comply with the restrictions (if any) imposed. EU businesses may need to work closely with overseas suppliers to ensure compliance.

COMMUNICATE WITHIN THE SUPPLY CHAIN

16. Communicate key safety information (eg: exposure scenarios) on substances down the supply chain using SDS or other means. EU businesses may need to obtain this information from overseas suppliers.

PRODUCERS AND IMPORTERS OF ARTICLES CHECKLIST

Checklist for EU businesses that make, import or place in the EU market articles which contain chemicals.

CREATE LISTS

1. Draw up an inventory of the articles made, imported or placed in the EU market containing substances. Put down the tonnage for these substances. If this is not possible, ensure that you have a thorough knowledge of all or potential SVHC substances in the article.
2. Make a list of all the customers and match them to the articles that are made, imported or placed in the EU market.

ASSESS NEED FOR REGISTRATION

3. Identify substances in articles which may need to be registered, i.e. substances in articles which are:
 - placed in the EU market over one tonne/yr; and
 - intended to be released under normal conditions/use; and
 - not excluded or exempted from registration.

EU businesses may need the help of overseas suppliers to identify these substances.

4. Ensure that information submitted in the registration is up-to-date.
5. Use the Substance Registration Checklist as a guide on the steps to register substances (if applicable).
6. Use the Working with Your Only Representative Checklist as a guide if you are intending to appoint an OR to carry out the registration on your behalf.

ASSESS NEED FOR NOTIFICATION

7. Identify substances in articles which are:
 - on the candidate list for authorisation; and
 - present in articles in concentrations above 0.1% w/w; and
 - present in articles in quantities above 1 t/a; and
 - bound to be exposed to humans or the environment.

EU businesses may need the help of overseas suppliers to identify these substances.

8. Notify ECHA, in the format prescribed, about the substances you have identified above from 1 June 2011. Use the Substance Notification Checklist as a guide to prepare the information needed.

COMPLIANCE WITH RESTRICTIONS AND AUTHORISATION

9. Comply with the restrictions (if any) imposed. EU businesses may need to work closely with overseas suppliers to ensure compliance.
10. Use only substances authorised for incorporation into articles as set out in the authorisation or if need be, apply for authorisation for uses(s) of substances listed in Annex XIV.

DOWNSTREAM USERS CHECKLIST

Checklist for businesses that use chemicals (including preparations containing substances) in the EU market.

MAKE LISTS

1. Draw up an inventory of the substances. Include new substances used as of 1 June 2008.
2. Draw up a list of substance suppliers and compile all the safety information (e.g. SDS) from suppliers.

EU businesses may need to obtain the latest information from overseas suppliers.

3. Draw up a list of customers

CONDUCT INTERNAL IMPACT ASSESSMENT

4. Assess the impact of REACH on substances used:
 - Do the substances need to be registered?
 - Are those substances currently on the list of pre-registered substances published by ECHA?
 - If the substances are not on the list and considered relevant, is there a need to ask ECHA to add the substance to the list?
 - What if restrictions are imposed on the substances?
 - What if the substances and their uses need to be authorised?
 - Are there alternatives/substitutes?
 - Will price of substances rise?
 - What if suppliers fail to register substances?

EU suppliers and their overseas suppliers may want to provide downstream users (DUs) with information for internal impact assessments.

MAKE USES KNOWN TO SUPPLIERS

5. Identify and align uses of substances that need to be made known to suppliers (those that suppliers are unaware of) based on the Use Descriptor System.
6. Provide the following documents to your suppliers:
 - a. Brief descriptions on the uses.
 - b. Exposure scenarios (ES) (optional).

EU suppliers may need to pass the information on to overseas suppliers, e.g. when overseas suppliers are responsible for conducting CSAs.

7. When receiving SDS with ES annexed, if the uses are covered within the ES, implement the risk management measures (RMMs).

USES NOT COVERED UNDER THE SDS ANNEX

8. For uses of substances which are not covered either
 - a. Inform the supplier of the use and wait for the updated SDS; or
 - b. Conduct own CSA (if the tonnage is greater than 1 tonne) and notify ECHA

ASSESS NEED TO PREPARE SAFETY DATA SHEETS (SDS)

9. Prepare and supply SDS and recommend appropriate RMMs and annex ES or by other means for further downstream use. EU businesses may need to obtain this information from overseas suppliers.

