



# Introduction to REACH

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U.S. Mission to the EU

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# 1. REACH Overview



# Background

- REACH is the system for controlling chemicals in the EU
- Main objectives:
  - Protection of health
  - Protection of environment
  - Free circulation of goods
  - Competitiveness and innovation
- Industry responsible to ensure safe use of chemicals
- REACH is managed by the European Chemicals Agency (ECHA)
- Member States are responsible for enforcing REACH



# Key Elements of REACH

## Registration, Evaluation, Authorization and Restriction of Chemicals

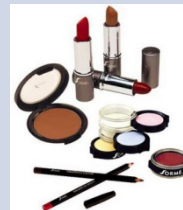
- **REGISTRATION**
  - Chemicals M/I in quantities > 1 ton/ year must be registered with ECHA
  - ‘No data, no market’
- **EVALUATION**
  - Registration dossiers are evaluated by ECHA
- **AUTHORIZATION**
  - SVHC (substances of very high concern) on Annex XIV are banned unless authorized for specific uses
- **RESTRICTION**
  - Annex XVII: list of restricted substances

# Products covered

**Substances** = chemical elements and their compounds



**Preparations** = mixtures of substances



**Articles** = finished products



# Any Exemptions?

- Substances **below 1 ton** do not need to be registered
- Substances totally exempted:
  - *Radioactive substances*
  - *Substances under customs supervision*
  - *Non-isolated intermediates*
  - *Waste*
- Substances exempted from certain procedures:
  - *Medicinal products*
  - *Food and feed*
  - *Polymers*
  - *Substances in Cosmetics*
  - *Medical devices*
  - *Annex IV and V*
  - *Active substances in Biocides and pesticides (deemed registered)*
- National exemptions for substances used in the interest of defense: <http://www.eda.europa.eu/reach/>

# REACH players

REACH obligations depend on the role in the supply chain:

- EU Manufacturer
- EU importer
- **Only Representative of non-EU manufacturers**
- EU Downstream user
- EU distributor

# 2. REACH Registration

# REACH registration deadlines

30 November 2010  
subst. > 1000t/yr & CMR & R50/53

2<sup>nd</sup> registration  
deadline  
in 564 days!



**31 May 2013**  
substances > 100t/yr

31 May 2018  
substances > 1t/yr

## 2013: What substances are covered?

- Substances between **100 t/ year** – 1,000 t/year
- Deadline applies to substances:
  - as such
  - in preparations
  - in articles (if intended release)
- Substances must have been pre-registered (2008)
- If you missed the pre-registration deadline:
  - Late pre-registration
  - Or, Register immediately

# Who can register?

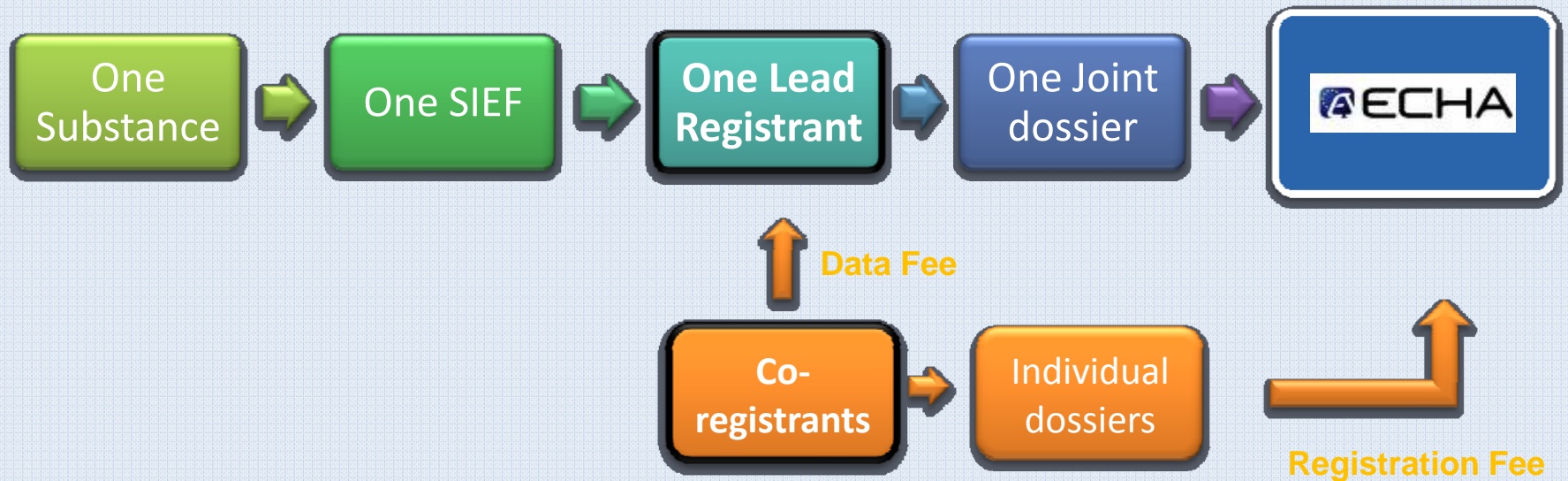
- Only EU manufacturers and importers can register
- What if I export to the EU?
  - You cannot register yourself
  - Product needs to be registered by:
    - **Your importer**
    - A company established in the EU that has been nominated as **your Only Representative (OR)**
    - Or, **Your supplier** 's OR (as part of his indirect imports into the EU)

