

How to comply with REACH and what are the special issues for non-EU companies

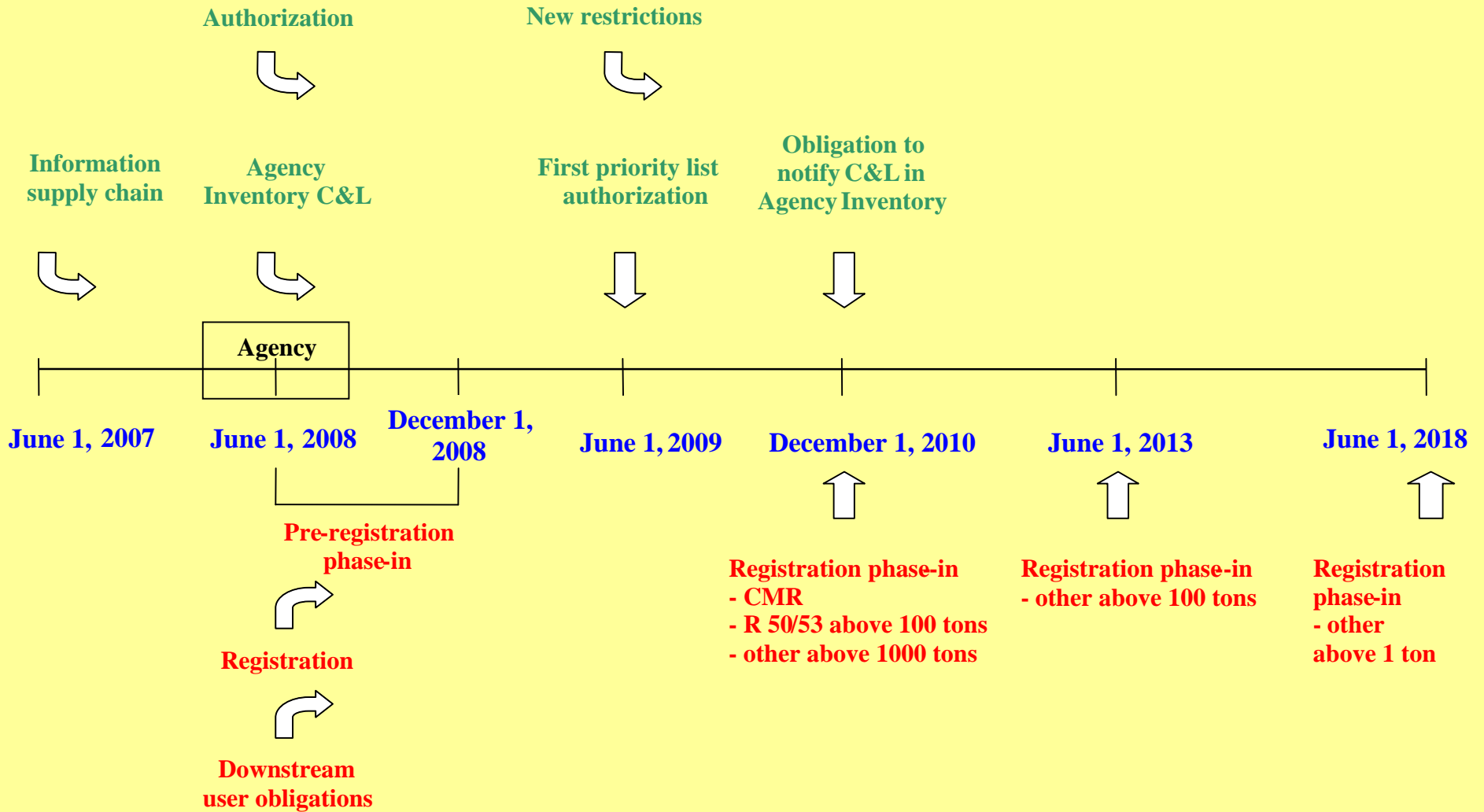
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REACH TIMELINES



- Substances subject to registration
- All substances

Special Issues for Non-EU Companies

Issue 1 – Options for (Pre-)Registration

Canada Manufacturers

- Only Representative
- EU Subsidiary
- EU customer acts as importer

Points to consider:

- Confidentiality
- Registration cost
- Flexibility



EU Customer

EU Customer

EU Customer

Special Issues for Non-EU Companies

Issue 2 – Number of Only Representatives

- European Commission has issued guidance that only one Only Representative per substance per manufacturer is possible for full volume of EU imports



Special Issues for Non-EU Companies

Issue 3 – Monomers in Polymers

- Polymers are exempt from registration but their (bound) monomers (above 2% w/w) must be registered by person in same supply chain. This is easier for intra-EU suppliers.
- Points to consider:
 - Lack of knowledge on identity of monomers and other components
 - Lack of knowledge on exact composition
 - Lack of data on components
 - Profitability vs registration cost

* Same for preparations.