COMPLIANCE WITH RESTRICTIONS AND AUTHORISATION

10. Comply with the restrictions (if any) imposed. EU businesses may need to work closely with overseas suppliers to ensure compliance.
11. Use only substances authorised for incorporation into articles as set out in the authorisation or if need be, apply for authorisation for uses(s) of substances listed in Annex XIV.

COMMUNICATE UP AND DOWN THE SUPPLY CHAIN

12. Communicate key safety information on substances down the supply chain using SDS or other means. EU businesses may need to obtain this information from overseas suppliers.

13. Communicate up the supply chain:

- a. New information of the hazardous properties of substances.
- b. Doubts on risk management measures provided by suppliers.

EU suppliers may need to pass this information to overseas suppliers so that they may take the appropriate actions (e.g. revising SDS).

CLASSIFY/LABEL SUBSTANCES

14. Ensure that substances are classified/labelled using the CLP regulation. EU businesses and their overseas suppliers may want to ensure all classifications/labels are consistent.

DISTRIBUTORS AND RETAILERS CHECKLIST

Checklist for EU distributors, including retailers, or substances and preparations containing substances. Their obligations are similar to that of importers or downstream users depending on their role within the supply chain.

1. Gather information and communicate up the supply chain:

- Where does the supply come from (EU or non-EU)?
- How substances are being used by customers.
- How substances are being distributed in the EU market.
- Potential hazards of identified uses of the substances.
- New information on the hazardous properties of substances.
- RMMs for hazardous substances.

EU suppliers may want to pass this information on to overseas suppliers so that they can take the appropriate actions (e.g. revise SDS).

2. Communicate, down the supply chain, safety information on chemicals including:

- SDS provided by suppliers.
- Information on ES provided by suppliers.
- New information on hazardous properties of chemicals.

EU suppliers may need to obtain this information from overseas suppliers. The latter may also wish to ensure that new information (e.g. revised ES) are swiftly communicated down the supply chain to avoid causing their EU customers to violate REACH. avoid causing their EU customers to violate REACH.

5.2

CHECKLISTS BY PROCESSES

These checklists are prepared according to processes businesses are likely to encounter when preparing for REACH. Steps in the process are performed by businesses in the EU. Some of these require the help of overseas manufactures/exporters.

WORKING WITH YOUR ONLY REPRESENTATIVE CHECKLIST

It is important that you are aware of how to work effectively with your only representative (OR) to ensure your interests are covered during registration and substance information exchange fora (SIEF) negotiations.

Below is a checklist for non EU businesses who are working with ORs to make the registration. Make sure you pick an OR that can handle the work and can be a sustainable business partner for many years to come.

FIRST JOBS

1. Ensure that your OR has sufficient background in practical handling of substances and data.
2. Have a signed contract with your OR on all aspects of the work you would expect them to undertake.
3. Develop a checklist with your OR to ensure your requirements are understood and can be met.
4. Ensure that your OR fully understands your substances, their uses, the degree of confidentiality you wish to maintain and your expectations about buying or selling data.
5. Ensure that your OR would be able to comply with any relevant national requirements for appointed ORs.
6. Work out a method of payment with your OR.
7. Get your OR to check other SIEF members, names and proposed registration deadlines.

SIEF WORK

1. Ensure that your OR is aware of what data you require for your registration. Note that for 1-10 tonne per year you need all data in Annex VII, and for 10-100 tonne per year you need all data in Annex VIII. For higher Annexes you should do testing proposals, when tests are missing. For these dossier (1-10 and 10-100) you need all data at submission.
2. Make sure you understand whether there will be a Joint CSR or whether you have or want to do your own CSR.
3. Ensure that you proactively communicate with your OR on your needs and keep them up to date with your imported quantities and downstream customers.
4. Get your OR to check the type of information that is offered within the SIEF (eg: if it is offered free of charge, whether this information is being used in the dossier).
5. Evaluate what the costs of further information/data would be (if required) and request your OR to verify the costs.
6. For procured data, know what level of information you wish to purchase (eg: fill study or robust summary).
7. Ensure that your OR would be able to provide advice or assistance with preparing the relevant documents and collecting the needed information for joint registration.
8. Determine when your dossier can be sent and when you are required to submit the dossier under joint registration.

