Locations

Synthomer Limited
Central Road
Templefields
Harlow
Essex CM20 2BH
United Kingdom
Tel: +44 (0) 1279 436 211
Fax: +44 (0) 1279 444 025

Synthomer Limited
Roundwood Industrial Estate
Wakefield Road
Ossett
West Yorkshire WF5 9BQ
United Kingdom
Tel: +44 (0) 1924 275 421
Fax: +44 (0) 1924 265 905

Synthomer Limited
2 George Street
Batley
West Yorkshire WF17 5AU
United Kingdom
Tel: +44 (0) 1924 441 160
Fax: +44 (0) 1924 474 897

Synthomer Limited
South Marsh Road
Stallingborough
Grimsby DN41 8DB
United Kingdom
Tel: +44 (0) 1469 573 361
Fax: +44 (0) 1469 571 346

Synthomer GmbH
Gwinnerstrasse 19
D-60388 Frankfurt am Main
Germany
Tel: +49 (0) 69 94179 0
Fax: +49 (0) 69 94179 211

Synthomer GmbH
Innerstetal 2
D-38685 Langelsheim
Germany
Tel: +49 (0) 5326 510
Fax: +49 (0) 5326 511 395

Synthomer BV
Ijsselstraat 41
5347 KG Oss
The Netherlands
Tel: +31 (0) 4126 81700
Fax: +31 (0) 4126 28602

Synthomer Hasselt BV
Randweg 16
8061 RW Hasselt (ov)
The Netherlands
Tel: +31 (0) 38 477 1839
Fax: +31 (0) 38 477 5620

Synthomer SA
Boulevard du Textile 1
B-7700 Mouscron
Belgium
Tel: +32 (0) 56 85 21 55
Fax: +32 (0) 56 34 48 52

Synthomer Middle East
PO Box 7544
2nd Industrial City
Dammam 31472
Saudi Arabia
Tel: +966 3 812 1045
Fax: +966 3 812 1263

Synthomer Sdn Bhd
16-03 Menara MPPJ
Jalan Tengah
46200 Petaling Jaya
Selangor Darul Ehsan
Malaysia
Tel: +60 (3) 7956 3997
Fax: +60 (3) 7957 7642

Synthomer Sdn Bhd
1 1/2 Miles, Jalan Batu Pahat
86000 Kluang
Johor
Malaysia
Tel: + 60 (7) 776 7878
Fax: + 60 (7) 776 8902

Synthomer LLC
460 Village Park Drive
Powell, Ohio 43065
USA
Tel: +1 614 847 1234
Fax: +1 614 847 1222

Synthomer South Africa
200 Lansdowne Road
Jacobs, KwaZulu Natal 4052
P.O. Box 12040, Jacobs 4026
Durban, South Africa
Tel: +27 31 480 8100
Fax: +27 31 480 8299

Registration, Evaluation & Authorisation of CHemicals

synthomer
International *technology* Individual *service*

Head Office

Synthomer Limited
Central Road, Templefields, Harlow, Essex CM20 2BH UK
Tel +44 (0) 1279 436 211 **Fax** +44 (0) 1279 444 025
Email: reach@synthomer.com

www.synthomer.com

synthomer
International *technology* Individual *service*

NEW EU CHEMICAL LAW

REACH regulation (EC) No. 1907/2006 is a new European legislation that came into force on 1 June 2007.

A key objective of this new EU regulation is to improve protection of human health and the environment.

It applies to all EU Members and will be enforced by national authorities within each Member State.

This new chemical legislation places the onus on industry to show, within a specific timeframe, that the chemicals it uses are safe.

It does this by enforcing that any chemical substance produced or imported into the EU in quantities of 1 tonne or more per year must pass under the scrutiny of the specific requirements detailed under **REACH**.

REACH stands for the Registration, Evaluation and Authorisation of Chemicals.

KEY STAGES

There are four key stages to **REACH** spread over 11 years.

Registration: industry is required to collate specific information on the properties of chemicals manufactured within the EU or imported into the EU in quantities of 1 tonne or more per year.

Evaluation: regulators assess the data to ensure that sufficient information has been submitted regarding the assessment on the safe use and handling of the substance.

Authorisation: substances with properties deemed to be of very high concern with certain hazardous characteristics must undergo an additional assessment for specific use. Authorisation for a particular use may be given if there are no reasonable alternatives available and providing that appropriate control measures are in place.

There is also an initial stage to **REACH**, pre-registration.

