

REACH
THE NEW
LEGISLATION
AND YOU
INFORMATION
THROUGH
THE SUPPLY
CHAIN



Lucite
International

REACH REFERS TO
THE REGISTRATION,
EVALUATION AND
AUTHORISATION
OF CHEMICALS FOR
MANUFACTURE OR
USE IN THE EU.

EVALUATION OF
USE REQUIRES
ENHANCED
COMMUNICATION
ACROSS THE
SUPPLY CHAIN

REACH PREPARATION REVIEW

Key deadlines for the first registration phase are reviewed below alongside the activities recommended to prepare for those deadlines.

REACH TIMELINE	INDUSTRY PREPARATION
<p>1 June 2007 REACH Entered into Force</p>	<ul style="list-style-type: none"> • Compile inventory of individual chemicals and substances in preparations. • Determine which are manufactured or imported, which remain in preparations and which are used in manufacturing. • Check exemptions for substances from REACH. • For those manufactured or imported determine: your annual volume, CAS number and EINECS or ELINCS number, availability of toxicology data, customer details, available usage data. • For those remaining in preparations compile: customer details, available usage data, list of suppliers, level of support from suppliers. • For those used in manufacturing compile: list of suppliers, own use scenario, level of support from suppliers, communication routes.
<p>1 June 2008 Pre-registration begins</p> <p>1 December 2008 Pre-registration ends</p>	<ul style="list-style-type: none"> • Suppliers should pre-register all substances, including components of mixtures, manufactured or imported in quantities greater than or equal to 1tpa. • Confirm if exposure scenarios are required for the substance and, if so, collate information on customer's downstream uses. • Determine which downstream uses will also need support from suppliers of raw materials and establish communication links in supply chain.
<p>1 December 2010 1st Registration deadline ≥1tpa cat 1 or 2 CMRs ≥100tpa dangerous to environment (r50/53) ≥1000tpa per registrant</p>	<p>By this time suppliers of substances subject to the first registration should have compiled a dossier assessing all the downstream exposure scenarios and developed a GHS* compliant eSDS that allows downstream users to confirm the risk management measures required for their use.</p>

Note: Guidance for Industry Preparation comes from REACHReady at CIA and REACH Centrum at CEFIC

* GHS = Global Harmonisation of Classification and Labelling

RESPONSIBILITIES UNDER REACH

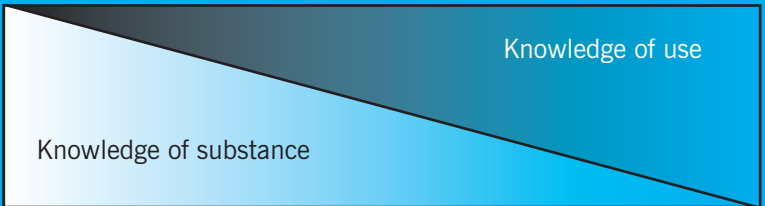
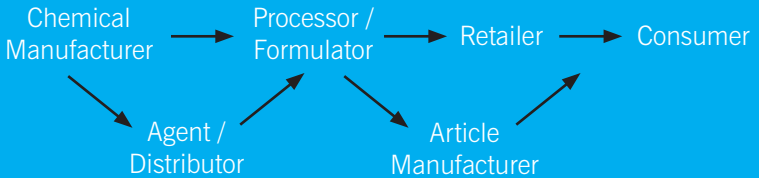
REACH moves the responsibility for assessment of safe use of chemicals from the regulators to industry.

Pre-REACH	Post REACH
<ul style="list-style-type: none">• Responsibility is with the authorities to assess safe use of chemicals.• Generic information on the substance is provided by producers.• Appropriate controls are identified and implemented by users.• Little information on use is required to be supplied by downstream users.	<ul style="list-style-type: none">• Responsibility is with industry to generate and evaluate substance data.• Industry is required to assess exposure associated with each identified use against the substance data.• Appropriate risk management measures need to be developed by suppliers and implemented by downstream users.• Downstream users are required to identify use of each substance and ensure it is communicated up the supply chain.

REACH requires industry to demonstrate that the risks associated with the level of exposure to the hazards of the substance are adequately controlled for each identified use in the supply chain.

INFORMATION AVAILABILITY WITHIN THE SUPPLY CHAIN

Below is an example of a simple supply chain:



REACH requires the knowledge of substance properties, that currently sits with manufacturers, to be passed down the supply chain to end users. Also, in order for exposure assessments to be developed, details of use scenarios need to be passed back up the supply chain to manufacturers from downstream users.

DETERMINING YOUR POSITION IN THE SUPPLY CHAIN

Responsibilities within REACH vary according to your position in the supply chain. More details are available [here](#).

