



REACH Overview for US Firms

Rosemary Gallant

Deputy Senior Commercial Officer

U.S. Mission to the EU



Seattle, April 7, 2008

Outline of Presentation

- REACH 101
 - What is REACH?
 - Preparing for Registration
 - Authorization of Substances of very high concern
- What's new?
 - Update on guidance documents
 - Guidance on substances in Articles
 - Guidance on Only Representatives of non-EU manufacturers
 - Regulation on Fees
- Where to get help?
 - EU tools for compliance
 - U.S. Mission REACH webpage



REACH 101



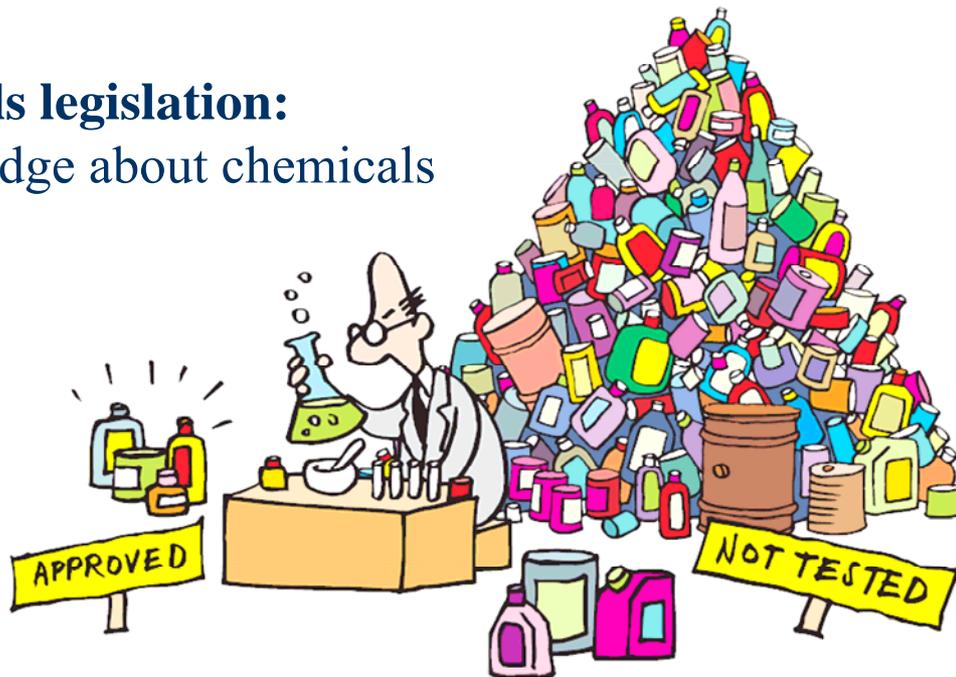
What is REACH?

- The new EU chemicals policy
- REACH stands for the **R**egistration, **E**valuation and **A**uthorization of **C**hemicals
- REACH objectives
- Industry to provide **chemical safety** information to a new European Chemicals Agency, ECHA
- Entry into force: 1 June 2007
- First business deadline: **1 June 2008**



Why REACH?

Current EU chemicals legislation:
Lack of public knowledge about chemicals



■ REACH places greater responsibility on industry to manage the risk of chemicals

Source: International Chemical Secretariat

The Pillars of REACH

European Chemicals Agency (ECHA)



Industry (responsibility for chemicals safety)

Authorities



REACH coverage

- If you belong to a supply chain producing/using chemicals and exporting to Europe, you are affected by REACH
- REACH covers approx. 30,000 substances:
 - Substances as such
 - Substances in preparations (mixtures)
 - Substances in products (Articles)



Impact on U.S. business

- Non-EU companies do not have direct obligations under REACH:
 - Your EU importer is REACH obligated
 - Unless you appoint an “Only Representative of a non-EU manufacturer”
- In all cases, you need to ensure your products comply (no data, no market)



Registration (1)

Scope:

- Registration applies to substances of **1 ton** or more/ year
- Exemptions:

Substances exempted from registration	Substances regarded as registered
Food or feedingstuffs	Active substance for use in biocides
Medicinal products	Active substance for use in plant protection products
Annex IV substances (on-going revision)	Notified substances
Annex V substances (on-going revision)	
Recycled or recovered substances already registered	
Re-imported substances	
Polymer	
PPORD	