Pre-registration: the first step to **REACH** is a pre-registration. By pre-registering you qualify for a transitional phased-in registration deadline which is dependant upon the tonnage and classification of the substance. If a pre-registration is not made then you will not qualify for a more gradual phase-in and must register the substance on 1 December 2008.

TIMELINE SUMMARY

All substances manufactured and / or imported into the EU in quantities of 1 tonne or more per year, even if only supplied in preparations (i.e. mixtures), will need to be registered under **REACH**. Companies operating within Europe will have the opportunity to pre-register between 1 June and 30 November 2008 in order to benefit from phase-in periods provided by the **REACH** legislation. Registration itself can begin as early as 1 June 2008. Non-EU manufacturers and formulators can appoint "Only Representatives" to act on their behalf.

WHAT HAS CHANGED?

Before REACH – unchanged policies	After REACH – new requirements
The regulating authorities are responsible for assessing the safe use of chemicals.	Responsibility shifts to industry to show that the chemicals it uses are safe.
Manufacturers are responsible for providing classification, labelling and safety data for substances and preparations irrespective of exposure scenarios.	Manufacturers and importers are responsible for developing exposure scenarios. Safety Data Sheets (SDS) remain as the designated form for communicating safety and risk management information.
Downstream users are not obliged to communicate their use up the supply chain.	Downstream users have a right to communicate their use of a substance up the supply chain to ensure that appropriate exposure scenarios and assessments can be made by actors further up the supply chain.
The downstream user carries out a risk assessment to determine appropriate controls for handling a substance for a particular use.	Safe use and handling measures for a particular use must be communicated by suppliers down the supply chain.
Companies have other product related obligations under various environmental, occupational and consumer legislation.	The presence of certain hazardous materials in finished products ("articles") must be communicated.
Different pieces of legislation apply to existing substances and new substances. A notification only applies to new substances.	Existing and new substances are treated under the same regulatory framework (REACH). Pre-registered existing substances are called phase-in. Novel or new chemistry is considered as non phase-in.

KEY MILESTONES

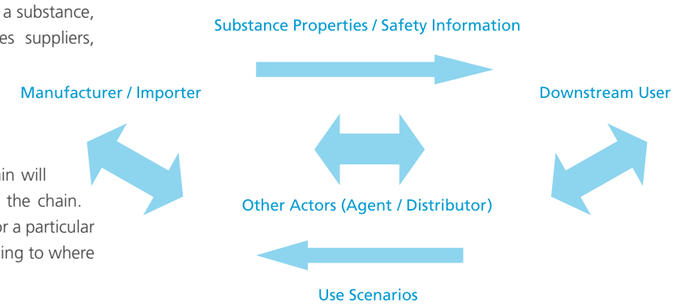
1 June 2007	**REACH** Legislation enters into force.
1 June 2008	Pre-registration begins (for existing "phase-in" substances).
30 November 2008	Pre-registration ends (for existing "phase-in" substances).
30 November 2010 (Phase 1)	Registration deadline for substances in quantities of >1000 tonnes per year and certain substances of very high concern.
31 May 2013 (Phase 2)	Registration deadline for substances in quantities of >100 tonnes per year.
31 May 2018 (Phase 3)	Registration deadline for substances in quantities of >1 tonne per year.

WHO DOES REACH APPLY TO?

The responsibility for compliance with **REACH** lies with any company responsible for manufacturing, importing, using or placing a substance, preparations or article on the EU market. This includes suppliers, distributors, downstream users and even retailers.

WHAT IS MY ROLE?

To ensure compliance with **REACH** the whole supply chain will be involved in communicating information up and down the chain. It is crucial to determine your position in the supply chain for a particular substance as responsibilities under **REACH** will vary according to where you are along the chain.



DEFINITION OF POSITIONS IN THE SUPPLY CHAIN:

Key definitions for positions along the supply chain are shown below:

Manufacturer: any legal entity established within the EU who manufactures a substance within the EU.
Importer: any legal entity established within the EU who is responsible for import.
Agent / Distributor: supplies a substance from a manufacturer or importer to another actor in the supply chain.
Processor / Downstream User: use substances to produce mixtures if another substance is created, then they become manufacturers.
Article Producer: manufactures an object where as opposed to the chemical composition, the shape, surface or design determines function.
Retailer: sells goods directly to a consumer.
Actors in the Supply Chain: for a particular substance, all manufacturers and / or importers and / or downstream users in a supply chain.
Only Representative: can be appointed by any non-EU manufacturer, downstream user or article producer to register a substance (and downstream use) on their behalf.

