

# REACH THE NEW LEGISLATION AND YOU



**Lucite**  
International

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

## REACH THE NEW LEGISLATION

### IN SUMMARY

**Registration:** industry is required to provide information on the safe use of chemicals manufactured or imported in quantities greater than 1 tonne per annum

**Evaluation:** the information provided by industry will be assessed for completeness, and

**Authorisation:** substances of highest concern will require additional assessment of use and may be approved if the controls are adequate, or alternatives are unviable. Alternatively, they may be restricted if the measures required to manage the risks are deemed inappropriate.

## REACH THE NEW LEGISLATION

### KEY MILESTONES

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 THE NEW LEGISLATION

### IN MORE DETAIL

Registration of substances within REACH is the responsibility of the manufacturer or importer. The timescale for registration and the amount of toxicology data required is dependent upon the manufacturers' tonnage or the substance properties. High volume substances, or substances of very high concern, will be prioritised through the registration process.

The process will begin with pre-registration of substances. This allows advantage to be taken of the phase-in periods for registration. Pre-registration will take place following establishment of the European Chemicals Agency in Helsinki.

### ONE SUBSTANCE ONE REGISTRATION

All manufacturers and importers who have pre-registered the same substance will participate in a Substance Interest Exchange Forum (SIEF). This will facilitate the sharing of toxicology data within the group and avoid duplication of studies. It will also be used to resolve any differences in the classification and labelling of the substance.

## PRE-REGISTRATION

### IN MORE DETAIL

Pre-registration requires a limited amount of data based upon:

- SUBSTANCE IDENTIFICATION (NAME, AND CAS AND EINECS/ELINCS NUMBERS)
- REGISTRANT'S NAME AND ADDRESS (EACH LEGAL ENTITY MUST REGISTER SEPARATELY)
- ANTICIPATED REGISTRATION TIMEFRAME BASED UPON VOLUME
- INDICATION OF SUBSTANCES FOR WHICH IT IS INTENDED TO BE USED AS REFERENCE AND READ-ACROSS TOXICOLOGY DATA.

Following pre-registration the Agency will publish the list of co-registrants for formation of the SIEF.

Failure to pre-register a substance means full registration must be completed within a year. Current guidance from CEFIC and CIA is to ensure all substances are pre-registered.

## THE REGISTRATION PROCESS

Once a substance has been pre-registered, the manufacturer or importer is required to compile a registration dossier for the substance. Following submission of the dossier within the timeframe set by substance properties or volume, it will be evaluated according to the timeframes set by the Agency. In addition to evaluation, substances may be subjected to the authorisation or restriction processes (see later).

The registration dossier will consist of an evaluation of the safe use of the substance. To complete this there are three areas of data requirement:

### 1. SPECIFICATION OF USE

The uses for which the substance is placed on the market require identifying and evaluating. This will require good communication up and down the supply chain to ensure manufacturers have adequately covered customer requirements.

### 2. CSA/CSR

A chemical safety assessment and safety report will be required. These will review the use scenarios, exposure data and substance properties. The result will be a detailed assessment to demonstrate safe control of the use of the substance.

### 3. EVALUATION OF TESTING REQUIREMENTS

The 'one substance one registration' proposal requires available data to be shared and assessed to avoid duplicate tests. The level of data required depends upon the volume of the substance or its' properties (if it is of high concern). The SIEF will assess the data and agree the gap analysis.

On completion of the registration the manufacturer is required to ensure that all identified uses and control measures are captured on a revised safety datasheet. This will also highlight any uses not advised.

## SUBSTANCES TO REGISTER

For the purpose of registration a substance\* can be thought of as a single chemical (e.g. methylmethacrylate). Mixtures of substances or preparations require each component to be registered for manufacture and onward use.

### Polymers\*

Polymers are initially exempt from registration and evaluation. However, they are not exempt from authorisation - hence materials contained within the polymer must be considered. Further legislation on registration of polymers will be developed within REACH timeframes. Note that polymers are manufactured by use of substances that may be subject to registration.