- The REACH Navigator: http://reach.jrc.it/navigator_en.htm

An interactive tool to determine if your substance is covered by REACH



Pre-Registration

Pre-registration:

- Pre-registration starts on June 1st
- Open for 6 months only (1 June – 1 December 08)
- Format: IUCLID 5 software or REACH-IT system: <http://iuclid.eu>
- No fees
- Limited dossier (company and contact information, substance name, envisaged registration deadline and tonnage band)
- Not mandatory, but key to continue export until registration completed:
 - Allows for extended Registration deadlines (2010 – 2013 – 2018)
 - “To stay in business under REACH, pre-register your chemicals!”
- More on pre-registration: see guidance document on ECHA website: http://reach.jrc.it/docs/guidance_document/registration_en.htm



Registration Cooperation

SIEF formation:

- SIEF: Substance Information Exchange Forum
- SIEF brings together pre-registrants of the same substance
- Aim of SIEF:
 - Share data
 - Agree on classification and labeling
 - Prepare for the joint submission of registration
- Data Sharing within SIEF: REACH requires the sharing of information for registration in exchange for compensation
- More on data sharing: see guidance document on ECHA website:
http://reach.jrc.it/docs/guidance_document/data_sharing_en.htm



Registration Contents

Registration dossier:

- Registration dossier to be submitted to ECHA:
 - Information on substance properties, uses and safe management
 - Registration information and deadline depend on tonnage
 - Chemical safety report for substances > 10 ton/ year
- The registrant must be EU-based:
 - EU manufacturer, importer, Only Representative
- Do registrants have to submit all their data jointly?
 - To be submitted jointly (by lead registrant): core data, classification and labeling, proposals for additional testing
 - To be submitted separately: company-specific information
 - Possible opt-out



Registration Timeline

Pre-registration



Registration

> 1000 t/y
CMRs (>1 t)
Very aquatic toxic
(> 100 t)

100 -
1000 t/y

1- 100 t/y

1 June 2008/
1 December 2008

2010

2013

2018



Registration Approach

Tips for registration:

- Check annual volume of substance (> 1 ton)
 - Check if exemptions apply to certain substances or uses
- ⇒ Pre-register, join SIEF, define deadlines for registration based on volume, participate in joint registrations



Example- Antioxidant

Antioxidant is produced and exported to the EU: 100 t/y

- 40t are used in food production => exempted
- 60t are used in other industries
- Total volume to consider for registration: 60t
- Pre-registration between 1 June and 1 December 2008
- Join SIEF for data sharing and registration
- Registration in the 1-100t band, by 2018



Authorization (1)

- Applies to substances of very high concern (SVHC)
- List of chemicals that may be subject to authorization:
 - **2008: Publication of the Candidate List** (1,500 substances):
 - Carcinogens, Mutagens, Reproductive Toxins (CMRs)
 - PBTs, vPvBs
 - Endocrine disruptors
 - Substances of ‘equivalent concern’
- List of chemicals that will be subject to authorization:
 - 2010: Publication of **Annex XIV** (20 substances/ year)
 - Priority substances: high volume, PBTs, wide dispersive use
 - Annex XIV: deadlines after which substances will be banned if not authorized
 - EU objective: Substitution of SVHC with safer alternatives

*No list yet –
watch out for
its publication!*

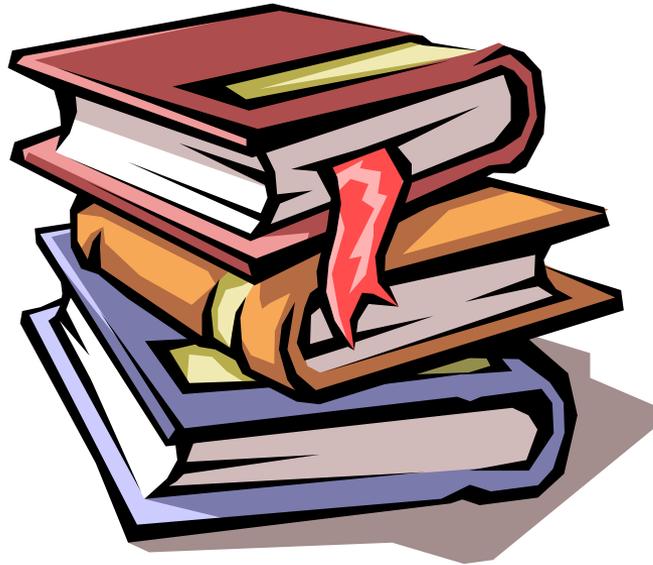


Authorization (2)