	DESCRIPTION / DEFINITION
Manufacturer	Any legal entity manufacturing a substance within the EU.
Importer	Any legal entity established within the EU responsible for import.
Agent / Distributor	Takes a substance from a manufacturer or importer and supplies it to another actor in the supply chain.
Processor / Formulator	Uses the substance to produce a mixture or polymer. If creates another substance then becomes a manufacturer.
Article Manufacturer	Manufactures an object where shape, surface or design determines function rather than chemical composition.
Retailer	Sells goods directly to a consumer.

supply chain for a particular substance. One of the first steps is to
be in the guidance documents from RIP 3.5.2.

SOME KEY ISSUES

- Pre-registration
- Substance identity
- Data availability, evaluation, sharing
- Development of exposure scenarios
- Registration
- Communication of risk assessment and risk management measures
- Development of eSDS.

- Determination of compositions
- Pre-registration of all substances
- Potential nomination of 'only representative' by overseas manufacturer
- Registration with SIEF
- Complex communications with downstream users.

- No obligation to register (cannot register)
- Complex communication up and down supply chain of use and exposure scenarios plus risk management measures
- Process required to manage information flow and avoid potential to become bottleneck
- Timeframes dictated by suppliers.

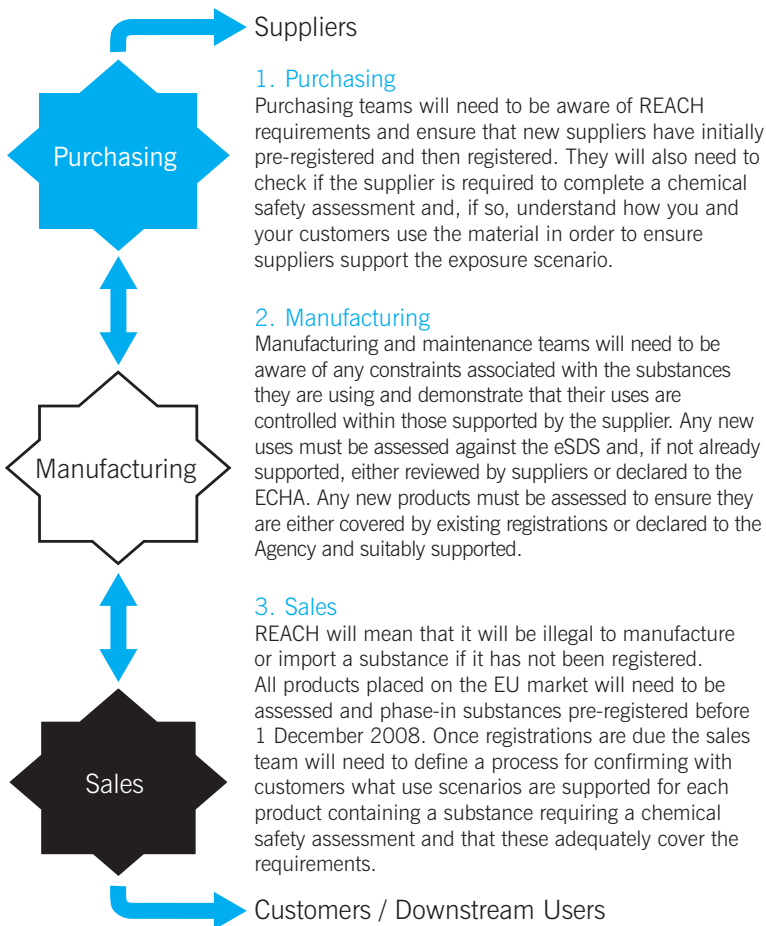
- No obligation to register (unless importing)
- Potential rationalisation of raw materials
- Complex communication up and down supply chain
- Compilation of multiple suppliers and substances eSDS.

- Articles are out of scope of REACH but substances are not
- Substances with international release require to be registered
- Potential rationalisation of raw materials
- Variability in suppliers registration timeframes.

- Potential rationalisation of products
- May have obligations as importer
- Driven by price and consumer purchasing power.
- Tight timeframe to supply information on substances subject to authorisation contained in articles

BUSINESS PREPARATIONS FOR REACH COMPLIANCE

REACH will be enforced by the National Competent Authority within each Member State. As it will be illegal to manufacture or import a substance for a use that is not supported, there will be some additional requirements of our business systems.



INFORMATION REQUIRED FROM RAW MATERIAL SUPPLIERS

Detailed below is the information purchasing teams are seeking from each supplier of substances:

1. PRE-REGISTRATION SUPPORT (to 1 December 2008)

- Is the supplier aware of REACH?
- Has the product been assessed and are all obligations understood?
- Will the supplier pre-register all applicable components in a preparation under REACH?
- What is the position of the supplier within the supply chain ie, will the supplier be registering or, if they are acting as a distributor or formulator, have they established communication routes to support registration by the manufacturer/importer?
- Is the supplier based within the EU and, if not, will they appoint an only representative to register?
- Is the supplier aware of any products that they are not intending to register?
- Who is the best contact to review REACH status and use and exposure scenarios in the future?
- How will the supplier communicate completion of pre-registration?
- When will registration be due?