### Articles\*

Whilst articles themselves are exempt, if they contain a substance of high concern or a substance that may be released upon reasonably foreseeable conditions of use then these will require notification or registration. As with polymers, articles are

manufactured by use of substances that may be subject to registration.

### Intermediates\*

Non-isolated intermediates are exempt, but on-site isolated and transported intermediates should be pre-registered. The registration dossier requirements for these substances are reduced.

### Exemptions\*

Some substances are exempt and will not require registration. These are covered in Annexes IV and V of the regulation.

\*Refer to useful links for definitions of phrases.

## EVALUATION

Following submission of the registration dossier to the Agency it will undergo two evaluations, each with different objectives.

### 1. DOSSIER EVALUATION

- All test proposals will be evaluated for substances over 100 tonnes. The aim of this check is to prevent any unnecessary animal testing.
- For each tonnage band, a minimum of 5% of the dossiers will be examined to verify compliance with the registration/test requirements and to check that the proposals for risk management are adequate.

### 2. SUBSTANCE EVALUATION

The Agency will coordinate with the Member States' National Competent Authorities to evaluate particular substances. Any substance may be evaluated, but prioritisation will be given according to risks to human health or the environment. This guidance on prioritisation will be published in the form of a rolling action plan on the Agency web site and will identify the Member State carrying out the evaluation.

Once a substance evaluation has been completed, the competent authority will consider how to use the information, e.g. authorisation, restriction or including update on Annex I of Directive 67/548/EEC (provisions relating to the classification, packaging and labelling of dangerous substances).

## AUTHORISATION

Authorisation will be required for each use of a substance belonging to specific groups, i.e. substances of very high concern:

- category 1 and 2 carcinogenic, mutagenic or toxic to reproduction (CMRs)
- persistent, bio-accumulative and toxic (PBTs), very persistent and very bio-accumulative (vPvBs), and
- other substances identified as causing serious and irreversible effects on humans or the environment.

The Agency will provide the expert opinion on the application for authorisation and the applicant will have the opportunity to comment. The Commission will review this and may grant an authorisation for specific uses if the manufacturer or importer is able to demonstrate that risks can be adequately controlled. If such evidence cannot be provided, authorisation can only be granted if an analysis shows that the socio-economic advantages of the specific use are predominant.

All authorisations will be reviewed after a time limit which will be set on an individual case basis

If a risk is identified as not being adequately controlled, the proposal to restrict marketing and use of a substance can be made by a Member State or by the Agency on behalf of the Commission. Decisions on restriction are taken by the Commission in consultation with the Member States.

The restriction procedure will regulate the manufacture or use of substances where it is considered that there is an unacceptable risk to human health or the environment. If necessary, this could result in the prohibition of these activities.

## 2007



### LEGISLATIVE MILESTONES

- 1 June
- REACH enters into force
  - responsibilities for change in form of material safety datasheets apply
  - safety datasheets required for vPvBs
  - changes to safety datasheets for substances of very high concern apply
  - obligation to notify customers of substances of very high concern within articles apply.

Other legal responsibilities are deferred until later deadlines.

### COMMISSION / AGENCY MILESTONES

From 1 June 2007 to 1 June 2008 Commission preparations will include the following activities:

- establishment of the European Chemicals Agency
- completion of the REACH technical guidance documents
- roll-out of IUCLID5 chemical database and software
- finalisation of the REACH IT system.

### INDUSTRY PREPARATION GUIDANCE

1. Prepare inventory list of individual chemical substances and preparations.
2. For each substance define, position within the supply chain.
3. For substances manufactured or imported, determine:
  - annual volume
  - CAS number and EINECS or ELINCS number
  - extent of availability of toxicology data
  - customer details
  - available data on use within industrial, professional and consumer sectors.
4. For substances purchased for use, compile:
  - list of suppliers
  - own use scenarios
  - level of support available from supplier for pre-registration and registration of use.

2008

**LEGISLATIVE MILESTONES**

- 1 June - titles associated with registration, data sharing and avoidance of unnecessary testing, downstream users, evaluation, authorisation, classification and labelling, information, free movement and transitional measures apply  
- regulation for existing substances repealed.