- Authorization granted:
 - If adequate control of risks to health or the environment; if not:
 - Socio-economic benefit greater than risks
 - And no substitutes
 - Authorization is company-specific, use-specific and time-limited
 - Be prepared to defend your use of the substance or to replace SVHC in your products by greener substitutes
- Black list effect of the Candidate List?
 - Customers may request that products do not contain substances on the Candidate List
 - De facto ban on substances before the authorization process
 - Are your substances potential candidates for authorization?



What's new?



Latest guidance documents

- RIP 3.1: Preparing the registration dossier (Only Representative) - final, **update published Feb. 08**
- RIP 3.2: Preparing the CSR - final, adoption March 08
- RIP 3.3: Information requirements – final, adoption March 08
- RIP 3.4: Guidance on data sharing – final, published Sept. 07
- RIP 3.5: Guidance for downstream users – final, published Jan. 08
- RIP 3.6: Guidance on C&L under GHS (to be finalized by March 09)
- RIP 3.7: Guidance on applications for authorization (adoption June 08)
- RIP 3.8: Requirements for articles - final, **awaiting publication**
- RIP 3.9: Guidance on socio-eco. analysis – final, adoption June 08
- RIP 3.10: Guidance on checking substance ID – final, June 07

ECHA website



http://reach.jrc.it/guidance_en.htm



New Guidance on Articles

- Specific requirements for substances in Articles
- Guidance will help you answer the following:
 - Do your products meet the EU definition of Articles?
 - Are your Articles subject to:
 - Registration?
 - Notification?
 - Communication related to SVHC content?
- Final guidance to be shortly available on the ECHA website (RIP 3.8): http://reach.jrc.it/guidance_en.htm



What is an Article?

- *“An **object**, which during production, is given a special shape, surface, or design that determines its function to a greater degree than does its chemical composition.”*
- Shape, surface or design must be more important than the chemical composition
- Article or substance/ preparation in a container?
 - Articles: cars, computers, clothes, batteries, packaging
 - Substance/ preparation in a container: wet cleaning wipes
 - Why the distinction matters? Limited requirements for Articles



Articles – Registration

- Registration of substances intended to be released from Articles
- What is an Article with intended release?
- Registration required if the substance:
 - Is “**intended to be released** under normal or reasonably foreseeable conditions of use”
 - Is **above 1 ton** in the article
- Registration deadlines and requirements: same as for substances and preparations
- No need to register if the substance has already been registered for that use (in any supply chain)!



Articles – Registration Example

Article with intended release:

- Yes: scented erasers
 - Fragrance is a substance intended to be released from an article
 - Fragrance to be registered if > 1 ton and not already registered for that use
 - Determine total amount of substance released
 - Check whether substance is registered for that use (consortia)
 - Pre-register, join SIEF, participate in joint registrations
- No: tires
 - The release is not intended: no registration



Articles - Notification

- Notification to the Agency of SVHC in Articles
- Notification required if the substance:
 - Is on the **Candidate List** (on ECHA website)
 - **Above 1 ton**
 - In **concentration > 0.1%**: applies to the article as produced or imported (not to the homogenous materials or parts of an article)
 - **Exposure** cannot be excluded during entire life cycle
- Notification deadlines and requirements: limited dossier, 6 months after Candidate listing from 1 June 2011
- No need to notify if the substance has already been registered for that use (in any supply chain)!