If a new supplier or substance is added to the portfolio then the pre-registration questions must be asked when assessing the supplier.

2. REGISTRATION (from 1 December 2008)

- What is the pre-registration number for the substance?
- When is the registration due?
- How has the supplier described use and exposure scenarios relevant to Lucite International and our downstream users?
- Are there likely to be any issues with the declared use scenarios where additional work on exposure may need to be considered?
- Are any use scenarios likely to be unsupported?
- How will suppliers communicate registration number and exposure scenarios?

At this stage a new supplier must be able to demonstrate that they have pre-registered and are progressing towards registration.

INFORMATION EXCHANGE WITH DOWNSTREAM USERS

Downstream users of a substance have no obligations to register. However, as it will be illegal for a substance to be supplied for a use that is not covered under a registration, downstream users will be seeking reassurance from suppliers that the substances they purchase will be fully supported.

Below is the information downstream users may require to gain that reassurance:

SUPPORT FOR PRE-REGISTRATION

- Will substances manufactured or imported be identified and pre-registered?
- Will substances suppliers have purchased and used in the formulation of preparations will be pre-registered by their suppliers?
- Will substances used by suppliers in manufacturing be pre-registered and available to ensure continued product supply?

SUPPORT FOR REGISTRATION

- Will substances pre-registered be supported through registration?
- Will use scenarios be supported both by suppliers and, where required, supplier's suppliers?
- Will systems be established for communication of data and progress updates?

STATUS OF PREPARATIONS AT LUCITE INTERNATIONAL

At Lucite International we are committed to full compliance at the earliest opportunity. Methacrylate monomers will be supported fully and all product ranges are being assessed to ensure REACH requirements are understood and met. An assessment of each of the product categories is given below:

EU Monomers

EU monomers will be fully registered and generic use scenarios are being developed. These will be translated into the format according to the technical guidance being developed and will then be sent to customers for confirmation that they cover all requirements.

EU Polymers / Resins / Composites

The manufacture of these products will be covered by registration of the monomers. Any substance placed on the market in a preparation or not bound to the polymer will be covered by the required use scenarios being fed up the supply chain to our raw material suppliers.

EU Sheets

These are classed as articles but the manufacturing process will be covered by the registration of the raw materials. However, if as a result of REACH we are made aware that one of our raw materials within the article becomes listed as a substance of high concern then we will notify customers immediately.

Non-EU Monomers

Imported volumes will be assessed and the necessary registrations will be completed. Use scenarios will be as for those for EU monomers and will be confirmed with customers.

Non-EU Polymers / Resins / Composites

These are being thoroughly reviewed to ensure the component materials are assessed and obligations fully understood to ensure necessary pre-registrations are completed.

Non-EU Sheet

These are articles with no intended release and as such the import of these materials to the EU is exempt from REACH registration. However, if as a result of REACH we are made aware that one of our raw materials within the article becomes listed as a substance of high concern then we will notify customers immediately.

REGISTRATION REQUIREMENTS UNDER REACH

	DEFINITION	EU MANUFACTURE
Substance	A single chemical.	All substances greater than or equal to 1tpa per legal entity require to be registered for use. Dossiers evaluating each use within the EU market against toxicology data are required before a date determined by either the substance properties or the volume manufactured.
Preparation	A mixture or solution of two or more substances.	Every component requires evaluation to ensure the manufacture and use of the preparation is registered by suppliers of the individual substances.
Polymer	A compound consisting of molecules made up of a series of linked monomer units.	Polymers are exempt, but composition is important to ensure that constituent monomers are assessed to determine if they remain in sufficient quantity to require evaluation. Some substances may not be chemically bound - here the product may need treating as a preparation containing a polymer element.
Article	An object where the shape, surface or design determines the product function to a greater degree than chemical composition.	Exempt from registration but if a constituent of the article may be released under reasonably foreseeable conditions of use and totals ≥ 1 tpa then that constituent requires registering for use by its supplier.
Intermediate	A substance manufactured to be consumed in a chemical process and converted to another substance.	Non-isolated intermediates are exempt. On-site isolated or transported intermediates require registering but the amount of detail required in the registration dossier is reduced.

NON-EU MANUFACTURE AND IMPORTED TO EU

All substances imported into the EU ≥ 1 tpa must be registered by the company importing. A non-EU manufacturer can nominate an only representative to register on their behalf, which allows them to cover all their downstream uses in their registration.

Importing a preparation requires all the component substances imported in a quantity ≥ 1 tpa to be registered.

