

REACH
THE NEW
LEGISLATION
AND
MANUFACTURE OF
SUBSTANCES
OUTSIDE THE EU

REACH – THE BASICS

REACH requires all substances manufactured or imported into the EU in a quantity greater than 1 tonne per annum (tpa) to be registered. This registration must include an assessment that the uses within the EU market are safe according to the toxicology data for that substance.

For substances manufactured outside the EU the obligation to register under REACH is with the party introducing the substance into the EU, i.e. the importer, unless the substance has already been registered in the supply chain. Whilst non-EU manufacturers cannot themselves register, they may nominate an 'Only Representative' based in the EU to fulfil the obligations of registration. The advantage of this process is that downstream customers of the non-EU manufacturer can use that registration to export the substance to the EU (either directly or within their products). For the case of non-EU Lucite International manufacturing sites, Lucite International UK Ltd will act as an 'Only Representative'.

This guide applies to the manufacture of the following materials at Lucite International:

i-Butyl Methacrylate
n-Butyl Methacrylate
Ethyl Methacrylate
2 Ethyl Hexyl Methacrylate
Methacrylic Acid
Methyl Methacrylate

The key milestones in the REACH timeline are as follows:

| | |
|-----------------|---|
| 1 June 2007 | Legislation enters into force (EIF). |
| 1 June 2008 | Pre-registration begins. |
| 1 December 2008 | Pre-registration ends. |
| 1 December 2010 | Registration deadline for substances placed on the market in quantities over 1000 tonnes per annum, or substances of very high concern. |
| 1 June 2013 | Registration deadline for substances placed on the market in the range of 100–1000 tonnes per annum. |
| 1 June 2018 | Registration deadline for substances in quantities of 1–100 tonnes per annum. |

REACH applies to all substances manufactured or imported into the EU in a quantity >1tpa. Registration is by the entity placing the substance on the market but this requires detailed communication of uses and risk management measures up and down the supply chain. As a result there could be effects seen throughout the supply chain. From the perspective of a non-EU manufacturer there are some key points to consider:

1. Purchasing of raw materials
2. Manufacture of products registered under REACH
3. Supply of products to customers ('Downstream Users')

PURCHASING OF RAW MATERIALS

The REACH registration process is phased according to the volume and hazards of the individual substance. However, each legal entity manufacturing or importing a material must register. As a result, if a raw material is purchased within the EU, it should be confirmed that the supplier is intending to register the manufacture of that substance to ensure continuity of supply.

1. All suppliers sourcing material from within the EU must confirm the product will be available after REACH registration deadlines
2. Any new EU supplier must confirm that supply of the material will not be affected by REACH

As REACH registration obligations are phased the questions we should be asking suppliers and the steps we should take are dependent upon the REACH timeline. The following pages indicate the requirements according to timing.

PURCHASING SUBSTANCES FROM AN EU SUPPLIER

PRIOR TO 1st JUNE 2008

REACH Obligations: No obligation to register, preparation phase

Confirm with supplier:

1. Substances purchased will be pre-registered
2. Determine anticipated registration deadlines
3. Review with supplier if material contains a substance that may be listed as a substance of high concern and potentially require authorisation in the future

1st JUNE 2008 – 1st DECEMBER 2008

REACH Obligations: Pre-registration phase. Existing substances need to be pre-registered to allow manufacturing in the EU to continue and to take advantage of the phase-in registration process. New substances should be registered before being manufactured in the EU.

Confirm with supplier:

1. Existing substances have been pre-registered under REACH and will continue to be supported
2. Registration due date for potential next milestone that could affect manufacturing in the EU

AFTER 1st DECEMBER 2008

REACH Obligations: Existing substances should be pre-registered or registered to allow manufacturing in the EU to continue. Pre-registration is not a guarantee of registration hence it is important to review deadlines with the manufacturer. New substances should be registered before being manufactured in the EU.

Confirm with supplier:

1. Substances purchased will be pre-registered
2. Determine anticipated registration deadlines
3. Review with supplier if material contains a substance that may be listed as a substance of high concern and potentially require authorisation in the future

MANUFACTURE OF SUBSTANCES OUTSIDE THE EU UNDER REACH

Manufacturing of substances outside the EU does not require registration under REACH. There are also no obligations to ensure that your use of a substance is covered by an extended safety datasheet (eSDS). However, if changes to the manufacturing process affect product composition of a registered substance then there may be some checks required.