RESPONSIBILITIES ALONG THE EU SUPPLY CHAIN

	Manufacturer	Importer	Agent / Distributor	Downstream User	Article Producer or Importer	Retailer
Pre-registration (including: correct identification of substance)	√	√	X	X	√ (currently for substances with intentional release)	X
Data gathering of existing data	√	√	X	X	X	X
Data sharing with Substance Interest Exchange Forums (SIEF's)	√	√	X	X	√	X
Development of exposure scenarios	√	√	X (unless they need to be involved)	√	√	X
Carrying out risk assessments	√	√	X (unless they need to be involved)	√	√	X
Registration	√	√	X	X	√ (only for substances with intentional release - unless already registered for that use)	X
Communication of use and exposure scenarios up the supply chain	X	X	√	√	√	√
Communication of risk (by means of a REACH compliant SDS) down the supply chain	√	√	√	√	X (but certain obligations exist if hazardous)	X (but certain obligations exist if hazardous)
Communication of certain hazardous materials in articles (i.e. packaging or other finished items that are not substances or preparations)	√	√	√	√	√	√ (Within 45 days of a consumer request)

IN MORE DETAIL

Central EU Authority: pre-registration and registration data must be sent to the European Chemicals Agency (ECHA) in Helsinki.

Pre-registration:

- no charge is made by ECHA for pre-registering a substance.
- a separate submission is required per substance, per legal entity (i.e. each company).

"One Substance, One Registration"

The following limited information should be included:

- substance identification (chemical name, CAS number, EINECS number).
- name and address of registrant (may be a third party representative).
- expected registration phase (1, 2, or 3), is based upon tonnage and classification.
- read-across references should be included for any substances that are structurally similar.

SIEF's: sharing of information (particularly toxicology data) is actively encouraged. To facilitate this, following the closure of the pre-registration period, for each substance, ECHA will issue a list of co-registrants. Substance Information Exchange Forums (SIEF's) can then be established to assess existing data and agree on analysis for missing data to avoid duplication of studies.

Registration: the tonnage and classification of a substance will dictate which phase of registration should be applied as well as the type and amount of certain information (e.g. toxicity data) that should be submitted by the manufacture / importer via the registration dossier. Priority throughout **REACH** will be given to high tonnage substances or substances of very high concern.

"Registration is per legal entity and must cover the substance use"

Substances of Very High Concern can include substances classified as CMR Category 1 + 2, PBT's, vPvB's and R50/53. CMR stands for carcinogenic, mutagenic or reproductive toxins (Category 1 relating to substances known to be carcinogenic to humans) and Category 2 (relating to substances that should be regarded as if they are carcinogenic to humans). PBT stands for persistent, bio-accumulative and toxic whilst vPvB's stands for very persistent and very bio-accumulative. R50/53: is a risk phrase assigned to those substances that are classified as "very toxic to aquatic organisms, may cause long term adverse effects in aquatic environment". Other indications of hazardous properties such as endocrine disruptors or respiratory sensitisers can also result in a substance being deemed to be of very high concern to human health and the environment.

Registration Dossier: for each chemical substance, a Registration Dossier will be required to be submitted by the registrant (i.e. manufacturer or importer). According to the regulatory guidelines the dossier must include a number of elements related to the hazard profile of the substance along with its use and application in the market so that the risks to human health and the environment can be evaluated accordingly. For any substance, even if it is not hazardous, **REACH** requires a minimum amount of information on its use to be registered. These generic descriptors of use can provide an important basis for considering how much hazard data are needed for the registration process. The Registration Dossier will therefore consist of two parts. Firstly, a technical dossier, detailing the intrinsic properties of the substance, including a proposal for the classification and labelling. Secondly, a chemical safety report (CSR) made up of chemical safety assessments (CSA) which can incorporate exposure scenarios for each identified use along the supply chain. Looking at these two sections as a whole should identify the safe handling and control conditions that must be applied to a substance for safe use. The dossier is submitted to the European Chemicals Agency for possible evaluation or other review.

Tonnage Dependent Test Data: the number of tests that are required to be submitted in the Registration Dossier is dependent upon the tonnage of substance manufactured in or imported into the EU. The greater the tonnage, the more tests are necessary. However, there is the possibility to avoid the need for the tests through 'exposure-based waiving', the application of other legislation, or expert assessment. There are also certain reduced requirements for specific types of materials.

	No. of Tests		
Tonnage per year:	Physchem	Ecotoxicity	Toxicity
>1000	17	24	20
100-1000	17	18	17
10-100	14	7	14
1-10	14	3	6

"No Data, No Market"

IUCLID 5: has been designed as an IT tool that can be used by industry to collate and store test data as well as preparing and submitting Registration Dossiers. The European Chemicals Agency will use this as the central data repository for all submitted Registration Dossiers. It will also have a **REACH**-IT system for communicating with the registrant.