Articles - Information

- Duty to communicate information on SVHC in Articles down the supply chain
- Objective: ensure safe use of the Article
- Applies to substances:
 - On the **Candidate List** (on ECHA website)
 - In **concentration >0.1%** in the article
 - No tonnage threshold: also applies below 1 ton
- Information to be communicated:
 - To whom? to the recipient of the article/ to the consumer on request
 - What? As a minimum, the name of the substance
 - When? Directly after Candidate listing/ Within 45 days of receipt of the request



Articles - Restrictions

- As of 1 June 2009, Annex XVII on Restrictions will replace the current Directive on the Marketing and use of dangerous substances
 - Example: Ban on azo-colorants in textiles will remain in place
- **Check restriction obligations in Annex XVII**
- Other legislation restricting or banning the use of certain substances in articles will continue to apply:
 - Example: ROHS Directive



Articles: case study

Example: textile

- MSDS indicates presence of:
 - ✓ *Antimony* < 0.1%, < 1t/year
 - ✓ *Lead* > 0.1%, < 1t/year
 - ✓ *Cadmium* > 0.1%, > 1t/year
- Check volume, concentration, intended release, exposure, candidate listing:
 - No registration required (no intended release)
 - Notification: required for cadmium (SVHC, exposure, > 1ton, > 0.1%)
 - Communication to customers should be made for lead and cadmium (SVHC, > 0.1%). Be ready to communicate:
 - Name of substance
 - Recommendations for safe use (ex. for consumers: “Keep out of reach of children”)
- Use available info. (MSDS), request information from suppliers
- Document your decisions to demonstrate compliance



Guidance on Only Representatives

- What is an Only Representative (OR)?

*“A natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the Community may by **mutual agreement** appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers”.* (Art. 8)

- Obligations of the OR:

- Fulfil the obligations of importers under REACH: OR will handle registration/ pre-registration, participation in SIEF

- Profile of the OR:

- OR must be EU-based, with a background in chemicals handling
- Availability and cost of Only Representatives

- Only representative or EU importer?



Guidance on Only Representatives

- Guidance on Only Representative: See guidance on registration, page 21- 24:
http://reach.jrc.it/docs/guidance_document/registration_en.htm
- Guidance remains unclear on some issues:
 - Who in the supply chain outside the EU can appoint an OR?
 - Distributors cannot appoint ORs
 - Indirect imports and confidentiality issues
 - One OR for several non-EU companies:
 - Aggregation of tonnages
 - Calculation of costs
- Discuss the best option for your supply chain

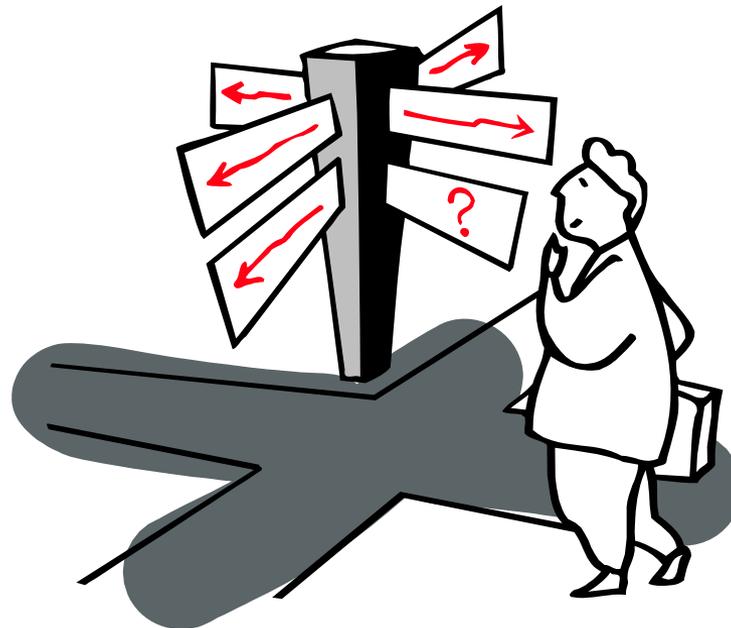


REACH Fees Regulation

- Draft regulation, to be adopted by 1 June 08
- Fees for Registration and Authorization:
 - Fee depends on tonnage, and whether joint or individual submission
 - Reduction for SMES
 - No fee for registration of a substance 1 – 10 tons
- Examples:
 - Registration: 1,200 € (low vol., joint submission) - 31,000 € (high vol., indiv. reg.) . SME reduction: 120 €
 - Authorization: 50,000 € (standard charge). SME reduction: 7,500 €
- Fees for confidentiality requests:
 - Relevant tonnage band (1,500 €), study summary (4,500 €)