CHANGE TO EXISTING PRODUCT COMPOSITION OR MANUFACTURE OF A DIFFERENT PRODUCT

Registration of substances under REACH requires confirmation of composition early in the process. Should the manufacturing process change such that the composition is altered the new specification should be checked against the registration. If the change takes this outside the original limits then it should be treated as manufacture of a different product.

Introduction of a different product will require a separate registration under REACH. If this is a substance classified as existing under previous legislation then it is possible that this could be pre-registered and given a phase-in registration timeframe according to volume. However, if this is a completely new substance then it will require immediate registration.

SALE OF SUBSTANCES FOLLOWING REACH

REACH requires each legal entity manufacturing or importing a substance in a quantity over 1 tpa to register that substance. This registration process is phased according to the substance properties and the volume manufactured or imported. In the case of non-EU manufactured substances, the obligation is with the importer to complete the registration unless they can demonstrate the substance has been registered within the supply chain.

If a legal entity importing a substance to the EU fails to meet the REACH registration timelines then it will be illegal for that legal entity to import that substance into the EU until they have completed the full registration.

The next pages look to review the registration timeframes associated with REACH, the effect that may have to customers of non-EU manufactured substances and the schedule for meeting the phased obligations.

TIMELINE FOR EXPORT OF SUBSTANCES TO THE EU

Prior to 1st June 2008

Substances can be exported and placed on the market as per existing procedures

1st June 2008 – 1st December 2008

New substances for the EU market will have to be registered under REACH and sold according to the recommendations in the use and exposure assessments included on the extended safety datasheet. Existing substances should be going through pre-registration and can continue to be sold as existing procedures.

After 1st December 2008

New substances will have to be registered under REACH and sold according to the recommendations in the use and exposure assessments included on the extended safety datasheet. Existing substances can be sold as normal if they are pre-registered and the registration date is due in the future. After registration they should be sold in Europe according to the recommendations in the use and exposure assessments included on the extended safety datasheet.

SCHEDULE FOR REGISTRATION OF SUBSTANCES

The substances we manufacture outside the EU will be pre-registered by Lucite International UK Ltd and supported through the REACH registration process. The key milestones for us to achieve this are:

| | | |
|--|---|-------------|
| Prior to 1 st June 2008 | Confirm list of substances manufactured outside the EU Compile available toxicology data Prepare generic EU use descriptions | ✓ ✓ ✓ |
| 1 st June – 1 st December 2008 | Pre-registration Continue to develop use scenarios into exposure scenarios as per technical guidance Enter into Pre-SIEFs | |
| December 2008 | Confirmation of status to sales team Pre-registration numbers to be available | |
| 1 st Jan 2009 | Enter into SIEFs | |
| 2009 | Share data requirements within SIEF Collate all exposure scenarios Agree risk management measures with downstream users Prepare registration dossier Update safety data sheet | |
| 1 st December 2010 | Latest Registration Updated safety datasheet to be sent to customers | |

EU customers will also require reassurance that their use and exposure scenarios will be included in our chemical safety assessments and incorporated onto our material safety datasheet. Non-EU customers may incorporate our substances into their products that are then exported to the EU. They too will seek reassurance of support. The level of support required will depend upon their position in the supply chain and the following pages aim to support this.

DOWNSTREAM USE OF SUBSTANCES

Specific Downstream User obligations under REACH will vary depending upon how and where the substance is used. EU customers will require reassurance that their use and exposure scenarios will be included in our chemical safety assessments and incorporated onto our extended safety datasheet. Non-EU customers may incorporate our substances into their products that are then exported to the EU. They too will seek reassurance of support.

Whilst this booklet covers the export of substances to the EU, we have prepared a number of similar booklets for our downstream operations that can be used to review these more specific issues and maybe of use to others in a similar position. These are:

MANUFACTURE OF SUBSTANCES IN THE EU

MANUFACTURE OF COMPOSITES IN THE EU

MANUFACTURE OF POLYMERS / RESINS IN THE EU

MANUFACTURE OF ACRYLIC SHEET IN THE EU

DISTRIBUTION OF ACRYLIC SHEET IN THE EU

MANUFACTURE OF COMPOSITES OUTSIDE THE EU

MANUFACTURE OF POLYMERS / RESINS OUTSIDE THE EU

MANUFACTURE OF ACRYLIC SHEET OUTSIDE THE EU

GENERIC OBLIGATIONS FOR DOWNSTREAM USERS

There are a number of generic obligations under REACH for users of substances within the EU. These may have additional implications that should be considered.