ACTIVE COMMUNICATION

1. Have regular dialogue with your OR and consider project managing all your requirements and determine certain deadlines and due dates with your OR.
2. Set deadlines with your OR, when you expect things to happen. Ask questions when these deadlines are not met.
3. Ensure that the registration dossiers are regularly updated as and when there is new information and inform ECHA accordingly.
4. Plan your resource needs for REACH and regularly reassess.

SUBSTANCE REGISTRATION CHECKLIST

Checklist for EU businesses and ORs registering substances under REACH.

PRE-REGISTER AND GATHER INFORMATION

1. Pre-register phase-in substances from 1 June 2008 – 30 November 2008 to enjoy phase-in deadlines. Ensure substances fall within the definition of phase-in substances before pre-registering.

EU businesses may need the help of overseas suppliers to identify phase-in substances.

2. Gather comprehensive data on the substances. This step involves:
 - Exchanging/sharing data with other pre-registrants.
 - Getting chemical information from suppliers.
 - Classifying/labelling the substances.
 - Finding out all the uses from DUs.

EU businesses may require overseas manufacturers/importers to carry out tests, prepare SDS, etc. to gather the necessary information for registration.

3. Contact other registrations of the same substance to form a consortium.

REGISTER THE SUBSTANCES

4. Prepare the necessary documents for the registration dossier.
 - a. Technical dossier (substances > 1 tonne/yr)
 - b. Chemical Safety Report (substances > 10 tonnes/yr)
 - c. Testing proposal (substances > 100 tonnes/yr)

Lead Registrant

The lead registrant must submit all the information that should be shared with the joint registrants of the same SIEF and identify the other registrants covered by this joint submission.

Joint Registrant

Joint registrants need only submit their own registration dossier containing information such as production volume and name of company after the lead registrant has submitted his dossier.

EU businesses may enlist the help of overseas suppliers to prepare the information and documents needed for registration.

5. Register new and existing substances using IUCLID 5 by the registration deadlines and pay the relevant registration fees.

Registration Deadlines

- a. New substances: 1 June 2008
All new substances must be registered from this date.
- b. Pre-registration: 1 December 2008
Pre-register existing substances to enjoy phase-in deadlines.
- c. 1st phase-in deadline: 30 November 2010
Substances > 1000 tonnes/year
Substances classified as CMR 1 and 2
Substances classified as R50-R53
- d. 2nd phase-in deadline: 31 May 2013
Substances > 100 tonnes/year
- e. 3rd phase-in deadline: 31 May 2018
Substances > 1 tonnes/year

EU businesses may require overseas manufactures/exporters to provide information for registration well ahead of deadlines or to share the costs of registration.

6. Wait three weeks to hear from ECHA. ECHA will contact registrants who have not submitted sufficient information. If ECHA does not contact the registrant, it means that the information is sufficient and the substances registered can be made, imported or used in the EU.

EU businesses will inform overseas suppliers of the outcome so that they can start making shipments to the EU.

7. The registration dossier will be evaluated by Agency. If further tests are needed, the registrant will be informed by ECHA.

EU businesses may require overseas suppliers to perform some of these tests.

SUBSTANCE AUTHORISATION CHECKLIST

Checklist for EU businesses applying for authorisation for the uses of substances in Annex XIV under REACH.

1. Gather comprehensive data on the substances. This step involves:
 - Exchanging/sharing data with other pre-registrants.
 - Getting chemical information from suppliers.
 - Classifying/labelling the substances.
 - Finding out all the uses from downstream users.

EU businesses may require their overseas manufacturers/importers to carry out tests, prepare SDS, etc. to gather the necessary information for registration.

2. Investigate safer alternatives/technologies for substances that require authorisation.

EU businesses may also ask their overseas suppliers to do the same so that all alternatives/technologies can be identified.

3. Prepare the following documents to apply for authorisation:
 - Uses for this authorisation and control of risk in a CSR
 - Substitution plan (where feasible)
 - Socio-economic analysis (if needed)

EU businesses may ask their overseas suppliers to provide documentation (e.g. proof that substitution is not feasible) needed to apply for authorisation.

3. Submit application for the use authorisation 18 months before the sunset date of the use of each substance and pay a fee to ECHA.
4. Wait to hear from ECHA. Authorisation will be granted for a specific use for a limited period of time.

