



European Commission

REACH Responsibilities

How companies can prepare

Vilnius - 25 April 2007

European Commission, DG ENTR, REACH Unit

Petteri Mäkelä



Outline

What should a company do first

How to prepare

Available Information

Available Assistance

What to do first - Step 1

Nominate your REACH responsible

- ◆ Identify a person who will be accountable for preparatory activities and compliance
- ◆ Ensure appropriate skill-set and management support
- ◆ Example

❖ *You'll have to excuse me, I'm a layperson here, a lowly receptionist / research assistant and I've been trying to decode this new program for days and I can't make heads or tails of it. If the chemicals we import to the EU are already in the EINECS database, do we still need to register with the Agency?*

Do you think this company's REACH preparations are in good hands?

What to do first - Step 2

Get to know information sources

◆ Legislation

- ❖ 1907/2007/EC
- ❖ Regulation: 15 Titles (234 pp) & 17 Annexes
- ❖ Available online

◆ Guidance documents

- ❖ Available for all main topics
- ❖ For novices & experts

◆ EU Chemicals Agency website

- ❖ Launch on 1 June 2007
- ❖ One-stop-shop for all information on REACH implementation

What to do first - Step 3

Identification of your company's REACH role/s

- ◆ Create an inventory of your substances
 - ❖ On their own
 - ❖ In preparations
 - ❖ Articles

- ◆ Consider exemptions

- ◆ Compile data on the volumes
 - ❖ ≥ 1 tonne ≥ 10 tonnes *etc.*

- ◆ Understand the sources of substances
 - ❖ Manufactured in-house
 - ❖ Bought from an EU supplier
 - ❖ Bought from a non-EU supplier

The role can be different for different substances

How to prepare

For substances you manufacture

- ◆ **Study Guidance on ECHA web-site on:**
 - ❖ Substance identity
 - ❖ Information requirements
 - ❖ Chemical safety report *etc.*

- ◆ **Identify sources of available data on substance properties**
 - ❖ In-house
 - ❖ External (e.g. EU Chemicals Bureau & OECD)
 - ❖ *Note: you need legal access to any data to use it your registration*

- ◆ **Identifying uses of your substance**
 - ❖ **Communicate with your customers**

- ◆ **Get trained with IUCLID 5 and use it as your data base for substances to prepare for registration**

How to prepare

For substances & preparation you import

- ◆ Understand the composition of the materials you import
- ◆ Discuss with your supplier
 - ❖ What information is available
 - ❖ Who will register
- ◆ Other actions similar to substance manufacturer

How to prepare

For substances you buy & use

- ◆ **Study Guidance on ECHA web-site on:**
 - ❖ Downstream user obligations
- ◆ **Consider sharing information on your uses with suppliers**
 - ❖ You may keep uses confidential but this may lead to a need to carry out a safety assessment in-house
- ◆ **Get ready to comply with the risk reduction measures communicated to you by suppliers**
- ◆ **Understand the changes in Safety Data Sheets and new information elements introduced by REACH**

How to prepare

For articles you import

- ◆ **Study Guidance on ECHA web-site on:**
 - ❖ Substances in articles
- ◆ **Make an inventory of articles with containers of chemicals**
 - ❖ e.g. Toner cartridge for a printer
 - ❖ Substances contained in these units need to be treated just like any other substance
- ◆ **Make an inventory of articles with intentional release of chemicals**
- ◆ **Understand information requirement in the article supply chain**
- ◆ **Understand notification requirements**
- ◆ **Actively communicate with your supplier**

What are the time lines?

- ❖ **Communication obligations** **from 1/06 2007**
- ❖ **Pre-registration** **1/6 - 1/12 2008**
- ❖ **Registration of substances** **2010 / 2013 / 2018**
 - **New substances** **from 1/08 2008**
- ❖ **Notification of substances in articles** **from 2011**
- ❖ **Authorisation** **open**
- ❖ **Restrictions** **on-going**

Available Information

The Regulation & Annexes

- ◆ Contain all legally binding provision
 - ❖ Available in local language/s
- ◆ Annexes provide technical information and formats to be used
 - ❖ Following annexes will be reviewed by 1.6.2008
 - Annex I: Chemical Safety Report
 - Annex IV: Exemptions
 - Annex V: Exemptions
- ◆ Can be accessed online at:

<http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2006:396:SOM:LV:HTML>

Available Information

Guidance

◆ Will be progressively made available on ECHA website

❖ Launch on 1 June 2007

www.echa.europa.eu

◆ Consists of:

- ❖ Concise overall guidance
- ❖ IT based Navigator tool
- ❖ Detailed technical guidance

How will the guidance look?

The screenshot shows a Microsoft Internet Explorer browser window with the following elements:

- Browser Title Bar:** "Untitled Document - Microsoft Internet Explorer provided by European Commission"
- Address Bar:** "http://194.185.30.69/reach_mockup/home.htm"
- Page Header:** "REACH Guidance" with the subtitle "Registration, Evaluation, Authorisation and restriction of CHemicals". A language dropdown menu is set to "English".
- Navigation Menu:** "About Reach", "Guidance Documents", "Formats", "Other Documents", and "NAVIGATOR".
- Main Content Area:**
 - Left Column:** A grid of images showing various chemical products like bottles, containers, and a bowl of fruit.
 - Right Column:**
 - NAVIGATOR:** A section titled "NAVIGATOR" with the sub-heading "what are my obligations under REACH?". It includes a molecular structure image and a button for "More info about Navigator".
 - DOCUMENTS:** A section titled "DOCUMENTS" with a sub-heading "consectetur adipiscing elit, sed diam nonummy nibh euismod tincidunt ut laoreet dolore magna aliquam erat volutpat sed". It includes a stack of blue folders and links for "Guidance Document", "Legal Text", and "Formats".
- News Section:**
 - Guidance on Authorisation application updated:** "A new version of the Detailed guidance document on authorisation application has been uploaded on this website. The following chapters have been revised and updated....."
 - Lorem ipsum dolor sit amet:** "consectetur adipiscing elit, sed diam nonummy nibh euismod tincidunt ut laoreet dolore magna aliquam erat volutpat sed"

The browser's taskbar at the bottom shows the Windows Start button, several open applications (including an email inbox and multiple document windows), and the system tray with the time set to 10:00.

Available Information

Questions and answers available on ECHA website

- ◆ **Generic questions and answers document**

- ❖ Several languages

- ◆ **Frequently asked questions data base**

- ❖ In English

Available Assistance

Associations

- ◆ Advise with REACH implementing questions, through workshops, sector specific guidance documents and practical tools
- ◆ Offer a platform for learning from each other
- ◆ Interact with the (National) Authorities and EU level organisation to address & resolve issues
- ◆ Sector specific helpdesk / consulting services

Available Assistance

Helpdesks

- ◆ Member States helpdesks are for:
 - ❖ General advice on obligations under REACHThey provide assistance in local language/s

SMEs who register can also contact

- ◆ Agency helpdesk for:
 - ❖ Advice on registration process & dossiers
 - ❖ IUCLID5 related questions

Available Assistance

External help

- ◆ Various companies provide services in:
 - ❖ What to do and how
 - ❖ Compliance audits
 - ❖ Safety assessments & preparation of chemical safety reports
 - ❖ Training
 - ❖ Dossier preparation
 - ❖ etc.

Summary

REACH will change business environment & practices

- ◆ **Accept the change - REACH will not go away**
- ◆ **Consider all sources of information & assistance**
- ◆ **Be proactive - take control**
- ◆ **Share the burden - participate to associations**