1. DECLARATION OF USE AND EXPOSURE SCENARIO

The registrant of a substance may, depending upon properties and volume, have to submit a dossier that includes an assessment of each identified use against the toxicology data and propose appropriate risk management measures. These are then required to be communicated through the extended safety datasheet (eSDS).

Exposure scenarios can be communicated by the customer (and a distributor is obliged to pass that information back up the supply chain) or developed by the manufacturer (possibly through trade associations).

2. IMPLEMENTATION OF RISK MANAGEMENT MEASURES

A downstream user must implement the risk management measures highlighted against the appropriate exposure scenario in the eSDS. If the list of scenarios does not cover that particular use then the customer either needs to declare it to the agency themselves (may be preferred due to reasons of confidentiality) or get the original registrant to conduct the assessment and update the dossier and the eSDS. A distributor may want to take the option of assessing downstream uses themselves rather than declaring these to their supplier. For registered substances, this needs to be done within a month of supply.

3. COMMUNICATION OF INFORMATION IN THE SUPPLY CHAIN

The effect of (1) and (2) is a lot of information needs to be passed through the supply chain. Supplementary to this booklet is REACH: THE NEW LEGISLATION AND YOU: INFORMATION THROUGH THE SUPPLY CHAIN that provides a more detailed assessment

4. TIMESCALES

Registration timeframes are according to the volume manufactured or imported by the registrant. It is important to note that, if the substance is supplied in a low volume by a distributor, the timeframe might be sooner than anticipated. Registration of LI monomers will be by 1st December 2010.

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 199/45/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 (i.e. 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 maybe 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.

DEFINITION OF SOME COMMON REACH ACRONYMS

| | | | |
|--------|--|--------|--|
| C&L | Classification and Labelling | IUCLID | International Uniform Chemical Information Database |
| CA | Competent Authority | LEO | Legal Entity Organisation |
| CAS | Chemical Abstracts Service Number | M/I | Manufacturer / Importer |
| CMR | Carcinogen, Mutagen or Reproductive Toxin | MS | Member State |
| CSA | Chemical Safety Assessment | MSDS | Material Safety Data Sheet |
| CSR | Chemical Safety Report | NLP | No Longer Polymers |
| DNEL | Derived No Effect Level | OECD | Organisation for Economic Co-operation and Development |
| DU | Downstream User | OSOR | One Substance One Registration |
| DUNS | D&B Unique Numbering System | PBT | Persistent, Bioaccumulative and Toxic |
| EBW | Exposure Based Waiving | PNEC | Predicted No Effect Concentration |
| EC | European Commission | PPORD | Product and Process Orientated Research and Development |
| ECHA | European Chemicals Agency | QSAR | Qualitative Structure Activity Relationship |
| EC No | EINECS or ELINCS Number | REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| EIF | Entry into Force | RIP | REACH Implementation Project |
| EINECS | European Inventory of Existing Chemical Substances | RMM | Risk Management Measure |
| ELINCS | European List of Notified Chemical Substances | RSS | Robust Study Summary |
| EP | European Parliament | SEA | Socio Economic Analysis |
| ES | Exposure Scenario | SIEF | Substance Information Exchange Forum |
| eSDS | Extended Safety Data Sheet | SME | Small and Medium Sized Enterprise |
| EU | European Union | SPORT | Strategic Partnership on REACH Testing |
| GHS | Global Harmonised System | SVHC | Substances of Very High Concern |
| GLP | Good Laboratory Practice | TGD | Technical Guidance Document |
| HPV | High Production Volume | vPvB | Very Persistent and Very Bioaccumulative |

FURTHER SUPPORT FOR REACH

There are a number of REACH service providers available. Listed below are some additional sources of support to help you understand your obligations under REACH:

UK Chemical Industries 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:
www.echa.europa.eu

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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