



**'REACH-ing Industry-
The New European Chemical Legislation'**

REACH in Practice

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Outline

- ◆ Obligations under REACH
- ◆ Phase-in vs. non phase-in
- ◆ Pre-registration
- ◆ Data sharing
- ◆ Deadlines for registration
- ◆ Duty of Communication
- ◆ Classification And Labelling Notification

Obligations under REACH

- ◆ Different obligations are specified under REACH
- ◆ Depending on the role in the supply chain
 - ◆ Manufacturer
 - ◆ Importer
 - ◆ Only representative
 - ◆ Downstream user
- ◆ First step is to identify what is your role and obligations under REACH

What do you manufacture/import

- ◆ Different obligations depending whether:
 - ◆ Substance – only substances have to be registered
 - ◆ Preparation – when contained in a preparation each individual substance needs to be registered. Substances that have been registered by the manufacturer/importer and that are being mixed in to a preparation by a downstream user, do not need to be registered again by the latter.
 - ◆ Article – individual substances in articles are also potential for registration

Substances exempted from REACH

- ◆ Radio-active substances
- ◆ Substances under customs supervision
 - ◆ in temporary storage,
 - ◆ in transit,
 - ◆ in a free zone or
 - ◆ in a free warehouse on the EU territory only transiting through the EU and under customs supervision
- ◆ Substances used in the interest of defence and covered by National exemptions
- ◆ Waste – imp:- the regulation does not exempt waste from its provisions but clarifies that waste is not a substance.
- ◆ Non isolated intermediates
- ◆ Transported substances

Does the substance have to be registered

- ◆ Above 1 tonnage
- ◆ Substances exempted from registration e.g.,
 - ◆ Food and feed
 - ◆ Medicinal products
 - ◆ Recycled or recovered substances already registered
 - ◆ Polymers
 - ◆ Biocidal products
 - ◆ Plant protection products
- ◆ Is it a phase-in or a non phase-in substance

Phase-in vs. non phase-in

◆ Phase-in:

- ◆ it is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS)
- ◆ it was manufactured in the Community, or in the countries acceding to the European Union on 1 January 1995 or on 1 May 2004, but not placed on the market by the manufacturer or importer, at least once in the 15 years before the entry into force of this Regulation, provided the manufacturer or importer has documentary evidence of this
- ◆ it was placed on the market in the Community, or in the countries acceding to the European Union on 1 January 1995 or on 1 May 2004, before entry into force of REACH Regulation by the manufacturer or importer and was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC but does not meet the definition of a polymer as set out in REACH

◆ Non phase-in: does not fulfil any of the above criteria

Phase-in vs. non phase-in

- ◆ Phase-in substances:
 - ◆ Different deadlines for registration apply
 - ◆ Only if the substance is pre-registered between 1st June 2008 and 1st December 2008
- ◆ Non-phase in substances:
 - ◆ Do not benefit from different registration deadlines and have to be registered before placing on the market
 - ◆ Requires first the submission of an inquiry dossier to determine whether a registration or another inquiry has already been submitted for the same substance for data sharing provisions to apply.

Pre-registration procedure

- ◆ Sign-up in REACH-IT
- ◆ The user needs to be logged in the system
- ◆ Three options how to go about it:
 - ◆ Online Pre-registration
 - ◆ by entering data for each pre-registration within the REACH-IT online wizard
 - ◆ Single XML Pre-registration (using IUCLID 5 pre-registration tool)
 - ◆ by creating a XML file for each substance to pre-register
 - ◆ upload the file to populate the REACH-IT online wizard and complete the pre-registration online
 - ◆ Bulk Pre-registration (using IUCLID 5 pre-registration tool)
 - ◆ by creating a XML file containing all substances to pre-register
 - ◆ upload the file to REACH-IT

Pre-registration

- ◆ Downstream users are to check whether the substance has been pre-registered.
- ◆ End October 2008 - Intermediate list of pre-registered substances
- ◆ January 2009 – list of pre-registered substances to be published
 - ◆ Substance identification: EINECS number, CAS number and names of the substance
 - ◆ Substance identification of the similar substances, if applicable
 - ◆ The first envisaged registration deadline
- ◆ If substance is not in the list the Downstream user may notify the Agency of
 - ◆ His interest in the substance
 - ◆ Contact details
 - ◆ Details of his current supplier

Data sharing

- ◆ Data collected through vertebrate animal testing must be shared, against payment.
- ◆ Substance Information Exchange Forum (SIEF) (for pre-registered substances)
 - ◆ prior to registration
 - ◆ before testing is carried out
- ◆ Inquiry process – for substances which have not been pre-registered
 - ◆ Potential registrant inquires from the Agency

