

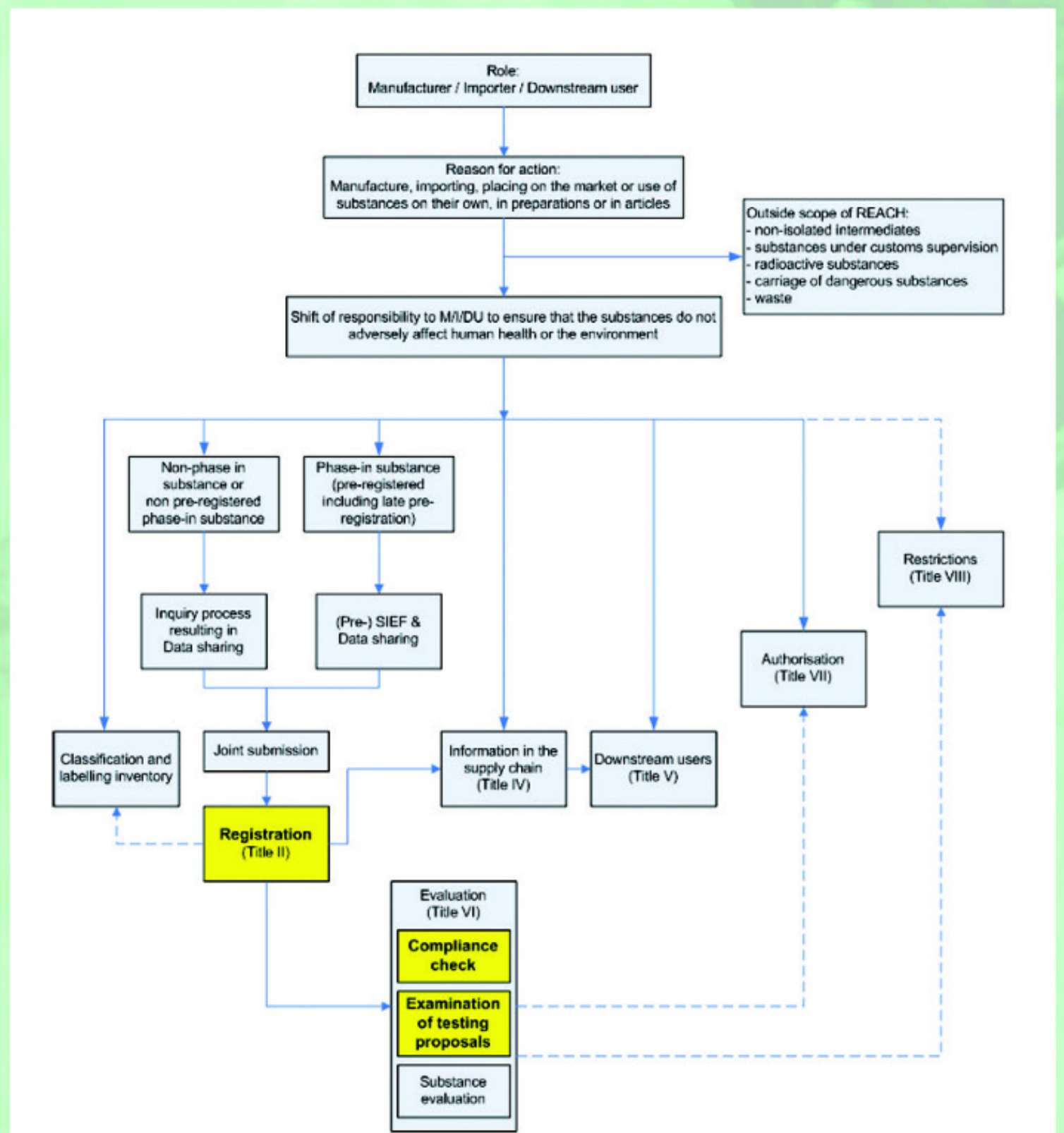
# The Ticking REACH Clock



The European Chemicals Agency (ECHA), the Agency, located in Helsinki, Finland manages the registration, evaluation, authorisation and restriction processes for chemical substances to ensure consistency across the European Union. These REACH processes were designed to provide additional information on chemicals, to ensure their safe use, and to ensure competitiveness of the European industry.

In its decision-making the Agency will take the best available scientific and technical data and socio-economic information into account. It will also provide information on chemicals and technical and scientific advice. By assessing and approving testing proposals, the Agency will minimise animal testing.