**COMMISSION / AGENCY MILESTONES**

- 1 June - fees and charges associated with registrations, updates to registrations, authorisations and appeals to be specified  
- Commission to have reviewed procedure for preparing CSRs and propose amendments.
- 1 December - Agency to have assigned registration numbers to substances currently registered as 'New Substances'  
- Member States to have notified Commission of provisions on penalties applicable for infringement of the regulation  
- Commission to have reviewed criteria for determining PBT and vPvB substances.
- End December - anticipated substances of very high concern (SVHC) identified and candidate list for authorisation published on Agency website.

**INDUSTRY MILESTONES**

- 1 June - pre-registration begins  
- registration of non phase-in substances begins.
- 1 December - pre-registration ends.

CEPIC/CIA GUIDANCE TO INDUSTRY: **IF IN DOUBT PRE-REGISTER EVERYTHING**

2009

**LEGISLATIVE MILESTONES**

- 1 June - restrictions process begins - any existing provisions of Member States relating to restrictions covered under directive 76/769/EEC are to have been included in Annex XVII (restrictions) by this date  
- previous directive to be repealed.

**COMMISSION / AGENCY MILESTONES**

- 1 January - Agency to have published list of substances pre-registered and first envisaged registration deadline on web site  
- Agency to make first recommendation of priority list of substances for authorisation.
- 1 June - Commission to have published inventory of Member States' additional restrictions on substances subject to authorisation, which may remain in place until 1 June 2013.

**INDUSTRY MILESTONES**

- 1 January - SIEF registration begins - requests for vertebrate animal test data must be answered within 2 months. Provision of proof of test costs must be made within 1 month of request.
- 1 December - first downstream user communication deadline - downstream users must have placed a request on their suppliers to register their use for the first registration deadline phase-in substances (unless registering the use and exposure scenario directly). Suppliers and distributors are responsible for passing this information back up the supply chain to the registrant.

2010

**LEGISLATIVE MILESTONES**

- 1 June
- Commission review of REACH Regulation which may be adapted to avoid overlap with other EU legislation
  - classification and labelling inventory begins.

**COMMISSION / AGENCY MILESTONES**

- 1 June
- Member States submit reports on operation of REACH regulation (including enforcement) in their respective territories
  - potential for Commission to have prepared draft amendment to restrictions (Annex XVII).

**INDUSTRY MILESTONES**

- 1 December
- first registration deadline for phase-in substances applies to:
    - ≥ 1tpa category 1 or 2 CMRs
    - ≥ 100tpa dangerous to the environment (R50/53)
    - ≥ 1000tpa per manufacturer or importer registering
  - roll-out of updated safety datasheets begins
  - registration of lower tonnage substances continues.

**After this date, it will be against the law to manufacture or import unregistered substances subject to this deadline.**

All information or advice provided as part of this REACH document is intended to be general in nature and you should not rely on it in connection with the making of any decisions. Lucite International Limited and the companies within the Lucite International group of companies try to ensure that all information provided as part of this REACH document is correct at the time of inclusion, but does not guarantee the accuracy of such information. Lucite International Limited and the companies within the Lucite International Limited group of companies are not liable for any action you may take as a result of relying upon such information nor for any loss or damage suffered by you as a result of you taking this action.

Further information about REACH can be found using the following useful links: European Chemicals Bureau: <http://ecb.jrc.it/REACH> (includes the text of the legislation, will be the link to downloads of the IT interface and also links to the various National Competent Authorities). CEFIC: [www.reachcenter.eu](http://www.reachcenter.eu) and CIA: [www.reachready.co.uk](http://www.reachready.co.uk) (both sites give a good interpretation of the legislation and have useful help desks). CEPE: [www.cepe.org/homepage.htm](http://www.cepe.org/homepage.htm) (European paint industry trade group), or contact the REACH team at Lucite International: [reach.info@lucite.com](mailto:reach.info@lucite.com)

Lucite International UK  
Limited  
Cassel Works  
P O Box 8  
Billingham  
England TS23 1LE  
T: + 44 1642 735000