# How to register?

- Submit a **Registration Dossier**:
  - to the European Chemicals Agency
  - in a software called IUCLID (<http://iuclid.eu/>)
  - consisting of:
    - A common part prepared with other registrants of the same substance (joint dossier)
    - An individual part with company-specific information
- To prepare your dossier:
  - share data with others in a **SIEF** (Substance Information Exchange Forum)
  - SIEFS bring together businesses registering the same substance

# REACH registration steps

1. Form/ join a SIEF
2. Share data in the SIEF
3. Prepare and submit the joint and individual dossiers:



# Challenges for 2013

- Lessons learnt from 2010:
  - REACH review
  - 86% of registrations by large companies
  - SIEFs not working well
  - Improve the quality of dossiers
- What to expect in 2013:
  - Less data available
  - More inexperienced companies and more SMEs in the SIEFs
- ECHA's recommendations:
  - SIEFs should be formed by December 2011
  - Chemical Safety Assessment: 31 December 2012
  - Joint dossier by Lead registrant: 31 March 2013
  - Individual dossiers: 31 May 2013



# 3. SVHC obligations



# What are SVHC?



- Substances of very high concern (SVHC) include:
  - CMRs (Carcinogenic, Mutagenic and Toxic to reproduction)
  - PBTs (Persistent, Bioaccumulative and Toxic)
  - vPvBs (Very Persistent and Very Bioaccumulative)
  - Substances of equivalent concern (e.g. endocrine disruptors)
  
- SVHCs may be placed on 2 lists:
  1. The Candidate List
  2. The Authorization List







# 1. The Candidate List

- Substances identified as SVHC are included in the Candidate List
- It is updated twice a year: [ECHA website](#)
- The Candidate List is:
  - The first step in the Authorization process
  - Creates legal obligations for companies:
    - **Communication of safety information in the supply chain** (Art. 33)
    - **Notification to ECHA** (Art. 7.2)

## 2. The Authorization List

- Objective of REACH Authorization:
  - Ensure that risks from SVHCs are properly controlled
  - Promote substitution
- The Authorization List = Annex XIV of REACH
- Substances on the Authorization List are banned unless authorized for specific uses
- There are 6 substances on the Authorization List
- Authorization does not apply to imported articles

# Summary of REACH Obligations

Products	Examples	Obligations	Conditions
Chemical substances		<b>Registration</b> Authorization Restrictions	<ul style="list-style-type: none"> <li>▪ <b>&gt; 1t/ year</b></li> <li>▪ Listed Annex XIV</li> <li>▪ Listed Annex XVII</li> </ul>
Chemical preparations (mixtures)	 	Registration (of substance) <b>Authorization</b> Restrictions	<ul style="list-style-type: none"> <li>▪ &gt; 1t/ year</li> <li>▪ <b>Listed Annex XIV</b></li> <li>▪ Listed Annex XVII</li> </ul>
Products containing chemicals (Articles)	  	Registration <b>Notification</b> <b>Communication</b> Authorization (not for imported articles) <b>Restrictions</b>	<ul style="list-style-type: none"> <li>▪ Intended to be released &amp; &gt; 1t/ y.</li> <li>▪ <b>SVHC &gt; 1t &amp; &gt; 0.1%</b></li> <li>▪ <b>SVHC &gt; 0.1%</b></li> <li>▪ Listed Annex XIV</li> <li>▪ <b>Listed Annex XVII</b></li> </ul>

# Thank you!

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<http://www.buyusa.gov/europeanunion/reach.html>