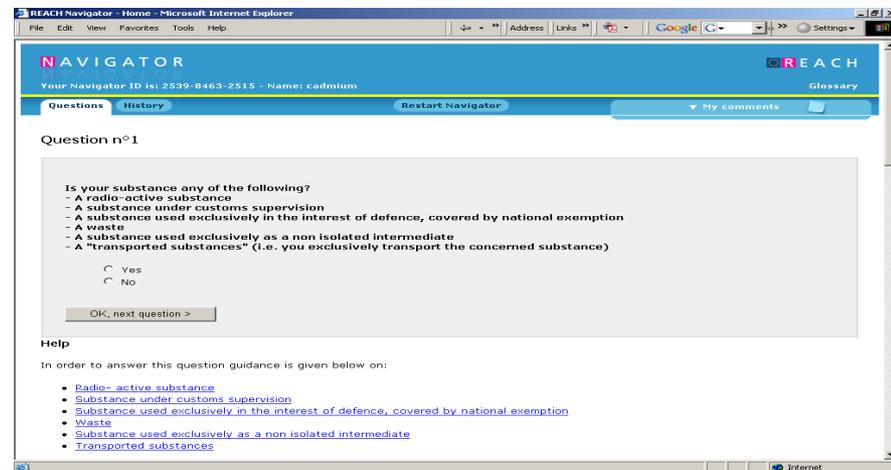
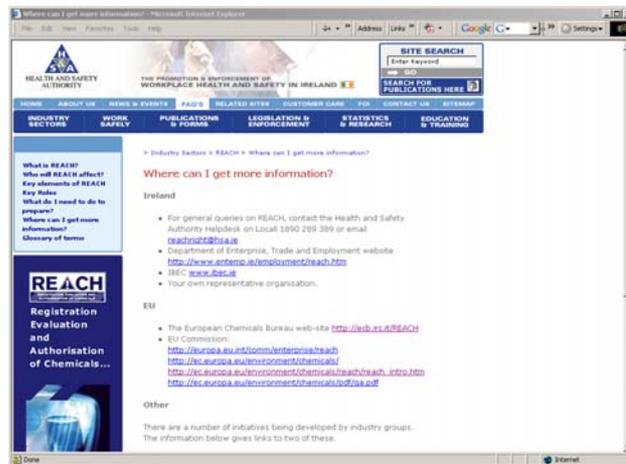
Where to get help?



EU tools for compliance

The Agency website

- REACH Navigator
(Enter substance, understand obligations)
- REACH Guidance
(Summary legislation, **guidance documents, formats**)

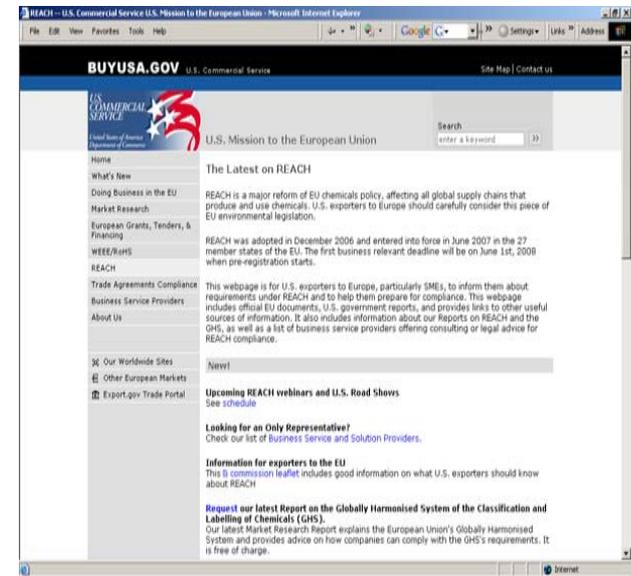
Member States Helpdesks

One example – Ireland



U.S. Mission REACH webpage

- New! REACH fees, REACH guidance documents, IUCLID 5, FAQs, consortia
- Link to REACH helpdesks
- List of REACH business service providers
- List of Only Representatives of non-EU manufacturers
- Upcoming REACH webinars and U.S. Roadshows



www.buyusa.gov/europeanunion/reach.html



Thank you!



Commercial Service

U.S. Mission to the European Union

Rosemary.Gallant@mail.doc.gov

Flavie.Guerin@mail.doc.gov

www.buyusa.gov/europeanunion