Special Issues for Non-EU Companies

Issue 4 – Classification and Labeling Inventory

- Obligation to agree with other manufacturers / importers by December 1, 2010 on common classification & labeling and to notify to ECHA.*
- How to agree?

* For all dangerous substances, including if exempt from registration

Special Issues for Non-EU Companies

Issue 5 – Revision of Annexes IV and V

- Entries into Annexes IV and V (exemptions from registration) will be reviewed by June 1, 2008. Commission will set criteria. Individual submissions are encouraged. Practical problem of input for non-EU manufacturers.



Special Issues for Non-EU Companies

Issue 6 – Articles

- ‘**Articles**’ are manufactured products for which shape or design is more important than the chemical composition, e.g. micro processors
- **Importers** of articles must:
 - register substances intentionally released during normal and reasonably foreseeable handling and use conditions and present in articles above 1 ton/year, and
 - notify SVHCs contained in articles above 0.1% w/w and substances present in articles above 1 ton/year
- Main issues:
 - lack of knowledge on the presence of SVHCs in imported articles (SVHCs are likely to be in the thousands)
 - difficulties in tracing long supply chains (see experience with RoHS)
 - (legal and practical) uncertainties

Special Issues for Non-EU Companies

Issue 7 – Candidate List

- First authorization list to be adopted as of 2009
- In the meantime, a so-called ‘candidate list’ will be issued likely in the second half of 2008
- Substances on this ‘candidate list’ are expected to be ‘de-listed’ by market forces
- Manufacturers should assess potential ‘candidate’ and ‘authorization’ substances to prepare for market de-listing (replacement by alternatives) and/or product defense

Special Issues for Non-EU Companies

Issue 8 – SIEFs

SIEFs will be work-intensive

- Possible strategies
 - case-by-case (product-specific) decisions
 - if data are available or quantities are low, direct registration avoids time-consuming negotiations and participation in SIEF
 - but may result in the substance being targeted for evaluation/authorization
 - if data are not available or quantities are high, pre-registration and participation in SIEF would allow manufacturer/importer to buy data or access to data

HOW TO COMPLY WITH REACH AND WHAT ARE THE SPECIAL ISSUES FOR NON-EU COMPANIES

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A. REACH Basics

A.1 Obligation to Register

Pursuant to Article 6 REACH (Regulation 1907/2006), any manufacturer or importer (per legal entity) must register with the new chemical agency (ECHA) any substances in annual quantities as of 1 metric ton. Three weeks after the registration has been submitted, manufacturing or import may start (Article 21). The registration obligation applies to both substances as such as well as substances in preparations (mixtures). Substances present in articles must also be registered (again above 1 ton) if they are intended to be released under normal or reasonably foreseeable conditions of use (there are also notification obligations for articles not releasing substances but containing particularly dangerous substances on a Community list to be established) (so-called Candidate List).

A.2 Exemptions

There are numerous exemptions from the above obligation to register embedded in the REACH Regulation (e.g. for substances in foods, minerals not chemically modified, polymers provided the monomers are registered, substances used in pharmaceuticals etc.).

A.3 Data Requirements for Registration

Registration entails the submission to ECHA of a large number of documents (Article 10). Depending on the quantity registered, some data requirements are waived. In general, a registration entails submission of a so-called technical dossier and a chemical safety report (for substances above 10 tons). The technical dossier must contain: identity of the manufacturer/importer; identity of the substance; information on manufacture and use; classification and labeling of the substance; guidance on safe use of the substance; study or robust study summaries (as the case may be) of the information derived from application of Annexes VII to XI REACH (standard information and testing requirements); an indication which of the information was reviewed by an assessor; proposals for testing; exposure information for substances in quantities of 1 to 10 tons; a confidentiality request if appropriate.

A.4 Joint Registration

REACH requires that if a substance is intended to be manufactured or imported by more than one legal entity, certain of the above data must be submitted jointly (Article 11), unless the joint submission would be disproportionately costly or submitting the information jointly would lead to disclosure of information which is commercially

sensitive or likely to cause substantial commercial detriment, or the person wishing to submit individually disagrees with the lead registrant on the selection of the information.