Evaluation: the Registration Dossier will be evaluated in two ways. Firstly, (to avoid unnecessary testing), for substances >100 tonnes all test proposals will be evaluated. Further checks will be made on a minimum of 5% of the dossiers in each of the other tonnage bands to ensure that applied test procedures, exposure scenarios and risk assessments are adequate. Secondly, any substance may then be further evaluated by a Member State Competent Authority, particularly if a substance is deemed to pose a particular risk to human health or the environment. Timeframes have been set out for the European Chemicals Agency's evaluation process, in line with the appropriate phase of registration. In this way, priority for review is given to those chemicals of highest concern and / or greatest tonnage.

Member State National Competent Authority: following evaluation by a National Competent Authority the substance may be referred for restriction of use or authorisation. The Competent Authorities are also responsible for making other decisions, such as on the classification and labelling of substance.

Authorisation: those substances designated substances of very high concern on the Candidate List will require authorisation under Annex XIV of the Regulation. This will be assigned per identified use to ensure that any risks are effectively managed and will be reviewed after a certain time period, decided upon a case by case basis. The European Commission will ultimately decide whether authorisation should be granted, taking guidance from the European Chemicals Agency. Authorisation may be denied, granted in full or granted for a limited number of uses depending upon the registrant's ability to demonstrate that adequate controls can be implemented or that the socioeconomic benefits outweigh the risks and that there are no viable alternatives.

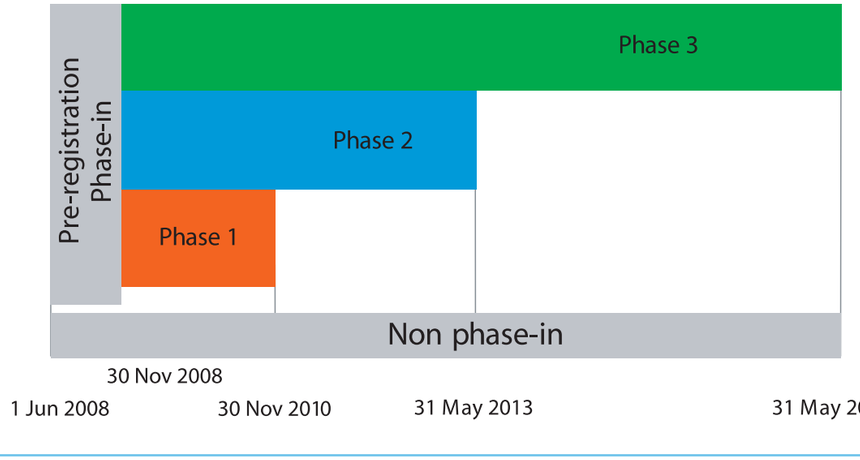
Restriction: a particular use of a substance may be restricted if adequate control measures cannot be demonstrated and the risk to human health and the environment is considered as being too high. The European Commission has the final say in this matter but will act in consultation with individual Member States.

Candidate List: substances of very high concern will be placed on a Candidate List prior to beginning the authorisation procedure. Once on the Candidate List, producers and importers of articles have particular obligations such as notifying and communicating the presence of such substances in products.

Revised Safety Data Sheets: will be used to communicate safety and risk management information, as necessary. Registered substances must have identified uses and control measures detailed on an extended safety datasheet. This will also highlight any uses advised against.

RIPs: with regard to obligations along the supply chain, use and exposure to humans and the environment of products containing hazardous substances need to be communicated upstream whilst looking downstream the manufacturer or importer has to give advice how to handle a product containing hazardous substances in a safe manner. Under **REACH**, the Commission has launched a number of REACH Implementation Projects (RIPs) that will provide guidelines that will help companies meet their regulatory obligations.

Deadlines for Registration



WHAT SUBSTANCES NEED TO BE REGISTERED?

Unless otherwise exempt, substances manufactured in the EU or imported into the EU in quantities of 1 tonne or more per year will be subject to **REACH**.

The REACH definition of a Substance is "a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition".

Exemptions: a number of exemptions exist for certain stages within **REACH**, usually where risks are expected to be low. Polymers, intermediates and articles are three examples where types of exemptions can apply. Full details for these exemptions (along with other exemptions that may be applied) can be found in the Regulation EC 1907/2006.