Pre-SIEF

- ◆ The REACH-IT module allows a pre-registrant to see who else has pre-registered the same substance. This is displayed on a substance specific pre-SIEF page.
 - ◆ General information:
 - ◆ substance identification
 - ◆ identification of similar substances, if applicable (substances which may facilitate the risk assessment of the substance)
 - ◆ Company specific information:
 - ◆ contact information as specified during pre-registration (the third party representative or the company contact person or the company's general contact details)
 - ◆ the envisaged registration deadline
 - ◆ the pre-registration number
 - ◆ remarks for the other pre-SIEF participants
- ◆ Companies who have pre-registered a substance will automatically become listed on the pre-SIEF page of this substance.
- ◆ To initiate discussions after pre-registration, a pre-registrant can volunteer on the pre-SIEF page to become SIEF formation facilitator.

SIEF

- ◆ For each pre-registered substance with the same identity
- ◆ Has no prescribed legal form, but is a forum to share data and other information on a given substance
- ◆ Participants in a SIEF are free to organize themselves in consortia or other forms of agreements as they see fit to carry out their obligations under REACH
- ◆ After 1 January 2009 a SIEF is formed when pre-registrants have agreed in a pre-SIEF that they manufacture or import the same substance.
- ◆ SIEF members need to nominate a Lead Registrant.
- ◆ They will share and assess data and prepare common parts of the registration (joint submission).
- ◆ Any SIEF member receiving a request for information that involves vertebrate tests must respond within 1 month.
- ◆ Compensation for sharing data is agreed among the respective SIEF members.

SIEF

- ◆ All SIEF Participants shall:
 - ◆ React to requests for information from other participants
 - ◆ Provide other participants with existing studies upon request

- ◆ Potential Registrants shall:
 - ◆ Request missing information from other SIEF participants
 - ◆ Collectively identify needs for further studies to comply with registration requirements
 - ◆ Make arrangements to perform the identified studies
 - ◆ Agree on classification and labelling

- ◆ Data Holders:
 - ◆ Must respond to any query from potential registrants if they hold the data relating to this query
 - ◆ Are not entitled to request data

- ◆ SIEFs shall remain operational until 1 June 2018

Deadlines for registration

Deadline to submit registration dossier to ECHA	Criteria for substances
30 November 2010 (at the latest)	Phase-in substances manufactured in the Community or imported in quantities of 1000 tonnes or more per year per manufacturer or per importer, at least once after 1 June 2007;
30 November 2010 (at the latest)	Phase-in substances classified as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2, in accordance with Directive 67/548/EEC and manufactured in the Community or imported in quantities reaching 1 tonne or more per year per manufacturer or per importer, at least once after 1 June 2007

Deadline to submit registration dossier to ECHA	Criteria for substances
30 November 2010 (at the latest)	Phase-in substances classified as very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment (R50/53) in accordance with Directive 67/548/EEC and manufactured in the Community or imported in quantities reaching 100 tonne or more per year per manufacturer or per importer at least once after 1 June 2007;
31 May 2013 (at the latest)	Phase-in substances manufactured or imported in quantities of 100 tonnes or more per year per manufacturer in the Community or per importer at least once after 1 June 2007;
31 May 2018 (at the latest)	Phase-in substances manufactured in the Community or imported in quantities of 1 tonne or more per year per manufacturer or per importer at least once after 1 June 2007.

Duty of Communication

- ◆ The registrant communicates with his Downstream Users so as to be able to prepare the registration dossier.
- ◆ In particular the registrant will need information about DUs uses and the risk management measures they have already put in place
- ◆ Provide a Safety Data Sheet (SDS) to customers
- ◆ The final Exposure Scenario developed for identified uses as part of the Chemical Safety Assessment has to be communicated to the registrant's customers as an annex to the SDS as this provides instructions of risk management measures that should be in place in order to ensure adequate control of risks.
- ◆ The SDS will have to be updated with the new information required by REACH for the first supply of the substance or preparation as soon as this information is required by the different title of REACH.

Classification And Labelling Notification

- ◆ Registrant must electronically notify the Agency the information related to classification and labelling of a substance when:
 - ◆ the substance is subject to registration, but has not yet been registered,
or
 - ◆ if the substance is within the scope of Article 1 of Directive 67/548/EEC and meets the criteria for classification as dangerous;
and
 - ◆ is placed on the market on its own or in a preparation above the concentration limits specified in Directive 1999/45/EC
- ◆ When:
 - ◆ before the 1st December 2010 for substances already on the market at that date or as soon as the substance is placed on the market for substances not yet on the market on the 1st December 2010
- ◆ This is not need if already registered.

Thank you for your attention

For more information:

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