Joint registration will trigger lower registration fees under REACH.

A.5 Only and Third Party Reps.

Importers may appoint so-called 'only representatives' to register on their behalf (Article 8). Both importers and EU manufacturers that do not wish to be identified by their competitors may appoint so-called 'third party representatives' for any dealings with their competitors. However, the manufacturer's or importer's identity will nevertheless be known to the ECHA.

A.6 Light Registration and Substances Regarded as Registered

Registration of certain categories of substances is facilitated. Less data needs to be submitted or only notification is required. Such facilitation is available for substances registered for product and process orientated research and development (PPORD) (Article 9), and intermediates (substances undergoing chemical synthesis) (Articles 17 et seq.).

Active substances of biocides and pesticides subject to Directives 98/8 and 91/114 are regarded as registered. Substances that have been notified under the existing EU chemicals legislation (Directive 67/548) are regarded as registered as well and will be rolled over into REACH (Article 24).

B. Pre-registration

A.1 Purpose of Pre-registration

In order to avoid the sudden registration at once of the expected 30,000 chemical substances in use in the EU, REACH contains a phased-in registration scheme for existing substances (Articles 23 et seq). These are substances (Article 2 (20)) that are either listed on the European Inventory of Existing Commercial Chemical Substances (EINECS); or were manufactured in the Community or its acceding Member States by the date of the respective accession but not placed on the market at least once in the 15 years before entry into force of REACH; or were placed on the Community market or the market of the acceding countries by the accession date before entry into force of REACH and were considered to be notified under Article 8 (1) of Directive 67/548.

Depending on the danger category and the quantity of the substance manufactured / imported, different registration deadlines for pre-registered substances apply. **Appendix 1** shows the various different dates and categories.

A.2 Details of Pre-registration

In order for companies to benefit from the phased-in registration scheme, they must pre-register with the ECHA within the pre-registration period of **June 1 through December 1, 2008**. First time market entrants may pre-register after this date.

Pre-registration just entails the submission of the name of the substance including its EINECS and CAS number or if not available any other identity codes; name and address of the pre-registrant; envisaged deadline for the registration and the tonnage band; and indication of comparable substances for potential read-across.

A.3. SIEF

By January 1, 2009, ECHA must publish on its website a list of substances pre-registered. Thereafter, all companies having pre-registered the same substance will automatically be considered members of a virtual so-called Substance Information Exchange Forum (SIEF) (Article 29).

The aim of each SIEF is to facilitate, for purposes of registration, the (1) exchange of study summaries and robust study summaries necessary for registration thereby avoiding the duplication of studies (animal tests); and also to (2) agree on the classification and labeling of the substances (to be submitted to ECHA by December 1, 2010) (Articles 113, 116).

C. To Do List

First Step: Fact Finding

- Set up inventory of all substances as such and in preparations / mixtures imported, manufactured or used in the EU (including process chemicals not present in final products), per site and per legal entity, and who supplies them from where;
- Set up inventory of all products marketed by your company (substances, preparations, 'articles');
- Establish tonnages of substances per site and entity;
- Identify applications/uses;
- Identify suppliers and customers;
- Collect updated applicable safety data sheets;
- Collect data on substances already in possession / ownership of your company

Second Step: Assessment of Substances Individually

- Within scope of REACH;
- Applicability of exemptions;
- Which REACH requirements and dates apply;
- Subject to authorization, restrictions;
- Existing restrictions;
- Availability of data; which data is required; which data is missing;
- Use and exposure categories;
- Review SDS, labelling, packaging;
- Action required (collection of data, upgrade SDS, registration, authorization, substitution etc).

Third Step: Assessment of Articles

- Does your company purchase / use / market any articles with substances subject to notification (CMRs, PBT, vPvB) at relevant concentrations;

Fourth Step: Suppliers and Customers

- Review supply and customer contracts for duration, liabilities, information requirements, insurance;
- Check whether suppliers will continue to deliver once REACH in effect;
- Assess whether your company will want to continue customer relationship;

Fifth Step: Various

- Formation of task forces and consortia under REACH necessary or desirable; identify and set up such; Data protection action needed;
- Set up formalized REACH record keeping and documentation management system;
- Set up REACH compliance review procedure and team;
- Review insurance contracts for REACH compliance coverage;
- Streamline supply structure;
- Streamline manufacturing.
- Identify and set up REACH compliance budget.

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