## REACH Timetable (main deadlines)



## Flowchart on REACH processes

ECHA have provided a flowchart aimed at giving a simple overview of the REACH processes, particularly with respect to activities involving ECHA. As a result the flowchart may inevitably give an over-simplification of certain aspects of complex processes and the inter-

relationship between them. ECHA have particularly stressed that only a small proportion of the substances subject to one process will be subject to the next (or a parallel) process. The processes shown in series do not necessarily occur in the sequence indicated by the arrows shown.

*continued on page 17*

Active Lead Registrants List Date	Formed SIEF
02/12/2009	2,072
25/11/2009	2,051
18/11/2009	2,025
11/11/2009	2,004
03/11/2009	1,974
October 2009	1,928
September 2009	1,766
August 2009	1,327
July 2009	982
June 2009	574
May 2009	293
April 2009	57
Total to date	17,053

**For registrant companies involved in REACH, joining a SIEF by the 1st December 2009 deadline was the latest critical goal they had to achieve to remain in compliance with REACH.**

Why this was urgent for your company: *According to the law, if you do not have a valid registration by that time (1st December 2009), your manufacture or importing would need to cease. Hopefully, all registrants complied and have become involved in the most appropriate SIEF for their substance(s).*

**The next Step: Becoming active in a SIEF**

SIEFs are formed by companies that intend to register the same substance. The SIEFs are established to facilitate the sharing of information, avoid duplication of new studies and agree on classification and labelling if necessary. Companies can become active by communicating with other SIEF members.

**Remember to a keep record** of all your SIEF activities from the beginning so that you can demonstrate your activity if you need to.

**Lead registrants**

The role of Lead Registrant was laid down by the REACH Regulation and is mandatory for each SIEF. Lead Registrants who were preparing for the 2010 registration deadline needed to advise and inform ECHA of their nomination by using the link on the ECHA website. Up until late November 2009 progress was still being made in the formation of SEIFs. *By time of publication - we will have passed the 1st December 2009 SIEF Formation deadline. Early 2010 I expect EHCA to report on the success of SIEF formation.*

**Companies can change their SIEF status:** If they decide to postpone their registration or they do not need to register, they can change their SIEF status from active to inactive. Companies can do this in REACH IT.

**Lead Registrants:** The Lead Registrants should inform ECHA of their nomination as soon as possible in order to be able to benefit from Lead Registrant webinars and advice.

SIEF members need to nominate a Lead Registrant to submit the joint registration dossier. The joint submission contains the main part of the technical dossier including the classification and labelling of the substance, (robust) study summaries and the proposal for further testing, if applicable. The Lead Registrant acts as a contact point for the registrants of other substances who want to 'read across' to the substance data for their own substance.

**SIEFs – Top Tips**

SIEFs (Substance Information Exchange Fora) are independent – they are not "owned" by ECHA. At the same time, they have a critical role within REACH and ECHA wants to do what it can to try to ensure that they succeed in the job they have to do.

SIEFs are formed by companies that intend to register the same substance. They are there to facilitate data sharing between the companies, and hence avoid duplication of studies and to agree classification and labelling where there is a difference between registrants. Members also need to provide others with existing studies, react to requests by others for information and work collectively to identify and carry out additional studies should they be needed. All this work is intended to lead to a single joint submission for each substance, with the minimum of additional animal testing and cost.

Industry stakeholders have made ECHA aware that there have been difficulties in getting some SIEFs started and potential

problems with communication between members. ECHA recently chaired a meeting of industry stakeholders and staff from the Commission. The meeting sought to discuss the problems that had arisen, clarify the requirements of SIEF members and help to ensure sharing of best practice between industry stakeholders.

ECHA has provided a REACH Fact Sheet (notes) aimed at companies who are joining a SEIF and highlight the main areas of discussion and potential solutions. ECHA has recognised that this is a new process and that other issues are likely to arise and further discussion may be needed. ECHA will continue to provide support, within the limitations imposed by REACH, to help to ensure that SIEFs and registrants can fulfil the tasks that they are asked to do.

ECHA has also prepared Guidance document on data sharing to help SIEFs complete their tasks, which is relevant to some of the issues raised in the Fact Sheet.

**Downstream Users**

ECHA have issued guidance in the form of a Fact Sheet for downstream users, refer to the following link to download a copy [http://guidance.echa.europa.eu/docs/fact\\_sheets/downstream\\_en.pdf](http://guidance.echa.europa.eu/docs/fact_sheets/downstream_en.pdf). Under REACH, a downstream user is a company (or a professional) who uses a chemical substance on its own or in a preparation in his industrial or professional activity. Substance manufacturers, **formulators of preparations**, producers of articles, craftsmen and service providers can all be downstream users. This guidance is particularly addressed to downstream users. EU lubricant blenders should ensure their customers see this document. These documents are available in the following 22 languages: *Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovakian, Slovenian, Spanish and Swedish.*