Polymers are exempt but constituent monomers must be registered by someone in the supply chain. A non-EU polymer manufacturer must identify the monomers and ensure they are registered if they wish to import into the EU. Other substances require registering as per preparations. The importer has responsibility to register in the supply chain.

Exempt from registration but if a constituent of the article is intended to be released under reasonably foreseeable conditions of use and totals ≥ 1 tpa then that constituent requires registering by the importer.

Substances imported into the EU for use in manufacture (reaction to another substance rather than being placed on the market) can be registered as transported intermediates with a reduced dossier.

Note:

Exemption from registration does not mean exemption from the whole of REACH. If a substance is identified for the candidate list then all uses must be authorised whether a single substance or contained within a preparation, polymer or article and there are increased requirements for notification through the supply chain.

FREQUENTLY ASKED QUESTIONS ABOUT REACH

1. When do you need to generate an exposure scenario?

Exposure scenarios are required for the registration phase for substances manufactured or imported in a quantity ≥ 10 tpa (Article 10, 14.1) and classified as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB (Annex I (0.6)).

2. What happens if my use is not covered by my supplier's registration?

A downstream user may make a request in writing for a use to be included. For phase-in substances this request must be made 12 months before the registration is due (Article 37.3). For registered substances, the supplier must complete the exposure assessment the later of prior to next supply (if the request was made at least 1 month before supply) or within 1 month (Article 37.3). A downstream user may prepare their own chemical safety report for any use outside the conditions described in an exposure scenario and this must be done within 12 months of receiving the registration number from the supplier (Article 37.4, 39.1)

3. What happens if my supplier fails to pre-register?

If a substance does not appear on the list of those pre-registered and published by the Agency by 1 January 2009 (ie no-one pre-registers) then a downstream user may notify the Agency of his interest and details of his current supplier. The Agency shall publish the name of this substance on its website in the event that there may be a potential registrant (Article 28.5). Otherwise, it would be possible to look for an alternative supplier who has pre-registered or to consider manufacturing or importing the substance. In the latter case, it is possible to submit a late pre-registration for that substance if completed within 6 months of first manufacture or import (Article 28.6) as long as it is more than 12 months before you would be due to fully register your volume. This option would allow import for 6 months whilst an alternative was sought.

4. What happens if I want to introduce a new use for a registered substance?

A downstream user may make a use known to the supplier and, if an exposure assessment is required, the supplier must provide that information before next supply or within 1 month of the request (Article 37.3). If a downstream user decides to register the new use directly to the Agency (potentially for reasons of confidentiality) then that assessment is required within 6 months (Article 38, 39.2).

5. What happens if I want to start manufacturing or importing a substance after pre-registration has ended?

See Q3.

6. How do I pre-register a substance?

IT tools are available from the ECB website which links from the ECHA website (see further info section for link). The system to be used for collating the data required for registration is IUCLID5 and is available as a free download from the website. Systems are being developed to allow this data to be submitted for pre-registration.

QUESTIONS ASKED BY DOWNSTREAM USERS

1. Do you expect that the substances contained in the product you supply will be pre-registered by you or your upstream supplier?

Yes. At Lucite International we have been assessing all our products to ensure we have identified those substances we manufacture or import and those that we use and place back on the market within preparations. We will pre-register those identified as manufactured or imported and we are working with suppliers to ensure those materials we purchase are also pre-registered and supported through registration.

2. Do you anticipate that all substances contained within your products will be registered?

Yes. We are working closely with suppliers to ensure raw materials are supported, and at this stage, we fully intend to register those substances we manufacture in Europe or import into Europe.

3. How will you communicate downstream use scenarios between customers and suppliers?

We have been working within our European trade associations to develop generic exposure scenario data. We have also been working closely with the RIP task force on development of the technical guidance to ensure we are able to translate the scenarios into a standard format. Once this is available we will confirm with customers that these adequately cover their use scenarios. If not, we will work with customers to develop additional scenarios. Those that are developed for products with components to be registered by our suppliers will be declared to our suppliers.

To find out more about REACH from Lucite International please contact:

Fiona Smith
Regulatory and Registration Manager
Lucite International
Cassel Works
PO Box 8
Billingham
TS23 1LE
United Kingdom
E: reach.info@lucite.com

FURTHER SUPPORT FOR REACH

This guidance document has been developed with the support of REACHReady. Contact details for REACHReady and additional sources of support to help you understand your obligations under REACH are listed below:



UK Chemical Industry Association REACH Service:

www.reachready.co.uk

UK National Competent Authority:

www.hse.gov.uk/reach

CEFIC REACH Service:

www.reachcentrum.eu

European Chemicals Agency:

http://ec.europa.eu/echa/home_en.html

For more information on preparations for REACH within
Lucite International:

www.reach-and-you.info/

For more information about Lucite International:

www.luciteinternational.co.uk

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