EU businesses will inform overseas suppliers of the outcome so that they can start shipping authorised substances into the EU and, perhaps, also look into long term alternatives/technologies.

SUBSTANCE NOTIFICATION CHECKLIST

Checklist for EU businesses to prepare notifications which must be submitted to ECHA starting from **1 June 2011**.

1. Draw up the notification in the format prescribed by ECHA. Notifications must contain:
 - Identity of the producer/importer
 - Registration number of producer/importer
 - Identity of the substance
 - Classification of the substance
 - Brief description of the uses of the article
 - Tonnage range

EU businesses may need information from overseas suppliers to identify, classify and determine uses of substances.

2. Submit notifications to ECHA within six months from the date the substance has been placed on the authorisation list.
3. Wait to hear from ECHA. ECHA may require the substance to be registered if the uses in the notification have not been registered with ECHA

SAFETY DATA SHEET CHECKLIST

Checklist for EU businesses to prepare SDS. EU businesses may require their overseas suppliers to prepare SDS instead.

1. Draw up SDS for any substance or preparations containing any substance classified as:
 - Dangerous
 - PBT
 - vPvBs
2. Make sure the SDS complies the pre-REACH rules on SDS and also the following REACH requirements:
 - a. Information in SDS must be consistent with CSA (if conducted).
 - b. ES (if any) must be attached to SDS.
 - c. Section 2 of the SDS should be 'Hazards Identification' and Section 3 should be 'Composition/Identification on Ingredients'.
3. Pass the SDS down the supply chain.

ANNEXES

SPECIFIC EXEMPTIONS

REACH is broken down into different Titles. The substances listed in the table below are exempted from specific REACH Titles.

REACH TITLES

- II Registration of Substances
- IV Information in the Supply Chain
- V Downstream users
- VI Evaluation
- VII Authorisation

Exempted Substances	Related Regulations	Exempted from Title
Medicinal products used within the following scope (refer to the list of related regulations)	726/2004/EC, 2001/82/EC, 2001/83/EC	II, V, VI, VII
Food or feeding stuffs in accordance to the following uses (refer to the list of related regulations)	178/2002/EC 89/107/EEC 88/388/EEC 1999/217/EC 2232/96/EC 1831/2003 82/471/EEC	
Substance considered to cause minimum risks	Annex IV	II, V, VI
Substances inappropriate for registration	Annex V	
Identical substances re-imported within the same supply chain	Article 2	
Recovered substances which have already been registered	Article 2	

Exempted Substances	Related Regulations	Exempted from Title
Transported isolated intermediates	Article 2	II (except article 8 and 9), VII
Polymer	178/2002/EC 89/107/EEC 88/388/EEC 1999/217/EC 2232/96/EC 1831/2003 82/471/EEC	II, VI
Medicinal products	726/2004/EC, 2001/82/EC, 2001/83/EC	IV does not apply to preparations intended for final use of these products.
Cosmetic products	76/768/EEC	
Certain medical devices	1999/45/EC	
Food or feeding stuffs	178/2002/EC	

EXISTING CHEMICAL REGULATIONS

The following regulations will be repealed after REACH comes into full force:

1. Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances
2. Commission Regulation (EC) 1488/94 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Regulation 793/93
3. Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations

4. Commission Directive 91/155/EC defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC
5. Commission Directive 93/67/EEC laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC
6. Commission Directive 93/105/EC laying down Annex VIID, containing information required for the Technical Dossier referred to in Article 12 of the seventh amendment of Council Directive 67/548/EEC
7. Commission Directive 2000/21/EC concerning the list of Community legislation referred to in the fifth indent of Article 13(1) of Council Directive 67/548/EEC

The following regulations will be amended:

1. Directive 1999/45/EC, concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

EUROPEAN
CHEMICAL AGENCY
(ECHA) GUIDANCE
DOCUMENTS

AVAILABLE ECHA GUIDANCE DOCUMENTS FOR BUSINESSES

Guidance documents have been developed by various REACH stakeholders such as industry, Member States (MS) and non governmental organisations (NGOs), to facilitate the implementation of REACH.

Businesses may use these guidance documents as a reference on how to fulfill their REACH obligations, suggested methodologies to use for different REACH processes, as well as understand how the different roles and activities which MS competent authorities will be required to carry out under REACH.

As the various REACH processes are implemented in stages, some guidance documents may only be available at a later stage. Updates to the guidance documents will be made periodically when there are new developments.