Exemptions

Polymers

Polymers, meeting specific **REACH** criteria are currently exempt from registration and evaluation. They are not however exempt from authorisation and all substances contained within the polymer must be taken into consideration (including bound monomers) and properly registered.

Intermediates

On-site isolated and transported intermediates must comply with reduced **REACH** requirements if strictly controlled however, non-isolated intermediates are exempt.

Articles

Intentionally released substances of >1 tonne per year must comply with the **REACH** requirements. Candidate List substances in articles must be communicated and may require a notification.

Although polymers and articles are covered by certain exemptions, the substances that are used to manufacture such materials may indeed be subject to the full registration requirements of **REACH** even if manufactured outside the EU.

It should be noted that should a substance be identified in the Candidate List then full scrutiny for all uses will be made, with increased communication requirements along the supply chain with authorisation being mandatory.

The REACH definition of a Polymer: is "a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributed to differences in the number of monomer units. A polymer comprises the following: a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant; b) less than a simple weight majority of molecules of the same molecular weight".

Preparations: REACH requires each individual substance or preparation (i.e. mixture and solutions) to be registered separately.

FIRST IMPLEMENTATION STEPS

Although implementation spans up to 11 years, many actions need to be taken in the first 18 months after coming into force and a number of regulatory obligations apply to parties throughout the supply chain.

2007

- **REACH** enters into force.
- ECHA is established.
- Technical Guidance documents drafted.
- **REACH** IT system (IUCLID5) launched.

Industry to prepare in-house inventory list for substances / preparations detailing whether these are manufactured or imported - identifying the following:

CAS / EU Number (EINECS / EILINCS / NLP), annual volume, position within the supply chain, suppliers / customers contact details, available data on use & toxicity scenarios, applicable exemptions.

2008

- Candidate List to be prepared by ECHA detailing substances anticipated as being of very high concern and therefore potentially requiring authorisation.
- Pre-registration begins.
- Registration of non phase-in substances begins.
- Pre-registration ends and SIEF formation begins.

Details regarding exemptions, registration fees, appeals, penalties to be confirmed.

2009

Agency to publish a list of the pre-registered substances.

SYNTHOMER'S ACTIVITIES - INFORMATION EXCHANGE ALONG THE SUPPLY CHAIN

Synthomer is commited to full compliance with the **REACH** requirements in full cooperation with our suppliers and customers. We have established a Steering Committee to manage the initial pre-registration stage and are working to an internal time line that will ensure business continuity throughout the pre-registration phase. During this period, once the transitional requirements for phase-in have passed and we enter into Phase 1 of registrations we will be taking the necessary steps to ensure that **REACH** becomes an integral part of our ongoing business. Our preparatory activities for **REACH** are in line with the UK Chemical Industries Association and CEFIC guidelines.

As you may be aware, we have already initiated discussion along the supply chain:

Communication with suppliers to ensure that they are:	Communication with customers to ensure that they are:
Aware of **REACH.**	Aware of our commitment to ensuring that their uses and exposure will be identified and supported in the future.
Aware of their obligations under **REACH.**	
Aware of our interest in them assuring pre-registration of their product.	
Establishing a primary contact for future communication.	

The vast majority of Synthomer products fall within the Polymer Exemption and aside from ensuring that the individual substances of the mixture or preparation are registered in their own right for the required use, most of our products therefore require little further assessment to comply with the current **REACH** legislation.

We have however reviewed our full product portfolio to identify products that do not meet the Polymer Exemption criteria so that appropriate action can be taken for those materials.

We believe that **REACH** provides Synthomer with the opportunity to add to our excellent record of regulatory compliance and Responsible Care and that working closely with our suppliers and customers both up and down the supply chain is key to ensuring compliance with **REACH.**

As the **REACH** timelines progress we will provide timely further communications appropriate to providing pro-active support and will inform you accordingly of any outcome that may be relevant to your business.

We look forward to working with you and continuing discussion on **REACH** in the future.

FURTHER INFORMATION ON REACH

The following is a list of additional sources of information which can assist in getting prepared for **REACH.**

European Chemicals Agency:

www.echa.europa.eu/home_en.asp

REACHCentrum Service:

www.reachcentrum.eu

REACHReady Service:

www.reachready.com

For further information concerning Synthomer's activities please refer to our website which you will find as follows:

www.synthomer.com
↳ Corporate
↳ Policies and Certificates
↳ **REACH** Statement

Karen Whiter
Regulatory Affairs Manager and
REACH Coordinator

Tel: +44 (0) 1279 436211
Fax: +44 (0) 1279 454286

reach@synthomer.com