Copies of these guidance documents are available for download on the ECHA website

GUIDANCE ON THE DIFFERENT PROCESSES UNDER REACH

GUIDANCE DOCUMENTS FOR BUSINESSES

Guidance on Registration

This document provides practical information on when and how to register a substance under REACH. There are 2 main sections of this guidance document, namely registration tasks and obligations and the other is covers the preparation of the registration dossier.

Guidance on Data Sharing

This document provides information on the data sharing mechanisms for phase-in substances and non phase-in substances. It includes information on communication within the SIEF, joint submission for registration. It also describes forms of cooperation, confidential business information issues in the context of data sharing.

Guidance for Intermediates

This document provides information on the registration of intermediates under REACH.

Guidance for Monomers and Polymers

This document provides information on how to deal with polymers and monomers under REACH.

Guidance on Scientific Research and Development (SRandD) and Product and Process Oriented Research and Development (PPORD)

This document provides information on the REACH provisions for substances which are imported, manufactured, imported or used in scientific research and development as well as product and process oriented research and development.

Guidance on Classification and Labelling Notification

This document provides information on when and how to notify a classification and labeling for a substance required under REACH.

Guidance on Requirements for Substances in Articles

This document provides information to producers and importers of articles to help identify obligations under REACH. It covers areas related to registration, requirements to notify ECHA and supply chain communication.

Guidance for Downstream Users

This document provides information to downstream users and explains their roles under REACH. It also covers how to prepare for REACH implementation.

Guidance on the Preparation of an Application for Authorisation

This document provides information on how to prepare an application for authorisation. It also provides guidance to on how to prepare and submit information for alternative substances and substance substitution plans.

Guidance on Socio-Economic Analysis – Authorisation

This document provides information for businesses making an authorisation application on how to prepare a socio-economic analysis. This information required during such an application.

GUIDANCE DOCUMENTS FOR DIFFERENT METHODOLOGIES UNDER REACH

Guidance on Identification and Naming of Substances in REACH

The name and identity of a substance is the key to REACH compliance. This document describes how to name and identify a substance under REACH.

Guidance on how to comply with the provisions of the new Regulation on Classification, Packaging and Labelling of Substances and Mixtures (CLP Regulation)

This document provides information to businesses and authorities on how to implement the new EU CLP regulation, which is based on the UN GHS and how to fulfill the relevant procedures.

Guidance on Information Requirements and Chemical Safety Assessment

This document provides guidance information on the collection and assessment of available information required for the preparation of the Chemical Safety Assessment and documentation within the Chemical Safety Report.

Guidance on IUCLID

This document provides information on how to use IUCLID 5 and to prepare the dossiers for the different REACH requirements.

REFERENCES
AND GLOSSARY
OF ACRONYMS

REFERENCES

1. Guidance on Registration, European Chemicals Agency
2. Guidance for Downstream Users, European Chemicals Agency
3. Guidance on Requirements for Substances in Articles, European Chemicals Agency
4. Guidance on Data Sharing, European Chemicals Agency
5. Guidance on Information Requirements and Chemical Safety Assessment – Chapter R12: Use Descriptor System, European Chemicals Agency

GLOSSARY OF ACRONYMS

CA – Competent Authority
CEFIC – European Chemical Industry Council
CLP – Classification, Labelling and Packaging
CMR – Carcinogens, Mutations and Substances Toxic to Reproduction
CSA – Chemical Safety Assessment
CSR – Chemical Safety Report
DU – Downstream User
EC – European Commission
ECHA – European Chemicals Agency
EEA – European Economic Area
EINECS - European Inventory of Existing Chemical Substances
ETAC – Export Technical Assistance Centre
EU – European Union
GHS – Globally Harmonised System
GLP – Good Laboratory Practice
IUCLID – International Uniform Chemical Information Database
M/I – Manufacturer/Importer
MS – Member State
OECD - Organisation for Economic Co-Operation and Development
OR – Only Representative
PBT – Persistent, Bioaccumulative and Toxic
PPORD – Product and Process Orientated Research and Development
REACH – Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM – Risk Management Measures
SDS – Safety Data Sheet
SIEF – Substance Information Exchange Forum
SVHC – Substance of Very High Concern
vPvB – Very Persistent, Very Bioaccumulative
w/w – Weight/Weight

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